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Alanya, an ancient city on the Mediterranean sea;  
Alanya was the capital city of Turkey in the 13th century

## From the Editor

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In this issue there are a good number of papers dealing with clinical and basic research, in addition to good number of paper on woman health. We are starting with this issue as well as special series on learning difficulties a problem that is faced by family physicians and good understanding of the problem improve management outcome. Helvacı, M.R et al tried to understand significance of hyperlipoproteinemias, clinically. The authors concluded that the accelerated atherosclerotic process all over the body may be the major consequence of the metabolic syndrome. Hyperlipoproteinemias may actually be acute phase reactants indicating the disseminated endothelial damage, inflammation, fibrosis, and eventual atherosclerosis by aging all over the body.

A number of authors dealt with woman issues, Hasan, A et al; address the significance of sonographic diagnosis of vasa previa in pregnancy outcome. They performed a multicenter study in 3 private hospitals in Iraq during a 5 years period. The authors concluded that although vasa previa is a rare lethal complication, Antenatal diagnosis is essential to improve fetal survival by colour Doppler ultrasonography. Heidari, G et al carried a descriptive study to evaluate the frequency of vaginal delivery following a previous C section. Based on this study, the phrase "once a cesarean, always cesarean" can change to "once a cesarean, often vaginal delivery". Moradabadi A.S et al conducted a research on on primiparous women in Bandar Abbas based on the health belief model. The authors concluded that it appears that enacting appropriate instructional plans by the medical staff can be effective in raising women's susceptibility and perceived severity of the consequences of cesarean.

Zarchi, M.K et al; did a cross-sectional study to investigate the clinical characteristics and 5 year survival rate of patients with squamous cell carcinoma of the cervix. According to 5-year decrease in survival rate with increasing stage of disease, screening of this cancer in at risk populations is essential for early diagnosis. Mokaberinejad, R; did a randomized, clinical trial was performed on 64 pregnant women with unexplained asymmetric Fetal Growth Restriction. The authors concluded that the potential of dietary treatment through the advises of Iranian traditional (Persian) medicine should be given more attention in helping to solve the challenges of modern medicine as a low-risk and low-cost method. Masihi S et al; studied the association of CVS and amniocentesis for Down syndrome with fetal loss was assessed. According to obtained results, it may be concluded that there is no association between CVS and amniocentesis for Down syndrome with fetal loss. Safi S et al; carried a cross sectional-analytical research conducted on 110 Mastectomy and Lumpectomy samples of breast cancer. They concluded that Further expression of ER in tumors with lower grades is predictable. As a result, it can be used as an indicator to predict better prognosis among patients with breast invasive cancer.

A number of papers presented alternative medicine approach. Aalami, H et al; showed that hybrid aromatherapy as a cost effective and uncomplicated method can improve sleep quality of patients with ACS admitted to CCU. Rafii, F et al; showed that training MS patients with urinary incontinence to perform pelvic floor muscle exercises can reduce the severity of their urinary disorders and promote their quality of life. Mehrdad M et al; compared the effects of chamomile's hydro alcoholic extract and imipramine on decreasing depression of laboratory mice. They concluded that chamomile extract can be a replacement for imipramine to reduce the depression symptoms, dose dependently. Mojtabaee, M et al; scrutinize the effect of the persian medicine "Milk-Cuscuta" on the hyperpigmentation of skin in the patients with melisma. The findings demonstrate that the consumption of the Cuscuta extract with milk can reduce the synthesis of melatonin and consequently results in the elimination of melasma.

Biabani, F et al; conducted a study to examine the effect of muscle relaxation on dialysis adequacy in patients on hemo-

dialysis. The authors concluded that the increased dialysis adequacy and its safety and ease, it is recommended that muscle relaxation be taught in hemodialysis wards.

A number of papers dealt with psychological aspects. Momtazi, S et al; showed that motivational interviewing as a group therapy was effective in glycemic control as well as treatment satisfaction of type 2 diabetes patients. Farahzadi S et al; showed that education is empowering couples group therapy on marital satisfaction have been effective in the experimental group. Moghadam L.Z et al; determined tend to rhinoplasty in terms of self-esteem and body image concern among university students. The results of this study show that the intention of doing rhinoplasty surgery among university students affected by level of their Self-esteem and also their concerns about their body image. Mohammadi, P et al; noted that observing patient rights by the healthcare staff and patients' awareness of the patient rights charter are crucial behavioral factors in hospitals that should be given a high priority so as to improve inpatients' recovery and comfort. Ghorbani, N et al clarifies the taking effect of self-compassion from culture and inconsistency of the Persian culture on self-compassion. Alboativi, H et al recommended based on their study that health care centers and the centers that are associated with veterans uses this intervention method in relation to veterans.

Ziaei, T et al; investigated the effectiveness of self-awareness based individual counseling on self-awareness of women in reproductive age. The authors concluded that the self-awareness based individual counseling session shows a positive effect on enhancing the private and public self-awareness and reducing social anxiety. Dehbaneh M.A et al; through their study concluded that early maladaptive schemas and dysfunctional attitudes and emotional-focused coping strategies can be important factors in the formation of body dysmorphic disorder. Shiravani, A et al tried to investigate the relationship between social trust and social indifference of the citizens. They concluded that, the relationship between public trust and political trust with social indifference has also been reported significant and negative.

Pondehnezhadan, A et al; showed that schema therapy leads to an increase in satisfaction with body-image, elevation of self-concept and reduction of body



maladaptive schemata in the Patients with deformity in experimental group, compared to the control group. Siadat-nezhad, S et al; aimed to translate and culturally adapt the Perinatal Grief Scale (PGS) in an Iranian target group. They recommend that the PGS-P be used to assess grief severity in parents after perinatal loss and to identify high-risk women who are more vulnerable so that the healthcare system could help them.

A number of papers dealt with basic research. Hovsepian S et al; investigated the interaction of some lipid regulatory genes polymorphisms with obesity in the occurrence of MetS in children. Identification of such interactions between modifiers like obesity with genetic variants could be helpful in development of preventative strategies for reducing the increasing trend of MetS in children. Farshchian, N et al compared RI and PSV of the MCA in normal fetuses vs. fetuses with mutation of the beta-thalassemia gene. The authors concluded that PSV of the MCA of fetuses with major beta-thalassemia was higher than normal fetuses. Abtahi, M.M et al; looked at the biological dosimetry method: a probable way for measuring percent depth dose. The authors recommend more research to make the biological dosimeters as a precise method for radiation therapy.

A topic of growing interest is safety and health. Porkavosh S et al; carried a cross-sectional descriptive and analytical study, they concluded that the adverse effects of VOCs on human and environmental health as well as the role of these pollutants in the formation of photochemical oxidants, appropriate actions related to monitoring and controlling these compounds should be considered in urban air. Maleki, A et al through a clinical trial concluded that the active warming of the patients in the operating room prevents reduced body central temperature. Also, the warming of the patients for a short time prevents the occurrence of hypothermia. Kashani, F.R et al; demonstrated that the establishment of patient safety standards can exert a significant effect on the quality of patient identification, blood typing, and the implementation of tests for determining ABO compatibility and blood transport and conservation in the haemovigilance system.

Keikhaei, F et al; assessed health literacy, determine lifestyle based on four dimensions of nutrition, physical activity, interpersonal relations, and mental health. Therefore, educations and interventions

in this group of people is recommended to improve health literacy. Almasi K et al; conducted a study to determine PLSs of nursing and midwifery students. The authors concluded that visual styles are the most common learning style for nursing and midwifery students.

Bendak L; investigated the importance of reading repetition for slow learners which reflects positively on their reading fluency and passage comprehension. The Results of this study showed significant statistical differences to the benefit of the experimental group over the control group regarding reading fluency and passage comprehension. Khalaj, E et al; investigated the effectiveness of education and cognitive self-regulation on academic burnout and cognitive dissonance and academic performance of elementary school girl students. The data analysis results indicate that all three research hypotheses, which was included: Learning of cognitive self-regulation strategies which causes to reduce the students' academic burnout, learning of cognitive self-regulation strategies which causes to reduce the students' cognitive dissonance and learning of cognitive self-regulation. Rezaeian, M et al provided an insight into developing a researchable question or a testable hypothesis. They provide a sensible guideline which should suit most aspects of academic, scientific, industrial and commercial research.

A number of authors considered community issues. Omeranava, M et al; evaluated the obesity rate among the children from first grade elementary schools. The authors concluded that the overall prevalence of obesity in Sari was high, which proposes the nasality for serious consideration in the health system, and designing, developing, and implementing of preventive approaches with regard to childhood obesity. Saadat M et al; investigated the role of aerobic exercise on subjective well-being of high school female students in yasuj. The results of covariance analysis showed that aerobic exercise exercises affect mental well-being, as well as various aspects.

Soltani-Nejad S et al Tried to determine the effect of training of quality of life on self-esteem of patients with hemodialysis. Due to the effect of training on increasing self-esteem and quality of life in patients with hemodialysis, it is recommended to concern training of quality of life as part of the training program in hemodialysis units, as well as other chronic diseases benefit of such training. Saffari, L

et al looked at the relationship between coaches' misconduct and the progressive motivation of elite female athletes. The components of misconduct explained the progressive motivation. Goodness of fit indices (NFI, SRMR), with their interpretation, showed that the model did not have a fairly suitable fitness and the indices should be interpreted with caution in SMART-PLS.

Ghanadi, K et al did a case-control on ulcer patients. The authors concluded that in general, peptic ulcer is considered as a common and serious problem all around the world and 5 to 10% of the population are affected by PU during their life. Therefore, the incidence and complications of this disease can be significantly prevented by correcting risk factors and lifestyle, as well as by improving the health conditions of the community. Meidani, M et al; looked at the use of quantitative polymerase chain reaction in diagnosis of Pneumocystis Pneumonia. The authors concluded that 12% of immunocompromised patients and 8% of non-immunocompromised were colonized by Pj which may progress to PJP or contaminate to susceptible individuals.

Emami, M et al; determined the prevalence of vitamin D deficiency and insufficiency in children and adolescents that presenting for primary care to pediatric orthopedic clinic. The authors concluded that there is a high rate of subclinical vitamin D deficiency in children referred to pediatric orthopedic clinic that is more evident in 6-10 years group. Kianmehr, M et; al did a study to to evaluate the effect of MRI on vital signs of patients. The results showed that 0.35 T magnetic MRI could decrease systolic, diastolic and mean arterial blood pressure, heart rate and respiratory rate; however, it did not influence body temperature index.

Nazer, M.R et al; Carried a retrospective study to investigate the prevalence of cutaneous fungal infections among patients referred to Mycology Laboratory. The authors concluded that saprophytic infections were more common than the dermatophytoses in Sari located in Mazandaran province with hot humid climate. Tricophyton mentagrophyte is the most common species among dermatophytosis but in the other studies the commonest form were Tricophyton rubrum, Tricophyton verrucosum, Tricophyton violaceum and Epidermophyton floccosum. The differences could be due to differences in climate.

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# Hyperlipoproteinemias may actually be acute phase reactants in the plasma

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## Abstract

**Background:** We tried to understand the significance of hyperlipoproteinemias, clinically.

**Methods:** We studied consecutive patients, applying for check up procedure, below the age of 70 years, to avoid debility induced weight loss in elders.

**Results:** The study included 252 cases (156 females), totally. The female ratio was significantly higher in the obesity (78.0%) than the overweight (51.7%,  $p < 0.001$ ) and normal weight groups (56.6%,  $p < 0.001$ ). The mean age increased from the normal weight (32.9 years) towards the overweight (45.0 years,  $p = 0.000$ ), and obesity groups, significantly (51.0 years,  $p = 0.006$ ). Parallel to the mean body mass index (BMI), the mean body weight increased from the normal weight (62.0 kg) towards the overweight (75.5 kg,  $p = 0.000$ ), and obesity groups, again (87.2 kg,  $p = 0.000$ ). Fasting plasma glucose (FPG), systolic and diastolic blood pressure (BP), total cholesterol (TC), low density lipoproteins (LDL), high density lipoproteins (HDL), and triglycerides all increased nearly in all steps from the normal weight towards the overweight and obesity groups parallel to the increased mean age, BMI and body weight, significantly.

**Conclusion:** The accelerated atherosclerotic process all over the body may be the major consequence of the metabolic syndrome. FPG, systolic and diastolic BP, TC, LDL, HDL, and triglycerides all increased parallel to the increased age, BMI, and body weight, significantly. Hyperlipoproteinemias may actually be acute phase reactants indicating the disseminated endothelial damage, inflammation, fibrosis, and eventual atherosclerosis by aging all over the body.

**Key words:** Hyperlipoproteinemia, acute phase reactant, metabolic syndrome, accelerated atherosclerosis

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## Introduction

Due to the prolonged survival of human beings, systemic atherosclerotic sequelae may be the major health problems in this century, and their associations with excess weight, some metabolic disorders, smoking, and alcohol are collected under the title of metabolic syndrome (1, 2). The syndrome is characterized by a low-grade chronic inflammatory process on vascular endothelium all over the body (3). The inflammatory process is accelerated by some factors including excess weight, smoking, alcohol, chronic infection and inflammations, and cancers (4, 5). The syndrome can be slowed down with appropriate nonpharmaceutical approaches including lifestyle changes, diet, and exercise (6). The syndrome contains indicators including overweight, white coat hypertension (WCH), impaired fasting glucose (IFG), impaired glucose tolerance (IGT), hyperlipidemia, alcohol, and smoking for the development of irreversible consequences including obesity, hypertension (HT), type 2 diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD), cirrhosis, chronic renal disease (CRD), peripheral artery disease (PAD), coronary artery disease (CAD), and stroke (7). In another perspective, the metabolic syndrome may be the most important disease of the human lifespan decreasing its quality and duration at the moment. The syndrome has become increasingly common all over the world, for instance 50 million people in the United States are affected (8). The syndrome induced accelerated atherosclerotic process all over the body may be the leading cause of early aging and premature death for both genders. For example, CAD is the leading cause of death in developed countries. On the other hand, plasma lipoproteins are under active metabolic control, and they may be influenced from several factors including body mass, physical inactivity, elevated blood pressure (BP), increased plasma glucose, smoking, alcohol, prolonged infection and inflammations, and cancers. We tried to understand significance of plasma lipoprotein levels, clinically.

## Material and methods

The study was performed in the Internal Medicine Polyclinic of the Mustafa Kemal University between March 2007 and April 2009. We studied consecutive patients applying for check up procedure between the ages of 15 and 70 years. Cases above the age of 70 years were excluded to prevent debility induced weight loss in elders. Their medical histories were learnt, and a routine check up procedure including fasting plasma glucose (FPG), total cholesterol (TC), low density lipoproteins (LDL), high density lipoproteins (HDL), and triglycerides was performed. Patients with devastating illnesses including type 1 DM, malignancies, acute or chronic renal failure, chronic liver diseases, hyper- or hypothyroidism, and heart failure were excluded to avoid their possible effects on weight. Body mass index (BMI) of each case was calculated by the measurements of the same physician instead of verbal expressions. Weight in kilograms is divided by height in meters squared, and cases with a BMI value of lower than 18.5 is defined as underweight, between 18.5-24.9

as normal weight, between 25.0–29.9 as overweight, and 30.0 kg/m<sup>2</sup> or higher as obese (9). Office BP was checked after a 5-minute rest in seated position with a mercury sphygmomanometer, and no smoking was permitted during the previous two hours. Eventually, cases were divided into the four groups as underweight, normal weight, overweight, and obesity. The mean age, weight, height, BMI, FPG, systolic and diastolic BP, TC, LDL, HDL, and triglycerides were detected in each group, and compared in between. Mann-Whitney U test, Independent-Samples T test, and comparison of proportions were used as the methods of statistical analyses.

## Results

The study included 252 cases (156 females and 96 males), totally. There were 83 cases in the normal weight, 87 cases in the overweight, and 82 cases in the obesity groups. The mean BMI values were 22.4, 27.2, and 34.3 kg/m<sup>2</sup>, respectively. The female ratio was significantly higher in the obesity (78.0%) than the overweight (51.7%,  $p < 0.001$ ) and normal weight groups (56.6%,  $p < 0.001$ ). The mean age increased from the normal weight (32.9 years) towards the overweight (45.0 years,  $p = 0.000$ ), and obesity groups, significantly (51.0 years,  $p = 0.006$ ). Parallel to the mean BMI, the mean body weight increased from the normal weight (62.0 kg) towards the overweight (75.5 kg,  $p = 0.000$ ), and obesity groups, again (87.2 kg,  $p = 0.000$ ). On the other hand, the mean body heights remained stable in the normal weight and overweight groups (165.8 cm in both), whereas it decreased in the obesity groups, significantly (158.8 cm,  $p = 0.000$ ), probably due to the female predominance of the obesity group. As the most significant result of the study, FPG, systolic and diastolic BP, TC, LDL, HDL, and triglycerides all increased nearly in all steps from the normal weight towards the overweight and obesity groups parallel to the increased age, BMI and body weight, significantly (Table 1).

## Discussion

Vascular endothelial inflammation is actually triggered by some metabolic risk factors for the development of systemic atherosclerotic endpoints, those probably are the leading cause of early aging and premature death for both genders in human beings. Physical inactivity, excess weight, smoking, and alcohol are probably the most common causes of the systemic endothelial damage and inflammation (10). Definition of the metabolic syndrome or aging syndrome or accelerated endothelial damage syndrome includes metabolic indicators including physical inactivity, overweight, smoking, alcohol, WCH, IFG, IGT, and hyperlipidemia for the development of irreversible endpoints including obesity, HT, DM, COPD, cirrhosis, CRD, PAD, CAD, stroke, early aging, and premature death (11, 12). In a previous study (13), prevalences of hypertriglyceridemia, hyperbeta lipoproteinemia, dyslipidemia, IGT, and WCH had parallel fashion to excess weight by increasing until the seventh decade of life and decreasing afterwards, significantly ( $p < 0.05$  nearly in all steps). On the other hand, prevalences of HT, DM, and CAD always continued

Table 1: Characteristics of the study cases

Variables	Normal weight	p-value	Overweight	p-value	Obesity
Number	83		87		82
<b><i>Female ratio</i></b>	56.6%	Ns*	<b><i>51.7%</i></b>	<b><i>&lt;0.001</i></b>	<b><i>78.0%</i></b>
<b><i>Mean age (year)</i></b>	<b><i>32.9 ± 13.0</i></b>	<b><i>0.000</i></b>	<b><i>45.0 ± 13.2</i></b>	<b><i>0.006</i></b>	<b><i>51.0 ± 9.9</i></b>
<b><i>Mean BMI† (kg/m<sup>2</sup>)</i></b>	<b><i>22.4 ± 1.5</i></b>	<b><i>0.000</i></b>	<b><i>27.2 ± 1.3</i></b>	<b><i>0.000</i></b>	<b><i>34.3 ± 4.2</i></b>
<b><i>Mean weight (kg)</i></b>	<b><i>62.0 ± 7.6</i></b>	<b><i>0.000</i></b>	<b><i>75.5 ± 8.5</i></b>	<b><i>0.000</i></b>	<b><i>87.2 ± 10.6</i></b>
<b><i>Mean height (cm)</i></b>	165.8 ± 8.4	Ns	<b><i>165.8 ± 9.5</i></b>	<b><i>0.000</i></b>	<b><i>158.8 ± 8.3</i></b>
<b><i>Mean FPG‡ (mg/dL)</i></b>	<b><i>95.2 ± 11.7</i></b>	<b><i>0.012</i></b>	<b><i>102.2 ± 22.1</i></b>	<b><i>0.018</i></b>	<b><i>109.2 ± 28.8</i></b>
<b><i>Mean systolic BP§ (mmHg)</i></b>	<b><i>115.3 ± 16.9</i></b>	<b><i>0.000</i></b>	<b><i>133.6 ± 23.6</i></b>	<b><i>0.000</i></b>	<b><i>147.3 ± 26.8</i></b>
<b><i>Mean diastolic BP (mmHg)</i></b>	<b><i>82.7 ± 8.5</i></b>	<b><i>0.000</i></b>	<b><i>90.1 ± 11.1</i></b>	<b><i>0.000</i></b>	<b><i>96.8 ± 11.9</i></b>
<b><i>Mean TC   (mg/dL)</i></b>	<b><i>180.5 ± 40.9</i></b>	<b><i>0.050</i></b>	<b><i>197.1 ± 39.6</i></b>	<b><i>0.016</i></b>	<b><i>211.3 ± 44.7</i></b>
<b><i>Mean LDL¶ (mg/dL)</i></b>	<b><i>109.1 ± 29.3</i></b>	<b><i>0.000</i></b>	<b><i>130.4 ± 30.9</i></b>	Ns	131.9 ± 37.0
Mean HDL** (mg/dL)	<b><i>40.9 ± 8.9</i></b>	<b><i>0.025</i></b>	<b><i>46.0 ± 10.7</i></b>	<b><i>0.050</i></b>	<b><i>50.1 ± 10.4</i></b>
Mean triglycerides*** (mg/dL)	<b><i>113.6 ± 73.1</i></b>	<b><i>0.003</i></b>	<b><i>136.3 ± 73.7</i></b>	<b><i>0.004</i></b>	<b><i>150.0 ± 85.2</i></b>

\*Nonsignificant (p>0.05) †Body mass index ‡Fasting plasma glucose §Blood pressure || Total cholesterol ¶Low density lipoproteins \*\*High density lipoproteins

to increase by aging without any decrease (p<0.05 nearly in all steps) indicating their irreversible properties. After development of one of the irreversible consequences, the non-pharmaceutical approaches will provide little benefit to prevent development of the others probably due to cumulative effects of the risk factors on the endothelial system for a long period of time (11, 12).

Obesity is probably found among one of the irreversible endpoints of the metabolic syndrome, since after development of obesity, nonpharmaceutical approaches provide limited success either to heal obesity or to prevent its complications. Overweight and obesity probably lead to a chronic and low-grade inflammation on vascular endothelium, and risk of death from all causes including cardiovascular diseases and cancers increases parallel to the range of weight excess in all age groups (14). The low-grade chronic inflammation may cause genetic changes on the epithelial cells, and the systemic atherosclerotic process may decrease clearance of malignant cells by the immune system, effectively (15). The effects of excess weight on BP were shown in a previous study (16) that the prevalence of sustained normotension (NT) was significantly higher in the underweight (80.3%) than the normal weight (64.0%) and overweight groups (31.5%, p<0.05 for both), and 52.8% of cases with HT had obesity

against 14.5% of cases with NT (p<0.001) in another study (17). So the dominant underlying factor of the metabolic syndrome appears as weight gain, which is probably the major cause of insulin resistance, hyperlipidemia, IGT, and WCH via a chronic inflammatory process (6). Even prevention of the accelerating trend of weight gain with diet or exercise, even in the absence of a prominent weight loss, will probably result with resolution of many adverse parameters of the syndrome (18, 19). But according to our opinion, limitation of excess weight as an excessive fat tissue around abdomen under the heading of abdominal obesity is meaningless, instead it should be defined as overweight and obesity by means of BMI since adipocytes function as an endocrine organ and they produce a variety of cytokines and hormones anywhere in the body (6). The resulting hyperactivities of sympathetic nervous system and renin-angiotensin-aldosterone system are probably associated with chronic endothelial inflammation, insulin resistance, and an elevated BP. Similarly, the Adult Treatment Panel III reported that although some people classified as overweight with a large muscular mass, most of them also have excess fat tissue, and excess weight does not only predispose to CAD, stroke, and other endpoints, it also has a high burden of other CAD risk factors including hyperlipidemia, HT, and DM (9).

Plasma lipoprotein levels probably are under dynamic control, and they may act as acute phase reactants indicating disseminated inflammation anywhere in the body. Physical inactivity, increased BMI, smoking, alcohol, elevated BP, increased plasma glucose, prolonged infection and inflammations, and cancers may cause overproduction of very low density lipoproteins (VLDL) in liver. VLDL carry endogenous triglycerides from liver to peripheral tissues either to use or to store. In capillaries of adipocytes and muscle tissue, 90% of triglycerides is removed by a specific group of lipases. These lipases degrade VLDL into intermediate density lipoproteins (IDL), and IDL and are then degraded into LDL by removal of more triglycerides. The fate of LDL is uncertain, and liver removes about 70%. A small amount of LDL in circulation is uptaken by scavenger receptors on macrophages that may migrate into arterial walls, where they become the foam cells of atherosclerotic plaques. Hyperlipoproteinemias can result either from overproduction or defective clearance of VLDL or increased conversion of VLDL into LDL. The increased lipoprotein levels by aging may actually be a result of physical inactivity, excess weight, elevated BP, and increased plasma glucose induced disseminated endothelial damage, inflammation, fibrosis, and eventual atherosclerosis all over the body. Eventually, high TC and LDL levels are independently associated with CAD. Familial hypobeta- and alpha lipoproteinemias are associated with decreased prevalences of CAD and other atherosclerotic sequelae, and they have been referred as the Longevity syndromes. Similarly, low HDL levels often occur in vegetarian populations, in whom LDL levels and CAD rates are low, too.

As a conclusion, the accelerated atherosclerotic process all over the body may be the major consequence of the metabolic syndrome. FPG, systolic and diastolic BP, TC, LDL, HDL, and triglycerides all increased parallel to the increased age, BMI, and body weight, significantly. Hyperlipoproteinemias may actually be acute phase reactants indicating the disseminated endothelial damage, inflammation, fibrosis, and eventual atherosclerosis by aging all over the body.

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# Vasa previa, does Doppler ultrasonography influence the outcome

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## Abstract

**Aim and Objective:** To address the significance of sonographic diagnosis of vasa previa in pregnancy outcome.

**Materials and Methods:** We performed a multicenter study in 3 private hospitals in Iraq during a 5 years period. Cases were obtained from the IVF centers and the obstetrician department in these hospitals. A prospective study was carried out; a total of 4,553 pregnant women at 18-20 weeks' gestation entered this study. During routine antenatal visit and ultrasound examinations, if the possibility of vasa previa was raised especially those in the high risk group (Table 1), the obstetricians were instructed to image the placental cord insertion with color Doppler imaging and classify this as normal or velamentous. These ultrasonographic findings obtained at 18-20 weeks' gestation were used for comparison with outcome data (clinical courses, perinatal outcomes, and placental pathology examinations).

**Results:** Eight cases of vasa previa were suspected at 18-20 gestational age among 4,553 women over a 5-year period. Six patients had confirmation of the diagnosis by the delivering obstetrician and/or placental examination (Figures 1-5). One of those women had preterm uterine contractions and one was allowed to deliver vaginally because subsequent late third-trimester scans showed that vasa previa was no longer present. All remaining 6 patients with confirmed vasa previa, were delivered by scheduled C-section and all infants had normal Apgar scores and survived.

**Conclusion:** Although vasa previa is a rare lethal complication, antenatal diagnosis is essential to improve fetal survival by colour Doppler ultrasonography. Once the diagnosis of vasa previa is made, a Scheduled cesarean section is the preferred method of delivery at 36 weeks' gestation, or when fetal lung maturation has been confirmed, will greatly improve the outcome and prevent catastrophic complication associated with it.

**Key words:** Vasa previa, Velamentous cord insertion, antenatal diagnosis - Colour Doppler

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## Introduction

Literally vasa previa means “vessels in the way, before the baby“. It is one of the most unexpected and tragic accidents in obstetrics. The condition is unique as it bears no maternal, but a high fetal, mortality ranging from 50-60% with intact membranes to 70-100% with ruptured membranes( 1, 2), with a prevalence of 1.5-4:10,000(3, 4) of which 10% occur in twins(5). In vasa previa fetal vessels crossing or running in close proximity to the inner cervical os (unsupported by the umbilical cord or placental tissue) , pose a high risk of rupture and fetal demise if not recognized before rupture of membranes. It can lead to fetal hemorrhage (Benkiser’s Syndrome) by rupture of vasa previa during labour, which may be followed by fetal death in 60-70% of cases (Michaels, 1955; Fox,1978). It is vital to recognize risk factors (Table 1) for vasa previa and diagnose this condition before the onset of labor so that fetal shock or demise is prevented. This study, which began in 2010 January 1, was prompted by the observation of a velamentous insertion of the cord using colour Doppler ultrasound.

Velamentous insertion of the cord was first described by Wrisburg (1) in 1773. Lobstein reported the first case of rupture vasa previa in 1801 (6) and the first ultrasound description of vasa previa dates back to 1987 (21 ). Before ultrasound became a common practice, the diagnosis of vasa previa was often made (too late) on the triad of ruptured membranes, painless vaginal bleeding and fetal distress or demise. During that era, the perinatal mortality rate associated with late identification of vasa previa ranged from 58–73%(22,23). Gray-scale ultrasonography has improved our ability to detect vasa previa(24,25); advances in ultrasound and the extensive experience gained over this long period have led to improved ability of color flow Doppler ultrasound in the diagnosis of this rare anomaly. Although several studies have reported the importance of using color or power Doppler ultrasound for the prenatal diagnosis of vasa previa(26,27,28,29,30), the accuracy of this technique for diagnosing vasa previa is not known, nor is the true incidence of this condition because even in skilled centers, specifically attempting to identify vasa previa, some cases are likely to be missed. Antepartum diagnosis is associated with improved outcomes and also facilitates elective delivery under controlled circumstances that allow rapid access to volume replacement and blood products, but does not eliminate morbidity and mortality of these rare placental anomalies. The aim of our study was to assess the influence of colour Doppler ultrasound on the outcome and to demonstrate the importance of detection and early response to achieve an optimal outcome. Finally, early recognition of this rare placental anomaly is necessary to avoid the extremely high fetal morbidity and mortality rate(27). However, infant death can still occur and elective preterm delivery may be associated with extended newborn hospitalizations from other complications of prematurity.

## Materials and methods

The Human Investigation Committee at Al-Jadriah private Hospital in Baghdad approved this multicenter study in cooperation with other committees. All gravidas in the period between the 1st of January 2010 until 31 of December 2014 were entered into this study. Women were scanned with a variety of ultrasound systems that provided a variety of gray-scale, color and endovaginal capabilities, in their second and third trimesters. We attempted to view the internal cervical os of 4,553 women with second trimester pregnancies during a 5–year period ,and if the possibility of vasa previa was raised , especially in those with high risk factors, the diagnosis was confirmed by colour-flow Doppler mapping of the lower uterine segment and cervical os. Ultrasonographic findings were correlated with clinical courses, perinatal outcomes, and placental pathology examinations.

## Discussion

Vasa previa is a rare occurrence. Vago and Caspi (31) report an incidence of this condition of 1:2761. It is precisely because of this rarity that the condition is often not diagnosed or even considered. The major unexpected and catastrophic complication from vasa previa is the rupture of the vessels carrying fetal blood, which lack the protection of Wharton’s jelly (32,33,34). This bleeding from a ruptured vasa, causing fetal exsanguination and death, occurs at or near delivery if the condition is undetected and results in a reported perinatal mortality rate in 50-60 % with intact membranes and 75-100 % with ruptured membrane’s(35,36,37).

The outcome is markedly improved when a prenatal diagnosis is done followed by elective C-section. The reduction in the fetal mortality depends on a Prenatal identification of a vasa previa, the desirable clinical goal, since these pregnancies have higher risks for adverse perinatal outcome. The use of colour flow imaging makes the reduction in the fetal mortality possible, especially in those pregnancies at high risk (Table 1). Ultrasound examination and colour-flow Doppler mapping of the lower uterine segment and cervical os in the second trimester is of great help and should result in vasa previa being easier to diagnose and becoming an increasingly rare cause of perinatal mortality.

In this prospective multicenter study all patients had 3 ultrasound examinations, 2 of which included transvaginal examinations of the cervix. All obstetricians were alerted to recognize the identified risks for vasa previa (Table 1) and the differential diagnosis of vasa previa on ultrasound (Table 2) 40. The condition was suspected in 8 pregnancies and confirmed in 6. One of the 8 patients had regression of the vasa previa noted on late third trimester rescanning and had uneventful vaginal delivery and one had preterm uterine contraction. We describe a successful outcome after detection of vasa previa during a second trimester scan with color Doppler imaging. In all cases of confirmed diagnosis of vasa previa the pregnancy proceeded uneventfully and healthy infants were born by scheduled caesarean section, which is considered the safest and preferred mode(38,39 ) of delivery in such an anomaly to avoid serious complications of fetal bleeding. Current evidence suggests that antenatal diagnosis of vasa previa

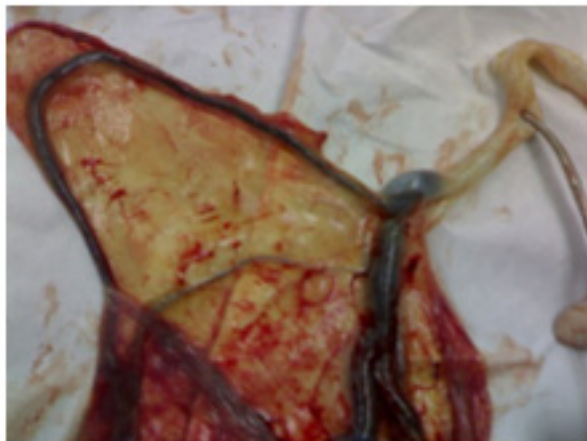
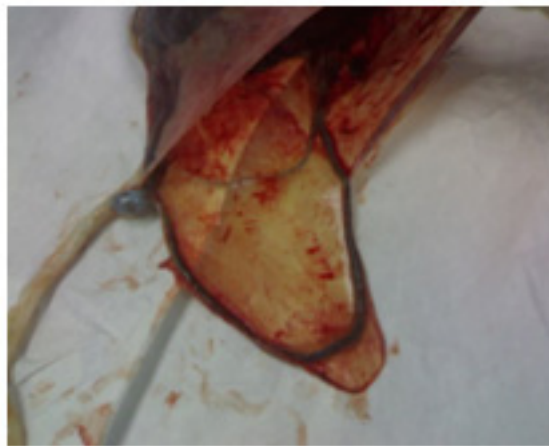
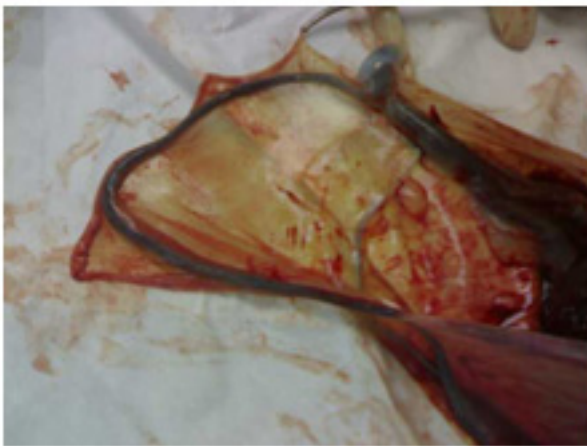
**Table 1: Risk factors for vasa previa\***

No	Risk factor	Reference
1	Placenta previa	9
2	Low-lying placenta	7,8
3	Multiple pregnancy	10
4	Multi-lobate placentas and velamentous cord insertion 1% in singleton 10% multifetal pregnancies	20 11-13
5	Placenta membranacea	19
6	In-vitro fertilization about 1:300 pregnancies	14-17 18

\* Information from references 7 and 20

**Table 2: Differential Diagnosis of Vasa Previa suspected on Ultrasound**

1	Chorioamniotic membrane separation
2	Normal cord loop
3	Marginal placental vascular sinus
4	Amniotic band



**Figures 1-5 : Postpartum appearance of the placenta with three-vessel umbilical cord free within the membrane**



is associated with improved outcomes. Evaluation of all patients in high risk groups (Table 1) with transvaginal color flow Doppler should be considered for better outcome.

## Conclusion

Although vasa previa is a rare lethal complication, antenatal diagnosis by colour Doppler ultrasonography is essential to improve fetal survival, but does not eliminate morbidity and mortality of this rare placental anomaly and physicians must be vigilant whenever amniotomy is performed, because all cases of vasa previa cannot be identified antenatally.

Once the diagnosis of vasa previa is made, a scheduled cesarean section is the preferred method of delivery at 36 weeks' gestation, or when fetal lung maturation has been confirmed; will greatly improve the outcome and prevent catastrophic complications associated with it.

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# Association of CVS and amniocentesis for Down syndrome with fetal loss

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## Abstract

**Background:** Despite different studies the association of CVS and amniocentesis for Down syndrome with fetal loss is not yet clearly known. Hence in this study, the association of CVS and amniocentesis for Down syndrome with fetal loss was assessed.

**Materials and Methods:** In this historical-cohort, consecutive subjects with single pregnancy attending the perinatology clinic for first trimester screening in 2014 and 2015 including the CVS and amniocentesis group and control subjects, were enrolled. The fetal loss rates at 7, 14, 60 days, were compared across the groups.

**Results:** There were no statistically significant differences for fetal loss rates across two groups ( $P > 0.05$ ) and 1.75% and 1.68% had loss in case and control groups. 9 out of 11 cases in the CVS and amniocentesis group occurred in the first seven days.

**Conclusions:** Totally, according to obtained results, it may be concluded that there is no association between CVS and amniocentesis for Down syndrome with fetal loss.

**Key words:** CVS, Amniocentesis, Down syndrome, fetal loss

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## Introduction

Amniocentesis and chorionic villus sampling (CVS) are two invasive methods for prenatal diagnosis and pregnant women should be informed about related risk of abortion (1, 2). The total risk of abortion is 1% and 1-2% for amniocentesis and CVS, respectively (1). The reported risks differ in various communities (3-6) and also between amniocentesis and CVS (7). So regarding the risk of abortion the prenatal screening differs according to maternal age and CFTS for Down syndrome leading to alteration of choice from amniocentesis to CVS (8-10).

The related procedure-related risk of fetal loss is decreased to 0.2% and 0.1% for CVS and amniocentesis respectively with improvement of sampling methods (11). High maternal age, smoking, increased nuchal translucency thickness (NT), and low PAPP-A level are related to increased risk of preterm labor and abortion (12-14). These factors are also related to chromosomal abnormalities leading to higher CVS rate (15-18).

Regarding selection bias of those with higher risk of fetal loss in clinical trials and lack of randomization the utilization of results is limited (19). Hence in this study, the association of CVS and amniocentesis for Down syndrome with fetal loss was assessed.



## Materials and Methods

In this historical-cohort, 5,216 (with follow-up in 4,078) consecutive subjects with single pregnancy and CRL of 45 to 84 millimeter attending to perinatology clinic for first trimester screening in 2014 and 2015 including CVS and amniocentesis group (n=628) and control subjects (n=3450) were enrolled. The informed consent form was signed and Helsinki Declaration was respected across the study.

NT and  $\beta$ -hCG and PAPP-A at first trimester and data about abortion history, IUFD history, gestational age (according to CRL), type of fertility (IUI, IVF, natural), BMI, smoking, parity, and maternal age were gathered. The fetal loss rates at 7, 14, 60 days, were then compared across the groups. The CVS with double blunt aspiration needle (18-G and 22-G) and amniocentesis with trans-abdominal ultrasound guide single needle 22-G were performed by an expert perinatologist.

The statistical analysis was done with SPSS version 24.0 software. The tests used were Chi-Square and Fisher and independent-sample-T and the significance level was 0.05.

## Results

The mean (standard deviation) age was 31.95 (6.89) and 31.07 (7.24) years in case and control groups, respectively ( $P > 0.05$ ). The mean (standard deviation) gestational age was 11.87 (1.34) and 11.46 (1.32) weeks in case and control groups, respectively ( $P > 0.05$ ). The mean (standard deviation) BMI was 26.73 (3.51) and 26.49 (3.32) kg/m<sup>2</sup> in case and control groups, respectively ( $P > 0.05$ ).

**Table 1: Previous gestational history across the groups**

Group	Case	Control	P Value
Gravid	1.23 ± 0.701	1.42 ± 0.744	> 0.05
Parity	1.32 ± 0.478	1.10 ± 0.387	> 0.05
Living child	1.05 ± 0.229	1.09 ± 0.422	> 0.05
Abortion	1.38 ± 0.976	1.32 ± 0.637	> 0.05

Previous gestational history, NT, CRL, PAPP-A, and Beta-HCG were alike across the groups (Tables 1-3). There were no statistically significant differences for fetal loss rates across the two groups ( $P > 0.05$ ) and 1.75% and 1.68% had fetal loss in case and control groups, respectively. 9 out of 11 cases in CVS and amniocentesis group occurred in the first seven days. There were no statistically significant differences for preterm labor rates across the two groups ( $P > 0.05$ ) and 2.07% and 2.06% had preterm labor in case and control groups.

**Table 2: NT and CRL across the groups**

Group	Case	Control	P Value
NT	1.54 ± 4.643	1.30 ± 1.004	> 0.05
CRL	56.93 ± 57.552	57.55 ± 7.142	> 0.05

**Table 3: PAPP-A and Beta-HCG across the groups**

Group	Case	Control	P Value
Value PAPP-A	4.34 ± 0.090	4.10 ± 2.251	> 0.05
Value BHCG	44.07 ± 31.366	41.28 ± 23.787	> 0.05
MOM PAPP-A	1.19 ± 0.772	1.13 ± 4.375	> 0.05
MOM BHCG	2.23 ± 2.367	1.67 ± 2.097	> 0.05

**Table 4: Fetal loss and Preterm labor across the groups**

Group	Case	Control	P Value
Fetal loss	11 (1.75%)	58 (1.68%)	> 0.05
Preterm	13 (2.07%)	71 (2.06%)	> 0.05

## Discussion

In this study, the association of CVS and amniocentesis for Down syndrome with fetal loss and preterm labor was assessed. Akolekar et al (20) assessed 33,310 live births, 404 miscarriage, and 142 stillbirth cases and reported that CVS had no effect on miscarriage and stillbirth, as found in our study.

Tabor et al (21) in Denmark reported the fetal loss rates of 1.4% and 1.9% for amniocentesis and CVS which was similar to our study. Antsaklis et al (22) in Greece assessed 69 cases of CVS and 347 amniocentesis cases in the second trimester and reported the fetal loss rates of 4.18% and 4.54% for amniocentesis and CVS. They concluded that CVS is good alternative for amniocentesis as can be concluded from our results.

A review study by Akolekar et al (11) about procedure-related risks for amniocentesis and CVS with use of CINAHL, EMBASE, MEDLINE, and Cochrane databases during 2000 to 2014 showed fetal loss in 324 out of 42,716 amniocentesis cases and 207 out of 8,899 CVS cases. Also the fetal loss was 1.79% in the control group. They showed that risk of fetal loss was low and negligible similar to our study.

Wulff et al (19) assessed 147,987 single pregnancies attending for first trimester screening. The risk of fetal loss was not higher for amniocentesis and CVS in comparison with control group. The rates were 0.08% and 0.21% at third and 21st days for CVS. The rate was 0.56% at 28th day for amniocentesis. They found that the rate of fetal loss was not significantly high as seen in our study.

Totally, according to the obtained results, it may be concluded that there is no association between CVS and amniocentesis for Down syndrome with fetal loss. However further studies with larger sample size and multi-center sampling would result in more definite results with larger generalization potency.

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# Interaction of GCKR, MLXIPL and FADS genes polymorphisms with obesity in the occurrence of childhood metabolic syndrome

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## Abstract

**Objective:** Considering the implication of better understanding of metabolic syndrome (MetS) pathophysiology in designing proper preventative and management strategies and the fact that dyslipidemia is one of the early and common features of MetS, the aim of this study was to investigate the interaction of some lipid regulatory genes polymorphisms with obesity in the occurrence of MetS in children.

**Methods:** In this nested case-control study, 300 frozen samples of normal weight and 300 samples of overweight/obese children aged 10-18 years old from the CASPIAN III study samples were selected randomly. The studied population was classified into four groups as follows: Normal weight participants with and without MetS and overweight/obese participants with and without MetS. Allelic and genotypic frequencies of GCKR (rs780094), GCKR(rs1260333), MLXIPL(rs3812316) and FADS(rs174547) polymorphisms were determined and compared in the four studied groups. Interaction of each studied Single Nucleotide Polymorphisms (SNPs) with obesity in the occurrence of MetS was evaluated also.

**Results:** In this study, 276 normal weight and 252 overweight/obese children were evaluated. Frequency of minor alleles of GCKR (rs780094) polymorphism in normal weight students with MetS was significantly

higher than normal weight students without MetS ( $P=0.04$ ), obese students without MetS ( $P=0.04$ ) and obese students with MetS ( $P=0.03$ ). Frequency of cc allele of MLXIPL (rs3812316) polymorphism in normal weight students with MetS was significantly higher than obese children with MetS ( $P=0.04$ ). The interaction of each studied SNPs with obesity had significant effect in the occurrence of MetS ( $P<0.001$ ).

**Conclusion:** In this study, we identified two SNPs which possibly are in association with metabolically unhealthy normal weight phenotype. The interaction of lipid regulatory gene polymorphisms with obesity result in the occurrence of MetS, whereas in each of the studies SNPs were not associated with MetS. Identification of such interactions between modifiers like obesity with genetic variants could be helpful in development of preventative strategies for reducing the increasing trend of MetS in children.

**Key words:** Metabolic syndrome, children, obesity, glucokinase regulatory protein, MLXIPL protein, fatty acid desaturases

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## Introduction

Childhood metabolic syndrome (MetS) with a prevalence rate of 3.3%, represents a cluster of risk factors including abdominal obesity, impaired glucose tolerance, dyslipidemia, and high blood pressure which is associated with increased risk of cardiovascular morbidity and mortality(1,2).

MetS is considered a polygenic trait with multifactorial etiology. The pathophysiology of the disorder is not yet clearly determined. In addition, recent advanced information about the mechanisms of its biochemical, physiological and genetic components make the understanding of MetS etiology more complicated. It is suggested that gene-gene, gene-environment or epigenetics could explain the mechanisms of MetS development in children (3,4).

Different studies worldwide have investigated various polymorphisms related to pediatric MetS. Results of a recent systematic review reported 60 genes and 125 polymorphisms related to childhood MetS. Accordingly, though there are polymorphisms which are related to MetS, but most of the reported SNPs were related to the components of MetS, mainly dyslipidemia (5).

There is increasing evidence indicated that the three core factors in the development of MetS are insulin resistance, inflammation and obesity. Obesity is an independent risk factor for cardiovascular disease with a well determined association with MetS. Findings of a recent study showed that prevalence of MetS was 11.9% and 29.2% in overweight and obese children, respectively (1).

It seems that the association between obesity and MetS is complicated, because in spite of the fact that MetS is more prevalent in obese children there are documents which have shown that there is a subgroup of obese patients who do not have MetS and conversely there is a subgroup of normal weight children with MetS(6,7). Presence of such subgroups suggested the possibility of interaction of susceptible genes with specific phenotypes or environmental factors in the development of MetS in children. Few studies have recently demonstrated that the impact of some metabolic trait related polymorphisms are modified by obesity or express only in the presence of obesity (8,9).

Epidemiologic studies indicated the high prevalence rate as well as increasing trend of MetS in Iranian children (10,11). Thus, considering the implication of better understanding of MetS pathophysiology in designing proper preventative and management strategies and the fact that dyslipidemia is one of the early and common features of MetS, the aim of this study was to investigate the interaction of some lipid regulatory gene polymorphisms with obesity in the occurrence of MetS in children.

## Materials and Methods

This study was designed as a nested case-control study and as a sub study of the third Childhood and Adolescence Surveillance and Prevention of Adult Non-communicable disease study (CASPIAN-III). The survey was conducted in 27 provinces of Iran during 2009-2010, including 5,528 schoolchildren aged 10-18 years old. Details and methodology of the survey have been described previously (12).

The protocol of this sub study was confirmed by the review board of Child Growth and Development Research Center and the Regional ethics committee of Isfahan University of Medical Sciences (research project number 193058)

We randomly selected 300 frozen samples of normal weight and 300 samples of overweight/obese children from the CASPIAN III study samples.

Weight categories as normal weight and overweight/obese were determined using BMI Z-scores defined by the World Health Organization (WHO)(13).

Using the recorded anthropometrics and biochemical data of the selected CASPIAN III samples, children with and without MetS were determined in the normal weight and overweight/obese groups.

MetS was defined based on definition of Cook et al. which was similar to that reported by ATPIII(14). According to the definition the coexistence of at least three of the following components was considered as MetS.

1. Waist circumference > 90th percentile
2. Weight, age and sex specific systolic and diastolic blood pressure > 90th percentile
3. FBS  $\geq$ 100 mg/dL
4. Age specific TG > 90th percentile( $\geq$ 110mg/dl)
5. HDL-C < 10th percentile( $\leq$ 40mg/dl)

The studied normal weight and obese/overweight population was classified in four groups as follows; Normal weight participants with and without MetS and overweight/obese participants with and without MetS. Allelic and genotypic frequencies of GCKR (rs780094), GCKR (rs1260333), MLXIPL (rs3812316) and FADS (rs174547) polymorphisms were determined and compared in the four studied groups.

Interaction of each studied SNPs with obesity in the occurrence of MetS was also evaluated.

### Genetic study

DNA was extracted from peripheral blood samples using the YATA DNA extraction kit (YATA, Iran) according to the manufacturer's protocol. The GCKR (rs780094), GCKR (rs1260333), MLXIPL (rs3812316) and FADS (rs174547) polymorphisms were identified by NCBI data bank. Primers of the four polymorphisms were designed by Beacon Designer 8.1(PREMIER Biosoft International,

USA) to flank the desired regions. The primers were synthesized by Bioneer (S. Korea).

Genotyping was performed by real-time PCR and high-resolution melt analysis (HRM) assay by a Rotor-Gene 6000 instrument (Corbett Life Science, Australia).

Using a Type-it HRM kit (Qiagen, Germany) the amplicons were generated according to the following program; one cycle at 95°C for 15 min; 40 cycles at 95°C for 15 s, 60.0°C for 15 s, 72°C for 15 s, one cycle of 95°C for 1 s, 72°C for 90 s and a melt from 70 to 95°C rising at 0.1°C per s. The amplification mixture of a total volume of 25 µL included 12.5 µL of HRM PCR master mix, 1.75 µL of 10 µM primer mix, 2 µL of genomic DNA as a template and 8.25 µL of RNase-free water. For each genotype reaction, we included sequence-proven major and minor allele homozygote and heterozygote controls.

Using the instrument software, the results of HRM were analyzed by comparing the melting curve shape between studied samples and known controls.

### Statistical analysis

Data was analyzed by IBM SPSS/PC statistical software version 21. The Hardy-Weinberg equation was tested to compare the observed genotype frequencies to the expected ones by  $\chi^2$  analysis. The continuous and categorical variables were presented as mean (standard deviation) and frequencies (percentage), respectively. The Chi-square and T-test were used to compare the categorical and continuous variables, respectively.

The association between each studied SNP and MetS and their interaction with obesity on the occurrence of MetS was analyzed using binary logistic analysis.

P value of less than 0.05 was considered as statistically significant.

## Results

In this study, from initially selected cases, 528[276(52.3%) normal weight and 252(47.7%) overweight/obese] children were evaluated. Mean (SD) age of studied children was 15.01(2.21) years.

From the studied population 114 students had MetS. From students with metabolic syndrome 149, 130, 135, 75, 36 and 3 students had 0, 1, 2, 3, 4 and five components of MetS. General characteristics and lifestyle related risk factors of children with and without MetS are presented in Table 1. Lifestyle related risk factors including prolonged screen time and low physical activity were not significantly different between children with and without MetS ( $P>0.05$ ). Familial history of Non communicable diseases was significantly higher in children with MetS than those without ( $P=0.009$   $X^2=5.91$ ).

Distribution of the genotypes and allele frequencies in children with and without metabolic syndrome are presented in Figure 1. Prevalence of minor alleles of FADS (rs174547) [tc and cc] were significantly higher in children with MetS than those without ( $P=0.04$ ,  $X^2=3.41$ ).

Using logistic regression analysis, there was not any significant association between studied SNPs and MetS ( $P>0.05$ ).

Prevalence of MetS in normal weight and overweight/obese children was 7.25 % (20/276) and 37.30 % (94/252), respectively ( $P<0.001$ ,  $X^2=70.28$ ).

General characteristics and lifestyle related cardiovascular risk factors of normal weight and overweight/obese children with and without MetS are presented in Table 2. Familial history of non-communicable diseases was significantly higher in obese children with and without MetS than normal weight children without MetS ( $P<0.05$ ). Lifestyle related risk factors were not significantly different between the four studied groups ( $P>0.05$ ).

The distribution of the studied SNPs genotypes and allele frequencies in normal weight and overweight/obese children with and without MetS are presented in Table 3. Frequency of the different alleles of studied SNPs were not significantly different between the four studied groups ( $P>0.05$ ).

Results of Pair wise comparisons of the genotype and allele frequency in the four studied groups were as follows: Frequency of minor alleles of GCKR (rs780094) polymorphism in normal weight students with MetS was significantly higher than normal weight students without MetS ( $P=0.04$ ,  $X^2=3.70$ ), obese students without MetS ( $P=0.04$ ,  $X^2=3.82$ ) and obese students with MetS ( $P=0.03$ ,  $X^2=4.15$ ).

Frequency of cc allele (major allele) of MLXIPL (rs3812316) polymorphism in normal weight students with MetS was significantly higher than obese children with MetS ( $P=0.04$ ,  $X^2=3.37$ ).

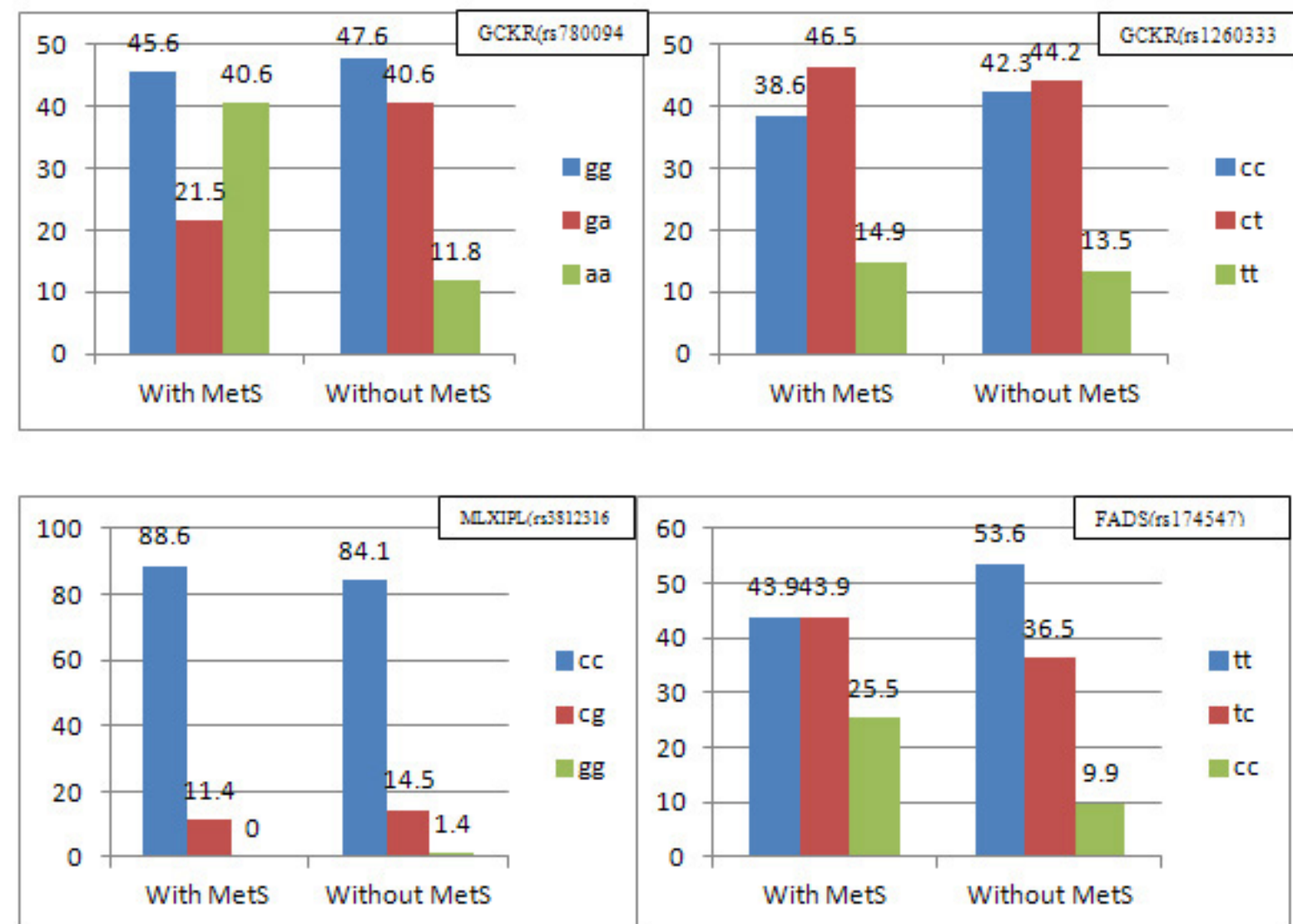
Results of binary logistic analysis regarding the interaction of studied SNPs with obesity in the occurrence of MetS are presented in Table 4. The interaction of each studied SNPs with obesity had a significant effect in the occurrence of MetS ( $P<0.001$ ).



**Table 1. Characteristics of children with and without metabolic syndrome (MetS)**

Variables	With MetS (n=114)	Without MetS (n=414)	P value
Age(years)*	15.46(1.93)	14.88(2.27)	0.01
Sex(female/male) [n(%)]	59/55(51.8%/48.2%)	214/200(51.7%/48.3%)	<0.001
BMI(kg/m <sup>2</sup> )*	27.90(4.93)	22.64(5.68)	<0.001
Familial history of Non communicable diseases [n(%)]	80(82.5%)	248(75.6%)	0.009
<b>Life style related risk factors</b>			
Prolonged screen time [n(%)]	106(94.6%)	391(95.8%)	0.37
Low physical activity [n(%)]	48(42.9%)	183(44.9%)	0.39

\*Mean (SD)

**Figure 1: Distribution of the GCKR(rs780094), GCKR(rs1260333), MLXIPL(rs3812316) and FADS(rs174547) allele frequencies in children with and without metabolic syndrome(MetS)**

**Table 2: General characteristics and lifestyle related cardiovascular risk factors of normal weight and overweight/obese children with and without metabolic syndrome (MetS)**

Variables	Normal weight without MetS n=256	Normal weight with MetS n=20	overweight/obese without MetS n=158	overweight/obese with MetS n=94	P value
Age (years)*	14.64(2.40)	15.05(2.08)	15.28(1.98)	15.55(1.89)	0.001
Sex (female/male) [n(%)]	149/107(58.2%/41.8%)	12/8(60%/40%)	65/93(41.1%/58.9%)	47/47(50%/50%)	0.007
Weight (kg)*	45.05(11.57)	48.10(10.60)	72.53(14.60)	77.95(15.72)	<0.001
Height (cm)*	154.25(14.25)	155.95(11.70)	156.81(15.50)	161.28(12.54)	0.001
BMI (kg/m <sup>2</sup> )*	18.55(2.04)	19.50(2.09)	29.26(2.64)	29.69(3.21)	<0.001
Abdominal Obesity [n(%)]	9(3.5%)	3(15%)	137(86.7%)	89(94.7%)	<0.001
Familial history of Non communicable diseases [n(%)]	143(67.8%)	11(78.6%)	105(73.4%)	69(83.1%)	0.06
<b>Biochemical measurements</b>					
<b>Blood pressure*</b>					
-Systolic	103.06(12.28)	109.80(16.18)	109.54(12.23)	123.68(12.54)	<0.001
-Diastolic	66.25(11.45)	69.80(11.29)	68.65(9.57)	74.93(9.95)	<0.001
<b>Lipids*</b>					
-Cholesterol	138.40(30.72)	157.75(35.23)	153.02(29.41)	166.85(38.52)	<0.001
-Triglyceride	74.0(22.58)	126.10(52.52)	105.44(50.31)	165.0(75.13)	<0.001
-HDL-C	43.70(10.91)	35.0(6.57)	44.91(11.59)	38.24(10.83)	<0.001
-LDL-C	80.55(27.35)	91.71(23.82)	87.51(24.18)	90.07(28.15)	<0.001
Fasting blood sugar*	85.34(22.53)	106.15(11.68)	88.01(10.43)	94.86(15.94)	<0.001
Hypertension [n(%)]	111(62.7%)	19(95%)	15(9.5%)	32(34.0%)	<0.001
Hypercholesterolemia [n(%)]	40(15.6%)	7(35%)	48(30.6%)	36(38.3%)	<0.001
Hypertriglyceridemia [n(%)]	16(6.3%)	10(62.5%)	56(40.6%)	29(59.2%)	<0.001
High LDL-C [n(%)]	35(16.4%)	5(29.4%)	25(18.4%)	18(25.4%)	0.26
Low HDL-C [n(%)]	95(37.1%)	15(75%)	49(32.7%)	47(58.8%)	<0.001
<b>Life style related risk factors</b>					
High screen time [n(%)]	238(94.4%)	18(90.0%)	153(98.1%)	88(95.7%)	0.20
Low physical activity [n(%)]	115(45.6%)	8(40.0%)	68(43.6%)	40(43.5%)	0.94

\*Mean(SD)



**Table 3: The distribution [n(%)] of the four studied SNPs genotypes and allele frequencies in the normal weight and overweight/obese children with and without metabolic syndrome (MetS)**

Genotypes and allele	Normal weight without MetS n=256	Normal weight with MetS n=20	overweight/obese without MetS n=158	overweight/obese with MetS n=94	P value
GCKR(rs780094)					0.09
GG	121(47.3%)	5(25%)	76(48.1%)	47(50.0%)	
ga	108(42.2%)	14(70%)	60(38.0%)	32(34.0%)	
aa	27(10.5%)	1(5%)	22(13.9%)	15(16.0%)	
GCKR(rs1260333)					0.67
cc	115(44.9%)	8(40%)	60(38.0%)	36(38.3%)	
ct	111(43.4%)	8(40%)	72(45.6%)	45(47.9%)	
tt	30(11.7%)	4(20%)	26(16.5%)	13(13.8%)	
MLXIPL(rs3812316)					0.45
cc	211(82.4%)	19(95.0%)	137(86.7%)	82(87.2%)	
cg	42(16.4%)	1(5.0%)	18(11.4%)	12(12.8%)	
gg	3(1.2%)	0(0.0%)	3(1.9%)	0(0.0%)	
FADS(rs174547)					0.56
tt	140(54.7%)	9(45.0%)	82(51.9%)	41(43.6%)	
tc	94(36.7%)	9(45.0%)	57(36.1%)	41(43.6%)	
cc	22(8.6%)	2(10.0%)	19(12.0%)	12(12.8%)	

**Table 4: Interaction between lipid regulatory genes polymorphisms and obesity in the occurrence of metabolic syndrome in children: the CASPIAN- III study**

Variable	OR	95%CI	P value	Adjust OR	Adjust 95%CI	P value
GCKR(rs780094) * obesity	1.749	1.44-2.11	0.000	1.717	1.39-2.11	0.000
GCKR(rs1260333) * obesity	1.776	1.47-2.13	0.000	1.769	1.44-2.16	0.000
MLXIPL(rs3812316) * obesity	1.98	1.53-2.56	0.000	1.963	1.48-2.59	0.000
FADS(rs174547) * obesity	1.90	1.58-2.30	0.000	1.860	1.51-2.28	0.000

\* The interaction of the single nucleotide polymorphism loci and obesity

## Discussion

In this study we investigated the interaction of four lipid regulatory genes polymorphism with obesity in the occurrence of childhood MetS. Our results indicated that the frequency of studied SNPs and their alleles was not different in children with and without MetS except for minor alleles of FADS. Frequency of the different alleles of studied SNPs was not significantly different between normal weight and obese children with and without MetS. But the interaction of the studied SNPs with obesity had significant impact in the occurrence of MetS.

In this study we selected four SNPs from three lipid regulatory genes of FADs, GCKR and MLXIPL. The following reasons could justify our selection. First we selected lipid regulatory genes polymorphisms due to the fact that dyslipidemia is one of the initial features of metabolic abnormality in MetS and previous studies reported that dyslipidemia is the most common component of childhood MetS in Iranian children (11,15). Second, based on our systematic review on polymorphisms related to MetS in children, except for GCKR (rs780094) which association with MetS has been reported previously, remainder SNPs have not been investigated in children yet(5).

In this study prevalence of MetS in normal weight and obese children was 7.25 and 37.30 %, respectively. Prevalence of MetS was nearly 5 times higher in obese than non obese children, which was similar to the results of previous research in this field (1).

Comparison of the studied four SNPs between children with and without MetS in the current study indicated that only minor alleles of FADS1 (rs174547) were significantly higher in children with MetS, but logistic regression analysis did not show any significant association between the polymorphisms and MetS.

FADS1 gene encodes the delta-5-desaturase enzyme which regulates unsaturation of fatty acids (16). Based on GWAS polymorphisms of FADS gene cluster have significant impact on lipid levels and glucose homeostasis. The association of FADS (rs174547) polymorphism with polygenic dyslipidemia and level of LDL-C, HDL-C and triglyceride have been reported in previous studies (17-19). Lack of association between MetS and FADS (rs174547) may be due to the fact that the SNP is simply associated with lipid levels and not MetS. In our systematic review we did not find any report regarding the association of the polymorphism with MetS. It seems that other additive environmental or modifiers in subjects with the minor allele of FADS (rs174547) could increase the susceptibility of MetS occurrence in children.



The frequencies of studied polymorphisms in our study were not different between the four groups of normal weight and obese children with and without MetS. Pairwise comparison indicated that normal weight children with MetS which could also be defined as metabolically unhealthy normal weight had a higher level of major allele (cc) of MLXIPL (rs3812316) than obese children with MetS. The finding could be explained by that there is a possible association between the polymorphism and the phenotype which should be investigated in future studies.

MLXIPL gene regulates glycolysis and lipogenesis in liver(20). GWAS reports indicated that the minor allele of MLXIPL functional variant, rs3812316, is strongly associated with lower triglyceride level(21). The association was reported for both Asian and European populations, but there are also studies which did not show such an association(22-24). A recent study in Slovakia indicated that cc allele is associated with higher relative risk of hypertriglyceridemia(25). Another study among children demonstrated protective function of minor alleles of the SNPs for triglyceride(26).

Another finding of pair wise comparison was the significantly higher frequency of minor alleles of GCKR (rs780094) polymorphism in normal weight students with MetS than normal weight students without MetS, obese students without MetS and obese students with MetS.

These findings also could suggest the association of the polymorphism with normal weight metabolically unhealthy phenotype, which should be evaluated in future research.

GCKR gene regulates the glucose homeostasis. Associations of different GCKR SNPs with triglyceride, insulin resistance and MetS have been reported by GWAS(27-29). Previous reports demonstrated the role of GCKR rs780094 polymorphism in dyslipidemia, high triglyceride level and impaired fasting glucose (30-32). In a study, in Taiwan the association between GCKR rs780094 and MetS and HDI-C has been reported among adolescents (33).

Findings of Yaghootkar et al. could confirm our suggestion regarding the association of GCKR rs780094 with metabolically unhealthy normal weight phenotype. They investigated genetic evidence for the phenotype linking to metabolic abnormalities including insulin resistance, type 2 diabetes, and hypertension and coronary artery disease. They identified 11 variants and GCKR was one of the identified variants (34).

In current research, there were not any significant differences in the frequency of different alleles of GCKR rs1260333 polymorphism between the four studied groups.

Previous studies have shown the association between GCKR rs1260333 and lipid levels, triglyceride, insulin resistance and metabolic syndrome (35,36). But results of a study in a pediatric population have demonstrated that though this SNP was associated with hypertriglyceridemia in children, the triglyceride increasing allele has protective

effect for insulin resistance (37). Our results in this study could be explained by the findings of above mentioned study.

In this study interaction of each studied polymorphism with obesity had significant association with the occurrence of MetS in children. This finding supports the hypothesis that interaction of lipid regulatory polymorphism with obesity may increase the susceptibility of occurrence of MetS in children and confirmed the modulator role of obesity in this field.

It is well established that genetic changes in DNA sequence could not solely describe the phenotypic changes and development of MetS and various gene environmental interactions have an important role in this field. On the other hand, the underlying mechanisms linking obesity to MetS are not determined yet and possibly it has complex pathways. There are limited studies in the field of interaction of obesity with genetic polymorphisms in the development of MetS. There is some evidence related to adipokines and adipose tissue. According to their suggestion obesity possibly could modify the impact of some genes related to MetS(8,9).

The implication of our findings was that gene-phenotype interactions modulate the risk for MetS in children. By identifying such interactions, the genetic susceptibility to MetS can be substantially reduced by appropriate management of childhood obesity.

Limitation of the current study was the small sample size of children with MetS, especially in the group of normal weight children with MetS. Though the sample size was small, they were selected from a nationwide sample and they were a representative sample of the Iranian population.

Strength of our research was its novelty. Another superiority of this study was that we investigated the interaction of lipid gene polymorphisms with obesity on MetS in the pediatric age group. It is well documented that evaluation of such associations in children is less likely to have confounding effects due to the fact that gene-environment, gene-phenotype and gene-gene interactions occur over time.

## Conclusion

Based on the results of this study, we identified two SNPs which possibly are in association with metabolically unhealthy normal weight phenotype. However the association should be investigated in future studies. We also indicated that the interaction of lipid regulatory genes polymorphisms with obesity result in the occurrence of MetS, whereas in each of the studies SNPs were not associated with MetS.

Identification of such interactions between modifiers like obesity with genetic variants could be helpful in development of preventative strategies for reducing the increasing trend of MetS in children as well as classification of high risk pediatric population for MetS based on their genetic and anthropometric characteristics.

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# Prevalence of Vitamin D Deficiency in Children and Adolescents Referred to Pediatric Orthopedic Clinic

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## Abstract

**Background:** Vitamin D deficiency is the most common nutritional deficiency in the world. Vitamin D is important for bone health and calcium metabolism and also has non skeletal health benefits. The aim of this study was to determine prevalence of vitamin D deficiency and insufficiency in children and adolescents presenting for primary care to the pediatric orthopedic clinic.

**Materials and Methods:** We retrospectively reviewed the records of a total of 212 children and adolescents between 1-15 years who referred to Mofid Children's tertiary center. The subjects were classified as three groups according to their Vitamin D status (deficiency  $\leq 20$  ng/mL, insufficiency 21-29 ng/mL and sufficiency  $\geq 30$  ng/mL) and also were divided according to their age (preschool 1-5 years, primary school age 6-10 years and adolescence 11-15 years).

**Results:** Altogether 62.2% of the subjects had Vitamin D level less than 30 ng/mL. Vitamin D deficiency was found in 77 cases (36.3%) and vitamin D insufficiency was found in 55 cases (25.9%). There is no significant difference between males and females in terms of low 25 hydroxy vitamin D levels. Prevalence of vitamin D deficiency and insufficiency was evidently lower in 1-5 years group than older age groups.

**Conclusion:** There is a high rate of subclinical vitamin D deficiency in children referred to the pediatric orthopedic clinic that is more evident in the 6-10 years group. This indicates a need for more comprehensive supplementation programs especially for school age children.

**Key words:** Vitamin D, Deficiency, Prevalence, Health.

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## Introduction

Vitamin D deficiency is the most common nutritional deficiency in the world(1). It is presumed to be one of the most common undiagnosed medical conditions (2). Prevalence of this disorder is about 30-80% in the pediatric and adult community(3-5). It has been estimated that one billion people worldwide have vitamin D deficiency or insufficiency(5). Effects of vitamin D deficiency is not limited to calcium metabolism and bone health; it has an essential role in decreasing risk of many chronic diseases such as Systemic Lupus erythematosus (SLE), rheumatoid arthritis, multiple sclerosis, type I diabetes mellitus, cardiovascular diseases, infectious diseases and cancers(6-8). This function is based on presence of vitamin D receptors in all cells and tissues in the human body and its participation in the adjustment of genes controlling cell proliferation and differentiation, apoptosis and angiogenesis(6,8). Very few foods, for example oily fish, egg yolk and wild mushroom naturally contain Vitamin D, but a major natural source of vitamin D (>90%) is from skin photosynthesis following ultra violet solar irradiation(9,10). In this process 7-dehydro cholesterol is converted to pre vitamin D3, that after isomerization forms vitamin D3. Both vitamin D3 (cholecalciferol) from photosynthesis in skin or dietary source and vitamin D2 (ergocalciferol) undergo hydroxylation in the liver to make storage form of vitamin D, 25-Hydroxyl vitamin D (calcidiol). In the kidney (also in colon, prostate, breast, brain,  $\beta$ -islet cells of pancreas, vascular smooth muscle cells and macrophages) hydroxylation of calcidiol creates the active metabolite, 1,25-dihydroxy vitamin D (calcitriol) (6, 9-11).

Calcitriol is responsible for increasing calcium absorption, bone resorption, and decreasing renal calcium and phosphate excretion to maintain bone health. The synthesis of calcitriol is mediated by parathyroid hormone (PTH), serum phosphate concentration and growth hormone(9-11). The primary objective of this study was determination of prevalence of subclinical vitamin D deficiency in children and adolescents who referred to pediatric orthopedic clinic and the secondary objective was to determine the relationship between levels of vitamin D with age, sex and cause of presentation.

## Material and Methods

This study was performed by Shahid Beheshti University of Medical Sciences and conducted in the Mofid Children's tertiary center, situated in Tehran, Iran. We retrospectively studied 212 primary care patients (1-15 years) who presented consecutively between August 1, 2016 to July 31, 2017 to pediatric orthopedic clinic. There were not any symptoms and signs that directly related to Rickets in history and primary examination of all cases. Exclusion criteria included chronic illnesses and use of medications known to affect bone metabolism. We surveyed age, sex, cause of referral, levels of serum calcium (Ca), Phosphorus(P), alkaline phosphatase (ALP) and 25-hydroxyl vitamin D [25(OH)D]. Serum calcium (Ca) and phosphorus (P) levels were measured using the end point colorimetric method [Pars Azmoon kit and Prestige (Biolis 24i) fully automated

autoanalyzer] and serum alkaline phosphatase (ALP) levels were measured by kinetic method [Pars Azmoon kit and Prestige (Biolis24i)] fully automated autoanalyzer, while serum 25 hydroxy vitamin D [25(OH)D] levels were evaluated by conjunction Ag-Ab ELISA method [autobio kit, Dynex2 fully automated ELISA].

For evaluation of results, the subjects were classified into three groups according to their vitamin D status (deficiency  $\leq 20$  ng/mL, insufficiency 21-29 ng/mL and sufficiency  $\geq 30$ ng/mL) (11-15). Subjects were also divided according to their age ( preschool 1-5 years, primary school age 6-10 years and adolescence 11-15 years). Range of Ca, P, ALP (12) of patients was compared between three groups of vitamin D level.

## Statistical analysis

Data analysis was performed by the IBM SPSS (Statistical Package for the Social Sciences, version 21.0) statistics. Continuous data were analyzed by the Kolmogorov-Smirnov test for normality distribution. All quantitative data were reported as mean  $\pm$  standard deviation and analyzed using the Student t-test or the Mann-Whitney U test, where appropriate. For comparisons between the 3 groups, the analysis of variance and the Tukey test were applied. Qualitative data were reported as frequency and percentage and analyzed using the chi-square and Fisher exact test, where appropriate. A P-value less than 0.05 was considered significant, and 95% confidence intervals (CIs) were calculated for adjusted odds ratios(ORs).

## Results

We retrospectively reviewed information of a total 212 children and adolescents aged between 1-15 years old. Main causes of referral to the pediatric orthopedic clinic in order of frequency were knee deformity, gait abnormalities (including rotational problem), lower limb pain and other causes.(Figure 1)

From 212 cases, 104 patients (49.1%) were female. Mean age of patients was  $4.8 \pm 3.3$  years.(Table 1)

Level of vitamin D was sufficient in 80 cases (37.7%), insufficient in 55 cases (25.9%) and deficient in 77 cases (36.3%). Abnormalities of laboratory findings are shown in Table 2.

Prevalence of vitamin D deficiency and insufficiency in sex and age groups are presented in Table 3. There was no difference between sex in terms of level of vitamin D. Level of vitamin D is evidently higher in the 1-5 years group than older age groups and the lowest level of vitamin D was seen in the 6-10 years group ( $P=0.013$ ).(Figure 2)

Mean age in the vitamin D sufficient group was  $4.3 \pm 3.3$  years, in the vitamin D insufficient group were  $5.1 \pm 3.2$  years and in the vitamin D deficient group was  $5.2 \pm 3.3$  years ( $P<0.001$ ). Mean ALP in the vitamin D sufficient group was  $536.6 \pm 207.8$  ng/ml, in the vitamin D insufficient group was  $583.5 \pm 224.9$  ng/ml and in the vitamin D deficient group was  $606.7 \pm 197.6$  ng/ml ( $P=0.007$ )(Table 4).

Figure 1: The cause of referral to pediatric orthopedic clinic

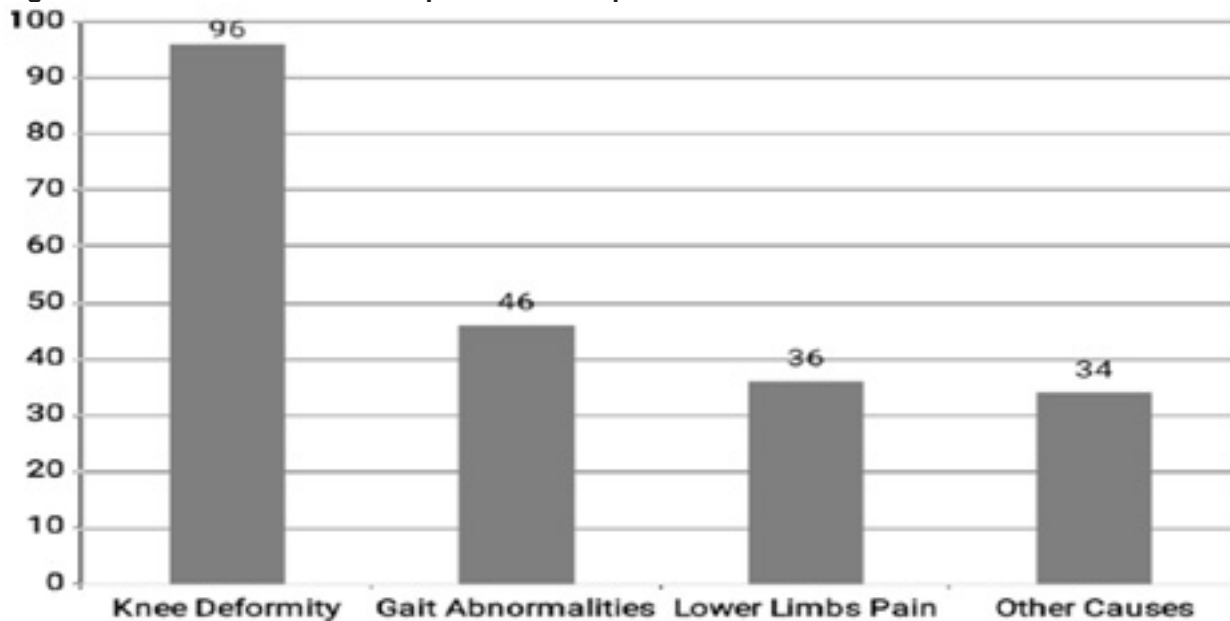


Table 1: Clinical Characteristics of the 212 Patients

Characteristic	Values
<b>Sex, No.(%)</b>	
Female	104(49.1%)
Male	108(50.9%)
<b>Age, years</b>	
Mean $\pm$ SD	4.8 $\pm$ 3.3
Range	1 - 15
<b>Calcium , mg/dl</b>	
Mean $\pm$ SD	9.73 $\pm$ 0.65
Range	8.1 - 14.0
<b>Phosphorus, mg/dl</b>	
Mean $\pm$ SD	5.11 $\pm$ 0.74
Range	2.2 - 7.2
<b>Alkaline phosphatase, IU/L</b>	
Mean $\pm$ SD	574.2 $\pm$ 210.1
Range	152 - 1600
<b>Vitamin D, ng/ml</b>	
Mean $\pm$ SD	30.78 $\pm$ 22.31
Range	3.0 - 178.0

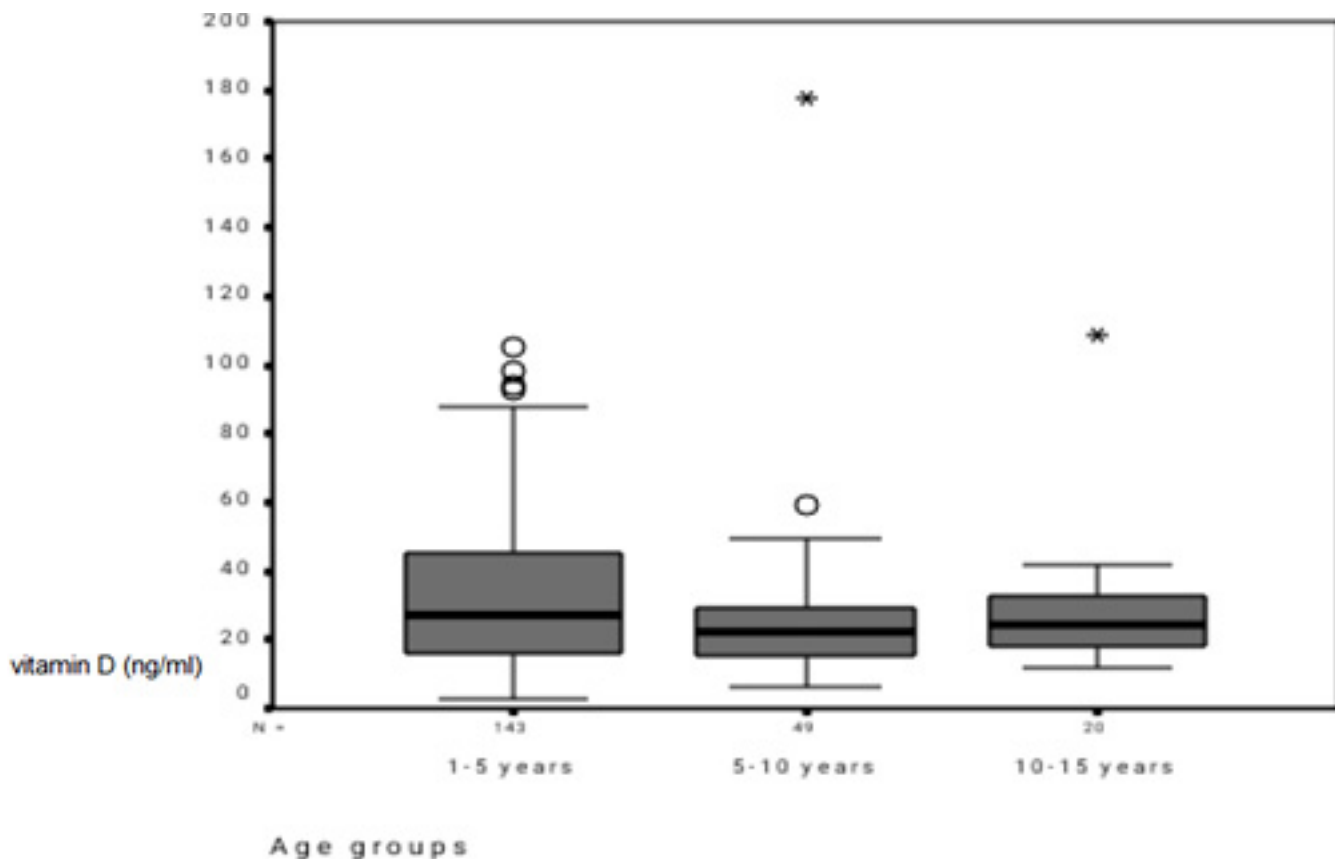
Table 2: Laboratory Findings in 212 Patients

Characteristic	No.(%)
<b>Hypocalcemia</b>	8(3.8%)
<b>Hypophosphatemia</b>	4(1.9%)
<b>Alkaline phosphatase Elevation</b>	196(92.5%)
<b>Vitamin D</b>	
Sufficient	80(37.7%)
Insufficient	55(25.9%)
Deficient	77(36.3%)

**Table 3: Prevalence of Vitamin D Deficiency with Sex and Cause of referral to pediatric orthopedic Clinic**

Variables	Vitamin D No.(%)		Odds Ratio (95%CI)	P-Value
	Sufficient	Insufficient/Deficient		
<b>Sex</b>				
Female	35(33.7%)	69(66.7%)	1.408(0.806-2.461)	0.258
Male	45(41.7%)	63(58.3%)		
<b>Age</b>				
1-5years	63(44.1%)	80(55.9%)	—	0.013
6-10years	10(20.4%)	39(79.6%)		
11-15years	7(35%)	13(65%)		
<b>Causes</b>				
Knee Deformity	37(38.5%)	59(61.5%)	—	0.036
Gait Abnormalities	11(23.9%)	35(76.1%)		
Lower limbs pain	13(36.1%)	23(63.9%)		
Others	19(55.9%)	15(44.1%)		

**Figure 2: Box plot of Age Variation in Vitamin D Levels. The median Vitamin D Level was higher in 1-5years than older age groups. The center line in the box indicates bars of minimum and maximum values. Circles and stars show more extreme values and out layers, respectively**



**Table 4: Relationship of demographic and Metabolic Characteristics with Vitamin D deficiency**

Variables (Mean ±SD)	Vitamin D			P-Value
	Sufficient	Insufficient	Deficient	
Age(years)	4.3±3.3	5.1±3.2	5.2±3.3	<0.001
Calcium (mg/dL)	9.8±0.6	9.9±0.8	9.6±0.6	0.948
Phosphorus(mg/dL)	5.2±0.7	5.3±0.7	4.9±0.8	0.077
Alkaline phosphatase (IU/L)	536.6±207.8	583.5±224.9	606.7±197.	0.007
Vitamin D(ng/ml)	51.4±23.7	24.9±2.8	13.5±4.4	0.073

## Discussion

Vitamin D deficiency is an important health problem and its worldwide prevalence is 30 to 80 percent in the pediatric and adult community (3-5). Deficiency is generally measured by 25-OH vitamin D (calcidiol) concentration, because it has a long half-life (2-3 weeks). 1,25 OH vitamin D3 has a short half life and is closely linked to parathyroid hormone production, so serum level of calcitriol doesn't reflect vitamin D status(10,11).

Vitamin D deficiency can be easily diagnosed in presence of clinical features of Rickets, but Rickets is an excessive form of vitamin D deficiency and can be considered as the tip of an iceberg(11).

Improved information about harmful non-skeletal effects of insufficient vitamin D before the appearance of Rickets led to a growing interest in diagnosing this pre rachitic, subclinical vitamin D deficiency(11,16).

In this study, we found a notable high prevalence of vitamin D deficiency and insufficiency among 1-15 years children and adolescents. Only 37.7% of cases had sufficient amounts of 25 hydroxy vitamin D and more than 62.2% had vitamin D deficiency and insufficiency( Table 2). There is a high prevalence of subclinical Rickets in children referred to the pediatric orthopedic clinic that confirms results of other studies about the importance of vitamin D deficiency as a health problem (1-5). There is no significant difference between males and females in prevalence of vitamin D deficiency or insufficiency (P-value=0.258), although Odds ratio of 1.408 (0.806-2.461) shows that risk of vitamin D deficiency is higher in girls(Table 3).

In comparison between age groups, we found that the rate of vitamin D deficiency and insufficiency is lower in 1-5 years group than older age groups (P-value=0.013), also mean vitamin D level was higher in the preschool age group. It may be due to preventive health care programs that are conducted for lower age groups. Lowest level of vitamin D was seen in 6-10 groups, so more comprehensive health care program for prevention of vitamin D deficiency can be considered in the school age group.

We also compared different causes of referral to the pediatric orthopedic clinic in terms of prevalence of vitamin D deficiency (Table 3) and we found significant difference between these groups (P-value = 0.036).

A variety of causes were described for vitamin D deficiency such as decreased skin synthesis (because of cultural practice, seasonal variation, atmospheric pollution and strict sun screen use), malabsorption, multiple short interval pregnancies, obesity, decreased dietary intake and drug interaction(10,11).

According to our study more attention should be paid to school age children and adolescents for prevention, diagnosis and treatment of sub clinical vitamin D deficiency, also we emphasis that a nationwide study can help to define the true prevalence and etiologic factors of vitamin D deficiency in children and adolescents.

Pediatric orthopedic is surgeon best to consider the high prevalence of subclinical vitamin D deficiency in patients who were referred to the clinic.

## Conclusion

There is a high prevalence of vitamin D deficiency and insufficiency in children age 1-15 years who referred to the pediatric orthopedic clinic (more than 62.2%). This high prevalence of poor vitamin D status is more obvious in school age and adolescent groups and this may be caused by decreased skin synthesis owing to low sunlight exposure, skin coverage, air pollution or low vitamin D intake. Improvement in mean of vitamin D level in children and adolescents can help to prevent many chronic diseases, so we recommend designing more comprehensive health programs for prevention and diagnosis of subclinical vitamin D deficiency especially for school age children.

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# Effectiveness of Self-awareness based Individual counseling on self-awareness of women in reproductive age

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## Abstract

**Introduction:** Self-awareness skills enable people to better identify their personality traits, needs, wants, goals, weak points, and emotions. Considering the importance of this skill, the present research investigates the effectiveness of self-awareness based individual counseling on self-awareness of women in reproductive age.

**Materials and methods:** This randomized field trial was conducted on 76 women in reproductive age referring to the health center of Gorgan City in 2016. The samples were selected based on convenience sampling and based on permuted block randomization, were assigned to two groups, intervention and control. The needed information was supplied by asking the participants to complete the Persian version of the self-awareness questionnaire of Realo and Allik before and one month after the intervention. The intervention group was subjected to six sessions of individual counseling through an eclecticism approach. The collected data, based on their normality or non-normality, were analyzed through the independent t-test, and Mann-Whitney and Wilcoxon tests in SPSS16 software.

**Findings:** No statistically significant difference was observed between the self-awareness score before and after the counseling in the control group ( $52.21 \pm 7.62$  and  $53.81 \pm 7.63$ , respectively) while the difference was significant in the intervention group ( $56.10 \pm 10.02$  and  $60.13 \pm 10.43$ , respectively,  $p$ -value  $< 0.009$ ). Moreover, there was a statistically significant difference between

the average scores of private self-awareness, public self-awareness, and social anxiety in the intervention group before and after the counseling, while this difference was not significant in the control group.

**Conclusion:** The self-awareness based individual counseling session shows a positive effect on enhancing private and public self-awareness and reducing social anxiety. Considering the role of self-awareness in enabling the women to deal with their problems and express their needs effectively, this counseling approach is recommended for improving the self-awareness skills of women, particularly those in the reproductive age.

**Key words:** individual counseling; self-awareness skill; reproductive ages

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## Problem statement

Self-awareness skills enable individuals to know themselves better and have a better understanding of their personal traits, needs, wants, goals, weak points, emotions, values, and identities (1). Self-awareness consists of three main dimensions: private self-awareness, public self-awareness, and social anxiety. Private self-awareness means the tendency to think and focus on thoughts, emotions, and inner motivations. Public self-awareness indicates a general awareness of the self as a social person in the view of other people. Finally, social anxiety represents the concerns and worry of people in the presence of others and hence the tendency to solitude (2). Self-awareness is among the most important life skills as such the World Health Organization (WHO) considers it among the five dimensions of life skills (3). According to Morin et al., self-awareness has positive consequences for people. These consequences include self-expression, self-evaluation, self-esteem, self-regulation, self-efficiency, and self-recognition. Researchers have evidenced the positive effects of self-awareness. For example, Richards et al. (2010) reported that self-awareness has a positive significant relationship with self-care. According to these researchers, self-awareness enables the individual to recognize better what is important for them (5). Oh et al. (2015) studied self-awareness and communication ability of nursing students and reported a positive significant relationship between these two variables (6). Ahmed and Elmasri (2011) reported the efficacy of self-awareness training on self-efficiency and autonomy of the participants (7). Finally, Moradpour et al. (2013) stated that training in self-awareness and assertiveness skills have a positive significant effect on overall compatibility and its components (i.e., social compatibility, emotional compatibility, and indoor compatibility) and the self-esteem of mothers with mentally retarded children (8).

An important issue is that when people have a vague image of themselves, indeed, they do not know themselves properly and face many inner challenges. As a result, the external forces form their personality and character (9). Studies conducted in this area show that poor self-awareness is accompanied by many mental-social problems such as depression, anxiety, inferiority complex, low self-esteem, communication problems, and feelings of solitude. Therefore, self-awareness skills would play a key role in coping with these problems (1).

According to the mentioned points, the role of self-awareness in different aspects of life, and lack of a systematic study on self-awareness in the literature, the present study aims to investigate the effect of individual counseling on self-awareness of married women in the reproductive age referring to the health centers of Gorgan City in 2016.

## Materials and methods

This study is a parallel-randomized field trial. The statistical population of this work includes all married women in reproductive age in Gorgan City referring to the health centers of the city. The samples were chosen based on the inclusion criteria of this study. The results of Vizeh et al., who reported an increase in sexual satisfaction from 11.6% to 27.9% after 3 months of intervention, were used to calculate the sample size (10). Based on the results of this work and considering a confidence level of 95%, the sample volume in each group with 5% dropout probability was considered to be 40 subjects. Sampling was performed in two steps. In the first step, among six urban centers, three centers were randomly selected. Next, the samples in each center were selected through the convenience sampling divided into the population and assigned into two groups, intervention and control. Samples were randomly allocated to two blocks for each center using a prepared Excel file. The inclusion criteria were having an education level above high school, lack of any unfortunate event within the past six months, lack of any chronic physical-mental disease, lack of drug addiction of the participant or her spouse. Exclusion criteria included unwillingness to continue to collaborate with research, occurrence of an unfortunate event, being recognized with psychological disorders during the study, and lack of completing more than 5% of the questionnaire. The instruments for data collection were demographic specification form and the Persian version of the Realo and Allik's self-awareness questionnaire.

The Persian version of Realo and Allik's (1998) self-awareness questionnaire consisted of 24 items, which are scored based on the 5-scale Likert tool from "completely agree" (= 4) to "completely disagree" (= 0). The validity and reliability of the questionnaires were assessed by Latifian and Seyf (2007) in Iran. The validity of the items in this scale was evaluated through the expert comments and the internal consistency of the scores. On the other hand, the reliability of the scale was evaluated using Cronbach's alpha coefficient, which was in the range of 0.57-0.84 and suggests their acceptable internal consistency (11). Among the items of the questionnaire, 10 items (1, 5, 7, 10, 11, 17, 12, 19, 20, and 24) were for private self-awareness, 6 items (3, 8, 13, 16, 18, and 22) for public self-awareness, and 8 items (2, 4, 6, 9, 14, 15, 21, and 23) for social anxiety. Also, items 3, 7, 9, 11, 14, and 23 were scored inversely (12). The minimum and maximum scores of the questionnaire were 0 and 96, respectively, and its average score was 48 (13, 14). Cronbach's alpha score of the questionnaire was calculated to be 0.68.

Sampling was done in three of the selected health centers after permission of the authorities. The researchers first explained the research objectives and, if agreed to, gave the participants an inclusion criteria form, demographic specification sheet, and self-awareness questionnaire and emphasized on completing all items. Next, women in the intervention group were invited to the Individual counseling, which was held in a pilot design within 6 sessions each



**Table 1: The content of individual counseling sessions based on self-awareness skill**

Session No.	Content
1	Introduction, explanation of the counseling rules and (talking about the session length and number, putting the cell phones into silent mode, etc.), emphasizing the confidentiality of the sessions, stating the purpose of the counseling, defining self-awareness, factors effective on it, and the role of self-awareness in life, identification and classification of feelings, summation, and giving the assignments of the next session
2	Defining the concept of "self" and giving the sheets to participants to explain themselves in terms of communication with others in environments such as house and with relatives, friends, and colleagues
3	Explaining the positive traits and their effect on personal lives
4	Investigating the negative traits and weak points, finding some solutions by the authorities to deal with them, and investigating the effects of these solutions on the participants' lives
5	Explaining the honors, talents, abilities, and skills as well as offering a definition for self-esteem according to the authorities and completing it with the counselor, if needed, and completing the self-esteem measure table
6	Explaining the individual goals, beliefs, and values, mentioning favorite locations and important people by the participants, and explaining the attitude of the authorities toward counseling sessions

lasting for 45 minutes. The contents of the counseling session were prepared (Table 1) according to student handbook of the life skills training by Mohammad Khani et al. (1). At the beginning of each session, the supplied materials of the last session were reviewed and the given assignments were examined. At the end of the session, the topics discussed in the counseling session were summed and some assignments were given for the next session.

The counseling was carried out based on the eclecticism approach. The counselor decided on the number of sessions based on the interpersonal differences of the referrals and the end of sessions based on the understood changes of feelings and moods of the participants, once all practices and exercises were performed. During the study, two participants left the research and the remaining 38 were subjected to 4 to 6 counseling sessions. The therapeutic sessions were held once a week during the first two weeks while the next sessions were held closer to each other and almost twice in a week. Posttest was performed one month after the last counseling session among 38 subjects from each group. To analyze the obtained data, SPSS16 software was used. To assess normality of the data, the Shapiro-Wilk test was performed. Also, descriptive statistics were used to describe the research subjects. Finally, independent t-test and pair t-test were applied to analyze the data if they were normal while Mann-Whitney and Wilcoxon tests were conducted for data non-normality assumption. After classifying the scores for each subject,  $\chi^2$  test and Fisher test were applied at a pre-assigned confidence level of 95% ( $F = 0.95\%$ ).

## Findings

According to the results of Fisher,  $\chi^2$ , independent t, and Mann-Whitney tests, the qualitative and quantitative demographic variables do not show a significant difference. The average age of subjects in the intervention and control groups was 30.89 and 29.92 years, respectively. Other information of the participants is presented in Tables 2 and 3 - next page.

The results of T-test and Wilcoxon test showed a significant difference between the overall self-awareness and its dimensions in the intervention group before and after the counseling while no statistically significant difference was noted in the control group (Table 4).

