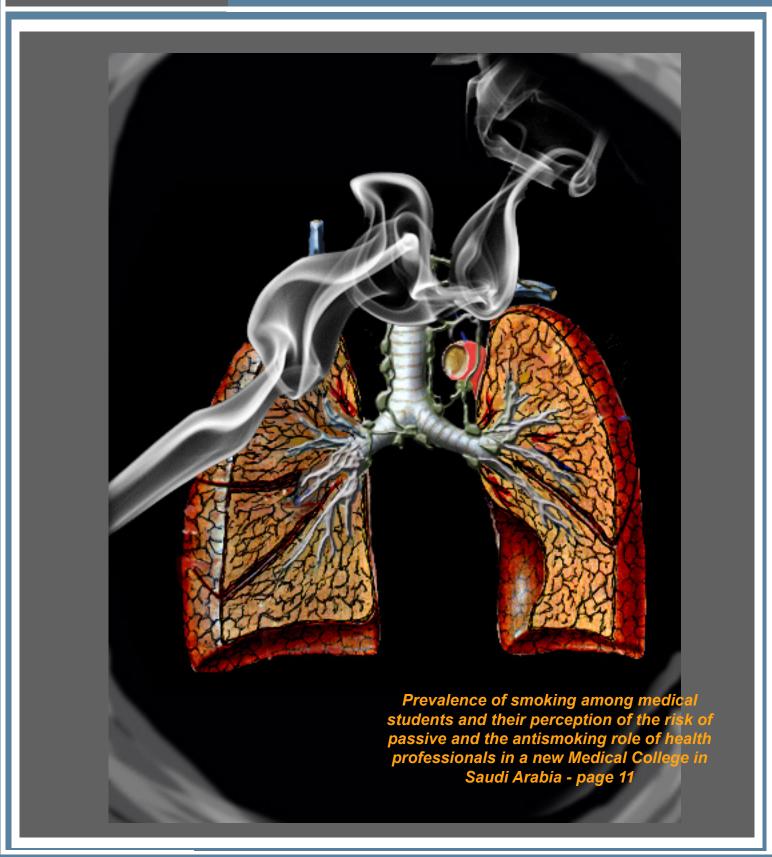


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### From the Editor

With the third issue this year we are pleased with the progress and have various papers received from all over the World and the Middle east region. A paper from Yemen examined the effects of magnesium sulfate in women with preeclampsia and unfavorable cervix at term on the duration of induction of labor. Fifty four women with severe preeclampsia at term with unfavorable cervix having magnesium sulfate and required induction of labor were selected as a case study group. They were matched to 42 women without preeclampsia who required induction of labor with similar cervical conditions as a control group. The authors concluded that magnesium sulfate use in women with preeclampsia who require induction of labor does not prolong the duration of induction of labor. A cross sectional study from King Fahad Medical City, in Riyadh assessed the prevalence of smoking among medical students. A self-administered questionnaire was distributed to all students enrolled in the second semester of the Academic Year 2008/2009. Overall 46.0% of all students had smoked and 25.4% were current smokers. The authors concluded that the prevalence of smoking is high among medical students, particularly males. Students have favourable attitudes but their perception of the risk of passive smoking on certain diseases needs corrective intervention.

A paper from India looked at the efficacy of low dose sibutramine in obese type-2 diabetes mellitus (T2DM) Indian patients. It is known that weight loss in obese type-2 diabetes mellitus (T2DM) patients can improve glycemic control, insulin level and lipid profile. Sibutramine produces a significant weight loss and hence better alycemic control. A 12week prospective, open label study was conducted in 117 obese patients with T2DM who were randomized to receive either sibutramine with antidiabetic drugs or anti-diabetic drugs alone. The main outcome measures were changes in weight, BMI, waist and hip circumference, glycemic control, lipid profile and evaluation of reported adverse events. The authors concluded that sibutramine in low doses produced statistically and clinically significant weight loss which was associated with improvements in glycemic and metabolic control. One of the drawbacks of the study is the short duration therefore the authors were not sure of the maintenance of the weight loss and the longterm side effects.

#### A cross-sectional survey from Iraq

assessed the Iraqi primary care referral system on a total of 336 patients referred from primary to secondary care and was conducted in Erbil, Irag in November 2010. A questionnaire was administered to all patients referred from three randomly selected primary health care centers. Data was collected on socio-demographic characteristics of referred patients, type and reasons for referral and referral process. This study demonstrated a near average referral rate at primary care level but with a high rate of self-requested referrals. Referred patients reported relatively easy access to secondary care settings. The findings may be regarded as preliminary data for further research into the referral system in Irag.

A qualitative study from Saudi Arabia looked at the stigma of expert patients of chronic diseases. This survey attempted to record the views of general practitioners regarding the role preferred by patients in shared decision making andliving with chronic diseases especially Diabetes Mellitus, Hypertension, and Bronchial Asthma and assessed the perspective about the barriers in shared decision making. This is based on a semi-structured survey of general practitioners. The results suggested that the potential to create a cadre of expert patients, people require health professional positive attitude and also need to rectify the problems mentioned by general practitioners

A paper from Turkey looked at funduscopic changes in white coat hypertension. The authors stressed that diagnosis and management of hypertension is complicated by the fact that blood pressure (BP) varies greatly depending on various stresses. In the doctor's office in particular, measurements are often too high, which is defined as white coat hypertension (WCH). They studied

consecutive patients with WCH and sustained normotension (NT) at and over the age of 50 years just to catch, if found, long term effects of WCH on eyes. The authors concluded that as a result of nonsignificant differences between WCH and sustained NT groups according to funduscopic findings, and the already known high prevalence of WCH in society even in early decades, WCH should be considered as a response of body against some metabolic stresses, and its follow up about progression to HT should be performed with regular home BP measurements.

A paper from Saudi Arabia looked at the Prevalence and pattern of smoking among patients attending the primary health care service, the National Guard health affairs. The authors followed a case control study where participants were selected randomly. The overall prevalence of smoking was 35.06%. Among diabetic patients the prevalence of smoking was 45.4% while it was 34.4% among non diabetics. Interestingly, the prevalence of smoking was higher in female diabetics than male diabetics. The authors concluded that smoking is a significant heath problem with a high prevalence among diabetics. Female gender, infrequent physical activity, and relatives with diabetes were highly associated factors to smoking among diabetics.

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## Assessment of the Iraqi primary care referral system: reporting a high self-requested referral rate

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## Abstract

Objectives: Due to a lack of empirical data on the Iraqi primary care referral system, this study is aimed at assessing patient referral from primary to secondary care.

Methods: A cross-sectional survey of 336 patients referred from primary to secondary care was conducted in Erbil, Iraq in November 2010. A questionnaire was administered to all patients referred from three randomly selected primary health care centers. Data was collected on sociodemographic characteristics of referred patients, type and reasons for referral and referral process.

**Results:** Physicians made an average 84 consultations and 5.1 referrals per full practice-day. The referral rate from primary to secondary care was 6.0%; 38.4% of all referrals were selfrequested. Lack of specific specialties in the primary health care centers (44.4%) and the need for further management in secondary care (43.0%) were the main reasons for the indicated referrals. The rate of selfrequested referral could not be explained by socio-demographic characteristics of the patients. Around 93% of the referred patients went to the referred hospital on the same day of referral.

Conclusion: This study demonstrated a near average referral rate at primary care level but with a high rate of selfrequested referrals. Referred patients reported relatively easy access to secondary care settings. The findings may be regarded as preliminary data for further research into the referral system in Iraq.

Keywords: Primary care, Referral, Self-requested, Erbil.

#### Introduction

Effective referral systems between different levels of health care delivery represent a cornerstone in addressing patients' health needs efficiently (1). Optimal referring processes are crucial for the effectiveness, safety and efficiency of medical care (2). Ideally, the Primary Health Care (PHC) centers are supposed to be the point of first contact of patients from which referral to the secondary and tertiary levels should follow a timely, smooth and organized process (2,3). The health services in Iraq are provided through a network of public PHC centers and hospitals where services are provided at very low charges. However, the Iraqi health system faces enormous problems that have mainly resulted from wars and economic sanctions during the last few decades (4,5). These problems are related to poor organization of services, over utilization of services, shortage or uneven distribution of staff and shortage of financial resources (4,6,7). Although the Ministry of Health has established a system for patient referrals, this mechanism does not function well because of the lack of other requirements for an efficient referral system (8,9).

Given the enormity of the current efforts to reform the health system in Iraqi Kurdistan and its potential effect on future generations, policymakers need data and knowledge on different aspects of the health system and on the key elements of reform. One of these key elements is the referral system. To our knowledge very limited research has examined the referral system in Iraq and Kurdistan region (10,11). Due to lack of empirical data on this important key element of health system, this study aimed to assess patient referrals from primary to secondary care in Erbil, Iraq and describe the patients' experience with the current health care referral system.

#### Methods

Erbil governorate is the capital of the self-ruling Iragi Kurdistan region. It comprises eight administrative districts and is inhabited by approximately 1.4 million persons (12). There are 12 public hospitals and 197 PHC centers. Out of these 197 PHC centers, 84 are main PHC centers that are run at least by one physician of which 14 are located in Erbil city (13). The others are small centers that are usually run by practicing nurses or medical assistants. The secondary care units of different specialties are mainly located in the public hospitals.

A cross-sectional survey of a sample of patients referred from primary care to secondary care in Erbil city was conducted in November 2010. The study was carried out at 3 randomly selected main PHC centers in Erbil city. These three PHC centers were Shahid Mohamad Bajalan PHC center, Shahid Nazdar Bamarni PHC center and Mala Afandi PHC center.

A sample size of 306 referred patients was calculated based on having a ±4 precision around an estimated prevalence of selfrequested referral of 15% with a 95% confidence interval. The sample size was increased to 345 to adjust for non-response. All patients referred from the selected centers to different secondary care settings, whether indicated or self-requested referral, were included in the study until the required sample size was collected. This was achieved over a period of 12 working days.

A questionnaire containing three parts was developed to assess the referral process based on extensive literature review and local experts' opinions. The survey instrument was tested on 10 referred patients and subjected to two cycles of modifications. The first part of the questionnaire included data on sociodemographic characteristics of the patient in addition to telephone contact details. The second part of the questionnaire included data on type and reasons for referral and the third part included data on patients' experience with the referral process,

in terms of visiting the secondary care centers or not and the day of visit.

Physicians at PHC centers invited all referred patients to participate in the study after being asked to give verbal informed consent. The first two parts of the questionnaire for each referred patient were filled in by the physicians at this stage. The total number of patients seen by the participating physicians during the study period was used as a denominator in calculating the referral rate. Through telephone interview on the next day, data of the third part of the questionnaire was collected.

All analyses were conducted using SPSS 15.0. The Chi-square test was used to test for significant association between categorical variables. A P value of < 0.05 was considered statistically significant. This study was approved by the Research Ethics Committee of Hawler Medical University.

#### Results

During the study period 5715 consultations were made; 345 (6.0%) were referred to the secondary care settings. The referral rates in the three different PHC centers were 9.0% (143/1590) in Shahid Mohamad Bajalan PHC center, 4.3% (130/3020) in Shahid Nazdar Bamarni PHC center and 6.5% (72/1105) in Mala Afandi PHC center. Physicians made an average of 84 consultations per day (range 13 to 146) and 5.1 referrals per full practice-day (range 1 to 13).

Out of the 345 referred cases, 336 (97.4%) agreed to participate in the study. The mean±SD age of respondents was 19.7±18.4 years with a male:female ratio of 0.9:1. Details of socio-demographic characteristics of study participants are shown in Table 1. Around 61% of the referred patients were indicated referrals as per the physicians' perception, while referral was requested by the patient or his/her parent in 129 (38.4%) cases. The main reasons for indicated referrals included lack of specific specialization at the PHC center (44.4%) and need for further management (43.0%). Referrals were made most often to pediatricians (31.5%) followed by surgeons (19.0%). Details of the referral characteristics of the respondents are shown in Table 2 (page 7).

The rate of self-requested referrals varied with the sociodemographic characteristics of the study participants; however, these variations were statistically nonsignificant. Self-requested referral was higher for those referred to otolaryngology unit than those referred to other departments/units (p<0.001). Details of the association between self-requested referral rate and socio-demographic and referral characteristics of respondents are shown in Table 3 (page 8).

Diarrhea and/or vomiting (41.6%) and chest infection (17.5%) were the most frequent health problems that prompted referral in those less than 15 years old. Musculoskeletal complaints (25.3%), eye problems (17.0%) and genitourinary problems (14.3%) were the most frequent health problems prompting referral in those aged 15 or over. Details of the health problems that prompted referral in adults and children are shown in Table 4 (page 9).

Out of the 336 referral cases, 234 attended the referred hospital; two patients only visited a nurse's private clinic. Around 93% of the referred patients attended the referral hospital on the same day of referral while 6.6% went the next day.