Table 2: A comparison of demographic quality variables between the intervention and control groups

Variable		Intervention group		Control group		P-value
		Frequency	Percentage	Frequency	Percentage	
Job	Employee	3	7.9	6	15.8	0.554*
	Housewife	30	78.9	25	65.8	
	Freelancer	2	5.3	3	7.9	
	Student	2	5.3	4	10.5	
	Unemployed	1	2.6	0.0	0.0	
Education level	Below diploma	2	5.3	6.0	15.8	0.055*
	diploma	22	57.9	12	31.6	
	Above diploma	14	36.8	20.0	52.6	
Ethnicity	Fars	34	89.5	30	78.9	0.346*
	Sistani	4	10.5	7.0	18.4	
	Turkman	0.0	0.0	1.0	2.6	

\*: Exact Fisher test

Table 3: Comparison of demographic quantitative variables between intervention and control groups

Variable	Intervention group		Control group		P-value
	Mean	Standard deviation	Mean	Standard deviation	
Age	30.8	6.37	29.92	6.67	0.51*
Age difference with husband	3.92	3.62	3.28	3.53	0.443*
Marriage duration	9.97	7.22	7.89	6.96	0.131**
Number of pregnancies	1.84	1.02	1.60	0.94	0.267**
Number of abortions	0.34	0.62	0.18	0.56	0.15**
Number of Childbirths	1.47	0.60	1.42	0.82	0.46**
Number of stillbirths	0.02	0.16	0.026	0.15	1.00**

\*: T-test \*\*: Mann-Whitney test

Table 4: Comparison of mean scores of self-awareness of women of reproductive age before and after counseling in intervention and control groups

Group	Intervention			Control		
	Before	After	P-value	Before	After	P-value
self-awareness dimensions	Mean $\pm$ standard deviation	Mean $\pm$ standard deviation		Mean $\pm$ standard deviation	Mean $\pm$ standard deviation	
Private self-awareness	26.78 $\pm$ 3.37	32.3 $\pm$ 4.52	<0.001*	25.92 $\pm$ 3.70	26.10 $\pm$ 4.11	0.939*
Public self-awareness	15.73 $\pm$ 3.19	17.78 $\pm$ 3.05	0.001*	14.31 $\pm$ 3.43	15.13 $\pm$ 3.24	0.189*
Social anxiety	13.58 $\pm$ 6.83	10.10	0.001*	11.97 $\pm$ 4.72	12.57 $\pm$ 4.93	0.308*
Total self-awareness	56.10 $\pm$ 10.02	60.13 $\pm$ 10.43	0.009**	52.21 $\pm$ 7.62	53.81 $\pm$ 7.63	0.164*

\*\*= Wilcoxon test \* = t- test



## Discussion

The present intervention study (with a pre- and posttest design) was conducted on 76 referrals to the health center of Gorgan City to determine the effect of self-awareness based Individual counseling on self-awareness of women in reproductive age.

Based on the results of this study in the pretest step, the overall self-awareness scores and the corresponding scores for its three dimensions were not significantly different between the intervention and control groups.

Investigating the effect of counseling on self-awareness shows that the mean scores of self-awareness and its dimensions after and before the counseling were significantly different. In this regard, counseling led to an increase in the scores of self-awareness and its dimensions for the private and public dimensions but had a negative effect on social anxiety. However, the mean score of none of these variables in the control group was not significantly different before and after the counseling. Compared to the intervention group, the score of social anxiety not only was not declined but was increased. In this regard, the findings of Amiri et al. (2017) show that negative self-evaluation and perception of negative evaluation of others are positively correlated with social anxiety (16). Hence, it can be concluded that probably refilling the questionnaire, fear of posttest score, and worry of researcher's assessment and judgment have raised the anxiety in the women of the control group.

The mean total self-awareness score and the scores of the private and public fields were significantly higher in the intervention group compared to those of the control group whereas for the social anxiety dimension they were lower in the intervention group compared to the control group; however, this result was not significant. It is worth mentioning that to discuss the findings related to self-awareness, to the best of authors' knowledge, no paper was found about the effect of counselling or education session on self-awareness of the women; rather, the rare works conducted on self-awareness are descriptive and the intervention-based ones had not measured it quantitatively. The results of previous work show that self-awareness has an important effect on life. For example, self-awareness skills were found to be significantly effective for anxiety control (17), selecting a coping strategy (18), and decreased internet addiction and a feeling of loneliness (19). Thus, considering the advantages of self-awareness for people and its relation to personality type, economic and social status, occupation status, age (20), conscientious, and agreeableness (21), it is necessary to conduct several similar studies to improve self-awareness skills.

## Conclusion

The results of the present study show that the individual self-awareness counseling raised the self-awareness level of women. In this regard, self-awareness skill has a high priority, compared to other life skills, as such it typically is considered as a prerequisite to social and interpersonal

relations. Thus, this intervention approach can be applied as an effective technique to enhance self-awareness of women.

According to the results of the present research, it is recommended conducting several similar works on women of different ages, men, adolescents, and children. Since all personality traits and characters are investigated and the ideal self, and real self, and the less noticed characters of the self are identified through the counseling sessions, performing individual counseling-based research is highly recommended. Among the limitations of the present study are the rare studies conducted about self-awareness compared to other life skills, which posed a difficulty to the research when preparing the method and discussion sections.

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# The Effect of Muscle Relaxation on Dialysis Adequacy in Hemodialysis Patients

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## Abstract

**Aims and objectives:** Hemodialysis is a main treatment for patients with renal failure. The improvement of dialysis adequacy is the most important factor in reducing complications and mortality in hemodialysis patients. This study was conducted to examine the effect of muscle relaxation on dialysis adequacy in patients on hemodialysis.

**Design and Methods:** This randomized controlled clinical trial was performed on 90 hemodialysis patients in Khatam al-Anbia and Imam Ali hemodialysis centers in Zahedan, Iran in 2014. The participants were selected through convenience sampling and assigned to the control and case groups through stratified block randomization with the block size of quadripartite (23 blocks of 4 /quadripartite). The control group received routine therapeutic measures, and the case group were trained for Benson muscle relaxation in three sessions in addition to the routine therapeutic measures. The patients in the case group were requested to do relaxation exercises for 15-20 minutes twice a day for one month. The dialysis adequacy was measured using the z02 software of the Health Ministry before and after the intervention. The data were analyzed in SPSS21 software using Chi-square test, independent t test, Mann-Whitney test, Pearson's correlation coefficient, ANOVA, and ANCOVA at significance level lower than 0.05.

**Results:** The results showed no significant difference between the two groups in terms of dialysis adequacy before the intervention ( $P = 0.818$ ) although the difference was significant after the intervention ( $P = 0.003$ ). Moreover, the dialysis adequacy significantly correlated with patients' age ( $P = 0.001$ ), sex ( $P = 0.039$ ), and occupation ( $P = 0.024$ ).

**Conclusion:** Regarding increased dialysis adequacy and its safety and ease of use, it is recommended that muscle relaxation be taught in hemodialysis wards.

**Key words:** muscle relaxation, dialysis adequacy, Hemodialysis Patients

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## Introduction

Chronic renal failure is generally a progressive and irreversible disorder in renal function that creates numerous complications due to systemic effects. Dialysis and eventually renal transplantation are the main treatments for end-stage renal disease (Mollahadi et al., 2010). Hemodialysis is the most common method of treatment for kidney patients in all countries (Namdar et al., 2013). In a study published in 2012, the prevalence rate of chronic renal failure was 242 cases per million people in the world which increases by 8% annually (Tayyebi et al., 2011). The annual prevalence rate of renal failure in Iran is 375 people. Dialysis patients experience many problems regarding their special physical and mental conditions. Measuring dialysis adequacy is one of the most important influential factors for Assessment of hemodialysis process (Esmaili et al., 2016). Promotion of dialysis adequacy has attracted medical researchers because it is one of the major determinants of life adequacy, disability, and mortality in dialysis patients (Hassanzadeh et al., 2010).

It is difficult to define and determine dialysis adequacy due to its abundant and variable parameters. The best indicator for the quality of dialysis is urea clearance. The best indicator for measuring the adequacy of dialysis is amount of urea clearance which is obtained by the  $Kt/V$  formula (Tayyebi et al., 2012, Borji et al., 2016).

Dialysis adequacy is the state of having  $Kt/V$  higher than 1.2; where  $k$  is the urea clearance by the dialysis machine,  $t$  is the duration of dialysis, and  $v$  is the concentration of urea (Kalender and Tosun, 2014).

Results of numerous studies have shown that increasing the  $Kt/V$  to 1.2 and URR to 65% is effective in prognosis of dialysis patients (Kalender and Tosun, 2014, Tayyebi et al., 2012, Borzou et al., 2009). Many factors, including duration of dialysis, velocity of dialysate, the use of high-speed dialyzer, and blood flow velocity affect dialysis adequacy (Shahdadi et al., 2017) but it is not possible or cost-effective to use some of these methods, also new hemodialysis methods are not sufficiently adequate (Salehi et al., 2016, Shahdadi et al., 2017).

Studies performed on the effect of some variables on dialysis adequacy include "The effect of hatha yoga exercises on dialysis adequacy" (Tayyebi et al., 2011), "The comparison of the effect of Quran recitation with that of normal condition, silence, Arabic music, and Iranian music on dialysis adequacy" (Alavi Majd et al., 2010), and "The effect of increased blood flow on side effects and adequacy of dialysis in hemodialysis patients with a low  $Kt/v$ " (Shahdadi et al., 2017) (BasiriMoghadam et al., 2014). The use of non-pharmacological complementary therapies has been further accepted and emphasized too much in the health system, (Hadadian et al., 2011). Relaxation is one of the complementary therapies. There are various methods of relaxation, including progressive muscle relaxation (Jacobson's), and Basirimoghadam examined the effect of progressive muscle relaxation technique on

fatigue of the patients on hemodialysis (Bassiri moghadam et al., 2014). However, the method introduced by Herbert Benson in 1970 is more favorable because it is easy to learn and teach to others (Monahan et al., 2007). Benson relaxation is a method of concentration that influences a wide range of physical and mental signs and symptoms, such as anxiety, pain, depression, temper, and self-confidence, and reduces stress (Otaghi et al., 2016, Kiani et al., 2017, Hinkle and Cheever, 2013, Yazdani and Setareh, 2012). Relaxation is expected to affect dialysis adequacy. In regard to the many studies performed on effects of facial relaxation, few studies have been performed on the effects of muscle relaxation on hemodialysis patients, including the effect of progressive muscle relaxation technique on blood pressure and dialysis adequacy of patients on hemodialysis (BasiriMoghadam et al., 2014), the effect of muscle relaxation on these patients' stress and anxiety (Elali et al., 2012), the effect of advanced muscle relaxation on these patients' sleep quality (Saeedi et al., 2012), and that the muscle relaxation reduces heart rate, reduces blood pressure, increases vasovagal blood flow, and reduces activity of the sympathetic nervous system (MOLAIE et al., 2012). Therefore, this study was conducted to examine the effect of muscle relaxation on dialysis adequacy in hemodialysis patients.

## Design and methods

This randomized controlled clinical trial was registered under the ethics code GMU.REC.1392.43 and the Iranian Registry for Clinical Trials code IRCT2014051117656N. The study population included all patients on hemodialysis in Khatam al-Anbia and Imam Ali hemodialysis centers in Zahedan, Iran in 2013-2014. The sample size was calculated as 42 patients in each group using formula for comparisons of means after a pilot study and taking into account the confidence interval of 0.95 and test power of 80%; however, 45 patients were assigned to each group to cover potential sample loss, and totally, 90 patients entered the study. The inclusion criteria of the study were as follows: minimum age of 18 years and maximum age of 65 years, a family history of hemodialysis for at least 2 months, undergoing hemodialysis 2-3 times a week, being conscious, acceptable listening and speaking ability for learning the relaxation method, no known mental diseases, such as severe anxiety and depression, no known muscular diseases, and having active medical records in the above-mentioned centers. The exclusion criteria of the study were as follows: any condition that occurred during the intervention and rendered the intervention impossible, such as death and travel, unwillingness to continue participation in the study, and failure to attend the training sessions.

Once the participants were selected on the basis of the inclusion criteria, and written consent was received from them, they were randomly assigned to the control and case groups through stratified block randomization with the block size of 4 patients. The instruments used to collect the data included a demographic questionnaire consisting of two parts, personal information (sex, age, marital status, educational level, and occupation) and information on the

disease and its treatment (a history of hypertension and diabetes and duration of renal failure and hemodialysis), a checklist for recording the dialysis adequacy before and after the intervention on the basis of the software found in the website of Transplantation and Special Diseases Management (Rafiee 2009), and relaxation record form.

First, the patients were requested to complete the demographic questionnaire, and their dialysis adequacy was determined. Then, the muscle relaxation technique was taught to the participants individually in the case group in three sessions. The patients practised the technique at home twice a day for 30 days. The patients performed the technique as follows: 1- sitting quietly in a comfortable position, 2- closing eyes gently, 3- relaxing all the muscles from the feet to the face and keeping calm, 4- breathing in through the nose, being aware of their breathing, breathing out gently through the mouth, and when the air comes out, mutter number one and breathe comfortably and normally, 5- continuing for 15-20 minutes and keeping the muscles relaxed, and then opening the eyes and not standing for a few minutes, and 6- not worrying if they have reached a deep level of relaxation but allowing relaxation to occur at its own pace. They should ignore disturbing thoughts, if any (elali et al., 2012). To ensure the exercise of the relaxation technique during the intervention, a checklist (relaxation record form) was given to the participants in order to record the day, time, and duration of relaxation and the cause of failure to exercise the technique, if any. An audio and video file of the relaxation training was also given to the patients. Furthermore, the researcher controlled the course of exercising the technique and completing the relaxation record form by telephone every other day in order to resolve possible problems related to the relaxation. The dialysis adequacy was eventually examined in both groups after the intervention. To calculate the dialysis adequacy of each session (the first and the thirtieth day), a blood sample was drawn from the patients once immediately before dialysis and once immediately after the dialysis and delivered to the laboratory for determining the level of urea. To draw the blood sample before hemodialysis, it was drawn from an arterial line before turning on the blood pump of the dialysis machine and immediately delivered to the laboratory. To draw the blood sample after hemodialysis in the last 10 minutes of dialysis: the speed of the dialysis machine's pump was set at 50 ml/m 20-30 seconds before drawing blood, and the sample was drawn from an arterial line before the sample clearance. Concentrations of urea were determined spectrophotometrically using assay kits from Pars Azmoon Company, Iran.

The patients' weight was determined before and after dialysis using a scale (Seca Co.) that was checked with a 2-kilo weight every morning. The patients' dialysis adequacy was examined using Kt/V and urea reduction ratio (URR) methods and the relevant software.

The velocity of dialysate was 500 ml/m and equal in all patients. Moreover, a dialysate containing sodium bicarbonate buffer was used for all patients, and the velocity of blood flow comprised 300 ml/m that was equal for all patients. In general, the type of filter, site of needle,

speed of the machine, time of dialysis, size of needle, drugs used during dialysis, temperature of the machine, and expertise of the personnel, which all somehow affect the dialysis adequacy, were equalized in all patients (in the case and control groups) on the blood sampling day.

Qualitative variables were reported as absolute and relative frequency, and quantitative variables were reported as mean and standard deviation values. The data were collected using SPSS 21 software and paired t test for comparing the degree of dialysis adequacy before and after intervention in both groups, independent t test for comparing mean age of participants and comparing differences in means of dialysis adequacy before and after intervention in both groups, Chi-square test for comparing the qualitative variables, ANOVA for examining the correlation of some qualitative variables with dialysis adequacy, Pearson's correlation coefficient for examining the correlation of Quantitative variables (age, weight before dialysis, hemoglobin, and pain) with dialysis adequacy, and ANCOVA for variables with  $P < 0.2$ , at significance level lower than 0.05.

## Results

The results showed that male and female patients respectively comprised 52 patients and 37 patients (totally 90 patients, of whom one patient died and was thus excluded from the study), and married and single patients respectively comprised 68 patients and 21 patients. Mean age of the participants was  $43 \pm 15$  years. The independent t test showed no significant difference between the two groups in terms of age. Most of the participants in both groups were male, married, illiterate, and housekeeper. According to the Chi-square test, the case and control group did not differ significantly and were equal in terms of demographic variables, including sex, marital status, education, and occupation. Moreover, most of the participants had a history of hypertension with no history of diabetes. The course of treatment with hemodialysis in the patients lasted 1-10 years. The Chi-square test did not show any significant difference between two groups in terms of the mentioned variables, and the groups were similar in this regard (Table 1 - next page).

The results of the dialysis adequacy showed the mean Kt/V higher than 1.2 and the mean URR higher than 0.65 before intervention in the case and control groups. The independent t test did not show any significant difference between the two groups in terms of dialysis adequacy before intervention although it showed a significant difference between the two groups in terms of mean Kt/V, as the mean Kt/V in the case group increased to 1.5. Although mean URR increased to 0.79 after intervention in the case group, the independent t test did not show any significant difference in this regard (Table 2).

ANOVA showed a significant correlation between dialysis adequacy after intervention and occupation ( $P = 0.024$ ), as the dialysis adequacy was higher in housekeeper patients. The independent t test showed that the dialysis adequacy significantly correlated with sex ( $P = 0.039$ ) and marital



**Table 1: Frequency distribution of demographic information and disease-related information of the participants**

Variable	Control, N (%)	Case, N (%)	P-value
Age (year)*	46.11 ± 14.754	40.41 ± 15.221	0.76
<b>Sex</b>			
Male	29 (64.4)	23 (52.3)	0.24
Female	16 (35.6)	21 (47.7)	
<b>Marital status</b>			
Single	8 (18.3)	11 (26.6)	0.404
Married	36 (81.7)	32 (73.4)	
<b>Educational level</b>			
Illiterate	15 (33.3)	15 (34.1)	0.69
Primary school	11 (24.4)	11 (25)	
Middle school	8 (17.8)	6 (13.6)	
High school	5 (11.1)	9 (20.5)	
High education	6 (13.3)	3 (6.8)	
<b>Occupation</b>			
Employed	11 (24.4)	7 (15.9)	0.50
Self-employed	18 (40)	17 (38.6)	
Housekeeper	16 (35.6)	20 (45.5)	
<b>Hypertension</b>			
Yes	33 (73.3)	30 (68.3)	0.28
No	12 (26.7)	14 (31.8)	
<b>Diabetes</b>			
Yes	9 (20)	13 (29.5)	0.29
No	36 (80)	31 (70.5)	
<b>Hemodialysis (mo)</b>			
< 24	8 (17.7)	12 (27.3)	0.19
24-120	34 (75.5)	31 (70.4)	
>120	3 (6.6)	1 (2.3)	

**Table 2. Comparison of the dialysis adequacy indexes before and after intervention in the case and control group**

Variable	Before intervention		P-value	After intervention		P-value
	Control	Case		Control	Case	
	Mean ± SD	Mean ± SD		Mean ± SD	Mean ± SD	
Kt/v	1.33±0.41	1.35±0.43	0.81	1.25±0.31	1.51±0.43	0.003
URR	0.68±0.19	0.66±0.93	0.67	0.65±0.15	0.79±0.61	0.14

status ( $P = 0.018$ ) in a way that female patients and single patients had higher dialysis adequacy. Pearson's correlation coefficient also showed a significant correlation between dialysis adequacy and age ( $P = 0.001$ ), as the dialysis adequacy decreased with an increase in age.

There was no significant correlation between dialysis adequacy and educational level in this study ( $P = 0.413$ ). There was also no significant statistical correlation between dialysis adequacy and blood pressure in this study ( $P = 0.882$ ). The results of ANCOVA showed that upon

reduction of the effect of confounders, including fasting, history of hemodialysis, urea nitrogen, and potassium, before intervention the two groups still differed significantly in terms of the dialysis adequacy ( $P = 0.012$ ). The effect of the confounder variable of potassium on dialysis adequacy was not significant ( $P 0.372$ ), but the effect of confounding variables of fasting, history of hemodialysis, and urea nitrogen before intervention on dialysis adequacy was significant ( $P < 0.05$ ).

## Discussion

The results showed the mean Kt/V and URR before intervention respectively as  $1.3555 \pm 0.3990$  and  $0.6666 \pm 0.9356$ , which did not conform to the results of previous studies, Raesifar's study (Raiesifar A. et al., 2009) and Tayyebi's study (Tayyebi et al., 2011) in which Kt/V was lower than the minimum level determined in Iran (1.2), and were higher than the standard values determined in Iran. These higher values might be due to timely and adequate provision of nursing care practices and instructions, following up the patients more than before, establishment of quality promotion and accreditation offices in hospitals for control of the course of treatment and patient care, daily patient visits by a nephrologist, use of more modern and efficient medical equipment, such as the new hemodialysis machine (Bibaran), and use of new high-efficient filters. Results of a study performed by Windus and Delmaz in France showed the mean Kt/V as 1.67 which, as in the present study, was higher than the standard level and resulted in survival of patients (Kelber et al., 1993).

The mean Kt/V increased in the case group after exercising the relaxation technique. The complementary medicine in other studies also tremendously affected the course of treatment in patients. The correlation of relaxation technique with variables affecting the dialysis adequacy, such as urea nitrogen and ultrafiltration, was not significant. However, the relaxation technique significantly correlated with patients' weight before dialysis, which was another influential variable ( $P < 0.011$ ), in a way that Kt/V decreased with an increase in weight before dialysis. As shown by the formula of Kt/V (V is in the denominator and has an inverse relationship with Kt/V) V refers to distribution volume of urea in body fluids. given that urea is simply distributed in all body fluids, V equals to the volume of body fluids and depends on sex, weight, and length of the body (Druml et al., 2017). Therefore, the weight before dialysis is inversely related to Kt/V, and this was confirmed also by the results of this study. As quoted by Daugidas, variations in body mass index (BMI) also affected the mean blood urea in Covasys's study (Druml et al., 2017, Daugirds et al., 2007).

The effect of relaxation technique has been examined in Ilali's study "The effect of Benson relaxation on the level of stress in hemodialysis patients" (elali et al., 2012) and Koushan's study "The effect of Benson relaxation techniques on the level of fatigue in hemodialysis patients" (Koushan et al., 2014) They achieved a decrease in the patients' stress and fatigue after intervention; patients undergoing hemodialysis for a long time suffer physiological mental stressors and experience changes in personality and lifestyle (elali et al., 2012). Furthermore, dialysis is a stressful process and is followed by various psychological and social problems that predispose patients to mental disorders (Elali et al., 2012). Fatigue is an important normal response to physical activities and long-term mental stressors (Koushan et al., 2014a). It seems that the relaxation technique affects the dialysis adequacy in regard to its influence on patients' stress and fatigue.

In Tayyebi et al.'s study "The effect of hatha yoga exercises on dialysis adequacy," the patients' dialysis adequacy increased significantly" (Tayyebi et al., 2011), and this agreed with the results of the present study. In Hojjat et al.'s study (2008) on the effect of Quran recitation and music on dialysis adequacy in hemodialysis patients, mean dialysis adequacy increased significantly (Alavi Majd et al., 2010), and more interestingly, Quran recitation was more efficient than music in dialysis adequacy. Basiri Moghadam et al.'s study (Basiri Moghadam et al., 2014) on the effect of advanced relaxation technique on blood pressure and dialysis adequacy in patients on hemodialysis in 2013 showed the improvement of dialysis adequacy by that technique, and this conformed to the results of the present study. Although Jacobson's technique was used in the above study, the duration of exercising the technique (one month) was equal to that in the present study. The results of this study showed a significant correlation between sex and Kt/V ( $P = 0.039$ ). Results of Raesifar et al.'s study (Raiesifar A. et al., 2009) did not show any significant correlation between sex and dialysis adequacy. The mean Kt/V in men and women in Lesan Pezeshki et al.'s study (Lesan Pezeshki et al., 2001) was respectively 0.45 and 0.48, and they associated this result with the better administration of dialysis in women probably due to the use of filters similar to those used for men although women are smaller than men. The result in the above study agreed with that in the present study. The independent t test showed a significant correlation between Kt/V and marital status ( $P = 0.018$ ), as the mean Kt/V in single patients was significantly higher than that in married patients probably due to the higher mental relief, lower daily preoccupation, and lower age of single patients against married patients.

Moreover, the results of ANOVA in this study showed a significant correlation between Kt/V and occupation, and the results of Tukey's post hoc test showed a significant correlation between dialysis and adequacy and employed and housekeeper patients, as employed patients had higher dialysis adequacy probably due to the mental relief and lower mental and physical stresses caused by the occupation in housekeeper patients against those in employed patients. According to the results of this study, there was a significant correlation between age and Kt/V ( $P = 0.001$ ), as Kt/V decreased with an increase in age, and this conformed to results of Mogharab et al.'s study (2010) in which the dialysis adequacy decreased with an increase in age although the correlation was not significant. However, Mousavi Movahed et al (2007) found a significant correlation in this regard; it seems that the dialysis adequacy greatly decreased with an increase in age and its adverse effects on the body, including lower concentration and learning ability. Therefore, it is suggested to take steps, such as increasing the duration of dialysis, changing the type of dialysis, and performing more sessions of dialysis, to improve dialysis adequacy.

## Conclusion

Methods used today to increase dialysis adequacy in patients include increasing the speed of pump, using high-flux filters, and increasing number and duration of hemodialysis sessions. Regarding the results of this study, the dialysis adequacy can be easily improved in hemodialysis patients through simple and costless Benson relaxation technique.

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# Assessing the effect of warming up the patient with forced air on the body central temperature during general anesthesia in patients aged 20-70 years under eye surgery in Farabi Hospital

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## Abstract

**Background and Objective:** Lowering of body central temperature is a common phenomenon during general anesthesia, which can potentially lead to unwanted complications such as coagulation disorders, delayed wound healing, increased wound infections, and increased cardiac complications for patients. Therefore, the purpose of this study was to determine the effect of intensive heating of patients by forced air on raising central temperature during general anesthesia.

**Materials and Methods:** This clinical trial study was performed on 60 patients (41 males and 19 females) who were candidates for elective ocular surgery in Farabi Hospital. Participants were divided into 3 groups of 20 participants after obtaining informed consent. In this study, in the first group (pre-warming), the patients were warmed up for 30 minutes before anesthesia with forced air at 38-42°C. In the second group (control), warming was not performed and in the third group (total warming) warming up lasted half an hour before anesthesia until the end of anesthesia. The body central temperature of the patients was measured and recorded before the start of anesthesia and every 15 minutes during surgery and in recovery by means of a tympanic thermometer and finally was compared and statistically analyzed.

**Results:** The incidence of hypothermia in the pre warming group was 45%, in the control group 55%, and in the total warming group, 10%. Also, 10% of the pre-warming group and 15% of the control group experienced severe hypothermia. The mean body temperature of the patients except at the beginning of the study showed a significant difference at all times in the three groups. Also, patients who were exposed to active warming in the operating room had a higher mean temperature at recovery and at the outlet, and their differences were statistically significant ( $p < 0.001$ ). There was no significant correlation between the body central temperature of the patients and their hemodynamic indices over time.

**Discussion and Conclusion:** In this study, it was shown that the active warming of the patients in the operating room prevents reduced body central temperature. Also, the warming of the patients for a short time prevents the occurrence of hypothermia.

**Key words:** Hypothermia, active warming, forced air warming, general anesthesia

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## Introduction

Body temperature is regulated by the central nervous system (hypothalamus). Heat information comes from deep skin and tissues; sensitive to cold cells and heat sensitive cells that are physiologically and anatomically different. As a result of heat, impulses that emanate from heat receptors are increased, and the cold receptors emit more impulse due to cold. General anesthesia reduces the temperature threshold for shivering and vasoconstriction by about 2-3 degrees. Disturbances in temperature setting responses, along with operating room coolness, makes patients more prone (vulnerable) to hypothermia. Reduction in body temperature after the onset of general anesthesia is a common problem, due both to the impairment of the thermoregulatory response and the lowering of the operating room temperature. Loss of temperature (heat) in the operating room is possible in 4 ways:

- 1) Evaporation;** which occurs after evaporation from the patient's body surface
- 2) Radiation;** the patient's body emits heat (temperature) to the environment
- 3) Conduction;** the heat (temperature) is transmitted to the surfaces in contact with the patient's body (such as a bed, etc.)
- 4) Convection;** in which the heat (temperature) is lost through the convective heat flow

The combination of these losses simultaneously through disrupting thermoregulation and receiving of intravenous fluids predisposes the patient to hypothermia during anesthesia.

The body's response to reducing temperature is through ways that increase heat production or reduce heat loss from the environment. Lower energy consumption modes, such as vasoconstriction, occur sooner than shivering. Due to anesthesia, the temperature control mechanisms are disrupted, and in addition, the operating room coolness and the extent of the surgery helps to lose heat. Reducing central temperature below 36 ° C is considered hypothermia and reduction to below 35 ° C as severe hypothermia. Estimates show that 50-90% of patients undergoing small and large surgery are prone to experiencing hypothermia (1).

This decrease in body temperature causes many complications, such as postoperative shivering which increases the oxygen consumption by a factor of several times, which may be problematic, especially in the case of heart problems, leading to post-operative myocardial ischemia and angina (2). Hypothermia can cause coagulation disorder, as well as increased susceptibility to infection and delayed wound healing. Increased hospitalization time and increased mortality within the hospital are considered as a significant complication of hypothermia (3).

Warming patients during anesthesia is performed by using forced air or warm-up blankets and aqueous systems (4, 5 and 6). For example, in a study by E. Benson on the effects

of active scrubs heater on body temperature regulation and postoperative pain reduction in patients undergoing TKA surgery, it was shown that a group of patients with active scrubs heater had higher temperatures in the post-anesthetic care unit and less need for opioids than those who used standard cushions (1). In another study by Anupama Wadhwa on the comparison of different warm-up methods, circulating water systems and forced air were compared. The findings indicated that circulating water systems warmed-up volunteers to hypothermia in a lesser time (7). Finally, in a study by Horn on the effects of short-term warm-up periods in preventing the formation of post-surgical hypothermia, there was a significant difference in the body central temperature between the warmed-up and non- warmed-up groups. Without warming-up 69% of the patients were hypothermic after anesthesia, while 8%, 7% and 6% of patients who were warmed-up for 30, 20 and 10 minutes, experienced hypothermia (8).

Considering that maintaining body temperature plays a very important role in health and reducing patient dissatisfaction during anesthesia and continuing treatment, as a result, we decided to design a study and investigate this method that can be used to prevent temperature loss during anesthesia. The aim of this study was to evaluate the effect of pre-warming and total warming using forced air method on the body temperature of patients undergoing elective ocular surgery. Also, the effect of body temperature on the hemodynamic status of patients and the incidence of PAS were evaluated. The purpose of this clinical trial was to determine the effect of warming-up patients on the reduction of body central temperature during surgery.

## Materials and Methods

In this study, 60 patients aged 30-70 years old with ASA I-II candidate for elective ocular surgery (Retina, cataract) under general anesthesia were divided into three groups of 20, after obtaining written consent for participation in the study. Patients with any history of diabetes, hypothyroidism, hyperthyroidism and hypertension were excluded from the study.

In this randomized study, the intervention group was warmed up in the first group 30 minutes before anesthesia with forced air at a temperature of 38-42 ° C (pre-warming). In the second group, the control group, warming- up was not done.

In the third group, warming-up was performed throughout the whole period of surgery (total warming).

In each of the three groups, premedication was performed with 0.03 mg / kg Midazolam and 2 mic / kg fentanyl and after induction anesthesia was performed with 2 mg / kg propofol and 0.5 mg / kg atracurium. After 3 minutes, the patient was intubated by anesthesiologist and was connected to the ventilator and the anesthesia was continued with isoflurane 1.5% in oxygen 100%.

Patients' body temperature, hemodynamic profile and operating room temperature were measured every 15

minutes by tympanic thermometer and operating room thermometer and was recorded in the data collection form. The duration of surgery was considered to be 90 minutes for each of the three groups. The hemodynamic characteristics of the patient, including heart rate and mean arterial pressure, at the same time as taking the temperature, was recorded in the form. Other variables including age, sex, surgical duration and weight were also recorded with the patient's records. Also, in the recovery room, the shivering incidence was evaluated and registered. Finally, after the

surgery, the patient was re-evaluated in the PACU and the recovery temperature (the temperature of entering the care unit after anesthesia) as well as the patients' body temperature at the exit temperature was obtained and registered.

The data were analyzed using SPSS software version 20 and the percentage of frequency, statistical indexes such as the mean and dispersion indexes such as standard deviation, were calculated for the data.

## Findings

In this study, 41 males and 19 females were examined. Of the total number of men, 12 people (29.3%) in the pre-warming group, 15 people (36.3%) in the group without warming and 14 people (34.1%) in the total warming group, and the total number of women examined (8) people (42.1%) in the pre-warming group, 5 people (26.3%) in the group without warming and in 6 people (31.6%) the total warming group were evaluated. The mean and standard deviation of weight, age, and operating room temperature are presented in Table 1. No significant difference was found between the three groups in these variables.

**Table 1: Mean and standard deviation of weight, age and operating room temperature**

Group		Age (year)	Weight (kg)	Room temperature (C)
	P value	0.09	0.5	0.5
Pre warming	Mean	44.1	73	24.88
	SD	14.8	12.4	2.05
Without warming	Mean	36.6	69.7	25.61
	SD	15.7	9	2.17
Total warming	Mean	27.5	72.8	25.28
	SD	17.3	12.2	1.86
Total	Mean	42.7	71.8	25.5
	SD	16.3	11.2	2.02

The mean and standard deviation of patients' body temperature in the sequence of the study in the three groups are presented in Table 2. The mean body temperature of patients showed a significant difference except for the beginning of the study at all times in the three groups. The incidence of hypothermia was 10% in the pre-warming group, 55% in the control group and 10% in total warming. Also, 10% of the pre-warming group and 15% of the control group experienced severe hypothermia.

**Table 2: Mean and standard deviation of patients' body temperature in the study sequence**

Group		Patient's body temperature on admission	The first examination of the patient's body temperature	The second examination of the patient's body temperature	The third examination of the patient's body temperature	The fourth examination of the patient's body temperature	The fifth examination of the patient's body temperature
	P value	0.5	0.00	0.00	0.00	0.00	0.00
Pre warming	Mean	36.62	36.3	36.2	36	36	35.9
	SD	0.30	0.6	0.6	0.6	0.7	0.8
Without warming	Mean	36.70	36.2	35.9	35.7	25.7	35.3
	SD	0.31	0.6	0.6	0.6	0.6	0.6
Total warming	Mean	36.76	36.7	36.6	36.6	36.6	36.8
	SD	0.30	0.6	0.6	0.6	0.7	0.8
Total	Mean	36.6	36.4	35.9	36.2	36.1	36.2
	SD	0.30	0.6	0.6	0.6	0.6	0.6

The mean and standard deviation of patient body temperature during recovery and discharge from the operating room in the three groups were as follows (Table 3). As can be seen, the mean body temperature of patients in recovery and discharge time also showed a significant difference in the three groups.



**Table 3: Mean and standard deviation of patient's body temperature during recovery and discharge from the operating room**

Group		The patient's body temperature range at the entrance to the recovery room	Patient body temperature when leaving the operating room
	P value	0.00	0.00
Pre warming	Mean	36	36.4
	SD	0.7	0.3
Without warming	Mean	35.8	36.2
	SD	0.6	0.6
Total warming	Mean	36.6	36.7
	SD	0.4	0.3
Total	Mean	36.1	36.4
	SD	0.7	0.5

The mean and standard deviation of patients' blood pressure in the study sequence in the three groups are presented in Table 4. As can be seen, the mean of blood pressure in patients did not show any significant difference at all times in the three groups.

**Table 4: Mean and standard deviation of blood pressure in patients in the study sequence**

Group		Patient's blood pressure on admission	The first examination of the patient's blood pressure	The second examination of the patient's blood pressure	The third examination of the patient's blood pressure	The fourth examination of the patient's blood pressure	The fifth examination of the patient's blood pressure
	P value	0.54	0.80	0.83	0.71	0.49	0.40
Pre warming	Mean	86.95	76.95	75.65	71.85	77.60	78.80
	SD	16.02	19.04	12.83	13.52	13.43	5.75
Without warming	Mean	88.15	79.25	77.70	74.15	76	75
	SD	19.01	20	16.30	11.88	21.13	12.12
Total warming	Mean	82.10	74.90	78.40	75.20	81.25	73.30
	SD	19.60	23.09	15.19	13.74	15.79	11.02
Total	Mean	85.73	77.03	77.25	73.73	78.28	75.87
	SD	18.16	20.50	14.64	12.93	14.12	9.16

The mean and standard deviation of patients' heart rate in the study sequence in the three groups are presented in Table 5. As can be seen, mean heart rate of patients did not show significant difference at all times in the three groups.

**Table 5 Mean and standard deviation of heart rate of patients in the study sequence**

Group		Patient's heart rate on admission	The first examination of the patient's blood pressure	The second examination of the patient's heart rate	The third examination of the patient's heart rate	The fourth examination of the patient's heart rate	The fifth examination of the patient's heart rate
	P value	0.69	0.74	0.18	0.55	0.05	0.26
Pre warming	Mean	0.78	87.35	87.30	84.85	82.75	88.60
	SD	13.60	15.93	9.76	12.57	10.68	10.38
Without warming	Mean	81.65	88.75	91.80	88.40	91.15	83.67
	SD	15.50	15.05	12.25	10.56	9.85	8.39
Total warming	Mean	79.50	85.25	85.30	85	85.65	93.18
	SD	11.54	12.73	11.61	11.64	11.25	8.70
Total	Mean	79.72	87.12	88.13	86.08	86.52	90.08
	SD	13.49	14.45	11.40	11.54	11	9.60

Analysis of variance with repeated measurements showed that age, weight, operating room temperature, blood pressure, heart rate, patient body temperature at the time of entry (admission), and the first, second and fourth examination of the body temperature, recovery, body temperature at discharge, the first, second and fourth examination of blood pressure and second, third, fourth and fifth examination of the heart rate, did not show a significant difference in the three groups studied over time. In analyzing these cases alone, in three groups, analysis of variance with repeated measurements again showed that only four variables of the second and fourth times of the body temperature examination and the first examination of blood pressure and the third examination of heart rate showed no significant difference in the three groups over time (Table 6).

**Table 6: Analysis of variance with repeated measurements of mean and standard deviation of body temperature, blood pressure and heart rate in the study sequence**

Effect	Value (amount)	F	Significance
Time	Pillai's Trace	427.72	0.00
	Wilks Lambda	427.72	0.00
	Hotelling's Trace	427.72	0.00
	Roy's Largest Root	427.72	0.00
Interaction between time and group	Pillai's Trace	1.37	0.22
	Wilks Lambda	1.39	0.22
	Hotelling's Trace	1.40	0.21
	Roy's Largest Root	2.74	0.05

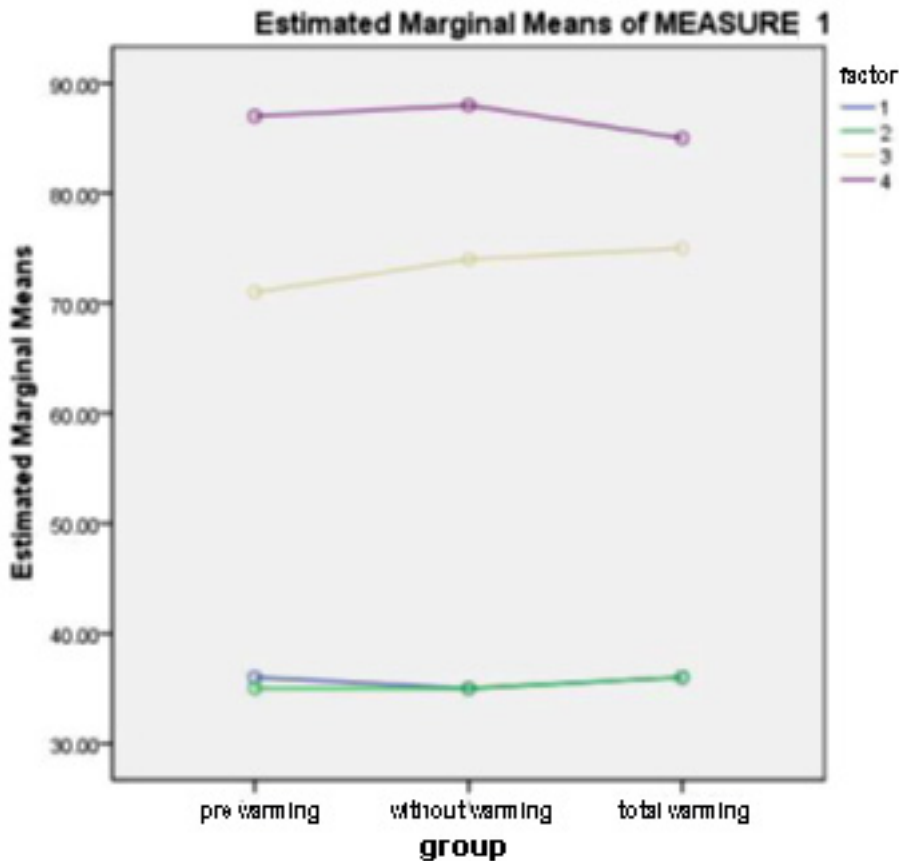
**Table 7: Analysis of the variance of intra-group effects**

Source of change		Sum of squares	df	Mean of squares	F	Significance level
Time	Linear	108651.78	1	108651.78	1008.75	0.00
	Quadratic	2742.53	1	2742.53	30.79	0.00
	Cubic	11547.50	1	11547.50	137.54	0.00
Interaction between time and group	Linear	79.57	2	39.78	0.36	0.01
	Quadratic	91.40	2	45.70	0.51	0.01
	Cubic	58.24	2	29.12	0.34	0.01
Error	Linear	6139.39	57	107.70		
	Quadratic	5076.19	57	26.73		
	Cubic	4785.42	57	48.55		

**Table 8: Analysis of the variance of out-group effects**

Source of change	Sum of squares	df	F	Significance level
Fixed (constant)	815512.07	1	7782.27	0.00
Group	25.43	2	0.12	0.88
Error	5973.08	57		

**Diagram 1: Comparison of the mean and standard deviation of the scores of the studied patients in the three groups in the study sequence**



## Discussion and Conclusion

Reducing central temperature below 36 ° C is considered as hypothermia and reduction to below 35 ° C as severe hypothermia. Estimates show that 90-90% of patients undergoing small and large surgery are prone to experiencing hypothermia (1). The incidence of hypothermia can cause a series of unwanted side effects in patients undergoing surgery, such as postoperative shivering which increases the oxygen consumption by several times, which may be problematic, especially in cases of cardiac problems, leading to myocardial ischemia and angina after surgery (2). Hypothermia can cause coagulation disorder, as well as increased susceptibility to infection and delayed wound healing. Increased hospitalization time and increased mortality within the hospital are considered as a significant complication of hypothermia (3).

Regarding this important condition, many studies have been carried out about the factors affecting hypothermia and various ways to prevent hypothermia (1, 7-10). So that by warming up the patients actively by water and forced air the occurrence of hypothermia and its complications can be prevented. In De Witte's study, among 27 patients divided into 3 groups, it was shown that those who were warmed-up by resistive heating for 30 minutes before receiving the anesthetic had a higher temperature than those in the control group, but those using the forced air were not very different from the control group (9). Another study by Sebastian Brandt and colleagues was conducted comparing two methods of heating in orthopedic patients. In this study, on 80 patients who underwent orthopedic

surgery two methods of forced air and resistive-polymer (RP) were compared in which the warming-up by RP was shown to be as effective as forced air (10).

Of course, pre-warming has also been effective and patients in this group have a higher temperature than the control group, which has led to similar results in previous studies. Patients undergoing active warming-up during the entire period of surgery showed a significant increase in temperature compared to the pre-warming group.

Patients who were exposed to active warming-up in the operating room had a higher temperature at the time of entry into the recovery room and when leaving the operating room, which was interpreted as statistically significant. In this design, shivering was not seen in any of the 3 groups. In previous studies, shivering was reported to be 3.5 to 14.4 (11, 12). It seems that the age of the studied population, the type of surgery (given that eye surgery is limited and with low bleeding) and warming up of patients are the causes of this finding in our study.

On the other hand, by analyzing other variables in the study, we concluded that age and weight of patients did not show significant correlation with body temperature during anesthesia. Also, by performing repeat measurement analysis, it was shown that there was no significant correlation between patient body temperature and hemodynamic indexes over time.

In general, in our study on the effect of warming-up the patients during surgery was investigated, and it was shown that active warming-up can prevent the occurrence



of unwanted hypothermia in patients undergoing GA. However, the incidence of adverse effects was not investigated. Future studies can address the effect of hypothermia on the incidence of complications of hypothermia (hemorrhage (bleeding), cardiac ischemia, wound infection, etc.). Of course, the realization of this issue requires the cooperation of surgeons in other fields. Also, due to the inaccessibility of a warmer in the routine room, the necessity of examining the effectiveness of the existing equipment and design of the heating (warming) devices of patients with a reasonable quality seems reasonable. On the other hand, given the complications of hypothermia, some studies may be designed to reduce the incidence of hypothermia, which could reduce the unwanted costs imposed on patients.

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# Translation and Validation of the Persian Version of the Perinatal Grief Scale in Iranian Mothers with an Experience of Pregnancy Loss

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## Abstract

**Objective:** Loss of pregnancy and subsequent grief is a very difficult experience in the life of expectant parents. Grief refers to the process of experiencing psychological, behavioral, social, and physical responses to loss, which is a natural process, but if it persists for a long time, it can become complicated, more severe and debilitating. We need a valid and reliable tool to measure grief after perinatal loss. Because of the lack of such a tool in Iran, this study aimed to translate and culturally adapt the Perinatal Grief Scale (PGS) in an Iranian target group, and determine the psychometric properties of the scale in this population.

**Material and Method:** During this methodological study, 330 women who had an experience of perinatal loss over the previous year were chosen through "Convenience" sampling from two teaching hospitals and Health Centers in Gorgan. The PGS was translated using the forward-backward translation technique. The validity of the PGS Persian version (PGS-P) was evaluated through face, content, and structural validity (confirmatory factor analysis), while its reliability was assessed using Cronbach's alpha coefficient. SPSS software version 16 and Amos software version 24 were used for data analysis.

**Results:** On the basis of the target group's and expert panel's comments in the validity stage, item 32 (Being a bereaved parent means being "Second-Class Citizen") was removed from the original scale. In reviewing the confirmatory factor analysis, all fitness indicators confirmed the 3-factor structure of the main scale with 32 items. All items had a factor load over 0.20. Cronbach's alpha coefficient for the total scale was 0.95 and ranged from 0.84 to 0.89 for the factors of PGS-P.

**Conclusion:** The results of confirmatory factor analysis and Cronbach's alpha coefficient showed that PGS-P is valid. Therefore, it recommends that the PGS-P be used to assess grief severity in parents after perinatal loss and to identify high-risk women who are more vulnerable so that the health-care system can help them.

**Key words:** Translation, validity, grief, perinatal loss, reliability

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## Introduction

Perinatal loss is the unwanted or unintentional loss of a fetus or infant through a miscarriage, stillbirth, or newborn death (through 28 days of life) (1), which account for one-third of the pregnancies in the world (2). It is a very bitter experience in the life of expectant parents, especially for the mother, and it is often accompanied by great pain, grief, and suffering (3,4).

Grief is a reaction to the loss of an object or person who has been extremely favored (5,6); this person can also be a fetus or an infant (6). The grief associated with the loss of pregnancy is a unique state of grief, since the child is a part of the parental identity and besides feeling emptiness, sad and physically exhausted, the mother who has pregnancy loss may feel that she is to blame, that she is a failure and that it may be repeated in subsequent pregnancies (2, 7). Although grief is a natural and non-pathologic response, it can be typified as complex or prolonged grief in cases where the symptoms are debilitating, pervasive, and severe (3), including symptoms such as intense passion for being with the deceased person, denial and disbelief, intense anger, and feeling of emptiness in life (8). The average rate of suicide in mothers with this type of grief is significantly higher than that of women of reproductive age in the general population or women with a history of live births (9, 10).

Studies published documenting the troubled emotions and reactions of women suffering from miscarriage, stillbirth, and fetal death have increased remarkably over the past two decades (4). Therefore, dealing with mothers after the loss experience is an indispensable part of their care to help ease the normal grief process (9). It is very important to investigate the grief process in these mothers in order to provide psychological support and necessary care for them (11).

Obviously, vulnerable mothers must first be identified, then evaluated and be consulted. To identify them, special tools are required (12). Since accurate information is provided through the use of a precise, reliable and sensitive tool (13), it seems necessary to design or to use existing tools to identify the process of grief in mourning mothers (12). Despite the similarity of "perinatal loss" grief with the grief caused by the death of other loved ones, in some cases they are completely different (2, 3, 7). The loss of a baby during the perinatal period almost always involves the loss of hopes, dreams, and expectations invested in the expected child (14). Therefore, the study of this kind of grief requires a special tool (2).

To have such a tool, the researcher has two options: a) designing a new instrument, which is a time-consuming process and requires the observance of specific scientific and specialized principles and, b) using previously validated instruments, usually questionnaires that are adapted for use in another "target" culture and language (15). So far, various scales or questionnaires have been designed in different languages that are also used in other countries.

For example, in the field of perinatal grief, among available tools, the Perinatal Grief Scale (PGS), which is in English, is considered the most comprehensive and precise tool for identifying potential complications in the grief process of parents, and it has been translated into more than half a dozen languages with successful results (6,16-18).

This scale was designed to investigate and comprehend the variations and changes in the grief process in women and men who experienced loss of pregnancy including miscarriage, stillbirth or fetal death and neonatal death (6). Moreover, it is widely used in research projects (6,16,18-20). It includes three subscales; "Active grief", "Difficulty coping" and "Despair". "Active grief" measures what is often considered normal grief, as it incorporates items such as sorrow, missing the child or crying. "Difficulty coping" measures difficulty with normal life activities and with other people, such as lack of support, feelings of guilt, and problems in marital relationships. "Despair" describes the potentially most serious effects of the loss. It involves existential feelings of helplessness and hopelessness (6,17). Scoring Instructions are such that the total PGS score is arrived at by first reversing all of the items except 11 and 33 (2,18). There are 11 statements related to each subscale that the respondent evaluates on a 5-point Likert scale that is limited by the statements completely agree and completely disagree with a neutral central point. Each respondent can score a total minimum of 11 and maximum of 55 points on each subscale. The total score of the PGS varies between 33 and 165 points. Higher scores represent higher intensities of grief. Values above 91 points represent potential psychiatric morbidity (2,6,17).

A review of studies showed in some countries, including Iran, grief after perinatal loss was not always considered, not only in the scientific texts and publications but also in clinical matters including psychological and counseling support (21). In Iran, there is very little information regarding the experiences of mothers following the loss of pregnancy, and more importantly, there is no specific protocol to support them (21). An explanation for the limited information on this issue can be the lack of appropriate tools for identifying the problems faced by bereaved parents, which leads to lack of progress in scientific and clinical research. Therefore, the present study aimed to translate and culturally adapt the PGS and evaluate the validity and reliability of the PGS Persian version (PGS-P) in Iranian women with an experience of pregnancy loss, so as to provide a tool for further research and for clinical identification of mothers vulnerable to complicated grief.

## Material and method

This methodological study was carried out in 2016 in Gorgan, a city in north Iran. It was approved and funded by Golestan University of Medical Sciences (with code of 391215).

Initially, the permission for translation and using the PGS were obtained on August 21st, 2015, from its original designer, Professor Toedter. The scale was then translated and culturally adapted based on a combination



of the approaches proposed by WHO, Wild, and Beaton, described below (22-24).

The questionnaire was translated independently by two translators fluent in both the source and destination languages and whose native language is Persian (Farsi). They were instructed to avoid verbatim translation and asked to give a clear translation with equalized concepts. Then, the two initial translations were compared by an expert panel including a psychiatrist, a gynecologist, a psychologist and the research team, and after slight modifications in wording, they agreed on the Persian version (22-24). In order to ensure the accuracy of the primary translation, the questionnaire was back translated into English by a fluent translator in both Persian and English, who did not participate in the previous phase and did not see the original version of the scale (22). Then the expert panel and the research team reviewed and compared the back-translated English version of the scale with the original version. After agreeing upon the translated English version (22-24), to assure the accuracy of the translation and equality of the concepts with the original version, the backward translated version was emailed to the original designer (24). After applying some modifications on the basis of the designer's recommendations, it was approved by her and the pre final Persian version of PGS was prepared and adjusted. In this step, Face, content, and construct validity were considered.

### 1. Face validity Assessment

The face validity of the pre-final PGS-P was assessed both qualitatively and quantitatively. Quantitatively, face validity assessment was done using the impact score method. In this connection, the questionnaire was given to 20 mothers with a history of diverse types of pregnancy loss (abortion, stillbirth and neonatal death), educational level of diploma to PhD, age distribution of 18 to 38 years, and various social classes. They were asked to express their opinions about importance of the items based on the 5-point Likert scale (very important = 5, important = 4, relatively important = 3, slightly important = 2, and not important = 1) (25, 26). For all 33 items of the tool, the face validity was calculated quantitatively through formula [Impact Score = Frequency (%) × Importance] and each item with a score higher than 1.5 was accepted (25). They were also asked to comment on the questionnaire regarding its flow, ease of use and comprehension, content, sentences and phrases, and ambiguous items (27).

### 2. Content Validity Assessment

The content validity of the pre-final version of PGS-P was also assessed both qualitatively and quantitatively. To assess qualitative content validity of the pre-final PGS-P, reactions to the questionnaire's content, modification comments about the scale, on wording, item allocation, and scaling of the items were sought from eleven experts (composed of one clinical sociologist, one family counselor, two reproductive health experts, two instrument designers, two psychiatric nurses, two psychologists, and one psychiatrist).

The content validity index (CVI) was used for the quantitative part of the assessment, and the responses given were also used for the qualitative part of the assessment. Accordingly, the same 11 experts were asked to rate all items in the pre-final PGS-P based on three criteria including relevancy, simplicity, and clarity, using a 4-point Likert scale. For example, we asked the experts to rate the relevancy of items on a 4-point Likert scale from 1 to 4. The 4 points for rating the relevance of the items ranged from 1 (not relevant) to 4 (highly relevant). CVI for each item was calculated using a formula [CVI = Number of raters giving a rate of "3" or "4" / Total number of raters] (28). Using guidelines proposed by Waltz and Bausell, CVI < 0.7 was unacceptable, CVI 0.7-0.78 required modification and revision, and CVI ≥ 0.79 was acceptable (29, 30). After providing explanations to the experts, minor modifications were made to some items with required modification and revision with the least possible changes to the original PGS. In the second round, five of the previous experts were asked to evaluate the relevance of the revised set of items and to compute the CVI (29).

Guided by input obtained from women in the target group and the expert panel's opinions, we subsequently revised the pre-final PGS-P. The final version of the PGS-P was prepared to use in the next stage to examine construct validity.

### 1. Construct Validity Assessment

To examine PGS-P construct validity, we also performed confirmatory factor analysis (CFA) (18). Since the CFA evaluates a predetermined model that is based on previous theories and studies, the number of factors is already predicted by the initial designer in the model; besides, it is known which items are subsets of which corresponding factors. Moreover, it is determined whether questions measure intended indices based on the factors (31).

CFA is a method of presenting structural equations used in determining goodness-of-fit between a theoretical model and data obtained from study samples (32). Compatibility of the model was determined using a maximum probability algorithm. There are several goodness-of-fit indices for deciding compatibility of the model, and it is preferable to use several indices (33).

Therefore, in the present study, to investigate the adjustment of the foreseen factors, the CFA stage was performed using the AMOS 24 software. Goodness-of-fit indices used included Chi sq/df, Root Mean Square Error of Approximation (RMSEA), Goodness-of-Fit index (GFI), Comparative Fit Index. RMSEA is an important index, with values less than 0.08 indicating acceptability. Appropriate values for other indices include CFI and GFI that is closer to 1, which is more desirable (34).

To perform the CFA, the ideal number of participants was considered to be 330 people, which is 10 times the number of items in the questionnaire (35). A convenience sampling method was used. The inclusion criteria were: 1) women who experienced a pregnancy loss no more than one year before the beginning of the sampling, 2) willingness to take

part in the study, 3) no history of treatment for psychiatric disorders or having a serious psychiatric problem now (based on self-declaration), 4) literacy to read and write. For this purpose, after coordinating with the head of two educational hospitals of Gorgan, the addresses and phone numbers of women with a history of perinatal loss during the past year were extracted from medical documents in the maternity and neonatal units and gynecologic clinics. After contacting them, the purpose of the research was explained. If they agreed to participate in the study, an appointment was established in a health care center close to their home or at their home.

Of approximately 400 women contacted, 330 participated. At their appointment, they were informed again about study objectives and also about the confidentiality of their responses. After giving written informed consent, they were asked to complete the demographic information form and the PGS-P.

#### 4. Reliability Assessment

To determine the reliability of the final version of the PGS-P, Cronbach's alpha was calculated to assess the internal consistency of the scale based on data from 330 women of the target group.

## Results

The demographic characteristics of 330 women participating in this research project showed that their ages ranged from 15 to 47 years, with an average age of 28.88(SD=6.22). Of the 330 women, 211 had experienced a miscarriage, 64 a stillbirth, and 55 a neonatal death.

The questionnaires were clear for them and took less than 10 minutes to complete.

In total, the impact score of 31 items in the pre-final Persian version of the PGS were greater than 1.5, only items #29 and #32 were lower than 1.5. Therefore, two items were candidates to exclude in this step. According to the views expressed by the target group in the validity stage, the Likert spectrum of "neither agree nor disagree" was changed to "no idea", due to the lack of transparency for them. There were also comments on modification of some terms in some items (#3, #29, #32) which were applied in the research team's investigations. Item #3, which was "I feel empty inside", was changed to "I feel emptiness from inside". Some participants had problems understanding item 32 (Being a bereaved parent means being "Second-Class Citizen") and item #29 (It's safer not to love).

Evaluation of the pre-final PGS-P CVI showed that the CVI of 31 items was higher than 0.79; hence, they were considered as the appropriate items. Only two items (#29, #32) obtained CVI scores less than 0.79, and based on the views expressed by 11 experts, some obscure words and phrases were reported and also some modifications were recommended to better understand the target group. According to their ideas (target group and experts) we applied modification as follows:

The phrase "Second-Class Citizen" in item #32 was changed to "lower social status". Item #29, "It's safer not to love" changed to "It's less problematic not to love somebody". Item #4, which was originally translated as "I can't keep up with my normal activities", changed to "I cannot continue my daily routines as before."

After considering the recommendations of experts regarding items with low score CVI, the pre final "PGS-P" was again sent to 5 related specialists and 5 mothers from the target group. Consequently, through the re-examination all items gained acceptable scores from experts and were confirmed by the target group except #32. So, based on the common views of the two target and experts' groups, item #32 was eliminated from the original scale due to low score, and the process was continued without these items. Generally, according to the results of pilot phase and suggestions by the expert panel opinion, and the research team, we made minor changes for some of items of PGS to provide better understanding for the mothers. Ultimately, the final PGS-P with 32 items in 3 subscales "Active Grief" with 11 items, "Difficulty of Coping" with 11 items and "despair" with 10 items was obtained<sup>1</sup>.

CFA was performed for assessment of construct validity on data obtained from 330 women who experienced pregnancy loss in order to provide the most appropriate model of PSG-P; in order to achieve a better result and improve the model, we examined the corrective indices. Evaluating the significant error variance, item #8 with item #9, item #10 with item #11, item #30 with item #31, the item #25 with #31 were implemented. After using some performable covariance, the desired results were obtained. Table 1 presents CFA results and Figure 1 shows the model. Therefore, the structure of the "PGS-P" was confirmed only by deleting a single item. In other words, the PGS-P with 32 items and three factors in Persian is trusted and can be used to evaluate grief of women who have a history of loss of their pregnancy.

The reliability of the scale was assessed using the internal consistency methods. Cronbach's alpha was calculated to assess the internal consistency reliability of the Persian version of PGS. Cronbach's alpha was calculated as 0.95 for the total scale and as 0.88, 0.87, and 0.84 for the subscales of Active Grief, Difficulty Coping and Despair respectively (Table 2).

## Discussion

The purpose of the present study was to describe the process of translation and cultural adaptation of the PGS and determine the psychometric properties of the Persian version of the scale. We were able to successfully translate and adapt the PGS. The PGS-P was developed while only one item was deleted from the original items in the scale. We did not face serious problems during the translation and cultural adaptation process of PGS. Although substantial changes to the original version were not necessary, we made minor changes in some

1. If anybody wishes to receive PGS-P, kindly contact the corresponding author.

Figure 1: Conceptual model of confirmatory factor analysis “PGS-P”

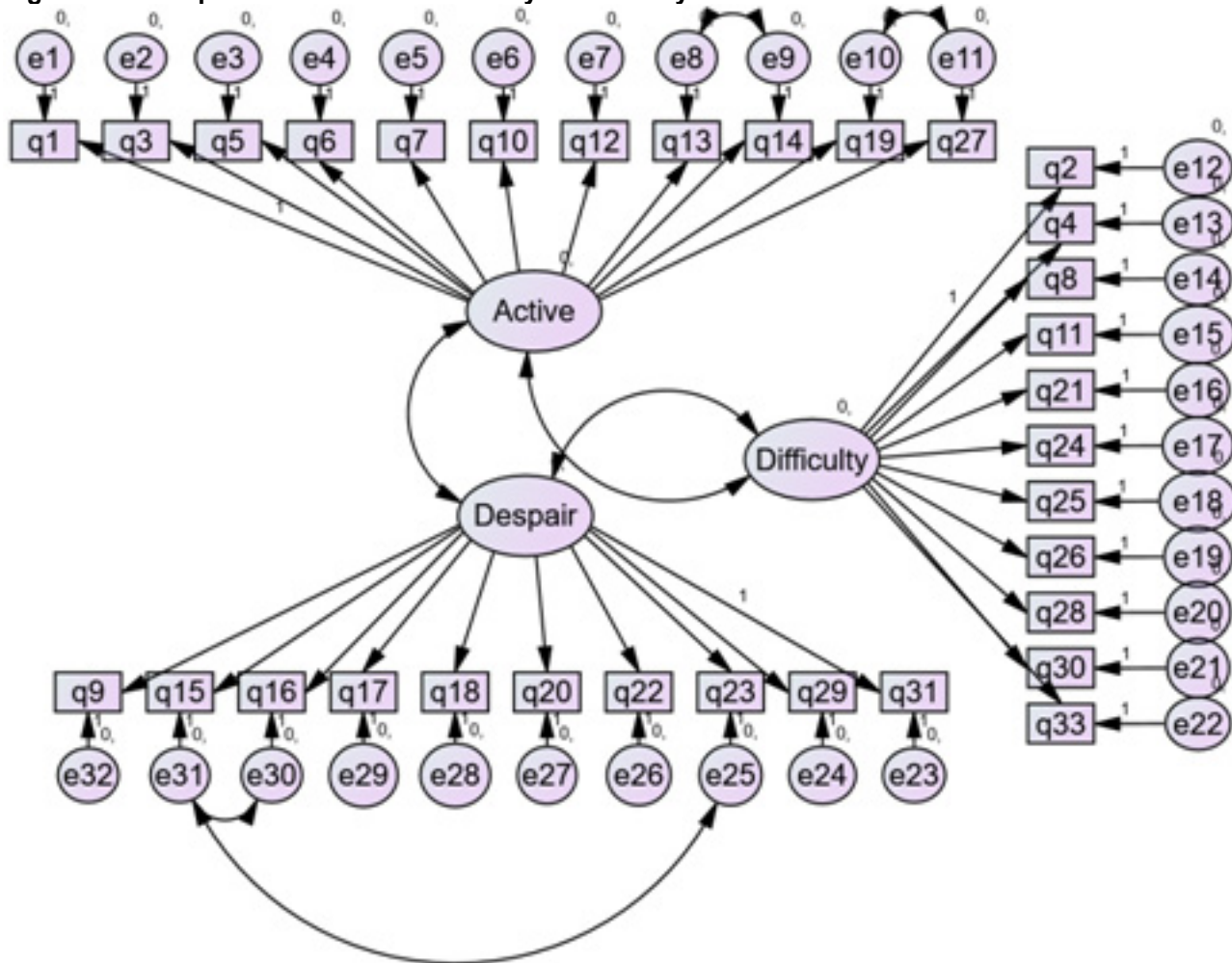


Table 1: Score of PGS-P fitness indices

PNFI <sup>1</sup>	PCFI <sup>2</sup>	GFI <sup>3</sup>	CFI <sup>4</sup>	RMSEA <sup>5</sup>	Chi sq/df
0.72	0.79	0.86	0.86	0.068	2.506

<sup>1</sup> Parsimonious Normed of Fit Index, <sup>2</sup> Parsimonious Comparative of Fit Index, <sup>3</sup> Goodness-of-Fit Index,

<sup>4</sup> Comparative Fit Index, <sup>5</sup> Root Mean Squared Error of Approximation

Table 2: Comparison of the results of reliability of PGS-P in present study and the original PGS

Subscales	Internal consistency; Cronbach's alpha (present study)	Internal consistency; Cronbach's alpha (Toedter's study)(36)
Active Grief	0.88	0.92
Difficulty Coping	0.87	0.91
Despair	0.84	0.86
Total	0.95	0.95

questions to facilitate mothers' understanding and to be culturally appropriate for Iranian mothers.

Other translators of the PGS have made a number of cultural adaptations. Ratislavová et al. (2013), who did their translation process based on the translation/back translation technique to translate the scale from English into Czech, changed the Likert scale item of “not disagree, not agree” to “I don't know”, since this term is used more often by the Czech people (6). Similarly, we changed

the “neither agree nor disagree” Likert item to “no idea”, because it was unclear for the mothers. Adolfsson et al., in their study in Sweden, replaced the 5-choice Likert scale with a 10-optional Likert scale since their community was more familiar with this number of options (37).

Since the equivalent word for “grief” exists in Persian, no change was made. However, Capitulo et al. in Spain encountered a challenge to replace the word. They did not find the equivalent word for “Grief” in Spanish and used



two words of “duelo and luto” instead. Since in Spanish the word “duelo” means sorrow and the word “luto” means mourning, the combination of these two words has the same meaning as the word Grief (20).

In validity assessment, after re-evaluating according to the women in the target group and experts' opinions, item #32 still was low in importance and was not relevant. Indeed, among the 3 criteria for the CVI assessment (simplicity, relevancy, and clarity), it lacks the most important criterion of CVI; “relevancy” (29). Both groups believed that in our culture, none of the mothers who experienced pregnancy loss would be judged as a person of “lower social status”; rather the people of our community sympathize with mourning mothers. Considering the advice of experts with experience in instrument development, it was decided to delete only the items that the target group and the experts both agreed to remove, so at this stage, item #32 was removed from the PGS-P, and the process was continued without it. In other studies of translating this scale into other languages, no report was provided regarding the item deletion at this stage; before the confirmatory analysis. Therefore, the removal of one or more items at this stage was not comparable with other studies.

The results of the CFA in the present study determined that model fitness indicators were appropriate. The “PGS-P” was confirmed with three factors- “Active Grief” (with 11 items), “Difficulty Coping” (with 11 items) and “Despair” (with 10 items). However, in the study of Ratislavová et al., who did not consider the fitting indices in the obtained data as acceptable through the CFA investigating, the EFA was evaluated using the probability of maximum Varimax rotation. Therefore, only one item was deleted and ultimately, a scale with three subscales “Active Grief” with 6 items, “Difficulty of Coping/ Despair” including 23 items and “Sin” with 3 items were obtained (6). In the study of Capitulo et al., Exploratory Factor Analysis (EFA) was performed prior to CFA. According to the results obtained in this step, from 33 items in the main scale, 19 items had a desirable factor expressed on two factors. Then, the CFA was performed and the scale was confirmed by two factors called “Active Grief” with 13 items and “Difficulty of Coping/ Despair” each with 6 items (38). In the study of Biatric et al., EFA was performed before evaluating the confirmatory factor analysis. After completing this step, the 4 items were removed from the scale, and all remaining questions appeared on the two “Active Grief” and “Complicated Grief” subscales that the two-factor structure of the scale was confirmed in CFA (39).

The results obtained in the reliability stage of the scale in the present study showed that the PGS-P has a high stability. Thus, Cronbach's alpha coefficients of the total scale and the subscales of “Active grief”, “Difficulty of Coping”, and “Despair” were appropriate. Consistent with the present study, Maniatelli et al. also reported the reliability of the scale using Cronbach's alpha coefficients (18). We didn't assess reliability using test-retest, since grief involves a dynamic concept with its intensity decreasing over time; according to some researchers, it has no stability feature (2, 40). Thus, the test-retest method cannot be reliable in

assessing the stability of this concept. Since the stability index decreases over time as a result of the dynamicity of this concept, the reliability, and stability of the scale may be considered as inaccurate, falsely. However, Biatric et al. used two methods of internal consistency assessment (Cronbach's alpha coefficients) and stability assessment (test-retest) to examine the reliability of this scale (38). Cronbach's alpha coefficient for the two subscales of “Active Grief” and “Complicated Grief” were reported as optimal.

## Conclusion

Considering the results of the present study, it can be concluded that PGS-P is appropriately valid and reliable, and the use of PGS-P in women with pregnancy loss experience is acceptable. Relying on findings from other studies (2,6,17) that identified a score of over 91 as possibly indicating complicated grief, participants in the study who had such a score were referred to a psychologist or psychiatrist for further assessment and treatment. The scale can be useful for identifying women who experience a high intensity of grief so that they can be offered consultation or support from medical and social systems.

Since no valid and reliable tool previously existed in this field of study in Iran, it seems that its use in clinical practice is justified, and we recommend using it in midwifery as well as in consultations for the bereaved, psychological counseling or by psychiatrists working with women after perinatal loss. Midwives could routinely use the PGS-P when assessing women after perinatal loss in the postpartum period and to avoid potential complications in the grieving process and recommended professional psychological help as needed. Moreover, considering the ease of implementation in this tool, understanding and completing it through the target group does not require much time and effort.

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# Effects of Pelvic Floor Muscle Exercises on Urinary Incontinence and Quality of Life in Patients with Multiple Sclerosis

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## Abstract

**Background:** Urinary disorders are common problems in patients with multiple sclerosis (MS). Urinary incontinence largely affects the physical, social, and emotional characteristics and activities of these patients.

**Objectives:** This study was conducted to determine the effects of pelvic floor muscle exercises on urinary incontinence and quality of life in patients with MS.

**Patients and Methods:** This quasi-experimental clinical trial adopted a pretest-posttest design. Convenience sampling was used to select 50 MS patients with urinary incontinence who presented to the Iranian Center of Neurological Research. The eligible patients were trained on pelvic floor muscle exercises and asked to practice the exercises for three consecutive months. The International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) and Qualiveen-30 were administered to measure the patients' level of urinary incontinence and quality of life, respectively. The participants completed the questionnaires before the intervention and at the end of the third month. The data were analyzed using paired t test and Pearson's correlation test.

**Results:** Of the total number of participants, 68.9% were women and 31.1% were men. Participants' mean and standard deviation of age, duration with MS, and duration with urinary incontinence were  $36.33 \pm 9.4$  years,  $9.06 \pm 5.11$  years, and  $2.39 \pm 3.71$  years respectively. The mean ICIQ-UI SF scores and the frequency and amount of urine leakage significantly decreased after the intervention ( $P < 0.001$  for all). Moreover, significant improvements in quality of life and all its domains were observed after the intervention ( $P < 0.001$ ). Moreover, There was a significant inverse relationship between urinary incontinence and all domains of quality of life ( $P < 0.001$ ).

**Conclusion:** Training MS patients with urinary incontinence to perform pelvic floor muscle exercises can reduce the severity of their urinary disorders and promote their quality of life.

**Key words:** Pelvic Floor Muscle Exercises, Urinary Incontinence, Quality of Life, Multiple Sclerosis

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## Background

Multiple sclerosis (MS) is a chronic disease in which patient independence requires training in self-care and self-management [1]. About 2.5 million people around the world [2], and 5-30 individuals per 100,000 people in Iran suffer from MS [3]. The prevalence of the disease is unfortunately on the rise in Iran and the number of MS cases recorded in different medical centers of the country have increased by three-four times over the past several years[4].

MS is characterized by a variety of unpredictable symptoms and periods including impaired coordination and balance, fatigue, visual disturbances, sensory changes, sensitivity to heat, cognitive and emotional disorders, and bladder and bowel dysfunction[5]. About 84% of MS patients complain about lower urinary tract dysfunction[6]. Lesions in the cerebral cortex, suprapontine, and spinal cord are among the neurological causes of urinary disorders in patients with MS[7]. Furthermore, overactive bladder and the consequent urinary incontinence are the most frequent bladder dysfunctions in these patients[8]. Urinary incontinence is a frustrating and debilitating disorder that manifests as obvious involuntary urine leakage. Urinary disorders exacerbate as MS progresses and patient mobility decreases. The proper functioning of the bladder is necessary to prevent life-threatening infections, kidney failure, and formation of kidney and urinary tract stones in patients with MS [7]. Urinary incontinence largely affects patients' physical, social, and emotional characteristics and activities and causes an embarrassing situation which leads to social isolation and reduced quality of life [9]. Considering the chronicity and incurability of MS, promoting patients' quality of life should be regarded as a major care objective[10].

Various treatment methods, such as surgery, hormone therapy, pharmacotherapy, electrical stimulation, pelvic floor muscle exercises, and mechanical devices, have been suggested for urinary incontinence. Pharmacotherapy uses anticholinergics and antimuscarinics, e.g. oxybutynin and tolterodine, and causes a number of side effects including constipation, dizziness, urinary retention, and skin rash [11,13]. Not only do surgical approaches need appropriate facilities, high expenses, and skilled surgeons, but they may also be associated with both complications and the relapse of urinary incontinence[14]. Pelvic floor muscle exercises are essential for the prevention and treatment of urinary incontinence[15]. These exercises are based on the fact that strong contractions of the pelvic floor muscles clamp the urethra and consequently increase urethral pressure and prevent urine leakage in case of a sudden elevation in intra-abdominal pressure[14, 16].

Health personnel, including nurses, can easily train patients with MS on pelvic floor muscle exercises as a non-pharmacological, non-invasive, and cost-effective method to control urinary disorders. Numerous studies have shown the effectiveness of pelvic floor muscle exercises on urinary incontinence [6, 9, 14, 18, 31]. Performing these exercises

can be effective in different positions, but the correct technique determines its efficacy. There is no scientific evidence indicating superiority of a particular pelvic floor muscle strengthening regimen in urinary incontinence, and reports in this field are contradictory [17]. However, in order to ensure the effectiveness of pelvic floor muscle exercises, nurses should constantly encourage and support patients and provide both oral and written instructions[18]. Despite the significance of nursing interventions in the treatment and care of patients with chronic diseases and the high prevalence of urinary incontinence in MS patients, people's perception of the quality of life, which is affected by their beliefs and culture, can be different in different societies. Similar studies have mostly been conducted on women in western societies. So little research has been conducted in this regard.

## Objectives

Therefore, the present study aimed to determine the effects of pelvic floor muscle exercises training on urinary incontinence and quality of life in patients with MS.

## Patients and methods

This quasi-experimental study adopted a single-group, pretest-posttest design. Convenience sampling was used to select 50 male and female eligible patients between February 2014 and July 2014 presenting to MS clinics of the Iranian Center of Neurological Research (Imam Khomeini Hospital, Tehran, Iran). According to previous studies[19], a significance level of 95% and a test power of 90% (based on the difference of mean and standard deviation of urinary incontinence) used in the following formula

$$n = \frac{(z_1 - \alpha / z + z_1 - \beta)^2 \times s_d^2}{d^2}$$

the sample size was calculated as 42 patients ( $d=10$ ,  $s_d=6.32$ ). With a sample loss rate of 20%, the number of participants was increased to 50 patients.

Adult, literate patients (age: 18-50 years) who had been diagnosed with urinary incontinence caused by MS (confirmed by a neurologist) were included if they scored lower than seven on the Expanded Disability Status Scale (EDSS). EDSS is a neurological scale that grades the level of disability in MS with a score that ranges from 0 (normal neurological findings) to 10 (death due to MS). Other inclusion criteria were the absence of severe cognitive disorders, chronic heart and pulmonary diseases, urinary tract infection, and excessive fatigue which prevented the patient from doing the exercises. Patients with a history of diabetes, gynecological and prostate surgery, benign prostatic hyperplasia, Cesarean section or vaginal delivery during the past six months, disease attacks during the past three months, and changes in the dosage of drugs affecting urinary incontinence during the past month, were not included. Moreover, pregnant or postmenopausal women, as well as individuals receiving diuretics or antihypertensive drugs, were not eligible for participation. The exclusion criteria were unwillingness to continue

participation (regardless of the reason), the incidence of acute medical conditions or acute disease attacks during the course of the study, and any changes in the dosage of drugs affecting urinary incontinence over the study period.

Data were collected using a demographic questionnaire (Demographics questionnaire had two sections: general information including age, sex, height, weight, Body Mass Index (BMI), place of residence, marital status, employment, economic status, type of insurance, and the need for assistance with daily activities, and MS information including type of MS, duration of having MS, frequency of recurrence in the past year, medication history, medication used for urinary incontinence, disability before and after intervention), the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF), and the Qualiveen-30.

The ICIQ-UI SF consists of four items: frequency of urinary incontinence ("0" never, "1" once a week, "2" two or three times a week, "3" once a day, "4" a few times a day, "5" always), volume ("0" none, "2" small amount, "4" moderate amount, "6" large amount), how much urine leakage affects your daily life (Visual analogue scale ranging from 0 "Not at all" to 10 "A great deal") and fourth item included eight questions related to the symptoms to determine the type of urinary incontinence. The scores range between 0 and 21 and higher values indicate more severe symptoms of urinary incontinence. This questionnaire has been used in numerous studies[20, 21] and its reliability and validity have been confirmed in Iran (Cronbach's alpha = 0.75) [22].

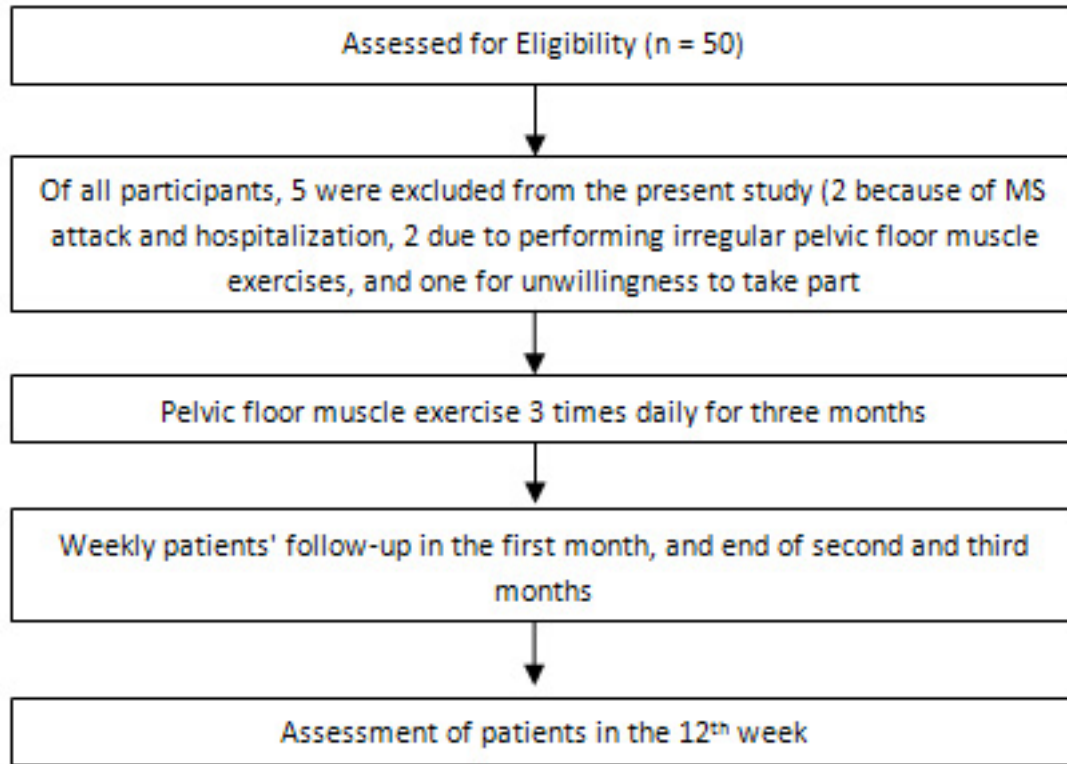
Qualiveen-30 evaluates patients' health-related quality of life through 30 specific items in four distinct domains: Bother with limitations (nine items), frequency of limitations caused by urinary disorders (eight items), fear (eight items) and feelings (five items). The items are scored on a five-point Likert scale with values ranging from 0 (no impact) to 4 (great negative impact) and greater total scores suggest poorer quality of life. The mean score of the items in each domain indicates the score for that domain and the overall score of Qualiveen is the mean of the four domains. This instrument has been used in various studies [19,23, 24]. Its validity and reliability in Iranian patients with spinal cord injury and MS have been previously confirmed (Cronbach's alpha = 0.82-0.95) [25].

The participants then completed the demographic questionnaire. Items related to BMI, type of MS, and EDSS scores before and after the training were marked by the researcher. Before the initiation of the study, the patients' EDSS scores were determined by a neurologist (as mentioned earlier, only individuals with scores lower than seven were included). The absence of urinary tract infection was confirmed through the normal results of urinalysis or urine culture. The subjects were also requested to fill out the ICIQ-UI SF and Qualiveen-30. The questionnaires were completed in the presence of the researcher in MS clinic after the patient was visited by the neurologist so that potential questions could be answered.

The researcher and research assistant had been trained about the exercises based on reliable resources and under the supervision of a nurse specialized in wounds, ostomy and continence. All training was performed according to the adult learning theory. This approach takes the living conditions and mental, physical, and experiential development of adults into account and allows the learners to learn what they need through self-control[26, 27]. The patients received individual, face-to-face training for about 20 minutes at the MS clinics. Patients were trained for pelvic floor exercises by a same-sex trainer. The subjects first received explanation about the anatomy and function of the urinary tract and the etiology, symptoms, complications, and treatment methods of urinary incontinence in MS patients. They were then provided with relevant pamphlets and pictures and lectured about pelvic floor muscle exercises. In order to identify muscles involved in urination, the patients were instructed to stop their flow of urine midstream for three seconds (but not to repeat this exercise too often). They were then asked to lie in a supine position with their knees bent and to squeeze the same muscles (as they did to stop urination) while they were breathing gently through the mouth and keeping all other pelvic muscles relaxed. They could gradually do the exercises in sitting and standing positions, as well. The subjects were recommended to start by holding the squeezes for three seconds and resting for five seconds. The goal was to increase the duration of each contraction to 10 seconds and to do 90-100 contractions a day (depending on each patient's ability and level of fatigue). The participants had to do the exercises three times a day (the timing was determined by the patients) for 12 consecutive weeks at home. Educational pamphlets about urinary incontinence in MS patients and pelvic floor muscle exercises were also distributed among the subjects.

In order to facilitate follow-up, each patient was provided with self-report checklists containing the number of muscle contractions at each time of practice, total number of muscle contractions per day, and the total time dedicated to the exercises. The participants were asked to complete the checklists every day. To resolve any problems and ensure the execution of the exercises, the researcher attended the MS clinic once a week and also phoned the patients weekly during the first month and at the end of the second and third months of the intervention.

The ICIQ-UI SF, Qualiveen-30, and self-report checklists were collected after three months (Figure 1). The patients who were not willing to continue participation or did not do the exercises regularly (less than 5 days a week) were excluded from the study. The questionnaires were completed by the patients when they went to the MS clinic without researcher's presence. Then the researcher collected the completed questionnaire.

**Figure 1: Consort Flow Diagram**

### Ethical Considerations

The present study was approved by the ethics committee of Tehran University of Medical Sciences (92/D/130/2715). It was also registered in the Iranian Registry of Clinical Trials (ID: IRCT2014010416063N1). All samples were at liberty to take part or withdraw, and were assured of confidentiality of data. The researcher ensured cooperation of authorities of Imam Khomeini hospital and MS clinic by presenting a letter of introduction from School of Nursing and Midwifery of Tehran University of Medical Sciences. Upon their recruitment, the patients were asked to sign an informed consent form and to provide their phone numbers (for follow-up).

### Data Analysis

Once the trial was terminated, the data were entered into SPSS 13 (SPSS Inc., Chicago, IL, USA). Normality of the data was confirmed using Kolmogorov-Smirnov test (all data were normal), so paired t-test was used to compare total scores of ICIQ-UISF, quality of life and its dimensions before and after intervention, and Pearson's correlation test to determine the relationship of total score of quality of life and its dimensions with urinary incontinence, age, BMI, duration of MS, duration of urinary incontinence and EDSS score. Statistical tests were performed at the significance level of  $P < 0.05$ .

### Results

The mean and standard deviation of age, BMI, duration of having MS and urinary incontinence in participants were  $36.33 \pm 9.4$  years,  $24.22 \pm 4.63$  kg/m<sup>2</sup>,  $9.06 \pm 5.1$  years and  $2.39 \pm 3.71$ , respectively.

Since five patients were excluded during the course of the study (two due to MS attacks and hospitalization, two for their failure to do the pelvic floor muscle exercises regularly, and one for unwillingness to participate), 45 patients completed the study. Table 1 provides the demographic and clinical characteristics of the participants.

There were significant differences in total scores of ICIQ-UI SF before and after the intervention ( $P < 0.001$ ) (Table 2). The total scores of quality of life, as well as the scores of all its domains, decreased after the intervention ( $P < 0.001$ ), i.e. the patients' quality of life improved after the intervention (Table 2).

The scores of ICIQ-UI SF had a significant direct relationship with scores of quality of life and all its domains ( $P < 0.001$ ). In other words, the patients' quality of life decreased significantly with an increase in urinary incontinence. There were also significant direct relationships between EDSS scores and the scores of quality of life and all its domains. In fact, higher EDSS scores were associated with lower quality of life.

A significant direct correlation was also detected between the duration of MS and the frequency of limitations ( $P = 0.02$ ). The patients' quality of life and its domains were not significantly related with their age, BMI, and duration of urinary incontinence.



Table 1: Demographic and clinical characteristics of the participating patients with multiple sclerosis (MS)

Variable	Frequency (percent)	
Age	18-30 years	14(31.1)
	31-40 years	11(24.4)
	41-50 years	20(44.4)
Body mass index	15-18.5	4(8.9)
	18.51-24.9	23(51.1)
	Over 24.9	18(40)
Type of MS	Relapsing-remitting	38(84.4)
	Secondary progressive	7(15.6)
Duration of MS	1-6 years	18(40)
	7-13 years	17(37.8)
	14-20 years	10(22.2)
Duration of urinary incontinence	Under one year	14(31.1)
	1-3 years	20(44.4)
	3-5 years	8(17.8)
	Over 5 years	3(6.7)
Use of drugs for urinary incontinence	Yes	14(31.1)
	No	31(68.9)
Expanded Disability Status Scale score	0-2	13(28.9)
	2.5-4.5	22(48.9)
	5-6.5	10(22.2)
Frequency of MS relapses over the past year	Without relapse	23(51.1)
	Once	16(35.6)
	Twice	3(6.7)
	More than twice	3(6.7)

Table 2: Urinary incontinence and quality of life and its domains before and after the intervention

Questionnaire scores	Variable		P Value <sup>b</sup>	CI95%
	before the intervention <sup>a</sup>	After the intervention <sup>a</sup>		
Total scores of ICIQ-UI SF	10.48±4.65	4.93±3.58	P < 0.001	4.65072, 6.46039
Bother with limitations	1.64±0.83	1.19±0.84	P < 0.001	.29805, .59578
Frequency of limitations caused by urinary disorders	1.45±1.37	1.1±0.77	P < 0.001	.21481, .47408
Fear	1.9±1	1.34±.96	P < 0.001	.36537, .75421
Feelings	1.21±1	0.87±0.86	P < 0.001	.25085, .46915
Total scores of Qualiveen-30	1.55±0.8	1.13±0.75	P < 0.001	.32588, .5296

<sup>a</sup> Values are expressed as mean ± standard deviation.

<sup>b</sup> paired t test

**Table 3: Correlation of quality of life and its domains with urinary incontinence and other demographic and clinical variables in patients with multiple sclerosis (MS)**

Domain of the quality of life	Variable											
	Urinary incontinence (ICIQ-UI SF)		Age		Body mass index		Duration of MS		Duration of urinary incontinence		EDSS score	
	r	p	r	P	r	P	r	P	r	P	r	P
Bother with limitations	0.50	< 0.001	0.09	0.51	0.21	0.15	0.23	0.12	0.06	0.65	0.32	0.02
Frequency of limitations caused by urinary disorders	0.50	< 0.001	0.15	0.31	0.18	0.23	0.33	0.02	0.13	0.37	0.55	< 0.001
Fear	0.48	0.01	0.14	0.34	0.17	0.26	0.03	0.79	0.02	0.85	0.28	0.05
Feelings	0.46	0.01	0.003	0.98	0.11	0.44	0.15	0.31	0.03	0.82	0.34	0.02
Total scores of Qualiveen-30	0.56	0.001	0.03	0.84	0.19	0.19	0.21	0.16	0.05	0.71	0.43	0.003

ICIQ-UI SF: the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form

EDSS: Expanded Disability Status Scale; a Pearson's correlation test

## Discussion

In the present research, total scores of urinary incontinence were significantly lower after three months of practicing pelvic floor muscle exercises. There were also significant reductions in the frequency and amount of urine leakage and the effect of urinary incontinence on patients' quality of life after the intervention. Similarly, Lucio et al. reported training on pelvic floor muscle exercises to significantly decrease the mean scores of ICIQ-UI SF in women with MS(19). Likewise, in a study on elderly women, Seyedrasouli et al. concluded that three months of pelvic floor muscle exercises along with bladder training and lifestyle modification significantly reduced not only the frequency and amount of urine leakage, but also the effects of urine leakage on patients' quality of life and the total scores of ICIQ-UI SF[28].

Golmakani et al. measured the amount of urine leakage eight weeks before and eight weeks after using vaginal cones and a behavioral intervention program (consisting of exercises to strengthen both the pelvic floor muscles and the bladder). The mean variations in the amount of urine leakage were significantly higher in the group receiving the behavioral intervention program than the group using vaginal cones[29].

Lower urinary tract disorders in patients with MS include urinary urgency, uncontrolled urination, and symptoms of urinary retention. Although the symptoms of lower urinary tract disorders have different prevalence, the presence or absence of symptoms is not a reliable indicator of the extent of bladder dysfunction[30]. Various studies have suggested pelvic floor muscle exercises as the first conservative treatment for patients with any type of urinary incontinence (including stress, urge, and mixed incontinence). Nevertheless, these exercises have been found to be more beneficial to individuals with stress urinary incontinence, as well as younger patients(14).

Some studies have indicated the higher efficacy of guided pelvic floor muscle exercises, such as the use of vaginal

cones, electrical stimulation, and biofeedback[14]. However, a controlled trial found vaginal cones, electrical stimulation, and pelvic floor muscle exercises to have similar effectiveness in the management of urinary incontinence[31].

Kashanian et al. compared two groups of patients who performed pelvic floor muscle exercises either unaided or by using a KegelMaster device. While the two groups had no significant differences in the incidence of complications during the course of study, the severity of urinary incontinence showed greater improvement in the group that did not use the KegelMaster device[14].

In the current study, the mean scores of quality of life and all its domains decreased after the intervention, i.e. the intervention could enhance the patients' quality of life in all domains. Similar to our findings, Lucio et al. reported significantly different Qualiveen-30 scores (and thus quality of life) between patients who followed a pelvic floor muscle exercise routine and the controls[19].

In a study in Turkey, Khorshid and Sar concluded that although pelvic floor muscle exercises improved the quality of life in women with stress urinary incontinence, such exercises required practice, encouragement, and reminders[32]. Therefore, we tried to eliminate barriers to proper and regular practice of pelvic floor muscle exercises by following the patients up through phone calls, presence in the MS clinic, and provision of training pamphlets and self-report checklists.

Ghasemi et al. found significant improvements in physical and mental quality of life of MS patients with urinary incontinence after the use of Swiss balls and biofeedback. Moreover, exercising with a Swiss ball was more effective than biofeedback in improving the patients' physical quality of life. This can be justified by the required level of activity and the need for concentration, cognition, balance, and respiration during the exercises[16].

A study that examined the quality of life in MS patients with overactive bladder syndrome indicated significant correlations between urinary symptoms and all dimensions of quality of life including perceived general health and role, physical, and social limitations[33]. Apparently, urinary incontinence can negatively affect all dimensions of quality of life regardless of the patients' sex, type of disease, and other factors.

Previous studies have reported contradictory findings about the effects of pelvic floor muscle exercises on different dimensions of quality of life. While some studies have suggested the absence of any effects[34], others have highlighted the efficacy of exercises in some or all dimensions of quality of life. We detected significant improvements in all dimensions of quality of life after three months of pelvic floor muscle exercises. The administration of the Qualiveen-30, which is a quality of life questionnaire specifically designed for patients with urinary incontinence caused by neurological disorders such as spinal cord injuries and MS, might explain such a finding. Most studies have used time-consuming and expensive urodynamic test or neuromuscular stimulation test to assess the efficacy of pelvic floor exercises on urinary incontinence [6,16,18,30] but we used a non-invasive, simple and inexpensive method, that is, standard questionnaires, to assess a non-invasive intervention.

Generally, although there is strong evidence indicating the effectiveness of pelvic floor muscle exercise in the treatment of urinary incontinence, the effect of a favorable training protocol remains unclear. Different studies have shown the effectiveness of various training programs, but superiority of one method over another has not yet been reported[35]. Proper identification of pelvic floor muscles and performing effective contractions is the key to deciding benefits of the intervention, and if patients fail to properly identify these muscles, exercises will have no positive effect on urinary incontinence, and may even have adverse effects.

A limitation of the study was the self-administered nature of data collection. Furthermore, the limited number of patients restrained the use of a control group. It is recommended that similar studies be conducted with a control group, for longer follow-up periods and comparison of different results obtained at different time periods.

According to the present study results, health personnel, including nurses, are recommended to train patients with MS on pelvic floor muscle exercises as a non-pharmacological and non-invasive method to decrease the incidence of urinary disorders and promote the quality of life in MS patients with urinary incontinence.

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# Frequency of Vaginal Delivery in Women with Previous Cesarean Section: A Single Referral Center Experience

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## Abstract

**Background:** Birth is the delivery of a baby at the end of the gestation that can occur naturally and without the need for special technology or can be done by caesarean section.

**Methods:** This descriptive study conducted to evaluate 685 patients admitted to Asalian hospital in Khorramabad (West of Iran) with a history of cesarean delivery who were again pregnant.

**Findings:** The results showed that the highest relative frequency of vaginal delivery (38%) was in women aged 22 to 26 years, also the highest frequency of vaginal delivery (69%) was in women who had one C-section and in women who in their previous cesarean section had Kerr incision compared to women who had a cesarean section with transverse incision (74%).

**Conclusion:** Based on this study, the phrase “once a cesarean, always cesarean” can change to “once a cesarean, often vaginal delivery”. Studies show that vaginal delivery after one or even several C-sections normally is relatively safe except in special cases like breech birth.

**Key words:** Pregnancy, Vaginal Delivery, Cesarean Section

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## Introduction

Birth is the delivery of baby at the end of the gestation that can occur naturally and without the need for special technology or can be done by caesarean section. Delivery time is usually associated with symptoms such as abdominal or back pain that gradually increase in pain duration and distance between each pain becomes shorter, as well as discharge or bloody discharge from the vagina (1-3). In a simple delivery, vaginal delivery can be divided into the following steps: The first phase, the onset of labor until the cervix is fully open. The second phase is from the full opening of the cervix till fetal extraction and the third phase is from fetal delivery until expulsion of the placenta (4, 5). Start of labor includes primary pains, active pain and transitional stage. =- Stage one may be 12-14 hours for people who have their first delivery and 5-6 hours for mothers who have had a previous delivery. The force of contractions of the uterus, opens the cervix and this opening is usually reported in cms that is determined by internal examination with one or two fingers. Full opening of the cervix is about 10 centimeters (6-8). Recently, according to research conducted for normal delivery, high attention has been given to those who already have a C-section (9-12). Generally, caesarean section has undesirable side effects and vaginal delivery is preferable. Caesarean section like many other surgical procedures has its own complications including need for anesthesia and problems that arise because of it, such as bleeding, and infections that can occur in the area of surgery, wound dehiscence, respiratory infections and pneumonia caused by aspiration, urinary infections, hernias and other problems that occur during surgery by cutting or by spreading it around, threatening patients' health (13-15). On the other hand, length of hospitalization for those who have vaginal delivery is less than persons who have C-section and it is beneficial to mother and also beneficial to hospitals and other patients and also has great economic advantages (16). In the past, experts believed that a person who had once had a cesarean section, in subsequent pregnancies should also have C-section in ensuing pregnancies, in other words, "once a cesarean, always cesarean". In fact, experts fear previous cesarean scars may rupture during vaginal delivery. But considering the benefits of normal delivery, experts permit natural childbirth to individuals who have a history of cesarean section and who do not have = contraindications for vaginal delivery. and study these groups (17, 18).

Despite the existence of various articles and research work in other countries, there is not enough research in Iran, and accordingly such research is necessary. The present study is conducted for profile examination of patients hospitalized in Assalian hospital in Khoramabad city (west of Iran) from 2012 to 2014.

## Materials and Methods

### 1. Study area

Lorestan province is located in the southwest of Iran, bordering the states of Markazi, Hamedan, Kermanshah, Khuzestan, Ilam, and Isfahan. The estimated population of Lorestan is 1,754,243. The district covers an area of approximately 28,294 km<sup>2</sup>. The province comprises 11 counties (Azna, Aligudarz, Borujerd, Pol-Dokhtar, Khorram-Abad, Dorud, Dure-Chegeni, Delfan (Nur-Abad), Selsele (Aleshtar), Kuhdasht, Rumeskan), 29 districts, and 85 habitations. (Source: [http://amar.sci.org.ir/index\\_e.aspx](http://amar.sci.org.ir/index_e.aspx)).

### 2. Collection of records of patients who had previous cesarean section:

All the cases that were referred to Assalian hospital of Khorram Abad (as a referral center) with previous cesarean section between October 2012 and November 2014 were included to determine the relative frequency of vaginal delivery after previous cesarean. Women from different parts of the province are mostly referred to this hospital.