#### Discussion

The study showed that the overall referral rate from PHC centers to secondary care settings was 6.0%; 38.4% of referrals were self-requested. Self-requested referrals were not associated directly with respondents' socio-demographic characteristics, but they were more commonly made to the otolaryngology unit than other departments/units. The most frequent health problems prompting referral were diarrhea/vomiting and

Socio domographia characteristic	N	(0/)
Socio-demographic characteristic	No.	(%)
Gender	400	(17.0)
Male	160	(47.6)
Female	176	(52.4)
Marital status	-	(00.5)
Single	79	(23.5)
Married	103	(30.7)
Under 15 years	154	(45.8)
Education (Years of formal education		
0	54	(16.1)
1-6	65	(19.3)
7-9	37	(11.0)
10-12	36	(10.7)
Over 12	19	(5.7)
Under 6 years	125	(37.2)
Age group (Years)		
0-9	135	(40.2)
10-19	56	(16.7)
20-29	49	(14.6)
30-39	38	(11.3)
40-49	34	(10.1)
50 and above	24	(7.1)
Employed		
Yes	54	(16.1)
No	128	(38.1)
Under 15 years	154	(45.8)
Residence		
Erbil city	311	(92.6)
Erbil city suburbs	10	(3.0)
Other district centers	6	(1.8)
Rural areas	9	(2.7)
Total	336	(100.0)

 Table 1: Socio-demographic characteristics of the respondents

chest infection in those less than 15 years old and musculoskeletal complaints, eye problems and urinary symptoms in those aged 15 or over. Referred patients reported a fairly easy access to the secondary care centers. There can be much variation in the referral rate from primary to secondary care. One systematic review of referral rates reported that rates varied from 0.35% to 20% of consultations and such variation remained largely unexplained (14). The referral rate reported in this study is lower than that reported in Duhok governorate of Iraq (15.4%) (11), but is comparable with the rate in other settings that have relatively efficient referral systems. Different studies from such settings have reported referral rates ranging from 4.4% to 5.1% (15-18).

The findings of this study illustrate sometimes extreme workload on physicians within the selected Iraqi main PHC centers where physicians made an average of 84 patient consultations per day and 5.1 referrals per full practice-day. This is in comparison with the findings of an American study where physicians made an average of 19.7 consultations and 1.23 referrals per day (15). The referral rate alone is not the best indicator of efficiency of the referral system as there is no optimal referral rate for each level of health services (19,20). While the problem of under-referral from general practitioners to specialists is more often documented in developing countries, over-referral is a more common problem in developed countries which is usually related to the tendency to push up medical costs (21,22). Thus and regardless of referral rate, inappropriate referral is a more important issue, but more difficult to study (14,20).

In practice the health needs of the majority of patients can be met in the primary care level (22). If the initial problem cannot be managed, the PHC physician should be the one who decides to refer the patient to a specialist. Self-referrals to secondary care or self-requested referrals through exerting pressure on the physicians will lead to system inefficiency. It is possible that some disadvantaged groups may suffer a lack of specialist care if secondary care physicians are overwhelmed by inappropriate self-referrals (23,24).

Over one third of referrals in this study were self-requested. This was more than twice the proportion reported by another study (15). In Iraq there is no system of general or family practice and patients can visit any health center or hospital without referrals (4). As a rule, the Iraqi health system in the Kurdistan region does not allow self-referrals and patients are required to have a referral from PHC centers, emergency hospital or physician's private clinics to secondary care services. This may have contributed to the very high rate of self-requested referrals reported in this study. However, this mechanism is relatively weak and unable to control all selfreferrals as some patients still

Characteristic	No.	(%)
Type of referral		
Indicated	207	(61.6)
Self-requested	129	(38.4)
Reasons for indicated referrals (n=207)		
Lack of specialty in PHC center	92	(44.4)
Need for further management	89	(43.0)
Lack of investigations in PHC center	18	(8.7)
Diagnosis difficulty	8	(3.9)
Departments/units selected for referrals		
Pediatrics	106	(31.5)
Surgery	64	(19.0)
Orthopedic surgery	48	(14.3)
Internal medicine	37	(11.0)
Otolaryngology	36	(10.7)
Ophthalmology	35	(10.4)
Dentistry	6	(1.8)
Obstetrics	4	(1.2)

Table 2: Referral characteristics of the respondents (n=336)

manage to visit secondary care settings without having a referral (10). The high rate of self-requested referral might indicate people's tendency to bypass the primary care level and seek direct care at secondary care level. Moreover, having a high rate of referred patients being seen in the secondary care setting on the same day of referral might indicate easy accessibility of this level of care.

The findings of this study approximate the pattern of specialty referral reported by previous research (15, 25-27). This study demonstrated a high rate of self-requested referrals to the departments/units of otolaryngology and pediatrics. High rates of selfreferrals to orthopedic surgeons, otolaryngologists, ophthalmologists and dermatologists have been reported in other contexts (25). In a study in the UK, pressure on physicians for referral was greater for referring patients to psychiatrists. rheumatologists, dermatologists and orthopedic surgeons (24).

To our knowledge, this is the first study on the primary care referral system in Erbil governorate. It adds to the limited knowledge on the referral system and provides a general description of the referral process from the primary care level to the secondary care level with special emphasis on self-requested referrals. Even though this study was limited to one governorate in Iraq, it can be considered an interesting case study for other parts of Iraq since the rest of the country shares the same health system. Such interest might go beyond Iraq to other developing countries that adopt similar health and primary health care systems. There are some limitations that merit consideration. The study only reports the experience at three PHC centers in Erbil city. Other governorates of Kurdistan region and Iraq, and less urbanized areas of Erbil governorate were not involved in the study. Nevertheless, we feel that the selected PHC centers are representative of the Iraqi health system and we expect to obtain

similar findings from other PHC centers and other governorates.

Further research is needed at secondary care level to assess the magnitude of actual self-referrals at secondary care centers. Research is also needed to understand the efficiency of the referral system and appropriateness of the referrals in order to understand the whole system in a more comprehensive manner.

#### Conclusion

This study demonstrates a near average referral rate at primary care level in Erbil city but with a high rate of self-requested referrals. Self-requested referral could not be explained by socio-demographic characteristics of the patients. Access to secondary care settings was relatively easy. The findings may be regarded as preliminary data for further research into the referral system with special emphasis on understanding the appropriateness of referral from primary care.

	Total no. of	Self-reque	sted referral	
Characteristic	respondents	No.	(%)	P value
Gender				
Male	160	68	(42.5)	0.146
Female	176	61	(34.7)	0.140
Marital status				
Single	79	27	(34.2)	0.756
Married	103	38	(36.9)	0.750
Under 15 years*	154	64	(41.6)	
Education (Years of formal education	on)			
Illiterate or primary schools	96	30	(31.3)	0.046
Secondary school or higher	86	35	(40.7)	0.216
Under 15 years*	154	64	(41.6)	
Age group				
Child <15 years	154	64	(41.6)	0.044
Adult ≥ 15 years	182	65	(35.7)	0.311
Employed				
Yes	54	23	(42.6)	0.007
No	128	42	(32.8)	0.237
Under 15 years*	154	64	(41.6)	
Department/unit of referral				
Pediatrics	104	44	(41.5)	
Surgery	64	8	(12.5)	
Orthopedics	48	23	(47.9)	20.004
Internal medicine	37	13	(35.1)	<0.001
Otolaryngology	36	25	(69.4)	
Ophthalmology	35	6	(17.1)	
Dentistry*	6	6	(100.0)	
Gynecology*	4	4	(100.0)	
Total	336	129	(38.4%)	

\* Excluded from the statistical test of association due to small sample or irrelevance

Table 3: Self-requested referral rate by socio-demographic and referral characteristics

Health problem	<1	5 years	≥15 years		Total	
	N.	(%)	N.	(%)	N.	(%)
Diarrhea/vomiting	64	(41.6)	0	(0.0)	64	(19.0)
Musculoskeletal complaint	6	(3.9)	46	(25.3)	52	(15.5)
Urinary symptoms	12	(7.8)	26	(14.3)	38	(11.3)
Eye problems	4	(2.6)	31	(17.0)	35	(10.4)
ENT problems	14	(9.1)	20	(11.0)	34	(10.1)
Chest infection	27	(17.5)	2	(1.1)	29	(8.6)
Abdominal pain	5	(3.2)	16	(8.8)	21	(6.3)
Mass/swelling	5	(3.2)	12	(6.6)	17	(5.1)
Chest pain	2	(1.3)	8	(4.4)	10	(3.0)
Headache	2	(1.3)	8	(4.4)	10	(3.0)
Trauma	6	(3.9)	2	(1.1)	8	(2.4)
Dermatological problem	1	(0.6)	5	(2.7)	6	(1.8)
Dental problem	2	(1.3)	4	(2.2)	6	(1.8)
Jaundice	4	(2.6)	0	(0.0)	4	(1.2)
Gynecologic problems	0	(0.0)	2	(1.1)	2	(0.6)
Total	154	(100.0)	182	(100.0)	336	(100.0)

Table 4: Details of the health problems prompting referral by age of respondents

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## Abstract

Objectives: To assess the prevalence of smoking among medical students, their perceptions of health professionals antismoking role and risk of passive smoking.

Subjects and Methods: A crosssectional study using anonymous, self-administered questionnaire among all students enrolled in the second semester of the Academic Year 2008/2009.

**Results:** Overall 46.0% of all students had ever smoked and 25.4% were current smokers. Current and ever smoking prevalence was significantly higher among males and senior students. There were no other significant differences according to the other sociodemographics studied. Non smokers have more positive perceptions concerning the antismoking role of health professionals and the risk of passive smoking than smokers, but differences were not significant. The highest perception score among smokers was for the statement that "health professionals should routinely advise patients who smoke to avoid smoking around children". For non smokers the highest was for the statement "Health professionals should routinely ask about their patients smoking habits". The highest perception for both smokers and non smokers regarding the risk of

passive smoking was for "passive smoking and lung disease", while the lowest for both was for "passive smoking and neonatal death". Male and first year students gave a significantly lower risk for association of passive smoking and some diseases.

Conclusion: Prevalence of smoking is high among medical students, particularly males. Students have favourable attitudes but their perception of the risk of passive smoking on certain diseases needs corrective intervention.

Key words: Smoking, prevalence, perception risk, passive smoking, medical students, Riyadh

#### Introduction

The harmful consequences of smoking on health have been well documented. Tobacco use is the leading global cause of preventable diseases. Studies have confirmed the quantitative relationship between smoking and many health hazards in the form of mortality, premature death and serious morbidity(1-3). Leading World Health authorities have emphasized the vital importance of participation and the positive attitude of health professionals in national and international tobacco control efforts. They encouraged physicians to be role models and provide their patients with regular tobacco interventions(2, 3). The same is expected from medical students as they are expected to be future physicians. They have to be non smokers themselves in order to be convincingly effective. Measuring perceptions and attitudes of health professionals and other sectors of the community towards smoking provides valuable information in understanding the social acceptance of smoking in a society(4, 5). Many national and worldwide surveys have monitored the smoking behaviors, beliefs, and attitudes of medical students(6-14). They showed that smoking is a real problem among medical students irrespective of the level in which they are enrolled, educational strategies or curriculum design.

This study aims to estimate prevalence of tobacco use and assess the perception of medical students of the role of health professionals in antismoking activities and the health risks of passive smoking in a new college of medicine in the Kingdom of Saudi Arabia (KSA). It is of interest and significance to see whether medical students in a new college of medicine will show similar or different trends compared to previous medical students in other colleges. This new college was established in year 2004 within King Fahad Medical City, a tertiary health facility of the Ministry of Health. As from the academic year 2009/2010 it became one of the colleges of King Saud Bin Abdulaziz University for Health Sciences. It is adopting a problem-based integrated

medical curriculum. It is hoped that the results will help in designing and implementing comprehensive corrective strategy if needed.

#### Subjects and Methods

This was a cross sectional study conducted in June 2009 in the Faculty of Medicine at King Fahad Medical City in Rivadh, All medical students, enrolled in the second semester for the Academic Year 2008/2009, were the population for this study. The study tool used was an anonymous, selfadministered questionnaire. It was based on a modified WHO questionnaire surveying smoking habits of health professionals and was used previously in studying smoking habits of physicians and health students in Riyadh(15-16). The questions were grouped into categories related to demographics, prevalence of cigarette smoking, reasons for smoking, not smoking, and for quitting attempts. Perceptions of students towards the antismoking role of health professionals and the risk of passive smoking were measured using a Likert scale of one to five points measuring the level of agreement with the statements. Score five means full agreement; score 1 means full disagreement with the statement. The higher the score the higher and more positive was the perception. Questionnaires were distributed during the classes by the authors. The students were informed that the results would be used for the stated research purposes only and their participation was voluntary. No identification was required. Filled questionnaires were collected and checked for completeness before being entered into a personal computer and analyzed using the Statistical Package for Social Sciences (SPSS) version 17. Descriptive statistics and t test. Mann Whitney test and ANOVA or Kruskal Wallis tests were used for continuous variables as appropriate after checking for normality.

Pearson Chi square and Fisher Exact tests were used for studying association of tobacco use and perception with the categorical variables (sociodemographics) as appropriate. Level of significance was set to be < 0.05 throughout the study. The number of participants' responses used in the discrete statistical analyses varied due to missing data for certain variables and hence totals may vary. Reliability analysis for internal consistency of the specific statements was assessed using Cronbach alpha technique which was 0.862. Participation in the study was totally voluntary but students were encouraged to participate emphasizing that information collected will be useful for them, the college and the community at large. Confidentiality was assured written and verbally; no identification was required, and assurance was given that results will be used for the stated research purposes. An 'ever smoker' was defined as someone who attempted smoking any tobacco product in the past. Ever smokers can be currently non smokers (exsmokers) or current smokers. A never smoker was one who had never smoked before. The study was approved by the Institute Review Board (IRB) of King Fahad Medical City.

#### **Results**

Completed questionnaires were received from 252 students out of 300 students who were enrolled during the study period, giving a response rate of 84%. Males constituted about 72% (182) and females the rest (70), 28%. Age ranged from 17 to 26 years with a mean of 20.74+-1.73 years (21.35+-1.57 for males and 19.19+-0.97 for females). About 61 % of the students (males and females) were enrolled in the first and second year and the rest (males only) were enrolled in third, fourth and fifth years classes. Almost 99% of the students were single. Overall 116 students (46.0%) were ever smokers and 64 (25.4%) were current smokers. The age of initiation of smoking ranged from 8 to 23 years with a mean of 16.3+\_3.3 years and was significantly higher in males than females (16.8+\_2.8 compared to 14.00+ 4.4) years. Current and ever smoking prevalence was significantly higher among males and older students. There were no other significant differences according

Sociodemographics N	Ever smoking Number smoking (%)	Current smoking Number smoking (%)
Gender Male =182 Female=70 P value	96 (52.7) 20 (28.6) 0.001	61(33.5) 3(4.3) <0.001
Age (years) <20 = 74 20-21 = 94 22+ = 84 P value	25(33.8) 44(46.8) 47(56.0) < 0.001	8(10.8) 25(26.6) 31(36.9) < 0.001
Father Education Intermediate = 41 Secondary = 133 University = 78 P value	19(46.1) 56(42.1) 41(52.6) 0.338	11(26.8) 35(26.3) 18(23.1) 0.850
Mother Education Intermediate = 93 Secondary = 126 University = 33 P value	43(46.2) 52(41.3) 21(63.6) 0.476	21(22.6) 32(25.4) 11(33.3) 0.476
Father Occupation Govt. Employee = 171 Self employed = 45 Retired = 33 P value	81(46.8) 18(40.0) 17(51.5) 0.578	42(24.3) 11(24.4) 11(33.3) 0.541
Mother occupation Employee = 121 Self employed = 10 Housekeeping = 121 P value	54(44.6) 7(70) 55(45.5) 0.298	33(19.0) 4(40.0) 27(22.3) 0.376

Table 1: Ever smoking and current smoking habit according to Sociodemographic characteristics

to the other sociodemographics as shown in Table 1. Table 2 (next page) shows mean scores of the students' perception of the antismoking role of health professionals and risk of passive smoking according to their smoking status out of a maximum of 5 points. The highest perception score among smokers was for the statement that "health professionals should routinely advise patients who smoke to avoid smoking around children". The highest perception score among non smokers was for the statement that "Health professionals should routinely ask about their patients smoking habits"

The highest perception score for risk of passive smoking for both smokers and non smokers was for "passive smoking and lung disease" while the lowest for both was for "passive smoking and neonatal death". Non smokers have more favorable perceptions but the differences were not statistically significant. Tables 3 and 4 show the perception of students of the antismoking role of health professional and the risk of passive smoking respectively according to gender, age and class level. There were significant differences in the perception of risk of passive smoking and neonatal death. Females, older students and fifth year students gave a higher risk score. Females also gave a significantly higher risk score for passive smoking and lower respiratory tract illness in children. Females, students aged 20-21 years and fifth year students were significantly more in favor of health professionals' support for smoke-free health facilities. Overall female students have significantly more positive perception than males and students in first year have asignificantly less favorable perception than the other levels.

Statements	Smoker	Non smoker	P value
Health professionals should routinely ask about their patients smoking habits.	4.34(0.97)	4.54(0.69)	0.076
Heath professionals should routinely advise their smoking patients to quit smoking	4.28(0.99)	4.42(0.80)	0.266
Health professionals who smoke should advise people to stop smoking	3.85(1.05)	3.91(1.11)	0.695
Health professionals should routinely advise patients who smoke to avoid smoking around children	4.44(0.96)	4.51(0.87)	0.271
Health professional should support smoke-free health facilities	3.88(1.049)	3.89(1.77)	0.214
Passive smoking increases neonatal death	3.76(1.00)	3.81(1.03)	0.726
Parents smoking during pregnancy increases the risk of Sudden Infant Death Syndrome	4.22(0.89)	4.27(0.97)	0748
Passive smoking increases the risk of lung disease in non- smoking adults	4.28(0.81)	4.47(0.78)	0.084
Passive smoking increases the risk of heart disease in non- smoking adults	4.03(1.02)	4.26(0.89)	0.093
Parents' smoking increases the risk of lower respiratory tract illnesses in exposed children	4.17(0.91)	4.28(1.03)	0.409

Female (0	1.42 0.82) 1.48 0.85) 0.617	4.39 (0.78) 4.36 (0.98)	3.75 (1.08) 4.05	4.39 (1.05)	3.36 (1.78)	4.11
		0.767	(1.03) <b>0.038</b>	4.60 (0.83) 0.121	(1.78) 4.09 (1.45) <b>0.001</b>	(0.73) 4.37 (0.61) <b>0.006</b>
20-21 4 22+ 4	1.41 0.79) 1.40 0.85) 1.47 0.90) 0.852	4.34 (0.84) 4.45 (0.817) 4.32 (1.0) 0.651	3.59 (1.09) 4.00 (1.03) 3.99 (1.07) <b>0.046</b>	4.51 (0.97) 4.49 (0.95) 4.51 (0.90) 0.983	3.16 (1.87) 4.04 (1.53) 3.89 (1.53) <b>0.005</b>	4.08 (0.68) 4.30 (0.75) 4.28 (0.63) 0.178
Second 4 (0 Third 4 Fourth 4 Fifth 4 (0 Fifth 4 (0 (0 (0 (0 (0 (0 (0 (0 (0 (0	4.37 0.87) 4.41 0.77) 4.61 0.78) 4.48 0.89) 4.55 0.87) 0.729	4.28 (0.86) 4.43 (0.69) 4.57 (0.95) 4.32 (1.06) 4.43 (0.92) 0.669	3.60 (1.16) 3.92 (0.94) 4.22 (1.17) 3.90 (1.07) 4.17 (0.93) 0.058	4.38 (1.10) 4.39 (0.97) 4.83 (0.49) 4.56 (0.95) .59 (0.83) 0.312	3.03 (1.83) 3.79 (1.58) 4.09 (1.68) 3.90 (1.53) 4.45 (1.09) <b>0.001</b>	4.00 (0.72) 4.19 (0.72) 4.57 (0.48) 4.29 (0.69) 4.47 (0.46) 0.003

Q.37\* Health professionals should routinely ask about their patients smoking habits.
Q.38\* Health professionals should routinely advise their smoking patients to quit smoking

Q.39\* Health professionals who smoke should advise people to stop smoking

Q.40\* Health professionals should routinely advise patients who smoke to avoid smoking around children

Q.41\* Health professional should support smoke-free health facilities

 Table 3. Mean perception scores of antismoking role of health professional according to sociodemographic characteristics Mean - (Standard Deviation)

#### Discussion

The Faculty of Medicine at King Fahad Medical City adopted a problem-based, integrated curriculum which promotes students' active learning, interpersonal skills and problem solving abilities. Such students are expected to be less stressed and less involved in stressrelated behaviors like tobacco smoking(9). The findings of this study, however, showed that tobacco smoking is highly prevalent among these medical students, particularly among males. This confirms the findings of previous national studies which showed that the trend is continuing irrespective of the period of survey, type of institution, curriculum or the educational strategy(6-9). Similar results were reported from studies in different communities worldwide(10-12). Nonsmokers showed more positive perception than smokers in this study in agreement with many other previously reported studies (17-19). Most students were concerned with the hazards posed by smoking. They encouraged health professionals to enquire about their clients smoking habits and advise smokers to quit. Like other studies this appears to send a strong message to national legislators to enforce appropriate regulations(12). Many studies showed high awareness of the hazards of smoking by medical students(9, 13, 14, 20). Other

Socio- demographics	Q.43*	Q.44*	Q.45*	Q.46*	Q.47*	MEAN Overall
Gender Male Female Pvalue	3.55 (1.02) 4.08 (0.93) <b>0.001</b>	4.17 (0.98) 4.37 (0.86) 0.107	4.34 (0.90) 4.37 (0.71) 0.726	4.12 (1.05) 4.18 (0.86) 0.691	4.09 (1.09) 4.38 (0.79) <b>0.027</b>	4.05 (0.72) 4.27 (0.58) <b>0.015</b>
Age (years) < 20 20-21 22+ P value	3.59 (1.07) 3.69 (0.95) 4.03 (0.99) 0.003	4.17 (1.01) 4.17 (0.99) 4.42 (0.78) 0.200	4.34 (0.91) 4.31 (0.85) 4.40 (0.71) 0.777	4.08 (1.12) 4.24 (0.87) 4.08 (0.95) 0.558	4.05 (1.12) 4.24 (0.90) 4.29 (0.86) <b>0.312</b>	4.03 (0.73) 4.13 (0.69) 4.24 (0.56) 0.205
Class First Second Third Fourth Fifth	3.48 (1.95) 3.82 (1.00) 3.87 (0.97) 3,85 (0.95) 4.31 (0.85)	4.12 (1.00) 4.25 (0.93) 4.35 (0.89) 4.32 (0.96) 4.52 (0.74)	4.34 (0.94) 4.29 (0.87) 4.57 (0.51) 4.29 (0.81) 4.41 (0.63)	4.00 (1.22) 4.23 (0.82) 4.38 (0.74) 4.10 (0.92) 4.14 (0.92)	4.02 (1.18) 4.21 (0.99) 4.43 (0.73) 4.20 (0.87) 4.59 (0.50)	3.98 (0.79) 4.16 (0.65) 4.31 (0.60) 4.14 (0.61) 4.39 (0.46)
P Value	0.007	0.421	0.674	0.537	0.082	0.052

Q.43\* Passive smoking increases neonatal death

Q.44\* Parents smoking during pregnancy increases the risk of Sudden Infant Death Syndrome

Q.45\* Passive smoking increases the risk of lung disease in non-smoking adults

Q.46\* Passive smoking increases the risk of heart disease in non-smoking adults

Q.47\* Parents' smoking increases the risk of lower respiratory tract illnesses in exposed children

 Table 4. Perception of the risk of passive smoking according to sociodemographic characteristics Mean - (Standard Deviation)

studies, on the other hand, reported deficiencies and poor knowledge scores of the risks of smoking for certain diseases including those of the lungs (21-23). Both the high prevalence of smoking and the low level of awareness about smoking-related diseases revealed by these studies is worrying and raising serious concerns. This may be due to deficiencies in terms of knowledge about the hazards of smoking, in curricula of medical schools. Expert reviews have suggested that undergraduate medical students should be equipped with knowledge, and attitudes to promote smoking cessation skills and this is needed more urgently in developing countries(24-26). Although progress has been made to address the teaching of tobacco in medical schools worldwide, more effort is required so that education on tobacco hazards and evidence-based smoking cessation is an ongoing part of the curricula of medical and other health institutes(27).

It is of concern that all students irrespective of their past or current smoking habits were not strongly advocating that "Health professionals who smoke should advise people to stop smoking." It is vital that all health professionals, irrespective of their smoking habit, should enquire about the smoking habits of their patients and advise those who smoke to quit.

The perception of medical students towards the negative effects of passive smoking on neonatal health is of concern. Passive smoking had been reported to lead to high rates of morbidity and mortality in neonates and infants(28, 29). Therefore all these aspects and facts have to be emphasized in the curriculum. Teaching medical students about smoking-related diseases and cessation intervention does result in an increase in knowledge, attitudes and their future behaviour as doctors in relation to advising smoking patients to quit(30,31). Meanwhile, other aspects of tobacco use control, such as legislation and tobacco tax policies, are also strongly recommended and should be formally incorporated into the undergraduate medical curriculum as the medical model alone is inadequate for dealing with the tobacco epidemic(32, 33). This study confirms what other studies have found that the superior knowledge of senior medical students is not associated with lower smoking prevalence. In the present study fifth year students have a much more positive perception of the hazard of smoking, but their ever and current smoking habits were not significantly different from other levels. This may need further exploration.