### 3. Statistical analysis

All statistical analyses were carried out using SPSS for windows version 11.5.  $P < 0.05$  was considered significant.

### 4. Ethical consideration

Approval of the study protocol was obtained from the Ethical Review Board of Lorestan University of Medical Sciences. Written informed consent was obtained from all the study participants or their parents/guardians .

## Results

From 685 admitted patients to Assalian hospital with previous cesarean section, 71 subjects had vaginal birth after previous caesarean section, showing that incidence of vaginal delivery in two years in this group is 10% and about 90% of these people have had repeat C-scection.

In terms of age, the highest relative frequency of vaginal delivery (38%) was in women aged 22 to 26 years and the lowest relative frequency of vaginal delivery (7%) was in women aged 37 to 41 years [Table1]. In this study, it was found that the highest frequency of vaginal delivery (69%) was in women who had one previous caesarean section [Table 2]. Also, it was found that the highest frequency of vaginal delivery (74%) was in women who had Kerr cut on the uterus in the previous cesarean section compared to women who had transverse shear in their previous cesarean section [Table 3]. Moreover, it was found that the highest frequency of vaginal delivery was in women where the cause of their previous caesarean section/s was breech position, fetal distress, and failure in progression of labour [Table 4].



**Table 1: Frequency distribution of natural childbirth by age, in 71 women who had previous cesarean section**

Vaginal Delivery / Age Group	Frequency	percentage
17-21	13	18.3
22-26	27	38.02
27-31	17	23.94
32-36	9	12.7
37-41	5	7.04
Total	71	100

**Table 2: Distribution of relative frequency of vaginal delivery based on previous cesarean numbers in 71 women with previous cesarean section**

Vaginal Delivery / Previous C/S Number	Frequency	Percentage
1	49	69.01
2	18	25.35
3	4	5.64
Total	71	100

**Table 3: Frequency distribution of natural childbirth based on previous incision in 71 women with previous cesarean section**

Natural Childbirth / Previous Incision	Frequency	Percentage
Kerr cut	53	74.65
Transverse shear	18	25.35
Total	71	100

**Table 4: Relative frequency distribution of vaginal delivery based on previous cesarean causes in 71 women with previous cesarean section**

Vaginal delivery / The Cause of Previous C/S	Frequency	Percentage
breach	19	26.77
fetal distress	16	22.53
failure in progression of labour	12	16.9
Twinning	3	4.22
Maternal hypertension	1	1.4
Placenta previa	5	7.04
Placental abruption	2	2.81
Cross state	4	5.63
unknown	9	12.7
total	71	100

## Discussion and Conclusion

In this study, frequency of vaginal delivery in women who had previous cesarean was examined. The highest relative frequency of vaginal delivery (38%) was in women aged 22 to 26 years with previous cesarean, probably due to the high number of pregnancies and the desire to have children in this age range.

The relative frequency of vaginal delivery in terms of previous cesarean number in women with a history of caesarean section was seen in women (69%) who have had only one C-section and that is perhaps mostly due to elimination of the previous cesarean causes as well as the willingness of the patient and the doctor for vaginal delivery.

In a study in 2017 that was performed on the possibility of uterine rupture during labor in women with a previous cesarean section, a population-based study was done on information obtained from the "Washington State Birth Events Record Database". The database recorded almost 95 percent of deliveries in Washington. In this study, recorded data were analyzed from 1987 to 1996 and 20,095 of them were seen as suitable for the study. The results of the study showed that the rate of uterine rupture in people who had caesarean after caesarean was 1.6 per 1,000 people; the rate of uterine rupture in women who after caesarean delivery had spontaneous pain was 5.2 per thousand people, in women who had pain without mediation of prostaglandins was 7.7 per thousand people, and for those who were identified by prostaglandins were 24.5 per thousand people. In general, the results of this study stated that in the study population of this research, in women with previous cesarean section, the risk of uterine rupture among those who had induced pain was more than those who had repeat caesarean section, especially in those where pain was caused by prostaglandins. The results of this study are consistent with the results of our research and actually suggest that vaginal birth after cesarean has no prohibition and only in a few cases can be problematic (19).

In another study conducted in Pakistan, from the study of 287 women where the causes of their previous caesarean section were breech birth, 77% of them had successful vaginal delivery. The results were fully compatible with our study (20).

In a study in America in a 10-year period (1989-1998) regarding the process of caesarean section and whether it was increasing or decreasing, it was found that the overall rate of caesarean delivery had decreased from 16% to 10% and in this study it was found that the primary caesarean delivery decreased from 9% to 7% and repeated caesarean rate decreased from 7% to 3% (21), thus the results of this study were fully compliant with our results.

About 3-4 percent of births are in breech position. A very important study was conducted in 2000 in 121 centers in 26 countries. In this study 2,088 women who were in abreech

delivery were selected and were divided into two groups till a group of them had Cesarean delivery and the other group had natural delivery to finally be compared with each other. As well the situation of children 6 weeks postpartum were analyzed. The results of this study showed that mortality during birth, child mortality and significant problems after the birth of the baby in the C-section group was significantly lower than those with normal delivery. However, mortality rates and maternal complications after birth were not significantly different in the two groups. Therefore, in this study it was found that for fetuses that are in breech position, Cesarean is better than vaginal delivery (22). The results of that study did not have much conflict with our study because we did not examine breech position and this was one of the defects of our investigation. The fourth result of our study also pointed to this issue.

In another study, published in 1987, in a 2-year interval in order to evaluate vaginal birth after caesarean section in America, 32,854 patients were considered and 2,708 of them had a previous caesarean section and of these, 1,465 patients had normal delivery in a subsequent pregnancy and most of them had successful deliveries. This study noted that "once a cesarean, always acesarean" should be changed and discarded (23). The results of that study are fully consistent with our study.

Finally, according to this study and surveys of other studies, we can say that the sentence "once a cesarean, always cesarean" must change to "once a cesarean, always vaginal delivery", because the benefits and importance of natural child birth are undeniable compared to caesarean section, as well as various studies have shown that in normal situation, vaginal birth after a cesarean, or even several times is almost always safe.

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# Motivational Interviewing as Group Therapy for Glycemic Control and Treatment Satisfaction of Patients with Type 2 Diabetes Mellitus

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## Abstract

**Introduction:** Diabetes Mellitus is the most prevalent metabolic disorder with considerable long term complications. Management of diabetic patients needs cooperation of a multidisciplinary team including a variety of specialties. Cooperation, motivation, enthusiasm as well as self-discipline, compliance, and satisfaction of the patients are necessary factors for the successful management of the disease. One of the proposed treatment modalities for better compliance and favorable outcomes for patients with chronic health problems, such as diabetes, is motivational interviewing.

**Materials and Methods:** In this research we have aimed at studying the effectiveness of group motivational interviewing among type 2 diabetic patients. We wanted to know whether it can be effective on glycemic control as well as the patient's satisfaction.

Thirty patients with a diagnosis of type 2 diabetes were randomly selected and divided into two matched equal case and control groups, each one including 15 patients. The intervention was four weekly sessions of group motivational interviewing. Each session was 90 minutes. Our assessments were lab tests including fasting blood glucose and glycosylated hemoglobin (A1C), as well as diabetes treatment satisfaction questionnaire (DTSQ). These assessments were done on both groups, three times including pre-test (one week before the first session), post-test (a week after the last session), and follow-up (two months after post-test). In order

to assess the patients' attitude towards motivational interviewing, our case group also completed the client satisfaction questionnaire (CSQ) after the final session of motivational interviewing.

**Results:** A1C was decreased significantly in the post-test in the study group and it had been maintained in follow up ( $P= 0.0001$ ). This decrease had a mean of 1.23 units. Treatment satisfaction increased significantly ( $P= 0.014$ ). These changes were not seen in the control group.

**Conclusion:** Our findings showed that motivational interviewing as a group therapy was effective in glycemic control as well as treatment satisfaction of type 2 diabetes patients.

**Key words:** Diabetes Mellitus, patient's satisfaction, motivational interviewing, glycemic control.

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## Introduction

Diabetes mellitus type 2 (DM) is a heterogeneous group of metabolic disorders characterized by varying degrees of insulin resistance, impaired insulin secretion, and increased glucose production. People with type 2 diabetes constitute about 90% of diabetic patients [1]. DM is a leading cause of morbidity and mortality. Its common complications include increased overall heart diseases, stroke, hypertension, renal failure, foot ulceration and/or infection, and visual problems [2]. Psychological consequences of diabetes can be anxiety, stress, depression, interpersonal and interfamilial problems, sexual dysfunction, and poor perception of health [3]. Although medications are the main tools for the treatment of diabetes, psychological factors are known to affect the disease progress, glycemic control, treatment satisfaction, compliance and generally its outcome [4-5]. Also psychological interventions have been shown capable of improving different aspects of illness perception and patients' compliance [6-7]. Cognitive-behavioral interventions have proved effective on glycemic control as well as relieving emotional problems including depression, anxiety, and stress in patients with type 2 diabetes [8]. Since psychotherapy can reduce the need for costly medical services and increase patients' mental health during the course of treatment of chronic medical diseases, it is important to use it in these conditions including diabetes [9]. Diabetes can be effectively treated when the patient is recognized as a member of the treatment team, not the one being treated. This requires patients' motivation and active participation in the managing of their own disease. Motivational interviewing can be a potential approach for this goal. Motivation has been shown as an important variable in metabolic disorders [10]. Motivational interviewing (MI) refers to a client-centered and directive approach which makes changes possible by strengthening the person's own motivation for and commitment to change [11]. Motivational interviewing was used to treat alcoholism in 1983. MI also has been shown effective in medical disorders, especially chronic diseases since 1990.

In a recently published study health care professionals who used MI considered it as the most important way to promote patient compliance and build empathy in the patient-doctor relationship [12].

Its effect on better patient-doctor relationship and treatment adherence has been confirmed in a number of chronic medical conditions including diabetes [13]. In some pediatric chronic conditions not only the child's own motivation is important but also the parents' motivation is important for treatment engagement and success [14]. MI can be "blended with other evidence-based clinical skills and approaches" [11]. MI has been shown effective even in a brief 20 minute single session [15]. A two year study using MI as a group work for patients with type 2 diabetes has shown significant benefit when blended with medical/nutrition therapy [16]. In a study among older adults study investigators evaluated the effectiveness of training diabetes self-management through MI to improve glycemic control in adults with a mean age of 64.9 years. A total of 66

diabetic patients participated in the MI intervention through video calls for 6 months, and the control group received video calls for healthy lifestyle education. Although A1C was reduced in both groups, the reduction was significant only in the experimental group. The experimental group also showed a significant increase in diabetes knowledge and self-efficacy [17]. A preliminary study was conducted among 26 Native Americans to evaluate the effectiveness of MI on improving the management of type 2 diabetes. The intervention was performed in two 30-minute sessions of individual MI, which led to a significant improvement in depression self-report symptoms, treatment satisfaction, and social-occupational concerns. A significant difference was observed in A1C levels among patients comparing before and after the intervention [18].

Another study showed that MI was effective in improving the illness perception, patients' role in management of type 2 diabetes and prevention of its complications, and these effects were sustained over a one-year follow-up [19]. Studies have shown that MI can improve readiness to change [20], systolic hypertension, depression, and self-care among patients with type 2 diabetes [21] and even for diabetes control among the patients hospitalized for cancer [22]. Although most studies have emphasized the positive effects of MI on diabetes [23], some studies have failed to show the effectiveness of this intervention for diabetic patients [24,25].

Group motivational interviewing has been applied in practice in recent years [26] and its effectiveness has been proven with a variety of medical diseases [27]. In most studies, MI has often been used in combination with other conventional clinical interventions and it has rarely been used a separate intervention [28]. Furthermore, those studies that employed MI alone mostly focused on drug abuse [29]. However, studies employing group MI have reported similar effects for both group and individual motivational interviewing [30]. In 2010, a study was conducted to compare the effects of group motivational interviewing and cognitive-behavioral group training (CBGT) on improving physical health outcomes in adults with type 2 diabetes. The participants in this study were randomly divided into MI, CBGT, and control groups. Each of the interventions included four 90-minute group sessions. The results showed a significant decrease in body mass index of the motivational interviewing and cognitive-behavioral group training compared with the control group. The MI group had a greater reduction in the mean A1C compared to the CBGT group as well [31]. Because of the difficulties of designing, conducting and assessing studies on group therapy, such studies are much less frequently used when comparing individual therapies [32]. In general it has been shown that in diabetes the MI approach changes the perception of uncertainty, supports independence, and increases personal ability, enhances the readiness and commitment to change, and improves patient participation in treatment. MI groups can also help patients in identifying their own problems [33].

## Materials and Methods

### 1. Participants

Eligible participants were selected through convenience sampling and randomly divided into experimental and control groups. A total of 30 patients with type 2 diabetes were selected from among the patients diagnosed with diabetes by an endocrinologist or internist based on medical history, clinical examination, diagnostic criteria for diabetes, and the latest examinations and lab tests. Inclusion criteria were as follows: age between 30 to 60 years old (practically all our participants were over 40 years old as most people with diabetes are between the ages of 40 and 59 years, across the world), having at least high school diploma, voluntary participation in the study and giving informed written consent, a diagnosis of type 2 diabetes based on the American Diabetes Association diagnostic criteria by an endocrinologist or internist, taking oral diabetes medications, and serum levels of A1C equal to or higher than 7. The participants included 16 women and 14 men. They were randomly divided into an experimental and a control group of 15 people in each.

Participants from both groups completed the Diabetes Treatment Satisfaction Questionnaire (DTSQ) and had the A1C test. The groups were matched for age, sex, education, duration of disease, marital status, and the A1C level. Exclusion criteria were psychotic disorders and other severe mental disorders, and/or severe cognitive dysfunction. People with gestational diabetes were not included in the study.

### 2. Intervention

Group motivational interviewing was the intervention used in the experimental group in this study. This intervention was performed by a psychiatrist (SM) as the group facilitator and a clinical psychologist as the co-facilitator in four weekly sessions. Each session lasted for 90 minutes. We used the protocol published (2015) by William Miller and Mark Steinberg in their book titled *Motivational Interviewing in Diabetes Care for group therapy* [34]. The presence of a co-facilitator with different skills and styles made it possible to have both better interpersonal dynamics of relationship between group members per se, and between them and the facilitators. Although motivational interviewing is designed mainly as an individual counseling approach, running it in group format makes it possible for each member to provide support for others to change. It also made group management easier.

The first session was considered as the orientation and engagement session for the group. Facilitators explained the group process as well as three main guidelines (rules) of the group which were confidentiality and positive/supportive feedback, and fair time sharing. In this session facilitators focused on facilitating group development and helping the group to build their optimal effectiveness. The primary task within the first session is to engage every participant and to establish an environment of trust and cooperation. Facilitators tried to involve group members to work together in order to make positive changes in their

lifestyle. We started with simple “ice breaker” open ended questions about what the group members wanted to know more about diabetes and what they have done already for its management. Reflective listening was used by the facilitators in responding to build relationship and convey empathy. Following introductions, the discussion expanded to eliciting each member’s hopes and expectations regarding their diabetes control and their experience in the motivational interviewing group. The main skills for this session were asking and listening.

The second session used an agenda mapping technique to help focus the discussion and enhance partnership within the group. Members shared ongoing achievements in managing their diabetes, their perspectives about their health, the impact of diabetes on their lives and core values. As a visual aid we drew a bubble sheet on a white board for a better understanding of the participants’ concerns and agenda mapping. Facilitators listened for opportunities to affirm each person’s strengths and values, and reinforcing positive attitude and activity for change (recognized as change talk within motivational interviewing). Evoking motivation of the group members was done by using affirming, reflective listening, and summarizing skills. Importance and confidence rulers were introduced and used from this session onwards. Elicit-provide-elicited was the MI approach that we used in this session.

In the third session, building on what the group already knew, we offered necessary information about different aspects of diabetes management. With group members’ permission, this information providing was accompanied by some advice. Evoking change talk was the primary task in this session. Commitment and confidence ruler were used again in this session.

The fourth session continued to expand on the information sharing and using open ended questions we tried to evoke and reinforce change talk. Discussing topics such as diabetic diet, physical activity, patient-doctor relationship, stress effects, and using medications were very interesting for the participants. Creating discrepancy was used as a tool for evoking motivation and we encouraged the participants to build a plan for maintaining the changes in the future.

### 3. Lab tests and psychological instruments

The blood glucose levels of the participants in the experimental group were measured a week before the start of treatment (pre-test), a week after the last session of the MI group therapy (post-test), and two months after the post-test (follow-up) through the HbA1c test. The tests were performed by a lab technician who was blind to the distribution of subjects in the experimental and control groups and were checked twice by a laboratory specialist, again blind to the study participants. A1c is the minor hemoglobin component which is produced by the chemical condensation of hemoglobin and glucose in red blood cells. The rate of A1c production is directly proportionate to average concentration of glucose within the red cells during its lifespan which is about 120 days. This makes



it an excellent marker of overall glycemic control during a four month time frame.

The participants also completed the Diabetes Treatment Satisfaction Questionnaire (DTSQ) in pre-test, post-test, and follow-up stages. At the end of the last intervention session, the participants in the experimental group completed the Client Satisfaction Questionnaire (CSQ). The questionnaires were anonymous and were coded by the researcher and distributed to the participants. The completed questionnaires were read and scored by a research assistant who was blinded to the research (single blind).

The control group also did the same tests with the same frequency and time intervals –without any psychological intervention. Diabetes treatment satisfaction in the control group was assessed in the same three stages through the DTSQ. The control group was considered as a waiting list and a similar intervention was done for them after performing the last tests. Finally, according to the objectives of the study, the data was analyzed in SPSS-20.

#### **Diabetes Treatment Satisfaction Questionnaire:**

This is a scale designed for the assessment of diabetic patients' satisfaction feeling regarding the treatment they are receiving. It has 8 items; each one is scored on a scale of 0-6. The DTSQs was originally developed in the early 1980s. It is used both for research and clinical assessment. DTSQ has been specifically designed to evaluate the treatment satisfaction of diabetic patients. The scales used in this questionnaire are appropriate for patients with type 1 and type 2 diabetes [35]. The DTSQ was translated by the research team into Farsi (Persian). This version's measurement properties and reliability were good (Cronbach's  $\alpha = 0.78$ ). The instrument construct validity as well as discriminative validity were also good, higher than designated acceptable criteria.

**The Client Satisfaction Questionnaire (CSQ-8):** This scale has been developed to assess client satisfaction in different clinical settings. The instrument has eight sentence-items and is answered on a 4-point Likert scale. Each item is scored from 1 to 4, and thus the possible total score would be between 8 and 32. Higher scores indicate better satisfaction. CSQ was used to evaluate patient satisfaction with counseling and health services. CSQ Reliability and validity has been tested in clinical settings. CSQ-8 has been translated into Farsi earlier and its validity and reliability has been shown (Cronbach's  $\alpha$  between 0.86 and 0.94) [36].

## Results

A total number of 30 patients (fifteen in each group) finished the study. Although we randomly assigned participants to case and control group, the A1C level was slightly different in the two groups at the beginning of the study.

The results indicated that the level of glycosylated hemoglobin in the experimental group significantly improved. This effect was sustained during the follow-up period. In the pre-test, the mean A1C level was 8.23 in the experimental group. This value reached 7.32 in the post-test (one week after the intervention) and 7.00 in the follow-up stage at 2 months after the post-test (Table 1 - next page).

Repeated measures confirmed the effect of group therapy through motivational interviewing on improving the A1C level in the experimental group at the significance level of  $P < 0.0001$  (Table 2).

ANCOVA was used to analyze the mean A1C levels in the control and experimental groups at the significance level of  $P = 0.0001$  to reconfirm the results. The hypothesis of equality of means between the two groups was rejected at the post-test and follow-up stages after excluding the possible effect of the pre-test and the existing differences reflect the impact of group motivational interviewing. In addition, the effect size of 11.01% was reported for the A1C level in the experimental group. (This intervention increased satisfaction with diabetes treatment in the experimental group, which persisted during the follow-up period. In the pre-test, the mean score for satisfaction with diabetes treatment was 22.4 in the experimental group and it reached 27.3 in the post-test (one week after the intervention) and 27.9 at follow-up (2 months after the post-test). Repeated measures confirmed the effect of group motivational interviewing on increasing satisfaction with diabetes treatment among patients in the experimental group at the significance level of  $P = 0.014$ .

ANCOVA was used to analyze the mean DTSQ scores in the control and experimental groups at the significance level of  $P = 0.016$  to reconfirm the results. The hypothesis of equality of means between the two groups was rejected at the post-test stage after excluding the possible effect of the pre-test and the existing differences reflect the impact of group motivational interviewing. In addition, the effect size of 17.85% was reported for satisfaction with diabetes treatment in the experimental group (Table 3).

We wanted to evaluate satisfaction with diabetes treatment in addition to satisfaction with psychological treatment (group motivational interviewing) in the intervention group. Satisfaction with psychological treatment was assessed using CSQ. Its results indicated that it can be used as a criterion for the assessment of satisfaction of type 2 diabetic patients. Their result was positive with group motivational interviewing. Maximum total score was 32 and the mean score was 25.53 and the mean to total score ratio is 79%.

**Table 1. Mean and standard deviation of HbA1C and DTSQ in MI and control group**

Indexes	Groups	Period	M	SD
<b>HBA1C</b>	MI Group	Pre-test	8.23	1.1037
		Post-test	7.32	0.9361
		Follow up	7.00	0.7977
	Control Group	Pre-test	7.98	0.7975
		Post-test	8.12	0.8596
		Follow up	7.99	0.8859
<b>DTSQ</b>	MI Group	Pre-test	22.4	4.53
		Post-test	27.3	5.27
		Follow up	27.9	4.70
	Control Group	Pre-test	24.8	3.98
		Post-test	24.3	4.25
		Follow up	25.6	5.28

**Table 2. Results of repeated measures of HbA1C and DTSQ in MI and control groups**

Indexes	Groups	N	F	P
<b>HBA1C</b>	MI Group	15	18.615	0.0001
	Control Group	15	1.068	0.372
<b>DTSQ</b>	MI Group	15	5.978	0.014
	Control Group	15	1.080	0.368

**Table 3. Results of ANCOVA of HbA1C and DTSQ in MI and control groups**

Indexes	Period	F	P
<b>HBA1C</b>	Post-test	20.264	0.0001
	Follow up	22.551	0.0001
<b>DTSQ</b>	Post-test	6.628	0.016
	Follow up	3.468	0.073

## Conclusion

The results showed that group motivational interviewing was effective in improving the level of glycosylated hemoglobin. When patients cooperated to improve their glycemic control and realized they could significantly affect this control, their satisfaction with diabetes treatment increased. One possible explanation is that these patients' expectation of endocrinologists and internists who were previously considered as the only people responsible for the treatment was reduced and patients considered themselves responsible for their own treatment. In our study patients have gained a better satisfaction with their previous treatment as well as good satisfaction

with the group motivational interviewing. These patients can influence and improve their own health through motivational interviewing and by increasing their motivation and achieving better self-efficacy and higher confidence. By this kind of change we can increase life expectancy and prevent the development of diabetes complications in these patients.

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# Evaluation of clinical features and 5 year survival rate of patients with squamous cell carcinoma of the cervix

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## Abstract

**Introduction:** Cervical cancer is the most common cancer among women that each year causes death of a large number of people. In most cases cervical carcinoma has squamous cell carcinoma pathology. Because this cancer is common, deadly and preventable, this study aimed to investigate the clinical characteristics and 5 year survival rate of patients with squamous cell carcinoma of the cervix.

**Method:** This cross-sectional study was conducted using a questionnaire on 80 patients with at least 5 years of cervical cancer who were treated in radiotherapy centers of Yazd during the year 2009. Data were analyzed using SPSS15 and the Log Rank and Chi Square tests.

**Results:** Overall, of the total number of patients, 38 patients (47.5%), had 5-year survival rate. The most common clinical symptom was irregular vaginal bleeding (33.8%), followed by bleeding after menopause (11.2%). Patients with early stage disease had a 100% survival rate and patients with an advanced stage had a survival rate of 44%. According to the results, stage of disease ( $P = 0.04$ ) and menopausal status of individuals ( $P = 0.004$ ) plays a role in survival.

**Conclusion:** According to a 5-year decrease in survival rate with increasing stage of disease, screening of this cancer in at risk populations is essential for early diagnosis.

**Key words:** Invasive cervical cancer, Cervix, Cervical carcinoma, Survival rate

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## Introduction

Cervical cancer is the most common cancer in women that each year causes death of a large number of people (1). Epidemiology of cervical cancer is related to different living conditions in different populations so that 80% of new cases of cervical cancer and deaths resulting from it, have been observed in developing countries (2). Annually 493,000 new cases of cervical cancer are diagnosed worldwide and it kills approximately 274,000 women per year (3). This cancer is preventable because it has a long pre-cancerous stage and it is easy to reach by screening methods, in addition lesion treatment before the invasion is complete and effective (4). Just offering free screening methods for cervical cancer cannot prevent the occurrence of invasive cervix lesions but proper training in using them is essential (5). The two main ways to prevent this cancer are primary prevention including: hygiene promotion, lifestyle, healthy sexual behavior and vaccination against human papillomavirus and secondary prevention including screening methods (6). Cervical cancer prognosis depends on the severity of the disease at diagnosis, but this is not the only factor affecting the prognosis. Factors such as tumor size, grade and lymph-vessel emissions are also major factors in prognosis (7). The survival of patients varies according to different stages of the disease so that at early stages survival rate is 90% but when the disease is in its advanced stages the 5-year survival rate drops to 50-70% (8). In the early stages usually there is no symptom but symptoms of later stages are vaginal bleeding, pelvic pain, pain during sexual intercourse (8). Also the rate of distant metastasis increases with the progression of the disease (7). Among the factors causing precancerous cervix lesions or risk factors, HPV, early age of first intercourse (under 16 years), multiple sexual partners, the high number of pregnancies over 20 weeks, can be mentioned and also factors that weaken the immune system, including AIDS (9). Cervical carcinoma in 80-90% of patients has squamous cell carcinoma pathology and in 7-10% of cases adenocarcinoma and in rare cases includes acute histologic type cancer such as clear-cell carcinoma and mesonephric types which constitute 1-2% of malignancy of cervical cancer (10). Dysplasia usually does not have any clinical signs and often it is diagnosed by cytologic findings in Pap smear test. Since dysplasia is a temporary stage in the pathology of cervical cancer, therefore its immediate diagnosis and treatment is very important. Chemo-radiation and radical surgery raises longevity for early stage cervical cancer but the effective treatment of patients is limited by disease progression (11). Due to the common, fatal and preventability nature of this cancer, the aim of this study is to investigate clinical characteristics and 5 year survival rate of patients with squamous cell carcinoma of the cervix.

## Method

This descriptive study is a retrospective analysis of survival and generally a cross-sectional study that was conducted on all patients with a minimum of 5 years of cervical cancer who had been treated during the year 2009 at one of the

radiotherapy centers of Shahid Ramezandadeh or Shahid Sadoughi hospitals of Yazd province, Iran.

### Inclusion criteria

Patients older than twenty years who had passed at least one year from the time of their marriage, and had Pap conditions were enrolled.

### Exclusion criteria

Patients with a history of breast cancer, history of CIN I and CIN II or ovarian cancer were excluded from the study.

The study is based on questionnaire data of 80 female patients.

The questionnaire included questions about the patient's age, stage, symptoms, menopause status and time of the initial diagnosis. Information of patients was recorded in designed questionnaires and then survival was defined by phone call.

### Statistical analysis:

All data were encoded and after being ensured about the integrity of data, information was analyzed using software SPSS version 16. Log Rank, Chi Square test and Kaplan Meir charts were used for statistical comparisons. In all statistical tests,  $P < 0.05$  was considered as significant level.

## Results

Frequency of clinical manifestations in patients are seen in Table 1. The most prevalent clinical symptom was irregular vaginal bleeding (36.2 %) and the lowest was abnormal Pap smear test (1.2 %).

The average of overall survival of patients:

Overall of 80 patients enrolled in the study, at 5 years 38 patients (47.5%) survived and 42 patients (52.2 %) died. Survival rate of patients in 6 months was 98.8%, one year 93.8%, 2 years 81.3%, 3-year 70%, 4-year 55% and 5-year 47.5%. (Figure 1)

Mean survival of patients according to age groups:

First group 30-44 years with 20 patients had survival rate of 60%, the second group 45-60 years with 36 patients had survival rate of 47.2%, the third group above 60 years with 24 patients had survival rate of 37.5%. There was numerical difference between survival rates in three age groups, but in spite of that, this difference was not statistically significant with respect to  $P = 0.31$  which was calculated from Log Rank test results. (Figure 2)

Average survival rate according to stage in patients:

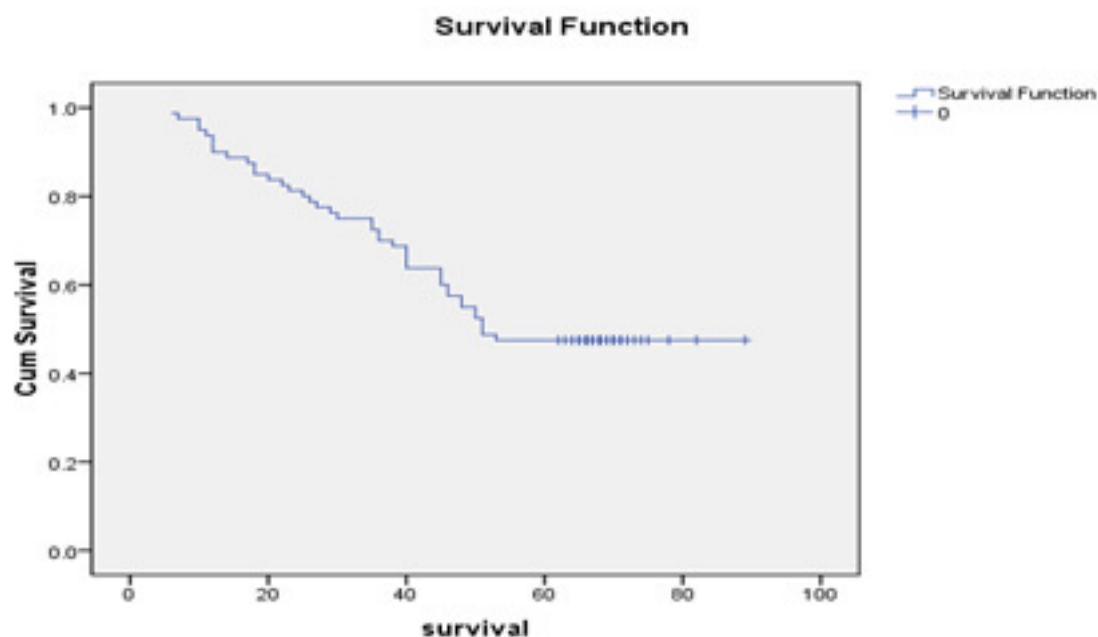
Five patients (6.2%) in this study were in the early stage and had 100% survival rate, and in advanced stage we had 75 patients (93.8%) who had 44% survival rate. According to  $P=0.04$  obtained from the Log Rank test, the difference between these groups was statistically significant (Figure 3).



**Table 1: Frequency of clinical manifestations in patients**

Clinical manifestations	Frequency	Percentage
Irregular vaginal bleeding	29	36.2
Bleeding after menopause	27	33.8
Spotting	9	11.2
Stomach ache	8	10
Abnormal vaginal secretions	3	3.8
Bleeding after intercourse	3	3.8
Abnormal Pap Smear Test	1	1.2
Total	80	100

**Figure 1: Mean of overall survival of patients within 5 years**



**Figure 2: Comparison of the mean survival of patients according to the age groups**

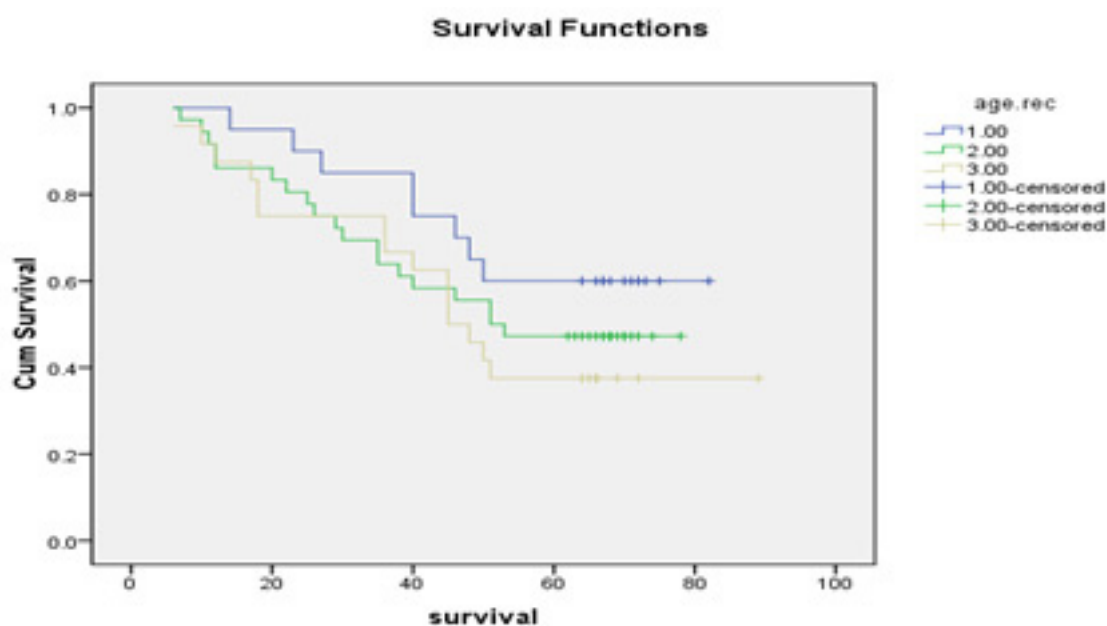


Figure 3: Comparison of the mean survival by stage

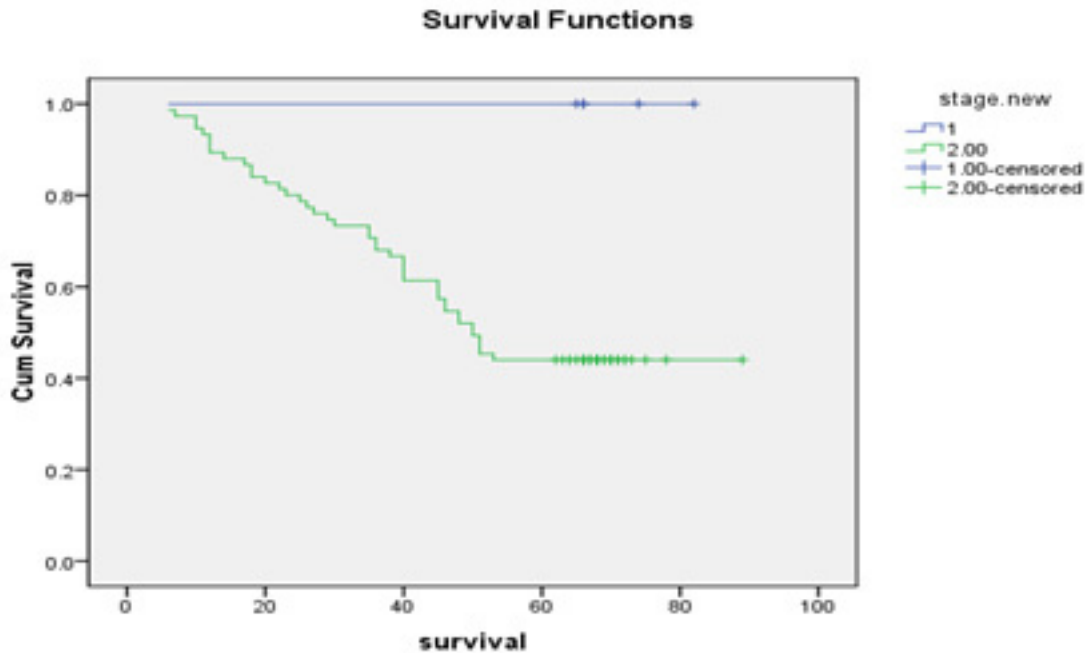
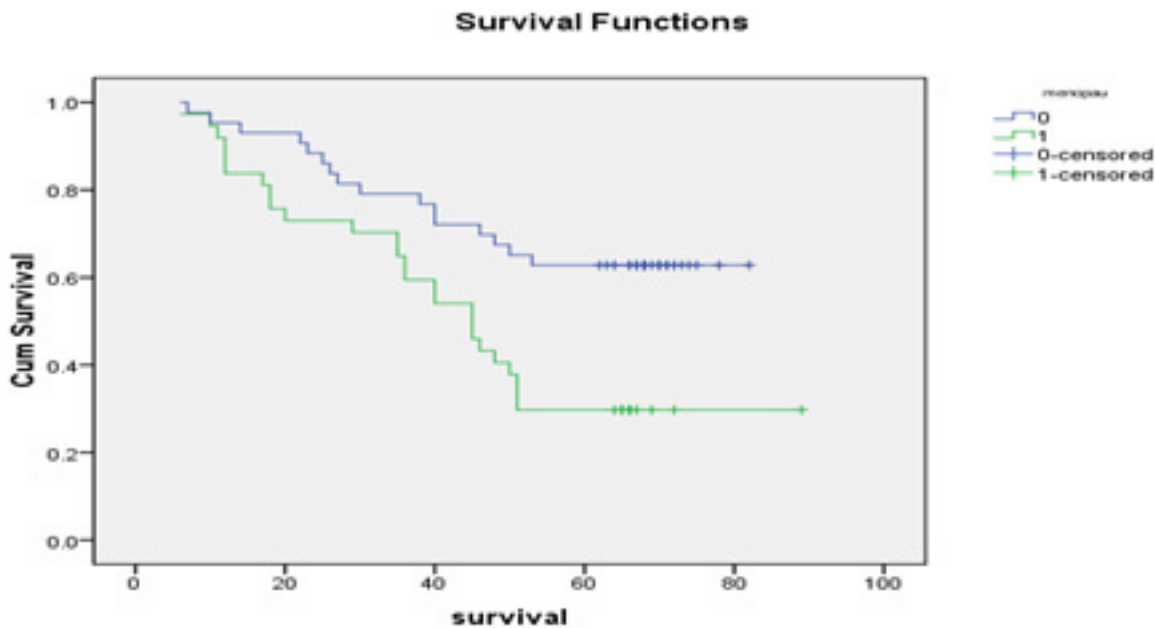


Figure 4: Comparison of the mean survival of patients according to menopausal status



Mean survival of patients according to menopausal status. Of the total number of patients in this study 37 patients (46.2%) were menopausal, with a survival rate of 29.7% and 43 patients (53.8%) were non-menopausal with a survival rate of 62.8%. According to  $P = 0.004$  obtained from the Log Rank test, there was no significant difference between mean of these situations (Figure 4).

## Discussion

This study was conducted with the aim of determining the 5-year survival rate of patients with squamous cell carcinoma of the cervix in 2008-2009 who referred to Radiotherapy Center of Shahid Ramezandadeh and Shahid Sadugi hospitals of Yazd and investigating factors such as age,

stage, diagnosis time and menopausal status on survival. The results of the present study showed there was no significant correlation between the survival and age. In a similar study in the US, SEER and colleagues studied three main groups of 20-49 years (56.9%), 50-69 (29.7%) and over 70 years (13.5%). According to the results of this study for all women 5 year survival rate decreased with increasing age, so that the survival rate in the first group was about 79%, second group 65%, and third group 49% (12). Results of two other studies by Federico and Carol showed that the age factor independently can affect prognosis of patients as older patients have considerably weaker survival rate and weaker screening pattern (13, 14). Another study that was conducted by Stacey A. Fedewa showed that older women are more likely to have cervical cancer so that in the final stages percentage of disease

had increased by increasing age(15). The results of the study of Jean-Luc Brun showed that age is a significant prognostic factor in women with cervical cancer and advanced stages of the disease significantly increases after 65 years(16). The results of these studies are inconsistent with results of this study. In the present study comparing the average survival of patients according to age groups showed no significant correlation. This inconsistency may be due to low population of this study which can act as a confounding factor for statistical analysis and also the present study only investigated the cases of cervical squamous cell carcinoma, but the above studies explored all cancers. Another study that was conducted by Michel and colleagues at the University of Michigan showed that the age factor does not affect the survival rate which is consistent with the findings of the present study (17). This result may be due to the study and consideration of the patient's general conditions and health of the elderly (which is influential on the response to treatment) in the study of Michel and lack of its investigating in other studies.

The results of this study showed that the survival rate of patients has adverse association with disease stage. In the SEER study as well as the present study the survival rate decreased with increasing stage (12). 59.2% of patients were in the early group and the rest of the patients were in the advanced group. In the present study only 5% of patients were in the early group that shows lack of screening culture among Iranian women so that only one case of cervical cancer was known from abnormal Pap smear and most patients have referred to doctor when symptoms started which obviously increases the stage of disease. In two other studies that were conducted by Wabing and Carol stage was recognized as a determinant of survival (14, 18). Also another study that was conducted by H.H. Chung showed that the survival rate is directly related to the disease Stage so that the 5 year survival rate for I, II, III, IV stages were respectively 94.2%, 69.7%, 38.9% and 21.1% (19). The results of these studies are consistent with the results of this study. If cervical cancer is not detected in early stages, cancer cells may also spread to other organs and also if the treatment is in the early stages it will be more successful but in advanced stages, there are severe complications, poor prognosis and poor response to treatment.

In this study, the survival rate for menopausal women was reported as 29.7% and for non-menopausal 62.8%. Study which was conducted by SEER showed that early stages of the disease in patients with lower age is more prevalent (stage 1 prevalence in patients under 70 years and over 70 was respectively 64.9% and 34.1%). In the event that disease progression in patients over age 70 has increased significantly it was (frequency of stage 4 in patients under 70 and over 70 years was respectively 5.9% and 14.4%) (12). This may show that in menopause the disease is more severe than other patients and presumably this lowers survival in menopause patients and this is consistent with the two studies that indicate the unfavorable situation of screening in higher ages. This result can be due to hormonal changes during menopause

because factors that have an impact on sex hormones and cause their swinging increase risk of cervical cancer. In this study, the most common clinical manifestations were irregular vaginal bleeding and bleeding after menopause. This result was consistent with Nushin Aziz's study where the most common initial clinical manifestations were: Irregular vaginal bleeding, foul smelling vaginal discharge, post coital bleeding and the study of Michael where 68% of patients had bleeding manifestations (17, 20). Various studies show that the most common symptoms of cervical cancer is abnormal bleeding so that cervical cancer has a very strong role in post-menopause bleeding and it is a major cause of malignancy. However, in the study of Anunobi the most common clinical manifestation was post-menopausal bleeding (53/3%) and 16.7% of patients were referred with inter-menstrual bleeding manifestations (21). This difference may be attributed to the older age of patients in the study of Anunobi.

## Conclusion

Given that cervical cancer is most common and the most deadly cancer among the female population and by increasing age and disease stage, the survival rate decreases, therefore, implementing a screening system and screening of populations at risk and also more effective treatment with a focus on cancer diagnosis in the early stages seems essential.

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# Quantitative Polymerase Chain Reaction in Diagnosis of Pneumocystis Pneumonia

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## Abstract

**Introduction:** Pneumocystis pneumonia (PCP) remains a serious cause of sickness and death in immunocompromised patients. Lung injury and respiratory impairment during pneumocystis pneumonia are mediated by marked inflammatory responses in the host to the organism. Quantitative PCR (qPCR) is more sensitive than microscopy for detecting Pj in BAL. The relevant threshold remains to be determined and may vary according to the underlying disease.

**Methods:** All BAL samples were obtained from immunocompromised and non-immunocompromised patients presenting with respiratory symptoms referred to the Department of infectious diseases of Alzahra Hospital, Isfahan, Iran. All statistical analyses were performed using SPSS (Statistical Package for the Social Sciences, Chicago, IL, USA) version 22.

**Results:** 2 patients (12%) of immunocompromised patients were positive for Pj. Among non-immunocompromised patients, 3 (8%) were positive for Pj. Fisher exact test demonstrated that Pj positivity was not significantly different between the two groups. The overall frequency of Pj positivity was estimated as 10%.

**Conclusion:** 12% of immunocompromised patients and 8% of non-immunocompromised were colonized by Pj which may progress to PJP or contaminate susceptible individuals.

**Key words:** Pneumocystis pneumonia (PCP), Quantitative Polymerase Chain Reaction, immunocompromised patients

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## Introduction

Pneumocystis pneumonia (PCP) remains a serious cause of sickness and death in immunocompromised patients (1). Respiratory impairment and lung injury during pneumocystis pneumonia are mediated by marked inflammatory responses in the host to the organism (2,3). The incidence of PCP in human immunodeficiency virus (HIV)-infected patients has decreased since the introduction of chemoprophylaxis and antiretroviral therapy (4-6). In fact, various opportunistic infections consisting of PCP, fungi and viruses may involve immunocompromised and transplanted patients (7-10). Meanwhile, the incidence of PCP in non-HIV immunocompromised patients is increasing (2-6). The importance of PCP diagnosis in non-HIV immunocompromised patients includes: 1- its non-specific symptoms. 2- It has been reported in almost all of immunocompromised and drug-dependent immunodeficiency patients, 3- high risk of fulminant respiratory failure and high fatality rate among these patients and 4- PCP is a preventable disorder. Therefore, rapid diagnosis would be valuable in clinical practice.

Studies highlighted the low burden of *Pneumocystis jirovecii* (Pj) in non-HIV immunocompromised patients and the lack of sensitivity of microscopic methods.(11) The use of the polymerase chain reaction (PCR) to detect pneumocystis nucleic acids has been an active area of research. PCR has been shown to have great sensitivity and specificity for the diagnosis of pneumocystis pneumonia from specimens of induced sputum and bronchoalveolar-lavage fluid (BAL). (12) Quantitative PCR (qPCR) is more sensitive than microscopy for detecting Pj in BAL. The relevant threshold remains to be determined and may vary according to the underlying disease (13).

The detection of Pj in individuals presenting without pneumonia or with pneumonia from another etiology has been defined as colonization or "carriage" (14). Conventional Pj PCR is qualitative and very sensitive, but does not differentiate between active PCP and Pj colonization. The aim of this study was to use Pj qPCR in order to detect and evaluate Pj colonization in immunocompromised and non-immunocompromised patients.

## Methods and materials

### Patients and clinical samples

All BAL samples obtained from immunocompromised and non-immunocompromised patients presenting with respiratory symptoms referred to Department of infectious diseases of Alzahra Hospital, Isfahan, Iran. The data were collected between January 2016 to January 2017.

### Staining methods

The bronchoalveolar lavage (BAL) and samples were stained and examined by a qualified microscopist at the Laboratory of Cyto-pathology, with 400 µl of fluid analyzed by Fast Giemsa and 400 µl of Papanicolaou staining.

### Real-time qPCR

A DNA extract solution from each sample was tested with a Pj qPCR targeting the Serine Endopeptidase KEXI gene of Pj as previously described.(15) From the portion of BAL fluid wash 2 remaining after microscopy and microbiological cultures, 1.5 ml were centrifuged at 10,000 × g for ten min. Supernatant was aspirated, and the cell pellet was stored in 200 µl of the washing solution at -40°C until further processing. After thawing, DNA was extracted using a QIAamp DNA minikit (Riboprep) according to the manufacturer's instructions, except that total DNA was eluted from the spin columns with 50 µl of elution buffer in order to increase the DNA concentration. 5 µl of this DNA extract was used for qPCRs.

All statistical analyses were performed using SPSS (Statistical Package for the Social Sciences, Chicago, IL, USA) version 22.

## Results

53 patients enrolled in this study (16 immunocompromised and 37 non-immunocompromised). Chi-square test did not reveal any statistical difference in the sex of two groups. (p=0.41) Independent t-test showed that the mean age of immunocompromised patients was significantly lower.

2 patients (12%) of immunocompromised patients were positive for Pj. Among non-immunocompromised patients, 3 (8%) were positive for Pj. Fisher exact test demonstrated that Pj positivity was not significantly different between two groups. The overall frequency of Pj positivity was estimated as 10%. Detailed data of patients is demonstrated in Table 1.

## Discussion

The most important diagnostic tool for pneumocystis infection is a high clinical suspicion. In the right clinical setting, an immunosuppressed patient with new onset of dyspnea or new symptoms of pneumonia, with or without radiological findings, should prompt further assessment, particularly if they are not receiving chemoprophylaxis. Since *Pneumocystis* cannot be cultured, the gold standard for detection is microscopic visualization of the organism (16).

The diagnostic performance of the microscopic visualization of Pj depends on the quality and type of sample, the number of organisms, and the experience of the microscopist. (17)The higher sensitivity of PCR for Pj detection has been demonstrated previously.(11) *Pneumocystis* colonization that is, detection of the organism or its DNA, without symptoms or signs of pneumonia, has recently been described, and accumulating evidence suggests that it may be an important clinical phenomenon. Sensitive molecular techniques such as PCR are frequently used to identify *Pneumocystis* colonization. (18)

In this study, we observed that qPCR results in the immunocompromised group did not have significant differences with those in the non-immunocompromised

**Table 1: patients' characteristics in immunocompromised (A) and non-immunocompromised group (B).**

A				
Chemotherapy/radiotherapy	Immunosuppressive	Bone marrow transplantation	Corticosteroids	
6	5	1	4	

B				
Chronic lung disease	Cardiovascular disease	Tuberculosis	Interstitial lung disease	No underlying disease
9	4	1	1	22

group. qPCR assay has the ability to detect *P. carinii* in lower respiratory tract specimens or oral washes. qPCR with application of cutoff values could improve the specificity of previously described qualitative PCR, by distinguishing between infection and colonization. It can help discriminate PCP from colonization and is in concordance with the hypothesis that the burden of Pj is lower in colonized people than in patients with PCP. (19)

A study conducted in 2004 showed that qPCR is useful for diagnosing non-HIV-infected immunocompromised patients, who often present with PCP with a low burden of Pj organisms and may not be diagnosed using microscopic examination.(1) PCR technique has advantages of being sensitive and noninvasive. Although PCR can detect colonization and still produce a false positive result, doctors should take account of clinical factors and be able to make the correct diagnosis. Early diagnosis and treatment are important for the survival of PJP patients without HIV infection, suggesting that a rapid and accurate PJP diagnosis method such as qPCR should be used in these patients with a low burden of Pj. (20)

A meta-analysis on 10 studies showed that PCR has good diagnosis accuracy and may be a useful tool for the diagnosis of PJP in immunocompromised patients. (21). Other studies highlighted the usefulness of qPCR in discriminating colonization from PCP (14, 15). It is known that colonization can sometimes lead to the development of PCP. (14)

We need to consider limitations when interpreting our results: this is a single-center study, and the number of patients is relatively small. Without a test capable of confirming or excluding the diagnosis of PJP, the classification of patients into definite or non-definite PCP is uncertain. However, one positive point of our study is that patients were classified by a multidisciplinary group of experts, ruling by consensus in view of all the clinical and complementary data. The fact that the experts did not know the qPCR results avoids classification bias. Our study had a small number of patients and the observed differences between the groups was not statistically significant. We can note that none of the enrolled patients in our study did not receive anti-pneumocystis prophylaxis. There is no current recommendation for anti-PCP prophylaxis or empirical therapy for non-HIV immunocompromised patients (21-23).

## Conclusion

In this study we observe that 12% of immunocompromised patients and 8% of non-immunocompromised were colonized by Pj which may progress to PJP or contaminate susceptible individuals. More studies with larger sample size are needed to differentiate Pj colonization from PJP and to assess cut off for Pj gene expression.

## Limitations of the study

Our study was conducted on a limited proportion of patients. We suggest further investigation on this aspect of infection.

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# Effect of MRI on Vital Signs of Patients

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## Abstract

**Introduction:** In medicine, the magnetic field is used in diagnostic tools such as MRI and in some therapeutic cases. This study evaluates the effect of MRI on vital signs of patients.

**Materials and Methods:** This was an analytical study carried out at a MRI center in Gonabad, Iran. Eighty-nine patients aged 20-60 years old with at least one previous MRI history for at least ten to thirty minutes were recruited and vital signs including body temperature, pulse, blood pressure and respiration were measured before and after MRI. MRI was done by 0.35 T magnetic field Newsoft device, China. Data was analyzed by using SPSS software, version 14.5, by using paired samples t-test ( $p < 0.05$ ).

**Results:** There was a significant difference between systolic, diastolic, mean arterial pressure, heart rate, respiratory rate before and after MRI ( $P < 0.001$ ). Systolic pressure was  $127.9 \pm 15.50$  mmHg and  $121.61 \pm 14.02$  mmHg before and after MRI, respectively. Diastolic pressure was  $80.08 \pm 9.85$  mmHg and  $76.42 \pm 9.43$  mmHg before and after MRI, respectively. Mean arterial pressure was  $96.02 \pm 0.66$  mmHg and  $91.48 \pm 0.36$  mmHg, before and after MRI, respectively. Heart rate was  $80.63 \pm 10.41$  per minute and  $71.58 \pm 10.22$  per minute before and after MRI, respectively; respiratory rate was  $18.08 \pm 11.31$  per minute and  $14.50 \pm 1.05$  per

minute before and after MRI, respectively. In addition, body temperature was  $36.98 \pm 0.08$  °C and  $36.33 \pm 2.19$  °C before and after MRI, respectively. This difference was not statistically significant ( $p = 0.30$ ).

**Conclusion:** The results showed that 0.35 T magnetic MRI could decrease systolic, diastolic and mean arterial blood pressure, heart rate and respiratory rate; however, it did not influence body temperature index. Therefore, measurements of these variables are recommended before and after MRI. MRI device is calibrated periodically in accordance with standards to ensure function of the device.

**Key words:** Magnetic field, blood pressure, heart rate, respiratory rate, body temperature

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## Introduction

Health status is reflected in vital signs; it is a part of nursing care to maintain the hemostatic status of body, cause vital signs to fall into normal range, and evaluate them [1]. Vital signs have been important for care providers in the past; currently, the most important measurable physiological criteria are vital signs which include temperature, pulse, blood pressure and respiratory rate [2].

When a nurse learns about the effect of physiological variables on vital signs and recognizes the relevance of changes in vital signs to other physical findings, the nurse can determine health problems of the patient. Vital signs and other basic physiological scales are used for solving clinical problems; examining vital signs is an essential factor in nurse-physician collaboration to determine the health status of the patient. The study of vital signs is an effective and rapid way to control the patient's condition or determine problems and to assess the patient's response to various actions and provide basic information about the general health of the patient [3].

Magnetic resonance imaging (MRI) is currently considered as one of the most important and most effective medical imaging techniques based on the magnetic field. This imaging technique provides very accurate and clear images of the organs in the body. In fact, this technique produces images with complete details of tissues and organs of the body without using X-rays; this advantage distinguishes it from other techniques [4]. Magnetic resonance imaging has become a common medical technique [5]; it is a daily challenge to maintain a safe environment for MRI for healthcare professionals, particularly considering the increasing number of clinical applications [6]. MRI, as a clinical diagnostic method since its emergence in the early 1980s, has seen more than 100 million diagnostic tests performed worldwide [7].

MRI devices, telecommunication and radar devices, wireless transmitters, cell phones, wireless telephones, microwave ovens, video devices and computer monitors are sources of electromagnetic fields [8]. Research shows that the generated electromagnetic fields can cause biological disturbances [9]. Electromagnetic fields have physiological effects such as increased body metabolism, vasodilatation, hyper pigmentation, effects on sensory nerves (relaxing effect), effect on muscle tissue, cellular and tissue destruction, general increase in body temperature, decreased blood pressure and ultimately increased activity of eccrine sweat on the human body [10]. There are also numerous epidemiological and laboratory reports on the effects of each of these fields on biological systems. Studies have shown that electromagnetic fields affect many vital phenomena such as cell growth and differentiation, ion transfers, free radicals production, apoptosis, enzyme activity, changes in hormones, changes in some membrane and intracellular proteins, angiotensin II, chromosome damage, nitric oxide levels, and immune system [10]. It is a daily challenge to maintain a safe environment for MRI for healthcare professionals, particularly considering the

increasing number of clinical applications [8]. Therefore, this study was conducted to determine the effect of 0.35 T magnetic field MRI on vital signs of patients referring to a MRI center.

## Materials and Methods

This analytical study was conducted at the MRI Center of the 22nd Bahman Hospital of Gonabad, Iran. To determine sample size, a pilot study was conducted for the main variables including heart rate, respiration rate, body temperature and systolic, diastolic and mean arterial pressure. Based on the formula for comparing the mean of two dependent populations, taking into account 0.95 confidence coefficient and 80% test power, sample size was calculated for all the above variables. Considering that more samples were obtained for diastolic blood pressure, 84 subjects were considered for the study considering the probability of a 10% drop in sample.

Samples were selected randomly from non-contrasting MRI patients by convenient non-probability method. In order to eliminate confounding factors, inclusion criteria were: the willingness to participate in the study, 10-30 min MRI, at least one previous MRI to have less anxiety, the age of 20-60 years, non-pregnancy, not taking drugs such as beta-blockers which may alter vital signs, absence of known psychological disorders and severe anxiety, absence of a history of underlying illness, mild or non-existent anxiety range in the Beck anxiety test before or after MRI, no comment by MRI personnel about the result. Exclusion criteria included: the patient's unwillingness to continue participating in the study and discontinued MRI imaging for any reason.

Once the project was approved by the Ethics Committee of the Gonabad University of Medical Sciences (GMU. REC.1393.90), the researcher selected the eligible patients referred to the MRI center. Objectives of the study were explained and written consent was obtained. Beck anxiety test was done. Before and after entry to the imaging room, temperature, blood pressure, respiratory rate and heart rate were examined. Prior to the above procedures, patients should have been present at least 15 minutes in a temperature range of 25-30°C and a relative humidity of 40-50% in order to prevent changes in temperature [10]. Procedures were performed for all patients in the supine position. Before entering the imaging room, the patients should be at least 5 minutes in a supine position; after leaving the imaging room, anxiety test and procedures were done immediately. If the anxiety test after MRI was moderate and severe, they were excluded from the study. The MRI device was a 0.35 T magnetic Newsoft, China, available in the 22nd Bahman Hospital of Gonabad. Blood pressure was measured using the Erkameter 3000 mercury barometric device, Germany. Body temperature was measured by the AMARELL mercury thermometer, Germany. Heart rate was measured by radial pulse per minute; respiratory rate was measured by observing chest for one minute by the researcher. Pulse and respiration were counted by using a clockwise full minute. To assess

reliability of the researcher responsible for measuring vital signs, they first controlled vital signs of the patients; within a minute, without changing the cuff of the barometer and the medical device and one of the nursing colleagues again controlled the vital signs. In order to determine scientific reliability of the data sheet, simultaneous observation was used by the researcher and the colleague; if there was a difference, it was again controlled by two people. Blood pressure was measured by the left hand according to nursing standards. Temperature was also sub-lingual according to nursing standards; it was recorded within three minutes after the thermometer was inserted. Data was collected and inserted in SPSS software version 14.5. Mean and standard deviation were used for normally distributed quantitative variables; absolute and relative frequencies were used for qualitative variables. Kolmogorov-Smirnov test was used to determine normality of data. Pairwise t-test was used to compare the mean of normally distributed quantitative variables including temperature, systolic, diastolic and mean arterial pressures, heart rate and respiratory rate per minute before and after MRI ( $P < 0.05$ ).

## Results

Eighty four patients participated in this study (45.2% male and 54.8% female). The average age of participants was 40.29 years; 56.2% had elementary education and 39.9% were housewives. In 73.8% of cases, MRI was done on the spinal cord and average time of MRI was 18.2 minutes.

Pairwise t-test showed a significant difference between systolic and diastolic blood pressure and mean arterial blood pressure, heart rate and respiratory rate before and after MRI; systolic and diastolic blood pressure and mean arterial pressure, heart rate and respiratory rate decreased after MRI ( $P < 0.001$ ). Moreover, t-test showed no significant difference between body temperature before and after MRI ( $P = 0.30$ ) (Table 1).

## Discussion

In this study, vital signs were measured and compared before and after MRI. The results showed that 0.35 T magnetic field MRI could decrease systolic, diastolic and mean arterial blood pressure, decrease heart rate and respiratory rate; however, it did not affect body temperature index. Chakeres' findings on ordinary people under 8 T magnetic field showed no significant change in the central temperature which was measured through the outer ear

and sublingual temperature with the optical fiber core; this is consistent with the current study [11]. A study on physiological responses to magnetic imaging process with a specific absorption rate of 0.6 W/kg showed a significant increase in temperature of tympanum and skin of the chest and abdomen, above the arm, hands and blood flow in the skin, which is not consistent with current findings [12]. Findings of Whittington on acute effects of 50 Hz magnetic field on cardiovascular system revealed no significant changes in blood pressure, which is not consistent with current findings [13]. Chakeres' findings on ordinary people under 8 T magnetic field showed that the only significant effect in the study of vital signs was the increase in systolic blood pressure, which is not consistent with current findings [11]. Chakeres' results on ordinary people under 8 T magnetic field, findings of Kim on adolescents and adults under 60 Hz magnetic field and findings of Sait on the effect of 50 Hz magnetic field on human heart rate showed no significant changes in heart rate, which is not consistent with current findings [11, 14, 15]. Yang's findings on subjects under 8 T magnetic field MRI and Scherlag's findings on magnetism and arrhythmia of dogs showed that heart rate significantly decreased, which is consistent with current findings [16, 17]. Chakeres' results on ordinary people under 8 T magnetic field and results of Kim on adolescents and adults under 60 Hz magnetic field showed no significant changes in respiration, which is not consistent with current findings [11, 14]. Yang's results on subjects under 8 T magnetic field MRI showed significant changes with increasing respiratory rate in the patient group, which is not consistent with current results [16]. The results of Kianmehr et al. on the effect of 0.35 T magnetic field on ECG showed that the heart rate decreased, which is consistent with current findings [18]. This difference in findings may be due to strength of magnetic field used and the method or subjects studied. Electromagnetic fields can affect the functioning of sympathetic-parasympathetic system. People who are in temporary contact with magnetic fields experience a decrease in sympathetic activity and an increase in parasympathetic activity, which can explain these findings. This change is due to addition of electrical potential, which is generated by flow of arterial blood in the presence of a magnetic field. One of the most important limitations of this study is the lack of control group due to ethical issues. In order to control this limitation, patients who were referred to the imaging center for the second time were selected and patients were exposed to identical conditions to eliminate severe and moderate anxiety before imaging.

**Table 1: Comparison of mean of vital signs in patients before and after MRI**

Variable	Before MRI	After MRI	p-value
Systolic blood pressure (mmHg)	127.90 ± 15.5	121.61 ± 14.02	<0.001
Diastolic blood pressure (mmHg)	80.08 ± 9.85	76.42 ± 9.43	<0.001
Mean arterial pressure (mmHg)	96.02 ± 10.66	91.48 ± 10.36	<0.001
Heart rate per minute	80.63 ± 10.41	71.58 ± 10.22	<0.001
Respiratory rate per minute	18.08 ± 1.31	14.50 ± 1.05	<0.001
Temperature (°C)	36.98 ± 0.08	36.73 ± 2.19	0.30



## Conclusion

Findings showed that 3.5 T magnetic field MRI could reduce systolic, diastolic and mean arterial blood pressure, heart rate and respiratory rate; however, it did not affect body temperature index. Therefore, measurements of these indices are recommended before and after MRI. Studies have shown that international standards on magnetic field MRI are more focused on effect of the field on metal bodies inside the body or around the patient, while it is essential to control vital signs of the patients because of potential effects of magnetic field of MRI devices on health (for example, a decrease in aortic blood flow, increased or decreased blood pressure, cardiac arrhythmia, and effects on brain functions).

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# Tendency to Rhinoplasty in University Students Based on the Level of Self-Esteem and Body Image Concern

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## Abstract

**Objective:** The increasing tendency of the Iranian people, especially the youth to cosmetic surgery has become one of the major psychosocial challenges. The aim of this study was to determine tendency to rhinoplasty in terms of self-esteem and body image concern among university students of Ilam city.

**Methods:** Two hundred and eighty-six students from Ilam city universities were entered into cross-sectional study using two-stage random sampling method. Data were collected using a 34-item questionnaire that includes demographic information, Rosenberg self-esteem scale (RSES) and Body Image Concern Inventory (BICI) by self-reported data gathering method. Data were analyzed using SPSS statistical software and for analyzing data, the descriptive statistics, chi-square test, t-tests and One Way ANOVA were used.

**Results:** The participants Mean±SD of age was 21.15 ± 2.28. Most of them were female (58.74 %), single (90.9 %) and studying in non-medical fields(57.34 %).The results of the study showed the significant differences between students tendency to rhinoplasty by gender (P=0.001), Field of Study

(P=0.046) and economic conditions (P=0.027). In addition, there were significant differences between mean scores of self-esteem and body image concern in our study population in terms of rhinoplasty status, (P≥0.05).

**Conclusion:** The results of this study show that the intention of having rhinoplasty surgery among university students is affected by level of their Self-esteem and also their concerns about their body image. In addition, the social determinants of health such as gender and economic conditions play a significant role in the tendency of university students to undergo rhinoplasty.

**Key words:** University Students, Rhinoplasty, Self-esteem, Body Image Concern

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## Introduction

Today, more than ever we are witnessing rhinoplasty among teenagers and even adults.(1, 2) According to statistical reports, Iran is one of the countries which has the largest level of rhinoplasty in the world. (3,4) Individuals with different attitudes and views decide to undergo it. Different studies are representative of common motives of people.(5, 6) As rhinoplasty is one factor for relative physical improvement and treating of respiratory disease, it does not represent a problem in that regards. But when the concern is for being more beautiful, it becomes an anomaly and a problem in young people, provoking many physical, psychological and social problems. The young age is sensitive and critical in respect to cognitive processes and regarding concerns that a person has in respect to society according to how others see his or her appearance and social comparison of them, this causes a concern in that person and creates a tendency toward rhinoplasty.(1) On the other hand, studies have shown that self-esteem plays a decisive role in the tendency of youth toward cosmetic surgery (CS). (5, 6) According to the aforementioned studies, physical appearance and body image constitute an important aspect of self-esteem in adolescents.(7) Body image dissatisfaction and concern about other's evaluation results in low self-esteem and a person who is constantly seeking approval of others, looking for a solution to improve his/her body image and increase self-confidence. (2, 7) According to studies, the relationship between self-esteem and body image dissatisfaction is a reciprocal affair. This means that body image dissatisfaction decreases self-esteem and low self-esteem leads to body image dissatisfaction. The results of various studies show that rhinoplasty can improve people's body image satisfaction and also increase their self-confidence. (8, 9) The aim of this study was to determine tendency to rhinoplasty in terms of self-esteem and body image concern among university students of Ilam city.

## Methods

The Total number of 286 students from Ilam city universities (122 medical sciences students and 164 non- medical sciences students) with convenience sampling design was entered into a cross-sectional study. Data were collected using a three-part questionnaire. The first part of the questionnaire was about demographic information including gender, field of Study, marital status, Family's economic condition and current status of participants about rhinoplasty. The second part was Rosenberg self-esteem scale (RSES). The RSES is a 10-item Likert type scale with items answered on a four-point scale from strongly agree to strongly disagree. This scale measures life satisfaction (e.g. On the whole, I am satisfied with myself) and to feel good about themselves (for example: At times I think I am no good at all). (10) The third part of the questionnaire included the 19-items Body Image Concern Inventory (BICI). The BICI is a brief self-report measure designed to assess multiple aspects of dysmorphic appearance concern, as opposed to only focusing on appearance dissatisfaction or one aspect of dysmorphic appearance

concern (e.g. I feel others are speaking negatively of my appearance), dissatisfaction with one's body image (e.g. I am dissatisfied with some aspect of my appearance), and the person's concern about participating in social activities (e.g. I have missed social activities because of my appearance). Participants were asked to answer the questions on a five-point Likert scale from never=1 to always=5. Students voluntarily participated in the study and completed self-report questionnaires. This study was approved by the Ethics Committee of the Ilam University of Medical Sciences. Data analysis was conducted using SPSS statistical software. For data analysis, descriptive statistics, chi-square test, t-tests and one way ANOVA were used and P-value less than 0.05 was considered as significance level.

## Results

Two hundred and eighty-six university students with mean age of  $21.15 \pm 2.28$  participated in this study and were mostly female (58.74 percent), single (90.9 percent) and studying in non-medical fields of study (57.34 percent). In addition, 9.09 percent of them had undergone rhinoplasty and 26.92 percent plan to do it in the future. The relative frequency and absolute frequency of subjects in terms of demographic characteristics are shown in Table 1 (next page). Comparing the rhinoplasty status in terms of demographic characteristics it showed that female students had significantly performed rhinoplasty more than boys and as well they were more likely than boys to have rhinoplasty in the future ( $P=0.01$ ). In addition, non-medical sciences students were significantly more likely than medical sciences students to have rhinoplasty in the future ( $P=0.046$ ), (Table 2). Also, the comparison of mean scores of self-esteem and body image concerns based on students rhinoplasty surgery status showed that self-esteem of students who had rhinoplasty surgery or those who want to do it in future was significantly lower than students who had no intention to have rhinoplasty ( $P=0.044$ ). Furthermore, body image concerns of students who had no intention to rhinoplasty was significantly less than students who had rhinoplasty or those who wanted to undergo it in future ( $P=0.001$ ), (Table 3).

**Table 1: The absolute and relative frequency of subject's demographic characteristics**

Demographic Variables	N	%
<b>Sex</b>		
Male	118	41.25
Female	168	58.74
<b>Status</b>		
Single / Divorced / Widowed	260	90.9
Married	26	9.09
<b>Field of Study</b>		
Medical Sciences	123	43.01
Non-Medical Sciences	163	56.99
<b>Economic Status</b>		
Weak	30	10.48
Average	187	65.38
Good	59	20.62

**Table 2: The absolute and relative frequency of subject's demographic characteristics in terms of current rhinoplasty status**

Demographic Variables	Participants Rhinoplasty Status			p-Value
	Has had rhinoplasty N (%)	Intends to have rhinoplasty N (%)	Does not intend to have rhinoplasty N (%)	
<b>Sex</b>				
Male	6 (2.09)	29 (10.13)	83 (29.02)	0.01
Female	20 (6.99)	48 (16.77)	100 (34.96)	
<b>Status</b>				
Single / Divorced / Widowed	21 (7.5)	71(24.72)	168(58.61)	0.08
Married	5 (1.66)	6(2.22)	15(5.27)	
<b>Field of Study</b>				
Medical Sciences	11 (3.84)	31(10.83)	81(28.32)	0.046
Non-Medical Sciences	15 (5.24)	46(16.08)	102(35.66)	
<b>Economic Status</b>				
Weak	4 (1.38)	10(3.61)	16(5.55)	0.027
Average	13 (4.44)	44(15.27)	130 (45.55)	
Good	9 (3.33)	23(8.05)	37 (12.77)	

**Table 3: Mean score and standard deviation of self-esteem and body image concern of study subjects in terms of rhinoplasty status**

Psychological variables	Participants Rhinoplasty Status			p-Value
	Has had rhinoplasty N (%)	Intends to have rhinoplasty N (%)	Does not intend to have rhinoplasty N (%)	
Self-Esteem	20.80 (1.25)	20.26 (1.38)	21.33 (1.40)	0.044
Body Image Concern	46.88 (9.07)	45.95 (11.69)	37.27 (11.76)	0.001



## Discussion

This study aimed to determine the tendency toward rhinoplasty in terms of self-esteem and body image concern among universities students of Ilam city. For determining the tendency of students to have rhinoplasty, they divided into three groups including: those who had rhinoplasty done in the past (RP-Group), those who want to have rhinoplasty in the future (RF-Group) and those who had no intention to have rhinoplasty in the future (NRF-Group). Results showed that the mean score of self-esteem in the NRF-Group is higher than other groups. Also, the NRF-Group reported lowest self-esteem. Based on previous studies, self-esteem is one of the most important predictors of cosmetic surgery in people. Zamani et al, (11) reported that self-esteem of their study subjects significantly increased after rhinoplasty surgery. Also other studies showed similar results. (1, 2, 12, 13) These findings suggest that students' satisfaction with their body image is a factor influencing their self-esteem. In addition, results of the present study showed that mean score of body image concern in the RP-Group and the RF-Group is significantly higher than in the NRF-Group. So, we can say that the intention of the students to have rhinoplasty is greatly in relation to satisfaction about their appearance. The relationship between self-esteem and body image satisfaction is a reciprocal interaction. It means when self-esteem is low, satisfaction with body image is low and the tendency toward cosmetic surgery will increase. In other cases, the lack of satisfaction with body image leads to decreasing of self-esteem. (14) Self-esteem is one psychological indicator that is affected by numerous socio-environmental factors. Fear of others judgment and evaluation has a negative impact on people's self-esteem. People with low self-esteem due to lack of internal reinforcement resources, seek external reinforcement such as approval of others. (1, 15) Therefore, these people are giving great importance to the judgment of others. Because of it, cosmetic surgery, like rhinoplasty, is one of the ways of improving their body image and getting other's approval.

Also, the results of this study showed that the RP-Group had a higher self-esteem in comparison to the RF-Group. This result is in line with the results of previous studies. (1, 15, 16) In the study of Pecorari et al (17) those persons who had cosmetic surgery reported a low rate of body image concern and their self-esteem was increased. Also, Sarwer et al (18) expressed that cosmic surgery is a way of enhancing individual's satisfaction from their body image and promoting physical and psycho-social health. However, students who had rhinoplasty in the past were worried more about their body image, while it was expected they reported low rate of body image concern in comparison to those who want to have rhinoplasty in the future. This result suggests that cosmetic surgery does not necessarily always lead to reduced concerns about body image and self-esteem does not improve. In support of the current result, Mohammadi et al (19) reported that cosmetic surgery doesn't significantly increase the self-esteem of subjects. Nevertheless, although cosmic surgery may not lead to increasing the rate of self-esteem

or decreasing the rate of body image concern, we cannot deny its psychological role in the tendency to cosmetic surgery and the growing demand for cosmetic surgery including rhinoplasty.

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# Patients' perspective on observing the rights of intensive care unit patients in teaching hospitals affiliated with Kermanshah University of Medical Sciences, Iran in 2015-16

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## Abstract

Observing patient rights is most important. The present study was conducted to determine the perspective of patients hospitalized in the intensive care unit on observing their rights. This present descriptive cross-sectional study consisted of 180 patients, hospitalized in the intensive care units of hospitals affiliated with Kermanshah University of Medical Sciences, Iran. Data collection tools were demographic questionnaires and a modified version of the patient rights charter questionnaire, which was completed by the patients. The majority of subjects (57.22%) were men, married (73.7%) and 50-59 years old (26.66%). Fifty-eight (32.22%) of the patients were aware of the patient rights charter, 60 (33.33%) were fairly aware and 62 (34.44%) were unaware. The rate of observing patient rights charter was reported as good by 44.73% and average by 55.27% of the study population. According to the results obtained, it is worth noting that observing patient rights by the healthcare staff and patients' awareness of the patient rights charter are crucial behavioral factors in hospitals that should be given a high priority so as to improve inpatients' recovery and comfort.

**Key words:** Perspective, patient rights, intensive care units

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## Introduction

Patient rights and their observation are as old as medical science (Amini et al., 2013). Hippocrates frequently urged his students to carefully observe patient rights (James, 2013). Patient rights are a pivotal index in defining standards for clinical services (Mousavi, 2016), and refers to the responsibilities of health centers towards patients. In other words, patient rights encompass legitimate and rational physical, psychological, spiritual and social needs, which are regulated by health standards and should be strictly implemented and observed by the healthcare team (Joolae and Hajibabae, 2012).

As a creature with physical, mental, social and spiritual dimensions, humans have rights irrespective of their health status, which cannot be defended, upheld and observed without others' assistance (Macdonald, 2010). The emphasis placed on observing basic human rights in healthcare practices, especially on respecting the dignity of the patient as a human, becomes particularly important when the patient's vulnerability makes them easily susceptible to the violations and weaknesses of the healthcare system (Seyed Farajollah et al., 2014).

Health service provision methods have dramatically changed over the past few decades. In recent years, the staff of healthcare organizations assumed they could make decisions on behalf of patients without respecting their rights (Vakili et al., 2014); however, current circumstances are different, as patients expect hospital staff to observe their rights. In fact, observing the principle of the patient rights charter is an important ethical behavior in medicine in any society (Bondeson and Jones, 2013). Countries such as Canada, the UK, the US, Germany, Switzerland, Australia and Sweden have also focused on and developed their patient rights charter, and hospitals and health centers are bound to respect it (Mousavi, 2016).

According to the perspective of most patients reflected in literature, the healthcare team violates some patient rights, including the need for responding to their requests, listening to their words and receiving information about diagnosis, treatment and the consequences and risks of treatment (Hu et al., 2010). Different studies report different degrees of observing the patient rights charter. A study conducted by Amini et al. (2013) titled, "The status of observing patient rights charter in outpatient clinics of Tabriz University of Medical Sciences: Perspectives of health service clients", found moderate and reasonable levels of observing the patient rights charter, and assessed the single dimension of "providing health services based on respecting patient rights to privacy" as good. That also rated with a high score in literature (Vaskooei Eshkevari et al., 2009).

The inherent nature of nursing necessitates respecting human rights such as cultural rights and the right to live and choose, respecting human dignity and behaving respectfully. High quality of health services is ensured by nurses in a respectful atmosphere (Ulrich et al., 2010); nevertheless, most Iranian patients are unfortunately

unaware of their rights, which are also disregarded by physicians and nurses causing problems for both patients and health service provision organizations. The provisions of these charters are also disrespected in hospitals for different reasons. Although this charter is extensively stressed by health system policymakers, it needs to be clarified for patients and health service providers who still identify it as ambiguous (Nejad et al., 2011).

The highest emphasis should be placed on patient rights in the ICU, as one of the most critical and professional parts of hospitals, in which patients may face acute conditions including altered level of consciousness and impaired decision-making caused by sedatives, pain, anxiety and fear (Mason et al., 2014). Given the importance of the subject, which is not well addressed in literature, and the need for determining a clear outline for a better health service provision, the research team investigated patients' perspectives on the status of observing patient rights in the ICU and CCU of selected hospitals in Kermanshah, Iran.

## Materials and methods

The present descriptive cross-sectional study was conducted in the ICU and CCU of Imam Reza Hospital, Imam Ali Hospital, Taleghani Hospital and Farabi Hospital. The census method was used to select eligible candidates from patients hospitalized in these units. Jouzi-Arkawazi et al. reported the rate of observing patient rights as 45% in patients' perspective (Jouzi-Arkawazi et al., 2010). With a confidence interval of 95% and a maximum error of estimate of 0.05, the sample size was calculated as 180 using the following formula:

$$n = \frac{z^2 \cdot 1 - \alpha / 2 \cdot P (1 - P)}{d^2} \quad (1)$$

The inclusion criteria comprised being hospitalized for at least 24 hours in ICU and CCUs of the study hospitals in Kermanshah and being conscious and able to respond to questions. The exclusion criteria consisted of unwillingness to continue responding to interview questions and developing critically ill conditions or reduced levels of consciousness.

Data collection tools were demographic questionnaires and the patient rights charter questionnaire. Permission was obtained from Jouzi-Arkawazi et al. (2010) for the use of their questionnaire developed for assessing patients' perspective on their rights. It was then adapted to the current standards in the Iranian patient rights charter (Parsapoor et al., 2010) and used along with the questionnaire developed by Rad et al. (2004) and Vaskooei Eshkevari et al. (2009), whose validity was confirmed by experts, including the faculty members of the School of Nursing and Midwifery at Shahid Beheshti University of Medical Sciences in Tehran, Iran. The 40-item questionnaire assessed patients' views on observing patient rights on a four-point Likert scale ranging from 1 to 4, with 1 representing 'never', 2 'sometimes', 3 'often' and 4 'always'. A total score of 40-80 indicated



a poor rate of observation, 80-120 a moderate rate and above 120 a good rate of observation. The validity and reliability of these questionnaires have been confirmed. Content validity ratio (CVR) and content validity index (CVI) were used to examine the validity of the questionnaires, which were presented to 10 faculty members of the School of Nursing and Midwifery at Shahid Beheshti University of Medical Sciences. The faculty members' comments were summarized and the questionnaires were modified accordingly. CVR was also calculated as 94% and CVI as 97%. The test-retest was used to confirm the reliability of the tool. The questionnaires were completed by 20 of the study patients twice, with 7 days in between, and statistical tests were used to determine the correlation of the responses. A correlation coefficient of  $r = 0.85$  calculated for the entire questionnaire confirmed the reliability of this tool.

After receiving approval for the research proposal, the necessary measures were taken to ensure its implementation, including receiving permission from Shahid Beheshti University of Medical Sciences, the Deputy of Education and the Office of Graduate Studies and then presenting it to the Deputy of Research at Kermanshah University of Medical Sciences. Moreover, permission was obtained from the authorities of the selected hospitals for conducting this study. The researcher then presented himself to the ICU and CCU of the study hospitals, briefed the subjects on the study objectives, received informed consent from them and collected the data. After making the necessary arrangements with the patients, the researcher went to the hospitals and distributed the questionnaires among the study population at times when there was no need for performing special procedures, including morning shifts from 9.30 to 10.30 when all patients had been visited and evening shifts after the visiting time from 16.30 to 17.30. The questionnaires were completed by the researcher through interviews with the patients. Sampling took 3.5 months from 23 July 2016 to 7 November 2016. SPSS-17 and descriptive statistics and indices such as mean and standard deviation were used for data analysis.

## Findings

The majority of the study subjects (57.22%) were men, married (73.7%), 50-59 years old (26.66%) and housewife (31.6%), and had an education level of below high school diploma (85.8%). A total of 64.2% of the patients had a history of hospitalization within the previous five years; over half (57.4%) reported a history of hospitalization in CCU and 38.8% in ICUs. According to the results, 58 (32.22%) of the patients were aware of the patient rights charter, 60 (33.33%) were fairly aware and 62 (34.44%) were unaware.

The rate of observing patient rights charter was reported good by 44.73% and average by 55.27% of the study population. A mean score of 121.85 was also calculated for the questionnaire data, which is higher than the mean score of patient appraisal of observing ICU and CCU patient rights.

It can therefore be argued that the study patients held positive attitudes towards the observation of ICU and CCU hospitalized patients' rights.

## Discussion

The majority (57.22%) of the study subjects were male. Similarly, Aghili et al. (2014) reported a contribution of about 53.1% for men in the study population. Married subjects accounted for 73.7% of the present study patients, nearly similar to the study of Jouzi-Arkawazi et al. (2010) (70.6%). Sharifi et al. (2013) reported a relative frequency of 83.4% for those with an education level of below high school diploma, which is consistent with the present study (85.8%).

In terms of employment status, the retired presented the lowest frequency (9.5%), while about one-third of the patients in both the present study (31.6%) and the study conducted by Jouzi-Arkawazi et al. (2010) (35.6%) were housewives.

In line with the present study, which estimated the patient awareness of the patient rights charter at about 32.22%, Sharifi et al. (2013) reported a moderate to acceptable rate of awareness in 30.7% of the patients.

Examining the patients' view on the observation of patient rights in Intensive Care Units revealed a mean score of 42.70 for the dimension of "Patients' right to properly receive health services"; 52.85% of the patients also rated this dimension good and 47.15% moderate. Moreover, the dimension of "Patients' right to properly receive adequate information" received a mean score of 17.24, and 51.28% of the patients assessed the observation of this dimension as good and 48.72% as moderate. The mean score of "Patients' right to choose and freely decide on receiving health services" was found to be 17.62, and 52.30% of the subjects rated it good and 47.70% moderate. "Providing health services while respecting the principle of confidentiality and patients' right to privacy" also received a mean score of 42.77, a good appraisal by 69.33% of the patients and a moderate appraisal by 30.67% of them. In addition, the mean score of "Patients' rights to having access to an efficient system for dealing with complaints" was 2.89; 26.66% evaluated it as good, 49.26% as moderate and 24.10% as poor.

The present study findings reported a good observation rate for "Patients' right to properly receive health services", which is consistent with the 54% rate of observation reported in the study of Nekoei Moghaddam et al. (2013) and also with the study of Merakou et al. (2001), who reported proper levels of healthcare services provided for patients. In contrast, Salimi et al. (2006) reported an observation rate of 30% for this dimension.

The health service recipients evaluated the observation of "Providing health services while respecting the principle of confidentiality and patients' right to privacy" of the patient rights charter as good. This finding is consistent with

those obtained by Sarkhil et al. (2013), who reported an observation rate of 78.13%, and by Özdemir et al. (2009), who reported the rate of observing patient privacy in Turkey as 86.1%. In contrast, Aghajani and Dehghannayeri (2009) reported low levels of observing patient privacy (50%).

The present study evaluated the observation status of the dimension of *"Patients' right to choose and freely decide on receiving health services"* as good, which is consistent with the study conducted by Amini et al. (2013), who evaluated health service recipients as moderate in terms of "having the right to choose". In contrast, Parsapoor et al. (2009) reported an unfavorable status for the rights associated with "patient rights to choose and decide" in educational hospitals.

The findings of the present study suggested good levels of observation for *"Patients' right to properly receive adequate information"*, which is consistent with the study of Arab et al. (2011), who reported an observation rate of 55.7%, but inconsistent with the study of Fotaki (2006), who reported poor observation (75%) for this dimension.

The present findings suggested a moderate rate of observation for *"Patients' rights to having access to an efficient system for dealing with complaints"*, which is inconsistent with the study conducted by Babamahmoodi et al. (2011), who reported an observation rate of 13.20%.

The overall mean score obtained for the study sample was 121.85, and the rate of observing patient rights charter was reported good by 44.73% and average by 55.27% of the study population.

Basiri et al. (2011) assessed health providers and patients' awareness of Patient Bill of Rights and its observation rate in an educational hospital in Gonabad, Iran, and suggested a 69.1% frequency of satisfaction with the observation of Patient Bill of Rights in the patients. A study conducted by Astaraki et al. (2015) titled "Evaluation of respect for patient's rights from the viewpoint of hospitalized patients in Shohada Ashayer Hospital of Khorramabad city" found 1.2% of the patients to hold good views on observing patient rights and 86.7% to have moderate attitudes.

Sadeghieh Ahari et al. (2015) studied the expectations and observation of the rights of patients in hospitals affiliated with Ardabil University of Medical Sciences in 2012, Iran, and found an overall rate of 50.69% for observing patient rights. A study conducted by Sharifi et al. (2013) titled "Evaluation of awareness on the patient bill of rights and observing rate on the patient's perspective in Imam Reza Hospital in Kermanshah in 2012" found 72.4% of the subjects to hold moderate views on patient rights observation.

Ravaghi et al. (2016) assessed awareness of and satisfaction with observing patient rights in patients hospitalized in general educational hospitals affiliated with Tehran University of Medical Sciences, and found 68.9% of the patients to be satisfied with the observation of their rights.

Kagoya et al. (2013) examined the awareness of, responsiveness to and observation of patient rights from the perspective of inpatients and health service personnel, and found at least 36.5% of the patients to have experienced challenges in observing their rights, at least once during their stay, which is not consistent with the present study. Shadfard et al. (2016), who investigated patients' perspectives on the awareness and observation of patient rights, reported a 31.4% rate for the satisfactory observation of patient rights.

Babamahmoodi et al. (2011) examined the view of patients in the educational hospitals of Mazandaran University of Medical Sciences, Iran on observing the patient rights charter. Based on the total score obtained for the patient rights charter, they reported a mere 14.59% rate for observing patient rights. They also found 16.63% of the patients to be satisfied with respecting patients and their privacy and avoiding discrimination among them, 14.17% with patients' rights to having access to their medical records, 14.15% with patients' rights to choose and freely decide and 12.20% with patients' rights to having their complaints dealt with.

Different research settings may be blamed for the discrepancies observed in the results of the present study compared to those in literature. The present study was conducted on patients admitted to the Intensive Care Units, in which a great emphasis is placed on the nurse/patient ratio, more intimate relationships emerge between the treatment staff and the patients and the entrance of medical students and nurses unaware of the patient rights charter is restricted.

The results of the present research can be used to notify healthcare system managers and health service providers of patient rights and help the necessary measures be taken to improve the status of patient rights. Developing the patient rights charter and presenting it to patients, physicians, nurses and administrative staff is an essential issue in healthcare centers. Publicly exposing this chart is also very valuable and effective. Further studies are recommended on assessing and comparing patients' views on observing patient rights in different hospital wards and in private hospitals. The present study limitations included patients' failing to respond honestly caused by fear of being deprived of the necessary care. The self-reporting nature of the study may also have caused inaccurate completion of the questionnaires. In order to overcome these limitations, efforts were made to provide the participants with the necessary explanations of the items in a peaceful environment.

## Conclusion

The study patients were found to have positive attitudes towards observing the rights of patients hospitalized in Intensive Care Units. Observing patient rights by health service providers and patient awareness of the patient rights charter are the crucial ethical features in hospitals that should be greatly emphasized to help with inpatients' recovery and peace of mind. Patients need to be aware of

all of their treatment stages as well as their rights and duties. In fact, presenting and explaining the patient rights charter to patients by the hospital staff upon patient admission or within the first days following admission to hospitals and health centers not only positively affect patients' health, but also cause peace of mind in the staff by preventing the potential consequences of patient unawareness of the charter.

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# Prevalence of Cutaneous Fungal Infections among Patients Referred to Mycology Laboratory of Toba Clinic in Sari, Iran: A Retrospective Study from 2009 to 2014

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## Abstract

**Objective:** Cutaneous fungal infections are non-invasive infections that manifest in different forms by affecting the skin, hair, or nail. Surveillance for fungal infections is important for making strategies to assess and to prevent these infections especially in Mazandaran Province; a region with a hot humid climate in northern Iran. This study aimed to investigate the prevalence of cutaneous fungal infections among patients referred to Mycology Laboratory of Toba Clinic in Sari, north of Iran.

**Materials & Methods:** In this retrospective descriptive analytic study, medical charts of 4,414 patients with cutaneous fungal infections diagnosis who referred to the Mycology Laboratory of Toba Clinic in Sari, Iran during 2009-2014, were selected. Demographic characteristics of the patients were also recorded. Fungal culture was requested for all patients suspected of cutaneous fungal infections. Collected data were analyzed using SPSS software.

**Results:** Of the total 4,414 cases, 4,309 cases underwent direct and culture examination; 1,567 (36.4%) cases were positive. The rate of fungal infections was significantly different in the two genders ( $p < 0.001$ ). The most common sites of fungal infections were on the leg skin in 1,111 (25.7%), face and neck skin in 600 (13.9%), hands in 588 (13.6%)

and groin involvement in 526 (12.2%). The most common identified fungal infections were saprophytic infection in 667 cases (42.2%), dermatophytic infection in 631 cases (39.9%) and candidiasis infection in 275 cases (17.4%) respectively. The most common dermatophytosis was *Trichophyton mentagrophytes* in 336 (21.24%).

**Conclusion:** This study demonstrates that saprophytic infections were more common than the dermatophytoses in Sari located in Mazandaran province with a hot, humid climate. *Trichophyton mentagrophyte* is the most common species among dermatophytosis but in the other studies the commonest form were *Trichophyton rubrum*, *Trichophyton verrucosum*, *Trichophyton violaceum* and *Epidermophyton floccosum*. The differences could be due to differences in climate.

**Key words:** Prevalence, Fungal infections, Dermatophyte, *Candida*, Saprophyte, *Malassezia*

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## Introduction

Cutaneous fungal infections (dermatomycosis) are common cutaneous infections that involve the skin and mucosal membranes with various clinical features. Dermatophytes are the most frequent cutaneous fungal infections and accessories of the skin. (1) In recent years, fungal infections have been more prevalent and always invade humans and other animals to produce infection, and can be, in some cases life-threatening. (2) Superficial fungal infections are especially important because the causative agents in most of the cases are normal flora. (1) In decreasing the risk of these causative agents, therapies are not adequate and management and preventive measures should be performed. (3, 4) Planning for control of the diseases without epidemiological studies about current prevalence of cutaneous fungal infections is impossible, because epidemiological studies provide adequate data for decision making and selecting the appropriate preventive strategies for controlling the disease and improve the teaching programs to persons at risk of the diseases.

Up to now, more than 40 types of Dermatophytes have been classified in three species; Microsporum, Trichophyton and Epidermophyton. (2) The distribution of Dermatophytes in a geographical area depends on various types of anthropophilic, zoophilic, and geophilic dermatophytes in the region. (4) Nowadays, in various countries, zoophilic Dermatophytes such as *Microsporum canis*, *Trichophyton mentagrophytes* and *Trichophyton verrucosum* are the main causes of Dermatophyte infections in humans. (3) However, the prevalence of the disease and the causative species of dermatophytosis vary in different areas around the world. In addition, the previous studies in Iran reported a different prevalence of dermatophytosis in various regions in this country. (5-14) The rate of infection depends on several factors such as age, temperature of the environment, amount of humidity, cultural status, and socioeconomic condition of the society. (15)

Fungi grow in warm and humid climates. People, who stay for a long time in warm and humid climates, are at increased risk of fungal infections. Linens, bathroom tiles, and the floor of pools are also favorite places for the growth of fungi. (2) Knowledge about the prevalence and etiologic agents and identification of the prominent species in every region are necessary for accurate and early diagnosis, appropriate treatment and planning of preventive strategies. In spite of several studies performed in different regions of Iran, there is no epidemiological study regarding cutaneous fungal infections in north of Iran, especially in Mazandaran, a northern province with a hot humid climate that is suitable for growth of fungi. For this reason, this study was done to determine the prevalence of cutaneous fungal infections among patients referred to Mycology Laboratory of Toba Clinic in Sari, Iran during 2009-2014.

## Methods

In this retrospective descriptive analytic study, medical charts of 4,414 patients with cutaneous fungal infections diagnosis who referred to the Mycology Laboratory of Toba Clinic in Sari, Iran during 2009-2014, were selected. Although, the study was retrospective, in terms of ethical considerations in research, patient's name remained undivulged. Demographic characteristics of the patients including: age on admission, gender, residence, history of certain medicine consumption, positive family history, level of education and occupation derived from the patient's medical charts, were recorded. Fungal culture was requested for all patients who were suspected of cutaneous fungal infections. If the previous culture report existed in the patient's medical record, type of infection and isolated infecting agent from the lesion was recorded in a researcher made questionnaire. Patients with previous history of oral or local anti-fungal medicine consumption were excluded. Patients with history of corticosteroid and immunosuppressive drug consumption were included. Recorded data were analyzed using SPSS software. The t-test was used to compare the mean between the two groups and to compare the mean for more than two groups, ANOVA was used. P-value less than 0.05 was considered significant statistically.

## Results

A total of 4,414 medical records of patients diagnosed with cutaneous fungal infection were evaluated. Of those 2,588 (58.63%) were females. The mean age of the patients was  $33.2 \pm 19.1$  years. The mean age of the female patients ( $34.3 \pm 18.1$  years) was significantly higher than the male patients ( $31.7 \pm 20.4$  years) ( $P < 0.001$ ).

The results of laboratory direct microscopy and culture were available for 4,309 of the patients. Among these, direct microscopy examination and culture was positive in 1,567 (36.4%) of the patients (Table 1).

Table 2, shows the rate of contamination based on the site of lesion by sex. The most common site of contamination was leg in 1,111 cases followed by face and neck in 600 cases, hands in 588 cases and groin in 526 cases. In the rate of contamination in all areas there was a significant difference by sex ( $P \leq 0.001$ ).

The results of fungi isolated from the specimens obtained from the lesions based on type of isolated fungi by sex are shown in Table 3. The most frequent isolated fungi from the specimen of the lesions was Saprophytes in 667 (42.2%) specimens followed by Dermatophytes in 631 (39.9%) and *Candida* in 275 (17.4%) specimens.

Different types of Dermatophytes and other isolated fungi based on clinical condition of the patients is shown in Table 4 (page 106). *Trichophyton mentagrophytes* were the most common Dermatophytes in all sites of the lesions.

Table 1. The results of laboratory direct microscopy and culture in the studied population

Results		Culture		Total
		Positive	Negative	
Direct Microscopy Examination	Positive	1461	9	1470
	Negative	106	2733	2839
<b>Total</b>		<b>1567</b>	<b>2742</b>	<b>4309</b>

Table 2. Frequency of Fungal infection based on site of lesion by sex in the studied population

Site of Lesion	Sex		Total
	Male	Female	
Scalp	182 (4.2%)	164 (3.8%)	346 (8%)
Face and Neck	287 (6.64%)	313 (7.24%)	600 (13.9%)
Trunk	144 (3.3%)	274 (6.3%)	418 (9.7%)
Hands	223 (5.2%)	365 (8.4%)	588 (13.6%)
Foot	461 (10.7%)	650 (15.02%)	1111 (25.7%)
Hand Nail	105 (2.4%)	296 (6.8%)	401 (9.3%)
Foot Nail	106 (2.5%)	229 (5.3%)	335 (7.8%)
Groin	277 (6.4%)	249 (5.8%)	526 (12.2%)
<b>Total</b>	<b>1785 (41.3%)</b>	<b>2540 (58.7%)</b>	<b>4325 (100%)</b>

Table 3. Frequency of fungi isolated from the patients specimen based on type of fungi by sex

Type of fungi	Species	Sex		Total
		Male	Female	
Dermatophytes	Epidermophyton floccosum	40 (2.5%)	60 (3.9%)	631 (39.9%)
	Trichophyton tonsurans	37 (2.34%)	58 (3.66%)	
	Trichophyton rubrum	40 (2.5%)	59 (3.7%)	
	Trichophyton mentagrophytes	146 (9.24%)	190 (12%)	
	Microsporum	1 (0.06%)	0	
Saprophytes	unknown (due to not clinically significant)	239 (15.12%)	352 (22.23%)	667 (42.2%)
	Cladosporium	0	3 (0.19%)	
	Rhizopus	2 (0.13%)	1 (0.06%)	
	Aspergillus	3 (0.19%)	8 (0.51%)	
	Aspergillus niger	8	6 (0.39%)	
	Alternaria	3 (0.19%)	1 (0.06%)	
	Penicillium	0	3 (0.19%)	
	Aspergillus flavus	12 (0.76%)	20 (1.3%)	
	Fusarium	1 (0.06%)	4 (0.25%)	
Achremonium	0	1 (0.06%)		
Malassezia	Malassezia	4 (0.25%)	5 (0.31%)	9 (0.6%)
Candida	Candida	104 (6.6%)	171 (10.8%)	275 (17.4%)
<b>Total</b>		<b>640 (40.5%)</b>	<b>942 (59.5%)</b>	<b>1582 (100%)</b>



**Table 4: Different type of Dermatophytes and other isolated fungi based on clinical condition of the studied population**

Type of fungi	Site of lesion										Total	
	Scalp	Face & Neck	Trunk	Hands	Foot	Hand Nail	Foot Nail	Groin				
Dermatophytes	Epidermophyton floccosum	7 (0.45%)	10 (0.65%)	11 (0.71%)	15 (0.97)	25 (1.6%)	9 (0.58%)	4 (0.26%)	18 (1.16%)			620 (40.1%)
	Trichophyton tonsurans	4 (2.26%)	17 (1.10%)	9 (0.58%)	13 (0.84%)	28 (1.8%)	9 (0.58%)	6 (0.4%)	12 (0.8%)			
	Trichophyton rubrum	35 (2.25%)	41 (2.66%)	35 (2.25%)	45 (2.91%)	28 (1.8%)	28 (1.8%)	23 (1.5%)	36 (2.3%)			
	Trichophyton mentagrophytes	0	1 (0.065%)	0	0	0	0	0	0			
	Microsporium	7 (0.45%)	15 (0.97%)	7 (0.45%)	16 (1.01%)	24 (1.555%)	8 (0.52%)	6 (0.4%)	11 (0.71%)			
	unknown (due to not clinically significant)	37 (2.38%)	90 (5.85%)	59 (3.85)	74 (4.8%)	146 (9.4%)	63 (4.1%)	36 (2.3%)	73 (4.7%)			
	Cladosporium	2 (0.13%)	0	1 (0.06%)	0	0	0	0	0			
	Rhizopus	0	1 (0.065%)	0	1 (0.65%)	0	0	0	1 (0.07%)			
	Aspergillus	2 (0.13%)	1 (0.065%)	2 (0.13%)	1 (0.65%)	1 (0.065%)	1 (0.06%)	1 (0.07%)	2 (0.13%)			
	Aspergillus niger	0	5 (0.32%)	2 (0.13%)	2 (0.13%)	2 (0.13%)	1 (0.06%)	0	1 (0.07%)			
Saprophytes	Alternaria	1 (0.064%)	0	0	0	2 (0.13%)	0	1 (0.07%)	0			651 (42.1%)
	Penicillium	0	2 (0.13%)	0	0	0	0	0	0			
	Aspergillus flavus	1 (0.064%)	5	3 (0.19%)	6 (0.39%)	6 (0.39%)	2 (0.13%)	3 (0.19%)	5 (0.32%)			
	Fusarium	0	2 (0.13%)	0	2 (0.13%)	1 (0.065%)	0	0	0			
	Achremonium	0	0	1 (0.06%)	0	0	0	0	0			
	Malassezia	2 (0.13%)	2 (0.13%)	1 (0.06%)	0	3 (0.19%)	0	0	1 (0.07%)			
Candida		20 (1.29%)	35 (2.27%)	23 (1.5%)	45 (2.9%)	66 (4.26%)	28 (1.8%)	22 (1.4%)	29 (1.9%)			268 (17.3%)
		118 (7.6%)	227 (14.7%)	154 (9.9%)	220 (14.2%)	389 (25.1%)	149 (9.6%)	102 (6.6%)	189 (12.2%)			
<b>Total</b>												<b>1548 (100%)</b>



## Discussion

In the present study, from a total of 4,414 patients, 4,325 cases were infected. Direct microscopy examination and culture was done for 4,309 cases. Of these, 1,582 cases had fungal infection; 631 (39.88%) had dermatophytes infection, 667 (42.16%) had saprophytes infection, 9 (0.56%) had *Malassezia* infection and 275 (17.38%) had candida infection. saprophytes infection was the most common infection. *Trichophyton mentagrophytes* (336 cases) was the most common dermatophyte infection followed by *Epidermophyton floccosum*, *Trichophyton rubrum*, *Trichophyton tonsurans* and *Trichophyton Microsporum*. In contrast, Nikpour et al in Shiraz/Iran, reported *Trichophyton rubrum* was the most common dermatophyte infection followed by *Trichophyton mentagrophytes*, *Trichophyton schoenleinii*.(5)

Shadeganipour et al in Isfahan/Iran performed a study on 12,000 dermatologic patients. They found that the prevalence of dermatophyte infection was 10.8% and *Tinea capitis* (72.1%) and *Trichophyton verrucosum* were the most common dermatophyte respectively.(6) Although their sample size was three times of ours, the result of our study showed that the prevalence of dermatophyte infection was 14.04% which was relatively similar to their results. Ten years later, Shadegani et al performed another study in Isfahan, Iran on 57,816 dermatologic patients. They reported the prevalence of dermatophyte infection was 13.3% which confirmed our result. They reported *Tinea capitis* (54.1%) was the most common fungal infection followed by *Tinea Pedis* (23.8%) and *Tinea corporalis* (8.9%) respectively.(7) They reported *Trichophyton verrucosum* (32.8%) was the most common dermatophyte isolated from the scalp, whereas, our study showed that *Trichophyton mentagrophytes* (5.64%) was the most common dermatophyte isolate in patients with *Tinea capitis*. The most common sites of fungal infections in the present study were feet (25.12%), face and neck (14.66%) and hands (14.21%) respectively.(7)

Omidynia et al. performed a study from October 1991 to June 1992 in the Hamadan province of West Iran to determine the extent and causative agents of dermatophytoses. Of 7,495 individuals, 681 (9%) were suspected of having cutaneous mycoses. From those, 259 individuals were infected with dermatophytes. *Tinea capitis* was observed in 62.9%, and *Tinea corporis* in 10.4%. *Tinea* was the most common type of dermatophyte. The most common isolated species reported by them were *Trichophyton verrucosum*, 78 (54.1%) and *Trichophyton schoenleinii*, 48 (33.3%), while, from 4,414 cases in our study, 620 (14.04%) cases had dermatophyte infection; of these, 8.54% involved *Tinea capitis*. Among the whole fungal infection in our study, 118 (2.67%) cases had *Tinea capitis* and 32.39% had fungal infection on the other sites of their body.(8)

In Falahati et al's study, epidemiology of dermatophytoses in an area south of Tehran, Iran was investigated. They found that the prevalence of dermatophytoses was 13.5%.

They revealed that *Epidermophyton floccosum* was the most frequent dermatophyte isolated (31.4%) followed by *Trichophyton rubrum* (18.3%). The frequency of all of types of *Tinea* was higher in males than in females.(9) Dissimilarly, in our study, involvement of females to all types of *Tinea* was higher than males.

In Lari et al.'s study, characteristics of dermatophytoses in 382 children under 16 years in an area south of Tehran, Iran was investigated. They found *Trichophyton violaceum* was the most frequent isolate (28.3%) followed by *Microsporum canis* (15.1%), *Epidermophyton floccosum* (15.1%), *Trichophyton rubrum* (13.2%), *Trichophyton mentagrophytes* (11.3%), *M. gypseum* (7.5%), and *Trichophyton verrucosum* (5.7%). *Tinea capitis* (39.6%) was the most common type of infection, followed by *Tinea corporis* (30.2%).(10) In our study, most of the patients were older than 16 years and the mean age of females and males were 34.3±18.1 and 31.7±20.4 respectively ( $P \leq 0.001$ ). In a study by Aghamirian and Ghiasian during 2004-2006 in Qazvin, the prevalence and etiological agents of dermatophytoses was assessed in 1,023 subjects suspected to cutaneous mycoses. Dermatophytoses were identified in 348 (34%) patients. They revealed that *Epidermophyton floccosum* was the most frequently isolated species in 32.8% of isolates, followed by *Trichophyton rubrum* (18.1%), and *Trichophyton verrucosum* (17.2%). *Tinea cruris* (31.9%) was the most common type of infection that affected particularly male patients. *Tinea corporis* and *Tinea pedis* were observed in 20.7% and 19% of their patients (11). In our study, the prevalence of *Epidermophyton floccosum*, *Trichophyton rubrum* and *Trichophyton tonsurans* were 2.24%, 2.22% and 2.12% respectively which was different from results reported by them.

In a study performed by Khosravi et al., during 1986-1991 about Dermatophytoses in Iran, 12,150 cases were evaluated. Of those, clinical diagnosis was confirmed in only 9,345 cases by laboratory examination. From 9,345 positive samples, 1,633 cases were positive only by direct microscopic observation and 429 only by culture and 7,283 by both techniques. *Tinea corporis* and *Tinea cruris* were the most common dermatophytoses respectively.(12) Although, our study was performed during a 5 year period, from a total of 4,414 cases, 4,309 cases had direct examination and culture and the most sites of infection were foot followed by face and neck, hands and groins, which was different to their results.

Edalatkha et al., evaluated the prevalence of various species of Dermatophytes in 15,498 patients referring to the Dermatology Clinic of Tabriz Haft-e-Tir Hospital. Only 1,562 (10%) were suspected to have fungal infection and only 559 cases had positive culture. The prevalence of Trichophytosis was 91.4%. *Tinea capitis* and *Tinea corporis* were the most common clinical form of the disease. *Trichophyton verrucosum*, and then *Trichophyton schoenleinii*, *Microsporum canis* and candidiasis were the most infecting agents. Their results were different from ours.(13)

Tabatabai et al., studied the epidemiological and other contributing factors on the establishment of fungal infections among patients referred to Rasul-e Akram Hospital in Tehran. Direct examination and culture was performed on 500 patients suspected of fungal infections. They identified a total of 253 fungi which included 51.4% dermatophytes, 20.1% Erythrasma, 18.6% candidiasis, 8.3% pityriasis versicolor and 1.6% nail Aspergillus. In the present study, we found no Erythrasma infection, and Malassezia infection, which in their study was 8.3%, whereas we reported it in 0.2% of our patients. The cause of difference was because of the accurate diagnosis of Malassezia infections in clinical examination and less need to send the suspected samples to the laboratory. Also, nail infection in our study was 0.18%. (14)

## Conclusion

It seems that the main cause of different results in our study is related to the Mycology Laboratory of Toba Clinic in Sari, Iran as a referral laboratory in Mazandaran Province and this center receives samples from all specialists in medical fields. On the other hand, because dermatologists are more expert in reporting the suspected cases of fungal infections, the significant differences may be due to the role of dermatologists where most of the patients are referred to the reference Mycology Laboratory. Preparing electronic sources for data gathering is recommended, because most of the data reported after 2009 were recorded manually. The causes of higher prevalence of fungal infection among females than males may be due to more referring of females to this center.

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# Self-compassion, mental health and work ethics: mediating role of self-compassion in the correlation between work stress and mental health

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## Abstract

This study examines the relationship between self-compassion, mental health and work ethics and the mediational role of self-compassion in relation to work stress and mental health.

114 employees of the Hyper-Star were recruited via convenience sampling and responded to the scales of Self-Compassion (SC), Anxiety- Depression (AD), Self-esteem (SE), Work ethics (WE) and Perceived Stress (PS). Data was analyzed by Pearson Correlation Coefficient and path analysis. According to the results, perceived stress has a direct relationship with anxiety and depression and a reverse correlation with work ethics, life satisfaction and self-esteem.

Despite the high and meaningful correlation of self-compassion with both mental health and perceived stress in isolation, self-compassion does not have any mediational roles with these factors.

After considering cultural relationships, according to French management system and employees of Iranian nationals, it can be concluded that self-compassion variable has a lack of consistency with Iranian culture and cannot play a role in terms of Work ethics. This clarifies the taking effect of self-compassion from culture and inconsistency of the Persian culture on self-compassion.

**Key words:** Mental Health, Perceived Stress, Work Ethics, Self-Compassion

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## Introduction

Health is a quality of life, which is not easy to define and its real-time measurement may be impossible. Experts have presented different definitions of this concept; although all definitions have almost a common subject, which is self-responsibility and choosing a healthy lifestyle (Babapoor, 2002).

Mental health is in fact something more than just lack of mental diseases. According to World Health Organization (WHO), mental health refers to ideal level of physical and spiritual well-being and ideal social function and is not just associated with lack of mental diseases and weaknesses. The main concepts of mental health include individual wellbeing, self-efficacy understanding, independence, competition, collective dependence and ability of cognition and recognition of feelings and logic of each other. The elements are also recognized as a level of wellbeing, since people can cope with daily and routine stresses, work creativities and healthy cooperation and competition and working with each other through understanding the abilities of each other (Frunk M, 2003).

Mental health is a level of mental wellbeing in absence of mental disease. Mental health can include interpersonal capabilities to enjoy life and to make balance between life and activity (Garooosi and Shabestari, 2011).

Stress exists everywhere and has a highlighted presence in the modern day stress. Independent from the real meaning of stress, the today's modern societies? Stress is a deeply serious problem. Real or imaginary, right or wrong, less or more; stress is not a simple and ignorable problem (Krieger et al, 2016).

Today's definition for stress includes the pressure or demand on a person, often more severe pressure than the abilities of a person to cope with. Work stress happens when there is no adjustment between abilities and resources of individuals to solve the needs. The self-thinking, and self-report caused by thinking, is e in consistence with objective data and statistical analyses caused by objective data and has high validity. One of the most common problems in workplaces is work stress. Work stress can affect the function of individuals while working and can also decrease individual performance. On the other hand, the same work stress can cause lack of observance of work ethics and can also endanger mental health (Saeidi, Ghorbani, Sarafraz and Sharifian, 2013).

Self-compassion is a warm and acceptance mode against some aspects of life disliked by the person and needing 3 main elements including firstly, self-kindness, and self-judgment; secondly, common humanity against isolation and thirdly, mindfulness against over-identification. Self-compassion means extension of compassion to the innate self of person against incompetency, failures and innate suffering. Self-compassion is a different concept from self-commiseration, since self-commiseration is caused by lack

of self-confidence, sacrifice and competency to cope with non-adaptive conditions. Self-compassion has different effects from self-esteem, which is a self-assessment feeling against the innate self (Krieger, Berger and Holtforth, 2016). Hence, this study has analyzed the correlation of stress and work ethics and mental health. Naturally, the correlation should be negative based on the variables. In other words, the more the stress is, the lower mental health and work ethics would be. Along with analysis of the correlation between the said variables, the role of self-compassion is analyzed as a variable moderating the correlations of other variables.

According to the promotion of activity of foreign companies in Iran and enforcement of regulations and management of non-Iranian people among Iranian employees, mental health and self-compassion, stress and work ethics are analyzed in the Maf Pars (Carrefour) Hyper Star Chain Store as a successful and powerful organization. Also, through comparing the results with other regions and points of the world, the role and power of the said variables and the probable variables involved in the study are specified and the research hypotheses are tested.

Alirezaei, Masah and Akbari (2012) have studied the correlation between work conscience and job performance. A correlation study was done on a sample consisting of 130 employees of Khomeinishahr and a total number of 55 employees were selected randomly. Data collection was done using Big Five-factor personality test of Costa and McCrea, duty checklist of Byrne et al and underlying performance analysis checklist by Conway. The data were analyzed using Pearson correlation and stepwise regression analysis. The results showed that dimensions of work conscience (reliability and success-orientation) are in positive and significant correlation with job performance (duty and underlying performance). The results of regression analysis showed that among dimensions of work conscience, reliability has the ability to determine the variance to 32% (Narimani, Fallah, Narimani and Hassanpour, 2012).

Soleimani, Abbaszadeh and Niaz Azari (2010) studied the correlation of work ethics with job satisfaction and job stress of employees. The sample size in this study was estimated at 216 people based on Morgan table, and sampling was done using cluster and random sampling method. For purpose of data collection, 3 questionnaires were used including 1) work ethics scale 2) Robins' job satisfaction questionnaire and 3) job stress questionnaire. Collected data was analyzed using correlation coefficient and multivariate regression. The results obtained from the study showed that there is positive and significant correlation between perception of employees of dominant ethics of work and their job stress.

The results of regression study showed that 3 dimensions of work ethics (attachment, perseverance and seriousness at work) can be significant predictors for job stress of employees (Garooosi and Shabestari, 2011).



Martin Holtforth et al (2016) studied the relationship of self-compassion and depression. The previous studies show that self-compassion is in negative correlation with depression symptoms. Although the studies have mentioned clearly that lack of self-compassion can itself result in depression symptoms, no study has been conducted till now to confirm that lack of self-compassion is a cause of depression. To test the hypothesis, 125 depressed outpatients under behavioral therapy were used and self-compassion and depression were measured using self-report method in intervals of 6-12 months. The results showed that lack of self-compassion can undoubtedly lead to depression symptoms; although the limitation is that self-compassion can't be its absolute reason. It means that a third factor is also involved in this field and it could be found that lack of self-compassion can increase vulnerability of individuals against depression.

A study has been conducted with the objective of studying the relationship of job stress, job burnout and quality of life of employees with organizational life atmosphere satisfaction in the Mohaghegh Ardabili University in the form of descriptive correlation research. In this study, 112 employees were selected as sample using random sampling. For purpose of data collection, questionnaires of organizational atmosphere, job stress, job burnout and quality of life were used. The results showed that there is negative correlation between job stress and quality of life and there is positive correlation between job stress and job burnout (Hajloo, 2012).

Pauley and McPherson (2010) studied the experience and meaning of compassion and self-compassion in people with depression and worry. 10 participants were selected, who had depression symptoms based on DSM-4 scale and were surveyed using semi-structural interview using items with basis of self-compassion. The results showed that people with high self-compassion have higher mutual understanding and can show better response to clinical treatments.

## Methodology

### Population, sample and sampling method

Samples in this study consisted of 114 (77 female and 37 male) employees with education level below diploma to MA in 6 levels including advertising seller, decoration employee, administrative employee, supervisor, department manager and CEO, selected using convenience sampling method. Sampling was done using convenience random sampling method and the inclusion criteria included to be employed in HyperStar Store. Maf Pars (Carrefour) Hyper-Star Store, the first branch of which was established in 2009 in Iran, is the largest chain store in Iran with the investment of Carrefour France to 75% and Majed Al-Fatim Emirates investment to 25%. The regulations are derived from Carrefour France and all French Senior Directors. The employees in the sales department and central office in this center are Iranian and the majority of employees are newly graduated people. The main job advantage of this

complex is submitting the talented individuals abroad for better job opportunities and advantages.

### Measurement instrument

The participants filled out the 140-item scale and the subscales analyzed in this checklist as mental health subscales included anxiety and depression, self-value and life satisfaction, perceived stress and work ethics.

**Self-compassion scale (SC):** (Neff, B, 2003) contains 26 items and the responses in this scale are ranged in a 5-point Likert scale from 1 (almost never) to 5 (almost always). The scale measures 3 bipolar components in frame of 6 subscales of self-kindness (5 items), self-judgment (5 reverse items), mindfulness (4 items), over-identification (4 reverse items), common humanity (4 items) and isolation (4 reverse items). Mean value of the points of 6 components of self-compassion are summated and a total value of self-compassion is obtained. The studies have shown high convergent validity (Neff, Kirkpatrick and Rood, 2007); discriminant validity, internal consistency and test-retest reliability of this test (Neff, A, 2003). Cronbach's alpha of the initial version of this scale is reported as 0.92 and Cronbach's alpha of this scale in a study in Iran is reported as 0.90 (Anjedani, 2010). Moreover, the correlation coefficient of this scale and Rosenberg's self-esteem scale is obtained at 0.85 in Iran (Ghorbani et al, 2009). Cronbach's alpha of self-compassion scale in this questionnaire is equal to 0.81.

**Rosenberg's Self-esteem Scale (1965):** this is one of the instruments widely used for measurement of self-esteem. The scale contains 10 items and each item refers to self-preference and self-acceptance. The responses are scored from 0 (mostly false) to 4 (mostly true). If the sentences are not the characteristics of a person at all, the respondent chooses "mostly false" and if the sentence is absolutely the characteristics of the respondent, they choose the option "mostly true"; otherwise, the options between the two scales are selected. Items 1, 3, 4, 7 and 10 are scored positively and items 2, 5, 6, 8 and 9 are scored negatively. The previous studies have reported reliability of alpha of this scale from 0.72 to 0.88 (Gary Little, Williams, Hancock, 1997). Other studies have also shown internal reliability of this scale with retest correlation to 0.61 during a 7-month period. In the study conducted by Ghorbani et al (2002), correlation coefficient of the scale and self-knowledge scale in Iranian samples is reported at 0.56 (Anjedani, 2010). Rosenberg's Self-esteem Scale is a widely applicable scale with high validity and reliability for evaluation and the previous studies have shown its high reliability in the Iranian population (Yamini and Tahriri, 2005, quoted from Hamzavi, 2009). Cronbach's alpha of self-esteem in the present study is obtained at 0.70 (Table 1 - next page).

**Satisfaction with Life Scale (SWLS):** this scale was made for evaluation and cognitive judgment of total satisfaction of person with life and not a special domain of life (Pout and Diener, 1993; Diner et al, 1985). Life satisfaction is different from being happy and positive emotions,

can be emotional aspects of life (Diner et al, 1999). This scale contains 5 items scored in 5-point Likert scale from 1 (totally disagree) to 5 (totally agree). The studies have reported internal reliability of this scale in the range 0.8 to 0.89. Analysis of factors in this scale showed one factor including total assessment of a person about life (Matheny et al, 2002; Diner et al, 1985). In this study, Cronbach's alpha is obtained at 0.83 (Table 1).

**Multidimensional Work Ethic Profile (MWEPE):** the 65-items multidimensional work ethic profile (MWEPE) scale is used including the items related to work and 7 subscales including self-confidence, ethics, hardworking, self-orientation at work, waste of time and delay in enjoying. This scale contains 5 phrases scored in a 5-point Likert scale from 1 (totally disagree) to 5 (totally agree). Studies have reported internal reliability of this scale in the range of 0.8 to 0.89 (Van Ness et al, 2010). Cronbach's alpha for the work ethic profile in this study is obtained to 0.95 (Table 1).

#### **Anxiety and Depression Scale (AD):**

This scale was made by Costello and Comrey (1967) and is applied to measure depression and anxiety as a scale. AD scale contains 23 items: 9 items measure anxiety as a feature and 14 items measure depression. Respondents should determine their agreement with each item using 5-point Likert scale. Validity and reliability of the scale is confirmed by Ghorbani et al (2002), so that the anxiety scale has Cronbach's alpha to 0.74 for Iranian trials and 0.78 for the US trials. Moreover, for depression scale, Cronbach's alpha is obtained at 0.88 in Iranian trials and is obtained at 0.91 in American trials. In another study (Ghasemipoor and Ghorbani, 2010), Cronbach's alpha for anxiety is obtained at 0.78 and is also obtained at 0.88 for depression and this shows high reliability of this scale. In this study, Cronbach's alpha for depression was obtained at 0.74 and for anxiety, 0.86.

#### **Perceived stress scale (PSS):**

Perceived stress scale contains 14 items and is among the limited instruments assessing overall stress level. The scoring type of this scale is based on 5-point Likert scale from 1 (never) to 5 (most of the time). The scores are named reversely for items 13, 10, 9, 7, 6, 5 and 4. The lowest score obtained is 0 and the highest score is 56. Higher score shows more perceived stress. Easy items are for purpose of understanding the answers and variables. PSS has high internal consistency and validity and reliability before and after test and predicting correlation of self-report and behavioral criteria. Cronbach's alpha for this scale is obtained in 3 studies respectively at 0.84, 0.85 and 0.86 (Cohen et al, 2003). Cronbach's alpha for perceived stress in this study is obtained at 0.72 (Table 1).

PSS is very close to score and the effect of life event. PSS can be applied to assess stress as a reason in behavior or disease.

#### **Scoring style:**

The scale is scored using 5-point Likert scale (totally agree, partially agree, neither agree nor disagree, partially disagree, totally disagree). Each item is scored based on concept of the item from 1-5. As there are positive and negative items in the scale, the scoring is reverse in negative items, so that point 5 is given in an item to the option "totally agree" and again one point is given to "totally agree" in another item. The trials read each item and announce agreement or disagreement based on options. There is no time limitation to fulfill the scale.

## Results

In Table 1, mean value, standard deviation (SD) and Cronbach's alpha associated with psychological variables (mental health, anxiety, depression, self-esteem, life satisfaction, perceived stress and work ethics) are shown in relation to the participants in this study. According to the Table 1, Cronbach's alpha of all structures is obtained in range 0.70 to 0.95, which shows high reliability of these structures.

#### **Testing hypotheses**

To test the research hypotheses, at the outset, two methods of Pearson Correlation and path analysis were used. The results in Table 2 show the correlation coefficient of perceived stress scale with self-compassion and relevant scales of mental health.

## Discussion

The results obtained from this study show that perceived stress is in negative correlation with mental health. In the statistical population of Hyper-Star Stores, according to special conditions and strong regulations, any kind of partial mistake at work receives a warning and the employee will be fired after 3 warnings. According to the conditions, perceived stress is high to take responsibility for negligence or even a small mistake of employees can intensify stress. According to the investigations, the correlation between perceived stress with life satisfaction and self-esteem is negative and its correlation with depression and anxiety is positive. Therefore, perceived stress is in negative correlation with mental health. This result is consistent with findings of Hajloo (2012) in a study with the objective of studying the correlation between job stress, burnout and quality of life of employees with satisfaction with organizational life atmosphere at the Mohaghegh Ardabili University. In this study, the results showed that there is negative correlation between job stress and quality of life satisfaction and there is positive correlation between job stress and job burnout. Under stressful conditions, employees have lower tolerance than at normal times and as a result, they have lower mental health under stressful conditions.

According to the investigations, self-compassion and work ethics are not significantly correlated.

**Table 1: Mean, SD and other statistics relevant to psychological variables**

	Number	Mean	SD	Cronbach's alpha
Self-compassion	114	3.11	0.48	0.81
Work ethics	114	3.70	0.50	0.95
Depression	114	2.89	0.72	0.74
Anxiety	114	2.32	0.72	0.86
Perceived stress	114	2.58	0.47	0.72
Life satisfaction	114	3.19	0.83	0.83
Self-esteem	114	3.48	0.48	0.70

**Table 2: Correlation coefficients of perceived stress and self-compassion with mental health scales (anxiety, depression, self-esteem and life satisfaction)**

Row		1	2	3	4	5	6	7
1	Perceived stress	-						
2	Self-compassion	-0.39**	-					
3	Work ethics	-0.20	0.18	-				
4	Depression	0.42**	0.41**	0.00	-			
5	Anxiety	0.57**	0.48**	-0.13	0.5**	-		
6	Self-esteem	-0.40**	0.47**	0.18	-0.39**	-0.57**	-	
7	Life satisfaction	-0.46**	0.21*	0.05	-0.18	-0.60**	0.36**	-

\*\*p<0.01 \*p<0.05

According to the strong correlation of culture with self-compassion, the variable is consistent with the existing criteria in Iranian culture.

With the analysis of correlation between perceived stress and work ethics, the investigations show that stress is in negative and reverse correlation with work ethics and hence, increased stress can cause declined work ethics.

According to the findings of Soleimani, Abbaszadeh and Niaz Azari (2010) on studying relationship of work ethics with job satisfaction and job stress of employees in 216 samples using cluster and random sampling; the results showed that there is significant and negative correlation between perception of employees of ruling ethics of work and job stress.

Through investigation of correlation between self-compassion and mental health, the self-compassion is in negative correlation with subscales of mental health including anxiety and depression and is in positive correlation with self-esteem and life satisfaction. Hence, self-compassion is in positive correlation with mental health.

Pauley and McPherson (2010) studied the experience of self-compassion in individuals with depression and anxiety and took semi-structural interview using items based on self-compassion for 10 companies and found that individuals with high self-compassion have better mutual understanding and can show better response to clinical treatment.

According to investigations of Holtforth et al (2016), according to cross-sectional studies, self-compassion is in negative correlation with depression. Although previous studies mention clearly that lack of self-compassion can lead to depression symptoms, no study has been conducted till now on this basis, that lack of self-compassion is a cause of depression. To test the hypothesis, 125 depressed outpatients under behavioral therapy have been used and self-compassion and depression are measured using self-report method in intervals of 6-12 months. The results showed that lack of self-compassion can undoubtedly lead to depression symptoms; although the limitation is that self-compassion can't be its absolute reason. It means that a third factor is also involved in this field.

According to findings of Hajloo (2011), there is negative correlation between job stress and quality of life and life satisfaction.

Correlation studies show positive correlation of self-compassion with life satisfaction of individuals. These results are also true in cultures of North America and Thailand and China (Neff, 2008). According to the investigations, the mediating role of self-compassion with perceived stress and work ethics is not confirmed. According to sample information derived from statistical population of Hyper-Star Store with systematic French management, lack of respecting human resources and rapid replacement of newcomers instead of former employees, and lack of respect of employer for employees have led to collapse of trust of human resources in the organization and reduced self-esteem feeling and the reduced self-esteem can lead to increased perceived stress. Increased perceived stress can decline work ethics. However, according to high



correlation between the main variables, because of lack of consistency of self-compassion scale with Islamic-Iranian culture, this scale has no mediating role. The mediating role of self-compassion is not confirmed in the correlation between perceived stress and mental health. Perceived stress is in high correlation with mental health. Although the correlation between the two variables is a very strong correlation, self-compassion has no predicting ability in regard to mediating role between perceived stress and mental health.

According to high perceived stress and low mental health and work ethics in Hyper-Star, the question is why employees continue working at such a place even with very high volume of work and low self-esteem? The evidences shows that because of the very excellent CV of the foreign company compared to other companies and because of providing an opportunity to submit employees abroad and according to use of newly graduated people, they accept to tolerate conditions and this shows low self-compassion of employees.

### Research Limitations

For sampling purpose, convenience sampling method is used and just those employees are used, who were ready to fill out the questionnaire. Convenience sampling method can decrease generalizability of results. According to this issue and that the author is employed in this store and although the author has promised to preserve their privacy, probability of wrong answers on behalf of some participants is high. According to employment of the majority of participants in the store and the crowd at the store during work hours and due to a large numbers of questions in the questionnaire, the participants may have become bored and be distracted and may have been unable to answer the questions properly.

### Suggestions for further studies

This study is done using convenience sampling method. To ensure data generalization, data collection using random sampling is suggested. According to French management of the organization among Iranian employees, the suggestion is to do further studies in Shahrvand Chain Stores with Iranian management and employees for better analysis of variables involved in the research and to study other aspects of mediating role of self-compassion. Hence, it could be possible to make better comparison of results and to generalize the results. Because of lack of correlation between self-compassion and work ethics and strong correlation of the two variables with the culture and according to rich Islamic context and integration of ethics with religious beliefs in Iranian culture and society, it would be better to study samples with scales of Muslim's Attitudes Toward Religious Scale and Muslim Experiential Religiousness in further studies and to compare the results.

Because of insignificant mediating role of self-compassion between mental health and work stress and mental health with work ethics, it would be better to take a reassessment

of a larger sample size. According to the analysis of correlation between self-compassion and culture and confirmation of correlations in this study, the suggestion is to take further study on investigating correlation between mental health and 3 factors including self-compassion, culture and work ethics.

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# Investigating the delivery type among primiparous women in Bandar Abbas according to the Health Belief Model

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## Abstract

**Introduction:** The past three decades have witnessed a growing rate of cesarean worldwide without causing any improvement in rates of mortality of mother and child. The majority of these deliveries have been due to non-medical reasons. Considering the optional delivery type, this research was conducted on primiparous women in Bandar Abbas based on the health belief model.

**Materials and methods:** The present descriptive/analytic research was conducted on 210 primiparous women visiting the healthcare centers of Bandar Abbas. Sampling was done based on randomized cluster sample selection method. The instrument was a questionnaire designed by the researcher based on the health belief model and perusal of the related literature. Data were collected by a questionnaire and analyzed using SPSS software version 16, chi-square and ANOVA tests. P value less than 0.05 was considered significant.

**Results:** From among the 210 participants, 73.8% of them were found to have had natural delivery, 26.2% had surgical delivery. The average age of mothers was  $24.56 \pm 4.96$

years (minimum 15 and maximum 43 years). Their average age of marriage was  $21.23 \pm 5.16$  years. No significant correlation was found between educational level, occupation, income and delivery type. A significant correlation on the other hand was observed between the constituents of health belief model and delivery types.

**Conclusion:** It appears that enacting appropriate instructional plans by the medical staff can be effective in raising women's susceptibility and perceived severity of the consequences of cesarean. Moreover, it can help to raise women's trust in their ability for natural delivery and to cut down on unnecessary caesarians.

**Key words:** delivery, primiparous women, health belief model, Bandar Abbas

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## Introduction

Natural (vaginal) delivery is considered as the best type of delivery in the majority of pregnant women. However, due to the increasing trend of caesarian (C-section) it is less welcomed than in the past. Although C-section is regarded as a great human achievement and has managed to save the lives of many mothers and infants over the past three decades it has grown vastly without lowering the mortality rate of mothers and infants (1). Unfortunately, there has been a rise of C-section and unnecessary medical interventions currently in such developing countries as Iran (2). In fact, unlike all surgery, C-section is accompanied by certain side effects which are occasionally truly hazardous (3). The mortality rate of C-section is seven times as high as natural delivery. Among its other side effects are uterine infection, postpartum bleeding, surgical problems and pelvic injuries (4). A body of research has indicated that the real rate of C-section in different countries such as developing countries is much higher than that recommended by WHO (10-15%) (5). In the U.S. the rate of C-section has risen from 20.7% in 1996 to 32.8% in 2011 (6). According to the statistics reported in 2013, the rate of C-section in Iran was 46% while the global standard is 5-15% (7). A great many researchers have indicated the high rate of non-emergent Caesarian surgeries in Iran (8-11). Afshari et al.'s investigation entitled 'A survey on the selection of delivery method by nulliparous pregnant women using Health Belief Model' in Samirom found significant divergences between the constructs of the model among the groups (12). Multiple factors have been mentioned in different studies as involved in the choice of the delivery type. Among them are the fear of painful natural delivery, fear of the side effects of natural delivery on the child, unawareness of the side effects of C-section, doctor's advice, prior experience of C-section, parents' higher education, occupation and ethnicity (12-17). One personally used model of behavioral change which is among the most practical theories is the Health Belief Model. One advantage is its inclusion of the construct that takes into account the key aspects of behavioral change (18). The Health Belief Model used as the key framework in the present research is one of the oldest behavioral change theories based on the principle that one shows healthy behavior once s/he feels the threat (the 'perceived susceptibility' construct); when s/he is aware of the hazards of the unhealthy behavior (the 'perceived intensity' construct); when they feel that showing the right behavior is to their own benefit (the 'perceived benefits' construct); when they realize that they can remove the barriers to healthy behavior (the 'perceived barriers' construct); and finally when they see themselves capable of healthy behavior (the 'perceived self-efficacy' construct) (19). The statistics from Hormozgan province showed that 42% of deliveries by C-section were performed in 2014. Considering these statistics and the wide gap between the actual rate of C-section and the ideal one there is a need for certain interventions to look into the factors involved in selecting the type of delivery according to this model. Appropriate instructional programs can help to promote safe and natural delivery. Therefore, this research aims to investigate the type of delivery in primiparous women

according to the constructs of the Health Belief Model.

## Materials and methods

This cross-sectional research is of a descriptive/analytic type and its population comprised all primiparous pregnant women who visited the healthcare centers of Bandar Abbas in 2015. The sample size was estimated through the formula

$$n = \frac{z^2 \sigma^2}{d^2}$$

(CI=95%, d=1 and attrition rate=10%) to be 210. The sampling method was clustering and the subjects in each cluster were selected through simple randomization. From among the 20 healthcare centers in Bandar Abbas, 12 were selected as clusters for the sampling. The ratio of each cluster was determined based on the population it covered. In the next phase, from among the women subjects, those who met the inclusion criteria were randomly selected and entered the study. The inclusion criteria were: primiparous women being pregnant for 28 weeks or more, no medical indications for C-section and consent to take part in the research. The exclusion criteria were incomplete questionnaires, termination of pregnancy. The data collection instrument was a questionnaire developed by the researcher based on the Health Belief Model. Cronbach's alpha was used to test the reliability of the questionnaire and in a pilot test the questionnaire was submitted twice (before and after a 10-day interval) to 30 subjects who met the inclusion criteria. The awareness section obtained a reliability of 89% while the constructs of the model gained a reliability coefficient of 81%. For the content validity, the comments made by five specialists in healthcare Sciences and Midwifery were used and the required adaptations were made to the items. The questionnaire consisted of three sections, the first of which entailed the subjects' demographic and socioeconomic information. The second section included the awareness items and those based on the Health Belief Model. The awareness questions of either delivery type were 15 in number. They were scored between 0 and 15. Each correct response would receive 1 and each incorrect response would score 0. An overall score between 0 and 5 meant a low awareness level; a score between 6 and 10 implied a moderate awareness level and a score between 11 and 15 pointed to a high level of awareness. The constructs of the model were to be rated in a 5-level Likert scale ranging from totally agree to totally disagree. The 'perceived susceptibility' construct (women's perception of the probability of affliction with the side effects of non-emergent C-section) consisted of 6 items in a 5-level Likert scale. Its score was between 6 and 30. A score between 6 and 14 would mean a low susceptibility while a score of 15-22 implied a moderate susceptibility and a score of 23-30 would be interpreted as high. The 'perceived severity' construct (women's perception of the barriers to natural delivery) included 10 items to be rated in a 5-level Likert scale. Its score was between 10 and 50. A score of 10-23 would be taken as low while a score of 24-37 would be interpreted as moderate and a score of 38-50 would be interpreted as high. The 'perceived self-



interpreted as moderate and a score of 38-50 would be interpreted as high. The 'perceived self-efficacy' construct (women's perception of the benefits of natural delivery) consisted of 10 items which were rated in a 5-level Likert scale as the overall score would range between 10 and 50. A score between 10 and 23 would imply a low perception while a score of 24-37 would mean a moderate perception and a score ranging between 38 and 50 would be taken as high. Mother's choice of the type of delivery was investigated through a behavioral intention item (having three choices: natural delivery, C-section, undecided).

Once the required permission was gained from the deputy of research at Hormozgan University of medical sciences the mothers' full consent to take part in the research was obtained orally. They were ensured of the confidentiality of the data they provided and the research was conducted according to all ethical issues. To see which type of delivery they actually finally opted for, they were followed up through phone calls after delivery. Data were collected by a questionnaire and analyzed using SPSS software version 16, chi-square and ANOVA tests. P value less than 0.05 was considered significant.

## Results

Among the 210 subjects, 149 (71%) decided to have a natural delivery, 36 (17.1%) decided to go for a C-section and 25 (11.9%) had not yet made up their mind. The average age of the mothers was  $24.56 \pm 4.96$  yrs. (minimum 15, maximum 43) and the average age of marriage was  $21.23 \pm 5.16$  years. 74 subjects (35.2%) had an academic degree (Table 1).

**Table 1: Distribution and significance level of the target variables in terms of the delivery type**

variable	Group	Natural delivery (f)	C-section (f)	Undecided (f)	Total f (%)	P-value
education	uneducated	4	0	0	4(1.9)	<b>.0263</b>
	Primary school	9	1	2	12(5.7)	
	Junior high school	12	3	0	15(7.1)	
	High school	27	5	9	41(19.5)	
	Diploma	46	11	7	64(30.5)	
	University	51	16	7	74(35.2)	
occupation	housewife	124	28	22	174(82.9)	<b>0.627</b>
	Blue-collared	1	0	0	1(0.5)	
	White-collared	20	5	3	28(13.3)	
	others	4	3	0	7(3.3)	
Income	low	22	3	2	27(12.9)	<b>.826</b>
	Average	82	21	17	120(57.1)	
	Above average	43	12	6	61(29)	
	high	2	0	0	2(1)	

The mean score of mothers' awareness of the benefits and barriers of delivery type was 6.63. 74 subjects (53.3%) had a low awareness level while 123 subjects (58.6%) had an average level awareness and 13 (6.2%) had a high awareness (Table 2).

**Table 2: Distribution of mothers' awareness level based on the constructs of the Health Belief Model**

variable	Low level F (%)	Average level F (%)	High level F (%)
Awareness	73(34.8)	123(58.6)	14(6.7)
Perceived susceptibility	58(27.6)	128(61)	24(11.4)
Perceived severity	27(12.9)	156(74.3)	27(12.9)
Perceived barriers	109(51.9)	91(43.3)	10(4.8)
Perceived benefits	8(3.8)	104(49.5)	98(46.7)
Perceived self-efficacy	30(14.3)	71(33.8)	109(51.9)

There was a significant correlation between the awareness score and selection of the delivery type ( $p=.011$ ). According to the statistics (Table 2), subjects' awareness of the type of delivery they selected based on the constructs of the Health Belief Model was average. A significant correlation was observed between the constructs of the model and the three groups of delivery type (Table 3).

**Table 3: Mean and standard deviation of awareness scores and the constructs of the Health Belief Model in terms of delivery type**

variable	Natural delivery	undecided	C-section	Total	P-value
	(SD) mean				
awareness	7.45 (2.61)	5.4(2.70)	6.13(2.67)	6.8(2.67)	.011
Perceived susceptibility	17.42 (4.02)	15.12(2.27)	14.91(2.90)	16.71(3.83)	<0.001
Perceived severity	18.98(3.96)	17(4.14)	16.47(3.22)	18.31(3.99)	<0.001
Perceived barriers	21.22(7.61)	26.6(4.87)	28.58(8.99)	23.12(8.15)	<0.001
Perceived benefits	37.10(6.01)	34.72(4.86)	35(5.97)	36.45(5.94)	.048
Perceived self-efficacy	14.96(4.27)	11.16 (3.07)	11.25(4.39)	12.67(4.39)	<0.001

## Discussion

In this research no significant correlation was observed between age and the type of delivery. Our findings were dissimilar to those reported by Piri et al. (22) and Mohammadi Tabar (23) which indicated a significant correlation of age and delivery type. However, the findings were not similar to those of Afshari and Ghaffari (12) Chang et al (20), Sharifi Rad et al (25), and Negahban et al (26). The findings were not similar to those reported by Mohammadi Tabar who found a significant correlation between education and the delivery type (23). No significant correlation between mother's age, occupation and education and deciding on the delivery type in the present research can be due to the homogeneity of the subjects in terms of age and being primiparous. According to the findings, the majority of mother subjects had an average or low awareness of the benefits or barriers of the types of delivery. Among the factors involved are the first experience of childbirth, lack of prior experience and insufficient pregnancy instructions from the health centers. In research by Yarandi et al. (27), Sharghi et al. (28), Ghaffari et al. (29), Afshari and Ghaffari (12), Sharifi Rad et al., mothers' awareness was average. The present findings were similar to the results of the body of research just mentioned (25). In their research, Faramarzi et al concluded that women's awareness of pregnancy is the result of other women's experience and that does not have a scientific basis. Therefore, negative attitudes towards natural delivery and unawareness of the side effects of C-section lead them towards selecting C-section (30). Awareness seems to be a key factor involved in health and is a primary step in deciding on a health-related decision. Therefore, due to the role awareness plays in selecting the type of delivery, holding consultation sessions with pregnant women and their spouses as well as making them aware of the side effects and hazards of C-section by medical centers can be helpful. The results revealed a significant divergence between the perceived susceptibility and severity scores. These findings were consistent with the results gained by Sharifi Rad et al. (25), Pakenham et al. (2006) (13), Fuglenes et al. (2009) (31), Afshari and Ghaffari (2014) (12). It is estimated that mother's perceived susceptibility and threat of the side effects of each delivery type on both mother and child can affect their choice of delivery. There was a significant correlation between the perceived benefits construct of the model and the types of delivery in the present research. The

natural delivery group had a higher mean score. According to the findings, this was not far from expectation. Mothers who had a higher score of perceived benefits opted more for the safe natural delivery. On the other hand, in terms of perceived barriers as one component of the Health Belief Model the higher score was that of the C-section group. In fact, women who intended to have a C-section viewed more barriers on natural delivery. The findings of the present research were consistent with those reported by Afshari and Ghaffari (12), Negahban et al. (26), Bagheri et al. (32) that mentioned the pain of natural delivery (perceived barriers) as a key factor involved in the choice of the delivery type. They are also similar to the findings found by Zamani et al. (33) as well as Khorsandi et al. (23). The above-mentioned body of research indicates that the perceived barriers and benefits can affect the choice of the delivery type. Accordingly, pregnant women go for the natural delivery once they: 1. perceive fewer barriers, 2. perceive many benefits for natural delivery, 3. feel the threats of C-section and its health-related hazards for both mother and child, 4. are encouraged by those who care to opt for natural delivery. Therefore, making proper decisions to remove the barriers to natural delivery can be effective with this respect. Another finding of this research was the significant correlation of the perceived self-efficacy score and the types of delivery. In the group which intended to have a natural delivery the self-efficacy score was higher. In a study by Afshari et al, the mean score of self-efficacy in the natural delivery group was higher than the C-section group (12). In Dilks and Beal's investigation, women with a higher self-efficacy score had a higher tendency towards natural delivery (35). Ridley et al's research indicated that the self-efficacy score of women who had a prior experience of C-section was lower than those who experienced natural delivery after a C-section (36). In their research, Khorsandi et al pointed out the role of self-efficacy in opting for the type of delivery is the fear of natural delivery (34). Therefore, appropriate strategies for promoting pregnant women's perception of the capability of natural delivery as well as instructions during pregnancy can be effective in this respect(37,38).

## Conclusion

According to the findings of this research, the majority of mothers were shown to have an average or low level of awareness of the negative side effects of the C-section. It seems that the implementation of the right instructional programs by the medical staff helps to raise women's perceived susceptibility and severity of the side effects of C-section. It also helps increase their trust in their capabilities of a natural delivery which cuts down the rate of unnecessary C-sections.

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# Relationship between Health Literacy and Life Style of Women in Khomeinishahr, Iran: A Cross-Sectional Study

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## Abstract

**Introduction:** Health education and lifestyle are factors affecting health. This study seems necessary to assess health literacy, determine lifestyle (based on four dimensions of nutrition, physical activity, interpersonal relations, and mental health) as well as the relationship between lifestyle and health literacy of 30 to 59 years old women referred to health care centers in Khomeinishahr, Isfahan, Iran.

**Materials & Methods:** In this descriptive-analytical study, 420 women between 30 to 59 years old, of 11 health care centers, were selected randomly. In this study, a standardized three-part questionnaire was used the validity and reliability of which has already been approved. The questionnaire consisted of three parts including demographic information including age, marital status, education level, economic status and health situation; lifestyle questionnaire and Functional Health Literacy questionnaire for adults. Data analysis was down by using descriptive and analytical statistics (Pearson correlation and multiple regressions) through SPSS 16 Software.

**Results:** The mean age of participants was  $39.69 \pm 8.06$  years old and 56.7% had an education level of under diploma. According to regression analysis, there was a statistically significant relationship between health literacy and dimensions of nutrition, physical activity, and mental health. There was no significant relationship between health literacy and interpersonal relationships. Regression analysis using Enter method showed that health literacy as predictor variable explains 31.2% of variance of lifestyle and its dimensions in women.

**Conclusion:** Nutrition, physical activity and mental situation were improved with increasing the level of health literacy. Therefore, education and interventions in this group of people is recommended to improve health literacy.

**Key words:** Life Style, Health Literacy, Women.

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## Introduction

Undoubtedly, lifestyle is one of the most significant factors affecting health (1). According to a comprehensive approach, health protective behaviors, regarding risk elimination and prevention, and health promoting behaviors are considered as two complementary parts of a healthy lifestyle. According to scientific evidence, choices and lifestyle of individuals may effect on their health and longevity (2). The term "lifestyle" which was introduced by Alfred Adler the Austrian psychoanalysts and founder of individual psychology school, is an underlying concept that is usually used to describe life method of people reflecting a wide range of values, beliefs, and social activities that affect health (3).

According to statistics related to death reasons, 53% of mortality causes relate to lifestyle of individuals (4). World Health Organization believes that it is possible to cope with numerous risk factors that cause death by changing and correcting lifestyle (5). Unhealthy nutrition, sedentary lifestyle and smoking can be named as some of the risk factors in chronic diseases. Removal of these risk factors may prevent early heart diseases, heart attack and diabetes type 2 in up to 80%, as well as 40% of cancers (6). On the other hand, health literacy has been increasingly considered as an effective factor for improvement of health implications and reducing inequality in health during the recent decade (7). Health literacy is a new concept that is used by many experts in both education and health majors. Health literacy is based on the idea that both health and literacy plays a vital role in daily life (8).. Health literacy is based on a series of abilities encompassing a range from the communicational base to a critical form. Natbeam (2000) defined three certain levels of health literacy including basic or functional health literacy that consists of some skills such as reading and writing requiring for effective function in a field of health; communicational or interactional health literacy consisting of advanced social and literary skills that enable the person to participate in health care actions, extract data and infer the concept from different forms of communication and use information to change situations; of critical health in which, the ability of critical analysis and use of information for engagement that overcomes structural obstacles of health (9).

Health literacy, as a social health component, is not just a technical subject consisting of reading and calculation skills, but also is the implication of interactions between individuals, culture and the society they live in. Cultural resistance is considerable in approaches to health care and understanding them, listening skills, speaking and writing, familiarity with language and concepts related to health, information and subjects to achieve health literacy (10).

According to studies conducted in recent decades, health literacy is a better predictor for health status compared to education, socio-economic situation, job, and race or gender (11). Health literacy enables individuals to have appropriate performance using advanced cognitive-social skills in new

and unknown situations related to health (12). Previous studies conducted in centers that provide services showed that patients with inadequate health literacy participate less in screening processes and less following of drug prescriptions and also have weaker health implications (13). Results obtained from the study conducted by Ford et al. indicated a lower percent of adults who had healthy life style in USA during 1996-2007 (14). Results obtained from a study of Tamakoshi et al. showed a reverse relationship between 6 factors of healthy lifestyle (no-smoking, no alcohol use, one hour daily walking, enough sleep about 6.5-7.4 hours, daily intake of vegetables, and normal body mass index), and mortality due to any reason, in men and women, so that these factors could reduce mortality up to 49% (15). Tokuda et al. conducted a study and showed a weak relationship between health literacy and physical-mental health status (16).

According to the mentioned points about the importance of lifestyle and health literacy as two significant factors affecting health, as well as the important role of women, who are vulnerable population, in health of society and family, it is essential to be aware of the health literacy level and lifestyle situation to plan and perform effective interventions in order to improve health. Therefore, this study aimed at evaluating health literacy and life style situation based on four dimensions of nutrition, physical activity, interpersonal relationships, and mental health as well as determining the relationship between lifestyle and health literacy in women referring to healthcare centers in Khomeinishahr, Iran during 2016.

## Materials and Methods

### Study Design and Population

This descriptive-analytical study was conducted through cross-sectional method on 30-59 years old women referring to healthcare centers in Khomeinishahr during 2016. Random sampling method was performed in 11 healthcare centers.

### Inclusion & Exclusion Criteria

Inclusion criteria consisted of age range of 30-59, voluntary participation, conscious consent, and minimum literacy of writing and reading; exclusion criteria consisted of lack of cooperation to fill out the questionnaire.

### Ethical Considerations

Research aims were explained to participators precisely and they were ensured about confidentiality of their information. Sample members entered into the study after announcing their consent on paper.

### Instrument & Scoring

To collect data, questionnaire was used in this research; this questionnaire consisted of three parts including 1- demographic data (age, marital status, education level, economic status, and health status), 2- questionnaire of adulthood lifestyle considering 4 lifestyle dimensions, and 3- questionnaire of functional health literacy of adults. The questionnaire of adulthood lifestyle has been designed

by Mehdipoor and its validity and reliability have been confirmed. This questionnaire was designed based on 4 dimensions of lifestyle including nutrition, physical activity, mental health, and interpersonal relationships and each of them consist of 10 questions based on a 4-point Likert Scale; the allocated scores are variable at range of 0-3 in which, option "always" is given score 3, "sometimes" score 2, "rarely" score 1, "never" score 0. Scores are calculated based on 120 after obtaining results (17). To examine health literacy of patients the short version of functional health literacy of adults' questionnaire was used. This questionnaire had been localized in previous studies and its validity and reliability had been confirmed; reliability of this questionnaire was reported as 0.69 for the calculation part and 0.78 for the comprehension part using Cronbach's alpha (18). This instrument is one of the most reliable health literacy questionnaires around the world. Validity and reliability of this questionnaire was also confirmed in the study of Baker; its reliability obtained as 0.68 and 0.97 for calculations and reading comprehension, respectively using Cronbach's alpha (19). Functional Health Literacy in Adults Questionnaire consists of 40 questions as well as two parts of reading comprehension and calculation. Ability of participants to read and understand two texts was examined in the reading comprehension part that consisted of 36 questions and each question had 2 scores; total score was calculated between 0 and 72. In the calculation part, the ability of understanding and performing based on practitioners' recommendations requiring calculations was examined. This part consisted of 4 health orders and 4 questions that were given 1 score and total score was obtained in a 0-4 range. Of total score obtained from these two parts, total score of health literacy obtained was a score between 0 and 100 so that functional health literacy of participants was divided into three parts of inadequate health literacy (0-53), border line (54-66), and adequate health literacy (67-100). Questionnaires were filled out through interview with patients considering a 20-40 minutes session for participants.

### Data Analysis

Ultimately, data obtained from questionnaires was entered into SPSS 16 Software then analyzed using descriptive statistics and tests including Pearson correlation, independent t test, Spearman correlation, and multiple regression analysis.

### Findings

Results of this study showed mean age of studied women at range of  $39.96 \pm 06$  (30-59); 45.7% had under-diploma degree and 12.4% had academic education. In terms of economic status, 58.8% were middle class, 26.4% were poor, and 0.5% were rich; 95% were married and 2.8% were widow or divorced (Table 1 - next page). Mean score of lifestyle among participants obtained was  $67.76 \pm 11.09$ ; according to the obtained scores in different lifestyle scopes, nutrition was at an average level with mean of  $19.68 \pm 3.21$ , physical activity was at lower-average level with mean of  $6.60 \pm 5.54$ ; mental health was at higher-average level with mean of  $20.93 \pm 4.85$ , and interpersonal relationships was at a higher-average level with mean of  $20.62 \pm 5.17$ . Average

level of total health literacy of women obtained was 63.89. Mean score of health literacy among participants obtained was  $21.97 \pm 7.34$  and  $2.67 \pm 0.92$  for reading comprehension and computation parts, respectively.

As can be seen in Table 2, there is a significant correlation between lifestyle and dimensions of physical activity, nutrition and health literacy of women in general and significant correlation between lifestyle and each of the dimensions of reading comprehension and calculations; while Pearson correlation coefficient did not indicate any significant relation between interpersonal relationships, total health literacy, reading comprehension, and calculations.

Findings in Table 3 were obtained from regression analysis using Enter method. Health literacy is a predictor variable that explains 31.2% of variance of lifestyle and its dimensions in women; therefore, the observed F is significant at level of  $P\text{-Value} < 0.05$ ; hence, regression can be generalized to statistical population.

According to the findings, health literacy has a direct effect on lifestyle dimensions including nutrition, physical activity, and mental health with coefficients of 0.058, 0.20, 0.074, respectively so that these values have been statistically significant ( $P\text{-value} < 0.05$ ); while health literacy of women had a minor effect on interpersonal relationships with affecting coefficient of 0.009 ( $P\text{-value} > 0.05$ ). In other words, health literacy can be the best predictor of some lifestyle dimensions including nutrition, physical activity, and mental dimension (Table 4).

### Discussion

This study was conducted to determine the relationship between lifestyle and health literacy. Lifestyle status of studied women obtained mean of  $67.76 \pm 11.09$ . Mehdipoor et al. conducted a study in which, lifestyle of middle-aged women had been assessed at the beginning of intervention so that the majority of participants had an average lifestyle (17).

The most common diet among women in this study consisted of breakfast, bread, rice, macaroni, and minimum fish consumption; hence, they did not use extra salt in their diet. Mean score of lifestyle related to nutritional habits were at lower-average level with coefficient of  $19.68 \pm 3.21$  and this result was not in line with the result obtained by Sajjadi et al. (20) because of the different age of participants and studied place; young rural women were studied in the mentioned research; such a result is logical since rural women do not use prepared and canned food.

Physical activity of women had the lower level with coefficient of  $6.60 \pm 5.54$  and majority of participants had the minimum level of physical activity so that some activities such as moving table, using vacuum cleaner and simple home chores had the highest frequency among other items of questionnaire. Tensile, aerobic, and physical activities during leisure time obtained lowest coefficients. In general, various studies have indicated low level of physical activities among Iranian women (21, 22).



**Table 1: Frequency distribution of demographic features of participants**

Variable	Frequency	Percent	
<b>Age</b>	<30	43	10.2
	30-35	116	27.6
	35-40	86	20.5
	40-45	78	18.6
<b>Marital status</b>	single	5	1.2
	married	399	95.0
	divorced	7	1.7
	widow	9	2.1
<b>First marriage age</b>	>45	97	23.1
	<20	339	80.7
	20-30	67	16.0
	30-40	8	1.9
<b>Education level</b>	uneducated	22	5.2
	reading and writing	58	13.8
	elementary and secondary	136	32.4
	high school	22	5.2
	diploma	130	31.0
	associate degree and BA	52	12.4
<b>Education level of husband</b>	uneducated	40	9.5
	reading and writing	53	12.6
	elementary and secondary	156	37.1
	high school	15	3.6
	diploma	109	26.0
	associate degree and BA	39	9.3
<b>Number of pregnancies</b>	0	10	2.4
	1 & 2	36	36.4
	3 & 4	117	44.0
	>4	130	17.1
<b>Number of children</b>	0	19	4.5
	1 & 2	170	40.5
	3 & 4	174	41.4
	>4	57	13.6
<b>Economic status</b>	rich	62	14.8
	middle	247	58.8
	poor	111	26.4
<b>Residential status</b>	private house	291	69.2
	rental house	99	23.6
	house of relatives	30	7.1

**Table 2: Correlation between health literacy and lifestyle**

	<i>Lifestyle</i>	<i>Physical activity</i>	<i>Nutrition</i>	<i>Mental health</i>	<i>Interpersonal relationships</i>
<b>Health literacy</b>	r=0.162** p=0.001	r=0.264** p<0.001	r=-0.128* P=0.011	r=0.110* p=0.027	r=-0.013 p=0.798
<b>Reading</b>	r=0.180** P<0.001	r=0.306** p=0.001	r=-0.148** p=0.003	r=0.122* p=0.014	r=-0.029 p=0.551
<b>Calculation</b>	r=-0.122* p=0.018	r=-0.219** p<0.001	r=0.118* p=0.019	r=-0.108* p=0.03	r=0.57 p=0.247

**Table 3. Multiple correlation coefficient between health literacy & lifestyle**

Criterion-predictor variable	Multiple correlation coefficient (R)	Squared multiple correlation coefficient (R <sup>2</sup> )	F coefficient	Sig level
<b>lifestyle and its dimensions-health literacy</b>	0.312	0.097	11.105	<0.001

**Table 4: Results obtained from regression analysis of the effect of health literacy on lifestyle**

Criterion variable	Predictor variable	non-standard beta coefficient		standard beta coefficient	t value	Sig
		beta	standard error			
<b>Nutrition</b>	<i>health literacy</i>	0.058	0.023	0.128	2.562	0.01
<b>Physical activity</b>	<i>health literacy</i>	0.20	0.037	0.264	5.516	<0.001
<b>Mental dimension</b>	<i>health literacy</i>	0.074	0.033	0.11	2.213	0.027
<b>Interpersonal relationships</b>	<i>health literacy</i>	0.009	0.035	0.013	0.257	0.798
<b>Total lifestyle</b>	<i>health literacy</i>	0.254	0.08	0.162	3.198	0.001

Mental health dimension of lifestyle obtained mean of 20.93±4.85 so that the majority of studied women were able to control stress and had suitable mental health in coping with daily challenges; this result was matched with result obtained by Sajjadi et al. (20).

Mean of functional health literacy obtained at 63.89±14.96 was in line with results obtained by Javadzadeh and Sajjadi et al. According to a study conducted by Javadi, although the score of total health literacy was higher than average level, there was a highest level of challenge in computational health literacy (20, 23) so that 20% of participants could calculate the correct time of drug usage. Since correct drug-therapy is one of the initial principles for successful therapy, weakness in computing time of drug usage may make risk in therapy process; hence, computational literacy of individuals should be improved. There was a significant relationship between health literacy and nutrition in this research so that increased health literacy led to better nutritional status; this result was in line with results obtained from studies conducted by Wagner et al. (24). According to studies conducted in this field, people with higher health literacy are adherent to health behaviors (25).

In addition, there was a positive relationship between physical activity and mental health; this result was in line with results obtained by Kim et al. (26). Seemingly, individuals with higher health literacy are more able in reading and comprehension of scientific references to solve problems related to health; according to other studies, the mentioned individuals have high-level lifestyle (20).

There was a reverse insignificant relationship between health literacy and interpersonal relationships; this result was not in line with results obtained by Sajjadi, Schillinger et al. (20, 27) so that individuals with higher health literacy had no better interpersonal communications; the reason for such difference was related to questions and target group. In this regard, the most important communicational problem between practitioner and diabetes patients in

a study of Schillinger was related to medical terms; in contrast, the relationship between patient and practitioner consisted of some issues such as referral, communication type, and satisfaction with communication since health women were studied in this research. In other words, health literacy is the best predictor of some dimensions of women's lifestyle such as nutrition, physical activity, and mental dimension.

## Conclusion

Since health literacy was considered in this research as a suitable predictor for lifestyle of women considering dimensions of nutrition, physical activity, and mental health, it is recommended to design and implement interventions in order to promote health literacy of women. As possible as, it is required to evaluate skills of individuals in receiving data from various communicational channels besides determining health literacy level and lifestyle status of them as well as providing training compatible with health literacy levels and lifestyle status before providing health data and implementing educational interventions; this action should be done considering some other factors such as age, communicational skills, and cognitive abilities in data providing at the time of making relationship and providing patients with teachings besides education level of individuals and educational references.

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# Risk Factors of Peptic Ulcer Disease in Khorramabad city, Southwest of Iran: A Case Control Study

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## Abstract

**Background & Aims:** The aim of this study is to determine the demographic characteristics, endoscopic findings, morphological and pathological characteristics of the ulcer in patients with peptic ulcer disease, and also to compare the odds ratio of exposure to possible risk factors of disease in patients with peptic ulcer disease and a healthy control group in Khorramabad city.

**Materials & Methods:** In the present case-control research, all the patients who had referred to a digestive tract sub-specialist's office in Khorramabad in 2015 and had been diagnosed with peptic ulcer disease via endoscopy and pathological studies were enrolled in the study. The control group were selected from among those referring to the ophthalmological and dermatological clinics of the Shahid Rahimi Hospital. The data collection instrument used in this study was a questionnaire that included items related to the demographic information of the patients, and also questions regarding the patient's background as to smoking, alcohol consumption, NSAIDs or corticosteroids usage, and peptic ulcer disease among first-degree relatives. The same data were collected from the members of the control group. All patients signed written consent forms regarding their participation in the study. The data were analyzed using SPSS software.

**Findings:** In the present study, 60 patients with PU and 60 subjects as the control group were examined. Most patients were between 30 and 44 years old (60%). In the present study, the mean age of patients with PUD was  $35 \pm 10.6$  years. Among all patients with PUD, three (5%) had gastric ulcer and

57 (95%) had duodenal ulcer. Anatomical location of all ulcers (3 cases) was in the small curvature of stomach and 47.4% of duodenal ulcers were in the anterior wall. In multivariate analysis, which was performed using logistic regression, there was a statistically significant relationship among history of NSAID use (PV = 0.047) and smoking history (PV = 0.042) with occurrence of PUD.

**Conclusion:** In general, peptic ulcer is considered as a common and serious problem all around the world and 5 to 10% of the population are affected by PU during their life. Therefore, the incidence and complications of this disease can be significantly prevented by correcting risk factors and lifestyle, as well as by improving the health conditions of the community.

**Key words:** Peptic ulcer disease, Duodenal Ulcer, Gastric Ulcer, NSAID, Smoking.

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## Introduction

Peptic Ulcer Disease (PUD) is a common disease in the digestive system which includes gastric and duodenal ulcers. In the United States, the prevalence of PUD is about 12% in men and 10% in women. Researchers believe that 15,000 deaths occur each year as a result of PUD complications. The economic effect of this disease is considerable so that each year \$ 10 billion is spent in the United States for the disease and its complications regarding direct and indirect healthcare costs (1). Peptic ulcer is ranked thirty in the world and thirty-first in Iran in terms of prevalence and disease burden (2). Duodenal Ulcer (DU) occurs in 6 to 15 percent of the western population. Incidence of these ulcers has steadily decreased from 1960 to 1980 and has remained constant since then. In higher ages, gastric ulcers are more likely to occur as compared with duodenal lesions so that statistics suggest a high incidence of this type of ulcer in the sixth decade of life. More than half of gastric ulcers occur in men and their prevalence is less than duodenal ulcers; this can be attributed to the fact that gastric ulcer is asymptomatic in most cases so that for a large number of patients, this disease is diagnosed after the occurrence of complications. Unlike duodenal ulcers, gastric ulcers have the capability to become malignant (1). Damage caused by *Helicobacter pylori* infection and the use of NSAIDs result in most peptic ulcers; many environmental factors are also effective in causing this disease, including infectious causes such as cytomegalovirus, herpes, as well as some drugs, including bisphosphonates, chemotherapeutic agents, crack, cocaine, potassium chloride and glucocorticoids. Epidemiological studies suggest that smoking increases the occurrence likelihood of peptic ulcer disease (1). Moreover, physiological stresses and psychosocial stress play an important role in the occurrence of peptic ulcer (3). Furthermore, in a number of studies, the role of psychological factors in the development of gastric ulcer has also been mentioned; this effect is exerted through an increase in acid secretion due to psychological stress (3 and 4). Clinical symptoms of this disease include epigastric pain, dyspepsia and abdominal distension, nausea and vomiting, weight loss and anorexia that can be accompanied with anemia of iron deficiency and the presence of hidden blood in the stool.

PUD can have a significant influence on patients' quality of life. Based on the findings of a number of studies, improving the quality of life can have a satisfactory effect on the treatment of peptic ulcer (5).

The aim of this study is to determine the demographic characteristics, to investigate the endoscopic findings, to determine the morphological and pathological characteristics of the ulcer in patients with peptic ulcer disease, and also to compare the odds ratio of exposure to possible risk factors of disease in patients with peptic ulcer disease and healthy control group in Khorramabad city.

## Materials and Methods

In the present case-control research, all the patients who had referred to a digestive tract sub-specialist's office in Khorramabad in 2015 and had been diagnosed with peptic ulcer disease via endoscopy and pathological studies, were enrolled in the study. In the present research, only patients residing in Khorramabad and its suburban areas were studied. The census taking sampling method was used. 60 patients diagnosed with peptic ulcer disease were selected as the volume of the sample. The control group that matched the experimental group in terms of age and sex were selected from among those referring to the ophthalmological and dermatological clinics of the Shahid Rahimi Hospital, provided that they had no gastrointestinal or rheumatologic diseases and no backgrounds of chronic physical and mental illnesses. The data collection instrument used in this study was a questionnaire that included items related to the demographic information of the patients, and also questions regarding the patient's background as to smoking (smoking more than 10 cigarettes per day for at least one year), alcohol consumption (with DSM-IV-TR criteria, and alcoholic products with daily consumption including beer, vodka, whisky, wine, fortified wine and hard liquor), NSAIDs or corticosteroids usage, and peptic ulcer disease among first-degree relatives. The same data were collected from the members of the control group. All the diagnostic studies for the diagnosis of the disease were carried out by a digestive tract sub-specialist. The validity of study was confirmed by expert panel.

All patients signed written consent regarding their participation in the study. The data were analyzed using SPSS software. Descriptive statistical methods, and the Chi-square test were used. In order to determine the intensity of the relationship between familial backgrounds of peptic ulcer disease and the development of PUD, the odds ratio estimate was used with a confidence interval of 95%.

## Findings

In the present study, 60 patients with PU and 60 subjects as control group were examined. Most patients were between 30 and 44 years old (60%). In the present study, the average age of patients with PUD was  $35 \pm 10.6$  years. The youngest patient was 16 years old and the oldest patient was 57 years old. There was no difference in the average age of patients with PUD and control group ( $PV = 0.25$ ). Most of the patients (60%) were male. In the present study, the sex ratio of male to female was 1.5 to 1. There was no significant difference between the two groups in terms of sex distribution ( $PV = 0.44$ ). In the present study, the majority of patients (85%) were married and most of them (40%) had secondary education or diploma; 25% of patients were high school or university students, and 20% of patients were workers. There was no statistically significant difference in the frequency distribution of marital status, educational level, and occupation of patients and control group (Table 1). In this study, 58.3% of patients and 56.7% of the subjects in the control group had blood type O. The difference in the frequency distribution of blood

types of the two groups was statistically significant (PV = 0.047) (Table 1). The mean of body mass index in patients with PUD was significantly higher than that of those without PUD (PV = 0.026). Among all patients with PUD, three (5%) had gastric ulcer and 57 (95%) had duodenal ulcer. Morphologically, all ulcers were of the Clean Base type (100%) and anatomical location of all ulcers (3 cases) was in the small curvature of stomach and 47.4% of duodenal ulcers were in the anterior wall (Table 2). Size of 70% of peptic ulcers in the patients under study was 1 and less than 1 cm and size of other ulcers was in the range of 1 to 3 cm. The number of peptic ulcers was one in 48 patients (80% of cases) and in 12 patients (20% of cases) more than one ulcer was diagnosed. The result of Helicobacter pylori test was positive in 57 patients (95%).

Epigastric pain (95%) and nausea (36.7%) were the most common clinical symptoms of peptic ulcer in patients under study. The history of regular smoking was positive in 15% of patients with PUD while it was 5% in the control group and this difference was statistically significant based

on chi-square test (PV = 0.038) (Table 3). Estimated odds ratio for PUD in smokers was 4.75 times higher than non-smokers. 13.3% of patients and 3.3% of subjects in the control group used to use non-steroidal anti-inflammatory drugs. This difference was statistically significant based on Chi-square test (PV = 0.048). Odds ratio of second-line peptic ulcer disease to NSAID use was 4.16 times higher than control group (Table 4). History of alcohol use was not positive in any of the patients with PUD and the subjects of the control group. History of regular corticosteroid use was positive in 4 patients with PUD (6.7%) while only 1 subject in the control group (1.7%) had history of corticosteroid use, and this difference was not statistically significant (PV = 0.17). History of PUD was positive in 8.3% of patients with PUD and 5% of subjects, and this difference was not statistically significant (PV = 0.46). Moreover, history of the use of anticoagulation drugs was not positive in any of the two groups. In multivariate analysis which was performed using logistic regression, there was a statistically significant relationship among history of NSAID use (PV = 0.047) and smoking history (PV = 0.042) with occurrence of PUD.

**Table 1: Frequency distribution of demographic characteristics of patients with PUD and control group**

Type of variable		Patients with peptic ulcer; Number (percent)		Number of healthy people; Number (percentage)		p- Value
Sex	Male	36	60	40	66.7	0.44
	Female	24	40	20	33.3	
Marital status	Married	51	85	46	76.7	0.24
	Single	9	15	14	23.3	
Education	not literate	3	5	3	5	0.44
	high school and less	18	30	16	26.7	
	secondary school & diploma	24	40	18	30	
	Academic	15	25	23	38.3	
Occupation	Farmer	3	5	6	10	0.62
	worker	12	20	10	16.7	
	businessman	10	16.7	13	21.7	
	house keeper	15	25	14	23.3	
	student	6	10	7	11.7	
	Military	6	10	3	5	
	Unemployed	6	10	2	3.3	
Public sector	2	3.3	5	8.3		
Blood type	AB	3	5	5	8.3	0.047
	A	14	23.3	21	35	
	B	8	13.3	12	20	
	O	25	58.3	22	36.7	

**Table 2: Frequency distribution of anatomical location of involvement in patients with duodenal**

Anatomical location of involvement	Number	Percent
Anterior wall	27	47.4
Posterior wall	6	10.5
Upper wall	9	15.8
Lower wall	6	10.5
Lower and anterior wall	3	5.3
Lower and upper walls	6	10.5
Total	57	100



**Table 3: Comparison of frequency distribution of regular smoking history in patients with PUD and control group**

Regular smoking history	With		Without		Total		p-Value	OR	95%CI-OR
	Number	Percent	Number	Percent	Number	Percent			
Patients	9	15	51	85	60	100	0.038	4.75	1.61-8.2
Control	3	5	57	95	60	100			

**Table 4: Comparison of frequency distribution of regular NSAID usage in patients with PUD and control group**

Regular NSAID use	With		Without		Total		p-Value	OR	95%CI-OR
	Number	Percent	Number	Percent	Number	Percent			
Patients	8	13.3	52	86.7	60	100	0.048	4.16	1.8-9.1
Control	2	3.3	58	96.7	60	100			

## Discussion and Conclusion

Despite the significant decrease in the mortality rate of peptic ulcer disease in recent decades, peptic ulcers continue to be a common and complicated problem affecting a large part of the population, resulting in high health costs in different dimensions of physical and mental health. The present study was carried out in order to investigate the risk factors of peptic ulcers in Khorramabad city. Among 60 examined patients, 95% suffered from duodenal ulcer and 5% suffered from gastric ulcer. It was revealed in a study performed by Baranizadeh et al. in a referral center in Tehran that 94.4% of all patients with PU were suffering from duodenal ulcer and 5.6% were suffering from gastric ulcer. The results of the present study are in line with the results of the mentioned study (7). The average age of patients in the leading study was 35 years and the highest frequency of the disease was in the age group of 30-44 years. In the study carried out by Baranizadeh et al., the average age of patients with gastric ulcer was 54.5 years and the average age of patients with duodenal ulcer was 51.5 years. The difference in the average age of patients in the present study with the average age of patients in the Baranizadeh study can be attributed to the differences between the two regions; differences such as different eating habits, genetic aptitudes of PUD involvement of the tribal peoples of Lor and Lak who inhabit Lorestan province in comparison with Turk and Fars residents of Tehran province as well as a different risk of environmental factors. In the study conducted by Baranizadeh et al., all patients referring to a referral center in Tehran as well as patients admitted to the hospital were examined. Some of these patients were suffering from complicated ulcers as well (7). In the present study, the majority of patients with PU were male and the sex ratio of male to female was 1.5 to 1. Moreover, in the investigation performed by Amnan et al. in the United States, the ratio of males to females suffering from duodenal ulcer was 4 to 1 and the ratio of males to females suffering from gastric ulcer was 2 to 1 (8). Furthermore, in the study conducted by Hwang in Taiwan, 67% of patients suffering from PU were male and 55.9% were between 20 and 45 years old (9).

The findings of this study indicated that most patients with PU were married and had secondary education or diploma, and most of them were housewives and workers. In

addition, in the study done by Amnan in the United States, high age, low level of education, low family income, and smoking were counted as risk factors for peptic ulcer (8). Therefore, it should be noted that low levels of literacy can lead to unhealthy lifestyles, improper dietary habits and increased risk of disease. In this study, almost all subjects with PU (95%) were infected with *H. pylori* infection. In the study carried out by Baranizadeh, 93.9% of patients with gastric ulcer and 100% of patients with duodenal ulcer were infected with *H. pylori* (7). Moreover, in several studies done in Southeast Asia and China, the prevalence of *H. pylori* in patients suffering from PU was found to be between 92.6% and 95.7% (13-10). Whereas, according to studies conducted in European countries, the prevalence of *H. pylori* infection in patients suffering from PU ranged from 33.9% to 57.7% (14-15). Therefore, according to the results obtained from comparing these statistics, the prevalence of *Helicobacter pylori* infection is lower in European societies as compared with Asian societies; it is likely that the prevalence of ulcerogenic *H. pylori* species is the same in the Iranian and Chinese population. It is reported in an investigation that the prevalence of *H. pylori* is 82% in patients with PU in Van, Turkey (16). In the present study, it manifested that regular smoking and regular use of NSAIDs are among risk factors that increase the risk of the prevalence of PU factor and the odds ratio for PU was 4.75 times higher in smokers as compared with non-smokers, and the odds ratio for NSAID use was 4.46 times. In the examination performed by ARO, cigarette smoking, aspirin use, and obesity were identified as risk factors for the prevalence of PU (17). In the study conducted by Baranizadeh et al. in Tehran, *Helicobacter pylori*, smoking, male sex and place of residence in the city were considered as major risk factors for duodenal ulcer, and *H. pylori* infection, regular smoking, and NSAIDs were considered as major risk factors for gastric ulcers (7). NSAIDs cause the failure of mucosal defense mechanisms and since it is difficult to identify patients at higher risk for complications and deaths from using NSAIDs due to the absence of warning signs, the probability of side effects of NSAID use increases in higher ages, when there is a history of ulcer, and when corticosteroid and anticoagulant drugs are co-administered. In the study performed by Shou-lee et al., it was found that there is a significant relationship between high consumption of aspirin and PU occurrence (18). In a study carried out in Taiwan, smoking

was considered a risk factor for the occurrence of PU (19). The results of the present study are in line with the results of the other mentioned investigations. In our study, prevalence of smoking was 15% and prevalence of NSAID use was 13.3% in patients with PU. These results indicate that smoking may play a role as an important factor in the etiopathogenesis of PU in our region. In fact, many other studies present a strong positive relationship among cigarette smoking, appearance of ulcer, and delay in ulcer healing (18 and 20). In this study, none of the patients with PU were alcoholic, which may be related to the low prevalence of alcohol consumption in our region. In some studies, genetic predisposition has been suggested as a risk factor for PU. In one study, it was shown that the incidence of ulcers was three times more in the immediate relatives of patients with duodenal ulcers compared with normal people (19). However, in our study, there was no significant difference between the occurrences of ulcer in the immediate relatives of patients with peptic ulcer compared with the control group; this non-significant difference is perhaps related to smaller sample size in this study and incorrect responses provided by some participants due to a failure in recall. Moreover in the present study, the blood type of most patients was O. In the study carried out by Lau, blood type O was mentioned as a genetic risk factor for PU disease (21). In this study, the mean of body mass index of patients with PU disease was significantly higher than that of control group. Furthermore, in the study done by Baranizadeh, patients with DU had a higher body mass index than patients who were not suffering from DU (7). In the present study, the majority of ulcers occurred in duodenal anterior wall. In addition, in the study that was performed by Turk Dogan in Turkey, 80% of ulcers were located in the first part of the duodenum and at the anterior level (16). Our study also had some limitations. This study was based on the endoscopy of some outpatients referring or referred to a private multi super specialty center and did not include population-based studies. And since patients were not hospitalized, perhaps the results of this study cannot be generalizable to the entire community of patients with peptic ulcer disease. In general, peptic ulcer is considered as a common and serious problem all around the world and 5 to 10% of the population are affected by PU during their life. Therefore, the incidence and complications of this disease can be significantly prevented by correcting risk factors and lifestyle, as well as by improving the health conditions of the community.

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# Evaluation of the Obesity Contributing Factors in first grade elementary school students from Sari, North of Iran

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## Abstract

**Background:** Obesity in children has raised worries about public health and hygiene. In this study, we intended to evaluate the obesity rate among the children from first grade elementary schools throughout Sari, in the north of Iran. Moreover, we evaluated the possible effects of mother's life conditions on the estimation of obesity in children.

**Methods:** In this descriptive cross sectional study, the study population included first grade elementary school students in Sari, north of Iran. Sampling was carried out through multi-stage and stratified randomization at level of the target students. Using stadiometer and digital scales, the height and weight were measured. Body Mass Index (BMI) was also calculated. A questionnaire about eating habits and socio-economic status of parents was employed. Data collection was conducted using phone interview with parents as well as the questionnaire's records. Analysis of data was conducted in SPSS v.22 using suitable statistical tests. IBM SPSS

Amos software was utilized for path analysis.  $P < 0.05$  was considered as statistically significant. **Results:** It was observed that 15% of the evaluated cases were obese. There was an association between BMI of the obese cases and lifestyle-related habits. Path analysis revealed significant impression of patient's habitus on the obesity of children.

**Conclusions:** Our results suggest that the overall prevalence of obesity in Sari was high, which proposes the necessity for serious consideration in the health system, and designing, developing, and implementing preventive approaches with regard to childhood obesity.

**Key words:** Obesity, overweight, risk factors, elementary students, life-style

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## Introduction

Over the course of the past few years, the issue of obesity and overweight has a growing concern among populations worldwide. In the 21st century, this issue has been the most challenging public health problem (1). The prevalence of obesity has been growing remarkably in pediatrics both in developing and developed countries during the past decades. Studies have demonstrated that children within the elementary school –period (6-11 years) have the highest prevalence and risk of being obese and overweight, and this rate has been evaluated to be approximately 18.8% (2, 3).

The challenging issue of obesity and overweight in cases during the period of childhood and teenage years has inappropriate and dangerous ramifications on premature mortality and morbidity as well as physical disability in the future ages of adulthood. Moreover, obesity by itself has been associated with numerous health problems during childhood(4). With respect to the findings of several studies all around the world, obesity during childhood has been related to numerous complications in the future including, hypertension, cardiovascular diseases, increased level of insulin, type 1 and 2 diabetes, reproductive, and orthopedic impairments (5). On the other hand, among the underlying contributing factors for obesity are genetic, metabolic, socioeconomic, cultural, parental and lifestyle, including diet, physical activity, birth weight, nutritional status, supplementary nutrition, type of child's recreation (6). However, the findings about obesity risk factors have been incongruous and inconclusive and various investigations have demonstrated that important factors are genetic background, physical activity (7-10), kind of synthetic milk consumed during neonatal period (11), high birth weight (12-14), hours of television watching (particularly if it is more than 2 hours per day)(15, 16), quality and quantity of regular meals during the day, and obesity and overweight in parents(17-20). On the contrary, some evaluations have observed that none of the previously associated risk factors for obesity were causing this impairment in cases with normal weight and overweight (21-23).

Considering the previous observations about pediatric obesity–related risk factors, it seems that evaluation of risk factors of obesity in children is indispensable with respect to the adverse and dangerous implications of obesity on health issues. Therefore, with regard to the different climatic and cultural differences in Iran and the lack of such a study in Sari (a city in the north of Iran), this study aimed to determine some effective factors in obesity among primary school students in Sari. Moreover, the pattern of parent to child effects about obesity were evaluated.

## Examination and methods

In this study, 180 seven year old students were selected via two-stage sampling method from urban areas of Sari. Sari is a city in the Mazandaran province in north Iran and had a population of 2,197 first grade students. In the first stage, 569 elementary schools, both public and private, were chosen, and, in the second stage, through a case-

control study, 60 obese (body mass index (BMI)  $\geq$  85th percentile of Iranian reference) children were selected as the case group, and the primary non-obese students (15th  $\leq$  BMI  $<$  85th percentile) were examined immediately after each obese student. These students who were age- and sex-matched, were selected as the control group. Overall, 120 students were included in the control group. This study was approved by the ethics committee of Islamic Azad University of Sari Medical Sciences. Written informed consent was obtained from parents and oral assent from students.

We used the Iranian reference for BMI percentiles (24). Height was measured by a stadiometer (Seca, Germany) in a standing position with bare feet (precision 0.5cm), and body weight was determined with subjects wearing light clothes and no shoes or socks, using an electronic balance. BMI was calculated as weight (kg) divided by height squared (m<sup>2</sup>).

Data were collected by questionnaire via direct interview with mothers. Interviews were performed by trained health professionals. The questionnaire included mother-reported information about her child regarding the age, sex, birth weight, birth order, number of family household members, duration of breast feeding, initiation age of complementary food, TV watching hours, playing electronic games, sleep duration, father age, mother age, mother weight, economic status, and parental obesity history. The economic status of family was assessed by having some equipment such as color TV, refrigerators, washing machine, video, computer, video CD, and accessibility to car and private home. In data analysis, economic status was defined as low, moderate, and good based on an average score 3, 4-6, and more than 7, respectively. Physical activity score was evaluated using the modified Baecke et al. questionnaire by asking the pupils (25).

In this study, the path analysis method was used to analyze the data and to evaluate the goodness of fit using the IBM SPSS Amos software. The path analysis is used to test the causal models and requires the setting of the pattern as a causal diagram and helps to identify what we are searching for. In the path analysis, the coefficient of determination is used, hence it is possible to evaluate the suitability of the model. Moreover, using the beta weight, which is called coefficient path in the path analysis, it is possible to determine the effect value of each variable. In addition, path analysis enables us to understand the mechanism of the effect of the variables on each other and to determine how much direct or indirect is the effect of each variable. In other words, path analysis provides a lot of information about the causal processes in a straightforward and understandable way(26).

In the path analysis method, there are several indexes for examining the fit of tested patterns, among which, root mean square error approximation (RMSEA), chi-square ratio to freedom gap ( $\chi^2 /df$ ), and ultimately insignificant quasi-test Chi ( $P \geq 0.05$ ) are main indexes of fit model in path analysis. Other indexes such as NFI, CFI and GFI represent the optimal fit pattern in structural equations such as path analysis (27).

Analysis of data was performed via SPSS software version 22 (SPSS, Chicago, IL, USA). To evaluate the normal distribution of the scale variables, the Kolmogorov–Smirnov test was used. The independent sample t-test or Mann-Whitney U test was used to compare groups

with continuous variables. Correlation analysis was conducted to analyze the relationship between BMI and characteristics of the cases. Scale data were expressed as mean  $\pm$  standard deviation (SD). A P value  $< 0.05$  was set to be statistically significant.

## Results

In this descriptive cross-sectional study, from 569 elementary school students, a total of 494 children were examined. It was observed that 14% of evaluated cases were obese. Table 1 shows demographic characteristics, children's lifestyle and family income. Most of the evaluated indexes did not have significant difference between the obese and control groups. However, age, BMI, and initiation month of supplementary food were indexes with significant difference.

**Table 1. Demographic characteristics, children's lifestyle and income status of the children under study (Part 1)**

Characteristic	Case (BMI $\geq$ 85 <sup>th</sup> percentile) N=74	Control (BMI=5 <sup>th</sup> -85 <sup>th</sup> percentile) N=420	P value
<b>Sex</b>			
Girl	40 (54%)	277 (65.95%)	0.123
Boy	34 (46%)	142 (33.81%)	
<b>Delivery Type</b>			
Natural	26 (35.14%)	159 (37.86%)	0.386
Cesarean	48 (64.86%)	256 (60.95%)	
<b>Delivery time</b>			
1	73 (98.65%)	398 (94.76%)	0.525
2	1 (1.35%)	17 (4.05%)	
<b>Number of Siblings</b>			
0	13 (17.57%)	66 (15.71%)	0.192
2	0 (0%)	4 (0.95%)	
3	34 (45.95%)	142 (33.81%)	
4	26 (35.14%)	180 (42.86%)	
5	1 (1.35%)	24 (5.71%)	
6	0 (0%)	4 (0.95%)	
<b>Number of Birth</b>			
0	10 (13.51%)	53 (12.62%)	0.693
1	45 (60.81%)	227 (54.05%)	
2	18 (24.32%)	125 (29.76%)	
3	1 (1.35%)	13 (3.10%)	
4	0 (0%)	4 (0.95%)	
<b>Father Education</b>			
Illiterate	0 (0%)	3 (0.71%)	0.294
Under Diploma	15 (20.27%)	88 (20.95%)	
Diploma	18 (24.32%)	149 (35.48%)	
Upper Diploma and B.Sc.	30 (40.54%)	120 (28.57%)	
M.Sc. and upper than M.Sc.	11 (14.86%)	53 (12.62%)	
<b>Mother Education</b>			
Illiterate	0 (0%)	2 (0.48%)	0.736
Under Diploma	11 (14.86%)	75 (17.86%)	
Diploma	28 (37.84%)	165 (39.29%)	
Upper Diploma and B.Sc.	30 (40.54%)	142 (33.81%)	
M.Sc. and upper than M.Sc.	5 (6.76%)	29 (6.90%)	
<b>Income million (Iranian Taman)</b>			
None	9 (12.16%)	57 (13.57%)	0.637
Less than 1.5	36 (48.65%)	221 (52.62%)	
1.5 to 3	25 (33.78%)	119 (28.33%)	
3 to 8	3 (4.05%)	19 (4.52%)	
More than 8	0 (0%)	3 (0.71%)	



**Table 1: Demographic characteristics, children's lifestyle and income status of the children under study (Part 2)**

<b>Current Employment Status</b>			
Yes	20 (27.03%)	120 (28.57%)	0.575
No	50 (67.57%)	283 (67.38%)	
<b>Employed in the past</b>			
Yes	24 (32.43%)	129 (30.71%)	0.69
No	41 (55.41%)	234 (55.71%)	
<b>Job working hours</b>			
None	50 (67.57%)	292 (69.52%)	0.053
Office time	15 (20.27%)	52 (12.38%)	
Circulatory shift	3 (4.05%)	17 (4.05%)	
Night	0 (0%)	1 (0.24%)	
Sessional	0 (0%)	7 (1.67%)	
Part time	2 (2.70%)	39 (9.29%)	
Other	2 (2.70%)	11 (2.62%)	
<b>Job type</b>			
None	49 (62.22%)	285 (67.86%)	0.236
Home	2 (2.70%)	24 (5.71%)	
Office	8 (10.81%)	33 (7.86%)	
Industry	0 (0%)	5 (1.19%)	
Agriculture	0 (0%)	3 (0.71%)	
Hospital	2 (2.70%)	11 (2.62%)	
Business	1 (1.35%)	17 (4.05%)	
Training	8(10.81%)	32 (7.62%)	
Other	2 (2.70%)	9 (2.14%)	
<b>Number of meals with mother-baked food</b>			
0	5 (6.76%)	27 (6.43%)	0.531
1	0 (0%)	2 (0.48%)	
1-2	1 (1.35%)	9 (2.14%)	
2	5 (6.76%)	21 (5%)	
2-3	5 (6.76%)	55 (13.10%)	
More than 3	57 (77.03%)	305 (72.62%)	
<b>Number of meals eating fast-food per week</b>			
0	49 (66.22%)	280 (66.67%)	0.795
Less than 3	20 (27.03%)	108 (25.71%)	
3 to 6	2 (2.70%)	14 (3.33%)	
More than 6	0 (0%)	6 (1.43%)	
<b>Number of meals eating without parents per week</b>			
0	55 (74.32%)	319 (75.95%)	0.610
Less than 3	12 (16.22%)	59 (14.05%)	
3 to 6	1 (1.35%)	16 (3.81%)	
More than 6	3 (4.05%)	12 (2.86%)	
<b>The way of going to school</b>			
Walking	14 (18.92%)	99 (23.57%)	0.741
Transportation vehicles	49 (66.22%)	262 (62.38%)	
Both	8 (10.81%)	50 (11.90%)	
<b>Hours watching TV per day</b>			
Less than 1 hour	17 (22.97%)	79 (18.81%)	0.592
1 to 2 hours	33 (44.59%)	209 (49.76%)	
2 to 4 hours	19 (25.68%)	94 (22.38%)	
More than 4 hours	2 (2.70%)	26 (6.19%)	

**Table 1: Demographic characteristics, children's lifestyle and income status of the children under study (Part 3)**

<b>Hours using computer per day</b>			
Less than 1 hour	49 (66.22%)	274 (65.24%)	0.490
1 to 2 hours	12 (16.22%)	53 (12.62%)	
2 to 4 hours	0 (0%)	5 (1.19%)	
More than 4 hours	0 (0%)	3 (0.71%)	
<b>Hours using mobile and tablet per day</b>			
Less than 1 hour	49 (66.22%)	283 (67.38%)	0.452
1 to 2 hours	11 (14.86%)	75 (17.86%)	
2 to 4 hours	3 (4.05%)	12 (2.86%)	
More than 4 hours	1 (1.35%)	8 (1.90%)	
<b>Hours spending at home without parents per day</b>			
0	2 (2.70%)	12 (2.86%)	0.810
1 to 3	59 (79.73%)	326 (77.62%)	
3 to 6	10 (13.51%)	58 (13.81%)	
More than 6	2 (2.70%)	23 (5.48%)	
<b>Dried milk consumption</b>			
Never	51 (68.92%)	273 (65%)	0.208
Rarely	1 (1.35%)	40 (9.52%)	
Sometimes	6 (8.11%)	30 (7.14%)	
Usually	2 (2.70%)	23 (5.48%)	
Always	11 (14.86%)	45 (10.71%)	
<b>Activity</b>			
Never	2 (2.70%)	5 (1.19%)	0.106
Rarely	6 (8.11%)	33 (7.86%)	
Sometimes	15 (20.27%)	57 (13.57%)	
Usually	30 (40.54%)	186 (44.29%)	
Always	17 (22.97%)	124 (29.52%)	
<b>Omitting a meal</b>			
Never	46 (62.16%)	281 (66.90%)	0.687
Breakfast	22 (29.73%)	104 (24.76%)	
Breakfast & Lunch	0 (0%)	1 (0.24%)	
Breakfast & Dinner	0 (0%)	1 (0.24%)	
Lunch	1 (1.34%)	9 (2.14%)	
Lunch & Dinner	0 (0%)	1 (0.24%)	
Dinner	3 (4.05%)	20 (4.76%)	
<b>Age*</b>	<b>7.59±0.494</b>	<b>7.47±0.499</b>	<b>0.040</b>
<b>BMI*</b>	<b>21.83±2.81</b>	<b>15.34±1.63</b>	<b>&lt;0.001</b>
<b>Childbirth weight*</b>	3.09±0.93	10.84±0.160	0.670
<b>Childbirth height*</b>	41.83±18.62	43.82±15.96	0.335
<b>Working hours*</b>	11.67±22.93	19.33±17.84	0.328
<b>Months nourishing with mother's milk*</b>	19.39±6.35	18.85±7.93	0.586
<b>Initiation month of supplementary food*</b>	<b>5.62±2.37</b>	<b>6.46±5.25</b>	<b>0.027</b>

Obese cases and controls were 7.59±0.494 and 7.47±0.499 years old, respectively, which was statistically significant (P= 0.040). Moreover, the BMI in obese and control cases demonstrated significant differences (21.83±2.81 vs. 15.34±1.63, respectively, P<0.001). The obese cases were observed to start supplementing with foods earlier than the control group (5.62±2.37 vs. 6.46±5.25, P= 0.027).

ANOVA analysis demonstrated that only job type (P= 0.005), hours of watching TV per day (P= 0.045), and hours of using mobile and tablet per day (P= 0.012) had significant association with the BMI level of the obese children (Table 2). Furthermore, correlation analysis disclosed no significant correlation between the scale data of the patients and their BMI (Table 3).



**Table 2. Relationship of different factors with BMI of children**

Characteristic of the cases	P value
Sex	0.616
Delivery Type	0.229
Delivery time	0.231
Number of Siblings	0.506
Number of Birth	0.125
Father Education	0.312
Mother Education	0.213
Income million (Iranian Toman)	0.210
Current Employment Status	0.066
Employed in the past	0.736
<b>Job type</b>	<b>0.005</b>
Number of meals with mother-baked food	0.997
Number of meals eating fast-food per week	0.061
Number of meals eating without parents per week	0.700
The way of going to school	0.551
<b>Hours watching TV per day</b>	<b>0.045</b>
Hours using computer per day	0.390
<b>Hours using mobile and tablet per day</b>	<b>0.012</b>
Hours spending at home without parents per day	0.067
Dried milk consumption	0.989
Activity	0.057
Omitting a meal	0.064

**Table 3. Correlation of BMI of children with their characteristics**

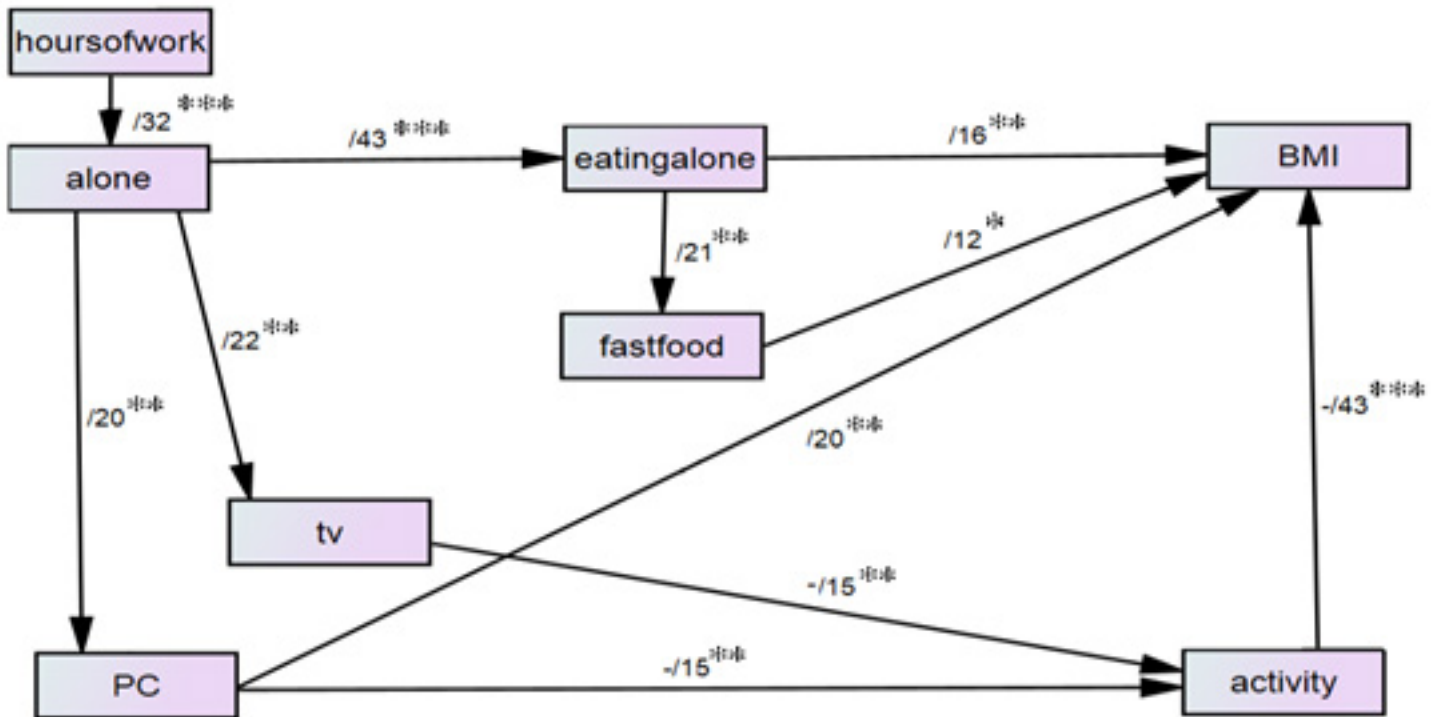
Characteristic	Pearson's correlation coefficient	P value
Age	0.061	0.606
Childbirth weight	0.071	0.548
Childbirth height	0.113	0.337
Working hours	0.125	0.296
Months nourishing with mother's milk	0.061	0.614
Initiation month of supplementary food	0.168	0.154

In this study, the relationship between mother's employment status and obesity in children was tested and path analysis was used due to the study of cause and effect relationships and control of other possible effective variables. After testing and removing the paths and variables that did not show significant correlation, the path of the relationship between variables in the final model is shown in Figure 1.