#### Conclusion

In conclusion, this study revealed that tobacco use among medical students in this new college is prevalent, particularly among males, similar to the situation among past medical students. The situation is not related to seniority of students, type of medical schools or educational methods In general medical students have favorable perceptions and attitudes towards smoking and its hazards, particularly for children, but there is room for more improvement. It is recommended to include tobacco use hazards and anti tobacco use strategies and activities in the curriculum with emphasis on the role of students during and after graduation in primary prevention of smoking and in smoking cessation activities.

#### Limitations:

As smoking behavior among students was self-reported there could have been reporting bias. Verification of self-reported smoking behavior could not be verified biochemically.

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## Prevalence and pattern of smoking among patients attending primary health care service - National Guard Health Affairs, WR

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#### Introduction

Smoking is a major preventable cause of morbidity and mortality world wide. Quitting smoking is the single most important thing smokers can do to improve their health.

Edward R in his paper published in the British Medical Journal in 2004 [1] discussed a model of the worldwide tobacco epidemic; firstly the rise and decline in smoking prevalence is followed by a similar trend for smoking related disease. Edward R [1] showed that the sub-Saharan and Africa region are still in phase 1 where there is low prevalence of smoking and the gender pattern of smoking showed that prevalence of smoking among males is higher than prevalence among females. Also the prevalence of death due to smoking is higher among males than females.

The World Health Organization described tobacco smoking as an epidemic with an estimated three million deaths annually world wide because of smoking. This figure is expected to rise to 10 million by the year 2020 or early 2030; if the current trend of smoking continues. [2]

Seventy percent of these deaths will occur in developing countries. [3]

Although Saudi Arabia does not grow tobacco or manufacture cigarettes, an average of 600 million SR are spent annually on tobacco [3]. Around 160 million is used for purchasing tobacco in Saudi Arabia every year [4].

People continue to smoke tobacco in spite of all the negative consequences because of nicotine

## Abstract

Objective: to determine the prevalence of smoking among adult diabetic subjects attending Medical Specialist Center (MSC) at National Guard Health Affairs, Jeddah and determine the pattern of smoking among diabetics.

Methodology: A cross sectional analytical study was designed. Participants were selected randomly. Data was collected through questionnaires filled in by participants. Medical records were viewed to complete data. Statistical analysis was done by SPSS software version 14.

Results: The overall prevalence of smoking was 35.06%. Among diabetic patients the prevalence of smoking was 45.4% while it was 34.4% among non diabetics. Interestingly, the prevalence of smoking was higher in female diabetics than male diabetics (22.9% vs 12.5%, P < 0.05).

Dyslipidemia and infrequent physical activity were the most associated variables to smoking with no significant difference between diabetics and non diabetics (p > 0.05)

Conclusion: Smoking is a significant heath problem with high prevalence among diabetics. Female gender, infrequent physical activity, and relatives with diabetes were highly associated factors with smoking among diabetics.

Key words: Diabetes, smoking, primary health care

dependence. In New York City, the prevalence of smoking among adults with diabetes was essentially unchanged in the last decade (17.1 in 2001 and 17.4% in 2010) while it has decreased in adults without diabetes, the rate of cigarette smoking declined from 23.7% to 15.2% in 2010. [5]

Few studies have been done to detect the prevalence of smoking among diabetics in Saudi Arabia. We hope our paper will add to this area of research.

#### Methodology

A cross sectional analytical study was designed. Subjects were selected randomly from patients attending Waha Medical Specialist Center which is one of the primary care centers belonging to the national guard health affairs in Jeddah city, during the activities of the world diabetes day 2010 . Two stations were sited and all attendees were invited to check their capillary blood glucose levels by glucometers and invited to fill in questionnaires. Based on their blood glucose results, participants were divided into two groups; diabetics and non diabetics. Participants' medical records were reviewed .The following data was collected; gender, age, social status, presence of diabetes (if fasting blood glucose >= 8mmol/l or random blood glucose >= 11.1mmol/l or on treatment), compliance with regular blood glucose monitoring, presence of relative(s) with diabetes, presence of high blood pressure ( if blood pressure > 140/90 mmHg or on treatment), presence of dyslipidemia (if total blood cholesterol > 5.2mmol/l or blood triglyceride 2.3mmol/l or on treatment), smoking history (type of tobacco smoking and frequency per day), engagement in active physical activity rather than daily home activity (frequency and duration).

Data was extracted and analyzed by using SPSS (version 14) software using personal computer.

#### Results

Three hundred and eighty five (385) subjects were included in our study. Among them 240 subjects were diabetics and 145 subjects were not diabetics. The overall prevalence of smoking was 35.06% (135 subjects). The prevalence of smoking among diabetics was 35.4% (85 subjects) while it was 34.4% (50 subjects) among non diabetics (RR 1.03) (Table 1). Among diabetic patients the prevalence of smoking among female subjects was higher than male subjects (36.7% vs 33.4%) (Table 2).

Among the smoker group, there is an association between hypertension, dyslipidemia, physical activity and relatives with diabetes (RR>1) (Table 3). Cigarette smoking was the dominant pattern of smoking (81.4%) in comparison with shisha smoking (18.6%) (Table 4). Among diabetic smokers, 94.1% were using cigarettes and 5.9% used shisha. Among diabetic smokers, 5% smoke < 10 cigarettes / day, 76.4% smoke 10 - 20 cigarettes/day and 11.6% smoke > 20 cigarettes /day (Table 4). Among the diabetic smoker group, hypertension and dyslipidemia were associated with female gender ( RR>1) (Table 5).

#### Discussion

Our study showed a high prevalence of smoking. The overall prevalence was 35.06%.

Among diabetic and non diabetic participants, prevalence was 35.4% vs 34.4%. Our results were not far from the results shown in studies done in Saudi Arabia which calculated the prevalence of smoking. Medhat M Bassiony in his review published in the Saudi Medical Journal showed that the prevalence of smoking in Saudi Arabia ranged from 2.4 - 53.3% [6]. The author explained that the wide range of prevalence in his review was due to differences in inclusion of different populations and using different criteria for current smoking and estimated the prevalence in different region and different times. [6]

In two studies [7-8] done among primary health care clients in Saudi Arabia, the calculated prevalence was not far from our results (25.3% and 34.4% respectively). The overall prevalence of smoking in our study was higher than the prevalence found by Almas et al in their paper published in 2003. Almas K et al found that the prevalence of smoking among people aged 50 - 85 years, was 25% [9].

Alhadd and his colleagues [10] found that the prevalence of smoking was higher than our results (52.3% vs 35.06%, P <0.05).

In our study the prevalence of smoking among diabetic patients was not statistically significant in comparison with non diabetic participants (35.4% vs 34.4% ,P > 0.05). Andrew J Karter and his colleagues [11] found that the overall prevalence of smoking among diabetic participants in a multicenter study was 15%. Interestingly they found age variation in the prevalence of smoking among diabetics. The highest prevalence was 25% among age group 25-44 years, 20% among age group 45 - 64 years and 7% among those > 65 years. The important note, is that the prevalence of smoking observed in adults aged 25-44 years with less than high school education, was 50% (CI 36-63%).

In our study, 75% of smokers had less than high school education.

MC Gulliford and colleagues [12] found that the overall prevalence of smoking among their diabetic participants was 16%. Smoking was more frequent in white European (men 22%, women 20%) than African Caribbeans (men 15%, women 10%) or Africans (men 8%, women 2%). Solomon and his colleagues [13] found the smoking prevalence among their diabetic participants was 5.5%. In our study, the prevalence of smoking among females was higher than male (36.7% vs 33.4%, P <0.05).

We think that stress is a big factor that drives women to smoke. These days, females are expected to work full-time, take care of households, raise children, and still have time to be attentive wives. We also notice that the psychological effect of the

	DM 240 subjects	Non – DM 145 subjects	P - value
Age	42.05 <u>+</u> 8.5years	41.1 <u>+</u> 10.8 years	>0.05
Prevalence of smoking	35.4%	34.4%	>0.05
Prevalence of hypertension	52.08%	13.79%	<0.05
Prevalence of dyslipidemia	64.58%	48.27%	<0.05
Prevalence of physical activity	75%	44.8%	<0.05
Prevalence of non - physical activity	25%	55.17%	<0.05

Table 1: Comparison between diabetic and non-diabetic group

	Female subjects with DM (150)	Male subjects with DM (90)	P value
Prevalence of smoking	36.7%	33.4%	< 0.05
Prevalence of hypertension	60.0%	38.9%	<0.05
Prevalence of dyslipidemia	66.7%	61.1%	>0.05
Prevalence of physical activity	86.7%	55.6%	<0.05
Prevalence of non - physical activity	13.3%	44.4%	<0.05

Table 2: Comparison between female subjects and male subjects with DM

	Smoker DM subjects (85)	Smoker non DM subjects (50)	P value
Prevalence of hypertension	58.8%	0.0%	<0.05
Prevalence of dyslipidemia	64.7%	60.0%	<.0.5
Prevalence of physical activity	70.5%	40.0%	<.0.05
Prevalence of non physical activity	29.5%	60.0%	<0.05
Relative with DM	82.3%	60.0%	<0.05

Table 3: Comparison between smokers with or without DM

Frequency	Smokers without DM (50 subjects)	Smokers with DM subjects (85 subjects)	P value
	Cigarette smokers (30 subjects)	Cigarette smokers (80 subjects)	
< 10 cig/day	16.7%	5.0%	<0.05
10 – 20 cig /day	66.7%	76.4%	
> cig 20 / day	16.7%	11.6%	
	Shisha smokers (20 subjects)	Shisha smokers (5 subjects)	
< 2 times /day	0.0%	0.0%	>0.05
>2 times / day	100.0%	100.0%	>0.05

Table 4: Pattern of smoking

	Female diabetic smokers (55 subjects)	Male diabetic smokers (30 subjects)	P value
Prevalence of hypertension	72.7%	33.3%	<0.05
Prevalence of dyslipideamia	72.7%	50%	<0.05
Prevalence of relative with diabetes	81.1%	83.3%	>0.05
Prevalence of physical activity	72.7%	66.7%	<0.05
Prevalence of non physical activity	27.2%	33.3%	<0.05

Table 5: Comparison between male diabetic smokers and female diabetic smokers

disease on females was much higher than on males.

We had found one limitation in our study, that the majority of our participants were above 40 years old and this may give the females the power to overcome the social stigma of being smokers. We recommend conducting of similar studies recruiting participants from different age groups to ascertain if we can get the same results.

#### Conclusion

Our study showed high prevalence of smoking among military employees and their families despite the awareness of the impact of smoking on health. Prevalence of smoking was higher among female diabetics than male diabetics which urges more studies to explore this finding deeply. There is need for urgent health efforts among the military population, particularly among females. Our study showed the need to construct antismoking clinics in the primary health care sector.

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### Magnesium Sulfate for Women with Preeclampsia does not Prolong the Duration of Induction of Labor

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## Abstract

Objectives: To examine the effects of magnesium sulfate in women with preeclampsia and unfavorable cervix at term on the duration of induction of labor.

Methods and Materials: Fifty four women with severe preeclampsia at term, with unfavorable cervix having magnesium sulfate and required induction of labor, were selected as a case study group. They were matched to 42 women without preeclampsia who required induction of labor with similar cervical conditions as the control group. Demographic data, duration of the latent phase, 1st stage, 2nd stage of labor and the total length of induction, were compared. **Results:** There were no differences between groups with respect to the latent phase (12.04  $\pm$  2.43 min vs. 11.52  $\pm$  1.47 min. p>0.05), total length of labor (17.14  $\pm$  2.13 min vs. 16.97  $\pm$  1.91 min. p>0.05) but the oxytocin dosage used in the study group was significantly higher (13.12  $\pm$  2.1 mu/m vs. 11.25  $\pm$  2.2 mu/m p<0.05). The other maternal and fetal outcomes were similar.

**Conclusion:** Magnesium sulfate use in women with preeclampsia who require induction of labor does not prolong the duration of induction of labor.

Keywords: Magnesium Sulfate, Preeclampsia, Induction of labor

#### Introduction

Magnesium sulfate was first used in obstetrics to prevent eclamptic seizures, in 1906 by Horn in Germany, who injected it intrathecally (1). Over the past 20 years, its use has expanded to include inhibition of preterm labor. Indeed, magnesium sulfate currently is probably the most commonly used parenteral tocolytic drug in the United States (2). However, it is reported in the literature that magnesium sulfate when given to women with preeclampsia is associated with decrease in uterine contractions and thus may impede the progress of spontaneous or induced labor and lead to unnecessary cesarean deliveries (2). In contrast, other studies revealed that magnesium sulfate does not affect the duration of labor or the rate of cesarean delivery (3). Magnesium competes with intracellular calcium at its binding sites, decreasing muscle contractility and stabilizing the membrane potential therefore, the resulting myometrial relaxation will arrest or even prolong labor, promoting cesarean section(4). Our objective of this trial was to study the impact of magnesium sulfate on the duration of labor in women at term with preeclampsia and unfavorable cervix when labor is induced, compared to electively induced pregnant women without preeclampsia having similar cervical conditions without magnesium sulfate.