Based on these results, parent's duration of work was effective in children's staying alone at home, and children who spend more hours per day alone spend more time watching TV and using computers. Therefore, these kids have less activity and more BMI. Furthermore, children who spent more hours a day at home alone, ate more meals alone and ate more fast-food and, hence, had higher BMI.



Figure 1. The final model of the path analysis model and its standardized effect size.



\*Pvalue<0.1; \*\*Pvalue<0.05; \*\*\*Pvalue<0.001

The fitting indexes of the model show that this pattern has a good fit. A summary of the fitting indexes of the model and its desirable amount is presented in Tables 4 and 5.

Table 4: Fitting model indexes and their optimal values

Fitting model index	Final model	Favorable value
Chi-squared	22.276	P value>0.05
Chi-square statistic to degree of freedom (CMIN/DF)	1.310	≤3
Goodness of fit index (GFI)	0.971	>0.9
Adjusted goodness of fit index (GFI)	0.939	>0.8
Non-normed Fit Index (NFI)	0.863	>0.8
Comparative fitness index (CFI)	0.961	>0.9
Root of mean square error approximation (RMSEA)	0.042	≤0.5

Table 5: Fitting model in path analysis to predict the obesity of (BMI) in students

Variable	Direct effect	Indirect effect	Total effect
Mother's working hours	-	0.020	0.020
Lonely time at home	-	0.063	0.063
The number of meals child eats at home alone	0.158	0.024	0.182
Fast food	0.116	-	0.116
TV	-	0.063	0.063
Computer	0.204	0.066	0.270
Physical activity	-0.428	-	-0.428

## Discussion

Over the course of past decades, risk factors of obesity in children have been evaluated to find out the adverse and dangerous factors of obesity on health circumstances. Considering the different lifestyles as well as cultural differences in Iran and the lack of comprehensive and large sample sized study in Sari, this study intended to evaluate contributing risk factors for obesity and being overweight among primary school students in this city. Moreover, we studied the pattern of parent to child effects about obesity in the cases.

In this cross-sectional study, a total of 494 children were examined from 569 elementary school students. We identified that 14% of evaluated cases were obese. We detected that most of the evaluated indexes did not have significant difference between the obese and control groups. However, age, BMI, and initiation month of supplementary food were indexes that indicated significant difference. Obese cases and controls were  $7.59 \pm 0.494$  and  $7.47 \pm 0.499$  years old, respectively, which was statistically significant. Moreover, the BMI in obese and control cases demonstrated significant differences. The obese cases were observed to have started supplementary foods earlier than the control group.

Obesity and being overweight during childhood has been remarkably regarded as a major problem and has been assigned as top priority in the health system in developing and developed countries particularly in recent decades. Numerous studies have been conducted about it, resulting in designing and implementing hygiene programs based on national interventions. To date, obesity and being overweight have been conferred as a major issue in developing countries, eventuating in a bulk of published papers(28-30).

To date, similar investigations have been carried out in other Middle East countries. A study in Iraq has disclosed the prevalence of childhood overweight and obesity to be 1.3% and 22.4%, respectively (31). However, we found that the prevalence of overweight and obesity was approximately 15% in children from Sari, which was higher than that population in Iraq. On the other hand, our findings were almost similar to the findings of some other countries in the vicinity of our region, such as Turkey and the Emirates (32% and 13.7%, respectively) (22, 29). In contrast, the prevalence of obesity in children from industrial cities of China was 26%, was higher than what was found in this study (30). The prevalence of obesity in Rasht, a city near to Sari, was higher than our findings (2).

Considering the evidence mentioned above, the total prevalence of obesity in the student children population from Iran seems to be high, proposing the necessity for serious implementations to counter this problem in the viewpoint of the health system, and a broad range of studies, programs and conducting of effective interventions with respect to reducing the childhood obesity rate.

The results of our study demonstrated significant association of gender and obesity, which is not in accordance with the findings of some other studies(32, 33). However, there are observations about the predominance of childhood obesity in boys (30, 34), as well as in girls (35). These discrepancies could be justified through sampling approaches or cultural and economic characteristics of the studied population. Cultures may determine the quality and quantity of paying more attention to boys or girls by the parents, which may affect the fate of children's weight. Nonetheless, it appears that boys are at higher risk for obesity and being overweight generally, implying the spending of particular attention to boys in the childhood period and assign obesity controlling programs to prevent future problems.

Among the important lifestyle-related factors contributing to the prevalence of obesity in children seems to be feeding habits, which is based upon socio-economic and cultural characteristics of the different communities. This problem has been concentrated vastly in several investigations and has also eventuated in designing and developing some strategies and interventions. A significant correlation was indicated between eating fast food and increased prevalence of obesity and overweight in children from Rasht (36), and Yazd (Iran)(37). These studies highlighted the role of high calorie food as one of the most important contributing factors for childhood obesity. Furthermore, it was also found in some other studies that high-calorie foods, fast food, and reduced amounts of vegetable and fruit consumption are important elements of childhood obesity (35, 38, 39).

Path analysis demonstrated that parent's duration of work was effective in children's staying alone at home, and children who spend more hours per day alone spend more time watching TV and using computers. Therefore, these children have less activity and more BMI. Furthermore, children who spent more hours a day at home alone, ate more meals alone and ate more fast-foods and, hence, had higher BMI.

There are some limitations and caveats in this study that need to be addressed. Choosing samples from urban populations, investigation of feeding habits and physical activity based on self-designed questionnaires are among the most important limitations and caveats of our study.

## Conclusion

Considering all the facts, this study indicated a high prevalence of obesity in children from Sari, that was significantly related to socio-economic factors such as job type, hours of watching TV per day, and hours using mobile and tablet per day. This study indicates that it is mandatory to pay serious attention to the issue of childhood obesity, conducting a more broad range of studies, investigation of underlying contributing factors, and developing favorable interventions.

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# Study on the Effect of Quality of Life Improvement on Self-Esteem in Patients on Hemodialysis

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## Abstract

**Background and Objective:** Evaluating self-esteem is important in patients with hemodialysis. Low self-esteem as a problem in patients with hemodialysis reduces adherence to treatment in these patients. The objective of the present study was to determine the effect of training of quality of life on self-esteem of patients with hemodialysis.

**Materials and Methods:** This is a clinical trial study. The society of this study consisted of patients referred to hemodialysis centers in Kerman, Iran. The sample size was 90 patients who were divided randomly based on target into two groups (in each case and control group,  $n = 45$ ). For both groups, the first test was performed. In the intervention group, a quality of life curriculum was delivered in a lecture, a question and answer, and an educational pamphlet during 3 45-minute sessions. The interval between each session was 10 days. The tools used in this study were demographic questionnaire, quality of life (BREF-WHOQOL) and Rosenberg's self-esteem inventory that was classified in high, medium and low level. Both groups were first tested and in an intervention group training program to improve the quality of life in the form of lectures, question and answer and to provision of educational pamphlets during the three sessions were conducted for 45-minutes with an interval of 10 days between each. After two months from the first test, both groups were tested for a second time and then data was analyzed using SPSS/15 Software and descriptive and inferential statistics (mean, standard deviation, Chi-square, independent t-test) were calculated.

**Findings:** There was no significant difference between the two groups in quality of life and self-esteem before training (respectively  $P=0.67$ ,  $P=0.6$ ). After the intervention, there was a significant difference between the two groups in quality of life and self-esteem. (Respectively  $P=0.001$ ,  $P=0.001$ )

**Discussion & Conclusion:** This study showed that training of quality of life improvement affects self-esteem of patients on hemodialysis. Due to the effect of training on increasing self-esteem and quality of life in patients with hemodialysis, it is recommended to train in quality of life as part of the training program in hemodialysis units, as well as other chronic diseases which may benefit from such training.

**Key words:** Quality of Life, Self-Esteem, Hemodialysis

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## Introduction

Chronic diseases can cause psychological and debilitating consequences in patients. One of these diseases is chronic renal failure. (1) According to statistics, the prevalence of chronic renal failure in the world is 260 cases per million people per year and this increases almost 6% annually. (2) According to the statistics of the Health Ministry, this disease increases 20 percent in Iran annually. (3)

Various methods are recommended for the treatment of patients with chronic renal failure and one of the most effective and most common is hemodialysis. Although, hemodialysis increases longevity in patients with kidney failure, it also poses several problems. Hemodialysis can change the lifestyle, health status and social functioning of individuals. In addition, this method imposes high expenditure and affects quality of life. (4, 5)

On the other hand, hemodialysis is a significant source of stress. According to a study, approximately 10% of patients with hemodialysis were admitted to psychiatric hospitals during one year. (6) These patients need great care in relation to psychological issues of hemodialysis. These people also know that their lives depend on hemodialysis and on the other hand it creates limitations and changes in their lives. Their treatment plan is difficult; sometimes these patients feel they are in a stage between life and death.

The risk of suicide in these patients is much more than normal people. Jobs, financial situation, nutritional concerns about marriage and sexual problems, readmission and the fear of death, changes their quality of life in the long-term. (7) Such that, the quality of life for patients in end-stage renal failure not only is lower than in ordinary people, but also is lower than other chronic diseases due to frequent hospitalization. (8) Hemodialysis is a long and stressful process, followed by mood disorders and psychological problems for the patients. (1)

Psychologically, chronic renal failure can lead to a dependence on others, low self-esteem and loneliness. (9) Because start of dialysis services for patients is starting a different experience, where standards and the rhythm of life began to change, their desires and abilities are impaired, followed by isolation and low self-esteem. (10)

Research that has been conducted since 1950 shows that diseases, treatment and complications relate to changed image and self-esteem in sick persons. (11) So these patients need to change their ability of coping with changes in lifestyle and behavior. According to the value and the price that these patients ascribe to themselves, their control and mental equilibrium is established. (6) These patients need special training in order to continuously improve self-esteem and motivation to participate in their own care behaviors. (10).

Accordingly, due to the chronic, dynamic and changing nature of the problem in these patients, having high morale and self-esteem can withstand their hardships and suffering. Since, no study has been conducted about the training of quality of life (physical, psychological, familial, social) on self-esteem of hemodialysis patients, the researcher aims to determine the effect of training of quality of life on self-esteem in these patients.

## Materials and methods

This clinical trial study was done on patients on hemodialysis who referred to Dialysis center in Kerman. Data collected in this study include:

1. The demographic questionnaire which included age, sex, marital status, education, occupation, income, housing status, income, duration of hemodialysis, time and number of hemodialysis hours per week.
2. The Rosenberg Self-Esteem Scale in five positive and five negative phrase sentences to each question from completely agree, agree, disagree and strongly disagree score (0-3).
3. Quality of Life Questionnaire (WHOQOL-BREF) which consists of 26 questions in the areas of physical health (7 questions) and mental health (6 questions) social relations (3 questions) and environment (8 questions) and two questions in any area. Both questionnaires with score (0-100) were classified in three High (66.7% -100%), moderate (33.4%-66.6%) and low (0%-33.3%) levels.

Content validity was used to examine the validity of the questionnaires. This means that after translation the questionnaires from the original opinion of 10 professors and experts was measured for clarity and simplicity and questions were assigned with numbers from 1 (strongly disagree) to 4 (strongly agree). Scores of items from 0.25 for choosing score 1 and score of 1 for choosing four were considered and in the end scores were calculated so that the average for both questionnaires was  $cv=0.77$ .

The reliability of both questionnaires was measured using test-retest and formula (Pearson Brown) and Cronbach's alpha. Reliability of Rosenberg's inventory has been measured repeatedly in Iran and other countries; using Cronbach's alpha coefficient Ozmen et al., and Rajabi et al obtained reliability above 0.8. (12,13) and Nejat et al by standardization of this inventory in Iran, Cronbach's alpha and intra-class correlation values in all fields of the questionnaire were reported above 0.70. (14)

Sathvik et al. calculated reliability of the questionnaire using Test-retest that showed high reliability. (15) In this study, Cronbach's alpha coefficient and Pearson and Brown was obtained respectively for Rosenberg Self-Esteem Scale ( $r=0.98$ ,  $\alpha=0.86$ ) and Quality of Life Questionnaire ( $r=0.95$ ,  $\alpha=0.85$ ).



The sample size was 45 subjects calculated using a statistical formula; then out of 153 patients with hemodialysis, 9 subjects were selected randomly (draw) according to inclusion criteria which included older than 18 years, passing at least 6 months of hemodialysis, a minimum level of literacy, lack of specific events affecting the self-esteem level (such as burns or change in body shape), kidney transplant and not continuing participating in the same study and were divided into two groups of 45 subjects.

Compliance with all the provisions of the Helsinki Declaration on Ethics of Research, as well as the aim of this study for patients, and written informed consent to participate in research, confidentiality of information and association of patients participating or not participating in the study, both groups were tested for the first time.

Then, according to the manual prepared by the researcher in the components including (physical, psychological, social and familial) with sections such as familiarity with kidney and its function, chronic renal failure and its causes, hemodialysis procedures during its complications, achieving ways to maintain the vascular arteries, diet, nutrient intake and limited food groups, how to calculate daily fluid, example of daily diet, control weight, control appetite and disturbed sleep, daily exercise, ways to boost morale and social and family relationships, leisure, happy way of living, relaxation and meditation and spiritual relationship that were developed after the approval of 10 experts from the Group of different nurses, doctors and nephrologist consensus was reached; during the third training session of 45 minutes with an interval of 10 days between each session, individually and in lectures were conducted and question and answer booklets were provided to participants.

After two months from the last training session, a second test was taken. Data obtained were analyzed using SPSS/15 software and descriptive and inferential statistics (mean, standard deviation, Paired t-test, independent t-test chi-square test) were calculated.

## Findings

Based on the results obtained in this study, the mean age of subjects in the case group was  $2.22 \pm 42.3$  years old and in the control group was  $2.26 \pm 43.12$  (57.8%). 57.8% of subjects in the case group were male. In the control group, 60% were male. In the case group, (66.7%) were married. In the control group (68.9%) were married people. The mean duration of hemodialysis in the intervention group was  $4.4 \pm 7.37$ , and in the control group was  $4.20 \pm 6.48$  years.

Starting time of hemodialysis in the intervention group was (37.8%) in the control group (40%) was 1-4 years and the number of hemodialysis in intervention group was (84.4%) and in control group was (82.2%) 3 times a week and hours of hemodialysis in the intervention group was (80%) and in the control group (75.6%) was 4 hours that in all cases demographic characteristics were similar between groups using the chi-square test ( $P \leq 0.05$ ). In terms of demographic characteristics there was no statistically significant difference between the two groups using chi-square test. (Table 1 - next page)

The findings related to the components of quality of life (physical, psychological, social relations and environment) and also overall life quality in both intervention and control groups, in pre-test and post-test in high, medium and low levels as shown in Table 2. According to this table, there is a significant difference between the percentage of patients in each of the levels classified into four components (physical, mental health, social relations and environment) and also quality of life in the two groups in pre-test and post-test.

Findings related to the comparison of components of quality of life (physical, psychological, social relations and environment) and also overall life quality in the pre-test and post-test in intervention and control groups in three levels of high, medium and low levels are shown in Table 3.

According to this table, in all 4 components (physical, mental health, social relations and the environment) and also overall quality of life in the two groups in the pretest of all sizes is ( $P \geq 0.05$ ) As a result there is no significant difference; but in the post-test of all sizes and also overall life quality is ( $P \leq 0.05$ ), thus there is a significant difference. Findings also related to self-esteem in the intervention and control groups, in the pre-test and self-esteem compared between the two groups in pre-test and post-test is shown in Table (4).

According to Table 4, there is no significant difference between the two groups in self-esteem of patients in the pretest ( $P \geq 0.05$ ), but there is a significant difference in the post-test ( $P \leq 0.05$ ).

Table 1: Demographic factors in two groups.

* P	percent of control	percent of intervention	Variable
			<b>Gender</b>
	40	42.2	Women
0.83	60	57.8	Men
	6.7	8.9	<b>Age</b>
			Lower 25 years old
	26.7	28.9	25-34
	17.8	13.3	35-44
0.92	15.6	11.1	45-54
	33.3	37.8	55+
			<b>Marriage status</b>
	26.7	26.7	Single
0.89	68.9	66.7	Married
			<b>Education</b>
	33.3	35.6	Primary
	26.7	31.1	Secondary
0.89	26.7	24.4	Diploma
	13.3	8.9	Academic
			<b>Job</b>
	4.4	2.2	Employee
0.98	6.7	8.9	Worker
	33.3	33.3	Housewife
	8.9	8.9	Free
	26.7	28.9	Retired
	20	17.8	Unemployed
			<b>Monthly income</b>
	37.8	35.6	2,500,000 rials >
	46.7	42.2	2,500,000 – 5,000,000 rials
0.71	15.6	22.2	5,000,000 rials <
			<b>Status of life</b>
	48.9	53.3	Living with couple and children
0.82	20	13.3	Living with couple
	26.7	26.7	Living with parents
	4.4	6.7	Living with children
			<b>Duration of starting dialysis (year)</b>
0.92	22.2	24.4	Lower 1 year
	40	37.8	1-4 years
	22.2	17.8	5-9 years
	13.3	13.3	10-14 years
	2.2	6.7	Above 15 years old
			<b>Times of dialysis in a week</b>
0.77	17.8	15.6	2 times
	82.2	84.4	3 times
			<b>Hour of dialysis</b>
0.61	24.4	20	3 hours
	75.6	80	4 hours

Chi-square = 2 χ \*Result of test

**Table 2. Frequency distribution of each component and quality of life among the two groups in pre-test and post-test**

Control group						Intervention group						
Post-test			Pre-test			Post-test			Pre-test			
low	middle	High	low	middle	High	low	middle	High	low	middle	High	
75.6	24.4	0	73.3	24.4	2.2	60	28.9	11	71.1	24.4	4.4	Physical component
71.1	24.4	4.4	71.1	24.4	4.4	35.6	48.9	15.6	68.9	26.7	4.4	Mental health
20	64.4	7	20	73.9	6.7	4.4	44.4	51.1	17.8	68.9	13.3	Social relation
48.9	48.9	2.2	48.9	48.9	2.2	24.4	68.9	6.7	44.4	53.3	2.2	Environmental health
62.2	37.8	0	64.4	35.6	0	24.4	68.9	6.7	60	40	0	Total quality of life

\* High (7-66.100) moderate (4.6-33.66) Low (0.3-33) numbers are based on the percentage in table.

**Table 3: Comparison of each component and quality of life between two groups in both tests**

Post-test (between two groups)				Pre-test (between two groups)			
p-value	df	$\chi^2$		** p-value	df	* $\chi^2$	
0.05	2	5.97		0.84	2	0.34	Physical components
0.003	2	11.7		0.97	2	0.05	Mental health
0.001	2	14.64		0.57	2	1.12	Social relations
0.04	2	6.19		0.91	2	0.18	Environmental health
0.001	2	14.49		0.66	1	0.18	Total quality of life

\*  $\chi^2$  = Chi-square \*\* $P \leq 0.05 = 2 \chi^*$

**Table 4: Distribution of frequency of self-esteem in three levels of two groups and comparing both tests**

Post-test			Pre-test			Self-esteem
low	middle	High	low *	middle	High	
42.2	51.1	6.7	44.4	48.9	6.7	Control group
4.4	35.6	60	35.6	55.6	8.9	Intervention group
P-value	df	$\chi^2$	0.77	*** p-value	df	** $\chi^2$
0.001	2	34.2	0.67		2	

Chi-square \*\*\* $P \leq 0.05 = 2 \chi^{**}$ ; \* High (66.7-100) moderate (33.4-66.6) Low (0-33.3) numbers are based on the percentage table.



## Discussion and Conclusion

Findings obtained in this study showed that quality of life in patients on hemodialysis in both physical and psychological domains is at a low level, in social relations and environmental health is at intermediate level and overall quality of life is at a low level. Taheri and Baraz reported the quality of life in patients on hemodialysis at a low level. (16, 17) Rodrigues et al stated in their study that mean score for quality of life in hemodialysis patients was lower than normal and this indicates low quality of life in these people. (18)

However, Mazairac in a study on 570 patients on hemodialysis reported the quality of life in the optimal level. (19) In this study, after training in the intervention group, quality of life increased to an intermediate level. Other studies have also confirmed the results. Alikari et al with training in form of counseling, booklets and educational films indicated a positive effect on the quality of life in patients on hemodialysis. (20)

De Moura Reboredo et al also showed that training exercises can improve the quality of life in patients on hemodialysis. (21) Loos Aya et al in France showed that self-care training affects quality of life in patients on hemodialysis, during one year, training affected the quality of life in people on hemodialysis and increased it in different aspects. (22)

Yen et al, in Taiwan also stated that training increases physical, mental and social aspects in patients. (23) Although the above study indicates the effectiveness of training on improving the quality of life in patients, however, in the mentioned studies the score of quality of life is different, and this is due to the different education programs applying different questionnaires to assess quality of life, as well as the different needs of patients.

This study showed that patients' self-esteem before training sessions was at intermediate level and after the intervention was at a higher level. This study is consistent with Chen et al on the effects of group therapy on self-esteem and depression. Their study showed that group therapy increases self-esteem and decreases depression in patients. (24) Lee et al showed in a study on patients with cancer that telling some stories of people with cancer increases their self-esteem, self-efficacy and positive attitudes in the patients. (25) Poorgholami et al also showed that follow-up care increases patients' self-esteem (1). All these research studies are consistent with the results of the present study.

According to the results, due to the fact that high self-esteem increases ability to adapt to different conditions and controls threatening aspects in patients on hemodialysis it is of utmost importance and it can be concluded that quality of life where it covers almost every aspect of life can affect the physical and mental aspects such as self-esteem in patients on hemodialysis faced with different complications of mortality and costs of treatment, quality of life, physical and psychological problems and have positive impact on them and eases the burden of their disease.

It should be noted, the limitations in this study are small sample size and short duration of the study. Therefore, it is recommended to conduct some studies with larger sample size and longer follow-up period. Also, some studies on the effect of family therapy, training of social relations on self-esteem of patients on hemodialysis should be conducted. Finally, since the objective of nursing research is to enjoy results that solve the problems and consequences of care, reduce costs, increase quality of service and improve the health of society, findings of this study can be used in various fields of nursing, family, community, media and training.

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# The effectiveness of empowerment of couples group therapy on marital satisfaction of couples referred to Better Life Counseling Centre, in Tehran, Iran

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## Abstract

This study examines the effectiveness of empowerment of couples' group therapy that focuses on marital satisfaction. A quasi-experimental study with pre-test, post-test control group was held for the couples referred to Better Life Counseling Centre in Tehran. Sampling method was available for 30 couples who met the criteria for entry into the study and for whom the basis of marital satisfaction was low. Enrich marital satisfaction questionnaire, was chosen. They were randomly divided into two groups (15 couples) and control (15 couples). Couples in the experimental group received group training sessions to empower couples in 10 sessions and each session took 180 minutes. The control group did not receive any training and therapy. After the training sessions, post-test in both groups was held, and was conducted simultaneously. Data analysis was performed by covariance. Results of the analysis showed that education is effective in empowering couples group therapy in marital satisfaction and was effective in the experimental group.

**Key words:** Education empowers couples,  
Marital satisfaction

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## Introduction

Most approve marriage as a social custom to meet emotional needs, and mental and emotional commitment, and it can be the first emotional and legal commitment in adulthood.

Since the ratification of marriage is considered as a milestone in the development of character, the choice of partner is one of the most important decisions in life. Nowadays, the basic reasons for marriage have undergone changes since the past. In today's society, reasons for marriage are mainly expressed as for the acquisition of love and affection, having a partner in life, satisfaction of emotional & psychological need. (Berian-Eshtin 1990-Sohrab-translation 1382).

Marriage and family, in addition to supplying and satisfying the emotional, psychological, security, and sexual needs of couples also provides a focus for a healthy and safe environment that provides support for family members. Of course, that if the relationship between the couple and the whole family, healthy, warm and intimate would be away from tension (Oraki, Jamali, Farajolah, Firooz Jayei, 1391). In between, satisfaction, intimacy & harmony between couples are the most importance. Because of it can lead to happiness (Wilson & Oswald, 2005), well-being (Diener, Gohm, Suh & Oishi, 2002), and public health for couples (Lamb, Lee & Demarris, 2003), and also plays an important role in maintaining family, duties of parents and parenting play (Tung, Campbl & Foster, 2003).

Due to the pleasant feeling that occurs after satisfaction and with compatibility between couples the lack of satisfaction and compatibility between couples reduces them and causes negative phenomena such as divorce (Gottman & Levenson, 2000).

Several researchers (Bakhshh, Asadpour, Khodadadizadeh, 1386, Besharat, Tashak and Rezazadeh, 1385), and (Lourniso, 2009), have written on adverse effects of this discontent among couples in



creating feelings of depression, anxiety, loneliness and emptiness, low self-esteem and reducing the physical and mental health of couples, as well as its adverse effects in creating many problems for children, including depression, isolation, lack of social competence, poor academic performance and communication problems.

As a result of unfavorable roles of dissatisfaction and conflict between couples on their health and their children, many researchers look for appropriate solutions in numerous ways from educational and therapeutic measures to improve this important function which include accepted studies by Halford (2015), Brooks (2011), and Weigel (2006). Brooks (2011) in a study examined the role of marital education enrichment, relationship and intimacy between couples and showed that this treatment increases the satisfaction of couples with marriage. Weigel (2006) examined the affect of marital instruction on marriage satisfaction and showed this treatment has been effective in increasing marital satisfaction. Iran has also done research in this area by Parvin, Fatemi, Aminian and Rafiei Vardanjani (1393), Sepahvand (1393), Vakili (1392) and Sadeghi (1389) that can be referred to. Parvin et.al (1393) In a study entitled impact of life skills training sessions on marital satisfaction of women working in Hajar hospital in Shahrekord as nursing staff, found that marital satisfaction scores were not statistically significantly different before and after intervention as a result of the intervention promoting marital satisfaction. The results of Sepahvand, Rasoulzadeh Tabatabai, Besharat and Allahyari (1393), compared an integrative couple therapy model based on self-regulation - attachment with the enrichment of marital couples marital satisfaction and psychological well-being and showed that the combination therapy based on self-regulation of couples; love and marriage enrichment programs in each of the dependent variables had significant differences compared to the control group.

Vakili (1392) in a study to compare the efficacy of couple therapy focused on emotion and marital conflict and interpersonal cognitive distortions where couples were referred to culture family houses in Isfahan city and showed that couple therapy focused on emotion and couple therapy cognitive-behavioral interventions reduced interpersonal distortion and reduced conflicts of marital couples. Sadeghi (1389) showed the effectiveness of training as enrichment of marriage life satisfaction and intimacy and that this method of teaching influences another training method that has been less discussed in the context of marital relationships, education in empowering couples. The educational approach tries to upgrade and change elements in a marital relationship, due to lack of consistency and marital satisfaction among couples and turn them into high adjustment and satisfaction.

This training aims to address the problems before they become critical and equip couples with the skills and insights needed to deal with future problems, to increase their satisfaction with the marriage. This training method sees the most common cause of marital problems as an inability to communicate well and healthily, and believes that many couples lack communication skills and are not

satisfied with their lives and in need of intervention specialized. They believe that healthy couples with skills training, explore new and effective methods and that they use more power and at the same time do not deprive others of their needs and achieve a better companionship for people strengthens their relationship.

According to mentioned materials, this present study aimed to identify balance effectiveness of instruction of spouses self-empowering to increase their satisfaction and sexual relations, to answer to the question. Does self-empowering spouse education increase their sexual relations satisfaction?

### **Research approach, statistics and sample population:**

This study is quasi experimental with pre-test, post-test and control group. The research population constituted all couples of Better Life council center in Tehran 1393. Sampling approach was available. They were 30 couples whose marital satisfaction test showed they have low marital satisfaction. Criteria of entry into the study included: age range between 20-35 years, after more than 5 years of marriage. Spouses needed to live in their own house.

Criteria also included lack of medical conditions such as cardiovascular, or pulmonary disorders and lack of any form of psychiatric disorders such as depression, and lack of action for divorce, Education had the least degree and participants had to have a common desire to participate in the program. Such participants were then selected and randomly divided into control and experimental groups.

Among the participants, 17 (28.3 percent) had the age of 30-25, 13 (21.7 percent) the age of 35-31 and 30 (0/50 percent) were in the 40-36 age profile. 8 people (13.3%) had an associate degree, 34 person (7/56 percent) had a bachelor's degree and 18 (0.30 percent) had a master's degree.

### **Measuring tool**

In this study the Enrich marital satisfaction questionnaire was used. This questionnaire was prepared in 1989 by Alson, Fournir and Darkman. It has 115 questions and evaluated 12 subscales. Questions are as 5 options (completely agree, agree, neither agree nor disagree, disagree, completely disagree).

This questionnaire evaluates subscales of idealistic distortion, marital satisfaction, personality issues, relationship, financial management, leisure activity, the roles of egalitarianism, sexual relation, ideological orientation, children and parenting, family and friends and also conflict resolution. Grading of the questionnaire is based on Likert 5 scale. Questions 3, 4, and 6 to 34 had scoring reversed. In other words, these questions will accrue score 1 to I completely agree and 5 to I completely disagree. Soleymaniyan and Navabinejad have reported and calculated internal consistency of the test for long form at 93% and 95% for short form.

Cronbach's alpha of this questionnaire in the present study was marked for subscales of idealistic distortion, marital satisfaction, personality issues, relationship, financial management, leisure activity, the roles of egalitarianism, sexual relation, ideological orientation, conflict resolution were equal in order of 72%, 85%, 76% and 83%.

### Procedure and data analysis

In this study the empowerment of training couples was defined as independent variables and the dependent variable was defined as marital satisfaction. Each couple, in the testing group took part in 15 sessions for 180 minutes of couple's empowerment training and the session was held twice a week.

The following provides a summary of what occurred in these meetings.

#### First session:

This session is run with the aim of briefing members and logic expressed and the objectives of the training session by the group coach after introducing himself to members to the members and then the member introduce themselves after which the education executive gives information to members about couples empowering education. Rules of the group: couples regular participation in all meetings, doing homework, presenting it in next meeting.

#### Second session:

This session was held with the aim of training in the form of an outline of the overall context, problems for each of the couples and awareness of each couple about the impact of irrational beliefs in creating and forming these problems.

#### Third session:

This session has the aim of intimacy and compatibility education between couples and education of different ways of behavior and performance for increasing marital intimacy.

#### Fourth session:

The aim of this session was improving sexual education. Training couples about sexual relations and informing of adverse effects of sexual dysfunction on relationships and training in good ways to improve sexual relations of couples.

#### Fifth session:

The purpose of this session is checking methods of conflict resolution. During this session couples are shown methods of appropriate and inappropriate behavior that can be effective on creating, or clearing marital conflict and to become acquainted with and taught conversation that helps in conflict resolution.

#### Sixth session:

This session has the aim of conflict resolution by education of problem solving such as defining problems and selecting of good methods for solving them. Also duties and obligations for each of these problems should be taken and couples trained in these ways.

#### Seventh session;

This session has the aim of discussing, compatibility of couples about capabilities and growth areas in religious beliefs.

#### Eighth session:

This session aims to rain in home management and how couples can solve domestic problems of daily life.

#### Ninth session:

This session aims to educate on effective relationships with family and friends.

#### Tenth session

Wrap-up session and final meeting and running the marital satisfaction post-test.

In this research we evaluated the raw data from the descriptive statistic average and standard deviation, descriptive statistics, covariance analysis using SPSS 21 to analyse data.

## Findings

In Table 1. The mean and standard deviation of the variables are presented.

**Table 1: Marital satisfaction mean scores of pre-test and post-test components of the test and control groups**

Control				Experimental				Variables
Post-test		Pre-test		Post-test		Pre-test		
Std	M	Std	M	Std	M	Std	M	
3.85	9.60	3.17	11.40	1.46	14.70	3.62	12.00	Idealistic distortion
5.02	19.70	4.69	20.60	3.85	23.33	4.97	19.36	Marital satisfaction
8.51	19.56	5.88	19.90	7.69	26.46	5.60	18.20	Personal issues
8.01	21.16	6.83	23.13	3.43	26.43	6.81	22.76	Conflict Resolution
6.08	22.26	4.97	24.66	2.59	23.93	5.38	23.66	Financial Management
5.25	21.23	5.20	21.33	5.43	21.76	3.72	21.23	Free time
7.35	28.80	6.21	30.53	6.20	28.06	7.46	27.63	Sexual relations
4.45	18.16	7.43	26.73	5.41	22.96	8.62	21.56	Relationship
7.19	14.60	3.81	19.73	5.77	21.50	4.30	21.20	Children
3.78	1083	5.14	14.36	1.46	14.70	5.06	14.66	Friends and relatives
5.00	19.33	1.70	19.30	3.85	23.33	2.58	19.30	Role of egalitarianism
9.40	20.03	4.36	21.06	7.69	26.46	3.03	22.53	Religious orientation

As can be seen in Table 1. The mean marital satisfaction test in the experimental group is higher than the pre-test. Levene's test was used to test the assumptions. In order to assume equal variances (significance level was greater than 0.05). In fact, if the level is significantly less than 0.05, the assumption of homogeneity of variances is violated. Levene's test results are reported in Table 2. According to the results in Table 2, the level of significance for each of the dependent variables is larger than 0.05. So the assumption of homogeneity of error variances is revealed.

**Table 2: Test to examine the assumption of homogeneity of variance of the error (Levene)**

Significance level	Df2	Df1	F	
0.372	58	1	0.808	Idealistic distortion
0.352	58	1	0.879	Marital satisfaction
0.903	58	1	0.015	Personal issues
0.468	58	1	0.533	Relationship
0.967	58	1	0.002	Financial Management
0.236	58	1	1.434	Free time
0.253	58	1	1.334	Sexual relations
0.350	58	1	0.888	Children
0.608	58	1	0.256	Friends and relatives
0.137	58	1	2.268	Role of egalitarianism
0.058	58	1	3.729	Religious orientation
0.424	58	1	0.648	Overall satisfaction

The results of analysis of variance for marital satisfaction of spouses in the post-test are presented in Table 3:

**Table 3: Univariate analysis of covariance on marital satisfaction of spouses in both experimental and control groups after adjusting for pre-test scores**

Ability test	Effect	Significance level	F	Mean square	df	Total squares	
1.000	0.562	0.006	73019.091	38583.173	1	38583.173	Overall satisfaction

Table 3 shows that by eliminating the effect of pre-test scores were for marital satisfactions in terms of membership there is a significant difference. This hypothesis is confirmed. So we can conclude that empowerment education in the experimental group had an impact on marital satisfaction. (According to the average of the scores given in Table 1, empowering education increased marital satisfaction in the test group versus the control group). The intervention effect was 562/0 and 000/1 statistical power.

The results of analysis of variance for marital satisfaction in the post-test are presented in Table 4:

**Table 4: Multivariate analysis of variance test of marital satisfaction scores in the experimental and control groups with control pre-test**

Significant degree	Error df	Hypo df	F	Value	
0.001	35	12	10.487	0.782	Lambda Wilkes

Table 4 shows the results of multivariate analysis of covariance (Wilks Lambda) on components of marital satisfaction, between the experimental and control groups where at least one of the dependent variables is significant. To find out which of the components are different between the two groups of univariate analysis of covariance was used in the MANCOVA test where results are reported (Table 5 - next page).

Table 5 shows that by eliminating the effect of pre-test scores we estimated between idealistic distortion, marital satisfaction, personality issues, communication, financial management roles egalitarianism, religion, children, parenting, family and friends for resolving the conflict in terms of membership there is a significant difference.

So it can be concluded that education in empowering couples in the experimental group had an impact on marital satisfaction. \



**Table 5: Univariate analysis of covariance marital satisfaction in both experimental and control groups after adjusting for pre-test scores**

Significance level	F	Mean square	df	Total squares	
0.000	31.008	303.859	1	303.859	Idealistic distortion
0.001	12.492	228.616	1	228.616	Marital Satisfaction
0.007	7.839	422.359	1	422.359	Personal issues
0.004	90108	381.123	1	381.123	Conflict Resolution
0.151	21.134	46317	1	46317	Financial Management
0.963	0.002	0.071	1	0.071	Free time
0.151	2.132	36.426	1	36.426	Sexual relations
0.001	12.854	326.754	1	326.754	Relationship
0.000	21.898	922.617	1	922.617	Children
0.000	18.799	169.190	1	169.190	Friends and relatives
0.001	13.955	253.957	1	253.957	Role of egalitarianism
0.019	5.924	313.074	1	313.074	Religious orientation

## Discussion and Conclusion

This study aimed to determine the effectiveness of empowerment to improve marital satisfaction in couples. The results of this study showed that couple's empowerment training improved marital satisfaction in the experimental group in the post-impact test. According to the results of Table 1, the average marital satisfaction in the experimental group, who received training, was higher in the post test than in the control group. This result was consistent with the findings of Oraki et.al (1391), and Eisanejad et.al (1390).

Oraki et.al (1391), in a study to assess the effectiveness of their marital relationship enhancement program on adaptation showed that this training increased the marital compatibility.

Eisanejad et.al (1390), during research on improving the effectiveness of enrichment of optimism and happiness of marital couples showed that the training is effective in improving optimism and marital happiness. One of the most important factors that affects the survival and growth of the family, healthy relationships and understanding between members, especially spouses is marital satisfaction and a well-functioning family infrastructure, that facilitates the role of parents and provides economic growth and life satisfaction. On the other hand there is dissatisfaction in relationships, in addition to the foregoing problems, causing difficulty in social relationships, and a tendency to social deviations and decline of moral and cultural values between couples. Satisfaction and marital compatibility is a situation in which a general feeling of happiness and satisfaction exists in the couple. Marital satisfaction as a couple adaptive process allows couples to feel satisfied with marriage and each other and to have common interests and activities and feel that their expectations are met with marriage.

The education of couple's empowerment shows the most important problem of couples is their inability to properly communicate, and due to this lack of proper communication skills many couples were not satisfied with their lives and

require specialized intervention. They believe that couples with good education skills discover and achieve effective new skills where they can have more authority over their lives and as they achieve their needs they don't exclude other and become more helpful and strengthen their close relations.

If marital satisfaction in the family is weak, especially in couples who don't have mutual understanding the family atmosphere will be cold and lifeless. Clinical experiences and studies also show that the root of many marital problems is lack of communication between couples. Lack of training in sexual relations may relate to limitations in our country's culture and back ground and education on these issues can improve intimate marital relationships. . The study was restricted to couple in the Better Life Counseling Centre and a wider sample selection would have been better. problems. What should not be ignored is it was effective and the research final results, were compounded by being of short duration of treatment and having time limits.

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# Effectiveness of schema therapy on body-image, self-concept, maladaptive schemas in patients with body dysmorphic disorder

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## Abstract

This study aimed to evaluate the effectiveness of schema therapy on body-image, self-concept, and maladaptive schemas in patients with body dysmorphic disorder. This is a quasi-experimental study, with pretest-posttest research plan and follow-up services. The research population comprised all patients with body dysmorphic disorder in Ahvaz city. The sample consisted of 10 people from this population having dysmorphic disorder whose selection was done randomly and when chosen, they were divided into two groups of experimental and control. Instruments used in this research are satisfaction with body-image questionnaire (Soutu and Garcia, 2002), self-concept questionnaire (Beck et al., 1990), body dysmorphic disorder questionnaire (Rabie et al., 1390) and the Young Schema Questionnaire (shortened form) (Schmidt, Joiner, Young and Telch, 1995; as quoted from Hamidpour, Dolatshahi, Poorshahbaz, Dadkhah, 1389). In this study, after the position of baseline, the intervention began and after 20 sessions of schema therapy for these participants was carried out, there was a follow up after the interval of one month. To analyze the data, multivariate analysis of covariance (MANCOVA) was used. The results of data analysis showed that schema therapy leads to an increase in satisfaction with body-image, elevation of self-concept and reduction of body maladaptive schemata in the patients with deformity in the experimental group, compared to the control group.

**Key words:** schema therapy, body-image, self-concept, maladaptive schemata, body dysmorphic disorder

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## Introduction

In order to achieve a healthy and satisfactory life and to comply with our own needs and those of others, having a realistic and appropriate self-image is a necessity. That is, if a person has a satisfactory feeling toward their own physical appearance, it is more likely for them to have a positive body-image. However, tension and anxiety, self-critical view, and low self-worth affect negatively the way a person feels about their body and leads them to change their appearance by various surgeries and other methods (Stewart, 2006; as cited in Hosseini, Ghasemi, Molaei Gonbadi & Rezaei, 1389). Body-image is a complex phenomenon which has recently been in the center of various experts' attentions, though it lacks a well-established definition. It is the mental representation of one's physical appearance (Cash, 2004). In effect, it is a mental image which embraces one's body-related beliefs as well as conscious and unconscious feelings (Omidi, Ghafrani pour Hosseini, 2006). Mental body-image is the way a person thinks about their physical appearance and each part of body mind. It is a multifaceted phenomenon, made up of tactile, optical and emotional aspects or feelings of people about themselves (Garousi, Nematollahi, & Rafsanjani, 1392). Body-image is usually defined as a degree of a person's satisfaction with their physical body and encompasses negative and positive feelings of a person about their body form and size. Negative self-image can lead to dissatisfaction with the body and having the feeling of being unattractive which means being too preoccupied with the physical appearance and brings about performance disorder (Keivan ara, Haghghian, & Kavezadeh, 1391). Satisfaction with body-image may include appearance evaluation which is the person's general evaluation about being physically attractive and the sense of being satisfied with their own appearance. Appearance orientation is how much a person invests in their own appearance and it includes a person's behavior frequency with the goal of physical appearance upkeep or improvement. Satisfaction with body organs is the same as satisfaction with specifics of body areas such as face, hair, muscles and so on. Overweight preoccupation is



defined as too much worry about being fat, caring about being overweight, going on a diet, and limiting the amount of food intake (Dehghani et al, 1390). Each individual has an image of themselves in their mind. In other words, general evaluation of an individual of their personality is called self-concept or self-image. This evaluation is a kind of mental evaluation that a person makes about their behavioral qualities and, as a result, self-concept might be positive or negative (Taghizadeh, 1379). Self-concept was firstly put forth as a dynamic organization by Laki (1998). To him, people's behavior is a display and motif with the purpose of self-stabilization in unstable conditions. In short, we can say that self-concept is a well-known frame by which we organize what we know about ourselves and, according to which, we process what is associated with ourselves. This generalized other includes specific components which act as personality tendencies. Three items of such components are individual difference in self-evaluation, belief in oneself in order to achieve desirable ends, and showing interest with the purpose of being influential on others by closely watching one's own behavior (Taghizadeh, 1379). In recent years, recognition therapy theory, in a narrow sense, and behavioral cognitive therapies, in a broader sense, have made a new destiny for mental therapies. One major component of the cognitive model is called "schema". Schema is not a new structure in cognitive sciences as Beck, when forming cognitive theory, made use of this concept to justify the mechanism of emotional-cognitive process (Rizzo, Tweet, Austin, Young, 2007, as translated by Moloudi and Ahmadi, 1390). Schema therapy, which was introduced by Young and colleagues (Young, 1990 & 1999, translated by Hamidpour and Andouz, 1386), is a modern and integrated treatment mainly based on concept development and classic behavioral-cognitive therapies. Schema therapy has combined the principles of behavioral-cognitive schools, attachment, Gestalt, object relationships, constructivism, and psychoanalysis into one conceptual model being the basis for a valuable type of therapy. Young emphasizes on the deepest level of cognition i.e., Early maladaptive schema.

The Early maladaptive schema is the oldest component of cognitive, beliefs, and unconditional feelings about oneself and is developed in childhood and adolescence, stemming from an interplay between the child's innate temperament, and the child's ongoing damaging experiences with parents, siblings, or peers. The development and high intensity of schema is the result of high distortion level and chronically damaging patterns throughout a person's whole life. Maladaptive schema is formed due to dissatisfaction with the conditions of basic emotional needs in childhood. Such needs involve safe attachment to others (including the need for security, stability, affection and acceptance), autonomy, self-sufficiency and identity, freedom in expressing the healthy needs and passions, self-excitation and entertainment, realistic limitations, and self-control. Young divided 18 schemata based on an individual's five emotional needs and called them schema domains. The first domain is Disconnection and Rejection, including abandonment/ Instability, Mistrust/Abuse, Emotional Deprivation, Defectiveness/shame, Social isolation/

Alienation. The second domain is Impaired Autonomy and Performance, including Dependence/Incompetence, Vulnerability to harm or Illness, Enmeshment/Undeveloped Self, and Failure. The third domain is impaired limits, including Entitlement/Grandiosity and Insufficient Self-control/ Self-discipline. The fourth domain is others' directedness, including Approval-seeking/ Recognition-seeking, Subjugation, and Self-Sacrifice. The fifth domain is over vigilance/Inhibition, including negativity/ Pessimism, Emotional Inhibition, Unrelenting standards/ Hypocriticalness, and Punitiveness.

## Research questions

Is schema therapy influential on body-image, self-concept and maladaptive schemata of the patients suffering from body dysmorphic disorder?

### Research hypothesis

**Hypothesis 1:** Schema therapy influences on body-image, self-concept and maladaptive schemata of the patients suffering from body dysmorphic disorder.

**Hypothesis 2:** Schema therapy influences on body-image of the patients suffering from body dysmorphic disorder.

**Hypothesis 3:** Schema therapy influences on self-concept of the patients suffering from body dysmorphic disorder.

**Hypothesis 4:** Schema therapy influences on maladaptive schemata of the patients suffering from body dysmorphic disorder.

**Hypothesis 5:** Schema therapy influences on body-image, self-concept and maladaptive schemata of the patients suffering from body dysmorphic disorder, when investigated in a one-month follow up stage.

### Procedure

The statistical population of the current research consists of all clients with body dysmorphic disorder who have referred to Ahvaz skin care Clinic. Ten patients, who according to the DSM-5 criteria were considered as having body dysmorphic disorder, were selected using convenience (availability) sampling, and then were divided into two groups of experimental and control. In this research, experimental method using a pretest and a posttest with a follow up stage on two experimental and control groups was exploited. Experimental and control groups were randomly made equal. Before the start of the experiment, a pretest and after the end of experiment, a posttest were run, after one month which, a follow-up was taken. Follow-up's aim was to explore the prolonged impact of the 3-month schema therapy on body-image, self-concept and maladaptive schemata of the patients with body dysmorphic disorder. That means, the schema therapy was considered as the independent variable of the study so that its influence on the dependent variables including body-image, self-concept and maladaptive schemata of the patients with body dysmorphic disorder is determined. The type of present study is experimental where a pretest and a posttest with follow-up are run on the experimental group.

## Measurement instruments

### 1. Satisfaction with body-image questionnaire (Soutu & Garcia, 2002)

Satisfaction with body-image (SWBI) questionnaire has 22 items and evaluates satisfaction or dissatisfaction of a person with their body. This questionnaire was firstly developed by Soutu and Garcia in 2002. It is scored following a five-point Likert Scale which was ranged from never to always. In Akhondzadeh's research (1391), the reliability of this questionnaire was guaranteed. Also, validity of it was reported to be acceptable. The questionnaire was analyzed by SPSS software and it was found that body-image is 74% positively related to marital satisfaction. In current research, alpha Cronbach method was used to determine the validity of the questionnaire and it was found to be 93% for the whole questionnaire which is acceptable.

### 2. Self-concept test (Beck et al, 1990)

Self-concept is the way we perceive ourselves. In other words, self-concept is an objective point of view that a person has of their own skills, characteristics, and abilities. There are several methods and questionnaires to evaluate self-concept, one of which is Beck's self-concept test (BSCT). This test, which was primarily developed in 1978 by Beck and Steer is based on Beck's cognitive theory, and has 25 items. Beck and colleagues (1985) reported the validity of 88% and 65% for this test; retests were done in one week and three months. Also, internal consistency coefficient for this scale is reported to be 80%. Reliability of this test when compared with the Rosenberg ego questionnaire is reported to be 55%. Furthermore, validity of this test is, using Cronbach alpha, said to be 80% for depressed men, 76% for depressed women, 78% for anxious men, and 78% for anxious women. In Iran, Mohammadi (1372) has reported the validity of this test, using Cronbach alpha, as 65% and 68%, respectively. Additionally, Dibajnia (1383) has obtained the figure of 79% Cronbach alpha for this test.

### 3. Young schema questionnaire (shortened form)

(Schmidt, Joiner, Young & Telch, 1995; as cited in Hamidpour, Dolatshahi, Pourshahbaz, & Dadkhah, 1389). This questionnaire has 75 items and was constructed by Young (1998) in order to evaluate 15 early maladaptive schemata including abandonment/instability, mistrust / abuse, social isolation / alienation, defectiveness/shame, emotional deprivation, dependence/incompetence, vulnerability to harm and illness, undeveloped self/enmeshment, entitlement/grandiosity, insufficient self-control/ subjugation, self-sacrifice, emotional inhabitation, unrelenting standards/ hyper criticalness. Each question is rated based on a 6-point scale (1 for completely false and 6 for completely true). In this questionnaire, every five questions evaluate one schema. Reliability and validity of this instrument has been confirmed through various research (e.g. John Baranoff & T.P.S. Oei, 2007). Normalization of this questionnaire was done in Iran by Aahi (1384) in Tehran University. Internal consistency was, using Cronbach alpha, found to be 97% in females and 98% in males.

### 4. Body dysmorphic disorder test

Evaluating metacognition aspects of body deformity, metacognition control strategies, thought or action coordination or mix of both, positive and negative metacognition beliefs, and safe behavior. In Rabie and colleagues' research (1390) where this questionnaire's reliability was studied on 200 students, it was found that body dysmorphic metacognition evaluation questionnaire and its components are positively and significantly related to the modified scale of obsessive compulsive disorder developed by Yale-Brown for BDD.

## Findings

Mean and standard deviation of body-image variable in experimental group in pretest were 31.20 and 1.64, respectively. These were 67.40 and 6.73 in posttest and 35.80 and 5.67 in follow up.

Mean and standard deviation of self-concept was 38.20 and 6.42 in pretest; 47.80 and 5.97 in posttest; and 50.20 and 6.37 in follow up.

Mean and standard deviation of maladaptive schemata in experimental group in pretest was 337.40 and 41.24; in posttest, 301.40 and 36.01 and in follow up, 283.40 and 26.63.

Mean and standard deviation of body-image in control group in pretest was 30.20 and 1.64; in posttest was 28.20 and 1.64 and in follow-up was 37 and 2.91.

Mean and standard deviation of self-concept in control group in pretest was 40.40 and 2.96; in posttest was 38 and 20.96 and in follow-up was 36.80 and 3.49.

Mean and standard deviation of maladaptive schemata of control group in pretest was 27.93 and 4.65; in posttest, 28.13 and 4.62; in follow-up, 28.0 and 4.56.

**Table 1: Equal assumptions variance error for body-image, self-concept, and maladaptive schemata**

Variable	Levin	F	Df1	Df2	Sig.
Body image	0.189	0.926	1	8	0.685
Self-concept	2.714	0.417	1	8	0.137
Maladaptive schemata	1.019	1.95	1	8	0.342

As can be seen from the table above, sig. value of body-image is 0.685, sig. value of self-concept is 0.138, and sig. value of maladaptive schemata is 0.342, all of which are greater than alpha level of 0.05. That is, F test value is not statistically significant and with 95% confidence, we can say that assumption of equality of variance error holds true.

**Table 2. Kolmogorov-Smirnov test to assess the data distribution normality**

variable	Body image	Self-concept	Maladaptive schemata
Number	10	10	10
Normal parameter	Mean	30.70	39.30
	Standard deviation	1.63	5.20
Kolmogorov-Smirnov value	0.840	0.802	0.453
Significance level	0.481	0.542	0.986

Results of Kolmogorov-Smirnov test, exploring the normality of data distribution, indicates that significance value of data distribution is greater than 0.05. That is, null hypothesis expressing the normality of data distribution is confirmed. That is, with 95% confidence, we have tested the research hypotheses, based on the parametric test assumptions.

**Table 3: Box test results to determine covariance and variance matrix**

index	Box value	F value	Df1	Df2	Sig. value
value	5.730	0.555	6	463.69	0.766

As can be seen from the table, sig. value is 0.766 which is greater than 0.05 and, as a result, with 95% confidence we can say that covariance homogeneity assumption is satisfied.

**Table 4. The assumption for body-image, self-concept and maladaptive schema regression slope**

variable	Ss	Df	Ms	F	Sig. value
Independent variable and body-image pre test	5.789	1	5.789	4.576	0.085
Independent variable and self-concept pretest	61.752	1	61.572	7.745	0.039
Independent variable and maladaptive schemata pretest	267.126	1	267.126	4.361	0.091

Since sig. value of the interaction between independent variable and body-image pretest, the one between independent variable and self-concept pretest, and the one between variable and maladaptive schemata pretest is greater than the alpha value of 0.05, the test calculated value is not statistically significant. That is, with 95% confidence we can say that regression slope homogeneity assumption is met.

**Table 5: Multivariate analysis of covariance (MANCOVA) on the posttest rates' mean of body-image, self-concept, and maladaptive schemata**

Test names	value	df hypothesis	df error	F	Eta square	Sig.	power
Pillai trace	0.998	3	3	441.03	0.998	0.000	1
Wilks' Lambda trace	0.002	3	3	441.03	0.998	0.000	1
Hotelling's trace	441.03	3	3	441.03	0.998	0.000	1
Roy's greatest root	441.03	3	3	441.03	0.998	0.000	1

As can be seen from the table, when controlling pretest, significance level of all tests demonstrates that there is a significant difference among body-image, self-concept and maladaptive schemata. To see which variables are different in the experimental group, when they are compared to the control group, two one-way covariance analyses in MANCOVA context were done, the result of which is shown in Table 5. The impact or the difference value is 0.998. In other words, 0.998% individual difference in posttests scores of body-image, self-concept and maladaptive schemata is due to the effectiveness of schema therapy.



**Table 6: Results of one-way covariance analysis in MANCOVA context on the posttest score means of body-image, self-concept, and maladaptive schemata in patients with body dysmorphic order**

variable	group	Sum of square	df	Squares mean	F	Sig.	Eta square
Body-image	pretest	43.11	1	43.11	4.73	0.081	0.486
	group	3571.22	1	3571.22	3571.28	0.000	0.987
	error	45.51	5	9.104			
Self-concept	Pretest	28.66	1	28.66	1.631	0.258	0.246
	Group	268.95	1	286.95	15.30	0.011	0.754
	Error	87.88	5	87.88			
Maladaptive schemata	Pretest	1932.16	1	1932.16	25.851	0.004	0.020
	Group	5754.336	1	5754.336	76.989	0.000	0.29
	Error	74.743	5	74.743			

As it can be seen from the table above, when posttest is controlled for both the experimental and the control groups of body dysmorphic patients, a significant difference between two groups with regard to the body-image, self-concept and maladaptive schemata variables can be observed. Thus, hypotheses 1, 2, 3, and 4 of the research are approved. In other words, schema therapy was tested with respect to the body-image, self-concept and decrease of maladaptive schema. The impact or the differences of body-image is 0.987 and it can be claimed 0.987 of individual differences in the posttest scores of self-image were due to the schema therapy. Furthermore, the impact or the difference of self-concept is 0.754 and it can be claimed that 0.754 individual differences in posttest scores of self-concept is due to schema therapy. Additionally, the impact or the difference for maladaptive schemata is 0.29 which shows that 0.29 percent of the individual difference in posttest scores of maladaptive schemata is due to the schema therapy.

**Table 7: Results of multivariate analysis of covariance (MANCOVA) on the body-image, self-concept and maladaptive schemata's follow-up scores means among the patients suffering from body dysmorphic disorder**

Tests name	value	df hypothesis	df error	F	Eta square	Sig.	power
Pillai trace	0.999	3	3	676.306	0.999	0.000	1
Wilks' Lambda trace	0.001	3	3	676.306	0.999	0.000	1
Hotelling's trace	676.306	3	3	676.306	0.999	0.000	1
Roy's greatest root	676.306	3	3	676.306	0.999	0.000	1

As can be observed from the table above, in follow-up stage where the posttest significance level is controlled, patients with body dysmorphic disorder in the experimental and control groups were significantly different with respect to the dependable variables (body-image, self-concept, and maladaptive schemata). To see which variable is different in the two groups, two one-way covariance analysis in MANCOVA context was done the results are depicted in Table 7. The impact strength or difference is 0.999. In other words, 0.999% of the individual difference in body-image, self-concept, and maladaptive schemata's follow-up scores was due to the influence of schema therapy. Statistical power is 1 and we can say that the occurrence of type II error was not probable.

**Table 8: Results of one-way covariance analysis in MANCOVA context on the posttest scores mean of body-image, self-concept, and maladaptive schemata in patients with body dysmorphic order**

variable	group	Sum of squares	df	Squares mean	F	Sig.	Eta square
Body-image	pretest	6.43	1	6.43	0.24	0.64	0.046
	group	1912.57	1	1912.57	71.93	0.000	0.935
	error	132.94	5	26.08			
Self-concept	Pretest	0.719	1	0.719	0.023	0.088	0.005
	Group	486.31	1	486.31	71.93	0.000	0.935
	Error	155.31	5	31.06			
Maladaptive schemata	Pretest	988.17	1	988.17	9.46	0.28	0.654
	Group	14700.88	5	14700.88	140.85	0.000	0.966
	Error	521.85	5	104.37			

As is clear from Table 8, when pretest is controlled, follow-up and control groups of patients with dysmorphic disorder are significantly different respecting body-image, self-concept, and maladaptive schemata. By way of explanation, schema therapy, when the self-image mean of experimental group's patients with body dysmorphic disorder in follow-up stage (one month later) with that of control group are compared, has raised the level of satisfaction with body-image in patients. Also, schema therapy, when we compare the self-concept mean of body dysmorphic disorder patients in the experimental group with that of the control group patients in follow-up stage (one month), has reduced maladaptive schemata of the patients. Statistical power of the experiment was 1 that means type II error was unlikely to occur, confirming Hypothesis 5 of the research.

In the current research, the influences of schema therapy on body-image, self-concept and maladaptive schemata in patients with body dysmorphic disorder was investigated. One finding showed that there is a significant difference between body-image, self-concept and maladaptive schemata of patients in the experimental group and those of patients in the control group.

Based on these, the main hypothesis of the research was corroborated. The findings of this research is in line with the previous studies (Nordahl, Helth, & Hogan, 2005; Kalwit et al, 2005), Kaziona (2004; Mohammad sadegh Montazeri et al., 1392; Masoome Ahmadian 1387; Mehrangiz Mohamadnejad, 1389; Rener et al., 2012; Jamalmohammadi, 1382; Salman Lotfabadi, 1389). Nourishing schema-related memories, emotional activation of schema, strengthening body sensation and cognitive maladaptiveness of schema lead to the improvement of schema and some positive behavioral changes in a way that patients learned to replace maladaptive confrontation styles with adaptive confrontation styles. Thus, the healing process involves cognitive, emotional and behavioral intervention. As the schema improves, the strength and frequency of its activation decreases significantly. So, if the schema is activated, the patient experiences less distortion and soon gets back to normal condition. Schema therapy provides a new psychotherapy system which specifically suits the patients with persistent and chronic psychological disorders (Young, 1990; Young & Tamara, 2007). That is to say, with the help of schema therapy, maladaptive schemata and their components can be drastically controlled in most people (Ironson, 2007). Also, schema therapy improved the body-image and self-concept of the patients with body dysmorphic disorder.

Other findings of the current study is that with the control of pretest for the patients with body dysmorphic disorder, satisfaction with body-image was significantly different ( $p > 0.005$ ,  $f = 3571/28$ ) in experimental and control groups. Results of this study, in addition to confirming some other previous research (Hill, Green, Anwar, Seymour, & Mayer, 2010; Mohammadsadegh Montazeri, 1391; Rener et al, 2012), is in line with the research of Jamalmohammadi (1382) and that of Salaman Lotfabadi (1389). Specifically,

Gidens (1991) says that the body becomes a place to create dreams and wishes. Mary Douglas (1996), also, refers to two physical and social bodies of every human being. She considers physical body as a small world which is closely linked to the social pressures (Gidens, 1991; Mary Douglas, 1996, as cited in Tavasoli & Modiri, 1391). Some say that the development of body-image is instinctive. Some others say that the society and social factors influence on it. That is, each individual faces various expectations in the process of socialization (Azadarmaki & Chavoshian, 1381). Some researchers consider body and preoccupation with it as an important modern life obsession which threatens individuals' and society's health. An individual's attitude toward life facts, ethics, desire and willingness is dependent on the image they have of themselves, i.e. the value they set on themselves (Khajenoori, Roohani, & Hashemi, 1390). Body dysmorphic disorder refers to preoccupation with one or more imagined or trivial defects in appearance which are not visible by others or are considered minor by them. When the person suffers, they have certain repetitive behaviors (such as checking themselves in the mirror, putting on too much make up, excoriation, seeking certainty) or mental preoccupations (such as comparing themselves with others) to alleviate the worries about their appearance (Ganji, 1395).

In people suffering from body dysmorphia, body-image is so weak or inappropriate which results in social and interpersonal problems and a fall in self-esteem. Low self-esteem is the feeling of being inefficient and the sufferers have the sense of being of no value. Experimental interventions and behavioral interventions, schema therapy interpersonal intervention, and cognitive interventions improved the body-image of the patients with body dysmorphic disorder and led to the elevation of self-esteem.

Other findings of the study is that when the pretest among the patients of both experimental and control groups was controlled, the self-concept was significantly different for the two groups. Results of this study, in addition to supporting some other previous research (Hill, Green, Anwar, Seymour, & Mayer, 2010; Mohammadsadegh Montazeri, 1391; Rener et al, 2012) is in line with the research of Jamalmohammadi (1382) and Salaman Lotfabadi (1389). A reason for such findings might be that the motif for all different behaviors is to protect and boost the perceived ego of oneself. Each part of an experiment is perceived based on the interaction with ego and certain behaviors are the result of such perception. In this case, we might say that only one motif prevails and that is inner personal motif which triggers every act of a human being from time to time in every situation and place. As Cambaz say, people are always incited and not one can be found not incited. This is an advantage for a trainer because this motivation stems from inside every learner (W et al, 1378, p.24). The main reason for such self-concept can be found in the critical period of childhood and adolescence. Development of self-concept is dependent on the reaction of others toward an individual and specifically a child. One theory says that in order to see oneself, we watch

the present reactions. Many researchers have found that the concept of a person about oneself relies on the image others have about that person because they can evaluate others' image of themselves and change it. Parents are one source of forming self-concept and the feeling of being valuable in children and adolescents. Personality development and its core are dynamic in a way that personality development is considered as a process not a product or a goal. Hence, the growth and accomplishment is an endless road and never rests inside a human. There is always a movement toward "becoming" or "a necessity" while the path is difficult and painful. The environmental conditions are sometimes so poor that the person cannot ascend and barriers are raised before their eyes (Taghizadeh, 1379, p.24). Schema is the result of a human attempt to achieve stability and power while it is known for people, despite being dreadful. It is easy and available and generally seems right. It seems that people are affected by the actions that activate their schemas and this is one reason for the influence of such schemas on later experiences. The way the patients think, their feelings and actions, and the way they interact with others play crucial roles and adults unconsciously imitate their childhood's harmful experiences. Schemas start developing from the beginning of childhood and adolescence as profiles, based on the reality of childhood environment. The defective nature of the schemas is always more obvious in later life stages when the patients repeat their schema confronting and interacting with other people. Schema is an old structure in the area of cognitive sciences, so Beck, at the very beginning of developing cognitive theory, used this concept to explain the emotional-cognitive process system of mental phenomena (Rizzo, Tweet, Austin, & Young, 2007; as translated by Moloudi & Ahmadi, 1390). Schema therapy, using cognitive, behavioral, experimental and interpersonal techniques, greatly aids the patients with body dysmorphic disorder to improve their positive self-concept.

Another finding of the current research is that when pretest is controlled, there was a significant difference between the control and experimental groups of the patients with body dysmorphic disorder. This finding is in line with Mehrangiz Mohammadnejad (1389), Sogol Yadollahi Bastani et al (1392), Asgharjafari et al (1392), Kalwit et al (2005), and Kaziona (2004). To justify such a finding we can say that the early life experience, including being annoyed as a child, having misadventures in childhood, personal values, and characteristics, and exaggerated tendency toward aesthetics are among the reasons leading to body dysmorphic disorder. Such negative aspects in childhood result in the development of conditional beliefs and thoughts which remarkably affect the cognitive, emotional and interpersonal areas of an individual performance. With bearing in mind the findings of this research about the effect of schema therapy on the patients with body dysmorphic disorder, it can be said that schema therapy, including using experimental techniques which rehabilitates cognition of childhood and childhood's memories, aids the various emotions, and especially suppressed ones, which has led to the emotional self-

ensorship and difficulty in expressing one's emotions, to be expressed. Combining four cognitive, experimental, behavioral and interpersonal techniques, schema therapy approach, in addition to questioning maladaptive schemas which is the main reason for inefficient and unreasonable thought development in patients with body dysmorphic disorder, makes the buried negative emotions and senses, including anger resulting from being annoyed as a child and childhood misadventure, come out.

Other findings of the research is that when the pretest was controlled, there was a significant difference between body-image, self-concept and maladaptive variables of the two, control and experimental, groups. To justify such a finding, it can be said that the improvement of schema requires a strong willingness to fight with schema and such willingness needs a lot of effort and good discipline. Schemata are hardly changed, because they are deeply interrelated with the person's beliefs about themselves and the environment around them. Though they might be harmful for the patient, schemata are all the patients know and they bring about safety and predictability for them. Patients resist losing their schemata, because the schemata form their personality core. The therapist and the patients associate in order to defeat the schema. This goal is usually an impossible ideal one, because most schemata are not completely treated and the memories attached to them cannot be thoroughly destroyed. However, when schemata improve, their activation frequency as well as patient's attachment to them decline and the time they are activated in the patient's mind is shortened. When the schemata improve, the patient reacts perfectly to the schemata stimulators. Thus, they select more ideal friends and maintain a more positive attitude toward themselves.

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# The comparison between early maladaptive schemas and dysfunctional attitudes and coping strategies in people with Body Dysmorphic Disorder and healthy people in a study population in Tehran

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## Abstract

Body dysmorphic disorder (BDD) is a relatively common disorder associated with body image impairment that causes clinically significant distress or impairment in social, occupational, or other important areas of functioning. There are many people who are placed under the aesthetic surgery blades instead of appropriate treatment. The existent evidence suggests that the formation of early maladaptive schemas and dysfunctional attitudes and ineffective coping strategies can affect these patients. The present study was conducted to compare early maladaptive schemas and dysfunctional attitudes and coping strategies in people with body dysmorphic disorder and healthy people. This research was conducted using causal-comparative method. The statistical population consisted of all individuals referring to the Lipomatic center for beauty and fitness in district 1 of Tehran in 2015-2016. The study subjects included two groups of 85 (170 persons) of patients seeking beauty care referred to the beauty center and healthy subjects among the personnel of Shahid Chamran Hospital in Tehran were selected using convenience sampling method. (Both healthy and BDD groups were selected after clinical interview and completed questionnaires). In this research, Young Schema Questionnaire (YSQ-205), Dysfunctional Attitude Scale (DAS-26), Lazarus and Folkman's Coping Strategies Scale (CSQ-66), Yale-Brown Obsessive-Compulsive Scale – and Body Dysmorphic Disorder (Y-BOCS) (YBOCS-BDD) were used. To analyze data, mean, standard deviation and multivariate variance analysis (MANOVA) were used in SPSS-22. Results showed that in four areas of early maladaptive schemas of disconnection and rejection, impaired autonomy and performance, impaired

limits and over-vigilance and inhibition, the mean use of these schemas were significantly higher in people with body dysmorphic disorder compared to healthy subjects. But in the other-directedness area there was no significant relationship between the two groups. Additionally, in terms of vulnerability toward dysfunctional attitudes toward perfectionism, need for approval of others and need to satisfy others there was a significant difference between the two groups of people with body dysmorphic disorder and healthy people. Individuals with body dysmorphic disorder had higher mean in dysfunctional attitudes. There was a significant difference in the coping strategies of people with body dysmorphic disorder and healthy people, so that the individuals with BDD use more emotional-focused coping strategies and healthy people use more problem-oriented coping strategies. Therefore, it seems that early maladaptive schemas and dysfunctional attitudes and emotional-focused coping strategies can be important factors in the formation of body dysmorphic disorder.

**Key words:** Early Maladaptive Schemas, Dysfunctional Attitudes, Coping Strategies, Body Dysmorphic Disorder

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## Introduction

Body dysmorphic disorder (BDD) is characterized by mental occupation (rumination) with one or more defects in physical appearance, which is not significant enough or, in the eyes of others, to be minor, and is associated with repetitive behaviors (such as checking oneself in the mirror, excessive makeup, skin cleansing, or seeking reassurance from others) or mental activities (such as comparing oneself with others) in response to concerns about appearance (American Psychiatric Association, 2013, translation of Rezaei et al., 2014). This mental occupation (rumination) in people with BDD causes a person to suffer or a disruption to his or her career, social, or academic performance, and the severity of this distress is so high that sometimes it needs clinical attention. If a small abnormality really exists, one's concern about this abnormality is extreme. The DSM-5 has brought the body dysmorphic disorder (BDD) into obsessive-compulsive disorders spectrum, because it is similar to obsessive-compulsive disorders. Little research has been done about BDD disorders and partly that is why patients refer most often to dermatologists, internists (infectious), or plastic surgeons rather than psychiatrists. One study found that more than 50 percent of college students in their study were at least partly concerned with one of their facial aspects, and these concerns (worries) have impacted significantly about 25 percent of these students on their feelings and performance (Sadock and Sadoch, translated by Ganji, 2015). The prevalence of BDD in the general population was reported at 7% in two studies (Otto, 2001). Also the prevalence of BDD in the United States according to DSM-5 is 2.4 percent. Available information indicates that the most common starting age is between the ages of 13 and 15, and women are more likely to become affected. Most patients are single. BDD is usually co-morbid with other psychiatric disorders. One study found that over 90% of BDD patients had a major depression episode in their lives; about 70% have experienced an anxiety disorder and about 30% a psychotic disorder (Sadock and Sadock, 2015, translation: Ganji, 2014). Similarly, BDD co-morbidity is also commonly associated with social anxiety (social phobia), OCD and substance-related disorders (American Psychiatric Association, 2013, translation: Rezaei et al., 2014). In a study conducted by Erica it was claimed that adolescents with BDD suffer from somatization disorder, obsessive compulsive disorder, and depression. (Erica, 2011). In a study by Sarver, 7% of cosmetic surgery patients have BDD diagnostic criteria (Sarver, Sirand, 2004). One of the psychological variables influencing the body dysmorphic disorder that needs to be recognized is early maladaptive schemas. According to Young (1990), early maladaptive schemas include deep cognitive structures including beliefs about oneself. Schemas are structures of reality that grow as the result of objective experiences from the environment. Particularly those that originated from the early stages of life have a more significant effect. The development (growth) of schemas often returns to childhood. According to Young (1999), some people create early maladaptive schemas due to their negative childhood experiences, which may also

include society's expectations that affect their way of thinking, feeling and behavior in the next sincere relationship and other aspects of their lives. Schemas that have grown in the early ages are often beyond the realm of consciousness, and when the stimuli of life stimulate one or more schemas, they are activated and process the personal information automatically in accordance with these schemas. Schemas are divided according to the five needs of the child's development into five areas of disconnection and rejection, impaired autonomy and performance, impaired limits, other-directedness, over-vigilance and inhibition (Young, Kolosko, Vishar, Bayat, Translated by Hamidpur and Andoz, 2014). Early maladaptive schemas do not result in specific mental disorders, but increase individual vulnerability to mental disorders. Young (1990, 1999) believes some schemas, especially those that are formed largely as a result of childhood adverse experiences, may be the core of personality disorders, mild manner problems, and many chronic disorders of axis I. One of the variables associated with body dysmorphic disorder is dysfunctional attitudes, the attitudes and beliefs that make a person susceptible to depression, or in general psychological distress, and prepare a person to interpret certain situations overly negatively and ineffectively. From the point of view of Beck, dysfunctional attitudes are inflexible and perfectionist criteria that a person uses to judge himself/herself and others. Since these attitudes are inflexible, extreme, and resistant to change, they are considered to be ineffective (dysfunctional) (Rock Roa et al., 2014). Coping strategies are another influential variable of body dysmorphic disorder. Based on Lazarus and Folkman's theory, coping behaviors in dealing with stress include two processes: the problem-oriented process in which a person encounters a problem that is the real cause of disturbance in him and the emotional processes on which the person tries to regulate his/her emotional response (Branon and Feist, 2006). Regarding the role of each of the coping styles on the overall health of the individual, researchers have found that people usually use two types of coping styles (emotion-focused, problem-oriented) in dealing with stressful situations. The results of study indicate the positive and effective role of problem-oriented coping style in increasing health and the negative role of emotion-focused coping styles in reducing health (Klinck, 1994, Translated by Mohammad Khani, 2004). Regarding the fact that BDD is = relatively common and chronic, and there are many people who are suffering from this disorder, and instead of treatment, they are under the blade of various cosmetic surgeries, therefore, research in this field and the identification of the underlying and continuity causes of BDD can be very helpful for prevention and treatment of it. In the search for research done in Iran and abroad, in the study conducted by Khosh Iqbal (2014) it was found that those who seek cosmetic nose surgery, as compared to non-applicants, are more dissatisfied with their physical image, and the applicant is more perfectionist. Additionally, the applicant group has more maladaptive schemas than the non-applicant group. According to Yiddalli Bastani et al. (2012) schema therapy reduces the symptoms of body dysmorphic disorder, and increases positive body image, self-esteem, and self-efficacy in people with body



dysmorphic disorder. Marmon and Eatal (2004) state that early maladaptive schemas are ineffective (dysfunctional) mechanisms that directly lead to psychological distress. In a study by McCinso and Jenny (2013), they found that early maladaptive schemas in adolescents could be associated with the psychological problems of axes I and II, problems such as inappropriate behavior, anxiety, depression, and, in general, endocrine and exocrine problems. In a study by Mirza'i Feizabadi and Ghanai Chaman-Abad and Taheri (2015) the variable of dysfunctional attitudes and femininity were a predictor of concern about body image. There was no significant difference between body image and scores of femininity and masculinity in both groups of those who had undergone cosmetic surgery and control. In the study by Kolosky and Kolosky and Boyce (2001), it was found that the dimension as a cognitive aspect of behavior is very influential in the process of creating tension. In the study on the relationship between dysfunctional attitudes and tension, people with dysfunctional attitudes, evaluate personal events and experiences as stressful. In a study by Wise and Benses (2009), it was found that coping with important life events is influenced by intermediary factors, and these intermediary factors are the same cognitive factors. In other words, the cognitive assessment, schemas, beliefs and attitudes of individuals about a condition effect on their compatibility. The results of Pico's (2001) studies state that stress-related illnesses and the deterioration of general health status are more commonly seen in those who are continually using emotion-focused coping. According to a study by Serafino and Mancus (2016), the results indicate that the reluctance to experience the thoughts related to appearance and negative feelings may lead to a negative relationship, the assessment of the body image to stereotypical behaviors and avoidance experiences. In a study by Alysse Baily et al. (2016), two-variable correlations showed that shame of the body has a positive relationship with self-objectivity, stereotypical appearance, and coping avoidance, but it has no relationship with positive logical acceptance. In addition, self-objectivity has a positive relationship with appearance, and coping avoidance, but it has no relationship with positive logical acceptance. Mediation analysis showed that shame of the body mediates to some degree in the relationship between self-objectivity and stereotypical appearance and coping avoidance, but does not mediate in the relationship between self-objectivity and positive logical acceptance. The main purpose of this research is the comparison of early maladaptive schemas and dysfunctional attitudes and coping strategies in people with body dysmorphic disorder and healthy people.

## Materials and methods

In this research, which is causal-retrospective (causal-comparative), early maladaptive schemas and dysfunctional attitudes and coping strategies have been compared as a dependent variable in people with body dysmorphic disorder (BDD) and healthy subjects. Statistical population of the research consisted of all referring people (including women and men) aged 18 to 40 years, with the minimum level of

diploma education to the beauty and fitness and lipomatic center of the 1st district of Tehran in 2015-2016. Healthy individuals were selected from the staff of Shahid Chamran Hospital in Tehran without body dysmorphic disorder (BDD). Both healthy and BDD groups were selected after clinical interview and completed the Yale Brown Obsessive-Compulsive Disorder for Body Dysmorphic Disorder. And those who were patient according to the DSM-5 criteria were selected as BDD. The statistical sample of the study is people with body dysmorphic disorder (BDD) and healthy people. Considering that random selection due to the large population size is difficult for ease in the sampling, the convenience sampling method with a four month period (March to June) was used. The sample size for this research was 170 people. Therefore, the sample size of the study was 85 subjects with BDD in one group and 85 healthy subjects in the other group. Information gathering by the researcher was conducted in the summer of 2016. Regarding the observance of ethical principles and based on willingness and satisfaction, the questionnaires were provided to the people and completed under the researcher's supervision.

### Information gathering tool

#### 1. *Young's Early Maladaptive Schema questionnaire (YSQ-205)*

This self-report questionnaire consists of 205 items to measure maladaptive schemas and 16 faulty schemas. In this questionnaire, the subject evaluates herself/himself on a six-point Likert scale (completely false, almost false, more true to false, slightly true, almost true and perfectly true). This questionnaire is available both in short form (75 items) and long form (205), and the researcher in this study used the long form for a more accurate assessment. In this study, the alpha coefficient from 83% to 96% for early maladaptive schema was obtained and the test-retest coefficient in the non-clinical population was obtained between 50% and 82%. This questionnaire showed a significant convergent and discriminant validity with a scale of psychological distress, a sense of value, cognitive vulnerability to depression and the semiotics (typology) of personality disorders. Internal reliability of test by calculating internal medicine coefficient of questionnaire and alpha Cronbach's coefficient a total score of questionnaire was reported 94% (Zolfaghari, 2008).

#### 2. *Dysfunctional Attitudes Questionnaire (DAS-26)*

This is a self-report questionnaire. The original version of this tool (DAS-40) was developed by Beck & Weissman in 1978. The 26-item version of this scale has been provided by a 40-item version of the A-form for application in the Iranian clinical direction and its psychometric quality has been prepared. It's Cronbach's alpha is 92%, the correlation with original form is 97% and its validity by predicting health with GHQ-28 scores was obtained at 56% by Ebrahimi et al. The DAS-26 scale has 26 sentences that the subject answers on a 7-point Likert scale and scores are between 26 and 182, and those who score above 82 on this scale are considered as high risk individuals in terms of cognitive vulnerability (Ebrahimi et al., 2012).

### 3. Lazarus and Fulkman's coping strategies questionnaire (CSQ-66)

This questionnaire examines the thoughts and reactions that are used to deal with everyday stressful events. This scale was developed by Lazarus and Fulkman in 1984 based on phenomenological cognitive theories related to stress and coping, known as psychological stress, assessment and coping theory, in 1985. This questionnaire consists of four problem-oriented coping styles (problem solving styles, positive re-assessment (re-evaluation, accountability (responsibility and search for social support) and four emotion-focused coping styles (direct confrontational styles, restraint [continence], avoidance, and denial). This questionnaire consists of 66 articles, 16 of these tests are deviant, and 50 others measure 8 coping styles (strategies). Each scale consists of a set of questions. Individuals respond to each on a Likert scale of four options, which shows the frequency of each strategy in this way. The zero score is applied to the answer "Not at all". Lazarus and Folkman reported a reliability coefficient of Cronbach's alpha for each subscale of problem-oriented style 60% to 75%, and for the emotion-focused style subscales in the range of 66% to 79%. In Iran, the internal consistency coefficient using Cronbach's alpha coefficient (61% to 79%) and the test-retest reliability of this test in the four-week interval was reported at 59% to 83% (Ghadamgahi and Dezhakam, 1998, quoted by Abolqasemi and Narimani, 2005).

### 4. The Yale Brown Obsessive-Compulsive Disorder for Body Dysmorphic Disorder (YBOCS-BDD)

This is a self-report 12-item questionnaire that measures the severity of the symptoms of body dysmorphic disorder. In an analysis on 125 outpatients diagnosed with body dysmorphic disorder, Rabiee found that this scale has a two-factor structure and two additional questions. These factors include: 1) obsessions 2) compulsions 3) two additional questions in the field of insight and avoidance. In general, studies have shown that this scale has good reliability and validity (Rabiee et al., 2010). In Rabiee's research Cronbach's alpha coefficient for the whole scale was obtained at 93%. The correlation between the forms using half-splitting method was 84% and the Gutmann's half-splitting coefficient was 91%, which is consistent with the Phillips findings (Phillips, 1997).

#### Data analysis method

To investigate the research hypotheses and analyze the data obtained from the research, SPSS-22 software was used in this study. In this research, we used mean and standard deviation the descriptive statistics section and multivariate covariance analysis (MANOVA) was used for hypotheses and comparisons of variables.

## Findings

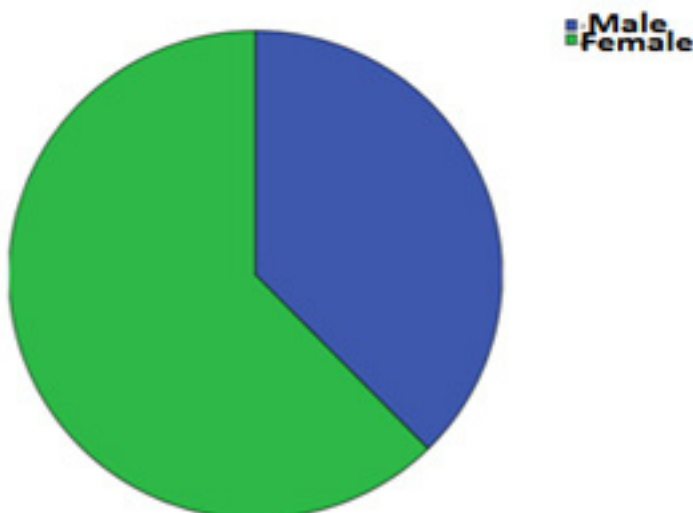
### Descriptive findings

**Table 1 Descriptive indexes of the group by sex**

Marital status	People with body dysmorphic disorder		Healthy people	
	Frequency	Frequency (%)	Frequency	Frequency (%)
Male	32	37.6	31	35.5
Female	53	62.4	54	63.5

As shown in the table above, most people in both sample groups of research are women.

**Diagram 1 Descriptive indexes of the group by sex**

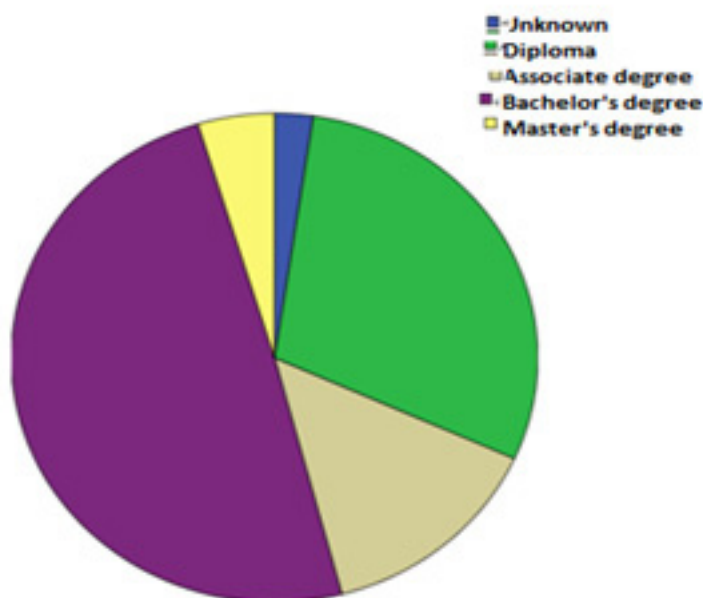


**Table 2** Descriptive indexes of the groups in terms of education

Education	People with body dysmorphic disorder		Healthy people	
	Frequency	Frequency (%)	Frequency	Frequency (%)
Diploma	25	29.4	26	30.6
Associate degree	12	14.1	12	14.1
Bachelor's degree	42	49.4	41	48.2
Master's degree	4	4.7	4	4.7
Unknown	2	2.4	2	2.4

As shown in the table above, most individuals in both sample groups have a bachelor's degree.

**Diagram 2:** Descriptive indexes of the group in terms of education



**Table 3:** Descriptive indexes of the group in terms of age

Variable	People with body dysmorphic disorder		Healthy people	
	Mean	SD	Mean	SD
Age	30.72	5.93	30.56	5.99

As shown in the table above, the mean age of individuals in both groups is about 30 years.

**Examining the normal distribution of data**

**Table 4** Kolmogorov–Smirnov test results to verify the normal distribution of data

Variable	Z	Significance level
Disconnection and rejection	1.43	0.03
impaired autonomy and performance	1.34	0.05
impaired limits	0.80	0.55
other-directedness	1.72	0.01
over-vigilance and inhibition	1.26	0.09
Problem-oriented	1.16	0.13
Emotion-focused	2.07	0.01
Perfectionism	2.07	0.01
Need to be approved by others	1.05	0.22
Need to satisfy others	0.80	0.43
Vulnerability	1.61	0.01



As shown in Table 4, the z-values of the Kolmogorov–Smirnov test for many are not statistically significant ( $P < 0.05$ ); therefore, the distribution of data is normal and a parametric test can be used.

**Table 5: Box test to examine matrix homogeneity**

Box's M	23.77
F	2.06
Df1	66
Df2	89993.30
Sig	0.17

As the box test indicates, regarding insignificance of Sig = 0.17,  $F(66, 89993.30) = 2.06$ , the homogeneity condition of the variance-covariance matrices is confirmed.

**Table 6: Leven's test for Homogeneity of Variances**

Variable	F	df1	df2	Sig
Disconnection and rejection	0.14	1	168	0.94
impaired autonomy and performance	5.10	1	168	0.03
impaired limits	0.08	1	168	0.78
other-directedness	51.94	1	168	0.001
over-vigilance and inhibition	2.80	1	168	0.11
Problem-oriented	3.01	1	168	0.07
Emotion-focused	2.91	1	168	0.09
Perfectionism	6.96	1	168	0.009
Need to be approved by others	1.24	1	168	0.27
Need to satisfy others	3.12	1	168	0.06
vulnerability	9.63	1	168	0.002

The Leven's test is performed to investigate the homogeneity of variances. As the results of the table show, in most components, the significance level of calculated F is greater than  $P \leq 0.05$ , which indicates that the difference between variances is not statistically significant and the assumption of homogeneity of variances is approved; therefore the results of the multivariate analysis of variance analysis can be reported.

### Inferential Findings

**Hypothesis 1:** There is a difference between early maladaptive schemas in people with body dysmorphic disorder and in healthy people.

**Table 7: Descriptive Indicators of early maladaptive schemes in patients with body dysmorphic disorder healthy people**

	Group	Mean	SD
Disconnection and rejection	Healthy People	139.71	36.53
	Body dysmorphic disorder	193.06	40.46
impaired autonomy and performance	Healthy People	89.6	26
	Body dysmorphic disorder	71.27	18.86
impaired limits	Healthy People	55.33	16.33
	Body dysmorphic disorder	71.26	18.86
other-directedness	Healthy People	66.93	21.36
	Body dysmorphic disorder	70.51	12.67
over-vigilance and inhibition	Healthy People	63.82	21.90
	Body dysmorphic disorder	69.41	13.84

In the table above, the mean and standard deviation of the early maladaptive schemas in people with body dysmorphic disorder and in healthy people are presented; as can be seen, in the mean of early maladaptive schemas in people with body dysmorphic disorder and healthy people some differences are observed. To examine the significant differences observed, the results of the multivariate analysis of variance are reported.

**Table 8: Leven's test for Homogeneity of Variances**

Variable	F	df1	df2	Sig
Disconnection and rejection	0.14	1	168	0.94
impaired autonomy and performance	5.10	1	168	0.03
impaired limits	0.08	1	168	0.78
other-directedness	51.94	1	168	0.001
over-vigilance and inhibition	2.80	1	168	0.11

The Leven's test is performed to investigate the homogeneity of variances. As the results of the table show, in most components, the significance level of calculated F is greater than  $P \leq 0.05$ , which indicates that the difference between variances is not statistically significant and the assumption of homogeneity of variances is approved; therefore the results of the multivariate analysis of variance analysis can be reported.

**Table 9: Results of the comparison of early maladaptive schemas in patients with body dysmorphic disorder and healthy people**

Sources of Changes	Sum of Squares Ss	Df	Mean of squares MS	F	Significance level
Disconnection and rejection	120977.79	1	120977.79	81.43	0.001
Error	249582.35	168	1485.61		
impaired autonomy and performance	18159.11	1	18159.11	36.14	0.001
Error	84415.48	168	502.47		
impaired limits	10800.15	1	10800.15	34.71	0.001
Error	52271.55	168	311.14		
other-directedness	543.62	1	543.62	1.76	0.19
Error	51790.82	168	308.28		
over-vigilance and inhibition	1327.21	1	1327.21	3.96	0.05
Error	56380.94	168	355.60		

According to the results of Table (9), the difference between disconnection and rejection with value of  $F(1,168) = 81.43$ , impaired autonomy and performance with the value of  $F(1,168) = 36.14$ , impaired limits with value of  $F(1,168) = 34.71$  and over-vigilance and inhibition  $F(1,168) = 3.96$ . There is a significant difference between the person with body dysmorphic disorder and healthy people ( $P < 0.05$ ); which in the schemas of disconnection and rejection, impaired autonomy and performance, impaired limits and over-vigilance and inhibition the people with body dysmorphic disorder had a higher mean than healthy subjects, and in other-directedness, with  $F(1,168) = 1.76$  no significant difference was found between people with body dysmorphic disorder and healthy subjects ( $p \leq 0.19$ ).

**Hypothesis 2:** There is difference between people with body dysmorphic disorder and healthy people in dysfunctional attitudes.

**Table 10: Descriptive indexes of dysfunctional attitudes in body dysmorphic disorder and healthy people**

Variable	Group	Mean	SD
Perfectionism	Healthy people	34.84	9.57
	People with body dysmorphic disorder	55.68	14.03
Need to be approved by others	Healthy people	14.40	4.12
	People with body dysmorphic disorder	18.67	3.20
Need to satisfy others	Healthy people	16.87	5.09
	People with body dysmorphic disorder	25.41	2.58
Vulnerability	Healthy people	13.85	4.46
	People with body dysmorphic disorder	16	3.36

In Table 10, the mean and standard deviation of dysfunctional attitudes in people with body dysmorphic disorder and healthy people are presented; as can be seen, the mean of dysfunctional attitudes in people with body dysmorphic disorder and healthy people is different and to evaluate the significance of observed differences, the results of the multivariate analysis of variance are reported.

**Table 11: Leven's test for homogeneity of variances**

Variable	F	df1	df2	Sig
Perfectionism	6.96	1	168	0.009
Need to be approved by others	1.24	1	168	0.27
Need to satisfy others	3.12	1	168	0.06
Vulnerability	9.6	1	168	0.002
	2.80	1	168	0.11

The Leven's test is performed to evaluate homogeneity of variances. As the results of the table show, in most components, the significance level of calculated F is greater than  $P \leq 0.05$ , which indicates that the difference between variances is not statistically significant and the assumption of homogeneity of variances is approved; therefore the results of the multivariate analysis of variance can be reported.

**Table 12: Results of the comparison of dysfunctional attitudes in patients with body dysmorphic disorder and healthy people**

Sources of Changes	Sum of Squares Ss	df	Mean of squares MS	F	Significance level
Perfectionism	18470.49	1	18470.49	81.43	0.001
Error	24232.12	168	144.24		
Need to be approved by others	775.11	1	775.11	56.93	0.001
Error	2287.18	168	13.16		
Need to satisfy others	3100.45	1	3100.45	190.09	0.001
Error	2740.17	168	16.31		
Vulnerability	196.99	1	196.99	12.62	0.001
Error	2623.01	168	15.61		

According to the results of Table 12, the difference between perfectionism with the value of  $F(1,168) = 128.66$ , the need to be approved by others with the value of  $F(1,168) = 56.93$ , need to satisfy others with the value of  $F(1,168) = 190.09$  and vulnerability with the value of  $F(1,168) = 12.62$ , there is a significant difference between people with a body dysmorphic disorder and healthy people ( $P < 0.01$ ); so that mean of dysfunctional attitudes in people with body dysmorphic disorder was more than healthy people.

**Hypothesis 3:** There are differences between people with body dysmorphic disorder and healthy people in coping strategies.

**Table 13: Descriptive indexes of coping strategies in people with body dysmorphic disorder and healthy people**

Variable	Group	Mean	SD
Problem-oriented	Healthy people	34.53	7.89
	People with body dysmorphic disorder	29.28	7.69
Emotion-focused	Healthy people	30.80	8.29
	People with body dysmorphic disorder	44.75	7.12

In the table above, the mean and standard deviation of coping strategies in people with body dysmorphic disorder and healthy people are presented; as can be seen, the mean of coping strategies in people with body dysmorphic disorder and healthy people is different and to evaluate the significance of observed differences, the results of the multivariate analysis of variance are reported.



**Table 14: Leven's test for homogeneity of variances**

Variable	F	df1	df2	Sig
Problem-oriented	3.01	1	168	0.007
Emotion-focused	2.91	1	168	0.09

The Leven's test is performed to evaluate homogeneity of variances. As the results of the table show, in most components, the significance level of calculated F is greater than  $P \leq 0.05$ , which indicates that the difference between variances is not statistically significant and the assumption of homogeneity of variances is approved; therefore the results of the multivariate analysis of variance can be reported.

**Table 15: Results of the comparison of coping strategies in patients with body dysmorphic disorder and healthy people**

Sources of Changes	Sum of Squares Ss	df	Mean of squares MS	F	Significance level
Problem-oriented	1170.09	1	1170.09	19.06	0.001
Error	10312.40	168	61.38		
Emotion-focused	8260.15	1	8260.15	138.23	0.001
Error	10038.80	168	59.76		

According to the results of Table 15, the difference between problem-oriented coping strategy with the value of F (1.168) = 19.06 and emotion-focused coping strategy the value of F (1.168) = 138.23, there is a significant difference between people with a body dysmorphic disorder and healthy people ( $P < 0.01$ ); so that people with body dysmorphic disorder use more emotion-focused coping strategy while healthy people use more problem-oriented coping strategy.

## Discussion

The purpose of this study was to compare the early maladaptive schemas and dysfunctional attitudes and coping strategies in people with body dysmorphic disorder and healthy people. Disconnection and rejection, impaired autonomy and performance impaired limits other-directedness over-vigilance and inhibition

*Hypothesis 1:* There is a difference between people with body dysmorphic disorder and healthy people in early maladaptive schemas.

Table 7: According to the findings, the mean of early maladaptive schemas are different in people with body dysmorphic disorder and healthy people. According to the results body dysmorphic disorder had higher mean in schemas of disconnection and rejection, impaired autonomy and performance, impaired limits and over-vigilance and inhibition than healthy subjects. This finding was in line with research of Khosh-Eghbal (2015), Yadollahi Bastani and colleagues (2012), Marmon et al. (2004) and McCinon & Jenny (2013). In explaining this finding, it can be said that people with BDD, with regard to their etiology, their past experiences, and harassment and maltreatment in childhood, values and personality traits tend to overestimate the aesthetics and from psychodynamic point of view, due to unconscious replacement of emotional or sexual conflict or feelings of humiliation, guilt, or poor self-concept and community's focus on appearance, these people are at risk and all of these issues have led to the formation of conditional beliefs and ideas that have a major impact on the individual's performance in the cognitive, emotional and interpersonal areas (Rabiee, 2011). Also, in

the other-directedness, there was no significant difference between people with body dysmorphic disorder and healthy subjects. This finding is not consistent with the research by Daon Alivand et al. (2015), Nilfrushan and Navidian and Shamommadi (2015). This difference is likely to be due to differences in the samples of these two studies. For example, in the study of Nilfrushan et al. (2015), with experimental group, 60 samples and women were considered as the statistical population, while in the present study, 85 samples were considered in two groups of male and female, and also in the research of Nilfrushan et al. (2015), the majority of surgery group had diploma degree, while in the present study the majority of the experimental sample were baccalaureate and in the study of Nilfrushan et al. (2015) the marital status was considered, while in the present study, marital status wasn't taken into account. Therefore, hypothesis 1 is confirmed in four main domains of early maladaptive schemas other than the fifth domain (other-directedness) in people with body dysmorphic disorder.

*Hypothesis 2:* There is a difference between people with body dysmorphic disorder and healthy people in dysfunctional attitudes.

Table 10: According to the findings, the dysfunctional attitudes are different in people with body dysmorphic disorder and healthy people. Based on results, there is significant difference between people with body dysmorphic disorder and healthy people in perfectionism, the need to be approved by others, the need to satisfy others and vulnerability. People with body dysmorphic disorder had a higher mean than healthy people in dysfunctional attitudes. These findings are consistent with Mirzai Feyzabadi's research (2015), Weiss et al. (2009), Koluwski et al. (2001),

and hypothesis 2 is confirmed. In explaining this research finding for people with body dysmorphic disorder, it can be said that the variable of dysfunctional attitudes predict worry about body image. The attitude dimension is the cognitive aspect of behavior and is very influential in the process of creating tension. People with body dysmorphic disorder with dysfunctional attitudes evaluate events and their personal experiences as stressful. And they are always looking for approval of others and keep satisfying others regarding their own shape and appearance, and this apparent perfectionism creates some damage and *tension for them*.

*Hypothesis 3:* There is a difference between people with body dysmorphic disorder and healthy people in coping strategies.

*According to the results of the findings, Table 13:*

There is a significant difference between people with body dysmorphic disorder and healthy people in problem-oriented and emotional-focused coping strategies, which people with body dysmorphic disorder more frequently use emotion-focused coping strategies while healthy people use problem-oriented strategies more frequently. The findings are in line with the research of Pico (2001), Ellis Bailey (2016), Sferino and Mancas (2016) and Hartman et al. (2015). Therefore, hypothesis 3 is approved (confirmed). In explaining this research finding, it can be said that shame about the body has a positive relation with self-objectivity, stereotypical appearance and coping avoidance (Ellis Bailey, 2016), and that the reluctance to experience thoughts about negative appearances and feelings may lead to a negative evaluation of body image and stereotypical outcomes and coping and avoidance experiences (Sferino and Mancas, 2016). People with BDD have a more negative body image, a negative attitude toward their physical appearance and more dysfunctional coping strategies (Hartman et al., 2015). Accordingly, people with BDD in the face of stress, intellectual, emotional and behavioral efforts to address visual and aesthetic impairments are more likely to use emotion-focused coping strategies. If the coping focuses on relieving emotional stress, it is known as emotion-focused coping. It can be seen that people with BDD face a high level of psychological stress in coping with a stressful situation.

In summary, research findings indicate that patients with body dysmorphic disorder have more early maladaptive schemas compared with healthy people, and in dysfunctional attitudes have more perfectionism, and need to be approved by others, need to satisfy others and vulnerability, and in terms of coping strategies they have more emotional-focused coping strategies. Therefore, it is possible to prevent the formation of this disorder in a more effective way by considering the variables affecting the body dysmorphic disorder Or through civil programs looking at the 'cosmetic surgery industry' and protecting vulnerable people through health processes and regulations, teaching children in schools that their appearance is not the most important aspect of who they are, and encouraging belief

in themselves, emancipating women from the 'marriage market', etc.

### **Research constraints**

Using convenience sampling is one of the research constraints that make generalizations difficult.

Failure to distinguish people with body dysmorphic disorder with a certain social and economic status, and non-identifying of family structure is one of the other research constraints.

Considering that the method of studying in this study is causal, retrospective or comparative, lack of control in this method is another limitation of this research.

The research tools are self-reporting questionnaires that can be answered with bias.

The mere reliance on questionnaires is one of the other research constraints.

### **Research suggestions**

Considering limited research on body dysmorphic disorder and the increasing rate of cosmetic surgery, for prevention and treatment, more research is needed.

The research by extensive statistical population and sample is required.

It is recommended the body dysmorphic disorder be investigated in different cultural and ethnic situations.

Given the limited research effort in the field of body dysmorphic disorder, it is suggested that interventional research be conducted in people with body dysmorphic disorder.

### **Functional suggestions**

Based on research findings in early maladaptive schemas, it is suggested that therapists in psychotherapy of people with body dysmorphic disorder put the schema therapy approach in their treatment plans.

Based on the findings, people with body dysmorphic disorder have more dysfunctional attitudes. Regarding this finding, it is necessary to focus more on cognitive distortions, beliefs, rules and attitudes in psychotherapy, and to emphasize attitudinal reformation.

It is suggested that in educational settings, measures to be taken to educate and appropriate use of coping strategies in the face of stress and mental stress in all ages.

It is suggested that the components and variables that have been addressed so far in the field of body dysmorphic disorder, to be deployed in the prevention and treatment of people with body dysmorphic disorder.

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# Studying the Correlation between Androgen Receptor (AR) Expression and Prognostic Factors in Invasive Breast Carcinoma

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## Abstract

**Background:** Breast cancer is the most common malignancy among women throughout the world. Androgen receptor is a receptor that belongs to the family of nuclear hormone receptors. This receptor functions in the cytosol of target cells as copying factors. These receptors are generally expressed on the neoplastic tissue of breast. However, the role of AR marker in breast cancer has not been defined clearly yet. The present research seeks to study the role of androgens in pre-awareness of breast cancer among women.

**Materials and Method:** This is a cross sectional-analytical research conducted on 110 Mastectomy and Lumpectomy samples of breast cancer referred to the pathology unit of Shahid Beheshti Hospital of Kashan and Alzahra University of Isfahan from 2010 to 2014. Androgen expression in 110 tissue samples was measured using anti-AR antibody in accordance with immunohistochemistry method principles. Furthermore, the correlation between AR expression and receptor of estrogen, progesterone, HER2neu, metastasis to lymph nodes, tumor grade, age and tumor size in patients' paraffin blocks was also studied.

**Results:** The following frequencies were reported for each tumor grade: 30.9% for grade one, 50.9% for grade two, and 18.2% for grade three. Totally, 61.8% of all cases had AR expression. Positive cases of ER were reported among 69.1% of the

participants, while positive cases of PR and HER2 were reported among 64.5% and 29.1% of cases respectively. Considering the correlation between AR expression and tumor grade, the following frequencies were reported for positive AR in each grade: 39.7% in grade one, 54.7% in grade two, and 2.9% in grade three. However, the negative cases of AR had the following frequencies: 16.7% in grade one, 40.5% in grade two, and 42.9% in grade three and the difference was statistically significant ( $P$ -value  $< 0.001$ ). However, no correlation was observed between AR expression and other indicators such as patient's age, tumor size, lymph node status, and ER, PR, and HER2neu hormone receptors.

**Conclusion:** Further expression of ER in tumors with lower grades is predictable. As a result, it can be used as an indicator to predict better prognosis among patients with invasive breast cancer.

**Key words:** Breast Cancer, Metastasis, Androgen Receptor, Tumor Grade, Lymph Nodes.

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## Introduction

Breast cancer is the most common malignant tumor and constitutes the most important cause of death as a result of cancer among women throughout the world. As many as 1 million cases of this disease are recorded every year around the world (1). Breast cancer cases are on the rise in Asian countries like Iran (2).

Invasive breast carcinoma constitutes a large and variable spectrum of complications with different radiographic, pathological, and biological properties in their clinical expression. The most widely used method of classification has been suggested by World Health Organization (WHO) (2nd edition) where this carcinoma is divided into the lobular and ductal types based upon growth structure and cytological properties of tumoral cells (3).

Old histochemical cases including tumor size, metastasis to axillary lymph nodes, histological grade and biomarkers such as ER, PR, and HER2neu steroid hormone receptors (Estrogen Receptor, Progesterone receptor, Neoadjuvant Human Epidermal Growth Factor Receptor 2) are valuable prognostic and therapeutic factors that are very useful in breast carcinoma (4).

The progress and treatment of breast cancers has shown that presence of hormone receptors such as estrogen and progesterone and biomarkers such as HER2neu in tumoral cells is associated with response to hormone treatments and chemotherapy and helps improve pre-awareness among patients. However, as many as 10 to 24 percent of patients exhibited none of these markers and did not benefit from these treatments. As a result, the need to discover newer exclusive tumoral molecules is obviously required(5).

Androgen receptor (AR) is a biomarker which has recently attracted a lot of attention in the field of breast cancer. As AR belongs to the family of hormone-steroid receptors with nuclear expression, it has a great deal of similarity with estrogen and progesterone receptors in terms of the functioning structure and topography (6).

AR is generally observed in 70% of all cases of breast cancer. The effect of this receptor on breast cancer is yet to be identified but androgen seems to cause proliferative changes in breast tissue (7). The risk of breast cancer among women in the post Menopause period increases as the androgen levels go up (8).

The high rate of breast cancer highlights the necessity of studying variable risk factors (such as clinical parameters and biological markers) in order to assess prognosis and obtain preemptive and therapeutic strategies. The role hormone receptors such as ER, PR, and HER2neu play in pre-awareness of breast cancer is proved (9). In spite of research conducted on androgen receptor, its role as a prognostic factor and its therapeutic importance in breast carcinoma is yet to be identified.

The high rate of breast cancer highlights the necessity of conducting further research in order to identify the prognostic causes of this disease and find useful therapeutic strategies. As a result, the present research was designed to measure the expression of AR marker in malignant breast cells and study the possible correlation of these prognostic factors including ER, PR, and HER2neu metastasis to lymph nodes, histological grades, tumor size, and patient's age.

## Materials and Method

This is a cross sectional-analytical research conducted on mastectomy and lumpectomy samples of breast cancer sent to the pathology unit of Shahid Beheshti Hospital of Kashan and Alzahra Hospital of Isfahan. The list of the patients was first explored and samples of breast cancer were randomly selected and studied. The background information of cases was extracted from patients' clinical files. H&E lams underwent morphological assessment so that the best paraffin blocks could be selected for Immunohistochemistry staining. Paraffin blocks and tissue pieces as thick as 5 microns were extracted from samples and they were stained using anti-AR antibody in accordance with Immunohistochemistry method principles.

All these steps were repeated once again to stain ER, PR, HER2neu markers. The stained lams were studied separately for each marker by two pathologists. If more than 10% of cells were positive regardless of staining level, the lams stained for AR marker were considered to be positive. [Figures 1, 2, and 3] present the tumoral tissue and staining level in terms of AR marker as no staining, weak staining and strong staining [Figures 1, 2, and 3].

Considering the frequency of ER marker occurrence among positive AR patients, with respective rates of 84 and 58 percent and statistical power of 80%, the sample size was 108 (54 positive AR patients and 54 negative AR patients) and finally 110 patients took part in the research. The following definitions were given for each prognostic factor:

ER: if it exists in more than 10% of the cells, it will be nuclear positive.

PR: if it exists in more than 10% of the cells, it will be nuclear positive.

HER2neu based upon rating from 0 to 3 and membranous coloring. Grades 0 and 1 are negative, grade 2 is the intermediate level and grade 3 is considered to be positive. Considering the results of FISH experiment, those in the intermediate level were finally categorized as positive or negative.

Lymph nodes engagement: no engagement, engagement in less than 4, engagement in 4 to 9 and engagement in more than 9 lymph nodes.

Tumor size: equal to or less than 2 cm, 2 to 5 cm, and more than 5 cm.

Tumor grade: based on Nottingham classification which considers the following three factors: tubular differentiation in malignant cells, polymorphism of nucleus, and mitosis level (each ranging from 1 to 3). It is finally classified into 3 grades: I: 3-5, II: 6-7, and III: 8-9.

#### Inclusion criteria:

- all samples of breast cancer who have undergone operation and had referred to the pathology center of Shahid Beheshti Hospital of Kashan and Alzahra University of Isfahan from 2010 to 2014.
- existence of sufficient tissue to study immunohistochemistry

#### Exclusion criteria:

- not sufficient tissue to study.
- incomplete clinical file or when it was not possible to trace particulars in hospital file.

All information of each sample including tumor grade, number of lymph nodes engaged, the positive or negative value of the recorded immunohistochemistry along with patient's age, tumor size, and the answer of FISH underwent statistical analysis.

Using the proper software (SPSS) and after removing the problems and errors, proper statistical methods were utilized to analyze the variables. Chi-square or Fischer's exact tests were used for qualitative variables mentioned in the assumptions of proposal, while t-student test was utilized for quantitative variables.

## Methodology

As many as 100 patients with invasive breast cancer were studied. 12.7% of the participants were younger than 35, 23.6% aged 36 to 45 years old, 26.4% aged 46 to 55, 20.9% aged 56 to 65, and 16.4% were older than 65 years. The average age of the patients was  $51.71 \pm 12.68$  years ranging from 28 to 83 years old.

14.5% of tumors were smaller than 2 cm, 57.3% were between 2 to 5 cm, and the remaining 28.2% had a size of 5 cm or more. The average tumor size was  $4.41 \pm 2.38$  cm with a range of 1 to 12.5 cm.

No lymph node metastasis was observed in 31.8% of cases, 28.2% had 1 to 3 engaged nodes, 25.5% had 4 to 9 engaged lymph nodes, and 14.5% had metastasis to 9 lymph nodes or more.

30.9% of tumors were grade I, 50.9% were grade II, and the remaining 18.2% were grade III.

Positive cases of ER were observed among 69.1% of participants, while positive cases of PR were observed among 64.5% of the patients. HER2neu marker coloring was positive for 29 patients, but it was negative for 71 patients and 10 patients were in the intermediate level. Considering intermediate patients' responses to FISH, 3 were positive and the remaining 7 were diagnosed negative. Positive cases of HER2neu marker were reported among 29.1% of participants and, totally, 61.8% had AR expression [Table 1, 2].

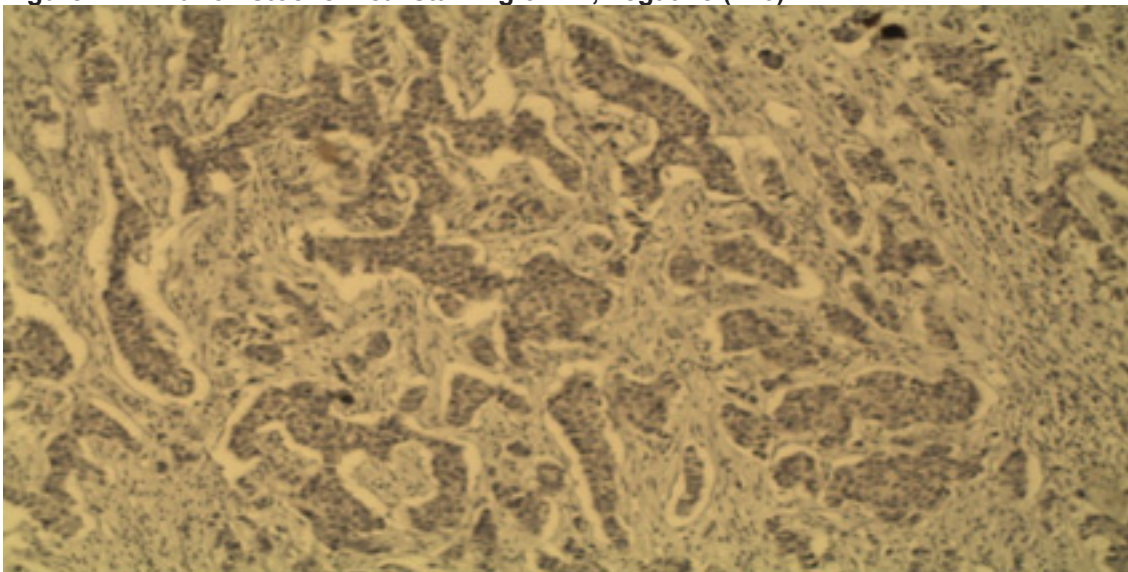
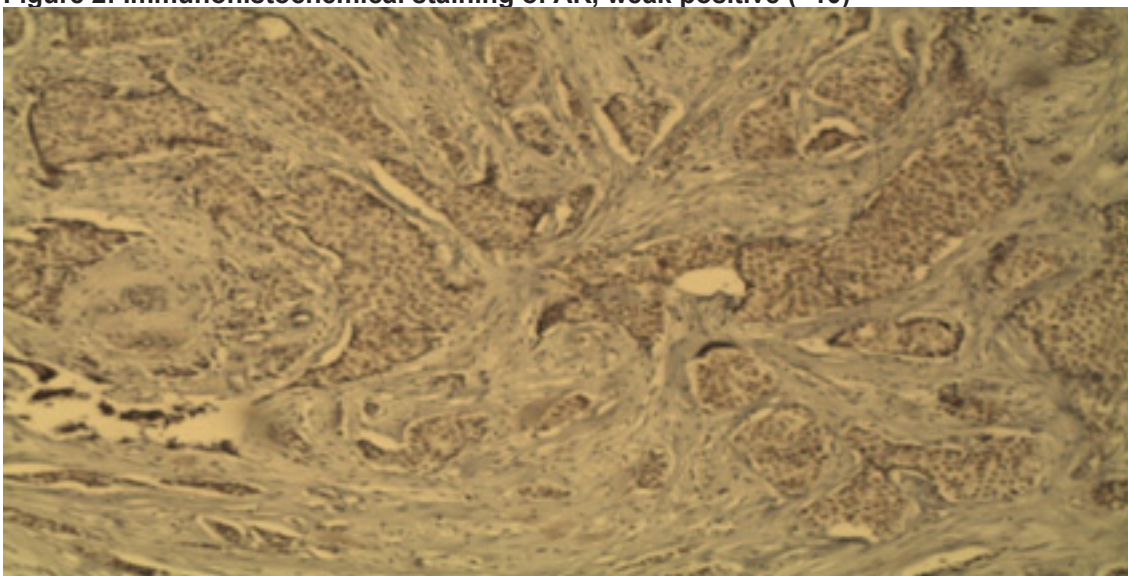
**Table 1: Tumor properties in pathological examinations**

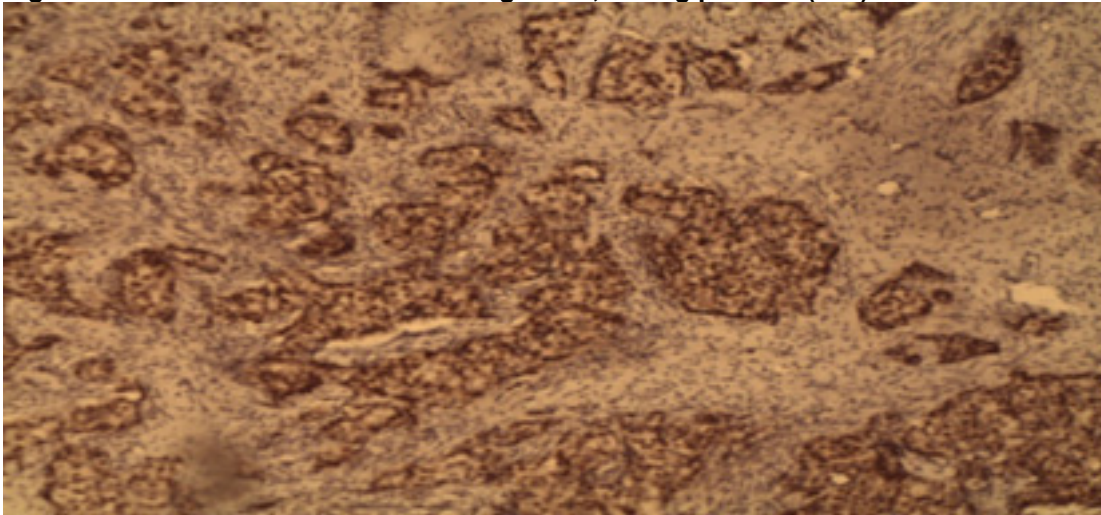
Pathological properties		Finding
Average tumor size (cm)	Frequency $\leq$ 2%	16 (14.5%)
	Frequency 2 – 5%	63 (57.3%)
	Frequency more than 5%	31 (28.2%)
Average lymph nodes engaged	Frequency (%) no engagement	35 (31.8%)
	Frequency (%) 1-3 nodes	31 (28.2%)
	Frequency (%) 4-9 nodes	28 (25.5%)
	Frequency (%) more than 9	16 (14.5%)
Tumor grade	I	34 (30.9%)
	II	56 (50.9%)
	III	20 (18.2%)



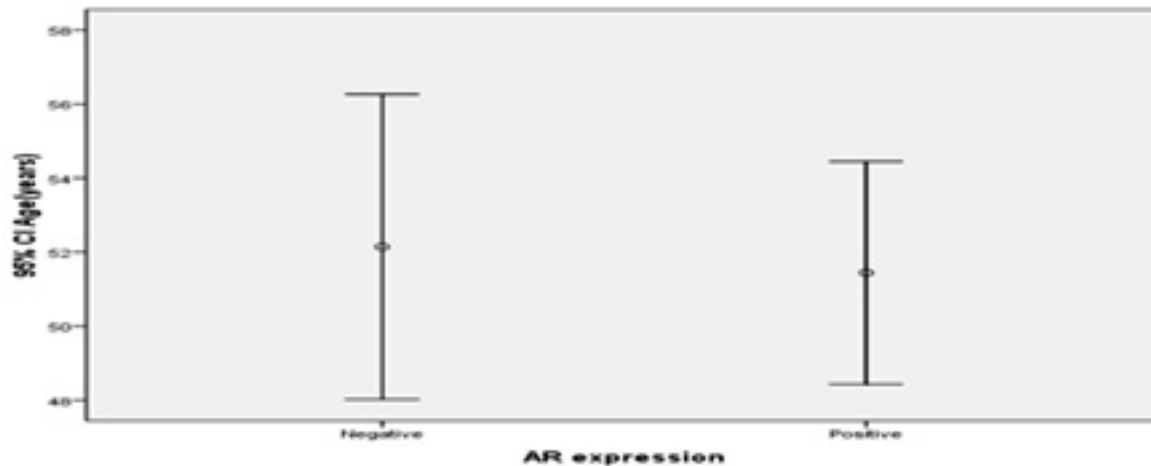
**Table 2: Statistical findings of Immunohistochemical analysis of prognostic factors**

Immunohistochemical marker		Finding
Average percent of ER staining	Frequency (%) positive ER	76 (69.1%)
	Frequency (%) negative ER	34 (30.9%)
Average percent of PR staining	Frequency (%) positive PR	71 (64.5%)
	Frequency (%) negative PR	39 (35.5%)
HER2neu	Frequency (%) positive HER2neu	32 (29.1%)
	Frequency (%) negative HER2neu	78 (70.9%)
Average percent of AR staining	Frequency (%) positive AR	68 (61.8%)
	Frequency (%) negative AR	42 (38.2%)

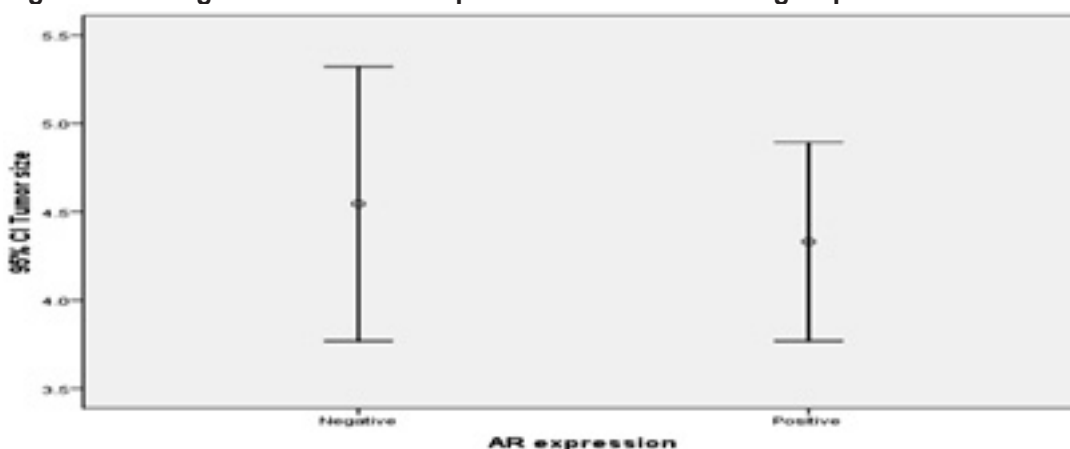
**Figure 1: Immunohistochemical staining of AR, negative (×10)****Figure 2: Immunohistochemical staining of AR, weak positive (×10)**

**Figure 3: Immunohistochemical staining of AR, strong positive (×10)**

Considering the correlation between AR marker and patients' age, the average age in the group with AR expression was  $51.44 \pm 12.43$  years old, while this mean in the group without AR expression was  $52.14 \pm 13.23$  years with no significant difference reported between the two groups ( $P$ -value = 0.779) [Figure 4].

**Figure 4: Average age of patients in +AR and –AR groups**

Considering the correlation between AR expression and tumor size, the average tumor size in the group with AR was  $4.33 \pm 2.32$  cm, while this average in the group without AR expression was  $4.54 \pm 2.49$  cm with no significant difference observed between them ( $P$ -value = 0.64) [Figure 5].

**Figure 5: Average tumor size of the patients in +AR and –AR groups**

Cases of no metastasis to lymph node in groups with and without positive AR were 32.4% and 31% respectively. Cases of metastasis to one to three lymph nodes in +AR and –AR groups were 29.4% and 26.2% respectively, while cases of metastasis to four to nine lymph nodes in +AR and –AR groups were 23.5% and 28.6%. Cases of metastasis to more than nine lymph nodes in +AR and –AR groups were 14.7% and 14.3% respectively and this difference was not statistically significant ( $P$ -value=0.946).



In terms of the correlation between AR expression and tumor grade, the following frequencies were reported for each grade with positive AR: 39.7% for grade I, 54.7% for grade II, and 2.9% for grade III. The following frequencies were observed for each grade with negative AR: 16.7% for grade I, 40.5% for grade II, and 42.9% for grade III. This difference was not statistically significant (P-value < 0.001) [Table 3].

The frequency of AR expression in positive ER group was 75%, while this frequency in negative ER group was 25% which constitutes no statistically significant difference (P-value < 0.088). The frequency of AR expression in positive PR group was 69.1%, while this frequency in negative PR group was 30.9% which constitutes no statistically significant difference (P-value < 0.202).

The frequency of AR expression in the positive HER2neu group was 32.4%, while this frequency in negative HER2neu group was 67.6% which constitutes no statistically significant difference (P-value = 0.338) [Table 4].

**Table 3: Correlation between AR expression and clinicopathological factors**

Factor		Positive AR	Negative AR	P-value
Tumor size	≤ 2 cm	11 (16.2%)	5 (11.9%)	0.59
	2 to 5 cm	40 (58.8%)	23 (54.8%)	
	> 5 cm	17 (25.0%)	14 (33.3%)	
Number of lymph nodes engaged	No engagement	22 (32.4%)	13 (31%)	0.94
	1-3 nodes	20 (29.4%)	11 (26.2%)	
	4-9 nodes	16 (23.5%)	12 (28.6%)	
	> 9 nodes	10 (14.7%)	6 (14.3%)	
Tumor grade	I	27 (39.7%)	7 (16.7%)	< 0.001
	II	39 (57.4%)	17 (40.5%)	
	III	2 (2.9%)	18 (42.9%)	

**Table 4: Correlation between AR expression and hormone receptors**

Hormone receptor		Positive AR	Negative AR	P-value
ER	Positive	51 (75.0%)	25 (59.5%)	0.08
	Negative	17 (25%)	17 (40.5%)	
PR	Positive	47 (69.1%)	24 (57.1%)	0.20
	Negative	21 (30.9%)	18 (42.9%)	
HER2neu	Positive	22 (32.4%)	10 (23.8%)	0.33
	Negative	46 (67.6%)	32 (76.2%)	

## Discussion

Although the role of ER, PR, and HER2neu markers as prognostic factors in breast cancer has been defined (10, 11), it is necessary to conduct further research in order to identify new factors and markers in this field. The present research has been designed to study AR marker expression on breast cancer tissue using IHC technique in order to determine its correlation with other prognostic factors such as hormone markers and clinicopathological findings.

A large number (61.8%) of the participants in our research expressed androgen marker which is in line with previous research in this field. However, various values have been reported regarding positive androgen in different studies. In researches by Sadighi et al., Monifar, and Alshenawy, as many as 49.1%, 60%, and 74.8% of patients expressed androgen receptor (12, 13, 14). This difference may be partially attributed to the extraction technique. Furthermore, difference in execution of Immunohistochemistry method including the type of antibody used to diagnose AR may

also contribute to this difference. These issues highlight the importance of conducting further research in this field.

The results of our research failed to show a correlation between patients' age and expression of AR marker. In our research, expression of AR was associated with lower grades of disease (P-value < 0.001). As a matter of fact, expression of AR marker was observed in 39.7% of grade I and 57.4% of grade II tumors. Only 2.9% of tumors with grade III were positive in terms of AR. In a research by Ensani et al, the expression of AR marker in grade I and II tumors was 73.9% and 66.7% respectively but AR marker was never expressed by anyone of grade III tumors which is in line with the results reported in our research (15). Many studies point to the fact that expression of AR marker is usually associated with good prognostic factors such as smaller tumor size and no metastatic engagement of lymph nodes, although no such thing was observed in our research (16).

The results of our research show no correlation between other markers of breast tumor including estrogen, progesterone, and Her-3 receptors with AR occurrence.



These results highlight the fact that it is impossible to draw a link between these tumoral markers and expression and intensity of AR. However, the positive state of androgen receptor has been accompanied by ER expression in most research (17, 18, 19).

Maybe this difference can be attributed to the genetic differences of patients living in various regions of the world (Iranian patients vis-à-vis patients from other parts of the world).

Although our research failed to show a significant correlation between AR expression and ER, PR, and Her-2 markers, a large percent of patients with positive ER or positive PR or negative Her-2 (75%, 69%, and 67.6% respectively) express androgen receptor. As observation of ER and PR markers and absence of Her-2 in breast cancer indicate a better prognosis of disease, we may conclude that AR is a good predictor of pre-awareness of breast cancer.

It turned out in our research that as many as 40% of patients with TNBC (Triple-negative breast cancer) express AR marker. As many as one third of the participants in Park's study exhibited AR, while 36% of patients in Safarpour's research were positive in terms of AR marker (5, 18). As these patients had the worst prognosis and benefited from no antiestrogen medical treatment of Her-2 targeted therapy, the need for new and more effective medicines in order to improve these patients' prognosis is felt. Considering the relatively high expression of AR marker in this group of patients, the possibility of this marker's prognostic role in this group is proposed.

## Conclusion

The results of our research showed that AR is expressed in a considerable group of breast cancers and is usually accompanied with lower grades of tumor. As AR is expressed in a significant number of TNBC patients, it may be a possible therapeutic target in this group of patients. This is a proposition that requires further investigation and research.

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# Comparison of resistance index and peak systolic velocity of fetal middle cerebral artery between normal and fetuses with mutated beta-thalassemia gene

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## Abstract

**Background:** Beta-thalassemia is the most common inherited single-gene disorder globally. In contrast to alpha-thalassemia, the role of resistance index (RI) and peak systolic velocity (PSV) of the middle cerebral artery (MCA) of the fetuses which are carriers for beta-thalassemia gene is not well understood. The objective of this study was to compare RI and PSV of the MCA in normal fetuses vs. fetuses with mutation of the beta-thalassemia gene.

**Methods:** In this analytic study, 55 pregnant women with gestational age of 12 weeks and more were included consecutively. The pregnant women had history of giving birth to neonates with major beta-thalassemia or they or their husbands had minor beta-thalassemia. They underwent chorionic villus sampling (CVS). Twenty pregnant women without laboratory indices of beta-thalassemia were included as the control group. They underwent color Doppler ultrasound to measure RI and PSV of the fetal MCA. The data were analyzed using analysis of variance (ANOVA), Kruskal-Wallis test, chi-square test or the Fischer's exact test.

**Results:** PSV of the MCA was significantly higher in fetuses with beta-thalassemia gene compared to control group ( $P < 0.05$ ). No significant difference existed regarding RI of the MCA between minor, major beta-thalassemia and control groups ( $P > 0.05$ ).

**Conclusion:** PSV of the MCA of fetuses with major beta-thalassemia was higher than in normal fetuses.

**Key words:** Major beta-thalassemia, peak systolic velocity, resistance index, middle cerebral artery, Doppler ultrasound

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## Introduction

Beta-thalassemia is the most common inherited single-gene disorder globally which is inherited in an autosomal recessive fashion. This disorder causes abnormal hemoglobin synthesis. Its homozygote form is called major beta-thalassemia and the affected patients need life-long blood transfusions to survive (1, 2). Beta-thalassemia is relatively common in the Mediterranean area, some areas of northern and western parts of Africa, the Middle East, the Indian subcontinent, and southeast Asia (3-5). The prevalence of beta-thalassemia gene is highest in the northern part of Iran near the Caspian Sea (about 10%), followed by Isfahan province (8%), southern parts of Iran (8-10%), and is about 4-8% in other areas of Iran(6).

When parents have minor beta-thalassemia, the chance of the baby having major beta-thalassemia is 25% at each pregnancy. Currently, more than 20,000 patients with beta-thalassemia live in Iran. Children with major beta-thalassemia need blood transfusion to survive as early as the first year of life. Blood transfusion is associated with several complications. Studies have mentioned that mothers whose fetuses have intermediate beta-thalassemia are willing to terminate their pregnancy (7-9).

Measuring peak systolic velocity (PSV) of the middle cerebral artery (MCA) of the fetus by ultrasound provides more rapid diagnosis of anemia (10). However, it is still not clear whether measuring PSV of the MCA can be useful in prediction of beta-thalassemia (11). In some case reports, it has been shown that PSV of the MCA of fetuses with alpha-thalassemia was higher than normal in the second and third trimesters (12-14). The exact perinatal diagnosis of beta-thalassemia can be done by DNA examination of the sample obtained by chorionic villus sampling (CVS) or amniocentesis (15). Currently, rapid results can be provided by PCR method within 1-2 days (16, 17). The perinatal prediction of beta-thalassemia by CVS or amniocentesis is associated with 1.5-2% risk of spontaneous abortion. Application of non-invasive methods such as measurement of MCA-PSV, CRT (cardiothoracic ratio), and placental thickness by two-dimensional ultrasound has decreased the need for invasive methods in the diagnosis of homozygote alpha-thalassemia (18). As 70% of the blood flow that circulates to the brain enters into the MCA and easy availability of this artery to ultrasound, MCA has become an important target in fetus Doppler ultrasound examination. It seems that increased velocity of blood flow in the MCA when anemia presents is due to increased cardiac output and decreased blood viscosity (19). In addition, as brain tissue is sensitive to oxygen, MCA reacts very rapidly to hypoxia. Therefore, PSV of the MCA can be used as a potential predictor of thalassemia and anemia. Recently, some studies have addressed the role of PSV and resistance index (RI) of the MCA in the diagnosis of thalassemia. It has been shown that MCA-PSV increases in fetuses with thalassemia in comparison to normal fetuses (20-24). Therefore, as the mentioned markers have not been studied in beta-thalassemia, we decided to study these ultrasound indices in beta-

thalassemia fetuses. We think that studying these markers will further our knowledge about non-invasive methods in the diagnosis of beta-thalassemia.

## Materials and methods

In this analytic case-control study, the study population consisted of pregnant women (gestational age of greater than 12 weeks) who had history of giving birth to neonates with major beta-thalassemia or they or their husbands had minor beta-thalassemia (thalassemia group, N= 55 subjects). Control group (20 subjects) consisted of pregnant women (gestational age of more than 12 weeks) whose complete blood count did not show anemia and who had no history of beta-thalassemia. They had a singleton pregnancy. Exclusion criteria were presence of systemic diseases such as hypertension, diabetes mellitus, and addiction to drugs, and taking medications.

The documented variables included age, gestational age, parity, gravity, and number of children with thalassemia. Then, color Doppler ultrasound was done using G50 (Siemens) with curve 3.5-MHz probe and RI and PSV of the MCA were measured. The sonographer was blinded to the assignment of the samples in the study groups. The fetuses of the thalassemia group were divided into three groups according to CVS results: major thalassemia, minor thalassemia, and healthy fetuses. The healthy fetuses were added to the control group.

## Statistical analyses

The difference of RI and PSV were compared between control and thalassemia groups. In order to determine the normal distribution of the data, the Kolmogorov-Smirnov test was applied. Analysis of variance (ANOVA), Mann-Whitney U test, or Kruskal-Wallis tests were used to compare continuous data. The chi-square test or Fisher's exact test was used to compare the categorical variables between the groups. The analyses were done using SPSS software (ver. 22.0).

## Results

Ten fetuses (13.3%) had major beta thalassemia, 20 had minor beta thalassemia, and 45 fetuses did not have beta thalassemia. Mean ( $\pm$ SD) age of the mothers was 28.56 ( $\pm$ 6.16) years (range, 17 to 44 years). There were no significant differences among the groups regarding age, parity, and gravidity (Table 1 - next page).

Four mothers (5.3%) had history of giving birth to a child diagnosed by major beta thalassemia, one mother had history of having two children with major beta thalassemia (1.3%), 14 had children with minor beta thalassemia (18.7%), five with two children diagnosed with minor beta thalassemia (6.7%), and six (8%) had children without beta thalassemia. Others including 45 mothers (60%) were primigravida.

There was no significant difference regarding RI of the MCA among the three groups ( $P= 0.40$ ), however a significant difference existed regarding PSV of the MCA ( $P< 0.001$ ); Table 2.



**Table 1: Comparison of age, parity, and gravidity among the three studied groups**

	Study groups			P value
	Major beta thalassemia	Minor beta thalassemia	Control	
Age	30.2 ( $\pm$ 5.59)	28.33 ( $\pm$ 6.47)	28.25 ( $\pm$ 5.86)	0.54
Gravidity	1.6 ( $\pm$ 0.51)	1.4 ( $\pm$ 0.61)	1.65 ( $\pm$ 0.98)	0.43
Parity	0.3 ( $\pm$ 0.48)	0.22 ( $\pm$ 0.47)	0.4 ( $\pm$ 0.82)	0.74

Data are presented as mean ( $\pm$ standard deviation)

**Table 2: Comparison of resistance index (RI) and peak systolic velocity (PSV) of the middle cerebral artery (MCA) among the three studied groups**

	Study groups			P value
	Major beta thalassemia	Minor beta thalassemia	Control	
RI	0.77 ( $\pm$ 0.01)	0.78 ( $\pm$ 0.03)	0.78 ( $\pm$ 0.01)	0.40
PSV, cm/second	31.16 ( $\pm$ 2.37)	18.8 ( $\pm$ 1.4)	17.99 ( $\pm$ 1.79)	< 0.001

Data are presented as mean ( $\pm$ standard deviation)

As observed, a significant difference existed regarding PSV between control group and thalassemia group. The PSV was significantly larger in the beta thalassemia group. Also, PSV of major beta thalassemia group was larger than in the minor beta thalassemia group ( $P < 0.05$ ). However, no significant difference existed between minor beta thalassemia and control groups regarding PSV.

## Discussion

Beta thalassemia includes a group of hereditary hematologic disorders characterized by decreasing or non-synthesis of beta-globin chain and eventually reduction in hemoglobin concentration and number of red blood cells (25). In recent ultrasound studies, fetal MCA-PSV has been referred for a rapid diagnosis of fetal anemia (10). But measuring of this index has remained uncertain in the prediction of beta thalassemia.

According to our results, mean PSV of the MCA in the major beta thalassemia group was significantly higher than that of normal and minor beta thalassemia groups. This finding is compatible with previous studies. It has been shown in previous studies that the level of fetal MCA-PSV increases in line with increase in hemoglobin concentrations (20, 22, 26, 27), and the MCA-PSV is a useful tool for diagnosing fetal anemia. Lam et al., similar to our study, found that MCA-PSV levels in alpha thalassemic fetuses were significantly higher than in the non-alpha thalassemic group (21). Srisupundit and colleagues, in agreement with our results, also found that when MCA-PSV measurements were 1.5 times higher than average values, the number of fetuses detected to have hemoglobin Bart's disease were higher in comparison to the group with MCA-PSV values less than 1.5 times of average MCA-PSV (28).

Another study reported that MCA-PSV levels in fetuses with hemoglobin Bart's disease was higher compared to normal fetuses (29). Leung and colleagues, in agreement with our findings, noted that non-invasive ultrasound parameters such as PSV of the MCA are helpful in the diagnosis and management of fetal anemia in pregnancy (10). Kowalczyk

et al., in concordance with the results of our study, reported that MCA-PSV levels in fetuses with severe anemia were higher than those without anemia. However, there was no significant difference between the MCA-PSV of fetuses with moderate, vs. those without, anemia (22).

Another report in compliance with our findings reported that MCA-PSV could predict anemia in a fetus with type 1 homozygote alpha-thalassemia (23). It has been shown that MCA-PSV of fetuses with normal hemoglobin was lower than those with anemia (24). It seems that hemoglobin reduction (anemia) increases the risk of heart conditions, heart rate and peripheral resistance, and decreases blood concentration, leading to an increase in cerebral blood flow to maintain oxygen transfer to the brain (30). On the other hand, reduction of blood hemoglobin is associated with hypoxia and lactate production, which is caused by dilation of blood vessels of the brain and increased blood flow (31). There is also a correlation between hemoglobin concentration and hematocrit and blood flow velocity of cerebral arteries (30). Therefore, when fetal hematocrit concentration increases, blood becomes more concentrated and MCA-PSV decreases (32).

Based on the current results, there was no significant difference between the groups regarding RI of the MCA. In agreement with our results, Mandic et al. reported that PI levels decrease along with the severity of anemia, but there was no difference in the amount of PI between fetuses with and without anemia (33). Although in previous studies, RI has been considered useful in early diagnosis of fetal abnormalities (35), no study has been conducted to compare RI between healthy fetuses and those with thalassemia. This has led to a lack of comparisons of

studies conducted in this regard. Therefore, for further investigation, cross-sectional and prospective studies on comparing RI of the MCA of healthy fetus and beta-thalassemia are recommended.

A limitation of this study was low sample size. It is recommended to conduct future studies of larger sample size. This was a cross-sectional study with no follow-up. Therefore, it is suggested that future studies should be designed with a long follow-up. However, the strength of this study is that so far no study has been done to compare these parameters in fetal beta-thalassemia. Therefore, considering the obtained findings, it can be said that the measurement of the MCA-PSV parameter is a non-invasive and a low cost method in beta-thalassemia fetuses.

## Conclusion

There was a significant difference between healthy and beta-thalassemia fetal PSV of the MCA. This was higher in the beta-thalassemia group. Also, MCA-PSV was higher in major beta thalassemia compared to the minor beta thalassemia group. However, no difference existed regarding PSV of the MCA between minor beta-thalassemia and control groups. It seems that MCA-PSV is a useful index to non-invasively assess fetuses suspected of having thalassemia.

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# Biological Dosimetry Method: a Probable way for Measuring Percent Depth Dose

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## Abstract

**Aim:** Since genetic materials are the critical targets of cell irradiations, obtaining the depth dose distribution by cytogenetic methods is supposed as an accurate and realistic method for dosimetry in the field of treatment.

**Material and Method:** In this study, five vials containing blood were positioned in a tissue equivalent phantom. The space between test vials was 12 mm and they were positioned at the maximum depth dose point.

**Results:** The results indicated that the calculated dose obtained by micronuclei assay method has a significant similarity to the dose calculated by the Ion Chamber. However, the limitation of the minimum needed blood which limits the minimum size of test vials, could destroy the spatial resolution.

**Discussion:** Authors recommend more research to make the biological dosimeters as a precise method for radiation therapy.

**Key words:** Biological Dosimetry; Percentage Depth Dose; Micronuclei; Phantom; Linear Accelerator

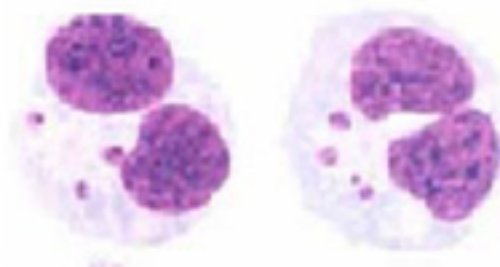
Please cite this article as: Yadolahi M. et al. Biological Dosimetry Method: a Probable way for Measuring Percent Depth Dose. *World Family Medicine*. 2018;16(1):193-197  
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## Introduction

In 1964, the investigation of chromosome aberrations (cytogenetic methods) was suggested as a biologic method for estimation of radiation dose [1]. Today, it's been years that the investigation of chromosome aberrations in blood lymphocytes has been used for the dosimetry of ionizing radiation [2]. The most important cytogenetic methods that are used for radiation dosimetry are metaphase analysis, G-banding, the premature chromosome condensation [PCC], the fluorescence in situ hybridization [FISH] and micronuclei assay using cytochalasin B (CBMN).

The Cytokinesis-block micronucleus (CBMN) was developed by "Marley" and "Fenech" in 1985[3]. Micronuclei (MN) is a small nucleus in addition to the main nucleus which results from chromosome breaks or the whole chromosomes lagging behind, during anaphase. By adding cytochalasin B to the lymphocyte cultures, cytokinesis will be blocked without inhibiting the nuclear division. The cytokinesis-blocked cells accumulate in the first division cycle and can be easily identified from their binucleate appearance (Figure 1). Therefore, the micronuclei (MN) can be easily, specifically and efficiently counted in these binuclei cells while excluding the non-dividing mononuclear cells [3].

**Figure 1: BN Cells with MN**



MN can arise from exposure to various clastogenic agents in the form of acentric chromosome fragments, as well as to aneugenic agents as whole chromosomes, to the extent that the MN index in human cells, is one of the standard cytogenetic tests of genetic toxicology tests. However, because ionizing radiation is a strong clastogenic agent, and thus a potent inducer of MN, the CBMN assay has proven to be a very reliable, thoroughly validated and standardized technique in the field of radiation biology to evaluate *in vivo* radiation exposure of occupational, medical and accidentally exposed individuals [4]. For instance, in a study which was conducted to investigate chromosome damage in individuals who occupationally had exposures to the low-level ionizing radiation, it has been indicated that the frequency of MN in the workers was higher in relation to the control group [5].

Many studies have shown that the number of radiation induced MN is strongly dependent on radiation dose as well as radiation quality [6-8]. For low LET radiation, linear quadratic dose-response relation has been reported. While a linear dependence is observed for high LET radiation, therefore it causes the radiations with more LET to be more effective in generating MN at the same dose levels.

Since one of the important goals in radiotherapy is to deliver the maximum amount of dose to the tumoral cells with the minimum damage to the cells of the healthy tissues, determination of dose distribution in the tissue or tissue equivalent phantom is of significant importance. Determination of this important parameter has a vast application and one of its most important applications is the confirmation of treatment planning. Today the depth dose distribution is determined by the use of physical dosimeters. Among the dosimeters used for PDD determination, the ionization chamber, TLD and types of silicon diodes could be referred to. The ionization chamber functions by measuring the charges produced by direct ionization in the gas [9,10]. Thermoluminescence Dosimeters are the crystal materials which function according to the thermoluminescence phenomenon [10]. The diode dosimeter is also a crystal of silicon which is mixed with some impurities. The irradiation causes an inductive electronic current in the diode; this current is measured by the use of an amplifier which is embedded on the diode [10].

Since the genetic materials are the critical targets of cell irradiation, obtaining the depth dose distribution by cytogenetic methods is suggested as an accurate and realistic method for dosimetry in the field of treatment. The main aim of this study was using CBMN method in order to obtain the depth dose distribution and comparing the obtained dose-response curve with a common dosimeter to investigate the capability of this method for obtaining the spatial dose distribution. The next goal was to make a tissue equivalent liquid material which becomes gelatinized at room temperature to hold the cells in stable positions. Hence, we approached a structure which was similar to body tissue.

## Materials and Methods

5 ml blood samples were collected in heparinized tubes from a healthy 29 year-old woman, then under sterile circumstances and under the laminar hood, each 1 mL of blood was poured in a vial with 1 cc volume and placed at different depths in a cylindrical container. The space between test vials was 12 mm and they were positioned at the maximum depth dose point (Figure 2). Then the liquid phantoms were added to the container containing the vials. Consequently by addition of a crosslinker, the phantom was gelatinized (Figure 3). After the irradiation, each 1.00 mL of blood, was added to 9.00 mL of RPMI 1640 culture medium (Gibco) containing 10% fetal calf serum, 20  $\mu$ L/mL phytohemagglutinin (Gibco), 50U/mL penicillin, 50  $\mu$ g/mL streptomycin, and 2mM glutamine (sigma). All cultures were incubated at  $37\pm 10^{\circ}\text{C}$  in a humidified atmosphere of 5%  $\text{CO}_2/95\%$  air (Figure 4). Cytochalasin B (Fluka; final concentration: 6  $\mu$ L/mL) was added after 44 hours of culture. At the end of 72 hours of incubation, the cells were collected by centrifugation and re-suspended in 0.075M cold potassium chloride for 8 minutes, at 1000 rpm; they were immediately fixed in a fixative solution (methanol:acetic acid, 6:1) three times. Fixed cells were dropped onto clean microscopic slides, air dried, and stained with a Giemsa solution. All slides were coded and scoring was done at  $40\times$  magnification for the frequency of micronuclei in cytokinesis-blocked binucleated cells with well-preserved cytoplasm. To be counted as micronuclei, candidates had to have a diameter between 1/16th and 1/3rd of main nuclei, be non-refractile, and not be linked to, or overlap with, the main nuclei [11]. Frequency of MN per 1000 BN cells was counted.

### A. Irradiation

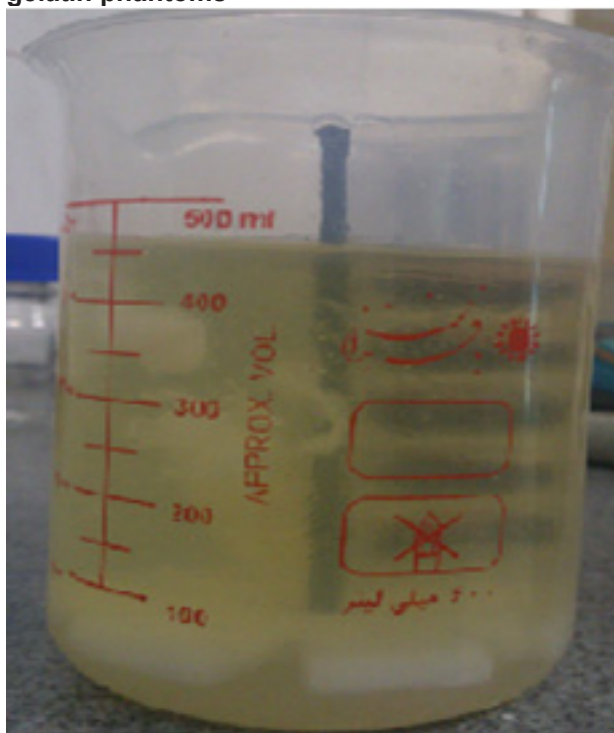
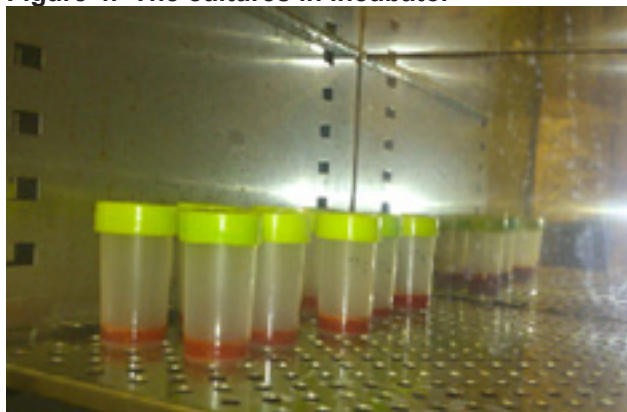
Irradiation was performed using a linear accelerator (Compact Elektra AU051) with 6 Mev energy and a dose rate of 350 MU/min. The field-size was 20 cm $\times$ 20 cm and the Source Surface Distance (SSD) was 100 cm. The dose at dose-maximum amounted to 4 Gy.

### B. Phantom Structure

In order to build a phantom to be malleable and capable of being molded like the container's shape, the best way is to use hydrogels that at the beginning are liquid and then it is possible for them to be gelatinized. One of the most important hydrogels is gelatin. But unfortunately the gelatin hydrogels have a weak structure and melt at a temperature around 30 degrees centigrade which makes working with this phantom difficult.

One of the most important reasons for the melting of the gelatin networks is the existence of the weak hydrogen bonds in the gelatin. Therefore, in order to avoid it melting it is necessary for this phantom to be made of a material which instead of hydrogen bonds, have stronger bonds like covalence bonds. After conducting different investigations, the Poly Vinyl Alcohol (PVA) (Merck Germany) (10% w/w) together with a cross linker was found suitable.

In order to build the phantom, first we dissolved PVA in the water at 90 degrees centigrade. When the PVA becomes completely dissolved, we turn off the heater to let

**Figure 2: The container containing the vials****Figure 3: The container containing vials with gelatin phantoms****Figure 4. The cultures in incubator**

the stirring continue without heating. Simultaneously, we prepare the cross linker on a stirrer in another container. This compound included 5cc of water and glutaraldehyde. The required materials for making the phantom are mentioned in Table 1. Then the crosslinker solution was added to the PVA solution at room temperature and evenly homogenized by stirring and the compound was moved to the container. This compound could be preserved at room temperature.

**Table 1: Required materials to make the phantom**

Amount (%)	Material
89.754	Water
10	PVA
0.246	Glutaraldehyde

The number of MN per 1000 BN as a function of depth in the phantom is demonstrated in Figure 5.

The statistical calculations have shown that the p-value concerning the relation of the depths 0.5 Cm and 1.7 Cm and also 1.7 Cm and 5.3 Cm is less than 0.001 and the p-value concerning depth 1.7 Cm in relation to the depth 4.1 Cm is less than 0.01. The depth 2.9 Cm in relation to the depth 4.1 Cm and also 2.9 Cm in relation to the depth 5.3 Cm has a p-value <0.05. Generally, the comparison of the cell groups located in five depths indicate a meaningful difference ( $P < 0.05$ ) in frequency of micronuclei.

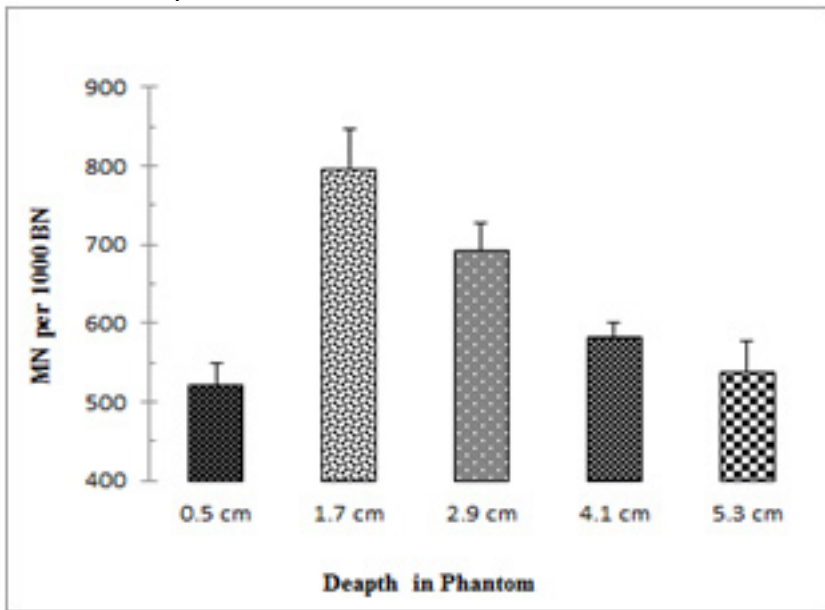
In another study, the frequency of micronuclei was obtained in lymphocytes of 5 healthy humans after irradiation with doses 0.3 to 5 Gy X-rays (Figure 6) [12], therefore, in our work, the PDD curve according to the depth has been drawn according to this study.

The PDD curve according to the depth has also been reached by ionizing chamber and finally the obtained PDD curve using MN method was compared with the obtained curve based on ionizing chamber (Figure 7). As has been shown in Figure 7 the results obtained using both of the methods have an acceptable similarity to each other. It should be mentioned that the study based on which we have drawn the calibration curve was performed in 250 Kev energy whereas the energy used in our work is 6 Mev and it is possible that a percentage of the difference between the responses obtained using the two methods of MN and ionizing chamber is caused by that. The influence of energy on the Frequency of micronuclei is now being investigated by the current group and in future studies, the corrections concerning this parameter would be implemented, if necessary.

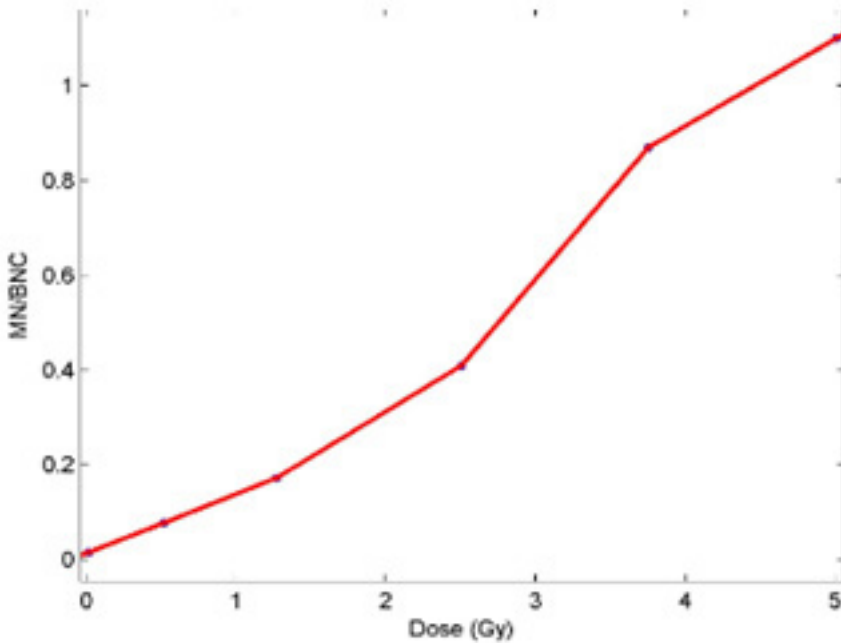
As was already expected, there is an increase in the amount of MN up to the "build-up" region and then the MNs were decreased with a moderate slope. The ascending and descending procedure of the MN with depth were compared with the dose measurement using the ion chamber. The results indicated that the calculated dose obtained by MN measurement method has a significant similarity to the dose calculated by the ion chamber. However, the limitation of the minimum needed blood which limits the minimum size of test vials, and could destroy the spatial resolution. Therefore, authors recommend more research to make the biological dosimeters a precise method for radiation therapy.



**Figure 5: The number of MN per 1000 BN as a function of depth in the phantom (the standard deviation has been shown in the figure as “error bar”)**



**Figure 6. MN/BNC in human lymphocytes after x-irradiation**

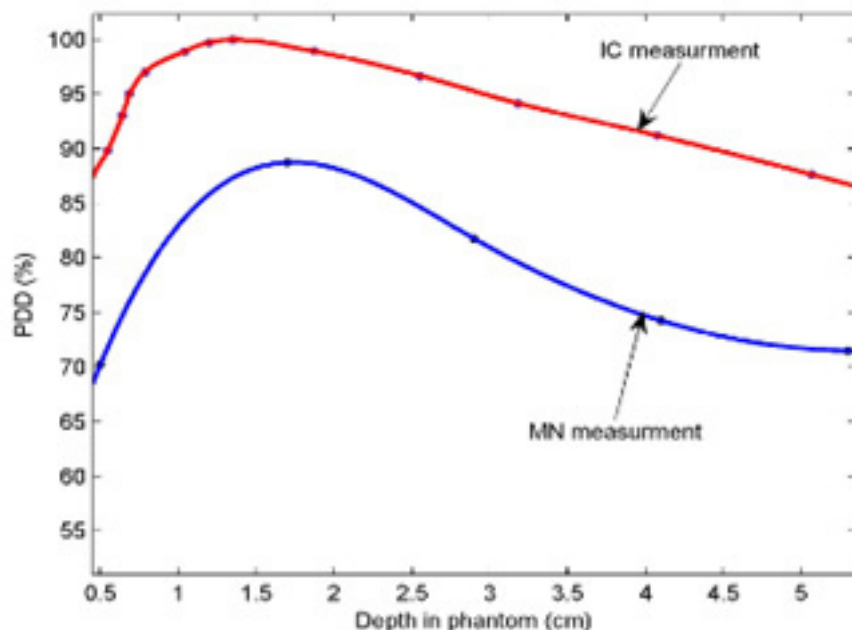


**Discussion**

In this research, the application of biological dosimetry for the measurement of PDD, has been investigated. The findings indicated a good correspondence to the PDD was resulted from an ion chamber. According to the achieved results in this research, it could be concluded that the biological dosimetry is potentially suitable for PDD measurement in radiation therapy. MN assay was used to assess individual radiation sensitivity between different patients undergoing radiotherapy [13]. The response of cancer patients to radiotherapy varies in severity due to differences in intrinsic cellular radio sensitivity.

**Conclusion**

The identification of radiosensitive patients, through the MN assay, will allow the individualization of patient’s treatment; therefore this method considers individual differences in response to the radiation. Furthermore, this tool, due to its substantial traits, has more relevance to the natural tissues by view of the response to the radiation but in the physical dosimeters category, these advantages do not exist. Nevertheless, more research in the direction of improvement of spatial resolution and dose resolution of this method is recommended for future research.

**Figure 7: PDD obtained using two methods of MN assay and ion chamber**

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# The comparative effects of chamomile's hydro alcoholic extract and imipramine on decreasing depression in mice

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## Abstract

**Background and Objective:** The goal of this study was to compare the effects of chamomile's hydro alcoholic extract and imipramine on decreasing depression of laboratory mice.

**Method:** Sixty mice in the weight range of 25 to 30 gram were divided into six groups: control, depression, imipramine and 50, 100 and 200 mg/kg doses of chamomile's extract. Injections were done intraperitoneal. Depression was induced by the use of tetrabenzazine. Then, the rate of depression was assessed by forced swimming test and tail suspension test. Duration of movement and immobility of the animal in each test indicates the degree of depression. Obtained data were analyzed using SPSS program.

**Results:** According to results, 50 and 100 mg/kg doses could not reduce the depression comparing to imipramine but 200 mg/kg dose significantly increased mobility time which shows decrease in depression level.

**Conclusion:** Therefore, it can be said that chamomile extract can be a replacement for imipramine to reduce the depression symptoms, dose dependently.

**Key words:** chamomile, depression, imipramine, forced swimming test, tail suspension test, little laboratory mice

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## Introduction

Depression is one of the common diseases of psychiatry and one of disabling mental problems among different societies (Kaplan et al. 2014). Depression is from intensive emotional disorders and about 21% of people of developing countries are suffering from it (Potdar and Kibile .2011). Depression is result of brain's biochemical changes and is one of common adult diseases. This mental disease has been reported in United States population and about 30% of adults face with depression at least once along their life time. Suicide percentage of depressed people is high. The rate of infection in women is 2-3 times higher than that of men. 70% of depressed people respond to anti-depressant drugs. The most important treatment for treating depression is medication that can be combined with psychotherapy (Cryan et al. 2002). Reports of World Health Organization show that depression is the second most debilitating factor after cardiovascular disease, causing severe social and economic losses.

Tricyclic anti-depressant drugs prevent norepinefrin absorption and somewhat serotonin after releasing into the synapse. These drugs were accidentally discovered, so that the first tricyclic drug (imipramine) was studying as a medication for schizophrenia because it was thought to be effective to raise the mood. It has been revealed the theory which these drugs increase the activity of norepinephrine was simplistic (Beck and Alford. 2009).

Also, it is appeared that when tricyclic drugs are used for weeks, change some other aspects of cell performance including how the receptors act and how the cells respond to the activation of receptors and the combination of neurotransmitters. Because these changes in cell performance occur along the period of inducing anti-depressant effects, one or more of these changes are involved in mediating mentioned effects (Bucher et al. 2015). Metabolism of imipramine causes the formation of oxygen free radicals which can affect DNA (Madrigal-Bujaidar et al. 2010).



The forced swim model has a number of advantages over previous methods in that it utilizes very mild stress, is short in duration, is easily standardized, requires only a video camera and either a manual or automatic behavioral scoring system to measure immobility and distance swum, and can be readily used for time course studies of onset of drug action. Moreover, since it utilizes a greater swimming area than the traditional (Porsolt) method it can be used to study interactions of depressive behavior with behavioral flexibility and perseveration. Finally, its use of mice makes it readily amenable to genetic and molecular analyses (Eric et al. 2011).

Chamomile is one of the oldest medicinal plants which has been proposed for anxiety and general depression (Srivastava et al. 2010). Active chemical elements in chamomile flowers are flavonoids of apigenin, quercetin, luteolin, and triptoides of  $\alpha$ - bisabolol and its oxides and chamazuline (Gardiner. 1999).

There is no extant clinical study about chamomile but it has been used for various diseases such as nervous disorders (migraine, facial nerves), digestion disorders (bloating, difficult digestion, gastric and ulcerous ulcers), menstrual disorders, skin disorders (eczema, hives), conjunctivitis, rheumatic pains and gout (Vallen. 2002).

The existence of a number of classes of antidepressant drugs with diverse pharmacological effects would lead one to expect that antidepressant drugs acting through different pharmacological mechanisms should produce different behavioral effects. Animal behavioral tests used to screen antidepressant drugs do not, however, discriminate between drugs that selectively enhance serotonin or norepinephrine transmission. Several components of human depression are differently affected by drugs selectively interacting with either serotonin or norepinephrine transmission. The ideal animal model for detecting antidepressant drug effects should thus be sensitive to all antidepressant drugs and should also display multiple components that are sensitive to specific drug classes. The revised scoring of the forced swimming test corresponds to a behavioral test for antidepressant drugs that meet these criteria (Lucki. 1997).

This study was carried to compare hydro alcoholic extract of chamomile and imipramine on depression of laboratory mice. This study was carried out to compare the effects of chamomile's hydro alcoholic extract and imipramine on decreasing depression of laboratory mice.

## Materials and Methods

In this study sixty mature mice in the weight range of 25 to 30g were kept in a temperature and humidity controlled room with 12:12 hour photoperiod for 10 days with free access to food and water.

Prepared chamomile flowers were grinded. 200 grams of obtained powder were poured in a sterilized erlen and 1000 cc of ethanol was added to it and was kept in

moderate condition for 72 hours. After that, erlen contents were shaken using shaker for five minutes. Erlen contents were filtered using Whatman paper. The obtained material was placed in a rotary machine for one and a half hours to evaporate its alcohol (Modaresi and Resalatpour. 2012). This extract was used to prepare 50, 100, and 200 mg/kg concentrations.

Sixty female mice in the weight range of 25 to 30g were divided into six groups:

- Control group: this group didn't receive any injection.
- Depression group: consisted of ten mice that were depressed by tetrabenazine.
- Imipramine group: this group consisted of ten mice treated with imipramine at a dose of 1.2 mg.kg after induction of depression.
- Treatment groups: Included 30 samples in three experimental groups that received intraperitoneal injections of chamomile extract 50, 100, and 200 mg.kg doses.

Depression was induced by injection of tetrabenazine in all samples (except the control group). To evaluate the depression, forced swimming test and tail suspension test were used for six minutes. Immobility time was ascribed to depression increment whereas increase in mobility was taken as antidepressant effect.

Obtained data were analyzed at two descriptive and inferential levels. Average and standard deviation were calculated in descriptive level whereas variance were used for inferential.

## Results

According to Table 1 (next page), average mobility time (in seconds) of control group was more than other groups and 100mg group had the least time. The situation was the opposite for immobility and 100 mg/kg had the highest time whereas control group had the least time ( $P<0.05$ ).

In forced swimming test also average mobility time (in seconds) of control group was more than other groups and 100 mg/kg group had the least time. Furthermore, 100 mg/kg group had the highest immobility time whereas control group had the least one ( $P<0.05$ ).

Figure 1 shows the mobility time (in seconds) of suspension test. The differences of 50 mg/kg and 100 mg/kg groups from imipramine and control groups were significant ( $p<0.05$  and  $p<0.01$ ) but not from depressed group.

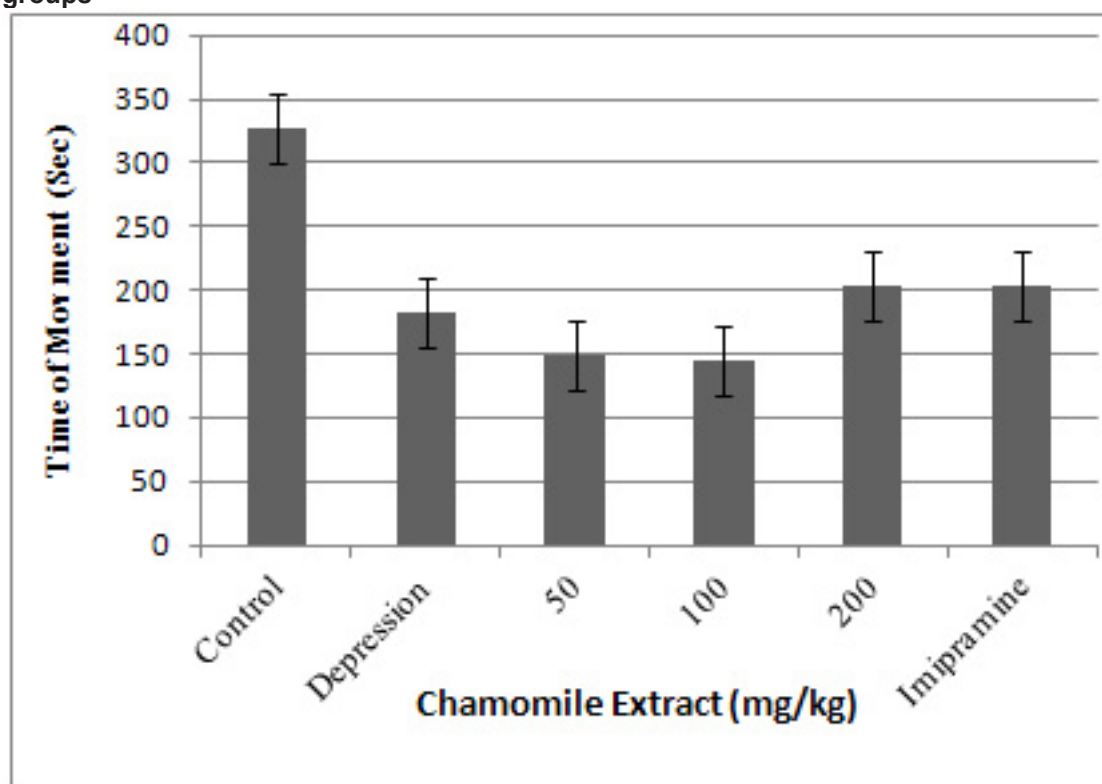
The difference of 200 mg/kg group from control group was significant ( $p<0.01$ ) but this group was not different from imipramine group.

Figure 2 shows the immobility time (in seconds) of suspension test. The differences of 50 mg/kg group from imipramine and control groups were significant ( $p<0.05$  and  $p<0.01$ ) but not from depressed group. The differences of 100 mg/kg group from imipramine and control groups were significant ( $p<0.01$ ) but not from depressed group.

Table 1. Average and standard deviation of variables

Group	Tail Suspension Test (Mobility)		Tail Suspension Test (Immobility)		Forced Swimming Test (Mobility)		Forced Swimming Test (Immobility)	
	average	Standard deviation	average	Standard deviation	average	Standard deviation	average	Standard deviation
Imipramine	204.2	43.25	155.8	43.25	150	32.13	210	32.13
Depressed	183.1	27.83	176.9	27.83	89.1	7.26	270.9	7.26
Control	326.7	27.03	32.3	27.02	250.3	38.67	109.7	38.67
50 mg/kg	148.3	35.83	211.7	35.83	81.7	19.97	278.3	19.97
100 mg/kg	144.4	25.58	215.5	25.58	74.1	8.41	285.9	8.41
200 mg/kg	203.7	50.73	156.3	50.73	222.3	10.11	137.7	10.11

Figure 1: Time of movement in the tail suspension test in Control, Depression, Imipramine and three experimental groups



The difference of 200mg.kg group from control groups was significant ( $p < 0.01$ ) but this group was not different from imipramine and depressed groups.

Figure 3 shows the mobility time (in seconds) of forced swimming test. According to graph, 200 mg/kg group increased mobility time, which is considered as an indicator of reducing depression.

The difference of 200 mg/kg group from control group was not significant but this group was significantly different from depressed group.

Figure 4 (page 202) shows the immobility time (in seconds) of forced swimming test. The difference of 200 mg/kg group from control group was not significant but this group was significantly different from depressed group.

## Discussion

Drugs for depression include antidepressant medicines, such as imipramine, which increase the nerve conduction of monoamines, mainly norepinephrine and less serotonin that has potentially dangerous, sometimes fatal, side effects. Monoamine oxidase inhibitors, which prevent the activity of monoamine oxidase, which, unfortunately, have some unpleasant side effects for some people. For this reason, most patients do not continue to take enough medication to reveal their anti-depressant effect (Machado et al. 2009).

Herbal medicine has many effects in facilitating the treatment of chronic diseases and related problems. Sometimes certain herbaceous species are sometimes used as medicinal plants, which have not yet been acquired by the new sciences and can be achieved through the experience of indigenous people. Akhundzadeh et al. (2005) showed a depressive effect of saffron extract compared to placebo (Milajerdi et al. 2016).

Figure 2: Time of immobility in the tail suspension test in Control, Depression, Imipramine and three experimental groups

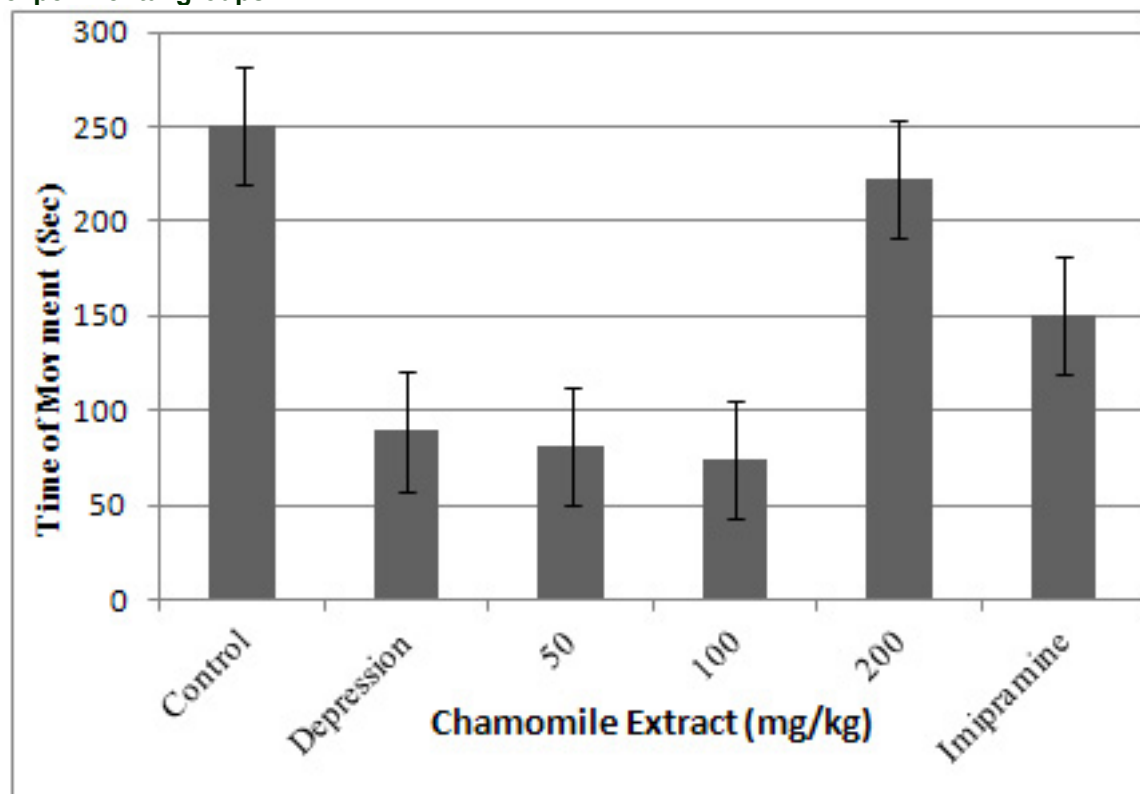
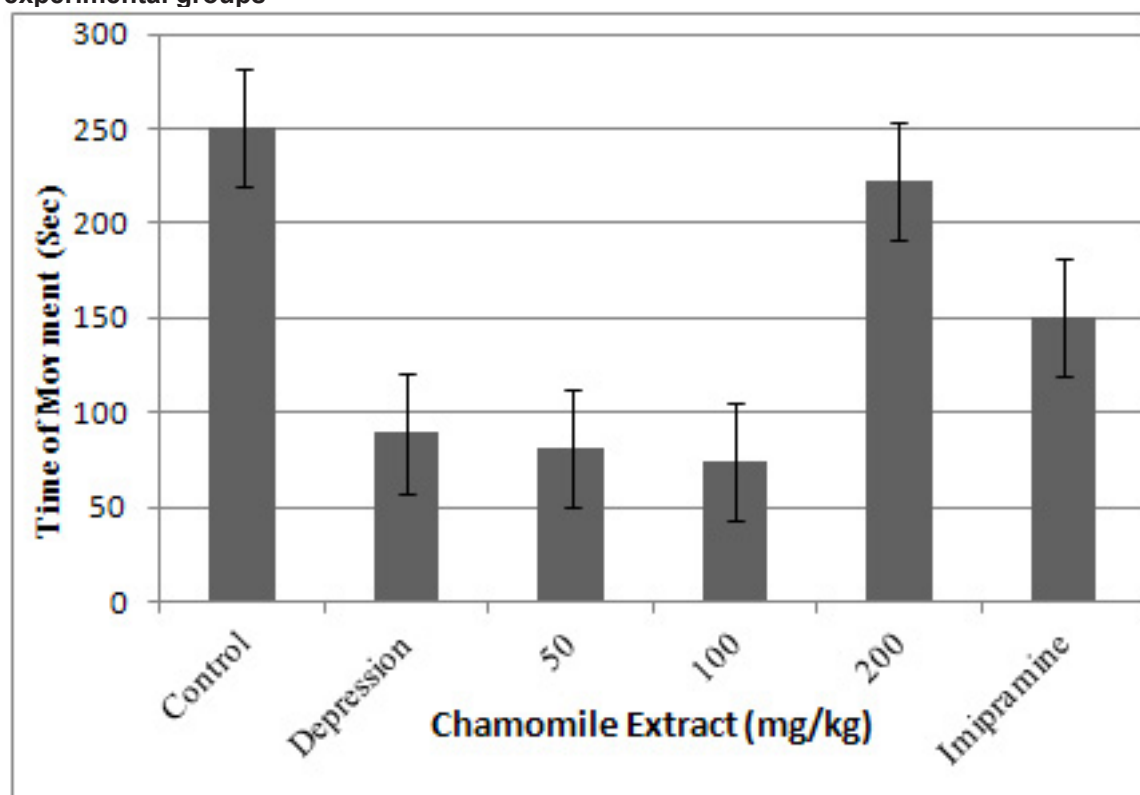
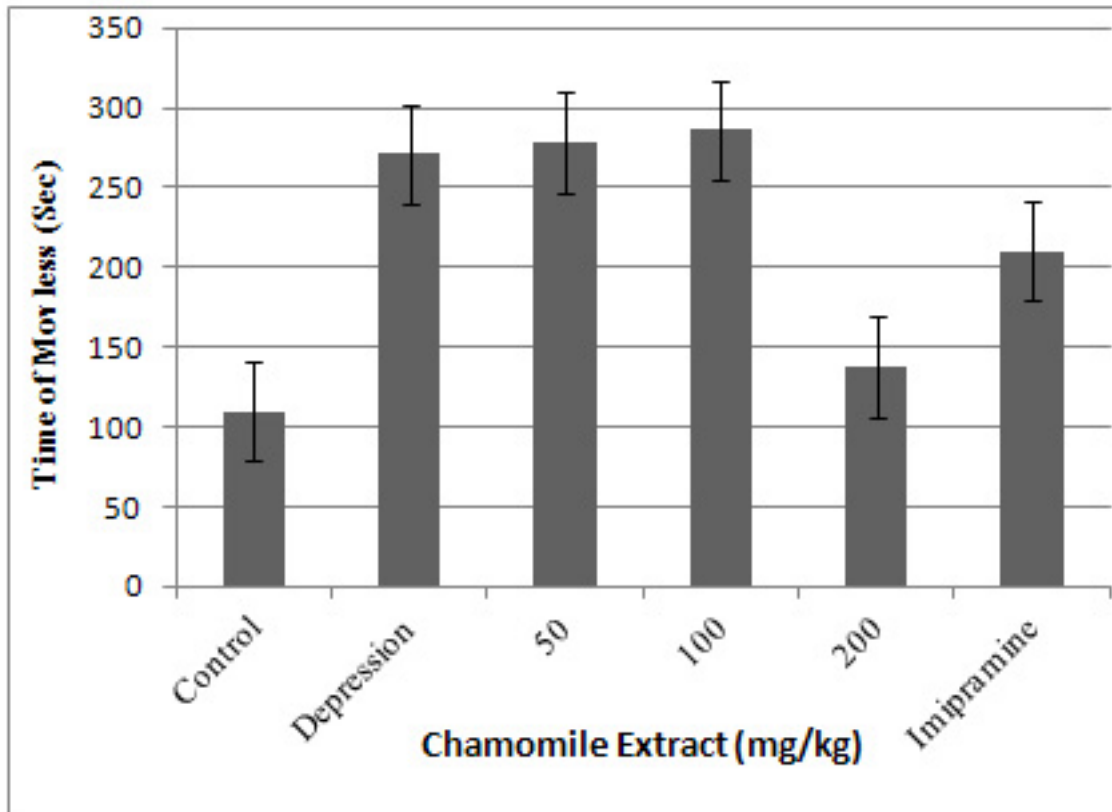


Figure 3: Time of movement in the forced swimming test in Control, Depression, Imipramine and three experimental groups





**Figure 4: Time of immobility in the forced swimming test in Control, Depression, Imipramine and three experimental groups**



Shiravi and Topal (2013) In the study of the effect of imipramine hydrochloride on anti-depressant effects of NMRI mice, the anomalies caused by imipramine include skeletal abnormalities, decreased growth, increased fetal deaths, and in cases of convulsion and maternal death (Shiravi and Potal. 2014).

Jafari et al. (2013) in a study titled Comparison of anti-depressant properties of different extracts of common petals of petals by forced swimming model in experimental mice, found that intraperitoneal injection (20 and 30 mg/kg and intravenous (10 and 50 mg/kg) of *Rosa canina* blue extract significantly reduced the immobilization time of the mouse in the forced swimming test, which was similar to that of fluoxetine (Jafari et al. 2013).

Machado et al. (2009) investigated the effect of hydro alcoholic extract of stems and rosemary leaves in two models of forced swimming test and tail tensile test in mice and found that in the forced swimming test at a dose of 100 mg/kg, and in the suspension test at a dose of 10- 100 mg/kg, the immobilization time was significantly reduced compared to the control group (Machado et al. 2009).

The results showed that the difference of some groups in the variables of both tests was significant and chamomile extract at doses of 50 and 100 mg/kg did not significantly differ from the groups of imipramine and the control group in both variables, both different tests were. Extract consumption at 200 mg/kg in both suspension and swimming tests with control group did not differ significantly.

## Conclusion

Chamomile's extract in 200 mg/kg doses increased movement time in forced swimming test significantly in proportion to control group which is depression reducing index. Therefore, Chamomile's extract is effective for reducing depression, dose dependently. On the whole, chamomile's extract with its antidepressant effects dose dependently can be a good replacement for imipramine.

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# The effect of the traditional medicine product “Milk-Cuscuta” on skin hyperpigmentation in patients with Melasma

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## Abstract

**Background:** There is relatively little information pertaining to the effects of Cuscuta extract on the hyperpigmentation of the skin.

**Objective:** The purpose of this study is to scrutinize the effect of the Persian medicine “Milk-Cuscuta” on hyperpigmentation of the skin in patients with melasma.

**Materials and Methods:** In this clinical trial, 70 patients with melasma (4 men and 66 women with the age range of 18 to 65 years) were studied. The patients received the dried extract (4.8 g) with 200 gr milk daily. The treatment continued for one month and then the patients were followed-up for two months. The efficacy of the treatment was determined through the Dermacatch apparatus, Melasma Area Severity Index (MASI) score, Investigator’s Global Assessment (IGA) and the patients’ questionnaires; all were performed at baseline, one month and three months after the treatment.

**Results:** The mean of the MASI score in one month after the treatment was  $5.1 \pm 3.2$  and in three months after the treatment was  $4.6 \pm 3.2$ . A significant difference was observed between the groups ( $P \leq 0.001$ ). At the end of the treatment, the melanin content was

significantly lower in one month ( $529 \pm 43.1$ ) and three months ( $515 \pm 46.1$ ) after the treatment against the pretreatment period ( $555 \pm 49.6$ ;  $P \leq 0.001$ ).

**Conclusions:** The findings demonstrate that the consumption of the Cuscuta extract with milk can reduce the synthesis of melatonin and consequently results in the elimination of melasma.

**Key words:** Cuscuta, hyperpigmentation, melasma, traditional medicine

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## Background

Melasma (also known as chloasma faciei) as a symmetrical skin disorder leads to the brown skin hyperpigmentation, especially in sunlight exposure areas (1, 2). The uttermost affected areas are typically found in the cheeks, forehead, and upper lip (3, 4). Melasma most occurs in the tropical regions and in all races, particularly among the Latin and Asian races (5). There are multiple factors including exposure to ultraviolet (UV) light, gestation (6, 7), genetic aptitude (8), endocrine dysfunction or hormone treatments (9, 10), and consumption of oral contraceptive tablets (11) that contribute to melasma.

Several studies reveal that melasma treatment has not been yet known as resistant to therapy (12, 13). The current treatments of melasma run the gamut from the use of broad spectrum anti-UVA and UVB opaque sunscreen such as zinc oxide, consumption of a bleaching gel, hydroquinone creams and low concentration steroids, arbutin, azelaic acid, AHA and retinoid (3, 4, 14, 15). Also, various lasers and tranexamic acid-containing oral medications are efficacious and a safe therapeutic modality for the treatment of melasma (16).

*Cuscuta reflexa* Roxb (*Cuscuta ceae*), which is known as “amarvela” or “akashbel” in the vernacular terminology, is a parasitic plant with slender yellow stems. It spreads in tropical and temperate regions and is commonly found in various regions of Bangladesh, Iran, India, China and some other countries. It grows on different host plants, mostly the thorny herbs (17, 18). The *Cuscuta* species has a wide range of biological activities, so its extract containing a number of  $\alpha$ -glucosidase inhibitory compounds (18), flavanone-reflexin (19), tetrahydrofuran derivatives and coumarin (20) has been used for the treatment of various diseases (13, 20).

The current review of the literature indicates that the present study might be the first controlled clinical trial that has examined the efficacy of *Cuscuta* in the treatment of a hyperpigmentary disorder in humans. To this end, the effect of “Milk-*Cuscuta*” was surveyed on hyperpigmentation of skin in patients with melasma.

## Objectives

This study aims to survey the treatment effects of a proposed Iranian traditional medicine “Milk-*Cuscuta*” on hyperpigmentation of the skin in patients with melasma.

## Materials and Methods

### 1. Study population and sample size

A clinical trial was performed on 70 patients (4 males and 66 females) at the Dermatology and Stem Cell Research Center in the Tehran University of Medical Sciences, Tehran, Iran. The patients completed the questionnaires of the permanent Inventory of Individual Information (personal, physical and mental characteristics) and were

treated after the initial diagnosis. Formal informed consent was obtained from all the patients prior to their enrolment. The study period was three months. The age range of female and male patients was between 18 to 65 years. The diagnosis of epidermal and normal melasma and a minimum 6-month duration of the disease were considered as the inclusion criteria.

Also, the exclusion criteria were as follows: (a) receiving oral contraceptives at the time of the study, (b) hemorrhoids, (c) hormonal disorders, (d) sunburn in the last three months, (e) laser therapy in the last three months, (f) pulmonary problems, (g) intolerance to the desired drug, (h) use of anti-staining drugs in the last three months, (i) pregnancy, and (j) clinical lactation. The evaluations were performed by the same investigators at baseline before treatment, one month after the treatment and at the end of the three months study.

At the beginning of the study, patients' medical histories were recorded with a particular focus on the onset time of the melasma symptoms, history of pregnancy, the use of contraceptive pills, sun exposure, drug history, previous treatments for melasma, family history of melasma and other influencing or exacerbating factors. All patients were provided with a standard broad-spectrum sunscreen with the sun protection factor (SPF)  $\geq 50$ . They were instructed to apply it to their entire face and to repeat the application every 3 hours during the day throughout the study period. With the approval of the Ethics Committee of Shahid Beheshti University of Medical Sciences, this study protocol was registered in the Iranian Registry of Clinical Trials (IRCT 2016030826967N1).

### 2. Plant material and extraction

The dried *Cuscuta chinensis* Lam. (*Cuscuta ceae*) aerial parts were purchased from the local herbal markets and authenticated by the expert botanists at the Traditional Medicine and Material Medica Research Center (TMRC) of the Shahid Beheshti University of Medical Sciences, Tehran, Iran. The *Cuscuta chinensis* aerial parts (77 kg) were extracted with water (90 °C, 15 min). The filtered extract was then dried by the spray drying method (Soha Jissa factory, Salmanshahr, Iran). The dried extract (4.8 g) was packed in the containers to be used in the clinical trial.

### 3. The quality control evaluation

The quality control analyses of the plant material were implemented according to the Unani Pharmacopoeia of India (21). The total phenolic contents of the aerial parts and the extract of the dried *Cuscuta chinensis* were also determined spectrophotometrically by using the Folin-Ciocalteu reagent (22). The thin layer chromatographic evaluation of the extract was performed and the relative retention factors (Rf) were compared to those reported in the reference (21). The extract was checked for microbial contamination according to the WHO quality control methods for the medicinal plant materials (23).

#### 4. Clinical assessment

First, all the eligible patients were interviewed and informed about the research objectives. Clinical evaluations and evaluation of the Melasma Area Severity Index (MASI) scores were performed by the same investigators at baseline, one month, and three months after the treatment. The MASI score was then calculated based on the Kimbrough–Green equation (24).

The criteria for clinical improvement of the patients were delineated by the physicians. The patient's consent, the measurement of the contents of melanin and hemoglobin on the melasma affected skin, which determines the degree of hyperpigmentation and erythema of the skin, were carried out by the Dermacatch (25). The mean of the MASI scores were calculated by the same investigators for all patients. To gauge the patients' viewpoints and attitudes towards the efficacy of the treatment, they were requested to select an item on the list that best described the effect of *Cuscuta* on their melasma lesions (the list being the same as the investigator's assessment list). The Investigator's Global Assessment (IGA) was performed in accordance with Lee's scoring system (26). The categories included: 1) no effect (i.e. no visible changes of pigmentation), 2) mild (visible decrease of pigmentation but still some visible border), 3) moderate (marked decrease of visible pigmentation, but still some visible border), and 4) excellent (complete loss of visible abnormal pigmentation).

#### 5. Statistical analysis

All the analyses were carried out using SPSS version 20. The  $p$ -value  $\leq 0.05$  was considered to indicate the statistical significance. For the comparison of both the MASI scores and the Dermacatch measurements in each drug group and since the data were found to be normally distributed, an independent  $t$ -test was used. The normality was assessed by the Kolmogorov–Smirnov test and the grades in objective assessment were compared using the Mann–Whitney test.

## Results

### 1. Baseline patient characteristics and demographic data

After evaluating 90 patients, 20 patients were omitted in two stages of the study because of issues like bloating, nausea, personal issues and/or non-adherence to the treatment. The flow diagram of the contributors in the trial based on the CONSORT guidelines is shown in Figure 1. The mean age of the patients was  $41.5 \pm 8.6$ , ranging from 18 to 65 years. The percent of participating females and males were 94.3% and 5.7%, respectively (Table 1).

### 2. The quality control assessment

The results of the quality control evaluation of *Cuscuta chinensis* displayed that the assessed parameters including total Ash (8.20%), acid insoluble ash (6.35%), alcohol soluble extractive (13.16%), water soluble extractive (16.00%), total phenol (pyrogallol equivalent per 100g plant material,  $462.16 \pm 18.20$  mg), total phenol (pyrogallol equivalent per 100g plant material,  $462.16 \pm 18.20$  mg), and total phenol (pyrogallol equivalent per 100g plant material,  $5.36 \pm 0.18$  g) were in acceptable limits (Table 2). The Rf's from the thin layer chromatography of the plant (according to the Pharmacopoeia of India) were similar to those of the references. Also, the microbial quality control of the extract did not signify any contamination of oral pathogens and could therefore be used by the patients in the present study (Table 3).

### 3. Clinical evaluation

The IGA scores and patients' viewpoints on efficacy at the end of the study are specified in Table 4. The mean of the MASI scores before treatment and one month after the treatment were  $7.5 \pm 3.99$  and  $5.1 \pm 3.2$ , respectively (Figure 2). There was a significant difference between two groups ( $p=0.001$ ). At the end of the treatment period (i.e. after three months of treatment), the mean of the MASI scores was  $4.6 \pm 3.2$  in the *Cuscuta* receiving group; the difference was meaningfully remarkable in comparison with before-treatment group ( $p < 0.0001$ ). The mean of the MASI scores were not considerably different after three month of treatment compared with those elicited after one months of treatment ( $p=0.6$ ), which confirmed the stability of the treatment.

With the use of the Dermacatch, the mean differences in the melanin content of the lesions and the surrounding normal areas were calculated before treatment, after one month's treatment, and after two months follow-up (Figure 3). Statistically significant differences were found between the groups that received *Cuscuta* before treatment ( $556 \pm 49.6$ ) compared to the one-month group ( $529.2 \pm 43.2$ ) with a  $p \leq 0.002$  (Figure 3). The mean melanin content was  $515.2 \pm 46.11$  at the termination of the study (after three months of treatment); so the meaningful difference was observed in comparison with the before treatment period ( $p \leq 0.0001$ ).

The effect of *Cuscuta* was studied in the treating cyclophosphamide-induced alopecia in mice, which resulted in hair growth of the mice and proliferation of active hair follicles (28).

Table 1. Baseline patient and demographic characteristics

Variables	
Age (mean $\pm$ SD)	41.5 $\pm$ 8.637
Gender n (%)	
Male	4 (5.7%)
Female	66 (94.3%)
Duration of melasma (month), mean $\pm$ SD	50.34 $\pm$ 27.78

Table 2. The quality control assessment of the plant material and the extract.

Assay	Results	Acceptable limit [2]
Total Ash	8.20%	Not more than 10%
Acid insoluble ash	6.35%	Not more than 9%
Alcohol soluble extractive	13.16%	Not less than 9%
Water soluble extractive	16.00%	Not less than 16%
Total phenol (pyrogallol equivalent Per 100g plant material)	462.16 $\pm$ 18.20 mg	-
*Total phenol (pyrogallol equivalent per 100g extract)	5.36 $\pm$ 0.18 g	-

Table 3. The microbial quality control of *Cuscuta chinensis* spray dried extract.

	<i>Staphylococcus aureus</i>	<i>Pseudomonas aeruginosa</i>	<i>Salmonella</i>	<i>Escherichia coli</i>	Total aerobic bacterial count (CFU/g)	Total fungi count (CFU/g)	enterobacteria (bile tolerant) per g/ml of material
<i>C. chinensis</i> extract	-	-	-	-	-	-	$\leq 1$

Table 4. The hyperpigmentation decrease grading in the *Cuscuta* receiving group assessed by the investigators and patients

Hypopigmentation grading	Investigator's Global Assessment	Patient's viewpoint
No effect	2 (3%)	1 (1.5%)
Mild	24 (34%)	17 (25%)
Moderate	43 (61.5%)	38 (54%)
Excellent	1 (1.5%)	14 (19.5%)



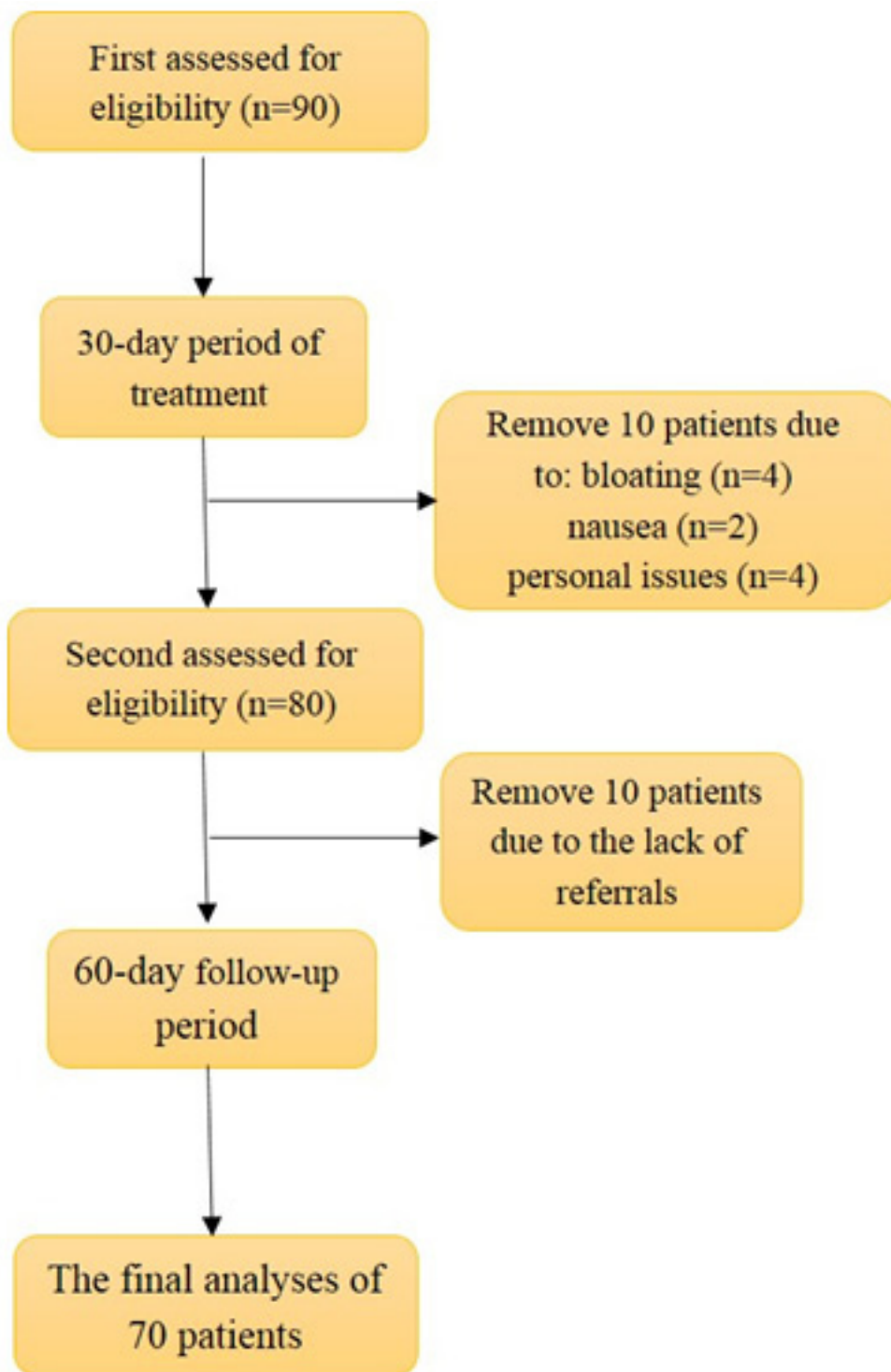
**Figure 1.** The flow diagram of the contributors in the trial based on the CONSORT guidelines

Figure 2: The MASI score before treatment, after one month's treatment, and after three months' follow-up.