#### Methods and Material

We conducted a prospective cohort study in Al-Thawra General Hospital, Sana'a throughout a year (February 1st 2010 to January 31st 2011). Pregnant women with preeclampsia and unfavorable cervix who required termination of pregnancy by induction of labor were enrolled in this study according to the following criteria:

- $1. \ge 37$  weeks gestation,
- 2. singleton pregnancy,
- 3. vertex presentation,

4. reassuring fetal heart pattern,

5. intact membranes.

We excluded from the study women with any of the following:

1. multiple pregnancy,

2. spontaneous labor (present with > 3 uterine contractions per 10 minutes, each lasting for  $\geq$  40 seconds),

3. malpresentation or any obstetric indications for cesarean section such as rapid deterioration of maternal condition,

4. intrauterine fetal death because the course of labor might be different,
5. contraindications for both magnesium sulfate and agents used for induction of labor such as prostaglandin, namely heart block, liver or renal failure, asthma etc,
6. obesity (body mass index ≥ 30.0).

Women were diagnosed as having preeclampsia if there is a systolic BP of at least140 mm Hg and/or diastolic BP of at least 90 mmHg on at least two occasions, at least 6 hours apart after 20th week of gestation plus proteinuria (300 mg or more per 24hours collection)

Fifty-four women met our criteria and were therefore given magnesium sulfate. Forty-two pregnant women at term having no preeclampsia who should have elective induction of labor for various indications such as oligohydramnios, post term, Rhisoimmunization or other medical disorders, were selected as a control group. They were matched by age, parity, gestational age, cervical findings and the methods of ripening cervix. Each participant gave verbal consent after full explanation of the study purpose and procedure.

A pre-study questionnaire was prepared to provide the following data: age, parity, gestational age, initial cervical findings, agents used for induction, duration of the latent phase, duration of the first and second stages of labor and the total length of labor. Maternal complications in terms of failed induction, cesarean section and other morbidity were recorded. Also the fetal birth weight, Apgar score at 1 and 5 minutes, and admission to nursery were obtained. Women allocated to magnesium sulfate infusion received 4 gm intravenously loading dose over 20 minutes followed by 2 gm per hour maintenance dose continuously for 24 hours post delivery. These women were monitored for potential signs of magnesium toxicity throughout the course of administration. These included eliciting patellar reflexes, assessing vital signs, urine output and checking for respiratory rate. Respiratory depression, or absence of patellar reflexes, were taken as evidence of toxicity. At this point the infusion was discontinued. Serum magnesium level assay is not routinely investigated.

Cervical ripening agents were given according to a standard protocol followed in this hospital. When the cervix is unfavorable (defined as Bishop score < 6), 50 ug misoprostol was placed intravaginally into the posterior fornix 4 hourly till adequate uterine contractions (defined as 3 or more per ten minutes each lasting 40 seconds or more) were attained, or abnormal uterine actions had developed. This was defined as: (a) tachysystole,  $\geq$  6 uterine contractions in 10 minutes for two consecutive 10 minute windows, (b) hyperronus, as a single uterine contraction of at least 2 minutes, (c) hyperstimulation syndrome, as the presence of tachysystole or hypertonus associated with abnormal FHR preterm.

Amniotomy was performed when the cervix was dilated  $\geq$  3 cm and the vertex was engaged. Oxytocin was infused when Bishop score was  $\geq$  6 with inefficient uterine contractions. Oxytocin was given by the usual method of dilute oxytocin solution infused at 2 mu/min. The infusion increased to a maximum rate of 32mu/min. at 30 minute intervals, as needed, to achieve the minimal effective uterine activity (3 contractions per ten minutes). During the course of induction, all women received the standard monitoring including intermittent or continuous fetal heart pattern. assessment of uterine contractions every hour and constant observation of vital signs hourly. Digital cervical examination was repeated 4-hourly in the first stage by the same person, if possible. The findings were recorded and the progress of labor was carefully followed according to our protocol. Women having preeclampsia received in addition, the specific care related to the condition including antihypertensive medication and monitoring of vital signs. The decision for cesarean section was made by the attending senior in the delivery room, and the indications were: failure of induction (defined as delivery not achieved within 24 hours), non-reassuring fetal heart pattern, new complaints (e.g.: hemorrhage). Ethical approval was obtained from the ethical committee in the hospital.

#### Statistical analysis

Data were processed using SPSS version 11.0 (SPSS inc. Chicago, IL, USA). Mean and standard deviation as well as proportion were used as appropriate for describing data. Chi square test (x2) was used for qualitative variables and student-t test for quantitative variables. P value < 0.05 was considered statistically significant.

#### Results

Table 1 (next page) presents the population characteristics and the clinical data for the study and control groups. There were no significant differences between the groups in mean age, parity, gestational age, and the initial Bishop score. The induction of labor was successful in 83.3% of cases in the study group vs. 85.8 % in the control group. No differences were observed in the rate of non-reassuring fetal heart pattern or labor complications leading to cesarean section. There were no significant differences between the magnesium-treated group and the control group in the frequency of misoprostol dosing required for cervical ripening (1.6  $\pm$  0.49 vs. 1.5  $\pm$ 0.5; P = 0.3149). Also there were no significant differences in the mean of total length of labor between study

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Variable	Case group (n = 54)	Control group (n = 42)	P value
Age, (yrs) Parity Gestational age, (week) Initial Bishop score Indications for induction · Post term · Oligohydramnios · DM · Others	23.06 ± 4.34 2.46 ± 1.26 38.88 ± 1.3 4.16 ± 1.3	22.9 ± 4.1 2.82 ± 1.1 39.16 ± 1.3 4.22 ± 0.676 5 (11.9) 21 (50) 6 (14.2) 10 (23.8)	NS NS NS NS

Data presented as mean  $\pm$  SD and n (%). NS: Non Significant

Table 1: Demographic and clinical data

Variable	Case group (n = 54)	Control group (n = 42)	P value
No. of misoprostol applications	1.6 ± 0.49	1.5 ± 0.5	0.3149
Use of oxytocin	41 (75.9)	28 (66.7)	NS
Amniotomy	13 (24)	9 (21)	NS
Oxytocin dose (mu/min)	13.12 ± 1.4	11.25 ± 2.2	< 0.0002*
Latent phase (hr)	12.04 ± 2.43	11.52 ± 1.47	NS
First stage (hr)	16.62 ± 1.4	16.06 ± 1.68	NS
Second stage (hr)	0.83 ± 0.73	0.616 ± 0.23	NS
Total length of labor (hr)	17.14 ± 2.13	16.97 ± 1.91	NS
Failed induction	9 (16.7)	6 (14.2)	NS
Fetal distress	1 (1.8)	1(2.3	
Cesarean section, total	10 (18.5)	7 (16.7)	NS
Indication:	000000000000		00000
<ul> <li>Failed induction</li> </ul>	9 (90)	6 (85.7)	
<ul> <li>Fetal distress</li> </ul>	1 (10)	1(14.2)	
Post partum hemorrhage	3 (5.5)	2 (4.8)	
Birth weight, g	2970 ± 427	3003 ± 422	NS
Apgar score < 2			
1 min	19 (35.1)	14 (33.3)	NS
5 min	9 (18)	6 (14.2)	
Admission to nursery	4 (7.4)	3 (7.1)	

Data presented as mean ± SD and n (%). \* extremely significant; SB: stillbirth.

NS: Non Significant.

Table 2: The outcome

and control groups (17.14  $\pm$  2.13 hr vs. 16.97  $\pm$  1.9 hr; P = 0.6853) respectively. There were statistical significant differences in the maximum doses of oxytocin required in the magnesium-treated group versus control group (13.12  $\pm$  2.1 miu/min vs. 11.25  $\pm$  2.1 miu/min; P < 0.0001,95% CI: 1.1 to 2.6 ) respectively. The cesarean section rates were 18.5% in the study group and 14.2% in the control group. The indications for cesarean section were failed induction in both groups and one case in each group had developed fetal distress. Postpartum hemorrhage was observed in 5.5% of women in the study group and 4.8% in the control group (P > 0.05). As regards the fetal and neonatal outcomes, there were no statistical significant differences in the birth weight, Apgar score at 1 and 5 minutes and admission to the neonatal intensive care unit. Only one case in the study group progressed to eclampsia but the vaginal delivery was imminent. No major medication side effects were noted but headache, nausea and flushing were recorded in 18%, 14% and 36% of the study group vs. 15% 16% and 38% of the control group respectively. Table 2 summarizes the outcomes.

#### Discussion

Our results show that magnesium sulfate when given to protect against seizure did not increase the need for frequent Misoprostol dose application compared to those women having the same cervical condition but without magnesium sulfate (P = 0.3149). This finding suggests that magnesium sulfate does not prolong the latent phase of labor. However, it is in contrast to some authors who concluded that magnesium sulfate slows the latent phase of labor but has little or no effect on the active phase of labor (5). Our analysis shows that the mean time from the onset of starting induction to the beginning of active phase of labor in the magnesium-treated group and control group was 12.04 ± 2.43 hours vs. 11.52 ± 1.47 hours: P = 0.1984 respectively. Nevertheless, it was observed that a higher proportion of women (75.9%) in the study group required oxcytocin augmentation than in the control group (66.7%), and the mean oxytocin dose was significantly higher in the study group than in the control group (P < 0.0002). These findings are comparable to another study (6). The present study demonstrates that the total length of labor was not significantly different between both groups (P = 0.4905). This suggests that the magnesium sulfate poses tocylytic effects on the uterus of pregnant women, which can be overcome by high doses of oxytocin. Witlin A.G. et al concluded in a randomized, double blind, placebo-controlled trial (1997)(6) that the presumed tocolytic effects of magnesium sulfate therapy on term labor appears to be surmountable by a small but statistically significant increment in the dose of oxytocin. However, the tocolytic effects of magnesium sulfate were initially reported by Hall et al in 1959 (7), but the subsequent published studies found that there is a transient mild decrease in frequency of uterine contractions with no significant changes in the intensity of uterine contractions. Magnesium sulfate is believed to exert its tocolytic effects through a non specific mechanism of action by competing with calcium (Ca++) for entry into myometrial cells through

voltage-gated calcium channel (8). This proposed mechanism of action necessitates a high level of magnesium sulfate concentration to inhibit uterine contractions. However, the dose-dependent action of magnesium sulfate likely explains why there is no clinical significant inhibition of uterine contractility when magnesium sulfate doses are limited to eclampsia prophylaxis. Given that near the end of gestation, there is a striking increase in the number of oxytocin receptors in the myometrial and decidual tissues (9) the receptor numbers have been shown to reach a maximum after the onset of spontaneous contractions either term or preterm (10). It is possible therefore that the action of oxytocin predominates on the induced uterus. This connection could explain why magnesium sulfate has benefit (more or less currently questioned) in prevention of preterm labor but not for uterus on active labor. However, further studies are needed to explore the effects of magnesium sulfate at term on the uterus with different doses of oxytocin. It is observed in the practice that many obstetricians prefer to delay the initiation of magnesium sulfate for women with severe preeclampsia at term when the delivery is decided to be induced under the belief that the drug has relaxation effects on the uterus and increasing the rate of cesarean section. However, the present study did not observe such effects and we therefore recommend initiation of the drug once the diagnosis of moderatesevere preeclampsia is established. Our present study could not confirm the high incidence of cesarean section and postpartum hemorrhage reported in previous studies (11). We found no intergroup significant difference in postpartum hemorrhage related to uterine atony. The likely suggestion is either the magnesium sulfate does not have a potential relaxation effect on myometrium when used in non-toxic doses or the maximum dose of oxytocin being given for the study group might reduce such action. In this study we could not find statistical differences between the two groups as regards the fetal outcomes measured by birth weight, Apgar score at 1 and

5 minutes, admission to neonatal nursery and perinatal mortality. It is reported that magnesium sulfate has a better safety profile when compared to other tocolytic agents (12). However, magnesium sulfate is not completely benign; in the neonate it can cause hyporeflexia, poor sucking and respiratory depression (12). Thus, the association of a drug with adverse fetal or newborn health events raises the need for a careful balance between the therapeutic benefits of the medication with the likelihood of fetal and neonatal harm. The limitations of the study are numerous. Firstly, we used the conventional sample size so the overestimation of the association could not be excluded and the results should be therefore interpreted with caution. However, the presented data in our trial could be used in other designed larger confirmatory studies. Secondly depending on our local protocol we used misoprostol vaginal tablet for cervical ripening in all induced women being cheap, available, easily applied and not needing refrigeration. Other agents like PGE2 may have a different association. Finally we could not assess the adverse effects of magnesium sulfate and Misoprostol separately because both drugs have the potential to produce similar minor side effects.