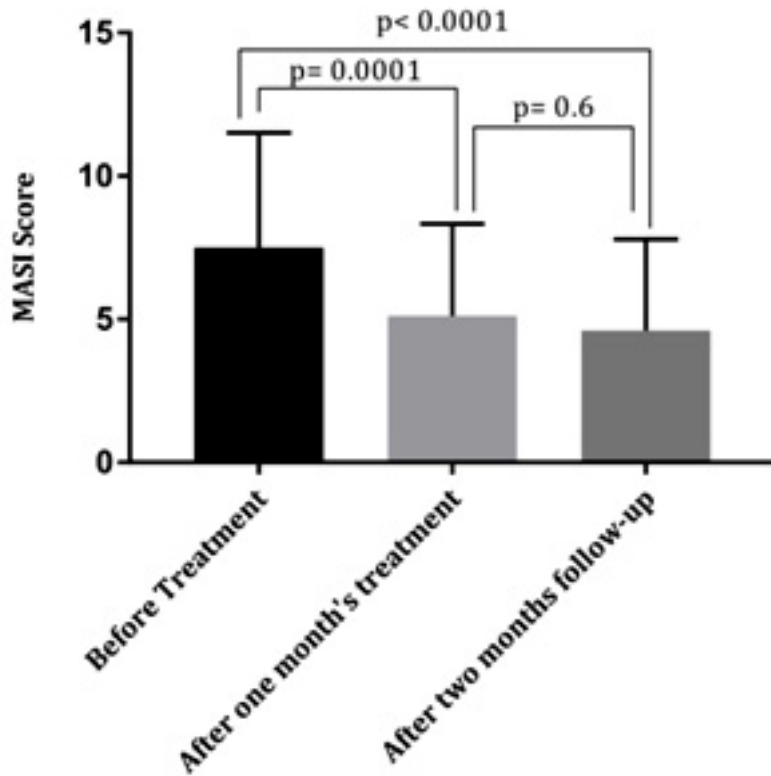
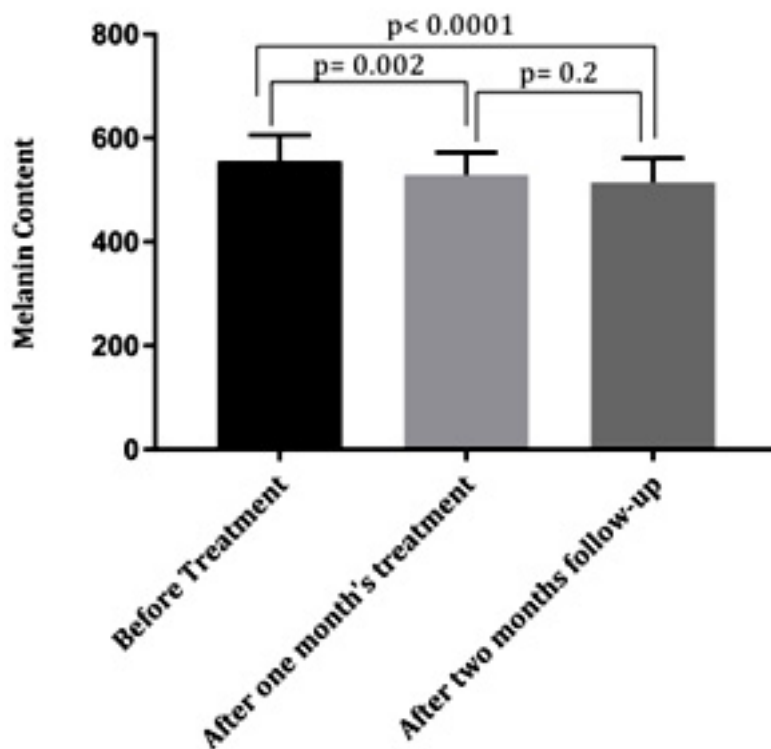


Figure 3: The melanin content of skin using Dermacatch before treatment, after one month's treatment, and after three months' follow-up.



## Discussion

The present study reveals that the consumption of *Cuscuta* extract with milk seemed to ameliorate and decrease the hyperpigmentation in the patients with melasma. Furthermore, the reduction of melasma after two months from consumption of *Cuscuta* extract showed that the *Cuscuta* extract shrinks the melanin synthesis. The study is in accordance with the previously published works as well.

Yeon Jung and colleagues have reported that the aqueous fraction from *Semen Cuscutae* (AFSC) wards off the p38 microphthalmia-associated transcription factor (MAPK), phosphorylation with suppressed cAMP levels and subsequently down-regulates the microphthalmia-associated transcription factor (MITF) and tyrosinase-related protein (TRP) expression. Therefore, their findings revealed that they caused a marked reduction of melanin synthesis and tyrosinase activity in the  $\alpha$ -MSH-stimulated B16F10 cells (27).

The effect of *Cuscuta* was studied in the treating cyclophosphamide-induced alopecia in mice, which resulted in hair growth of the mice and proliferation of active hair follicles (28).

Another study reported that the ethanol extract of *Cuscuta reflexa* Roxb has some potential antihistaminic properties (29). It has been also stated that the consumption of whey, together with field dodder, can target the quintessential pathophysiological facets of the atopic dermatitis by reducing inflammation, aiding immunomodulation, improving the skin lesions and modifying the skin barrier function. This amalgam can also be used as a complementary treatment for the atopic dermatitis with minimum ramifications for reducing the intensity and frequency of attacks (30).

Moreover, the milk protein proffered some advantages in controlling the atopic dermatitis. The milk protein stimulated the osteoblast proliferation and differentiation and is able to reduce the risk of the osteoporosis and osteopenia developments due to the inflammatory nature of the diseases and the long-term consumption of corticosteroids (31-33).

In addition, the treatment of melasma is severe, prolonged and symptomatic (34). It has long been identified that *Cuscuta reflexa* comprises a number of compounds like flavonoids, kaempferol, quercetin, coumarins and flavonoid glycosides (19). Also, since quercetin is one of the derivatives of *Cuscuta*, it can block the intermediate materials involved in the allergies and can act as an inhibitor of the mast cell secretion which is a factor of paramount importance in the pathogenesis of atopic dermatitis attacks (35). The *Cuscuta* aqueous extract can be effective in the prevention and the treatment of various cancers, especially papilloma and skin cancers (36). Other studies also have found that the consumption of some kinds of food as well as the soda-extracting herbal medicines such as *Curainia Sophia*, *fumitory*, *Polypodium vulgare*, *Aftimon* and eating

*terminalia Chebula* can reduce melasma (37). It would not go amiss to state the fact that in some studies, the anti-melanogenic effects of *Cuscuta* have been investigated in vitro on mouse melanoma; so, it can be construed that by suppressing cAMP, they decreased the activity of tyrosinase and the synthesis of melanin (27).

The findings of the current research reveals that the treatment with *Cuscuta* met the requisite primary upshot of diminishing the melanin content of the lesions after 1 and 2 months follow-up. The consumption of *Cuscuta* extract with milk can reduce the synthesis of melanin and ameliorate the elimination of melasma.

It is hoped that the clinical trials such as the present one will be conducted in the near future to pave the way to determine more cogently and accurately the depigmentation efficacy of *Cuscuta* in comparison with other known skin depigmentation compounds in humans.

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# The effect of a diet based on Iranian traditional (Persian) medicine versus a diet based on modern medicine on the birth weight of neonates with the history of asymmetric intrauterine growth restriction: a randomized clinical trial

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## Abstract

**Introduction:** Due to the complications and high incidence rate of Low Birth Weight in Iran, it is one of the most important challenges of obstetrics. In the absence of effective therapeutic approaches, attention to the potential of Iranian medicine along with modern medicine can be helpful.

**Methods:** A randomized, clinical trial was performed on 64 pregnant women with unexplained asymmetric Fetal Growth Restriction. Patients were randomly divided into two intervention groups: traditional diet and modern diet . During the 30 days intervention, every 10 days, food consumption was checked with food recall questionnaire. Finally, birth weight was recorded. Analysis of covariance was used to assess the effect of intervention on birth weight. In all analysis 0.05 was considered as statistical significance level.

**Results:** Although there was no significant difference between energy, macro and micronutrient in-

takes (after controlling magnesium intake) there was a significant statistical difference between the two groups in birth weight. The weight gain in the traditional diet group was better ( $F = 38.61$ ;  $df = 1$ ;  $p \leq 0.001$ ) Similarly, the incidence of LBW in this group was significantly less, statistically ( $P \leq 0.001$ ).

**Conclusion:** The potential of dietary treatment through Iranian traditional (Persian) medicine should be given more attention in helping to solve the challenges of modern medicine as a low-risk and low-cost method.

**Key words:** traditional persian medicine, birth weight neonates, asymmetric intrauterine growth restriction

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## Introduction

Low birth weight (LBW), which refers to weight of a baby under 2500 grams, is one of the most important factors in the mortality and morbidity of neonates [1]. The cause of LBW is either preterm labor, or fetal growth restriction (FGR) or both. It is estimated that the risk of death of a term newborn from 1500 to 1999 is eight times that of infants weight between 2000 and 2999 [2]. Neonates with LBW are more likely than neonates with normal birth weight to have growth disorders and deal with chronic conditions, such as type 2 diabetes, high blood pressure, and other cardiovascular diseases in adolescence [3-5]. According to statistics released by UNICEF in 2000, twenty million infants born weighing less than 2500, account for 15.5% of the total births of 2000 in the world [6]. Given the high incidence of LBW and its complications, this has become a major global health problem [7]. In addition, due to the fact that air pollutants play an important role in the development of LBW and since Tehran is among the most polluted cities in the world, this problem can become a major national challenge [8-10]. The determinant of embryo weighing is its genetic potential, which is affected by maternal, fetal, placental and environmental factors. In order to achieve the maximum growth potential of the fetus, it is important to provide a suitable uterine environment [11]. Prevention of Low birth weight (LBW) is possible by providing a good level of health for mothers before and during the pregnancy particularly adequate nutrition for mothers from pre-pregnancy and during pregnancy [12]. The question is, whether the fetuses with unexplained FGR to be prevented from getting low birth weight through taking pregnancy interventions. According to some meta-analyses, Fetal Growth Restriction (FGR) has occurred when there is low birth weight with unknown cause; there were no interventions such as administration of glucose or amino acids, increased plasma levels, administration of oxygen and low dose aspirin to improve FGR. Even abstaining from smoking and prescribing anti-malarial drugs did not have any effect on the improvement of the condition and normalization of fetal development after the diagnosis of FGR and these factors just a preventive role [13, 14]. Nutritional interventions in mothers without malnutrition also have no effect on FGR and consequently are not effective in preventing the occurrence of LBW in these patients [15-17]. In Iranian traditional (Persian) medicine resources, some foods have been introduced that, regardless of the amount of calories produced, can increase body sizes according to the laws of Iranian medicine [18-21]. In Iranian traditional (Persian) medical clinics these dietary recommendations are recommended to improve the weight gain of fetuses and their mothers [22, 23]. In this study, it was decided to determine the effectiveness of a balanced diet containing recommended foods in the literature of Iranian traditional (Persian) medicine on birth weight of embryos with unexplained asymmetric FGR.

## Methods

### 1. Design

In order to evaluate the efficacy of Iranian (Persian) medicine, a clinical trial was designed with two intervention groups. One group received a diet based on Iranian traditional (Persian) medicine and the second group received a modern medicine regimen. The diet was evaluated on entering the trial and every 10 days by a dietary recall questionnaire, and every five days with telephone call. The birth weight was recorded from the birth information card at the time of delivery.

### 2. Sample

Singleton pregnant women were selected from a prenatal clinic where their embryos were diagnosed FGR with ultrasound during the third trimester of pregnancy, and if any cause was not diagnosed for the FGR; mothers who did not have chronic disease, such as diabetes or hypertension; and if the BMI of the mothers was 18 to 30 in the pre-pregnancy period; the age of mothers was over 18 years of age; and they had normal Doppler or just umbilical artery resistance and did not have significant oligo-hydramnios, after signing the written consent.

The sample size was calculated using G\*power 3.1.9.2 software for analysis of ANCOVA. The errors of the first type (alpha) and the second type (beta) were considered 0.05 and 0.2, respectively. Partial Eta Squared was considered 0.41 as well. Given that in this study, two variables were controlled during the analysis, hence the required sample size was calculated at 32 individuals in each group taking into account 10% of the fall. During the study, 30 patients were in the traditional Iranian diet group and 34 in the classical diet group.

### 3. Instrument

For diagnosis of FGR, Biometric Ultrasound was used and the weight was estimated using Hadlock formula [24]. According to the Callen criteria, the estimated weight under the 10% growth curve was considered equivalent to FGR [25]. The confidence level for the Hadlock formula has been reported between 0.73 and 0.91 [26]. CRL Ultrasound in the first trimester was used to estimate the fetal age.

Recall questionnaire was used to assess calories, macronutrient and micronutrient intake during intervention. The confidence coefficient of the recall questionnaire is calculated to be 0.58 to 0.74, which is particularly true for women in the adult age range [27].

### 4. Procedure

The present study was conducted at Akbarabadi Hospital, Tehran, during 8 months from September 2016 until the end of June 2017. The trial plan was registered with IRCT2017011631984N1 (IRCT2017011631984N1) and received from the Afzalipour Ethics Committee (Kerman, Iran) the Code of Ethics. (IR.KMU.AH.REC.1395.60)

Two groups were designed to evaluate the effectiveness of the diet based on Iranian traditional (Persian) medicine.



Mothers were randomly divided into two groups with four blocks. In order to control the socio-economic factors and the effect of fetal sex, the variables of embryo gender and maternal education level were used to block them to ensure their distribution in two groups. One group received a diet based on Iranian traditional (Persian) medicine and another group based on classical nutrition science. They were required to observe the diet for four weeks. The amount and manner of observation was monitored every four to five days by telephone. Every 10 days a food recall was taken. The results of the three recalls were analyzed with Food Processor program and for comparison of amount of calorie, macronutrients and micronutrients; the mean of three recalls was used. Patients were excluded from the study for any bug in Biophysical Profile or NSD, reluctance to continue cooperation, termination of pregnancy during intervention, failure to comply with at least 80% of the diet or hospitalization for any reason.

### 5. Diet design

In this study, in order to design and modify the pregnant mother's diet, Harris Benedict's formula (proportional to pre-pregnancy weight, height, and age) was used to calculate the amount of energy required for the basal metabolism. The basal energy was multiplied by the activity factor, and the amount of energy needed for pregnant women in the third quarter (452 kcal) were added then the amount of daily needed energy was calculated [28], and finally the amount of energy was divided according to the exchange list among food groups [29].

Food formulations that are supposed to lead to the growth of the body according to the Iranian traditional (Persian) medicine from the five books: Exireazam (in Persian), Quanoon (in Arabic), Moalejateaghili (in Arabic), Sharholasbab (in Arabic) and Tebeakbari (in Persian), were prioritized and selected on the basis of availability, compliance with the current taste of the people, and the lack of risk in pregnancy. The amount of received calorie and macronutrients were the same between the two intervention groups and only the type of foods were different.

### 6. Statistical analysis

The statistical package for social sciences (SPSS) software version 22 was used for the statistical analysis. Variables were assessed for normality based on the Shapiro-Wilk test. Baseline characteristics of the intervention and control groups were compared using independent-test for continuous variables and chi-square test for categorical variables.

Analysis of covariance (ANCOVA) was used to evaluate whether the means of the birth weight were equal across the treatment groups, while statistically the effects of other continuous variables that are not of primary interest (i.e. gestational age and magnesium intake). 0.05 was considered as statistical significance level.

## Result

In the classic diet group (CDG), 44% of the newborns were female and 56% were male. In the traditional diet group (TDG), the number of female and male newborns was equal and there was no statistical difference between two groups in fetal gender.(diagram1)

At the beginning of the study, difference of the mean age of mothers in the two groups was not statistically significant ( $p = 0.2$ ). Also, there were no significant differences in the mean of other variables including maternal weight, pre-pregnancy BMI, gestational age and estimated embryo's weight, but the difference of delivery age was statistically significant between the two groups ( $p = 0.014$ ) (Table 1).

The results of comparing the mean calories and macronutrient intakes and the effective micronutrients in embryo weighing in the two groups showed that there was no significant difference between the two groups during the intervention except in magnesium (Table 2).

Table 3 shows the average birth weight based on the covariance analysis (adjusted according to the gestational age and mean magnesium intake) by the TDG and CDG group. Analysis of covariance shows that the average weight in the TDG group is generally higher than the CDG group (254 g) and the difference of birth weight in the two groups is statistically significant.

Incidence in the TDG and CDG groups was 13.3 and 76.5%, respectively. Regarding the occurrence of LBW, there was a statistically significant difference between the two groups ( $P \leq 0.001$ ).

## Discussion

According to the findings of this study, a one-month diet containing foods resulting in growth in accordance with Iranian medical texts led to an increase in the birth weight of newborns with asymmetric FGR during the third trimester of pregnancy and a reduction in the incidence of LBW, which contradicts the findings of articles that resulted in nutritional interventions not reducing the incidence of LBW in mothers without malnutrition [17, 30]. There are, of course, limited articles that have influenced the type of food regardless of the amount of calories in improving the weight gain of the human embryo [31]. For example, in a study in Japan, the fetuses of mothers who had rice and fresh vegetables in their diet was more heavy in comparison with the fetuses of mothers who had breads mostly in their diet [32].

Based on the results of this study and similar studies on the independent effect of the type of food on the development of the fetus, it may be concluded that food in addition to providing calories and nutrients is also effective on the growth mechanism.

There is widespread evidence of placental abnormalities in FGR and today it is reported as a cause of the occurrence

**Table 1: Comparison of baseline Mean (SD) of variables in CDG and TDG groups**

Group	Gestational age	Delivery date	Maternal weight1	BMI	Age	Fetal weight1
CDG	228.12 ±11.8	264.21±6.13	71.58 ±6.1	23.08± 0.39	27.00 ±5.2	1410±266
TDG	231.57 ±13.1	269.30±9.84	72.28 ±8.6	23.25 ±0.46	28.57 ±4.4	1519± 340.5
P value	0.27	0.014	0.71	0.79	0.20	0.15

Note: CDG: classical diet group; TDG: traditional diet group; BMI: body mass index

**Table 2: The Mean (SD) intake of energy, micro and macronutrients during intervention in the intervention groups**

group	Carbohydrate	Iron	Magnesium	Protein	Energy	Fat	Folate	Cobalamin
CDG	248 ±30.9	11.5 ±2.8	225 ±31.4	58±10	1925 ±128	80 ±15.1	285 ±73.1	2.1± 0.65
TDG	252±30.7	12±3.2	243±36.2	60±8.5	1962±122	83±11.6	293±53.5	2.2±0.76
P value	0.57	0.36	0.033	0.39	0.25	0.48	0.69	0.44

Note: CDG: classical diet group; TDG: traditional diet group

**Table 3: Comparison of Mean (SD) birth weight in the intervention groups after adjustment by the variables of delivery age and magnesium intake**

group	Crude	Adjusted*	N
CDG	2383.24±217.65	2441.41±26.93	34
TDG	2761.00±303.64	2695.06±28.80	30

Note: F =38.61; df =1; p=<0.001

\*Adjusted by the variables of gestational age and magnesium intake

of no reason asymmetric FGR [11]. The mechanism of the probability of the effect of air pollution on the growth of the embryos is also assumed to be the effect of some contaminants on the growth and blood supply of the placenta [33]. It is assumed that any treatment that can improve the weight of these fetuses will be affected by the improvement of the placental blood supply. The active metabolism of the placenta like hormone secretions, nutrient supply to the fetus and waste material disposal makes the proper function and the size of the placenta vital in the health and well-being of the fetus. And when in the presence of proper food and in the absence of secondary causes of FGR, the birth weight is inadequate, it can be concluded that the transfer of food to the fetus is disturbed through the placenta. Considering that according to the Iranian medicine texts, easy digesting nutritious foods with warm and humid quality (ba keyfiat garm va martoob in Persian) are easy to pass through narrow channels and rapidly absorbed [18, 20, 34]. It may be concluded that in the TDG group type of food and observance of the rules of nourishment in the Iranian (Persian) medicine have led to the improvement of blood supply in the placenta and thus the improvement of nutrient delivery from the mother.

The most important limitation of this study was the lack of access to Doppler ultrasounds, which could be helpful in evaluating the effect of diet on placental perfusion.

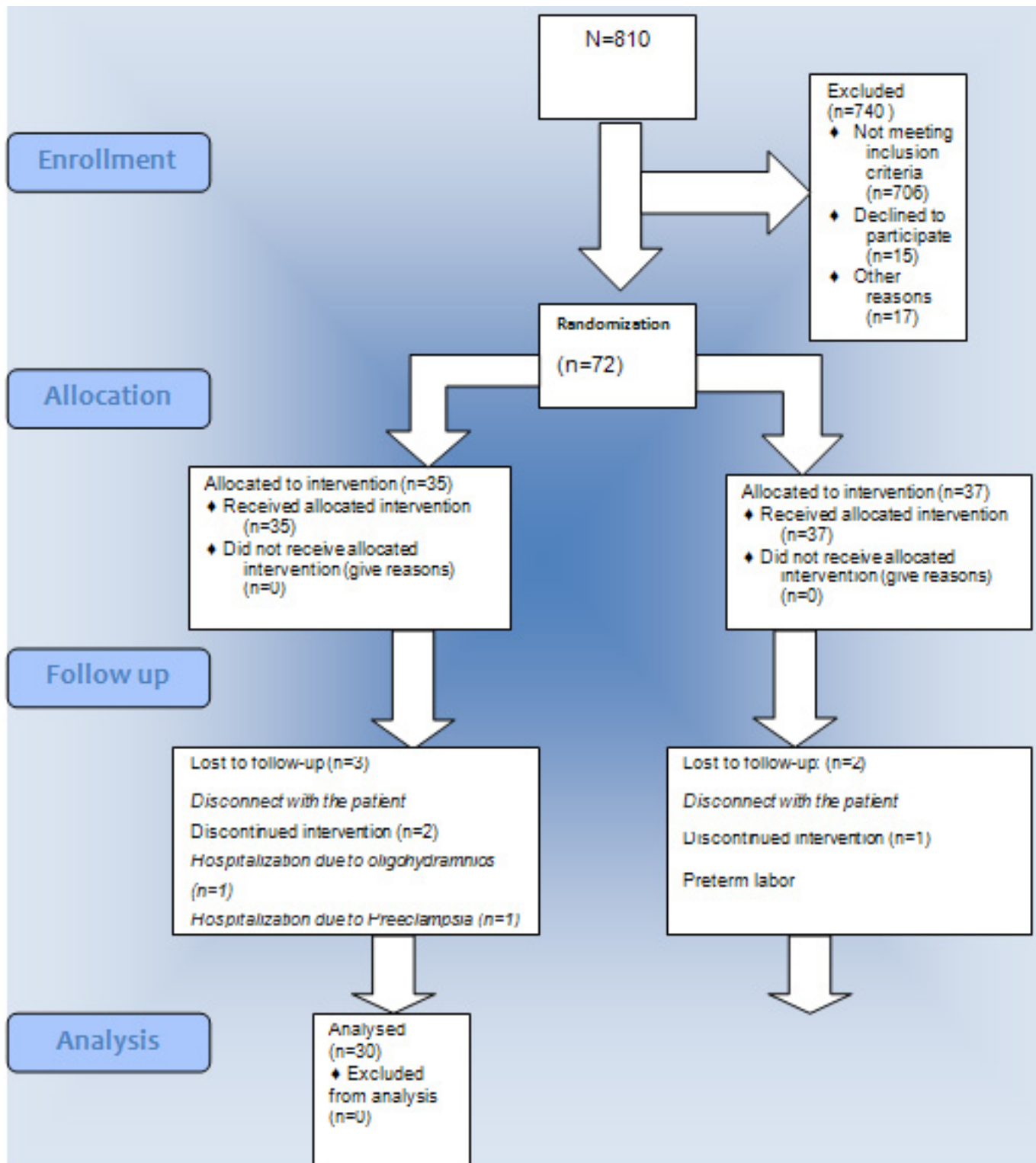
The strong point of this study is that it is the first study on evaluation of the effect of an Iranian (Persian) medicine-based diet on weight gain and birth weight of neonates with FGR.

Finally, reviewers recommend re-evaluation along with a Doppler ultrasound record in order to study the effect of a diet containing warm and humid quality (ba keyfiat garm va martoob in Persian) on embryonic growth.

## Conclusion

Considering the importance of LBW in the health of the community and the growing uncontrollable air pollution in large cities as an accepted factor in the incidence of LBW and FGR, using safe and low-cost methods and the potential of complementary medicine along with modern medicine such as in this study can be helpful. The potential of food therapy through the teachings of Iranian (Persian)

Figure 1:





medicine along with modern medicine should not be forgotten in helping to solve the challenges of modern medicine.

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## Appendices

Figure 2: diet plan based on Persian (Iranian) medicine

Breakfast	<i>Harire badam</i> <sup>*</sup> , bread & honey	Rice-milk, bread & honey	Eggs & bread	Butter & carrot/quince jam	<i>Halim</i> <sup>*</sup> , sugar & cinnamon	Almonds, bread & honey	Milk-rice & honey
Snack I	Milk & dates	Apple juice	Apple juice	Milk and dates	Milk and dates	Milk and honey	Apple juice
Lunch	Mung, rice & lamb	Lamb Kebab & Bread & basil	Rice, chicken kebab & olives	<i>Abgoosht</i> <sup>*</sup> , bread & basil	Rice with quince & prunes stew	Rice, lamb kebab & basil	<i>Abgoosht</i> <sup>*</sup> , bread & basil
Snack II	Sweet Pomegranate	Dried Figs & almonds	Almond and raisins	Sweet Pomegranate	Almond	Apple	Sweet Pomegranate
Dinner	Chicken Kebab & bread	Bread & barley soup	Milk-rice & bread	lamb, carrot, green beans & bread	Bread & barley soup	<i>Nargessi</i> <sup>*</sup> & bread	Chicken kebab & bread
Before sleep	Milk & honey	Milk & honey	Milk & dried figs	Milk	Milk	Milk & dried figs	Milk & honey

Note:

\*Harire Badam in Persian language which is a kind of Pudding containing almond and rice flour

\*Halim in Persian language which is a kind of supp containing lamb and wheat and ate with sugar and cinnamon

\*Abgoosht in Persian language which is a kind of broth containing lamb meat, chick pea, rice, potato spices like cinnamon, turmeric

\*Nargessi in Persian language which is a kind of omelets containing cooked spinach with fried egg

Figure 3: diet plan based on classic medicine.

Breakfast	Walnut, bread, cheese, cucumber, tomato	Bred, egg, tomato, milk	Boiled lentils and bread	Bred, egg, tomato	Walnut, bread, cheese, cucumber, tomato	Walnut, bread, cheese, cucumber, tomato	Bread, butter, jam or honey
Snack I	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt
Lunch	Rice, Stew, Green vegetables	Kebab, Rice, Salad salad	<i>Tahchin</i> <sup>*</sup> , salad	Rice, Stew, yogurt	Rice, Kebab, yogurt	<i>Tahchin</i> , yogurt	Rice, Stew, Salad salad
Snack II	fruit	fruit	fruit	fruit	fruit	fruit	fruit
Dinner	Soup, bread	Soup, bread	Meat cutlet, bread	Meat stew, bread,	Baked beans bread, salad	Bread & chicken	Olivier salad, Tomato, bread
Before sleep	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt	Milk or yogurt

Note:

\*Tahchin: Rice cooked with yogurt, egg, meat and saffron

# The effectiveness of painting treatment on quality of life, hopefulness and happiness of hospitalized veterans

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## Abstract

Given the importance of veterans' psychological issues and the need to apply interventions that are effective in this field, this research is aimed at determination of the efficacy of a group painting therapy on the veterans' quality of life, hopefulness and happiness. The current study is a quasi-experimental research with pre-test, post-test, along with a control group. The statistical society of this study included all the hospitalized veterans in the Bonyad Shahid and Eisargaran Rehabilitation Center of Ahvaz (Foundation of Martyrs and Veterans Affairs). From the society people, 24 subjects were classified into two groups of painting treatment and control via the available method. To collect data, the questionnaires of quality of life, Miller's hope questionnaire, and Oxford's happiness questionnaire were used. The results of the data analysis showed painting therapy has a positive effect on the veterans' quality of life, hopefulness, and happiness. Considering the results, it is recommended that health care centers and the centers that are associated with veterans use this intervention method in relation to veterans.

**Key words:** Painting therapy, quality of life, hopefulness, happiness, veterans

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## Introduction

Veterans are one of the segments of society who need social support the most due to their position. These people have trauma as a results of war and endured their injuries in defending their honour and country during war and it is not only the people themselves, but also their families who are still fighting the consequences (Nabataian, Ghamarani, Zakerian, Mehdizade, 2014). Normally, physical problems lead to disability. But, psychological trauma will remain with the victims a long time after the war. Not only can the injured person be mentally impaired, but the family environment also is at risk (Anisi, 1998). Therefore, especial attention should be given to improve these people's mental characteristics. One way to improve their mental characteristics is to use interventional approaches. Among the treatment methods that are discussed in psychology, art therapy is an approach that has been of interest to psychologists and various studies have shown its effectiveness, (Esmaili, Purabaeian Esfahani and Dabashi (2014), Costello, Perez-Gomez, Perez, Velasco, Perez, Capos, Mayoral, (2010), Lim Lee Man, Jeong, Chonan, Daejeon, (2014)). Art therapy is defined as healing mental disorders through art mediums through which clients can reveal their inner sides to help the therapist to analyze what he has to offer and to take steps to other treatment methods. Art therapy should enable authorities to obtain an adequate understanding of the individual capacities and capabilities (Landgarten 1996, Hashemian and Buhamze, 2005). One of the methods of art therapy is painting therapy. Painting therapy is to provide individuals with opportunities to freely express themselves through colors and lines, feelings, emotions and needs and even their knowledge in a way that they are willing to divulge (Fisher 2003, translated by Hashemian and Buhamza, 2006). Painting therapy causes a better understanding of self, reduces stresses that are caused by contacts between people, increases their self-confidence and improves social capacities and competencies (Ahmadi,



Sam, Hosseini, Sefidchian, 2015). Painting is an artistic experience that is essentially a sort of training and creativity development. As a result of the abstract quality and strong properties of the painting process in the technique of drawing with a pencil in hand, in addition to creating an opportunity for the patients' expressing their temperament, practicing various social roles and creating an opportunity to express their inner conflicts, it helps mental balance and facilitates the interaction between people and comfortable expression of mentality (Ghanbari Hashemabadi, Ebrahimi Nejad, 2011).

Quality of life is one of the most important overall components of health (Mirzamani, 2001). According to the World Health Organization definition of quality of life, is the people's perception of their position in life in terms of culture, value system where they live, goals, expectations, standards and priorities; so it is quite individualistic and is not visible to others and is based on the individuals' understanding of their different aspects of life (Bonomi, Patrick, Bush Nald, 2000). Quality of life is known as an important component of health; so that the results of health services should not only increase life expectancy, but also to improve the quality of life (Kaplan, 2003). Initially, better quality of life was defined as prosperity and life longevity, but now, the quality of life is put against the quantity and it is defined according to broad aspects of health. That is why today's treatments should be focused on modification and changing the quality of life and expanding capabilities and creating life satisfaction for individuals (Ghasemi, Kajbaf, Rabiei, 2011).

Another important component in working with veterans is happiness. Happiness consists of three basic components of positive emotions, life satisfaction and the absence of negative emotions such as depression and anxiety. Moreover, positive relations with others, purposefulness of life and growth of personality, love of others and positive recognition, social commitment, positive mood, sense of control over life, physical health, satisfaction of self and psychological consciousness are key components of happiness. Happiness is one of the most important human needs that majorly influences the formation of personality and mental health (Veengoven, 2008). It is a positive concept for health so that it is vital and important to maintain it (Chohen, 2002). Since the amount of the veterans' happiness may be negatively affected by their condition, it was considered as one of the dependent variables.

Hopefulness may also be negatively affected as a result of veterans' injuries. Hope is one of the substantial foundations of balance and mental strength that characterizes life achievements. Hope is the ability to design paths to desired goals despite obstacles and it is the necessary motivation to pass these paths (Schneider, 2002). One of the effective factors on the rate of life expectancy is the amount of individualistic and social happiness. Hope as a coping strategy is created in various fields of education, sport, mental health, occupation and job and is among the positive structures that are highly effective on mental

and physical health (i.e. optimism and hope); the hope structure has been given increasing interest. Hope is strong when it involves valuable targets that while having challenging obstacles, it is possible to achieve them in a medium term (Kar, 2015).

According to the description above and considering that no studies have been conducted on the effect of painting therapy on veterans, the purpose of this study was to examine the matter of whether painting therapy can contribute to the quality of life, hopefulness and happiness in veterans in a positive way.

## Research method

The research methodology is a testing and field method in which the effectiveness of the independent variable (painting therapy) on dependent variables (quality of life, happiness and life expectancy) is studied. Accordingly, 24 people were selected using available method from the hospitalized veterans in the Rehabilitation Center of the Ahvaz Foundation of Martyrs and Affairs of Veterans and they were placed in two groups of control and painting therapy experiment group. First, ten persons were given a pre-test. Subsequently, the independent variable, the painting therapy was applied to the participants in the study for 10 one hour sessions and then, the changes of dependent variable were measured. The present research is experimental research with pre-test, post-test and control group and the random selection was also used. For statistical analysis, the methods of descriptive statistics and repeated analysis of covariance were used with the software SPSS Ver.18. In this study, the following tools were used to measure the given variables.

**The World Health Organization Quality of Life Questionnaire:** This instrument evaluates four areas of physical health, mental health, social relations and environmental health (each area respectively involves 7, 6, 3, 8 items) with 24 questions and two first questions are not related to any of the areas and generally study the health and quality of life status. Therefore, the questionnaire has a total of 26 questions (Khoushemehri et al., 2012). The validity of this scale is reported as adequate in two methods of convergent validity and on the reliability of the scale, the developers of the WHO scale of quality of life, in their results in 15 international centers of this organization reported Cronbach's alpha coefficient to be between 0.83 – 0.73 for four subscales and the total scale (Nassiri et al., 2006). In the present study, the questionnaire reliability coefficients were obtained in accordance to the method of Cronbach's alpha as 0.78.

**Oxford Happiness Questionnaire:** The Oxford Happiness Questionnaire was developed by Argyle, Martin and Crossland in 1989 to provide a total measure of happiness. The questionnaire was revised by Argyle in 2001. There are several sets of sentences in this questionnaire. The examinee reads each group of sentences. Then, he or she selects the alternative that expresses their feelings during the last week and days that were the best. Each of the

Description of painting therapy sessions	
First, with the explanation that there is no good bad painting as far as art work is concerned and any activity that is done in any way is worthwhile, we began to warm up the group together so that their trust was built for the people to freely express their thoughts, feelings for each other and problems in the group. Then, all kinds of painting tools such as coloring pencils, markers, watercolor and pastel colors were put on the table and the subjects were asked to choose any tool they wishes and to select a topic of interest or importance to draw.	First Session
When beginning the painting and observing the use dark colors, subjects were asked to use the colors such as yellow that affect their minds, cause their psychological relief and reduction of nervous exhaustion and increased their positivism. Orange can be soothing and gives psychological strength to humans and green, in addition to its relieving effect, can cause a balance in emotions and purple reduces the sensitivity to pain in the body. Most of the group members used these colors and it evoked their childhood interests.	Second Session
It was discussed with the group members to be conscious of their different emotions and to express them in their proper time, and they were asked to paint their current feelings using colors and appropriate designs; different feelings and emotions like anger and hatred were observed in the paintings that caused the group to laugh and finally, the skill of anger management was taught.	Third Session
The paintings from one or two members who were relatively less active and painted very simply, with the help of group members and examiners, turned into beautiful paintings and it encouraged them to speak about the paintings.	Fourth Session
Starting with family members, one of subjects drew a black wall between three family members and himself and he was asked to explain about it if he wished; following that, all but one person talked about their relations and aspirations that they had about their family and about their relations with nurses, psychologists and psychiatrists as well.	Fifth Session
Writing a couplet of poetry by one of the members, the group along with painting, began to compose verses and the session environment became poetic.	Sixth Session
To increase the people's focus and attention as issues were raised by the members, painting on glass and pottery was done. It was as the design was selected by the people and stuck behind a glass with their help, its lines were by black marker and colored in carefully, a design was drawn on the pottery and afterwards, members colored its various parts with colors of their interest and created beautiful works.	Seventh, Eighth, Ninth Sessions
The last session began with group work as a large piece of cardboard was given to the members as they were asked to paint on any parts of it that they like, and helping each other to complete paintings created a passion for the members. Taking part in artistic group activities helps people to overcome their fear of direct confrontation with their feelings and to develop trust, mutual respect, and more communication among the group members.	Tenth Session

alternatives on this questionnaire is given a score of 0, 1, 2, 3 respectively. The final score of happiness is achieved via summarizing the 29 scores. Scores range from 0 to 87. The higher the score, the more the happiness is and the lower the score, the lower the happiness is y. In this study, the Oxford Happiness Questionnaire was used to measure happiness. Several studies validated the content validity of the structure of the scale at the same time (Kamari and Sheykholeslami, 2015). In the present study, the questionnaire reliability coefficients were obtained in accord with the method of Cronbach's alpha as 0.75.

**Miller Hopefulness Questionnaire:** The Miller Hopefulness Questionnaire which was developed by Miller and Powers in 1988, is one of the most known and promising tools to measure hope. The initial questionnaire of 40 questions later on raised to 48 questions in subsequent versions. This questionnaire in Likert Scale form is scored from "Strongly disagree" (score 1) to "Strongly agree" (score 5). Each person is given a minimum score of 48 and maximum of 240 and the more the person's score is, the more hopeful they are. The reliability and validity of this instrument has been proved in several studies (Darvishi, 2009). In the present study, the questionnaire reliability coefficients were obtained in accordance with the method of Cronbach's alpha as 0.69.



## Findings

The mean and standard deviation of the participants' age in this study were 49.01 and 3.01 respectively. Also, the youngest participant was 44 years old and the oldest participant was 55. In terms of education, five people were below high school diploma and 19 people had a high school diploma or higher.

**Table 2: Summary results of multivariate analysis of covariance on the mean post-test scores**

Amount of Effect	Level of Meaningfulness	Error degree of freedom	Hypothesis degree of freedom	F	Value	Test
0.83	0.001	17	3	27.69	0.83	Pilaei effect
0.83	0.001	17	3	27.69	0.17	Wilks Lambda
0.83	0.001	17	3	27.69	4.88	Hotling effect
0.83	0.001	17	3	27.69	4.88	Roy's largest root

Contents of Table 2 shows that there is at least one significant difference between the two groups in terms of dependent variables of quality of life, hopefulness, and happiness. To investigate the difference, the one way covariance analysis was conducted on the MANCOVA context of the dependent variables.

**Table 3: ANCOVA test results on mean scores of the post-test research variables**

Eta coefficient	Level of Meaningfulness	F	Mean squares	Degree of freedom	Sum of squares	Dependent variable
0.66	0.001	38.31	1727.37	1	1727.37	Quality of life
0.55	0.001	23.32	5987.47	1	5987.47	Hopefulness
0.69	0.001	43.95	2566.04	1	2566.04	Happiness

The results in Table 3 show that the dependent variable of quality of life is the significant difference between two groups (38.31 =F and 0.001 = P). Similarly, the differences between two groups in variables of hopefulness (23.32=F and 0.001=P) and happiness (43.95=F and 0.001= P) were significant. To evaluate the effect of intervention in the follow up stage, a covariance analysis was used and its results are reflected below in Tables 4 and 5.

**Table 4: Summary results of multivariate analysis of covariance on the follow-up mean scores of the dependent variables.**

Amount of Effect	Level of Meaningfulness	Error degree of freedom	Hypothesis degree of freedom	F	Value	Test
0.52	0.005	17	3	6.17	0.52	Pilaei effect
0.52	0.005	17	3	6.17	0.47	Wilks Lambda
0.52	0.005	17	3	6.17	1.09	Hotling effect
0.52	0.005	17	3	6.17	1.09	Roy's largest root

Table 4 shows that in the follow-up stage, there is at least a significant difference between the two groups in the dependent variables which include quality of life, hopefulness, and happiness. To investigate the difference, a one way covariance analysis was conducted on the MANCOVA context of the dependent variables. The results of the analysis are presented in Table 5.

**Table 5. ANCOVA test results on mean scores of the follow-up research variables**

Eta coefficient	Level of Meaningfulness	F	Mean squares	Degree of freedom	Sum of squares	Dependent variable
0.40	0.002	13.13	778.42	1	778.42	Quality of life
0.02	0.524	0.42	57.30	1	57.30	Hopefulness
0.46	0.001	16.36	855.05	1	855.05	Happiness

Results of Table 5 show that the difference between groups in terms of quality of life and happiness in the follow-up stage, was significant. However, there was no significant difference observed between the experiment group of painting therapy and the control group in terms of the dependent variable in the follow-up stage.



## Conclusion

This study aimed to examine the effectiveness of painting therapy on the veterans' quality of life, hopefulness, and happiness. The results showed that painting therapy caused improvement in all the dependent variables which is consistent with research from Esmaili, Pourabasian Esfahani and Dabashi (1393), and Costello et al (2010). In explaining this hypothesis, it can be stated that painting therapy causes a better understanding of self, reduction of stress that is caused by contacts between people, increase in self-confidence, and finally the improvement of social capabilities and capacities (Ahmadi et al., 2015). The purpose of painting therapy is to provide the individuals with an opportunity to express their feelings, emotions, needs and even their knowledge freely and wishfully through colors and lines (Landgarten, 1981). Painting is an artistic experience that was originally a sort of training and creativity development. As a result, the abstract quality and robust nature of the process of painting is revealed through drawing techniques with a pencil in hand and group painting. In addition to providing an opportunity for the patients to express their creativity, this method helps them to practice different social roles and creates an opportunity for them to express their inner conflicts to reach the principle of mental balance and facilitates the interaction between people and exposing and expressing of their mentalities (Ghanbari Hashemabadi et al., 2011). These are all positive effects of painting therapy in the current research which positively influenced the dependent variables in veterans. Although, it is worth noting that the therapist rather used painting as a "tool" not a "cure" A tool that facilitates the therapeutic relationship, allows a more accurate assessment of resources, and is used typically as an adjunct to other therapies such as family therapy (Joharifard, 2011). Thus, maybe this is the reason why the painting therapy could have significant positive influence over the dependent variables (quality of life, hopefulness, and happiness) which have strong emotional components. On the other hand, the positive effects of the applied intervention itself, might have happened due to its group nature. Psychological research always shows that a group itself has positive therapeutic impacts on people's health. In the case of veterans regarding their limitations, perhaps this group intervention provided them with an opportunity to benefit from the positive effects of being with others and to enjoy their social support. Sometimes, amputation, body deformation and lack of hope and control, and long-term pain, collapses the patients' mental system. Meanwhile, the art therapy reduces these patients' frustration and with making them hopeful, enhances their expression of integrity and helps patients express their feelings and emotions using non-verbal methods. While doing art work, an internal dialogue takes place in which the difficulties and how they are formed, is represented for the individual. Art therapy is confined to no age and the best result can be achieved through art in any age and gender (Mohammadi, 2010). Paintings are able to provide you with new ways of looking at your own world and position, as well as helping you with problems, the solving of which needs flexible thoughts and innovative solutions and also

serving a relief from a period of oppressive issues (Brown, 1992). According to the above mentioned matters, it can be said that painting therapy is a beautiful and effective way to enhance the clients' emotional, communicative, and verbal skills and to discharge and express their failures and worries and to learn constructive ways to strengthen themselves when facing problems. Painting therapy in a group manner, allows people to view their feelings and emotions and reconstruct their problems with a new understanding and also, provides an environment for expressing one's feelings and emotional discharging, and with enhancing adaptability and creating group discussions it blocks increased depression through expanding the group support, and increasing the people's outflow and level of happiness. Ultimately it should be noted that these emotions can bring back the individuals' confidence and hope. According to the results of this study that show the positive effect of painting therapy on the veterans' quality of life, hopefulness, and happiness, using painting therapy as a complementary therapy is recommended for improving the veterans' quality of life, hopefulness and happiness in the centers that involve serving veterans. It is also noteworthy that one of the limitations of the present study was the impossibility of random sampling.

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# The Effectiveness of Cognitive Self-Regulatory Education on Academic Burnout and Cognitive Dissonance and Academic Achievement of Elementary Students

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## Abstract

The main objective of the present study is to investigate the effectiveness of education and cognitive self-regulation on academic burnout and cognitive dissonance and academic performance of elementary school girl students. The research method of this research is based on quasi-experimental type with pre-test-posttest with control group. The statistical population of this research included 40 elementary school girl students of Qom city who were selected through random sampling and were placed as 20 in the control group and 20 in the experimental group where the subjects were trained during 10 sessions in self-regulation strategies with no educational intervention in the control group. The tool of self-regulation educational package was used in ten sessions and another tool used was Brosu et al. (1997) academic burnout and a further tool related to the Cognitive Dissonance Questionnaire of Remon Jonz (2001). Academic performance was also calculated by obtaining the final scores of the students. In order to analyze the data, Covariance test (ANCOVA), homogeneity of variances and Levin test were applied.

The data analysis results indicate that all three research hypotheses, which included: Learning of cognitive self-regulation strategies to reduce the students' academic burnout, learning of cognitive self-regulation strategies to reduce the students' cognitive dissonance and learning of cognitive self-regulation strategies to progress the students' academic performance.

**Key words:** Cognitive self-regulation, Academic burnout, Cognitive dissonance, Academic performance

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## Introduction

Today, self-regulation in educational psychology and teaching has been allocated an important place, because emphasis on this concept introduces a situation in which the learner's role increases in the learning process. The self-regulation approach is a complex process that creates changes in self-regulation skills of strategic knowledge, abilities and motivation of learners (Maris, 2013). It is more than two decades since the role of the self-regulation model has been proven as an educational approach to the development of academic strategies and self-regulation among students with special learning and cognitive problems. (Graham et al., 2013).

In the cognitive self-regulation training program in order for the learner to develop the ability to accept learning responsibility, the four skills of goal determination, self-monitoring, self-assessment, and personal rewards are taught to the students. (Egene and Kaochak, 2012).

From Zimmerman's view (2010), self-regulation learning consists of three main components of cognition, metacognition and motivation, which in our present research, the cognitive training section is our intended subject. Cognition includes the necessary skills for encryption, memorizing and remembering information, and consists of the subsets of simple problem solving strategies, thinking and critical strategies. Self-regulation only occurs when the students are allowed to learn that which they can tradeoff the satisfaction and desirability of their actions and goals. Zimmerman, (2008), from his point of view, the perception of freedom of action in a supportive context to the students and learners can help meet their needs, expectations and demands for clear goals (Graham et al., 2013).

From Bogatere's view (2009), self-regulatory behaviors are controversial, in which the child has the right to choose and decide. Of course, there are few students who are completely self-regulated and those who acquire self-regulation with less effort, are likely to learn more and report higher levels of performance and academic satisfaction, and can also coordinate between their dimensions and cognition, and thus they are not involved in academic burnout.

Cognitive dissonance is an unpleasant feeling that occurs based on a situation when a person has two conflicting thoughts at the same time. This theory states that the individuals have ways to reduce inconsistencies and they do this by changing their beliefs and actions (Festiger, 1975). According to this theory, the cognitions of one person, such as thoughts, attitudes and beliefs, may be coherent, inconsistent or unrelated, then the degree of created inconsistency depends on two factors: (1) The uncoordinated cognitions; (2) The importance of each cognition.

This theory has many applications in various fields, such as politics, education, and learning. To create interest and change the attitudes and behaviors in such a way to coordinate each other and to reduce the degree or importance of each of the heterogeneous elements or to increase the degree or importance of consistency cognition is the way of reducing cognitive dissonance (Behner and Wank, 2005).

In general, students who have passed the cognitive self-regulation education and have been able to take responsibility for their learning and create a special order among their cognitive knowledge, never experience cognitive dissonance, and their academic performance is improved, and with interest and motivation to learn and do not suffer from academic burnout. (Sha'ari Nezhad, 1992, quoted by Farzamikhah, 2014).

Both cognitive self-regulation and cognitive dissonance parameter have a close relationship with another variable, academic burnout. As Miller (2006) states, the cognitive self-regulation is an integral part of learning. He claims that there is a relationship between cognitive self-regulation with learning and academic performance.

Perky (1990) states that cognitive coordination among individuals will not only be effective in the field of education, but also this cognitive coordination can assist the person towards growth and development and prevent academic burnout. Cognitive dissonance can create a kind of burnout which covers various aspects of life, including the field of education and which leads to academic burnout (Quoted by Farzamikhah, 2014).

Academic burnout is the same feeling of tiredness because of the demands and requirements of education and having a sentimental feeling without interest toward the school assignments and a feeling of disability as a student. Academic burnout includes the three components of emotional exhaustion, pessimism, and lack of efficiency. (Sha'ari Nezhad, 1992, quoted by Farzamikhah, 2014).

With regard to the importance of cognitive self-regulation and its impact on academic performance, our purpose in the present study is to teach cognitive self-regulation strategies to students who can improve their academic performance by using it and reduce their cognitive dissonance and prevent academic burnout.

At the end of the research, we answer this question as to whether cognitive self-regulation education of the students can achieve the mentioned results, which includes reduction of cognitive dissonance and improvement of the curriculum performance quality.

## Research Literature

### Cognitive Self-Regulation Strategies:

The different definitions of self-regulation are provided. Zimmerman (2002) describes self-regulation learning based on spontaneous thoughts, emotions, and behaviors that individuals use to achieve their goals. Zimmerman (2002) states that "The self-regulation learner is an active participant in their own learning; it means that in terms of motivation, metacognition, and behavior the learning process has their active involvement."

With regard to the motivational dimension, the self-regulated learner is assured of their own ability, he/she is independent and curious, and in other words, has self-esteem and more inner interest. With respect to cognitive processes, the self-regulated learner during the learning and when doing assignment planning, is involved in self-assessment targeting. In terms of behavioral processes, the self-regulated individual organizes to optimize the learning, and creates suitable environments (Zimmerman, 2002).

Rohuti (2000) defines self-regulation learning as "Voluntary control of learning and factors affecting on learner's learning motivation" (Quoted by Azizi Abarghoei, 2010). According to theories of will, motivational factors are distinct from voluntary factors (Corno, Cool, 2007; Quoted from Taheri, 2014).

The academic self-regulation strategies mean that the learners organize their learning in terms of behavioral and motivational meta-cognitive beliefs (Namdarpour, 2011, quoted by Farahani, 2013).

### Academic Burnout:

Academic burnout can be described as a chronic stress response in students who initially have been involved with the educational requirements. This response is due to a difference between students and others' expectations for their academic success in the field of education (Salmela and Aro, et al. 2009).

Yang (2005) defines academic burnout as "Students in the learning process because of the stress of the academic period, or due to a course of study or other psychological components that cause emotional exhaustion modes, a tendency to disregard individual identities (Personality deterioration) and also shows the feeling of low personal development" (Quoted by Jalilian, 2012).

### Academic Performance:

Academic performance and its effective factors are one of the pivotal and fundamental variables in education. In fact, it can be said that academic performance of students has been allocated an important contribution of the existing research in the field of educational psychology. There are different definitions of academic performance. Atkinson defines academic performance as an acquired ability or individual acquisition. (Quoted by Jafar Tabatabai et al., 2012). It can be said that academic performance is as

follows: the success in passing of different lessons by the students or learners and showing the proper performance in society or their lives based on the learned =material.

### Cognitive Dissonance:

The theory of cognitive dissonance was presented by Festinger in 1957. This theory is the most popular cognitive consistency pattern and most effective theory in social psychology. The starting point for this theory for Festinger was the situation in which we are usually in = does not follow according to our attitudes (Behner and Vaank2002, quoted by Safari Nia 2010).

As the theory of cognitive dissonance was presented by Festinger in 1957, it begins with this assumption that different cognitions (Knowledge and information elements) can be related to each other. If two cognitions are related to each other, they are either coordinated or dissonant. Two cognitions are coordinated when one of them is logically deducible from the other, and when they are dissonant with each other = it can be deduced from the other (Zandi, 2010).

## Research Background

The results of Moghadasi's research (2015), about the relationship between target orientation and perceived social support with academic burnout of the students showed that there is a relationship between target orientation components and perceived social support resources with academic burnout. The other findings showed that the target of dominant-avoidance, the target of dominant-orientation, and perceived family-based social support were able to predict academic burnout, as well as the obtained results indicate the difference between male and female students in the combination of target orientation, perceived social support and academic burnout.

Nekoei (2015) investigated the relationship between creativity, motivational beliefs, self-regulatory learning strategies with the academic achievement of male students. The results showed that self-regulation was effective in their academic achievement.

Tahmasebi (2015) investigated the relationship between the impact of metacognitive strategies on the motivation of progress and the academic burnout of elementary school girl students where the results showed that there is no significant difference between the two groups of control and experiment in terms of the motivation of academic achievement. The analysis results also showed that the metacognitive strategies of learning is affected on the students' academic burnout and caused reduction of academic burnout in the experimental group.

Newsome, Day and Catano (2014) investigated the relationship between emotional intelligence, cognitive ability, cognitive self-regulation and personality traits with academic achievement. The research results showed that both cognitive ability and some personality traits such as extraversion and self-control, as well as cognitive self-regulation had a significant relationship with

academic achievement, but emotional intelligence had no relationship with academic achievement, so it can be said that emotional intelligence is not identical in the intelligent and normal students.

Nouta et al., (2013) in their research were paid to investigate the relationship between the use of self-regulation strategies with academic achievement and academic acceleration in their subsequent tests. Their sample was the students of the last years of high school in Italy.

In this research, a self-regulation interview program was used which was focused on cognition, motivation and behavioral strategies that are applied in the course of learning in the class and non-class environment.

The results showed that these strategies in Italian language courses, mathematics and technology had a significant impact on learning these lessons; other classes' average and university exams. Motivational self-regulation strategies were a significant predictor of success in the final examinations for high school diplomas.

## Research Methodology

The method of this research is based on quasi-experimental type with a pretest- posttest plan with control group. The statistical population of this research included 40 people of elementary school girl students of Qom city who were selected through random sampling and 20 people were placed in the control group and 20 people in the experimental group where the subjects during 10 sessions were trained in self-regulation strategies while there was no educational intervention on the control group. They = tools used were a self-regulation educational package in ten sessions and the other was Brosu et al's (1997) academic burnout and another tool related to the Cognitive Dissonance Questionnaire of Remon Jonz (2001). The academic performance was also calculated by obtaining the final scores of students, and the validity of questionnaires was calculated by experts and reliability of the questionnaires were approved by Cronbach's alpha coefficient equal to 0.78, 0.81 and 0.82, respectively.

### Self-regulation group therapy performance method:

In the 10 sessions of 2 hours, the following cases were taught to the control group students:

**Session 1: (Subject of the Session: Self-assessment):** It is expected that the learners receive an accurate understanding of the meaning and concept of self-assessment and in addition to recognizing their strengths and weaknesses by focusing and calculating on their past behaviors and comparing them with expected levels and take steps could be taken to improve their performance.

### Session 2: (Subject of the Session: Targeting and Planning):

The learners' familiarity with a good target (Clear, apparent, use of time, measurable in the form of positive sentences). Increase the probability of reaching the target through

adjusting of activities, focusing on the priority targets in the priority and avoiding diversions from that route.

**Session 3: (Subject of the Session: Organizing and transferring information):** Familiarity with increasing the efficiency of daily work, prioritizing according to necessity, planning in a scientific way.

**Session 4: (Subject of the Session: Searching for information and recording and taking notes):** The learners familiarity with different ways of summarizing, taking notes and encoding.

**Session 5: (Subject of the Session: Self-outcome):** The learners' familiarity with how to reward and punish their successes and failures and to create mental imagery.

**Session 6: (Subject of the Session: Environmental management):** The learners' familiarity with how to prevent irregularities and disorganization, analysis of their current situation, and also dominating on the external environment and available resources.

**Session 7: (Subject of the Session: Self-efficacy):** Increasing learners' ability in order to meet challenging issues, commitment to their activities and interests, and overcoming the feeling of hopelessness and disappointment.

**Session 8: (Subject of the Session: Correct ways of studying):** The learners' familiarity with the scientific methods of studying and quantitative and qualitative enhancement of study efficiency.

**Session 9: (Subject of the Session: Assistance from people (Peers, teachers and adults):** The learners' familiarity with the use of synergistic methods that help their academic achievement.

**Session 10: (Subject of the Session: Time Management):** The learners' familiarity with prioritization of life, improving the time and duration of exploitation of time, understanding the value of time.

In order to analyze the data, covariance test (ANCOVA), homogeneity of variances and Levin test were used.

## Findings

**First hypothesis:** The cognitive self-regulation strategies education causes reduction of the students' academic burnout.

In order to test the first hypothesis, covariance test (ANCOVA) was used, and its results are presented in Table 1.

Based on the obtained data from Table (1), with the control of the effect of pre-test, a significant effect was found between the group subjects factor at the level of 0.01 ( $P = 0.01$ ,  $F(1,41) = 32.6$ ), so that the information in Tables 2-3 also show, the "Academic burnout" scores of subjects in experimental groups after intervention have significantly decreased, so the null hypothesis at the level of 0.01 is rejected and with 99% confidence level, can be assured that "Cognitive self-regulation strategies education" has



**Table 1: Summary of ANCOVA test for intergroup factor to investigate the impact of cognitive self-regulation strategies on reducing academic burnout**

Source of Changes	Square Sum	Freedom degree	Square mean	F ratio	Significance level	Effect size
Covariance	3160.6	1	3160.6			
Group	298.4	1	298.4	345.5	0.01	0.903
Error	338.4	37	9.1	32.6	0.01	0.469
Total	4123.1	40				

**Table 2: Summary of ANCOVA test for intergroup factor to investigate the impact of cognitive self-regulation strategies on reducing cognitive dissonance**

Source of Changes	Square Sum	Freedom degree	Square mean	F ratio	Significance level	Effect size
Covariance	4250.1	1	4250.1			
Group	91.4	1	91.4	378.6	0.01	0.911
Error	415.4	37	8.1	8.1	0.01	0.180
Total	60064	40				

**Table 3: Summary of ANCOVA test for intergroup factor to investigate the impact of cognitive self-regulation strategies on academic achievement**

Source of Changes	Square Sum	Freedom degree	Square mean	F ratio	Significance level	Effect size
Covariance	198.4	1	198.4			
Group	21.4	1	21.4	68.7	0.01	0.752
Error	106.9	37	2.9	7.4	0.01	0.167
Total	10275	40				

reduced the "Job burnout" of Qom elementary girl students. The effect size also indicates that about 46.9% of the reduction of "Academic burnout" of subjects is explainable by groups.

**Second hypothesis:** The cognitive self-regulation strategies education causes= reduction of the students' cognitive dissonance.

The research second hypothesis was also tested by covariance test (ANCOVA). Its results are presented in Table 2.

The results of Table 2 show that with the control of the effect of pre-test, the F-value related to groups at the level of 0.01,  $F(1,37) = 8.1$  is significant. This result means that there is a significant difference in terms of "Cognitive Dissonance" between the groups.

The comparison of Tables 1-4 also suggests that the mean of "Cognitive dissonance" of subjects who were under cognitive self-regulation strategies education, has significantly been reduced, so that the null hypothesis at the level of 0.01 is rejected and with 99% confidence level, it can be assured that "Cognitive self-regulation strategies education" has reduced the "Job burnout" of Qom elementary school students. The effect size also indicates that about approximately 18% of the variance

of "Cognitive dissonance" of subjects is dependent on "Cognitive self-regulation strategies education".

**Third hypothesis:** The cognitive self-regulation strategies education causes improvement of the students' cognitive achievement performance.

The research third hypothesis was also tested by covariance test (ANCOVA) model. Its results are presented in Table 3.

Based on the obtained data from Table 3, with the control of the effect of pre-test, a significant effect was found between the group subjects factor at the level of 0.01 ( $P = 0.01$ ,  $F(1, 37) = 7.4$ ) so that there is a significant difference between experimental and control groups in terms of "Academic achievement". It can be concluded that "Cognitive self-regulation strategies education" is effective in Academic performance achievement, so that the amount of this effectiveness has been estimated as equal to 16.7 percent.

## Results

The main objective of the present study was to investigate the effectiveness of education and cognitive self-regulation on academic burnout and cognitive dissonance and academic performance of elementary school girl

students. The data analysis using covariance analysis showed that the cognitive self-regulation strategies education causes reduction in the students' academic burnout, the cognitive self-regulation strategies education causes reduction in the students' cognitive dissonance, and also the cognitive self-regulation strategies education causes improvement in students' academic performance. The results of this study along with the research results of Shafiei Sorek and Badri Gargari (2011) showed that there is a relationship between self-regulation learning and academic burnout and self-regulation can reduce academic burnout. This hypothesis is consistent with the research results of Abarghoei(2010) and the results of Carior (2003) which indicated that the students had better academic achievement after becoming familiar with self-regulatory strategies.

The results of this study along with the results of Panahandeh (2013) which was about the relationship between cognitive self-regulation and the academic burnout of girl students in human and medical sciences showed that the higher the use of cognitive self-regulation during learning to be increased, the academic burnout is reduced and academic performance is better and more consistent.

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# Effects of Applying Repeated Readings Method on Reading Fluency and Passage Comprehension of Slow Learners

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## Abstract

Children who are slow learners face difficulties with their reading fluency and passage comprehension. The purpose of this study is to investigate the importance of reading repetition for slow learners which reflects positively on their reading fluency and passage comprehension. For this purpose, twenty slow learners, whose ages ranged from 5.5 to 8.5 years and who are studying in grades 1, 2 and 3, were recruited from two private schools in Lebanon. Those students were divided equally into two groups, a control and an experimental group. The measuring instrument used in this study was the Woodcock-Johnson III Test of Achievement reading fluency and passage comprehension sections. A pretest was done on all 20 students during the first trimester of the 2016-17 school year. Then a repeated English readings program was applied for two trimesters on the experimental group. Descriptive statistics and independent samples t-test were used to analyze the findings. Results of this study showed significant statistical differences to the benefit of the experimental group over the control group regarding reading fluency and passage comprehension.

**Key words:** slow learners, reading fluency, passage comprehension, Woodcock-Johnson III test of achievement.

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## Introduction

Although the definition of the slow learner varies, characteristics of slow learning children are quite similar. Slow learning children have difficulty in literacy, especially in reading (Borah, 2013), and are slightly slower when compared to their peers in the same age group (Sugapriya and Ramachandran, 2011; Pujar, 2006). Slow learners have an attainment level in all academic subjects that is equal to their actual intellectual ability. In other words, their attainment level in all academic subjects is as low as their IQ level. Because of their below average IQ, they are often being called intellectually disabled. Nevertheless, they may be good at other activities that do not involve academic learning, such as sports (Krishnakumar et al., 2006).

Fluency is viewed as an important goal of reading instruction in an ever increasing trend. The routes to fluency development seem reasonably clear. One route is to give students extensive practice reading books that are at their zone of reading development. By encountering high-frequency, common words in a variety of meaningful contexts, students acquire the ability to recognize the words automatically. The other route for building fluency is to use the many varieties of repeated readings (Rasinski et al., 2012).

Applying basic skills automatically is usually achieved through practice. In reading, decoding is a basic skill, one that is absolutely essential to success. Not only should students be able to decode words and phrases with a high degree of accuracy, they must also be able to decode them automatically with minimal attention or effort. Practice through repeated readings helps them get there (Rasinski, 2003). Readers transitioning into fluency learn to intone whole phrases at a time; they do not read haltingly or word by word, as novice readers do. And they do not have to point to the words. When reading text at their own instructional level, they slide along at an even pace because their sight vocabulary is large and they possess a number of strategies that help to keep them going. Unlike the word-by-word finger point readers, fluent readers barely glance at most common words and, according to eye movement detected in relevant research, they even skip highly predictable words (Cole, 2004).

When humans become fluent at a task, they can devote their attention to other related tasks. In reading, the most significant related task is comprehension (Rasinski, 2003). Reading comprehension is the act of meaning-making while reading. While this seems simple enough, understanding how readers make meaning is not so simple. Reading teachers often refer to this meaning-making as active comprehension. Reading researchers have developed various models of comprehension to help teachers not only understand the comprehension process, but also to help identify effective models of comprehension instructions. Comprehension, though not static, is the result of comprehending. During the initial phase of retelling, protocol readers recall as much about the text as they can without specific prompting. This is different from many classroom procedures where readers interact in directed reader response either through discussion or answering questions, or through specific written responses (Altwerger et al., 2007).

Advocates of high standards and expectations usually believe that gaps in reading achievement can be eliminated with good teaching, but slow learners need a specially designed reading curriculum. Functioning generally on a higher level than students with mental retardation, but on a lower level than average students, are a large number of students known as slow learners. They usually form around 14% of all students. Slow learners tend to be concrete in their thinking, need help with strategies and organization, and are eager for success. They need much guidance from the teacher to develop sequential skills in word recognition and in comprehension. By listening to stories read aloud and being engaged in successful reading experiences, the slow learner might well make reading a lifetime endeavor (Marlow, 2012).

Mason and Hagaman (2012) stressed on the importance of reading comprehension intervention research for students with learning disabilities (LD). They added that reading comprehension is considered one of the most critical skills needed for success in school and the workplace in a modern society. The authors highlighted that many students with LD have difficulties in understanding what has been read and require explicit reading comprehension instruction to develop this valuable skill.

Repeated readings were devised by Samuels (1979). In repeated readings, readers read a simplified text repeatedly to help automatize word recognition, leaving more cognitive resources for higher order comprehension processes. Teachers use this reading strategy to help students who have less experience with reading fluently to develop fluency and comprehension and gain confidence in processing words (Kuhn and Stahl, 2003). This current study aims to investigate if repeated readings can help slow learners in grades 1, 2 and 3 to improve their reading fluency and passage comprehension.

## Literature review

In a study on repeated readings effects, Yeganeh (2013) investigated how repeated readings can affect reading fluency and comprehension among English as Foreign Language (EFL) students. This study involved an 8-week quasi-experiment carried out on monolingual and bilingual university level Iranian students of English using improved reading comprehension testing procedures. Results suggested that the experimental group (ten monolingual and ten bilingual students) who were exposed to repeated readings, gained in reading fluency and comprehension significantly more than the control group ( $n = 20$ ). At the same time, comprehension performance of bilingual students was significantly higher than that of monolingual students, although no significant differences in fluency have been found among monolingual and bilingual students.

Gorsuch and Taguchi (2008) studied the effects of repeated readings on developing reading fluency and reading comprehension among EFL students in Vietnam. The authors indicated that reading in a foreign or second language is often a laborious process, often caused, among other things, by underdeveloped word recognition skills. The authors added that developing fluency in foreign language reading has become an important pedagogical issue and one major component of reading fluency is fast and accurate word recognition. Their methodology involved an 11-week repeated readings quasi-experiment carried out on university-level Vietnamese learners of English using improved reading comprehension testing procedures. Results of this study suggested that the experimental group ( $n = 24$ ) gained in reading fluency and comprehended significantly more than the control group ( $n = 26$ ). The authors concluded that their results have implications for future uses of repeated readings in foreign language context, future reading comprehension test design, and the need for measurement of working memory during short- and long-term use of repeated readings.

Most of the conducted research concentrated on students without any disabilities or difficulties in learning. The current research study aims to fill in this gap. It aims to investigate the effects, if any, of repeated readings on improving the reading fluency and passage comprehension of children who are slow learners.

## Methodology

A quantitative approach was used in this study where 20 slow learners, whose ages ranged from 5.5 to 8.5 years and studying in grades 1, 2 or 3, were recruited from two private schools in Lebanon. Those students were divided equally into two groups, a control and an experimental group. The experimental group experienced three 30-minute specially tailored repeated readings sessions per week over a period of two trimesters. In particular, each student in the experimental group was given a story based on his/her predetermined reading level. Then hard words were selected and explained. After that, the student

listened to the passage and was asked to repeat it as many times as necessary till he/she reached the required fluency level. If two students were almost of the same level of reading, they were asked to attend the same session and switch roles while reading. This repeated readings practice is similar to what is reported in the literature (Kuhn and Stahl, 2003). The control group went on with their regular curriculum activities over these trimesters.

The measuring instrument used in this study was the Woodcock-Johnson III Test of Achievement reading fluency and passage comprehension sections. A pretest was done on all 20 students during the first trimester of 2016-17 school year. Then an English repeated readings program was applied for two trimesters on the experimental group. Descriptive statistics and independent samples t-test were used to analyze the findings.

## Results

Reading fluency results of all students in the control group are given in Figure 1 while those of students in the experimental group are given in Figure 2. Descriptive statistics of performance of both groups in reading fluency are presented in Table 1.

Then improvement in reading fluency test scores of all students within the control group were compared to those of the experimental group using an unpaired single-sided t-test. The test showed that the experimental group showed significantly better performance in reading fluency test score than the control group ( $p=0.00$ ).

To calculate the effect size of the t-test, Cohen's d value was used. This value is calculated using the formula  $Cohen's\ d = (M2 - M1) / SD_{pooled}$  where M2 is the mean improvement value of experimental group and M1 is the mean improvement value of control group.  $SD_{pooled}$  was calculated using the formula  $SD_{pooled} = \sqrt{((SD1^2 + SD2^2) / 2)}$ .  $SD_{pooled}$  in this case is found to be equal to 0.75 and Cohen's d value to be equal to 3.99. This reflects that repeated readings lead to significant improvement in reading fluency of students with learning difficulties.

The same procedure was then applied for passage comprehension and the results of all students in the control group are given in Figure 3 (page 236) while those of students in the experimental group are given in Figure 4. Descriptive statistics of performance of both groups in reading fluency are presented in Table 2.

Like reading fluency test, improvements in passage comprehension test scores of all students within the control group were compared to those of the experimental group using an unpaired single-sided t-test. The test result revealed that the experimental group showed significantly better performance in passage comprehension test score than the control group ( $p=0.00$ ).

To calculate the effect size for t-test, Cohen's d value was used again in a similar way to reading fluency test results.

$SD_{pooled}$  in passage comprehension case is found to be equal to 1 (one) and Cohen's d value to be equal to 4.36. This again reflects that repeated readings lead to significant improvement in passage comprehension of students with learning difficulties.

## Conclusion

Repeated readings intervention was applied on a group of ten (grades 1-2-3) students with learning difficulties who formed the experimental group over two trimesters. It was not applied on another ten students of the same conditions and levels who formed the control group. Results clearly show that repeated readings intervention did help slow learners in developing their reading fluency and passage comprehension skills based on Woodcock-Johnson III Test of Achievement. It is recommended, therefore, that school authorities embed repeated readings within their curriculum for slow learners to help them in improving their reading fluency and passage comprehension skills. It is also recommended here to conduct more research in this area to explore other ways that would help in teaching slow learners.

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Figure 1: Reading fluency results of control group.

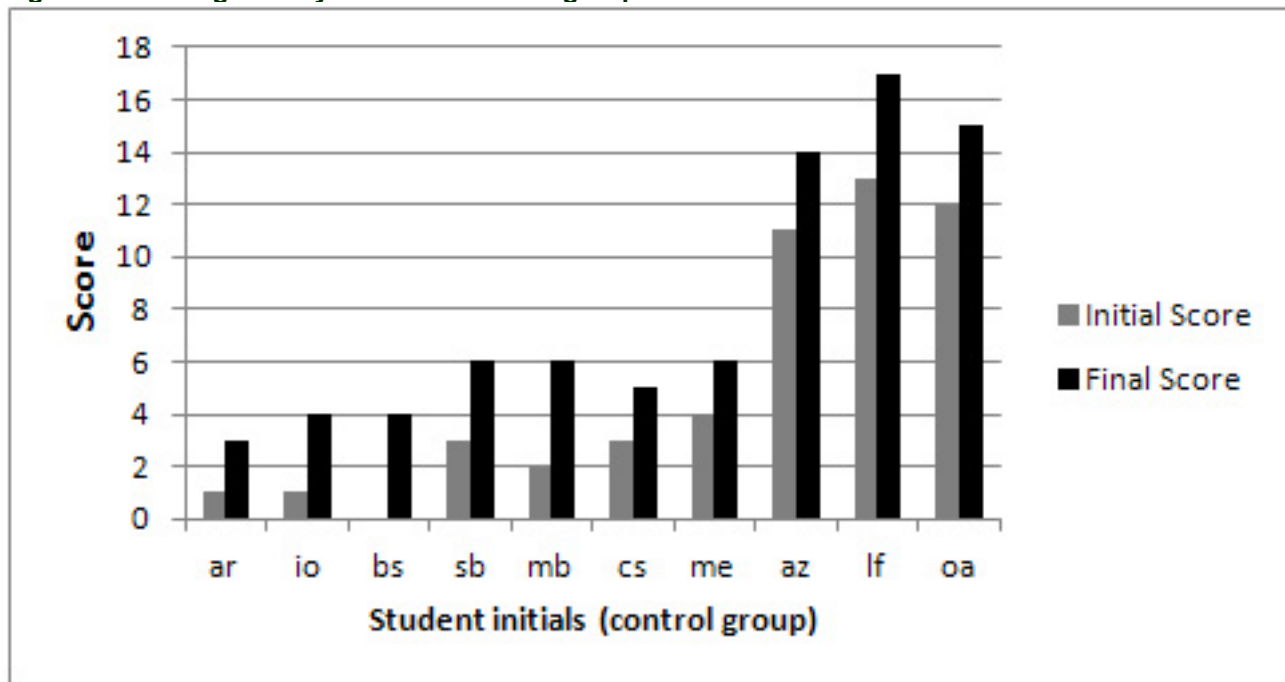


Figure 2: Reading fluency results of experimental group.

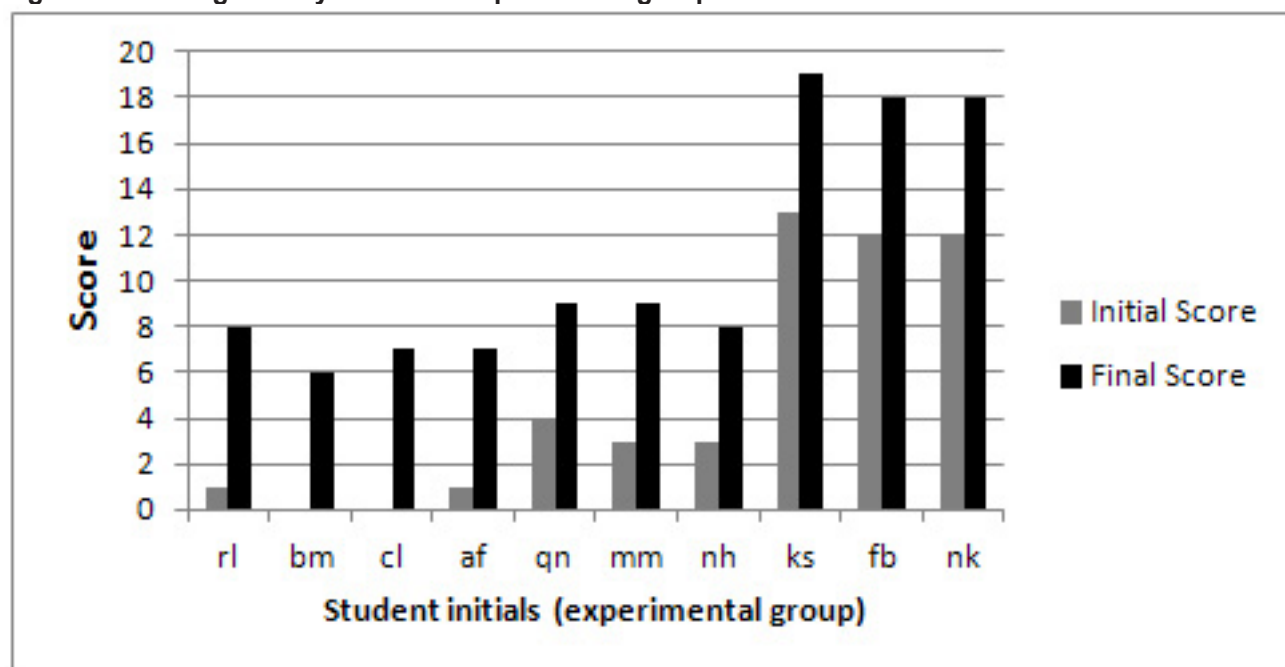


Table 1: Descriptive statistics of reading fluency test

	Beg. of year average	St dev	End of year average	St dev	Average improvement	St dev
Control Group	5	5	8	5.2	3	0.8
Experimental Group	4.9	5.3	10.9	5.2	6	0.7

Table 2: Descriptive statistics of passage comprehension test.

	Beg. of year average	St dev	End of year average	St dev	Average improvement	St dev
Control Group	9.2	5.1	12.8	4.2	3.6	1.3
Experimental Group	9.2	4.2	17.2	4.2	8	0.7

Figure 3: Passage comprehension results of control group.

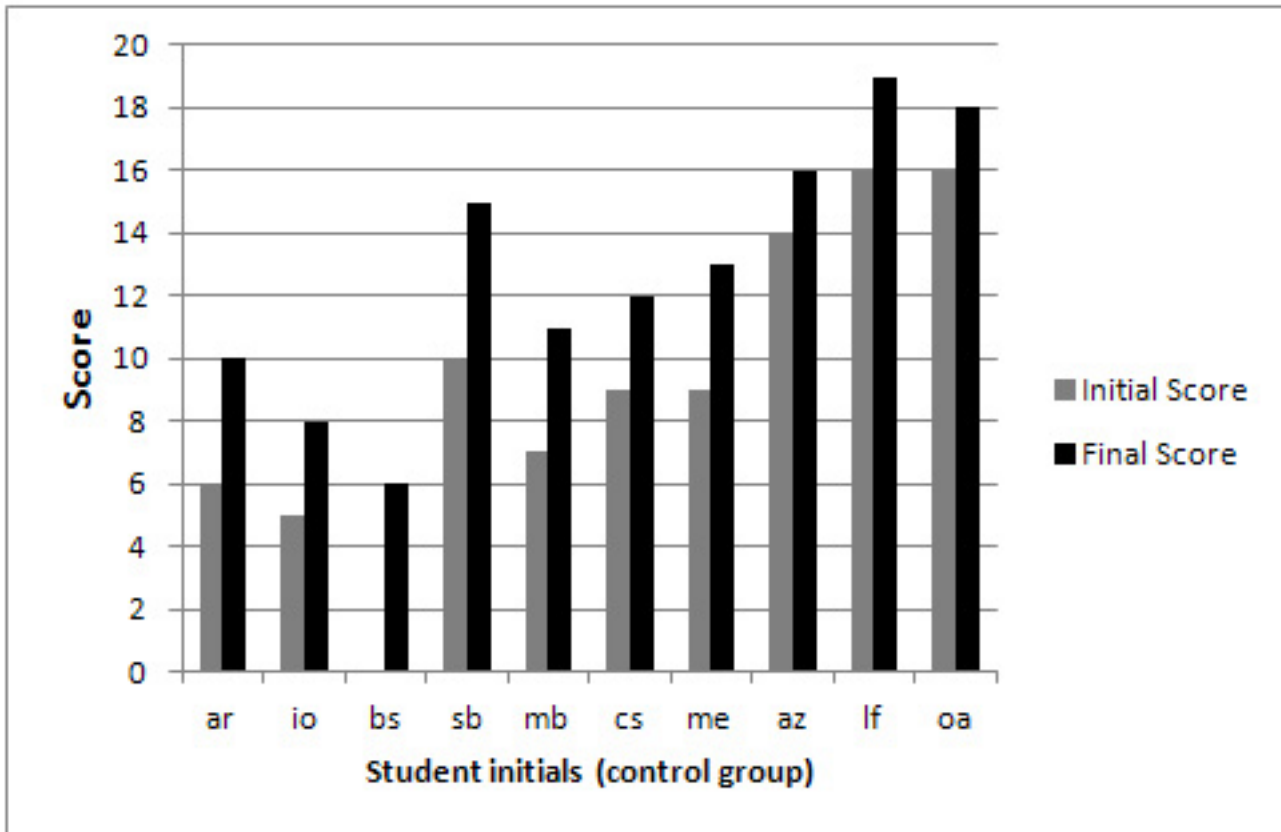
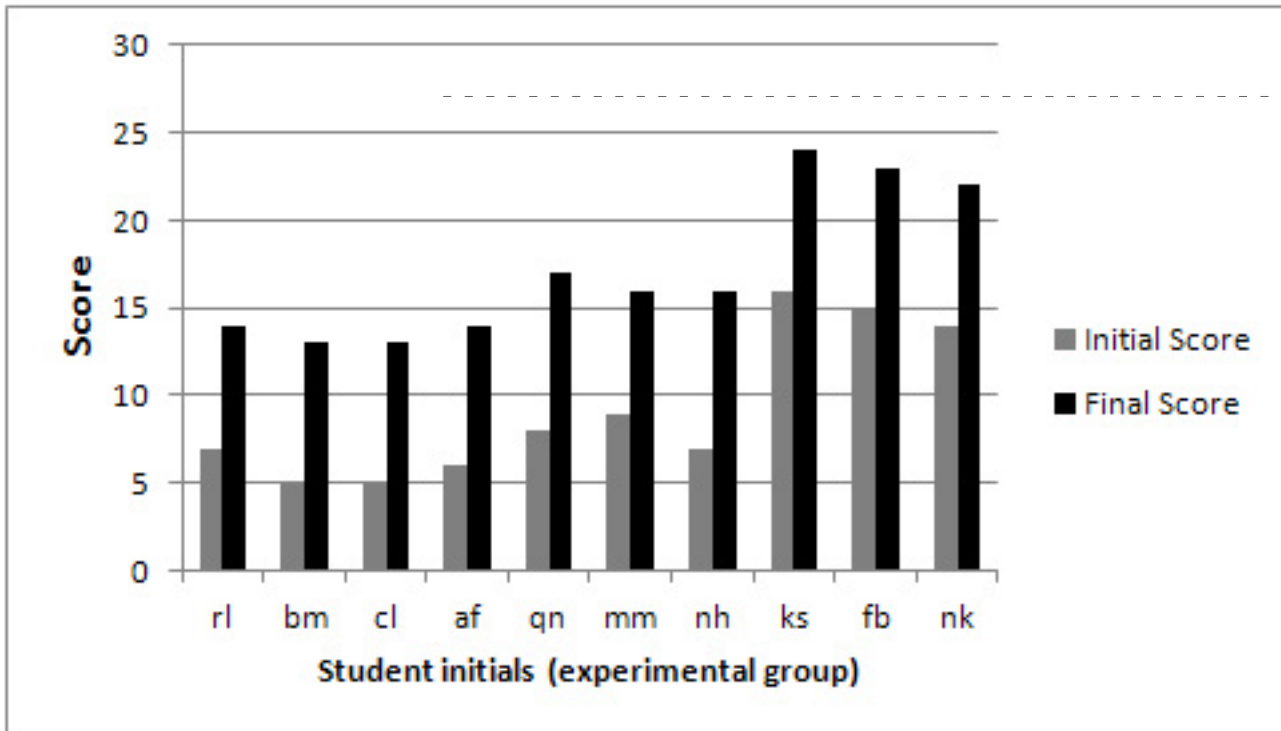


Figure 4: Passage comprehension results of experimental group.



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# How to develop a researchable question or a testable hypothesis

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## Abstract

Research can be defined as a systematic way to collect, analyse and interpret data in order to complete a work efficiently and appropriately, answer a question, invent a commodity or to test a hypothesis. Whatever the aim of the research its sole purpose is to find the best route to achieve the desired outcomes. To meet this aim and appropriately conduct the research you need a valid hypothesis. Therefore, developing a researchable question or a testable hypothesis is the first step forward in beginning research. For the student, academic or novice researcher it is important to determine how to come up with a researchable question or a testable hypothesis. Therefore, the chief aim of the present article is to provide a theoretical guideline that can be applied to most forms of academic research.

**Key words:** novice researcher, academic research, theoretical guideline researchable question, testable hypothesis

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## Introduction

Research has been the basis of human achievement to date, whether conducted formally or informally and is part of the thought process behind humanity's scientific, industrial and technological achievements. Its aim is to provide the required data for informed decision making and selecting the appropriate strategies or systems on the basis of such research.

In the modern era its applications include the sciences and social sciences, technology, engineering, geology, geophysics, food chemistry, indeed all human advances have likely been the subject of a hypothesis at some stage. For the academic or tertiary student, a well chosen research project is often the first opportunity to start your career and make your name in life and if you have a passion or great interest in a particular topic it can be the start of your lifetimes' work and your professional reputation.

## Research

Research can be defined as a systematic way to collect, analyse and interpret data in order to ask a question or to test a hypothesis. Therefore, developing a researchable question or a testable hypothesis is the first step in beginning research (1). It is worth mentioning that there are usually two types of academic research i.e. descriptive and analytic. The chief aim in descriptive research is just to answer a researchable question whilst the chief aim of analytic research is to test a hypothesis (2).

The most important difference between these two is related to the time of the research. Descriptive research gathers data on a subject or topic over a specific period, or cross section of time. This explains why cross sectional research can be another name for descriptive research. Analytic research is accomplished in a longitudinal view of time. It means all data gathered for a subject is at the very least in two specific periods of time and compared between those periods. This explains why longitudinal is another name for analytic research.

When you research a specific subject e.g. epidemiology of suicide, or even something more specific, e.g. epidemiology of self-immolation, you carry out a circle or a process of unlimited, but related descriptive and analytic research, as demonstrated in Figure 1. The starting point in this process is descriptive studies that not only are designed to answer the questions but also provide a platform for developing appropriate hypotheses that should be tested by analytic research over time.

For instance, you may start by asking a specific question e.g. "What is the prevalence of self-immolation around the world?" Answering this question (3) may lead to determine that there seems to be a "geographical belt of self-immolation in some Asian countries" (4). Now you can carry out analytic research to test this hypothesis so that: "Asiatic culture of these countries has no role in shaping this geographical belt." It is worth emphasizing the hypothesis should be stated as a null statement.

Given that advanced students are required to conduct research (5), it is important to determine how they can come up with a researchable question or a testable hypothesis? Therefore, the chief aim of the present article is to provide an appropriate guideline.

### How to develop a researchable question or a testable hypothesis

For the academic or PhD student in any scientific, industrial or technological field of study and who may not have a specific or required application or purpose, the task is more theoretical.

In order to develop a researchable question or a testable hypothesis a novice researcher should enter the process with three distinct steps which include:

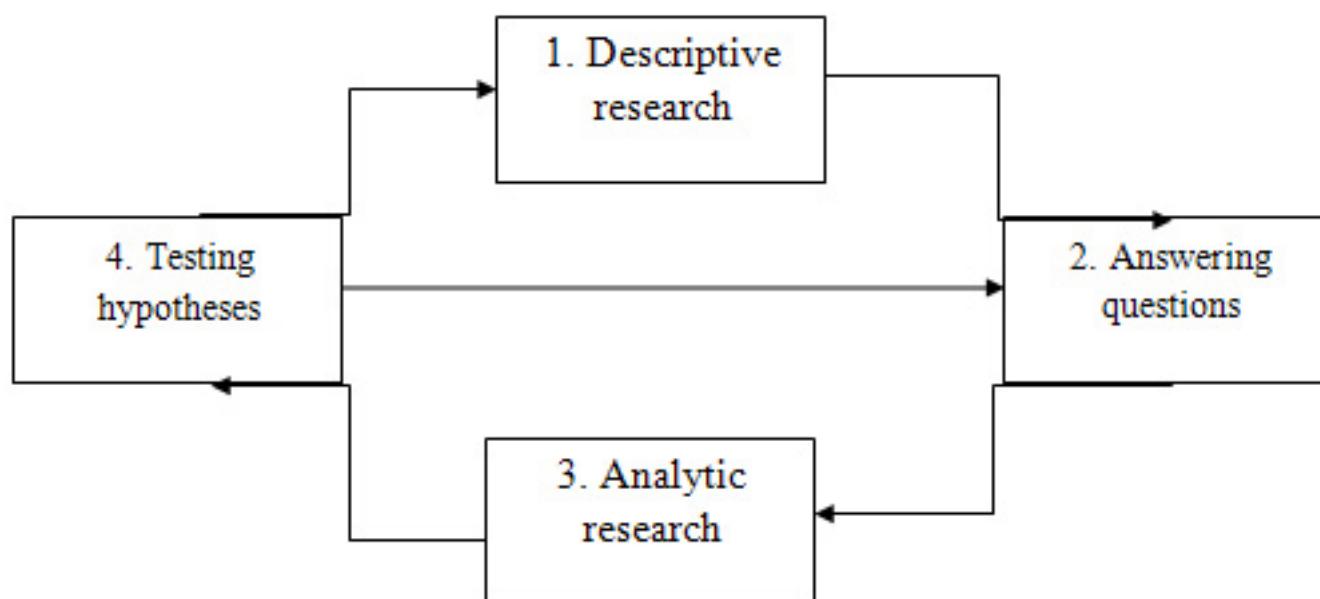
1. Developing a critical mind,
2. Putting yourself in the circumstances that develop ideas,
3. Doing comprehensive literature review to validate or formulate an idea into a researchable question or a testable hypothesis.

### Developing a critical mind

In order to develop a researchable question or a testable hypothesis you need a "critical mind". You should ask relevant and fundamental questions when confronting a new problem, a new situation, a new event, a new report, etc. You should not just watch, read, and listen without critical appraisal. Preferably the approach should not be just 'filling time' or 'meeting a requirement', but finding something totally worthwhile and necessary to research. Research projects are often the first opportunity to start your academic career and make your name in life and if you have a passion or great interest in a particular topic it can be the start of your lifetimes' work and your professional reputation.

For example, when you are watching a procedure you could ask: "Is there a better way to do that? (1)"

Figure 1. The relation between descriptive and analytic research



Likewise, when reading a new book (6) or a new research article (7) you may ask: "What is the purpose of this paper?" "Are the methods correct?", "Do the researchers come to a valid conclusion?" "Would it be possible to design a better research approach or hypothesis" "What are the implications of the results?" etc.

Putting yourself in the circumstances that develop ideas By having or developing a critical mind i.e. a mind that asks relevant and fundamental questions when confronting new situations, the next step is putting yourself in the circumstances that can develop these ideas. These may include:

1. Your daily life experiences. If you study or work, your daily life experiences may always bring you ideas from which you would be able to develop either researchable questions or testable hypotheses. Lectures and classroom discussions may be rich sources of generating ideas. Similarly, when you work as a trainee or a new worker in industry, a laboratory, clinic, hospitals, etc. you will have a unique environment where ideas may be applied or developed.

2. Critical appraisal of a new book or a new article in your area of interest may provide you with other rich sources of ideas. You should also be familiar with the most important journals in your area of interest. When you have found such an article or book reading the abstract should readily advise you if the work is interesting and informative (8).

3. Taking part in a seminar, symposium, congress, workshop or other scientific gatherings should provide other rich sources of new observations. This is the purpose of scientific gatherings. They also provide a venue for asking questions and discussion with those who have generated these ideas. Furthermore, scientific gatherings provide you with an excellent environment to network (9 & 10).

4. Mass media, internet, social media (11 & 12) may also provide you with rich sources of ideas, but it is important to be wary of interest groups peddling invalid or opinionative content (13).

### **Doing a comprehensive literature review to formulate or validate an idea into a researchable question or a testable hypothesis**

All 'new observations' however need to be supported by a comprehensive literature review (14). As there are very few 'new ideas' you may find that the topic has already been covered in part or fully. If you are committed to your idea then you can see if the previous research was valid or extensive enough, or if it leads to new research paths that should or could be further explored. Only by carrying out a thorough literature review will you be able to formulate your ideas into a researchable question or a testable hypothesis (Figure 1). This third step is also imperative since if you are embarking on new research without carrying out comprehensive literature review you may inadvertently commit research misconduct (15-18).

## Conclusion

In order to develop a researchable question or a testable hypothesis as a novice researcher you should enter a process with three distinct steps which include: developing a critical mind, putting yourself in the circumstances that lead to develop ideas and conducting a comprehensive literature review to formulate an idea into a researchable question or a testable hypothesis.

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# Examining the preferred learning styles (PLSs) of nursing and midwifery students of Urmia University of Medical Sciences

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## Abstract

**Introduction:** Education happens at universities to improve the level of students' academic achievement, and concerning this, paying attention to the styles by which students learn plays a crucial role in improving the quality of education and achieving educational goals. The present study was conducted to determine PLSs of nursing and midwifery students in Urmia University of Medical Sciences.

**Methods:** This study was conducted as descriptive cross-sectional with participation of 100 second year (and students of later years) students in nursing and midwifery by census method. Data was gathered using VARK learning style questionnaire whose validity and reliability were confirmed and analyzed by SPSS 16 and descriptive and inferential statistics.

**Results:** The priority order of students' PLSs was so that the visual style was the most common, and kinesthetic learning style was the least common style used by the students. Other results indicated no statistically significant relationship between learning styles with gender, field of study and students' interest in their field of study ( $P < 0.05$ ).

**Discussion and Conclusion:** Visual styles are the most common learning style for nursing and midwifery students. Accordingly, using visual education media can improve students' learning, so it is recommended that professors apply evidence-based teaching so as to improve the quality of education at the nursing and midwifery faculties.

**Key words:** learning style, nursing students, midwifery students, education

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## Introduction

The purpose of nursing education is preparing students for professional work (1). Training and learning play a significant role in the development of nursing skills and the proper implementation of care and more understanding of this point leads to more targeted and consistent behavior (2). In line with this learning, in accordance with their individual differences, students process the information in various ways (3). These practices have an important effect on the outcomes of educational activity as well (2). Hence, it should be said that effective learning and gaining nursing expertise will not be reached regardless of how students properly learn and what is today called students' learning style.

Learning style is one of the main processes of education (2) and is a part of individual differences (4) affecting learning (5). Learning style is a natural, habitual, unique and persistent preferred method used to absorb, process, and maintain information and new skills (6). Awareness of the students' learning style can change and adjust educational methods in line with these styles and result in higher educational efficiency (7). Thus, their identification and guidance can play an important role in selecting teaching methods and imparting concepts and knowledge to learners and ultimately improving the level of education (8). This comes from the fact that lack of proper learning of some learners, despite the presence of the best teachers, can show a lack of fit between teaching and learning styles (9). Thus, outcomes of learning will improve if learning is in line with students' learning styles (10). Awareness of students' learning styles can also directly or indirectly contribute to positive points such as enhancing learning motivation in students (11), organizing the learning environment, teachers' interaction with students (12), eliminating educational system failures (13), helping improve the teaching structure with the tendency toward students' individual choices, and ultimately the proper development of educational approaches (8).

Determining the learning style in the majority of studies in Iran has been conducted using Kolb Learning Style Inventory, and maybe, it is the justification why learning style and its related concepts are not clearly explained and the variables are not fully recognized in Iranian nursing education (2). Today, one of the newest ways to determine learning styles is VARK questionnaire, developed by Lincoln University of New Zealand in 1998. VARK approach is based on three principles: everyone has their own styles, the learner's motivation is increased when different learning styles of learners are taken into account, and educational concepts are learned through utilization of senses and different perceptions of educational content (8). Accordingly, students' learning styles are divided into visual, aural, reading-writing, kinesthetic, and sometimes a combination of the mentioned styles (8, 14).

The results of various studies have given various results about the common styles of student learning, so that in some studies, the preferred style of students is visual (7,

15, 16), aural (6, 17), kinesthetic (18) and reading-writing (8). In some other studies, student PLS is not a particular style but a combination of them (19, 20).

The diversity of the results shows the importance and necessity of conducting studies to measure the learning style of students of each university. This becomes more prominent as promoting the quality in the design and presentation of education requires attention to the learner's learning style (7). Accordingly, today, in many colleges around the world, students' learning styles assessment is done as a necessary requirement for the awareness of the professors of the students' capacities (6). Thus, our study was aimed at determining the learning styles of nursing and midwifery students of Urmia Nursing and Midwifery Faculty, so that its results could be used to improve the quality of nursing education.

## Method

The present study was descriptive cross-sectional where 100 students of nursing and midwifery of Urmia University of Medical Sciences were selected from among third and higher terms of nursing and midwifery in census form and studied as the sample. VARK questionnaire was used for collecting data, where learning styles are specified in four categories: Visual, Aural, Read & write, and kinesthetic. The questionnaire consisted of 16 four-option questions, where each option represented one of the learning styles: A was related to visual, B to aural, C to reading-writing, and D to kinesthetic styles. After submitting the questionnaires to the students, the required guidance was given to them. Students were completely free to choose options, so that they could select 1, 2, 3, and even four choices. Ultimately, given the priorities selected, the scores for the options of each style were summed up and a final score was recorded for each style and prioritization of the styles was determined, so that a higher score in each of the learning types showed more tendencies of the students towards that style. To determine the validity of the questionnaire after its translation and resolving the ambiguities of translation, we used content validity and the views of faculty members. The reliability of the questionnaire was estimated using Cronbach's alpha coefficient as 0.9 after completion by 15 students. Ultimately, data was analyzed using SPSS 16 and descriptive and inferential statistics. At the level of descriptive statistics, mean and standard deviations were used to show the central tendency indices with independent t-test used at inferential statistics.