#### Conclusion

Magnesium sulfate administration for women with preeclampsia at term with unfavorable cervix who are going to be induced, does not prolong the duration of labor induction in comparison to women undergoing labor induction without magnesium sulfate.

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## Efficacy of low dose sibutramine in obese type-2 diabetes mellitus (T2DM) Indian patients

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#### Introduction

Obesity is reaching an epidemic proportion worldwide [1] and is emerging as an important health problem in India too. The prevalence range in different states varies from 10 to 50 percent [2]. Management of obesity is a challenging task because of rapid evolution of unfavorable life styles and its association with various co-morbidities, among which the most relevant are diabetes mellitus, arterial hypertension and cardiovascular diseases [1].

Most patients with type-2 diabetes mellitus (T2DM) are obese, dyslipidemic and insulin-resistant and the majority of cases require high doses of hypoglycemic and hypolipidemic drugs. It is usually difficult to regulate metabolic parameters with high doses [3]. Modification of dietary habits and subsequent weight loss can improve glycemic control, insulin level and lipid profile in these patients [4]. Weight loss confers important benefits in obese type 2 diabetic patients. In subjects with a body mass index (BMI) between 30 and 40 kg/m2, weight loss of 10% often lowers fasting plasma glucose by 1-2 mmol/l and HbA1c by 1%. These effects are comparable to those of oral hypoglycemic drugs [5].

Unfortunately, dietary restriction alone does not lead to adequate weight loss [6]. Sibutramine, a selective inhibitor of the reuptake of monoamines, primarily serotonin and noradrenalin and to a lesser extent dopamine, leads to weight loss [7]. Few studies have been undertaken with sibutramine in which weight

### Abstract

Aim: Weight loss in obese type-2 diabetes mellitus (T2DM) patients can improve glycemic control, insulin level and lipid profile. Sibutramine produces a significant weight loss and hence better glycemic control. The data on the Indian population is lacking hence we thought it worthwhile to determine the various effects of low dose sibutramine hydrochloride in obese type-2 diabetes mellitus (T2DM) patients.

Methods: A 12-week prospective, open label study was conducted in 117 obese patients with T2DM who were randomized to receive either sibutramine with antidiabetic drugs or anti-diabetic drugs alone. The main outcome measures were changes in weight, BMI, waist and hip circumference, glycemic control, lipid profile and evaluation of reported adverse events.

**Results:** At 12-weeks patients on sibutramine showed a significant (p<0.05) weight loss as compared to the control group. Improvement in HbA1c, fasting plasma glucose and 2 hour postprandial plasma glucose was significant (p<0.05) in the sibutramine group as compared to control. Sibutramine patients also showed improvements in lipid profile. Overall, sibutramine was well tolerated.

Conclusions: Sibutramine in low doses produced statistically and clinically significant weight loss which was associated with improvements in glycemic and metabolic control. Sibutramine was generally well tolerated in obese T2DM patients. loss has proved to be beneficial in improving glycemic control also [8, 9]. There is enhancement in insulin sensitivity along with weight loss in type 2 diabetics with sibutramine [9]. However, there is a paucity of data on the effects of sibutramine on the Indian population for weight loss in T2DM patients. Hence, this study was planned to evaluate the effect of sibutramine on weight loss, glycemic control and lipid profile in obese type 2 diabetic patients.

#### Material and Methods

#### Patients

This prospective, randomized, parallel, open, controlled study was conducted in patients visiting the diabetic clinic of Christian Medical College and Hospital, Ludhiana, a tertiary care hospital. Clinic visits were scheduled at screening (visit 1), after 6 weeks (visit 2) and 12 weeks (visit 3). The patients were randomized using random number table to receive either sibutramine 10 mg/day with anti-diabetic drugs or anti-diabetic drugs alone. Medical compliance was determined from the returned tablet count. The study protocol and informed consent were reviewed and approved by the Institutional Ethics Committee of Christian Medical College and Hospital before the study initiation and written informed consent was obtained from each patient prior to enrolment in the study. The study was conducted in accordance with ICH-GCP guidelines.

Adults 30-60 years of age of both sexes with diagnosis of T2DM for more than one year, and Body Mass Index (BMI ?27kg/m2) were enrolled in the study [10]. Patients with poorly controlled hypertension, hypothyroidism and hyperthyroidism, psychiatric illness, angle closure glaucoma, lactating and pregnant women, renal failure or patients taking antidepressants or anorectic agents or hypolipidemic medications were excluded.

#### Treatment

Group 1 patients received Tab sibutramine 10 mg/day with prescribed diet and anti-diabetic

drugs whereas, group 2 patients received prescribed diet along with anti-diabetic drugs. The antidiabetic drugs prescribed to the patients belonged to Sulfonylureas, biguanides, thiozolidiendiones and insulin group.

All subjects received an educational program of dietary, exercise and behavioral strategies to facilitate weight loss. At baseline, each subject's basal energy requirement was calculated. Using these data and an estimate of the subject's typical activity level, the dietician prescribed an individualized diet that would promote a 500 to 1,000 kcal reduction in daily energy intake. Subjects also received an individualized exercise prescription that included, at a minimum, walking for 30 min three times weekly added to usual activity.

At baseline and each follow up visit, the patient underwent a physical examination and had their blood pressure, heart rate, weight, height, waist and hip circumference measured. Waist to hip ratio was calculated. Waist circumference was measured with the patient standing and the measurement was taken at the midpoint between the highest point of the iliac crest and the lowest limit of the costal margin at the midaxillary line. The hips were measured at the point where buttocks protrude most.

Glycemic parameters (fasting plasma glucose, 2 hour post prandial plasma glucose) were estimated at baseline, 6 weeks and 12 weeks. While glycosylated hemoglobin (HbA1c) and lipid profile (total cholesterol (TC), triglycerides (TG), high density lipoproteins (HDL) and low density lipoprotein (LDL)) were estimated at baseline and 12 weeks.

Safety evaluation included spontaneously reported adverse events throughout the study and as detected by the physician.

#### **Statistical analysis**

Data was tabulated as mean  $\pm$  standard error of mean (SEM) and percentage change. The data was

analyzed using analysis of variance (ANOVA), Student t-test (two tailed) and nonparametric tests (Kruskal Wallis, Chi-square). A subgroup analysis was done. P<0.05 was considered as statistically significant.

#### Results

Of 175 screened patients, 117 patients were enrolled in the study. 15 patients were withdrawn from the study due to protocol deviation. 3 patients were lost to follow up after 6 weeks of therapy (2 patients in Group 1 and 1 patient in Group 2) whereas 4 patients were lost to follow up after 12 weeks of therapy (1 in Group 1 and 3 in Group 2). 95 patients (48 in Group 1 and 47 in Group 2) completed the entire 12 weeks of the study.

The demographic and baseline parameters were comparable in patients in both groups (Table 1). The changes in percentage of weight, BMI, waist circumference and waist-hip ratio are shown in Figure 1. There was weight loss in both groups at 12 weeks. There was significant difference between mean percentage decrease in weight in both groups (5.21% ± 0.36 vs 1.47%  $\pm$  0.28; P < 0.05). In addition to this, more patients (23 vs 2; 47.9% vs 4.2%) in the sibutramine treated group reported loss in weight > 5% at 12 weeks as compared to the control group. Two patients in the sibutramine treated group lost > 10% of their baseline weight at 12 weeks while none in the control group lost ?10% of their baseline weight at 12 weeks (Figure 1 - page 32).

Similarly, the mean percentage reduction in BMI was significantly greater in the sibutramine group than in the control group  $(5.17\% \pm 0.38 \text{ vs})$  $1.4\% \pm 0.27$ ; p < 0.05), as well as waist circumference (2.38% ±0.19 vs  $0.65\% \pm 0.17$ ; p < 0.05) and waist-hip ratio (1.73% ±0.2 vs 0.59% ±0.16; p < 0.05). Subgroup analysis showed that there was significant mean percentage reduction in BMI in group 1 in patients with > 5% weight loss as compared to group 2 and patients with < 5% weight loss in Group 1 (7.28% + 0.27 vs 1.4% + 0.27 and 3.06 + 0.17; p < 0.05), waist

Parameter	Group1 (n=48)	Group2 (n=47)	p value	
	(Mean <u>+</u> S.E)	(Mean <u>+</u> S.E)		
Age (years)	47.12 <u>+</u> 0.88	49.16 <u>+</u> 1.22	p=0.178*	
Sex (M:F)	17:31	23:24	p=0.26#	
Weight (kg)	82.69 <u>+</u> 1.43	83.55 <u>+</u> 1.66	p=0.696*	
BMI (kg / m <sup>2</sup> )	32.94 <u>+</u> 0.47	32.38 <u>+</u> 0.50	p=0.423*	
Waist (cm)	107.52 <u>+</u> 0.99	107.84 <u>+</u> 1.54	p=0.860*	
Waist Hip Ratio	0.96 <u>+</u> 0.007	0.97 <u>+</u> 0.008	p=0.308*	
Fasting Blood	176.16 <u>+</u> 7.2	161.90 <u>+</u> 7.95	p=0.187*	
Sugar (mg/dl)				
PPBS	211.62 <u>+</u> 6.99	200.14 <u>+</u> 8.65	p=0.305*	
HbA <sub>1c</sub>	8.90 <u>+</u> 0.29	8.79 <u>+</u> 0.30	p=0.786*	
Triglycerides	170.54 <u>+</u> 9.41	175.2 <u>+</u> 8.09	p=0.308∞	Table 1: Demographic
Cholesterol	194.76 <u>+</u> 5.06	190.88 <u>+</u> 4.76	p=0.796∞	profile and baseline parameters of both
HDL	44.22 <u>+</u> 1.52	44.54 <u>+</u> 1.62	p=0.764∞	groups
LDL	117.48 <u>+</u> 4.34	116.26 <u>+</u> 3.80	p=0.978∞	

circumference (3.21% + 0.17 vs 0.65 + 0.17 and 1.54% + 0.11 ; p < 0.05)and in case of waist hip ratio there was significant reduction compared to group 2 (1.89\% + 0.25 vs 0.59 + 0.16; p < 0.05).

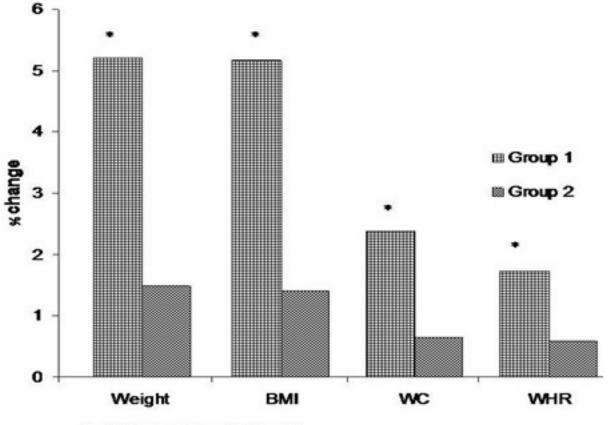
Figure 2 (page 32) depicts changes in glycemic parameters. Fasting plasma glucose levels fell significantly below baseline in patients treated with sibutramine, but it did not change significantly in the control group (133.13  $\pm$  3.19 vs. 149.72  $\pm$  3.99; p<0.05). There was significant mean percentage reduction in fasting plasma glucose at 12 weeks in the sibutramine group as compared to control group (20.35%  $\pm$  2.58 vs. 0.19%  $\pm$  4.22; p< 0.05). Also there was significant mean percentage reduction in 2 hour post prandial plasma glucose in the sibutramine treated group as compared to the control group (20.03%  $\pm$  3.07 vs. 7.31%  $\pm$  3.49; P < 0.05). Mean percentage decrease in HbA1c values was significantly more in the sibutramine group (13.98%  $\pm$ 1.50 vs 6.84%  $\pm$  2.71; p< 0.05).

Subgroup analysis showed that there was significant mean percentage reduction in Glycemic parameters in patients in Group 1 with >5% weight loss as compared to group 2; FPG (22.40 + 2.40 vs 0.19 + 4.22; p < 0.05), PPPG (23.02 + 3.27 vs 7.31 + 3.49; p < 0.05), HbA1c (15.78 + 1.59 vs 6.84 + 2.71; p < 0.05).

There was no difference in the lipid profile in both groups except for the levels of HDL which was significantly higher in Sibutramine group as compared to control group (51.8 mg/ dl  $\pm$  1.34 vs. 46.48  $\pm$  1.50; p<0.05). The mean percentage change in the HDL level was significantly more in the sibutramine group (20.43% + 2.88 vs 5.37% + 1.22; p < 0.05) as compared to control group (Figure 3 - page 33).