## Results

From among 100 students among whom the questionnaires were distributed, 80 students returned them - 80% of the questionnaires were returned completed - of whom 54 were females (67%) and 26 were males (33%). The mean and standard deviation of the styles were as follows: aural learning style,  $33.5 \pm 4.3$ ; reading-writing,  $30.7 \pm 3$ ; kinesthetic,  $29.4 \pm 6$ , and visual  $42.5 \pm 5.5$ , and according to the results of t test the differences between them were statistically significant. Thus, the results indicated that

the most frequent learning style was visual and the least kinesthetic. No significant differences were found between nursing and midwifery students in determining the relationship between learning styles and student's field of study. Moreover, there were no significant differences between learning styles concerning students' gender ( $P > 0.05$ ). According to non-parametric statistical test of Chi-square, there was no significant difference between learning styles and students' interest in their field of study ( $P < 0.05$ ).

## Discussion and Conclusion

The order of the learning styles of nursing and midwifery students was visual, aural, reading-writing and kinesthetic. This means that the common learning style of nursing and midwifery students in Urmia is the visual style where learners learn the content better by viewing and presenting information such as viewing images, symbols and diagrams (7, 14). The level of human learning by sight is more than the other five senses (about 75%). Students' study and learning methods are based on the use of visual sense, and they learn the concepts better presented in form of conceptual maps, figures, diagrams, models, and replicas. Thus, the student's preferred style is visually oriented (7). The common style of students in various studies is a diverse range of all four existing styles. In a study completely in line with the present result and in the study of Amini, PLSs of most medical students with a mean score of  $39.26 \pm 6.87$  was visual and the least used style was kinesthetic (7).

In the present study, there was no significant difference between students' learning styles and gender. This finding was consistent with the results of studies in this regard (6, 7, 23). Perhaps no significant difference here is because most of the time in a school, various lessons are taught to both students of the same sex in the same way, and this is school education having a great role in student's PLSs, and then the university cannot effect much change

on it. (6). This reason can further justify the findings of this study denoting the lack of significance of the relationship between students' learning styles with the student's field of study, as well as the degree of interest of students in the topic.

In the present study, VARK questionnaire was used to determine the student's PLSs. On the one hand, given the emergence and prevalence of new media and technology in the learning and learning process and the necessity of using various senses by the learner, a new tool is needed to identify the students' sensory learning styles, appropriate media and educational materials. On the other hand, VARK learning style advantage is that it can come up with information on learning strategies and media methods appropriate to these styles (7). Thus, knowing that each student has a type of learning style can assist teachers in selecting the proper teaching method and the type of educational aid (8). Thus, given the capabilities of this questionnaire, it is necessary to be aware of the students' PLSs, so that based on the results; one can apply the appropriate methods to provide education. Consequently, conducting empirical studies is recommended for use for teaching strategies to promote student learning according to the learning style. Moreover, it is recommended to carry out studies to determine the possibility of using VARK tool as a screening test for the learning cycle weaknesses and the possibility of providing individual recommendations for improving the learning process in the students. Given the results, it is recommended that the professors of medicine faculty pay utmost attention to students' learning style in selecting the methods of teaching to make teaching more desirable and make learning more effective for learners. Furthermore, it is suggested that professors should pay attention to other effective variables in learning style in their teaching and avoid the same teaching style for all students.

**Table 1. Distribution of students**

Percent	Frequency	Demographic Variable	
33	52	Male	Gender
67	108	Female	
6	9	Married	Marital status
94	151	Single	
74	118	20-22	Age
26	42	23-25	

**Table 2. Student learning styles**

Standard deviation	Average	Learning style
5/5	42/5	visual
4/3	33/5	aural
3	30/7	reading-writing
6	29/4	kinesthetic



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# The Relationship Model between the Misconduct with Motivation Coaches Elite Female Athletes

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## Abstract

The aim of this study was to present a model of the relationship between coaches' misconduct and the progressive motivation of elite female athletes. The method of the study was a factor analysis and in terms of implementation, it was a field study. The population of the study consisted of all elite female athletes composed of two team-based and two individual sports including cycling and rowing who were invited to the national team camp in 2016. The total sample size of 190 athletes was selected. Data was collected using questionnaires including Bloorizadeh's examination of the experience of misconduct (2013), Lange and Frisch's progressive motivation (2006). Pearson correlation coefficient and regression analysis were used to predict the change and method of factor analysis, and T-test was used to examine the fitness of model and determining the effect was done by statistical software such as SPSS, Excel and SMART-PLS. The results of the study indicated that there were multiple relationships between the components of misconduct and the progressive motivation of elite female athletes. The components of misconduct explained the progressive motivation. Goodness of fit indices (NFI, SRMR), with their interpretation, showed that the model did not have a fair suitable fitness and the indices should be interpreted with caution in SMART-PLS.

**Key words:** Progressive motivation, Misconduct, Elite athletes, Female athletes.

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## Introduction

The increasing expansion of sport is such that millions of people around the world associated with sports, especially athletes, coaches, referees and club managers, photographers, reporters, and those involved in sports press and other mass media, are working in sports related activities (6). For this reason, sport is an important part of our culture and society, and includes coaches, athletes and people at all stages of life. Coaches can have positive and negative effects on the environment of the lives of athletes at different levels of the championship. The coaches are the key leaders and managers of every sports team. Therefore, they should be familiar with the principles and methods of team leadership, how to use coaching power and an effective relationship with athletes (7). In today's advanced world, no athlete can progress very well without a knowledgeable and capable coach. According to Robben Frost, coaches are the main pillar of the sports teams. Championship sport, on the one hand, stimulates the motivation and modeling for physical activities among different classes of society, especially the youth, and on the other hand, with the positive effects on the international dimension, it causes further familiarization of different countries and cultures with each other, and a deeper understanding of different nations. Research indicates that nowadays, athletes often have to endure psychological and physiological burdens brought on by their coaches to gain excellence in sport (12).

Regarding this, misconduct is a pattern of the physical, sexual, emotional violence, or neglect by someone who acts as a helper (such as parents and coaches) which results in actual or potential injury to the athlete. Typical known types of misconduct include physical misconduct, sexual misconduct, emotional misconduct and neglect (11). So far, some cases of the occurrence of misconduct have been studied in sport, but there is not sufficient applied research for the codification of ethical rules and regulations. Nowadays, athletes often have to endure psychological and physiological burdens from their coaches to gain excellence in sport, so that the line

between misconduct and practice is unclear (2). A coach can motivate athletes with proper behavior. Progressive motivation is one of the important psychological characteristics that has a direct impact on the performance of athletes in competitive sport. The motivational processes are defined by their psychological characteristics that reinforce and direct the individual's progressive behavior (11).

In this regard, Afshar (2014) investigated the relationship between coaches' misconduct and the effectiveness and satisfaction of elite wrestlers of Alborz province in Iran. The results showed that there is a negative significant correlation between coach's misconduct, which generally has four sub-indicators such as emotional misconduct, physical misconduct, sexual misconduct and coach's neglect, coaching effectiveness and satisfaction of athletes.

In a study, Lavoie (2016) investigated coach's performance, the athletes' satisfaction, and the use of an action-driven motivation model. The findings showed a self-efficacious relationship between action oriented personality and coach's performance with athletes' satisfaction [9].

Fikrat (2014) conducted research titled "The Relationship between Coaching Leadership Style and Progressive Motivation: A Study on Soccer Players." The results of the study indicated that there was a significant relationship between the leadership styles of coaches with the progressive motivation of athletes. The results also showed that from among components of leadership style of coaches including social support and democratic behavior, there was a significant relationship between them and the progressive motivation of athletes (6).

Research has shown that some non-standard coaching methods can be considered as a threat to psychological and physiological health. Research and study in the field of the championship sport to improve performance is very important from the point of view of managers and sponsors, because determining the factors affecting the level of the progressive motivation of the players and ultimately team performance, contributes significantly to the success of the teams. Considering the importance of these features, few studies have been devoted to getting a comprehensive theoretical model of the progressive motivation of players in sport to consider the evolutionary variables of the progressive motivation. If one knows the relationship between the players' motivational situation and their misconduct, then one can assume that in the form of a theoretical model, the recent variable contributes to the explanation of the progressive motivation of the athletes. The ambiguity on coaching effectiveness and their relationship with progressive motivation of the athletes has led to the development of many research projects. Contradictions in the field of theoretical discussions and background of the research are the source of the question of this study. Through providing the following conceptual model, the present study tries to seek an answer to the following question: Is there any relationship between the sources of power and coaches' misconduct with the progressive motivation of the elite female athletes? What is the model if the answer is positive?

## Methodology

The research method was factor analysis and in terms of implementation, it was a field study. The population of the study included all elite female athletes consisting of two team-based sports including basketball and futsal, and two individual sports groups including cycling and rowing, who were in Premier Leagues and who were invited to the national team camp. The total sample size of 190 athletes was selected. Data was collected using questionnaires including Bloorizadeh's examination of the experience of misconduct (2013), Cronbach's alpha coefficient 0.90, and Lange and Frisch's progressive motivation (2006). Cronbach's alpha coefficient of the questionnaire was 0.90. The formal validity of the questionnaires was verified by the sports management professors. To analyze the collected data, descriptive statistics were used to summarize and categorize the raw data and calculate the mean, frequency, standard deviation and plotting of the graphs and tables. Inferential statistics methods such as Pearson correlation coefficient were used to investigate the relationship between research variables and regression analysis in order to predict the change and method of factor analysis and T-test was used to examine fitness of the model. To determine the effects, statistical software such as SPSS, Excel and SMART-PLS were applied.

## Results

The results of the study indicated that in the present study, the mean age of participants was 25.01 years. In this study, average attendance of participants at national team was 4.5 years. 68.5% of participants majored in physical education and 31.5% of them studied in disciplines other than physical education. Most of the participants had a bachelor's degree (46.7%). The lowest number was related to associate degree (10.9%), and none of the participants had PhD. The resulting figure 3.57 represented the progressive motivation higher than mean in research samples.

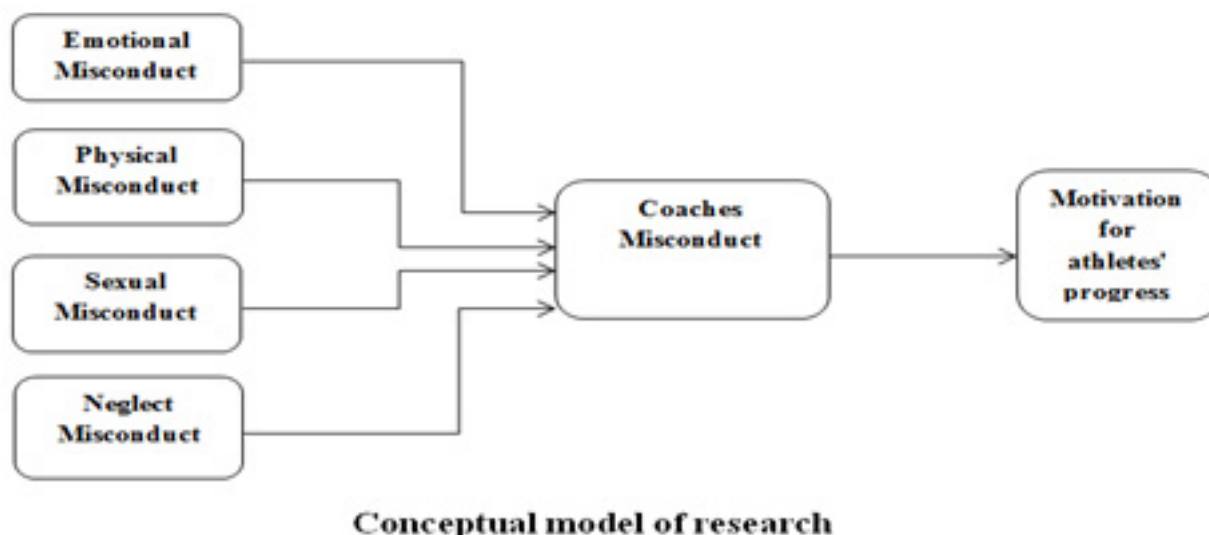
According to the results of this study, the mean of coaches' misconduct in four subscales of misconduct were as follows: emotional misconduct (0.55), physical misconduct (1.05), sexual misconduct (0.44) and coach's neglect (0.92), which indicates a low level of misconduct among the coaches of the disciplines studied.

Given the number of participants based on the central limit theory, the distribution of data can be assumed normal. In addition, to robust data against the violation of assumptions Bootstrap confidence intervals were used. Finally, SMART-PLS software was used for formulating and testing the model.

The results of multivariate regression analysis in Table 4 showed that there were multiple relationships between the components of misconduct and the progressive motivation of the progress of elite female athletes ( $F(185.4) = 9.27$ ,  $P < 0.000$ ). Given the value of coefficient of determination, the components of misconduct explain 0.16 of variance of the progressive motivation. Therefore, null hypothesis is rejected.



Figure 1



Similarly, the results of the Durbin-Watson test in Table 1 showed that the value of these statistics was between 1 and 3, which indicates the assumption of the independence of errors in the regression.

Table 1. Statistical characteristics of regression

R	R <sup>2</sup>	SE	Durbin-Watson
0.45	0.16	5.06	1.92

Table 2. Results of regression analysis

Source	SS	Df	MS	F	Sig.
Regression	951.2	4	273.8	9.27	0.001
Remaining	4741.5	185	25.6		
All	5692.7	189			

Table 3 shows the coefficients of the components of misconduct. As you can see, only sexual misconduct is a significant predictor of the progressive motivation.

Table 3. Coefficients

Indices	B	Beta	t	P	BCa 95 %	Tolerance	VIF
Fixed amount	36.7	-	60.9	0.001	[35.38, 4.09]	-	-
Physical misconduct	0.13	0.02	0.205	0.865	[-1.1,1.3]	2.92	0.342
Emotional misconduct	-1.08	-0.16	-1.9	0.057	[-2.0, 1.25]	1.75	0.569
Sexual misconduct	-4.13	-0.44	-4.5	0.001	[-6.1, -2.08]	2.17	0.460
Neglect misconduct	1.4	0.19	1.59	0.151	[-0.3, 46.04]	3.14	0.318

In addition, all values of VIF were lower than 10, and all the statistical tolerance was higher than 0.2. Therefore, one can confidently conclude that there is no collinearity between the predictor variables.

Besides, the value of the common index with cross-validation (CV com) was 0.20 for progressive motivation and 0.52 for misconduct. Moreover, added index value with cross-validation (CV Red) for the intrinsic variable was 0.06 for progressive motivation and 0.10 for misconduct. All of these values are higher than zero, which means that the observed values were well reconstructed and the model of Figure 2 (next page) has predictive ability.

Finally, R<sup>2</sup> for the progressive motivation was equivalent to 0.25, which is considered moderate and the value is 0.16 for misconduct which is also moderate.

In Table 4 (next page), goodness of fit indices (NFI, SRMR), along with their interpretation, shows that the model did not have a fairly suitable fitness and the null hypothesis was confirmed. However, in PLS-SMART, indices should be interpreted with caution.

Figure 2: Developed model

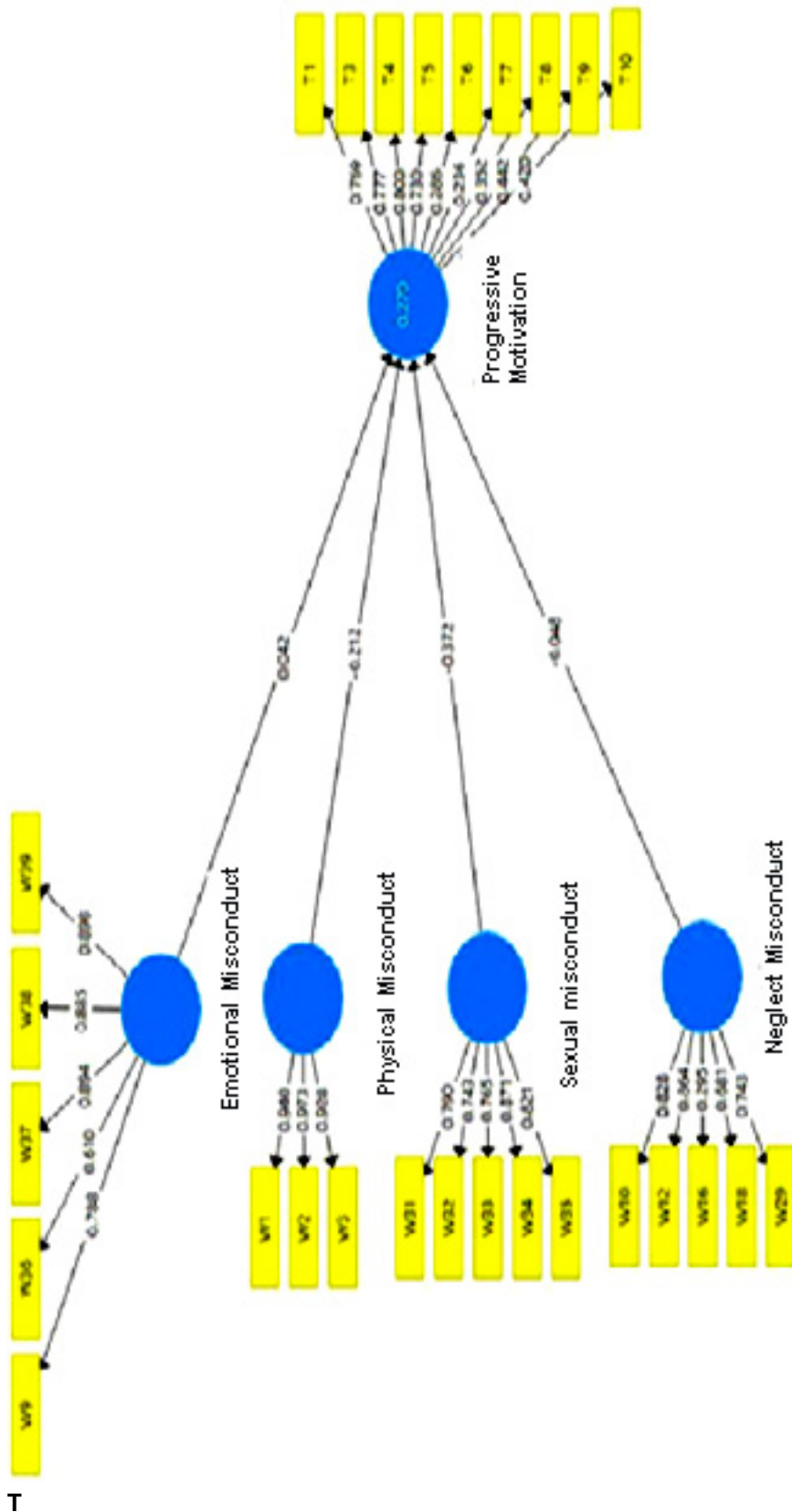


Table 4. Goodness of fit indices

Indices	Amount	Interpretation
NFI	0.53	Values higher than 0.9 are acceptable
SRMR	0.15	Values below 0.10 in PLS are acceptable

## Discussion and Conclusion

The results of this study using multivariate regression analysis show that there are multiple relationships between the components of misconduct and the progressive motivation progress of elite female athletes. According to the value of determination coefficient, the components of misconduct explain 0.16 the variance of the progressive motivation and sexual misconduct is a significant predictor of the progressive motivation. The results of this study are consistent with the results of the research by Afshar (2012), and Bloorizadeh (2013). The behavior is a pattern of physical, sexual, emotional violence or neglect by a helper (such as parents and coaches), which leads to the actual or potential injury in the athlete (8). The four typical known types of misconduct are: physical, sexual and emotional misconduct, and neglect. Finally, it should be made clear that both children and adults are vulnerable to misconduct, harassment and bullying in terms of experience. Actually, much of the research that has been conducted to date on misconduct, harassment and bullying in sport were based on interviews with adults and only a few researchers have argued that the dynamic imbalance power between the coach and athlete in the sports environment creates a vulnerability situation against misconduct to the athlete and is not limited to the age of the athlete. In addition, it should be noted that misconduct, harassment and bullying can occur among people of the same gender. Both men and women may commit misconduct, harassment or bullying by their same-gender, or there can be experienced cases of misconduct, harassment and bullying by women or men of the same gender (11). Contradictory research findings were not found in the result of the present study. Harassment is defined as the unwanted unilateral or group actions or forced behaviors committed in a position of authority (such as coach, high-ranking officials and managers) against the athlete. These behaviors are vulnerable to injury and as a result, harassment occurs outside the context of supporting relationships (12). This term refers to behaviors that violate human rights laws of individuals. It seems that harassment like misconduct is based on the misuse of power and trust of others (12). Individuals may experience harassment individually or in a group. Unfortunately, many studies confirm the existence of misconduct among sports coaches. The present study also showed that coaches' misconduct, especially sexual misconduct, predicted a decrease in the progressive motivation of the elite female athletes. Therefore, it is emphasized that sports coaches should behave with their athletes with good attention and try to identify the best ways to deal with athletes in training, practice, and matches.

The general conclusion indicated that the coaches can have positive and negative effects on the environment of the lives of athletes at different levels of championship. Research indicates that behavior of individuals is effective and can stimulate progressive motivation or reduce it. However, there is a controversy among the researchers considering the impacts of misconduct. On the other hand, athletes today often have to endure psychological and physiological burdens by their coaches to gain excellence

in sport, so that the line between misconduct and practice is unclear.

The results of this study show that there is a relationship between the components of misconduct and the progressive motivation of elite female athletes. Therefore, the managers and those involved in sport should pay special attention to these variables during the promotion and the evaluation of the coaches and their appointment. The familiarity of the coaches with methods to use the correct behavior, the advantages and disadvantages of behavior and its impact on the progressive motivation of athletes, as well as the destructive effects of misconduct and its components shall be emphasized. However, despite the correlation, goodness of fit indices and their interpretation show that the model does not have a fairly suitable fitness and indicators should be interpreted with caution.

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# Investigating the Role of Aerobic Exercise on Subjective Well-Being among High School Girls in Yasuj High School in 2017

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## Abstract

The purpose of this study was to investigate the role of aerobic exercise on subjective well-being of high school female students in Yasuj. The present study is a semi-experimental and pre-test post-test design that was done as a field experiment using a control and experimental group. This study investigated the effect of six weeks aerobic exercise on the mental well-being of high school girl students in Yasuj. The statistical population of this study included all female high school students in Yasuj who were studying in 2017. For this purpose, a sample of 42 students was selected and divided into two groups of test and control. Sampling was random cluster. Data were analyzed using descriptive statistics and inferential statistics including covariance analysis or comparison of scores with SPSS-22 software. The results of covariance analysis showed that aerobic exercises affect various aspects of mental well-being, and created mental well-being of students in the experimental group.

**Key words:** aerobic exercise. Mental well-being

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## Introduction

Kristensen states that one of the problems of the human community is the problem of unemployment and its complications. Part time work, especially for teens and young people, especially during the summer holidays of schools and educational centers, can be harmful and must be remedied, or occasionally filled with unemployment that is beneficial or at least harmless. Many deviations, such as drug addiction, theft and harassment, street fighting, sexual deviations, etc. are the result of idleness (1).

Exercise has many forms in the world, and many groups deal with it in various ways. Some people are professional athletes and part of groups of amateur athletes (2).

Physical exercise, can be gained during sport, especially sports that are continuous.. Open-air exercises such as cycling, walking, swimming, and so on relieve depression in a large number of cases. Research findings indicate that exercise and activity of the body affects mental health, self-efficacy, anxiety and depression and self-esteem. Medical science, in addition to screening and prescribing drugs and operations that deal with various diseases, also uses exercise as a means to improve patients' well-being. Some physicians encourage their patients to exercise for various conditions, such as to relieve numbness, weight loss and muscle weakness, such as low back pain, neural and muscular coordination in some forms of paralysis, rehabilitation, lack of appetite, having anxiety or emotional feelings, agitation, depression, feeling absurd, and many other conditions. (3).

The results of various studies have shown that performing different types of exercises, in addition to many physical benefits, has a beneficial effect on coping with neurological and psychological problems. Considering the positive effects of exercise on the health and well-

being of the human being, the culture of sport should be further addressed. On the other hand, in order to achieve sustainable development in any society, in addition to planning, proper management and the use of appropriate technology, the use of efficient human resources is very important. A society that has healthy human beings will have the opportunity to take a more immediate course for real development. (4).

The results of many studies have shown the beneficial effects of exercise. Meghdadi et al. (2003) in a study on students of Shahid Chamran University of Ahwaz, entitled "The Effect of Aerobic Exercise on Mental Health," showed that aerobic exercise has a positive effect on mental health, depression, and anxiety, whereas aerobic exercise has a significant effect on physical complaints and social function. Also, there is a significant relationship between aerobic fitness with depression and anxiety and the increase in aerobic fitness has been associated with decreasing depression and anxiety. However, there is no significant relationship between aerobic fitness with physical complaints and social function (5). Pour Ranjbar et al. (2003) in evaluating the effect of aerobic and anaerobic exercises on students' anxiety showed that exercise is an effective and safe way to reduce anxiety. It seems that both aerobic and anaerobic exercise can reduce effective anxiety. Therefore; it can be used to reduce anxiety depending on the physical condition of each type of exercise (6).

Exercise and sports are designed to enrich the hours of leisure and create happy moments and a sense of tranquility and comfort at the community level. In addition, it is considered as a solution to many of the physical and psychological problems of people in society. Correct and regular exercise as an important part of everyday duties of any person can affect the health and community health and fulfill the duties and responsibilities of the community (7). This mission becomes more important when it comes to the place of the school due to the role and dignity of this constructive center. If family settings, for any reason, do not provide a place for learning about the necessity of doing sports for students, school education will be a valuable opportunity, in addition to exercising leisure time and strengthening physical strength and optimal use of these times, with the most desirable possible activity, which ultimately brings health and well-being, and to enjoy its psychological and social benefits. Also, research has shown that exercises have beneficial psychological effects that include: high levels of general well-being, positive mood, and low levels of depression and anxiety.

The important psychological characteristic that healthy people should have is a feeling of well-being along with a sense of efficiency. The sense of well-being of this type is defined as: a positive feeling and a general satisfaction of life that includes self and others in different areas of the family, or occupation. From Rhine's point of view, there are two main approaches to the definition of well-being: pleasure and virtue. The predominant view of pleasure by psychologists is that well-being is equal to the mental happiness associated with the experience of pleasure

versus the dissatisfaction experience that affects the well-being. (8). In the twenty-first century, psychology has expounded that man has to spend his rational energy on the positive aspects of his experience. Subjective well-being is an important structure in the study of personality interpretation and is defined as a positive evaluation of life and the balance between positive and negative emotions (9), and given the fact that mental disorders are common in many modern societies, our society is no exception to this. Also, given the fundamental role that aerobic exercise plays in everyday life and the intellectual and personality processes of individuals, the researcher seeks to respond to the question as to whether aerobic exercise is effective on the mental well-being of high school girl students in Yasuj in 2017.

## Research Method

The present study is a semi-experimental and pre-test post-test design that was done as a field experiment using a control and experimental group. This study investigated the effect of six weeks aerobic exercise on the mental well-being of high school girl students in Yasuj. The statistical population of this study included all female high school students in Yasuj, who were studying in the school year 2017. The community size was 525 people based on statistics. To determine the sample size in the current study, considering the significant level (0.05) and the effect volume (0.51) with the power of 0.8 for each group, 22 was selected. Sampling was a random cluster. The research tool is a questionnaire and descriptive statistics and inferential statistics including covariance analysis or comparison of scores were used to analyze the data. Statistical analysis was performed using SPSS22 software.

## Research Findings

### The main hypothesis:

Table 1 (next page) shows the results of a variance covariance analysis to examine the effect of aerobic exercise on mental well-being. According to the results obtained from the analysis of covariance in the table, the effect on the intervention (group) is significant (5.22). According to the results, it can be said that aerobic exercise has affected mental well-being and the research hypothesis is confirmed.

### Hypotheses

In order to investigate the effect of intervention on the well-being components, multivariate covariance analysis of post-test scores with pre-test control was performed. Table 2 shows the results of multivariate covariance analysis on post-test scores of well-being components with pre-test control.

Table 2 shows that there is a significant difference between the test and control groups in terms of at least one of the dependent variables (components of mental well-being). Analysis of covariance in the text of MANCOVA on dependent variables was performed to examine the difference.

**Table 1: Results of a variance covariance analysis to examine the role of aerobic exercise on mental well-being**

Indicator	Sum of squares	Average squares	F	The significance level	Square Eta
Variable	384.29	384.29	5.27	0.001	0/26
pre-exam	482.21	482.21			
Intervention group	3824.72	92.28			

**Table 2: Summary of multivariate covariance analysis for controlling the mean post-test of components of well-being with pre-test control in test and control groups**

Effect	Test	Value	F	df hypothesis	error df	Significance level
group	Pillai's trace	0.85	10.98	3	1	0.01

**Hypothesis 1:** Aerobic exercise is effective on the social well-being of high school girl students in Yasuj.

Table 3 shows the results of covariance analysis in the text of MANCOVA to examine the role of intervention on the social welfare component. According to the obtained result, it can be concluded that the intervention on social welfare component was significant ( $P = 0.01$ ;  $P = 5.71$ ). According to Eta, it can be said that the effectiveness of this component was (0.29).

**Table 3 shows the results of covariance analysis in the text of MANCOVA to examine the effectiveness of intervention on the component of social welfare.**

Effect	The dependent variable	df	Sum of squares	Average squares	F	The significance level	Square Eta
group	Social welfare	1	512/13	512/13	5/71	/002	0/12

**Second hypothesis:** Aerobic exercise is effective on the psychological well-being of high school female students in Yasuj.

Table 4 shows the results of covariance analysis in the text of Mancova to examine the effectiveness of intervention on the component of psychological well-being. According to the obtained result, we can say that the intervention on the psychological well-being component was significant ( $P = 0.01$ ;  $F = 4/58$ ). According to Eta, it can be said that the effectiveness of this component (0.06) was.

**Table 4 shows the results of covariance analysis in the text of MANCOVA to examine the effectiveness of intervention on the component of psychological well-being**

Effect	The dependent variable	df	Sum of squares	Average squares	F	The significance level	Square Eta
group	Psychological well-being	1	454.28	454.28	4/58	/002	0.06

**Hypothesis 3:** Aerobic exercise is effective on the emotional well-being of high school girl students in Yasuj city.

Table 5 shows the results of covariance analysis in the text of MANCOVA to examine the effectiveness of intervention on the emotional well-being component. According to the obtained result, it can be concluded that the intervention on the emotional well-being component was significant ( $P = 0.01$ ;  $P = 0.61 = 3.61$ ). Considering the square Eta, it can be said that the effectiveness of this component was (0.05).

**Table 5 shows (in Farsi) the results of covariance analysis in the text of MANCOVA to examine the effectiveness of intervention on the component of emotional well-being**



**Table 5 shows (in Farsi) the results of covariance analysis in the text of MANCOVA to examine the effectiveness of intervention on the component of emotional well-being**

Effect	The dependent variable	df	Sum of Squares	Average Squares	F	The significance level	Square eta
Group	Emotional well being	1	466/39	466/39	3/61	/002	0/05

## Conclusion

The findings of this study showed that aerobic exercise is effective on the mental well-being of high school female students in Yasuj. Therefore, the results of covariance analysis showed that aerobic exercises influence on mental well-being, as well as on different aspects of mental well-being, and caused mental well-being of students in the experimental group. Aerobic exercise, is best gained from sports that are continuous, usually creating a positive effect on people's creation and includes exercise in the open air such as cycling, walking, swimming, and so on. It relieves depression in a large number of cases. It also provides recreational opportunities, amusement and friendship for students, as well as the liberation from stress, anxiety and isolation through group participation in the above-mentioned sports programs and thus it determines the importance of sport and more attention should be paid to this.

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# Assessment of Concentration Changes and Temperature Effect on Total Volatile Organic Compound in the Air of Yasuj City in Iran

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## Abstract

**Background and objectives:** Volatile organic compounds (VOCs) are among major pollutants in urban air, which can be associated with known effects and complications. Therefore, the aim of this study was to assess concentration changes of total volatile organic compounds (TVOC) and the temperature effect on the concentration of pollutants in the air of Yasuj city.

**Materials and methods:** In this cross-sectional descriptive and analytical study, the samples were collected from the main squares of the city of Yasuj during two cold and warm seasons at the traffic peak hours of vehicles (7-22) in accordance with full factorial design. This study was carried out in several stages. Firstly, direct-reading device (First Check) was used to measure the concentration of total volatile organic compounds. At this step, the digital device (Model HD50, made in France) measured the temperature simultaneously. In the next step to determine the type of VOCs, environmental sampling pump and activated-charcoal sorbent tubes were used to collect some air samples. After sample preparation, the pollutants were extracted using carbon disulfide. Analysis of the samples was performed by GC-MS device. Data were analyzed using SPSS version 16 software.

**Results:** Based on the results, the mean TVOCs concentration in the air of Yasuj city was 1058ppb. The concentration of these compounds showed the highest value in the warm season and in the afternoon hours within the midweek days. Concerning the effect of temperature on TVOCs concentration, it can be said that the concentration of these compounds was enhanced with increasing temperature over 10°C.

**Conclusion:** With regard to the adverse effects of VOCs on human and environmental health as well as the role of these pollutants in the formation of photochemical oxidants, appropriate actions related to monitoring and controlling these compounds should be considered in urban air.

**Key words:** Volatile Organic Compounds; Air Pollution; Outdoor Air; Yasuj

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## Introduction

Air pollution is one of the most important human problems, which is resulting from the release of various pollutants into the atmosphere. The volatile organic compounds (VOCs) are of the major pollutants in the air.

The VOCs are a large group of gaseous hydrocarbons that evaporate at extremely high speed. These compounds are emitted from a variety of sources, including power stations, gas stations, industries, gasoline and diesel vehicles, processes of using dyes etc. The diversity of these gases in different environments depends on the spatial and temporal changes in the sources of emissions, meteorological parameters and other factors. The EPA has listed a wide variety of these compounds as hazardous air pollutants (1-3).

Some of the VOCs cause adverse effects on human and environmental health. For example, exposure to benzene can lead to several types of diseases, such as leukemia, immune system abnormalities, neurological disorders, cardiovascular diseases, respiratory illnesses, etc. (4, 5). Some of the VOCs harmful effects on the environment include participation in the formation of photochemical smog and bad ozone in the lower layer of the atmosphere (6). If there is a release of the VOCs, the concentration of these compounds, similar to other pollutants in atmospheric air, will be influenced by several factors, including meteorological factors (temperature and relative air humidity), the topographical features of the earth's surface and so on. Therefore, it is essential to be aware of the meteorological parameters in which the dispersion process affects the air pollution and causes the decrease or increase in the concentration of air pollutants (7, 8).

Given the importance of the VOCs concentrations in the atmosphere in terms of health and the environment, as well as understanding the situation and changes in air quality levels, this study was conducted to evaluate the changes in TVOCs concentration in the air of Yasuj city and the influence of temperature on the concentration of pollutants in the air of the city.

## Materials and methods

The city of Yasuj in southwestern Iran is the capital of Kohgiluyeh and Boyer-Ahmad Province. The total population of the city consists of approximately 120 thousand in 2016 and its area is over 24 km<sup>2</sup>. Since it is a non-industrial city and motor vehicles are likely to play a major role in air pollution, hence, the crowded areas and main squares were selected as sampling sites in this cross-sectional descriptive analytical study.

Totally, 1,500 samples were collected from ten main squares of the city of Yasuj during two cold and warm seasons (winter and spring) at the traffic peak hours of vehicles (7-22) in accordance with full factorial design.

In order to facilitate statistical analysis, sampling times were classified into three periods, before noon, afternoon and night. In addition, the days of sampling were also divided into the early days of the week, midweek days and the late days of the week.

This study was carried out in three stages. Firstly, direct-reading device (First Check, made in England) with photoionization detector was used to measure the concentration of total volatile organic compounds. The device equipped with a 0.45-micron filter sucked the air with flow of 250 ml per minute and determined the concentration of total volatile organic compounds (TVOCs) by ultraviolet light detector. At this step, the digital device (Model HD50, made in Kimo Co., France) measured the temperature simultaneously. In the next step to determine the type of VOCs, environmental sampling pump (Model HFS-513A, made in America) and activated-charcoal sorbent tubes were employed to collect some air samples from places with significant concentration of the VOCs. In the third step, carbon disulfide was used to extract pollutants from activated-charcoal sorbent tubes. Then, the samples were injected into the gas chromatography–mass spectrometry (GC-MS) according to NIOSH 2549 (model Y16100, made in Korea). Finally, the chromatogram output from the GC-MS detected the most abundant of the VOCs in the urban air.

In this study, SPSS version 16 software was used to analyze the results and to draw the charts. Part of the results have been reported as descriptive statistics (mean, standard deviation). The graph of the regression was constructed to determine association between variables.

## Results

In this study, the minimum and maximum TVOCs concentrations were measured as 230 ppb and 1650 ppb in the cold season, as well as 160 ppb and 2200 ppb in the warm season. According to the results presented in Table 1 (next page), the TVOCs concentration was higher in the warm season than in the cold season.

The most TVOCs concentration in the warm season was observed in the afternoon hours and in midweek days and the lowest concentration was found before noon and late days of the week (Figure 1). In the cold season, the highest concentrations of these compounds was found at nighttime and in the late days of the week and the lowest concentration was also observed before noon and in midweek days.

Concerning the type of the VOCs, based on the peaks of air sample injection to GC-MS device, the most abundant of the VOCs in the air of Yasuj city accounted for aromatic compounds such as 2-ethyl-1,3 (2H) -Dithion-1H-Isoindol, 1,3Bis (trimethylsilyl) benzene, 2,4 - Di-tert-butylphenol, dibenzosuberane and N-Butyl-benzene sulfonamide (Figure 2).



**Table 1: Summary of statistics related to samples taken during the study**

	TVOC samples in cold season (ppb)	TVOC samples in warm season (ppb)	Total TVOC samples (ppb)
Number of samples	750	750	1500
Mean	808	1309	1058
Standard deviation	0.251	0.262	0.3586
Minimum	230	160	160
Maximum	1650	2200	2200

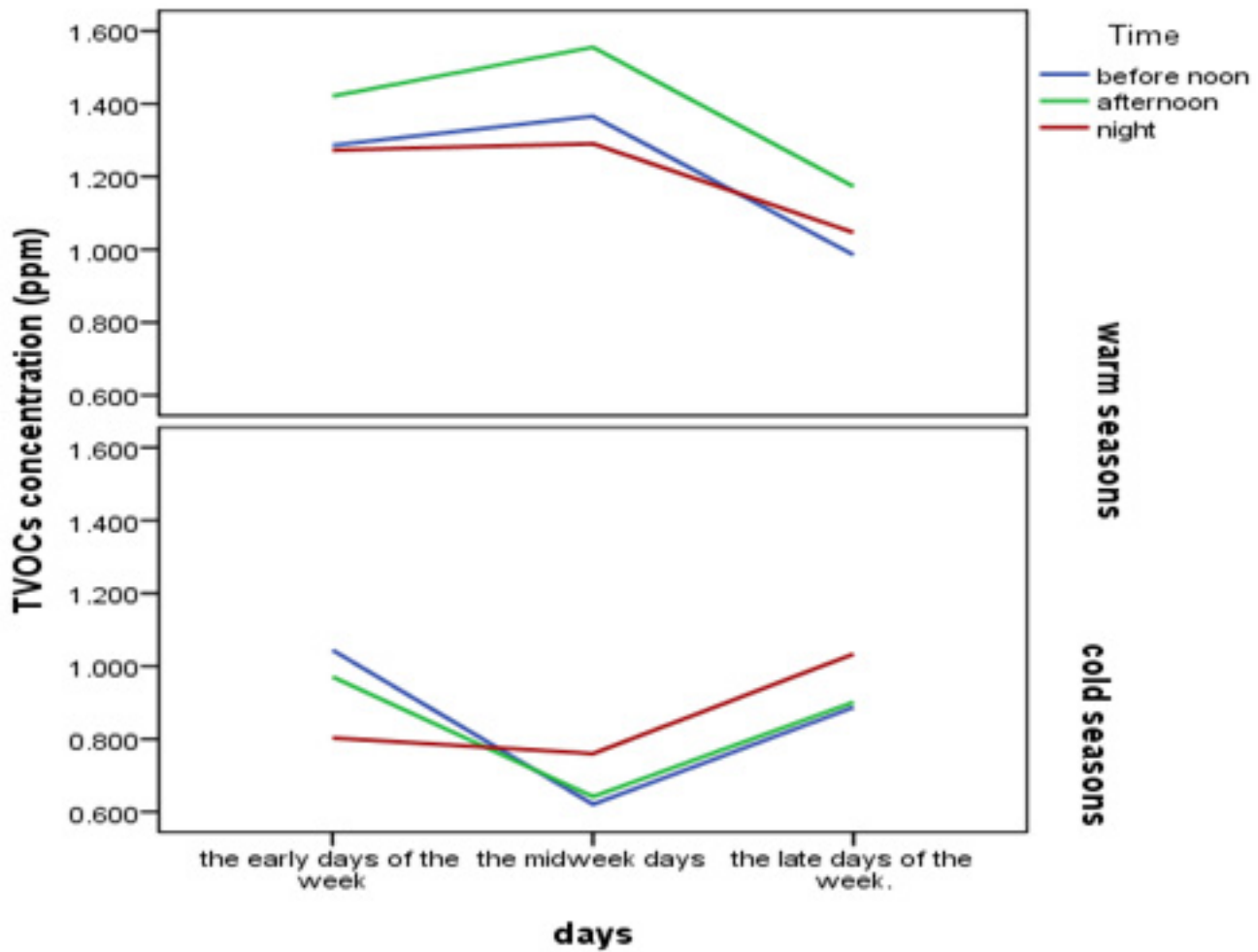
**Figure 1- Temporal variations of the volatile organic compound concentration**

Figure 2: An example of chromatogram obtained from injection of air sample of Yasuj city to GC-MS devices

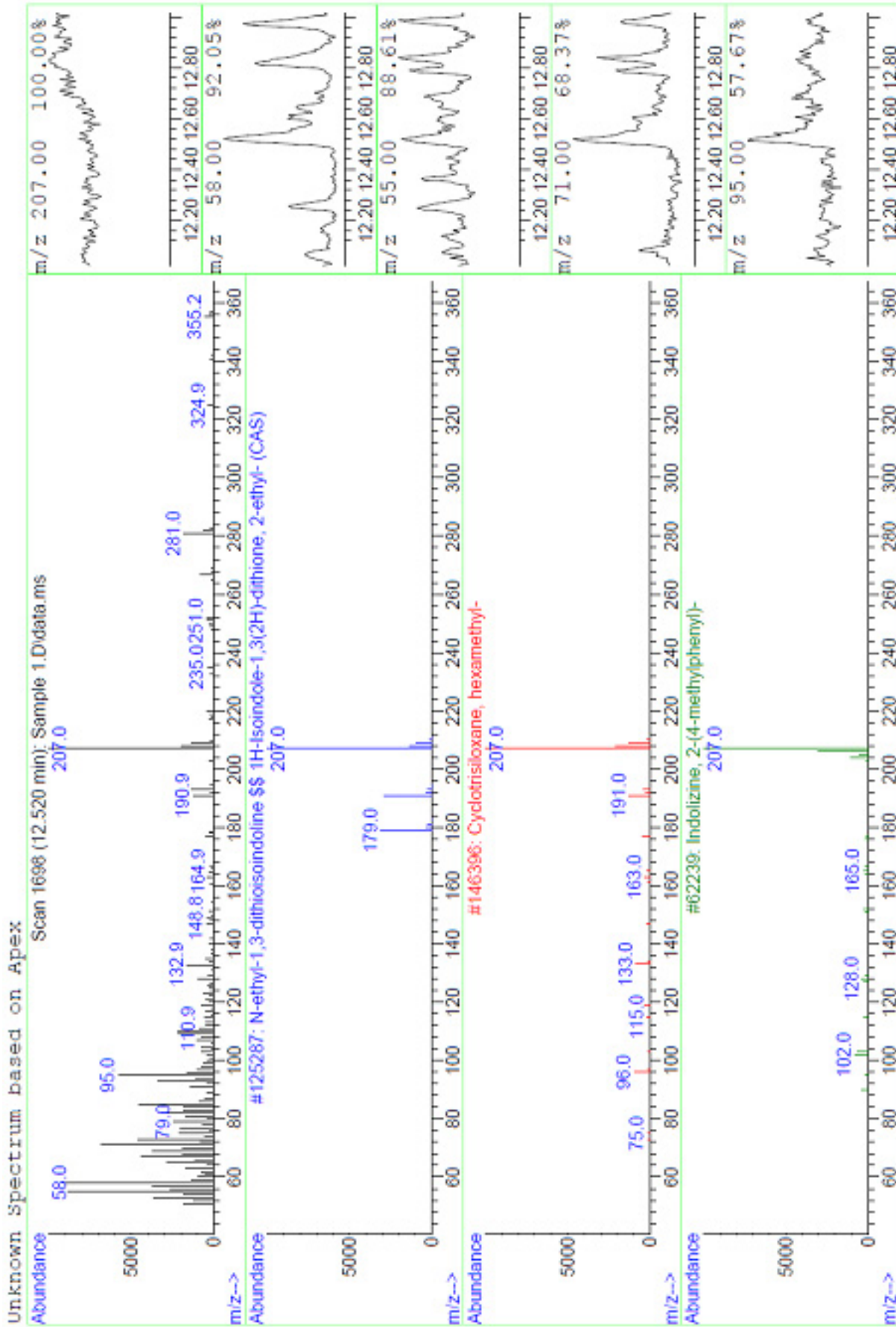
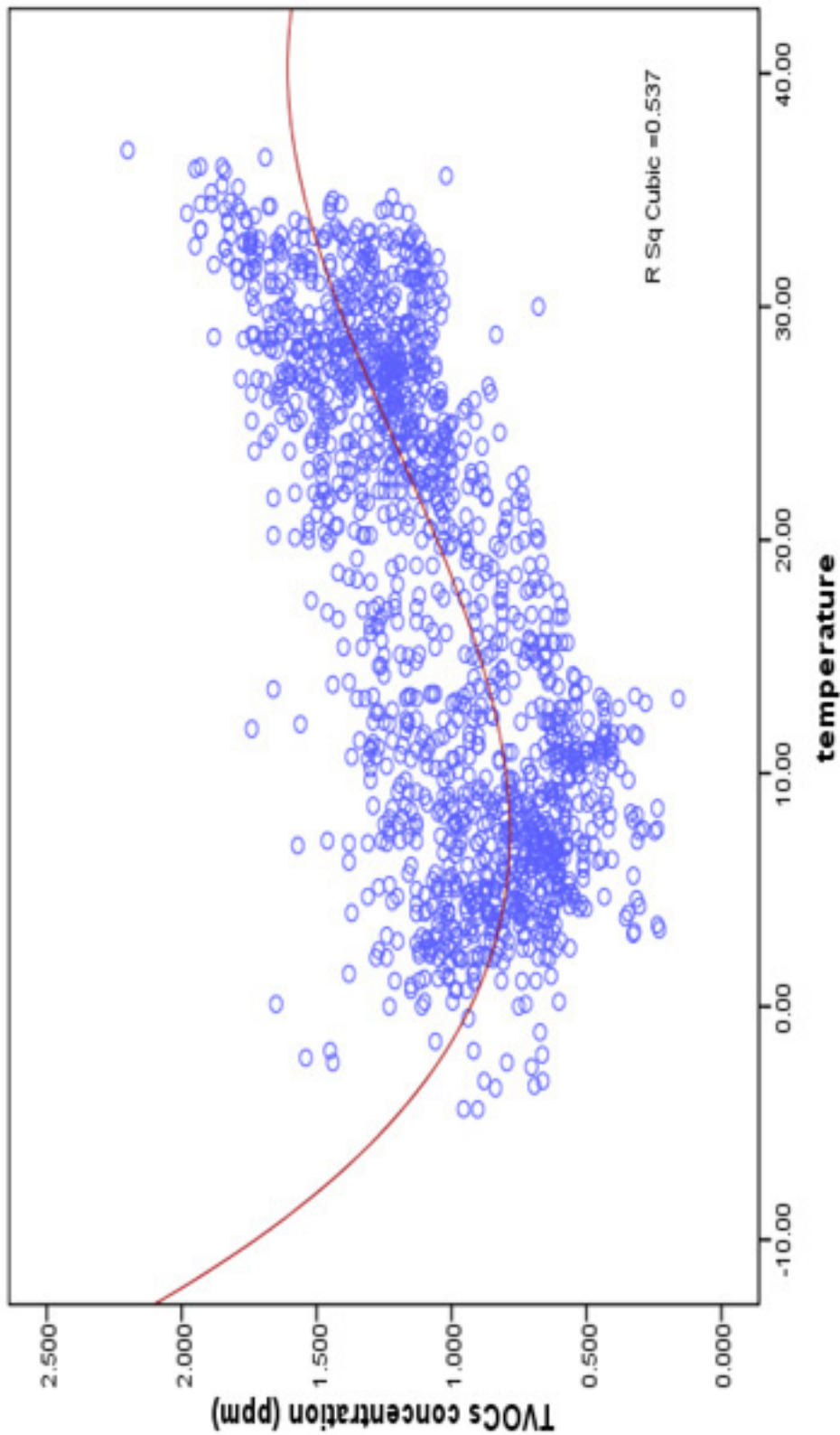


Figure 3 depicts the effect of air temperature on the TVOCs concentration in the air of Yasuj city. Based on this figure, the TVOCs concentration was enhanced with increasing temperature over 10°C.

**Figure 3: Effect of air temperature on the concentration of total volatile organic compounds**





## Discussion

According to the results of this study, the maximum TVOCs concentration was observed in the afternoon hours of midweek days. The findings from this study are consistent with research of Sarkhosh et al. in Tehran, Iran, and Na et al. in Seoul, South Korea, based on the high VOCs concentration in the afternoon (2, 9).

The results of this study show that the TVOCs concentration was higher in the warm season compared to the cold season. Nguyen et al. during a study in Korea measured 56 kinds of VOCs in the air. Based on these results, the highest VOCs concentration (aromatics except for benzene) was found in summer (10). One reason for the increased VOCs concentration in the mentioned periods has been the temperature increases. As the results this study showed, the TVOCs concentration was elevated with increasing temperature. The reason for this can be attributed to increased evaporative emissions from vehicles and other sources of these compounds due to temperature rise. However, other factors can also be involved in this regard, such as frequent daily travels, increasing the likelihood of temperature inversion, reduced precipitation and pollutants washing in the warm seasons.

In this study, the type of the VOCs in the air of Yasuj city was evaluated as well. Based on the results, the most abundant of the VOCs in the air of the city are composed of aromatic hydrocarbons. The studies Sarkhosh et al. in Tehran, Iran, and Nguyen et al. in Korea, also showed that the highest VOCs concentration in the air of these cities was related to aromatic compounds (2, 10).

According to Geng et al. in Shanghai, China, and Tie et al. in Mexico City, aromatic compounds were the major causes of ozone formation in these two cities (11, 12). Among the factors affecting the increase in the concentration of these compounds in the air, it can be pointed to human activities such as vehicles fuel, residential heating demand, cooking in homes, industrial and production activities.

## Conclusion

With regard to the adverse effects of volatile organic compounds on human and environmental health as well as the role of these pollutants in the formation of photochemical oxidants, appropriate actions should be considered to reduce air pollution in the cities; for example, the use of natural gas instead of petrol, vehicle exchange program, regulations of vehicle control like vehicle technical examination, the expansion of green spaces around the squares and streets of the city and so on.

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# Haemovigilance System Quality After Establishment of Patient's Safety Standards: Quality of Patient Identification, Blood Typing, and Transport and Conservation of Blood and Blood Components

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## Abstract

**Field:** Patient safety friendly hospital initiative incorporates a set of patient safety standards such as the critical standard of safe blood and blood components in the group of safe clinical service standards based on evidence. Haemovigilance is a country-wide surveillance system for monitoring the health of blood and blood components in all the stages of blood transfusion from the donors to the recipients, the collection and analysis of the data related to the undesirable effects of blood transfusion, and issuing alarms in order to correct and take the necessary measures to prevent the repetition of such effects. The present study was an attempt to investigate the quality of patient identification, and transport and conservation of blood and blood components after the establishment of patient safety standards.

**Materials and methods:** The study was conducted in two consecutive steps on one group of patients in Baharloo Hospital of Tehran, Iran. The data collected in 2011 (the beginning of the establishment of patient safety standards) were compared with those collected in 2016 (5 years after the establishment of the standards). As many as 100 blood bags estimated by Cochrane's formula were collected using the collection checklist and were compared with the data belonging to the beginning of establishment of this system. Data analysis was conducted using descriptive statistics indices, paired t-test, and SPSS 22 software.

**Findings:** The finding of the present study revealed that the mean of indices evaluated after the establishment of patient safety standards was higher than that obtained at the beginning of the establishment of the

standards. Using paired t-test, this increase in mean was found to be statistically significant for each of the indices ( $P < 0/01$ ).

**Conclusion:** The results demonstrated that the establishment of patient safety standards can exert a significant effect on the quality of patient identification, blood typing, and the implementation of tests for determining ABO compatibility and blood transport and conservation in the haemovigilance system.

**Key words:** Haemovigilance System, Patient Safety Standards, Patient Identification, Blood Typing, Transport and Conservation.

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## Introduction

Blood health, as a global concern, particularly in developing countries, addresses all aspects of the transfusion chain. (1)

According to the International Haemovigilance Network, the definition of haemovigilance may be 'a set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood components, and to prevent their occurrence or recurrence'. (2)

Haemovigilance in its broader sense encompasses other important aspects of transfusion safety; surveillance of donors to ascertain the residual risks of transfusion-transmitted infections, traceability of transfused blood components, monitoring of blood utilization, epidemiology of transfused patients, and monitoring of the hazards of blood conservation. Compilation of this information, together with clinical assessment of transfused patients, has the potential to provide much-needed evidence of the outcomes, risks and benefits of blood transfusion, and transfusion alternatives.(3)

Since establishment of the first national haemovigilance system in France in 1994, such systems have identified issues requiring attention and helped improve blood product safety and transfusion processes. (4)

Limited conservation time and processes such as blood health screening, determining the group and cross-matching which require costs for employing personnel and laboratory equipment, add to the importance of proper blood request and utilization (5). Cold chain in blood transfusion is a set of crucial and integrated activities in which equipment and manpower play a significant part, such that inefficiency in each section of the chain results in serious disorder in its performance (6). Hence, establishing a multiple surveillance system to re-investigate blood transfusion stages enhances the safety of this activity (7). Disorder in the cold chain may be due to various reasons such as lack of standard equipment such as standard transport boxes and fridges and freezers designed to conserve blood and blood components, and lack of practical standard instructions, lack of surveillance and monitoring over the process of transport and conservation of blood and blood products (8).

A Less common form of haemovigilance is the direct observation system, based on direct observation of transfusion by appropriately trained technical staff at the patients' bedside and verification of adherence to standard operating procedures.(9)

In the blood transfusion chain, there may be numerous errors in the stages of transportation, request, and transfusion of blood and blood components. Most of these

errors are non-technical. By rechecking and correcting operation methods in such processes, such errors can be prevented and the side effects of the transportation of blood and blood products can be reduced (10). The causes of the errors in the blood transfusion chain include: incorrect transfusion (the patient does not need blood or blood products but they are transfused to him/her); lack of identification of patient during sample collection or during the transfusion of blood and blood components into the patient; incorrect labeling; errors in the transport of blood from the blood bank to the hospital or hospital wards; errors in the transfusion of blood or blood components-not following blood conservation, storage and transport principles-; and technical errors (such as experiments conducted incorrectly) (11, 12).

The patient safety friendly hospital initiative started in 2007 with the aim of tackling the major problem of unsafe care in this area. This project has been designed as a useful instrument for evaluating patient safety by considering different aspects of patient safety and drafting standards in each aspect. (13) A critical standard which falls into the category of evidence-based safe clinical service standards is in the field of safe blood and blood component transfusion. (14)

Based on numerous problems and errors in the blood transfusion chain, since the establishment of healthy blood and blood component transfusion safety standard in patient safety friendly hospitals in 2007 by the WHO Regional Office for the Eastern Mediterranean, no research has attempted to correctly implement this standard and correctly control the operation methods of this process in Iran.

In order to enhance the health of patients who undergo blood and blood component transfusion, and to reduce the undesirable events and reactions caused by the transfusion, it is essential that the activities of the blood bank including the processes, equipment and staff be monitored and standardized. (15)

This study was an attempt to help enhance patient health and safety and to assess one of the vital standards of patient safety at Baharloo hospital, Tehran, Iran, which is a patient safety friendly hospital which started to establish this system as a pilot investigation so as to monitor the implementation of methods pertaining to the stages of patient identification, blood typing, and blood and blood component transport and conservation in the haemovigilance system, to assess and monitor the enhancement of this system since the establishment of the system, to investigate the existing impediments, and to attempt to modify the processes according to the standards of WHO and Blood Transfusion Organization so as to create an index for measuring in other systems and to take appropriate measures nationally.



## Materials and Methods

In order to do this research a One Group Pre-test / Post-test Design study was conducted to evaluate the quality of implementation of the haemovigilance system in Baharloo hospital in Tehran, Iran. For this purpose, the data of the year 2011 (the beginning of the execution of the standards) were compared to that from year 2016 (5 years after the implementation of the standards).

The statistical population contained all the blood bags used at the hospital since the execution of the patient safety standards at the Baharloo hospital up to the present (from year 2010 to 2016). Convenience sampling was used to select the samples. The data were collected during July through to November of the year 2016. The sample size was estimated using the Cochran formula.

The data were collected via a checklist which contained 3 dimensions and 27 items checking blood and blood's components safety. The items of the checklist were developed using different sources such as the Iranian Blood Transfusion Organization checklist for evaluation of haemovigilance system, the WHO's checklists, blood and component monitoring checklist used by several Iranian hospitals, interviewing the training supervisor and the blood transfusion experts of the hospital's blood bank, and Patient Safety assessment manual book(26). A three point Likert scale (i.e. 1= weak, 2= moderate, and 3= good) was used to score the items of the checklist. The experts' opinion was used to validate the checklist. The data were collected through direct observation which began since the announcement of the blood and blood component request until the completion of injections or the return of blood to the hospital's blood bank .The data were analyzed using paired t-test.

## Findings

The findings revealed that the mean gained score for the quality of patient identification, quality of blood typing and the conduction of ABO compatibility test, quality of blood and blood component transport and conservation at the hospital after the establishment of patient safety standards (2016) was considerably higher than that at the beginning of the establishment of the standards (2011) (Table 1 and Diagram 1). In addition, according to the results of the paired t-test, this difference is statistically significant (Table 2).

In order to help better understand the results of the related indices in Table 1, the mean scores obtained at the beginning of and after the establishment of safety standards are presented in Diagram 1 (page 264).

## Discussion

No study was found to share the focus of the present study in the literature. However, numerous studies have been conducted on the use of some strategies for healthy blood transfusion into patients, including studies conducted to 'determine the quality of patient identification during

sample collection, labeling blood bags, and blood and blood component transfusion'.

Use of machine-readable identity control technology, particularly based on a barcoding system, is an appropriate tool for patient bedside control. Experience at Juntendo university hospital has shown that barcode identity control system had a good performance at a hospital with 70,000 blood and blood component transfusions without even one case of error, and the system's compliance was 99 percent.

Bernardello, et al (2009), introduced a secure blood system to guarantee the traceability of the transfusion. This system records the various stages of the transfusion process, the health care workers involved and any immediate transfusion reactions. The patients and staff are identified by fingerprinting or a bar code. The system was implemented within Ragusa hospital in 16 operative units (ordinary wards, day hospital, operating theatres). In the period from August 2007 to July 2008 blood components were transfused within the hospital, of which 5,606 (77%) used the secure blood system. Overall, 1,777 patients were transfused. In this year of experience, no transfusion errors were recorded and each blood component was transfused to the right patient. The secure blood system guarantees complete traceability of the transfusion and also the ability to identify the wrong patients or blood components. The use of fingerprinting to identify health care staff (nurses and doctors) and patients obliges the staff to carry out the identification procedures directly in the presence of the patient and guarantees the presence of the doctor at the start of the transfusion. (17)

Unfortunately according to the reports of the National Haemovigilance Office (2011) about some serious adverse events in the year 2011 (135 cases), 26 cases were due to transfusion of an incorrectly labeled component, 17 cases were due to incorrect component/ production transfused, 6 cases were due to transfusion of incorrectly stored component, 3 cases of incorrect ABO group transfused, 1 case of incorrect RhD group transfused and 20 cases of unnecessary transfusion.(18)

According to a report titled "transfusion of incorrectly labeled unit" by National haemovigilance office (2011), 4 cases of unit labeling errors on SD plasma, 6 cases of Data entry error on laboratory information systems, a case of laboratory information systems information technology error, no blood group on label in hospital's blood bank, and 4 cases of transcription error at sample collection and a case of transcription error at initial admission in clinical area have been the serious adverse events that have occurred.(18)

According to Escoval, et al's research (2014), in member countries of Europeancommunity, about the component label information, have shown that, in 100% EU and Non EU countries the following information is installed on the components: official name of the component, unique numeric or alphanumeric donation identification, name of

**Table 1. Results of indices relating to the condition of establishment of patient safety standards in terms of blood and blood component transfusion**

Evaluated indices	At the beginning of establishment		After establishment	
	Mean	Standard deviation	Mean	Standard deviation
1. Quality of patient identification during sample collection, labeling blood bags, and transfusion of blood and blood components	4.22	1.087	6.63	0.794
2. Quality of blood typing and implementing ABO compatibility test	1.22	1.010	3.96	0.196
3. Quality of transport and conservation of blood and blood components at the hospital	5.52	1.049	12.90	0.301
3.1. Quality of conservation of blood and blood components in the blood bank fridge and controlling the fridge temperature	2.38	0.599	5.00	0.000
3.2. Quality of blood transport from the blood bank to the ward	1.60	0.568	5.90	0.301
3.3. Quality of conservation of blood and blood components at the ward	1.54	0.539	2.00	0.000

**Table 2. Paired t-test results**

Investigated indices	Results of paired t-test prior to and after establishment		
	Test result	Degree of freedom (pdf)	t
1. Quality of patient identification during sample collection, labeling on blood bags, and transfusion of blood and blood components	0.000	99	17.45
2. Quality of blood typing and implementation of tests to determine ABO compatibility	0.000	99	26.83
3. Quality of transport and conservation of blood and blood components at the hospital	0.000	99	65.53
3.1. Quality of the process of conservation of blood and blood components in blood bank fridges and adjustment of the fridge temperature	0.000	99	46.71
3.2. Quality of blood transfer from the blood bank to the ward	0.000	99	65.24
3.3. Quality of conservation of blood and blood components in the ward	0.000	99	8.52

**Diagram 1. Results of indices relating to the condition of establishment of patient safety standards in terms of blood and blood component transfusion**



producing establishment, ABO group, Rh D group, date or time of expiry. Volume, weight or number of cells in the component observed 89.5 % in EU and 90.9 % in Non EU countries. Storage temperature has been observed 89.5 % in EU and 81.8 % in Non EU countries. Name, composition and volume of anticoagulant and/or additive solution have been stated 100 % in EU and 72.7 % in Non EU countries. 70% (73.3% in the EU) use a single national coding system for blood components and 50% (57.9% in the EU) apply International Society of Blood Transfusion (ISBT) 128. (19).

According to the study by Robillard (2011), in Canada's haemovigilance system, there has been 29.3%, 7.9%, 1.4%, and 1.6% of error in sample collection, use of samples, characteristics of the donors, and request for blood and blood components, respectively. Of all the errors and mistakes reported, 6% have occurred in registration and labeling the products and 4.3% have been related to the reception of the wrong samples. (20)

Results of the study by Moshi et al.'s (2006) in the South African national blood service has shown that, 2 cases were reported from misidentification at collection and 10 from misidentification at transfusion. Also 2 cases from issuing the wrong blood for the wrong patient were reported. (21) Serious Transfusion Incident report (2010) reported 11 cases of near miss events (out of 26 cases) in labeling and documentation. (27)

Callum et al. (2011) stated that 15.5% of 122 hospitals noted at least annual occurrence of incorrect registration. In a report from a hospital that requires ABO-confirmation on all new patients, a 10 % AB-mismatch was observed when compared to the historic group related to patient registration errors. In a report of the details of 118 ABO-discrepancies at 35 hospitals in France, 5% were attributable to registration errors.(22)

Bolton-Maggs and Cohen (2013), showed in their research that where audits have been repeated, progressive improvements in standards can be shown. For example the 2011 re-audit of bedside administration showed an improvement in the numbers of patients wearing wristband at the time of transfusion, and better monitoring. Overall, the percentage of patients wearing a wristband had increased from 86% in 2003 to 99.5% in a 2011 audit. The recent audit shows that there were still problems, particularly in pediatrics where children and neonates were less likely to be wearing wristbands (absent in 9.5% and 12.9% respectively) than adults (absent in 1.8 %).(23)

Koh (2011), too, recommends the using of robots, barcodes, identification based on radio frequency, computer-assisted transfusion management system, and computer assisted system for blood utilization to determine the identity of patients in whole blood transfusion processes and thus reduce possible errors. (24)

Therefore, pre-transfusion bedside control of the patient is the most vital step in predicting the wrong transfusion. Human errors are the most common cause of bedside identity control errors, which can be reduced using optimal strategies. (16)

Investigation of the literature shows that no study has been conducted on the 'quality of blood typing and ABO compatibility tests'. However, numerous studies have investigated the reports of errors in blood typing and tests. Those studies show that transfusion of incompatible blood leads to the most acute transfusion reactions.

In addition, according to a global database on blood safety for 2011 from 148 countries, WHO (2013) stated that the reasons for discarding donated blood included expiry (33.4%), incomplete whole blood collections (21%), processing problems (13.6%) and problems during storage (3.1%) (25).



In their study on acute blood transfusion reactions, Teimoori Naghdeh et al. (2007) maintained that the ABO compatibility has been 0.03% which is higher than the global statistics (0.004%). (26)

According to National Haemovigilance Office Report (2011), near miss events which occurred at the hospital blood bank in 2011 were 44 cases. In the report of cases of near miss and mandatory serious adverse events reported in 2011 (60 cases), there were 9 cases of errors in testing donations, 11 errors in processing, 1 case of error in storage and 22 cases in distribution. Also, in the report of serious adverse events (135 cases), there were 5 cases of transfusion of other antigen incompatible RCC, 3 cases of transfusion of expired component, and, in the report of "transfusion of incorrectly labeled unit", there were 10 cases of transposition of labels in a single crossmatch and 1 case of no blood group on label in hospital's blood bank. (18)

According to the Serious Transfusion Incident report (2010), from 26 reports of near miss events, 5 reports were declared related to the laboratory. (Failure to have blood available resulting in delay of transfusion and transcription error in laboratory system)(27)

According to the study by Escoval, et al. (2014), in the EU countries, in all European and non-European countries, blood type and Rh group were mentioned as the information of blood component labeling.

In their study on the serious risks of blood transfusion in England, Taylor et al. (2009) reported that in 2009 the total numbers of reports were 1,279 cases which had undergone an increase of 23% as compared to the year 2008 (1,040 reports). Of these errors, 230 cases were related to the initial measures taken by the laboratories' blood banks at the hospitals, which also accounted for 18% of the reports in 2008. Besides, the number of laboratory errors (accounting for 149 out of the 282 cases of wrong blood transfusion which accounted for 53% of the reports in 2009) had increased in comparison to the 50% in 2008. (28)

Robillard (2011), in his research stated that in the period between 2003 and 2005, all Quebec hospitals were progressively computerized with the same blood bank software. Thus, each hospital can query the blood bank database of all other hospitals to see if the patient is present and information such as blood group, previous transfusions, previous transfusion reactions, and special requirements will appear on screen. Also according to the type of errors reported, laboratory errors and mistakes are as follows: sample reception (4.3%), sample testing (12.6%), unit selection (0.3%), unit manipulation (2%) and unit storage (5%).(20)

Results of the study by Moshi et al. (2006) in the South African national blood service have shown that 53.57% reports were due to laboratory errors, and a significant increase in failure to identify antibodies was observed in comparison to the data obtained in 2005. (21)

Callum et al (2011) in a blood research reported that 28 cases of ABO typing errors had been observed by the identification information systems in 26 hospitals in the Pittsburgh area over a 2 year period. The yield was impressive; they detected 28 major ABO typing errors at 16 hospitals served by their information system. In 8 cases, the sample collection error could have led to an ABO-incompatible transfusion reaction, had the error not been detected. A similar system has been implemented in the Province of Quebec, Canada, and has been associated with a decrease in the incidence of acute and delayed haemolytic transfusion reactions. (22)

Also, in another study on the role of follow-up in the blood bank activities by auditing and training the blood bank staff of the hospitals, Sharifi et al. maintained that standard blood typing, cross match test, and quality control between the two inspections had an increase of 19, 21 and 10 percent in state hospitals and 12, 17, and 5 percent in the private hospitals, respectively. (15)

With respect to 'quality of transport and conservation of blood and blood components at the hospital', the findings of the present study revealed that the establishment of safety standards has a considerable impact on this aspect.

Investigation of the literature showed that no study has shared the focus of the present study. However, numerous reports have been issued regarding the quality of transport and conservation. For instance, according to the global database on blood safety for 2011 from 148 countries, WHO (2013) indicates that 3.5 million blood donations were discarded out of the 67.3 million whole blood donations reported, and that 0.9% of it was caused by error in transportation.(25)

In their study, Asadi Fakhr et al. (2012) demonstrated that only a small number of the employees (3.3%) are sufficiently aware of the procedure and condition of conservation of blood and blood components, and 96.7% of them make performance errors. (29)

In their study, Teimoori Naghdeh et al. (2010) showed that 34 percent of hospital blood banks lack standard conditions, which can be due to lack of special blood bank freezers; and, that only 66 percent of the hospitals enjoyed defined standard conditions. This has led to inconvenience and low quality of conservation of blood and blood components at the blood bank. (30) Sharifi et al. in their study reported that the indices related to the 'establishment and utilization of special blood bank equipment such as fridges, freezers, platelet shaker incubators' improved in the interval between the two inspections by 42%, 32%, and 9% at state hospitals and by 28%, 17% and 8% at private hospitals. Besides, they maintained that periodic audits together with training and informing the blood bank staff of the use of standard methods and renewing blood bank equipment have played a significant role in this regard. (15)

According to the Annual Reporting of Serious Adverse events and reactions (SARE) 2013, in the 26 member states in 2011, 2,953 adverse events were reported in

total, of which 200 events (6.77%) were due to processing, 336 events (11.38%) were due to storage, 320 events (10.84%) were due to distribution, 76 events (2.57%) were due to materials, and 764 events (25.87%) were due to compatibility testing, transport, information technology, system errors and bacterial contamination.(31)

Also, Taylor et al. (2009) in their study of England's blood transfusion serious risks program reported that the number of storage errors was 196 cases in 2009, which had increased by 41% in comparison with that in 2008. Of course those errors have not caused death or disease, and no deviation before transfusion had been recorded. (28)

According to the National Haemovigilance Office Report regarding mandatory serious adverse events reporting (2011), 57 cases of adverse events had occurred at the blood banks of hospitals involved in transfusion of blood units, of which 6 cases of errors had occurred during the storage in Red Blood Cell Components. Also, of the mandatory near miss events accepted from hospitals' blood banks in 2011 (44 cases), 7 cases were due to errors in storage (3 cases due to human error and 4 cases for unknown reasons) and one case was due to errors in distribution (human error). (18)

Robillard (2011) also stated that 5% of errors reported in the laboratory were caused by errors in storage and 1% were caused by errors in distribution.(20)

According to the Serious Transfusion Incident report (2010), of 26 near miss events, 2 were due to error in storage and handling and 1 was due to inappropriate blood component distribution.(27)

The reports indicate that most errors and mistakes are due to the shortage of equipment, inefficient training and supervision by the authorities. Periodic audits, training and providing information as well as application of standard methods can play a significant role in correcting these errors. (15)

Considering the above discussion, it can be argued that blood safety officers and other similar roles serve as the key module of the haemovigilance team in many countries. Sufficient laboratory and medical support is essential for all hospital activities. (22)

There is also the need for a clear and concise informed consent process, and an established guideline for the appropriate infusion rate, with adequate monitoring of vital signs. The process of blood transfusion into a patient includes numerous steps, and if individuals do not remember each and every step, failures in the host will always be inevitable. (22).

Effective patient blood management means optimal use of blood and blood components through appropriately set standards and guidelines that produce the right unit of blood for the right patient at the right time and under the right conditions. Sadly, low policy implementation rates, inadequate financial resources and the lack of

trained human resources in many countries are barriers to appropriate Patient Blood Management. (32)

The transfusion community has a proven track record in facilitating the huge progress in blood safety and it is time that we re-focus our process improvement projects closer to the bedside. (22)

In this line, hospital transfusion committees should oversee haemovigilance activities and reporting, and ensure that hospital senior management is aware of, and responds to, serious reactions and events, especially where systems issues are contributory. (33)

Kasraian (2014) demonstrated that physicians and nurses have insufficient information about blood transfusion medicine, and training can increase their information in this respect. (34)

Research of Siddiqui et al (2012), show that the PSFHI provides compelling evidence that assessment of patient safety standards in hospitals is feasible and applicable even in resource-poor settings. Implementation of the patient safety standards has increased the level of awareness of participating hospitals as well as patients. Most of the safe and evidence-based critical standards of the domain of clinical services (mean 63%, range 14-86%) are met by many hospitals and need more improvements in their levels. (35)

## Conclusion

Establishment of patient safety standards can exert a considerable effect on the quality of patient identification, blood typing, implementation of ABO compatibility test, and the transport and conservation of blood and blood components in the haemovigilance system. Therefore, it is recommended that patient safety standards be appropriately established for blood and blood components at other similar hospitals, as well.

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# Effect of Hybrid Aromatherapy on Sleep Quality of Patients with Acute Coronary Syndrome Admitted to Cardiac Care Unit

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## Abstract

**Background and objective:** Sleep disorder and reduced rest during admission to hospital is a stimulating factor of heart attacks in coronary artery disease patients. There are different ways to improve sleep quality.

**Method:** Aromatherapy is one of the methods used to improve sleep quality. This study determines the effects of hybrid aromatherapy on sleep quality of patients with ACS admitted to CCU. This clinical trial was conducted in 2016 on 60 patients diagnosed with ACS and admitted to CCU of the 22 Bahman Hospital, Gonabad. The patients were recruited by using convenient sampling and assigned randomly to control and experiment groups.

**Results:** The experimental group received aromatherapy with a combination of essential oils of lavender, *Matricaria recutita* and neroli (6:2:0.5) for three consecutive nights; the control group received no intervention. At the beginning and the end of the study, visual VSH scale was filled out to assess sleep quality. The collected data was analyzed by using SPSS20, independent t-tests, Chi-square test and exact Fisher test ( $p < 0.05$ ). Each group contained 30 samples who were not significantly different in terms of underlying characteristics ( $p > 0.05$ ).

**Conclusion:** There was a significant difference in mean score of post-interventional and pre-interventional sleep quality, effectiveness and sleep supplementation ( $p < 0.001$ ). The mean score of sleep quality and sleep supplementation increased in the control group and decreased in the experiment group, while the mean score of sleep effectiveness decreased in the control group and increased in the experiment group. The results showed that hybrid aromatherapy as a cost effective and uncomplicated method can improve sleep quality of patients with ACS admitted to CCU.

**Key words:** aromatherapy, sleep quality, acute coronary syndrome

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## Introduction

More than any other diseases, ischemic heart diseases cause mortality and disability in developed countries and impose economic costs. Ischemic heart diseases are the most common, the most serious, the most chronic and the most dangerous diseases in the United States where 13 million people suffer from these diseases. More than 6 million people suffer from angina pectoris and more than 7 million people have had a myocardial infarction. High fat and energy diet, smoking and sedentary lifestyle are associated with prevalence of cardiovascular diseases. [1] In Iran, incidence of cardiovascular diseases is high, accounting for 90 thousand deaths annually. According to available statistics, 46% of mortalities are caused by cardiovascular diseases. According to the Ministry of Health and Medical Education, about 39% of all patients referred to healthcare centers suffer from cardiovascular diseases. [2] Acute coronary syndrome (ACS) is a manifestation of coronary artery disease which includes a wide range of diseases including unstable angina pectoris, non ST-segment elevation MI and ST-segment elevation MI. [3] Patients who are restricted to a particular treatment environment due to a therapeutic problem are both exposed to sensory overload and sensory deprivation. An important category of these patients includes those who are admitted to intensive care units and are prone to both problems, namely, sensory deprivation and sensory overload due to exposure to a high-noise environment and constraint of movement caused by being attached to different devices; this can in some cases lead to psychosis in the intensive care unit. [4] The occurrence of acute diseases, regardless of their origin, makes the patient susceptible to psychological and physiological complications. When providing care to critically ill patients, the focus is on prevention of complications related to the disease, including mental health problems such as hallucinations, depression, anxiety and sleep pattern disturbances. [5] One of the important components of the human lifestyle is sleep and rest. Sleep is one of the most important circadian cycles [6], and is the basis of physiological processes. [7] Illness and hospitalization are closely related to sleep disorders; a majority of patients complain of sleep deprivation and sleep disorders in the first three nights of admission and a majority of patients consider several causes for sleep deprivation, although severity of effect of these factors is different. [8] Generally, diseases can have negative effects on sleep or, conversely, low sleep quality can lead to symptoms in the individual. [9] Hospitalization specifically causes disturbances in sleep patterns and insomnia. [10] These disturbances may be caused by various external factors such as environmental noise, light, frequent interventions of personnel, and inappropriate bed conditions or internal factors such as pain, delusions, depression, and stress. [11] Sleep medications are the first line of treatment for insomnia which can potentially cause severe side effects. [12] Although these medications may induce or prolong the sleep process, sleep quality may still remain low. Additionally, the use of these medications can lead to complications such as resistance to effect of the drug, as

well as symptoms of discontinuation during the sudden withdrawal of the drug, and sometimes exacerbated sleep disorders. [13] Alternative therapies such as acupressure, acupuncture, aromatherapy, therapeutic touch and music therapy are effective therapies on sleep disorders. [12] One of these treatments is aromatherapy. One of aromatherapy techniques is the inhalation of essential oil by applying essential oils on the clothes or pillows of patients. [13] Aromatherapy refers to the use of volatile oils or aromas extracted from aromatic plants for therapeutic purposes. This treatment is the second complementary medicine among nurses and it is widely used in clinical practice. [9] Application of complementary therapies such as aromatherapy is part of the nursing professional goals. Unlike clinical therapies, complementary therapies, in spite of being economical, lack any serious complications and drug interactions in most cases and they are simple and well-accepted by the patient. [15] Aromatherapy is used to relieve pain, anxiety, depression, insomnia, fatigue, asthma, and even provide self-confidence, success, and creativity. [16] *Matricaria Chamomilla* is a plant used in traditional medicine to help sleep and relax. Traditionally, *Matricaria Chamomilla* has been used in different parts of Iran due to its fever-lowering effects, effects on nervous and immune systems, sleep, sedation and analgesia. [17] One of fragrances highly used as a sedative is *Lavandula angustifolia* from the family Labiatae; its effective ingredients include linalool and linalyl acetate. Linalool acts as a sedative by influencing gamma-Aminobutyric acid receptors in the central nervous system [18], while linalyl acetate has a narcotic function. [19] Another fragrance is neroli; in traditional medicine of Iran, neroli is known as a sedative and sleep booster. A study on the effect of aromatherapy with neroli essential oil on sleep quality of patients hospitalized in the cardiology ward showed that although this treatment could improve all aspects of hospital sleep, this type of aromatherapy can be considered as a new treatment for patients with sleep disorders due to its effect on quality and depth of sleep. [13] These studies show that lavender, chamomile and neroli are effective in improving sleep quality. Due to the emphasis on aromatherapy, however, it is more beneficial to use a combination of herbal essential oils rather than to use them separately. [32, 33] It seems that the combination of these three essential oils is more effective in improving sleep quality. Therefore, this study tends to examine the effect of inhaled aromatherapy using a combination of essential oils of lavender, chamomile and neroli (6:2:0.5) on sleep quality of patients with acute coronary syndrome admitted to CCU for three days. If the result is positive, it can be used as a simple, inexpensive, available, effective and acceptable treatment for patients. It is worth noting that complementary therapies also lead to independence of the patient and can be used by the patients themselves with simple tools.

## Literature review

Through a pre-test and post-test quasi-experimental study with a control group, Atashi et al. (2015) examined the effect of aromatherapy with rose-red essential oil on sleep quality of athletes before competition. The statistical population included futsal players of the Islamic Azad University, Tehran Branch. Twenty players were selected by convenient sampling and divided into control and test groups. The instruments included demographic information questionnaire and Pittsburgh Sleep Quality Index. The test group received aromatherapy by red rose essence for 4 nights. Each night, three drops of red rose essence were instilled on their pillow and they inhaled the essential oil for 8 hours. The control group did not receive aromatherapy. People filled the Pittsburgh Sleep Quality Index on the morning of the fifth day (on the morning of the competition). This study showed that 4 nights of aromatherapy intervention had no significant effect on sleep quality of athletes before the competition. [23]

Moghadam et al. (2016) conducted a randomized clinical trial to study the effect of aromatherapy by lavender essential oil on sleep quality of ICU nurses. This study was conducted on 70 nurses working in ICUs in control and test groups. This study showed that inhalation of lavender essential oil had a beneficial effect on sleep quality of ICU nurses and could be used as a useful technique to improve sleep quality of these nurses. [24]

Najafi et al. (2014) conducted a clinical trial to examine the effect of aromatherapy with lavender on sleep quality of 60 hemodialysis patients referred to dialysis centers of Akhavan Kashan and Shohadaye Langjan Hospitals of Zarinshahr Hospitals. The patients were selected by continuous sampling. By using block randomization, the patients were divided into test (30) and control (30) groups. This study showed that aromatherapy with lavender essential oil had a positive effect on sleep quality of hemodialysis patients and could be used as a non-invasive, easy and inexpensive method for treatment of sleep disorders in these patients. [25]

Zeighami et al. (2014) conducted a study to examine the effect of neroli essence on sleep quality of 60 cardiac patients admitted to CCU. This study was a clinical trial with control group, pre-test and post-test. Two CCUs were divided into control and intervention groups based on random assignment. Patients admitted to these wards were enrolled according to inclusion criteria. The results showed that aromatherapy with neroli essential oil had a significant effect on hospital sleeping quality of two groups ( $p < 0.05$ ). Findings of this study showed that aromatherapy with neroli essential oil can be used as an auxiliary treatment for sleep disorders in cardiac patients. [20]

### Hypotheses:

Aromatherapy is effective in reducing sleep disorder of ACS patients admitted to CCUs.

Aromatherapy is effective on sleep effectiveness of ACS patients admitted to CCUs.

Aromatherapy is effective in reducing sleep supplementation of ACS patients admitted to CCUs.

## Materials and methods

This study was a controlled clinical trial using random, parallel and single-blind methodology. Using convenient sampling, patients were recruited by considering and controlling variables and the intended parameters; then, the patients were randomly assigned to experiment and control groups. The experiment group was examined to determine the effect of hybrid aromatherapy on ACS patients admitted to CCUs. The studied population included patients diagnosed with ACS and admitted to CCU of the 22 Bahman Hospital, Gonabad. The sample included 60 patients diagnosed with ACS who were referred to the hospital for treatment and were willing to participate in the study. Considering data obtained from a similar study [24], sample size was estimated at 28 for each group using mean comparison formula at 95% confidence interval and 90% testability. By considering 10% likelihood of sample loss, 30 samples were selected for each group; totally, 60 samples were recruited for the study. Instruments and materials used for data collection included:

1) information form including demographic and underlying data such as age, gender, occupation, marital status, education, family size, frequency of hospitalization, known underlying diseases, administration of sedative drugs, level of daily activities, and drinks which are effective on sleep including tea or coffee and smoking; and physiological indices form before and after each course of aromatherapy:

2) **Verran and Snyder-Halpern Sleep Scale (VSH Sleep Scale):** this scale was developed by Snyder-Halpern and Veran in 1987 to measure individual mental responses to sleep in adult patients admitted to the hospital. This scale measures one's perception of last night. This scale was the best choice, since it is easy to respond to and requires minimal time and the least cost compared to other equipment and techniques. [26] This instrument is a 15-item visual scale which is filled out by paper and pencil and used to assess sleep of hospitalized patients. This scale measures one's perception of last night. VSH scale is a valid, valuable scale which includes various sleep parameters, such as sleep disturbances, wake-ups, difficulty in sleeping and sleep duration. The score of each item is from zero to 100 mm (it is graded every 5 mm) and participants mark their understanding of sleep at this distance. This scale measures sleep disturbance (sleep latency, interrupted sleep), effectiveness (how sleep is effective in creating happiness) and sleep supplementation (nap, day dreaming). Scores of these subscales are 0-700, 0-500 and 0-400. *Disturbance* measures interrupted sleep and sleep latency. *Effectiveness* measures sleep quality (relaxation and sleep depth) and sleep duration (sleeping hours in bed). *Supplementation* measures naps and sleep after waking up in the morning. For disturbance



and supplementation, higher scores indicate higher sleep disorder. For effectiveness, higher scores indicate better sleep. Arab et al (2013) used this questionnaire and confirmed its reliability by considering its Cronbach's alpha estimated at 0.78. [27]

Once the project was approved by the Regional Ethics Committee, Gonabad University of Medical Science (IR.GMU.REC.1394.61) and registered in the Iran Clinical Trial Center (IRCT2015122922682N4), the qualified samples were recruited. Written informed consent was obtained from the subjects. Samples were randomly assigned to experiment and control groups using permutation blocks (15 blocks of four) and random numbers table. Six possible scenarios (AABB, ABAB, BBAA, BABA, ABBA, BAAB) were listed. The number of blocks required was determined randomly, based on which subjects were assigned to experiment group (B) and control group (A). The author introduced himself and explained the objectives to patients. Written informed consent was obtained from the patients. The patients were asked to fill out a demographic data questionnaire. Records of the patients were completed; initial assessment was done. Sleep score of people was determined and recorded. Subjects were randomly assigned to experiment and control groups. Intervention (aromatherapy) was done for the experiment group. The control group received no intervention and only received routine care. The experiment group received usual drugs by nurses; then, they were exposed to a combination of lavender, *Matricaria recutita* and *neroli* essential oils (6:2:0.5) for three consecutive nights at 21:00. The patients or their relatives were asked to instill two drops of combined essential oils (Gorgan Giah-Essence Agro-industry and Pharmaceutical Company) contained in a dropper on a cotton ball. The cotton ball was then held under the nose of the patients. The patients closed their eyes and took 10 deep breaths. Then, the cotton was pinned to the collar of the subjects. The patients unpinned the cotton once they woke up and threw it away. The author practically illustrated to patients how and where they should pin the cotton. The control group did not receive any intervention during the study. Note that the research assistant, who studied and filled the hospital sleep questionnaire for the patient, had no other role in this study and was blind to the hypothesis and unaware whether the patient was in the control or experiment group.

Data was analyzed by SPSS20 ( $p < 0.05$ ). Kolmogorov-Smirnov test was used to determine normality of quantitative variables. Independent t-test was used to compare mean of normally-distributed quantitative variables including age, weight, height, number of children, sleep disturbances, sleep effectiveness and sleep supplementation in two groups. Chi-square test was used to compare qualitative variables including gender, income, education, occupation, residence, hospitalization history, underlying disease, history of sedative drugs and drug abuse. Where Chi-square test could not be used, Fischer's exact test was used to compare qualitative variables including marital status and pre-sleep drinking in the two groups.

## Results

### General Characteristics:

As shown in Table 1 (next page), independent t-test showed no significant difference in mean age of subjects in the two groups and these groups were homogenous ( $P=0.1$ ). There was no significant difference in mean weight of the subjects in the two groups ( $P=0.080$ ). There was no significant difference in mean height of the subjects in the two groups ( $P=0.16$ ).

As shown in Table 2, there was no significant difference in gender between the two groups ( $P=0.14$ ) and the two groups were homogenous. As shown in the table, there was no significant difference in income between the two groups ( $P=0.26$ ). According to Chi-square test, there was no significant difference in the occupation of subjects in the two groups ( $P=0.40$ ) and the two groups were homogenous. There was no significant difference in residence of subjects in the two groups ( $P=0.59$ ) and the two groups were homogenous. Moreover, there was no significant difference in hospitalization history between the two groups ( $P=0.20$ ) and the two groups were homogenous. There was no significant difference in underlying diseases between the two groups ( $P=0.79$ ). There was no significant difference in sedative drug use between the two groups ( $P=0.43$ ). There was no significant difference in drug abuse between the two groups ( $P=1$ ) and the two groups were homogenous. Moreover, Fisher's exact test showed no significant difference in marital status of subjects in the two groups ( $P=1$ ) and the two groups were homogenous. Hypothesis Testing:

As shown in Table 3, there was a significant difference in mean score of pre-interventional ( $P=0.005$ ) and post-interventional ( $P < 0.001$ ) sleep disturbance between the two groups; however, there was a significant difference in difference of pre-interventional and post-interventional score in the two groups ( $P < 0.001$ ). Mean of sleep disturbance increased in the control group and decreased in the experiment group. According to Table 3, there was a significant difference in the mean score of pre-interventional ( $P=0.01$ ) and post-interventional ( $P < 0.001$ ) sleep effectiveness between the two groups; however, there was a significant difference in mean difference of pre-interventional and post-interventional score in the two groups ( $P < 0.001$ ). Mean of sleep effectiveness decreased in the control group and increased in the experiment group. According to Table 3, there was a significant difference in mean score of pre-interventional ( $P=0.02$ ) and post-interventional ( $P < 0.001$ ) sleep supplementation between the two groups; however, there was a significant difference in difference of pre-interventional and post-interventional score in the two groups ( $P < 0.001$ ). Mean of sleep supplementation increased in the control group and decreased in the experiment group.

Table 1: comparison of age, weight and height of subjects in both groups

Age	N	Mean $\pm$ SD	Independent t-test
Control	30	58.90 $\pm$ 10.73	t=1.65 df=58 P=0.1
Experiment	30	54.33 $\pm$ 10.72	
Weight (kg)	N		
Control	30	69.30 $\pm$ 13.44	t=0.25 df=58 P=0.80
Experiment	30	68.53 $\pm$ 10.07	
Height	N		
Control	30	172.07 $\pm$ 7.50	t=1.41 df=58 P=0.16
Experiment	30	169.57 $\pm$ 6.17	

Table 2: Comparison of gender, income, occupation, residence, hospitalization, drug use, underlying disease in the subjects of both groups

Gender	Control N (%)	Experiment N (%)	Result
Male	25 (83.3)	20 (66.7)	$\chi^2=2.22$ Df=1 P=0.14
Female	5 (16.7)	10 (33.3)	
Total	30 (100)	30 (100)	
Income			
<1 million	23 (76.7)	19 (63.3)	$\chi^2=1.27$ Df=1 P=0.26
1-2 million	7 (23.3)	11 (36.7)	
Total	30 (100)	30 (100)	
Occupation			
Employee	9 (30.0)	11 (36.7)	$\chi^2=1.82$ Df=2 P=0.40
Self-employed	16 (53.3)	11 (36.7)	
Unemployed	5 (16.7)	8 (26.7)	
Total	30 (100)	30 (100)	
Residence			
Urban	18 (60.0)	20 (66.7)	$\chi^2=0.29$ Df=1 P=0.59
Rural	12 (40.0)	10 (33.3)	
Total	30 (100)	30 (100)	
Hospitalization history			
No	13 (43.3)	18 (60.0)	$\chi^2=1.67$ Df=1 P=0.20
Yes	17 (56.7)	12 (40.0)	
Total	30 (100)	30 (100)	
Underlying disease			
No	13 (43.3)	14 (46.7)	$\chi^2=0.07$ Df=1 P=0.79
Yes	17 (56.7)	16 (53.3)	
Total	30 (100)	30 (100)	
Sedative drug use			
No	10 (33.3)	13 (43.3)	$\chi^2=0.63$ Df=1 P=0.43
Yes	20 (66.7)	17 (56.7)	
Total	30 (100)	30 (100)	
Drug abuse			
Yes	5 (16.7)	4 (13.3)	Fisher's Exact Test: P=1
No	25 (83.3)	26 (86.7)	
Total	30 (100)	30 (100)	
Marital status			
Single	1 (3.3)	1 (3.3)	Fisher's Exact Test: P=1
Married	29 (96.7)	29 (96.7)	
Total	30 (100)	30 (100)	



**Table 3: Comparison of mean of sleep disturbance, effectiveness and supplementation before and after intervention in two groups**

Phase	Sleep	Control Mean $\pm$ SD	Experiment Mean $\pm$ SD	Independent t-test
Before	Disturbance	278.90 $\pm$ 113.09	369.83 $\pm$ 103.59	t=2.92; df=58; p=0.005
	Effectiveness	315.37 $\pm$ 68.05	266.10 $\pm$ 77.37	t=2.62; df=58; p=0.01
	Supplementation	171.27 $\pm$ 70.57	208.47 $\pm$ 50.66	t=-2.34; df=53; p=0.02
After	Disturbance	317.40 $\pm$ 82.17	131.47 $\pm$ 42.66	t=11.00; df=44; p<0.001
	Effectiveness	300.93 $\pm$ 53.87	408.93 $\pm$ 30.04	t=-9.59; df=58; p=0.001
	Supplementation	200.27 $\pm$ 58.35	76.20 $\pm$ 44.98	t=9.22; df=55; p<0.001
Difference before and after	Disturbance	29.50 $\pm$ 97.20	-238.37 $\pm$ 122.82	t=-9.37; df=58; p<0.001
	Effectiveness	-14.43 $\pm$ 66.64	142.83 $\pm$ 75.55	t=-8.55; df=55; p<0.001
	Supplementation	29.00 $\pm$ 71.55	-132.27 $\pm$ 66.69	t=9.22; df=58; p<0.001

## Discussion and Conclusion

This study examined the effect of hybrid aromatherapy on sleep quality of patients with acute coronary syndrome admitted to CCU. The results clearly show the beneficial effect of hybrid aromatherapy on sleep quality of patients with acute coronary syndrome admitted to CCU. Concerning the comparison of sleep disturbance, effectiveness and supplementation in the experiment and control groups, the results showed that hybrid aromatherapy decreases sleep disturbance by reducing mid-sleep awakenings, reducing movement during sleep, increasing sleep depth, reducing the time for getting ready for sleep and reducing sleep latency. Moreover, hybrid aromatherapy increases sleep effectiveness by increasing rest upon awakening, improving subjective quality of sleep, increasing sleep adequacy, and increasing total sleep period at night. Additionally, hybrid aromatherapy reduces sleep supplementation by reducing morning and afternoon sleep, and generally daytime sleep and full wake up after arousal. Different studies have proved the positive effects of aromatherapy in improving sleep quality of cardiac patients admitted to CCU. Hajibagheri et al showed that Rosa damascene aromatherapy can significantly improve sleep quality of heart patients admitted to CCU. According to this study, Rosa damascene aromatherapy reduces sleep latency and sleep disturbance and improves sleep effectiveness and quality and sleep duration. Moreover, it is effective in reducing daytime sleep disorder. [28] Moeini et al. found that lavender essence aromatherapy reduces sleep disturbance and thus increases sleep quality of patients with ischemic heart diseases admitted to ICU. [29] Although the above studies have examined the effect of different aromas on sleep quality of cardiac patients admitted to CCU, the main nature of all these studies has been aromatherapy in hospitalized patients. Therefore, the results and mechanisms noted in all of the above studies support current findings and show the positive effect of aromatherapy on sleep quality of patients admitted to CCU. Moreover, many studies have been done on effect of aromatherapy on sleep quality of other clinical and non-clinical conditions such as hemodialysis, postmenopausal women, students and nurses, all of which show a significant role of aromatherapy in improving sleep quality. Najafi et al. showed that lavender aromatherapy has a positive effect in improving sleep quality of hemodialysis patients.

[25] In this regard, Dabirian et al showed that inhalation of lavender essential oil has a beneficial effect on sleep quality of patients undergoing hemodialysis. Lavender essential oil inhalation improves sleep quality, including subjective sleep quality, sleep latency, sleep adequacy, sleep duration, sleep disturbance and daily dysfunction in hemodialysis patients. [30] Although condition of patients and people is different in these studies, all of these are consistent with results of the present study. In explaining improvement of sleep quality, according to the studies conducted, linalool present in lavender inhibits the release of acetylcholine and changes the function of ion canal in the neuromuscular junction site. In addition, linalil acetate has a narcotic function and linalool acts as a sedative. [31] Moreover, smell stimulant receptors in the nose convert the odour into nerve impulses and sends them to the limbic system. Based on literature, aromatherapy stimulates feelings such as pleasure, anger and anxiety and influences heart rate, blood pressure, respiration, activity of brain waves and release of hormones which regulate the amount of insulin, body temperature, stress, metabolism and hunger. Since the limbic system also influences the nervous system, smells can stimulate and release neurotransmitters and endorphins in the brain, which makes people feel good. [20] Finally, sleep is one of the most important elements in human life which is associated with rebuilding of physical and emotional powers. It is essential to maintain regular sleep courses to gain fitness and health. According to findings, aromatherapy improves sleep quality of patients with acute coronary syndrome admitted to CCU. These findings are clinically important in nursing care, since improving these indicators without medication is an important health care goal and can reduce the complications associated with drug interventions. Moreover, it is very important to improve sleep quality and other symptoms in these patients because of the reduced cardiac function, and to reduce and prevent progression of myocardial ischemia. Based on results of this study and the important role of aromatherapy in improving sleep quality of these patients and due to the high prevalence of this disease in all societies, since the aromatherapy is a cheap and simple nursing intervention, training and application of this treatment by healthcare providers, particularly nurses, can be an effective step to improve sleep quality of these patients and an opportunity for the health team, particularly nurses, to provide better care for these patients.



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