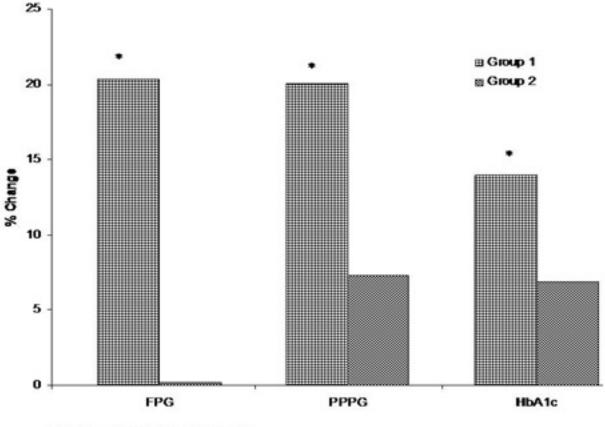
In analysis of subgroups, significant increase in HDL (29.62% + 2.57 vs 5.37% + 1.22; p < 0.05) was seen in patients with >5% weight loss in Group 1 as compared to group 2.

All the patients in both groups received either Biguanides/ sulfonylureas/Thiozolidinedione or combination therapy. The dose of anti-diabetic drugs was comparable in both groups during the entire



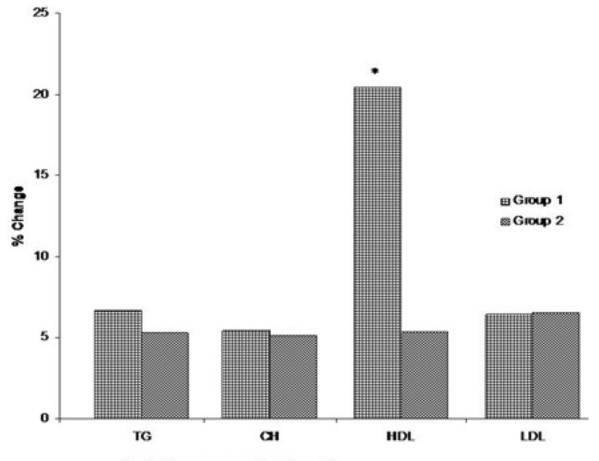
\*p<0.05 as compared to Group 2





\*p<0.05 as compared to Group 2

Figure 2: Percentage change in Glycemic Parameters in both groups



\*p<0.05 as compared to Group 2

Figure 3: Percentage change in Lipid Profile in both groups

duration of the study period. Two patients in the sibutramine group and one patient in the control group were taking insulin apart from oral antidiabetic drugs. One patient in the sibutramine group and none in the control group was a smoker, six patients in the sibutramine group reported consumption of alcohol and four in the control group.

The vital parameters in both groups were comparable at all intervals of time.

There was no serious adverse event reported in either groups. There were more adverse events reported in the sibutramine group as compared to control group but none of the adverse events reported was so severe that it required termination of treatment. The adverse events reported did not require reduction in dose or any therapy for the treatment of adverse events. 4 patients with sibutramine and none of the patients in the control group reported adverse events. The effects were mild and did not require any medication. Two patients reported with dry mouth and one each with insomnia and constipation.

#### Discussion

One of the common health consequences of obesity is type 2 diabetes mellitus so antiobesity management is a prerequisite in treating diabetic patients [11]. Modification of dietary habits and subsequent weight loss can improve glycemic control, insulin level, and lipid profile findings however, unfortunately, diet restriction alone usually does not lead to adequate weight loss [3].

In the present study addition of sibutramine (10mg per day) caused significant weight loss and improvement in metabolic parameters. A subset of patients treated with sibutramine reported > 5% loss of their weight at end of 12 weeks of therapy. Two patients (4.2%: 2/48) lost more than 10% of their baseline weight at end of 12 weeks of therapy. Overall, 52% (25/48) of the patients treated with sibutramine lost > 5% of their baseline weight at the end of the study. There was also weight loss in the control group (percentage weight loss 1.48 %), only three patients (6%) in the control group lost > 5% of their weight and no patient lost > 10% of weight at the end of 12 weeks of therapy. Earlier studies also reported weight loss in patients treated with placebo [12, 13]. The weight loss was more in patients treated with sibutramine as compared to control group. In these studies also, more patients in the sibutramine group lost more than 5 % of weight [13, 14].

These results of the weight loss in this study are in agreement with previous studies in obese T2DM patients with sibutramine. However, in most of these studies sibutramine was used for a longer period or in higher doses (15-20mg/day) [12, 13, 15]. In our study the lowest dose of sibutramine (10mg/day) has shown these results. In the present study there was also significant decrease in anthropometric parameters in the sibutramine group. There was significant decrease in waist circumference, BMI and waisthip ratio in patients treated with sibutramine. The anthropometric parameters usually change according to weight loss [16]. In our study we also observed the same pattern. There was a decrease in these parameters in the control group also; however the decreases in these parameters were significantly more with sibutramine as compared to control group. Patients with >5% weight loss in Group 1 had more percentage decrease in BMI as compared to group 2 and patients with < 5% weight loss in Group 1.

Our results showed statistically significant improvement in glycemic control in the sibutramine treated patients. Fasting and postprandial plasma glucose levels and HbA1c decreased to a greater degree in this group than in the control group. These significant differences are in all likelihood related to the weight loss that occurred in the sibutramine treated individuals. The improvement in glycemic control was more in a subset of patients in patients in Group 1 with >5% weight loss as compared to group 2 and patients with < 5% weight loss in Group 1. Our results are in agreement in this regard with previous studies in obese T2DM patients with sibutramine [3,12, 15]. Again these beneficial effects were at a lower dose and for a shorter period of sibutramine use as compared to other studies.

Epidemiological studies and prospective therapeutic trials have revealed that glycemic control reduces microvascular and macrovascular complications of diabetes in patients with either type of disease. Every 1% reduction in HbA1c decreased cardiac complications from 9 to 40%, depending on the population and type of diabetes [17]. In our study, sibutramine produced a significant increase in the HDL level of obese patients with T2DM. Obese, overweight high-risk and abdominally obese patients are often susceptible to develop an adverse lipid profile also known as the 'lipid triad' (elevated LDL, low HDL, elevated triglycerides) which is one of several contributing risk factors for developing cardiovascular disease (CVD) [18]. Reduction of LDL cholesterol has been shown to be associated with reduced cardiovascular morbidity and mortality in diabetic patients [19]. Serum HDL level showed maximum improvement in patients who lost ?5% of their weight in Group 1. Our results indicate that sibutramine is of potential benefit relative to cardiovascular risk in obese patients with T2DM.

Sibutramine was approved by(the US Food and Drug Administration (FDA) in November 1997 for weight loss and maintenance of weight loss in obese people, as well as in certain overweight people with other risks for heart disease. After reviewing data from the Sibutramine Cardiovascular Outcomes Trial (SCOUT) which showed 16 percent increase in the risk of serious heart events, including non-fatal heart attack, non-fatal stroke and death, in patients receiving sibutramine, FDA subsequently notified healthcare professionals and patients about voluntary withdrawal of sibutramine from the U.S. market in 2010 [20]. The European Medicines Agency (EMA) also decided that sibutramine must be withdrawn because of safety concerns [21]. It has also been withdrawn by the Drug Controller General India (DCGI) in 2011 [22], but low doses of sibutramine used in our study done prior to 2010 did not show any serious adverse event reported later. The use of low dose sibutramine should be thought of as anti-obesity therapy which is safe instead of high doses which are associated with increased adverse effects.

In conclusion, the findings of our study show that a low dose of sibutramine (10mg/day) is effective in decreasing weight and improving glycemic and metabolic control in as short a duration as 12 weeks in Indian obese T2DM. The use of low dose sibutramine in Indian obese patients with T2DM is safe, effective and offers an attractive approach for weight loss in these patients. Given the overwhelming research focus on this disease, it is likely that the coming years will bring more treatment options, raising the chance that our patients will have meaningful and sustained weight loss.

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#### Abbreviations

T2DM	Type 2 Diabetes mellitus
FPG	Fasting Plasma Glucose
PPPG	Post Prandial Plasma Glucose
HbA1c	Glycosylated Hemoglobin
TG	Triglycerides
СН	Cholesterol
LDL	Low Density Lipoproteins
HDL	High Density Lipoproteins
Wt	Weight
BMI	Body Mass Index
WC	Waist Circumference
WHR	Waist-Hip Ratio

## Expert patients of chronic diseases; is it still a stigma in Saudi Arabia?

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## Abstract

Background: Share decision making now is an essential part of every consultation however its acceptance is still debatable. Thus we carried out this survey to record the views of general practitioners regarding the role preferred by patients living with chronic diseases, especially Diabetes Mellitus, Hypertension, and Bronchial Asthma, in shared decision-making and assess the perspective about the barriers to shared decision-making.

Method: This is a qualitative study based on a semi-structured interview of general practitioners. It was conducted in 2010 from January to September during a process of training of general practitioners for consultation and communication skills. The purposive sample of 52-64 general practitioners has been selected from six different urban and rural areas of Saudi Arabia. They all were working under the umbrella of the Ministry of Health and participated in a semistructured interview.

**Results:** Only a small number of patients (7%) were classified as preferring roles as an active partner, whereas a collaborative role was opted by only a handful (12.7%) and the majority (78.5%) were happy to become a passive partner. The mostly GPs (81.6%) were annoyed by the little interest of administration in involvement of patients, followed by the complaint of overburden (74.1%). Interestingly, 46.8% mentioned that even patients were not accepting of this idea, to talk about their management as laymen, and 59% pointed out that there is also a problem of

awareness. Some doctors (34.1%) also blamed illiteracy.

**Conclusion:** The results suggested that for the potential to create a cadre of expert patients, people require health professional's positive attitude and also need to rectify the problems mentioned by general practitioners.

Keywords: Patient participation; Decision making; Patient advocacy, Expert patients

#### Introduction

In Saudi Arabia, currently the greater part of the population is suffering from chronic diseases. The older population suffers more however than the younger population who are also not intact and contaminated with chronic diseases as well as due to their lifestyle. (1) Although while efforts are under way to explore the current exact situation of the burden of chronic diseases in Saudi Arabia, different small studies (2,3) have warned that the prevalence of Diabetes is very high and almost a quarter or more of the 30 - year old population have this disease; the incidence is even increasing in school children and estimated at 27.52/100,000/year in 2010. Regarding asthma, it is estimated that almost 23% of the population is suffering (4) from it while another study shows that only 5% are controlled. (5) The situation of hypertension is also not good and a study shows that the prevalence is 26.1 in crude terms, with predominately males suffering more. (6)

During this time, the notion of the expert patient seems to have been criticized by doctors at least as much as it has been welcomed (7,8). The other professionals are motivated to prefer clients to take an interest in the issues they face. However, the idea of expert patients rather irritates the health professionals initially, but was accepted later on in other parts of the world (7). The paradigm shift of patients as an expert is being accepted recently in Saudi Arabia at training level but not totally practiced and implemented to the full degree. (9) There are several reasons mentioned for not involving patients in decision making however the three most often reported barriers were: time constraints, lack of applicability due to patient characteristics, and lack of applicability due to the clinical situation. However to foster implementation of shared decisionmaking in clinical practice we will need to address a broad range of factors. (10) As an argument some

health professionals say that in patients' characteristics, the one barrier is literacy rate; but it might not be applicable here in Saudi Arabia because almost 98% of the population is literate. (11)

This study is an effort to at least get views of the general practitioners regarding the role of patients in decision making and accept the patients as an expert on their diseases because so far the idea is only in debate and still difficult to initiate on the part of health professionals.

#### Method

This is a qualitative study based on semi-structured interview of general practitioners (GPs) during a training program conducted in different urban and rural areas of Saudi Arabia and has two phases; the 1st phase is to get the perspective of GPs and the 2nd phase will be conducted on patients in the same catchment areas after finishing the whole training program. The purposive sample, ranged from 52-64 GPs from six regions making a total of more than 337 GPs and this sample represents almost 50% of the total 680 GPs who were participating in the training program as a compulsory exercise for all working GPs in those areas. (Table1). All these GPs are dealing with, on average, 60-70 patients per day and almost 15 - 20% patients have chronic diseases.

It was a part of a training program for GPs and we initially conducted two modules for communication and consultation skills and tried to make them aware of all consultation skills including involvement of patients in decision-making. At the beginning of the third module, as part of training, a semi-interview (12) was conducted based on some predesigned small questions. We attempted to get views from them, about the role of patients specifically having Diabetes Mellitus, Asthma and Hypertension, in decisionmaking based on five roles and also a classification (13,14) of their role as active, collaborative and passive. They were also asked

to give their views regarding the barriers to involvement of patients in management of these chronic diseases and recorded the answers on the bases of a Likert Five rating scale (15).

The sample size calculations were not performed, as it was a purposive sample and representing at least 50% of the population as a whole. However the ratio of sample and population represents enough the real population. The data was fed into SPSS version 15 and a simple analysis was done. The variables were compared based on chi-square and student t-test with significance level of 5%.

#### Results

Of the total participating GPs, almost 50% of GPs agreed to spare their time and give a semi-interview. The mean age of the sample was 39.75 years (±2.5) with the composition of 4:1 ratio of males to females (75% were male and 25% females). The area-wise distribution ranged from 15% to 19% from each of the six areas. The characteristics of GPs showed that only 18% have any postgraduate qualification in family medicine. The mean year of experience was around 13(±3.2). The sample had diversity in nationalities; it was mainly composed of Egyptians (22%), Sudanese (18.3%), Indians (16%), Saudis (12.7%), Pakistanis (12.2%), and Bangladeshi (07.1%), followed by others (Table 1 - next page).

The general practitioners preferring each role is described in Table 2 (page 39) according to their views, based on their offer to patients. Only a small number of patients (7%) were classified as preferring Roles 1 and 2, that is, active. Whereas, collaborative Role 3 was opted for by only 12.7% and the majority (78.5%) were happy to become passive, as in Roles 4 and 5. When comparing these views with different characteristics of GPs, there was no significant difference (p-value > 0.05) found in any regard of age, experience and qualification etc.

S. No	Characteristics	Frequency (%)
1	Gender Males Females	253(75) 84(25)
2	Sample distribution Area wise Riyadh (only city included)* Medina (only city included) Aseer (only city included) Abaha (whole area) AlJouf (whole area) Hafaralbatin (whole area) Total	64(18.9) 52 (15.4) 65 (19.2) 52 (15.4) 52(15.4) 52(15.4) 52(15.4) 337
3	Age groups 25 – 30 years 31 – 35 years 36 – 40 years 41 – 45 years 46 – 50 years >50 years	32 (09.4) 83 (24.6) 80 (23.7) 73 (21.6) 46 (13.6) 23(06.8)
4	Qualifications Postgraduate (Certificate in family medicine) Only graduate (MBBS or MD)	61(18.1) 276 (81.8)
5	Experiences 5 – 10 years 11 – 15 years 16 – 20 years >20 years	105 (31.1) 133(39.4) 69(20.4) 30 (08.9)
6	Nationality Saudis Egyptians Pakistanis Indians Sudanese Syrians Bangladeshis Others (Jordanian, Somalis, Nigerian etc)	43(12.7) 74(21.9) 48(12.2) 54(16.0) 62(18.3) 21(06.2) 24(07.1) 11(03.2)

\*Riyadh, Medina and Aseer are the big regions so only selected the main cities from these regions.

Table 1: General Practitioners (GPs)' characteristics (n=337)

In Table 3, it is explained that GPs have some barriers in order to make shared decision-making. The mostly GPs (81.6%) were annoyed by the little interest of administration in involvement of patients, followed by complaints of overburden (74.1%).

Interestingly, 46.8% mentioned that even patients were not accepting this idea to talk about their management as laymen and 59% pointed out that there is also a problem of awareness. Some doctors (34.1%) also blamed illiteracy.

#### Discussion

The concept of patient as an expert, has been accepted lately in Saudi Arabia at an educational level but not totally practiced and implemented in full (9). In a sense all patients and carers are experts, regardless of how much medical knowledge they may have. This is because of the experience of living with their condition and their personal beliefs, priorities, and attitudes to risk. This study highlighted the views of general practitioners (GPs) regarding the role of patients in decision-making. The results showed that a small number of patients are classified as an active role player, meaning that they wanted to participate in decision making, while the greater part either wanted to be a sleeping partner, or just to collaborate in management decisions. Several studies have demonstrated that the patients' preferred role in decision making varies, with some patients preferring to take on an active role in making decisions related to their healthcare and others preferring to remain more passive (16).

Consequently, experts recommend that clinicians determine each patient's preferred decision style and tailor their interactions accordingly (16, 17). Preferably, participation is associated with improved satisfaction and clinical outcomes (18-22). The literature pointed out that the factors which modify patients' preferred role should be addressed before physicians determine the level at which their patients wish to participate. Another study (18) found that patients' perceived seriousness of the decision was associated with an increased desire to participate.

When comparing these views with different characteristics of GPs, there was no significant difference (p-value > 0.05) found in any regard of age, experience and qualification etc. In Saudi Arabia, the diversities of nationalities of GPs might play a role in having different perceptions about the role of patients, based on their training and background cultural values. However, the results nullify this hypothesis and the larger part had a similar opinion. Thus it is

Preferred roles	Classified Roles	Freq (%)	
They prefer to make the final selection about which treatment they will receive (Role 1)	Active	13 (03.8)	
They prefer to make the final selection of their treatment after seriously considering the doctor's opinion. (Role 2)	Active	16 (04.7)	
They prefer that their doctor and they share responsibility for deciding which treatment is best for me. (Role 3)	Collaborative	43 (12.7)	
They prefer that their doctor make the final decision about which treatment will be used, but who seriously considers their opinion. (Role 4)	Passive	66 (19.5)	Table 2: Patients' preferred role in decision-making according to Genera
They prefer to leave all decisions regarding treatment to their doctor. (Role 5)	Passive	199 (59.0)	Practitioners' views (n=337)

		Points on Continuum Frequency (%)				
S. No.	Barriers	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	Lack of awareness	200(59.3)	63(18.6)	13(03.8)	24(07.1)	37(10.9)
2	Time constraints/overload	250(74.1)	51(15.1)	05(01.5)	15(04.4)	16(04.7)
3	Illiterate people	115(34.1)	52(15.4)	11(03.2)	99(29.3)	60(17.8)
4	Patients don't accept this idea	158(46.8)	39(11.5)	23(06.8)	80(23.7)	37(10.9)
5	Don't have proper training	51(15.1)	05(01.5)	00	200(59.3)	81(24.0)
6	No support from administration	275(81.6)	49(14.5)	01(0.2)	07(02.0)	05(01.5)

 Table 3: GPs' perspectives regarding barriers in acceptance of patients being partner of management (n=337)

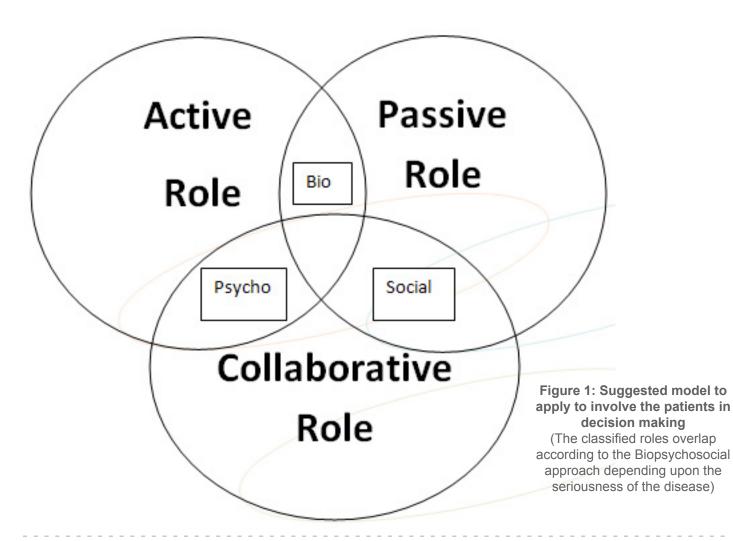
assumed that this idea from the beginning was not getting acceptance among GPs and they are still not fully convinced, therefore they are having similar thoughts.

Regarding the barriers, the greater part was upset by the little interest of administration in involvement of patients, followed by complaints of overburden (74.1%). Other literature also highlighted the same problem and it is mentioned that for these anxious and overworked medics, the expert patient is the demanding patient, the unreasonable patient, the time consuming patient, or the patient who 'knows it all' (19).

Interestingly, almost half of the GPs mentioned that patients weren't accepting of the idea of talking about their management as laymen. Sixty percent pointed out that there is also a problem of awareness whereas one third also blamed illiteracy. When compared with the available literature, it is evident that older age is associated with preference for a more passive role; other demographic factors, included gender, education and race do not consistently predict patients' role preferences (16, 17, 23-27).

A recent qualitative study suggested that role preference is variable and is related to how strongly patients feel about specific treatment options or diagnostic procedures. (28) These results suggest that a patient's preferred role in decision-making may be related to their choice predisposition, or level of certainty regarding their desire to initiate or avoid therapy. Based on these findings, therefore we have to determine if a patient's level of certainty, a potentially modifiable factor, is related to their preferred role in decision making as measured by the Control Preferences Scale (29).

The role of the patient being an active partner still has some ambiguity especially in that part of the world where still not implemented into practice. However when the term 'patient expert' was coined in 1999 in the UK it wasn't accepted initially and a survey (30) by the pharmaceutical industry body reported that only 21% of doctors were in favor of the government's proposals on the expert patient; 58% predicted an increase in the workload of general practitioners; 42% believed it would increase NHS costs; and only 12% thought it would improve relationships between doctors and patients. In 2003, the MORI (31) survey of health professionals found that 63% of doctors think that in the long run better informed patients will require more of their time, a rather higher proportion than nurses (48%) but less than pharmacists (76%) (18).



Do the GPs sitting in their offices realize that many of their patients, particularly those living with debilitating medical conditions, are disproportionately non-working, old, and poor? Nevertheless, it is required that all physicians in general and GPs particularly, apply the "Bio-psychosocial" approach mixed with the roles of patients (Figure 1) in an implicit health care model. This model implies that there are several reasons to participate in decision making and they are based on, and overlap from time to time, from biological reasons, that is, seriousness of diseases, to social reasons like cost, and sometimes psychological reasons for example, under stress etc. Let's take an example of taking medicine by patients, as every patient has their own beliefs about medicines and are known to be the most important determinant of whether and how medicines are taken (24). Though this fact is not new to doctors, research has shown that patients'

perspectives (including their desire and ability to take medicines) are seldom discussed when medicines are prescribed (25).

Doubtlessly GPs must understand that the patients are living with these diseases since a long time therefore if they would accept their views as experts then patients feel more satisfied, however uninformed or misinformed patients must be corrected. Patients' expertise is valuable because by understanding the patient's views and situation, the doctor is better equipped to identify a solution that will lead to a successful outcome.

Generally in a semi-structured interview, it is difficult to judge the intention of respondents because they respond to what they think is the correct answer, which produces bias in the results. In this study GPs are defining the roles of patients; indeed they know their patients, however it doesn't necessarily represent the true feelings of the patients. Thus it is required to conduct a study to compare GPs views with the patients' views on large scale.

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## Funduscopic changes in white coat hypertension

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# Abstract

Background: Diagnosis and management of hypertension is complicated by the fact that blood pressure (BP) varies greatly depending on various stresses. In the doctor's office in particular, measurements are often too high, which is defined as white coat hypertension (WCH). Although already known to have a high prevalence in society, prognostic significance of WCH remains controversial.

Methods: We studied consecutive patients with WCH and sustained normotension (NT) at and over the age of 50 years just to catch, if found, the long term effects of WCH on eyes. Funduscopic examination was performed by the same ophthalmologist who was unaware of the patients' subclassification. Keith, Wagener, and Barker's classification of hypertensive retinopathy (HR) was used to define the funduscopic findings. **Results:** Fifty-six WCH and 51 sustained NT cases were studied. No case of grade III or IV HR was observed in either group. Eight cases of grade I HR (14.2%) were detected in the WCH group, whereas this ratio was 9.8% (five cases) in the sustained NT group (p>0.05). Similarly, although three cases of grade II HR (5.3%) were detected in the WCH group, this ratio was 3.9% (two cases) in the sustained NT group (p>0.05).

Conclusion: As a result of nonsignificant differences between WCH and sustained NT groups according to funduscopic findings, and the already known high prevalences of WCH in society even in early decades, WCH should be considered as a response of the body against some metabolic stresses, and its follow up about progression to HT should be performed with regular home BP measurements.

Key words: White coat hypertension, normotension, hypertensive retinopathy

#### Introduction

Hypertension (HT) increases risks of major cardiovascular events (peripheric artery disease, myocardial infarction, dissecting aortic aneurysm, and stroke) and renal failure. Thus blood pressure (BP) control is the mainstay for prevention of such events. But diagnosis and management of HT is difficult due to the fact that BP varies greatly depending on physical and mental stresses. Additionally, elder individuals tend to have an abnormal circadian rhythm and a normally higher systolic BP than younger individuals. Besides that, in the doctor's office in particular, measurements are often too high, which is called white coat hypertension (WCH). Prognostic significance of WCH remains controversial. Whether or not WCH cases have an abnormal autonomic-cardiac regulation similar to that observed in HT patients is unknown, and it is unclear whether or not ambulatory BP progresses in time and exhibits an increased cardiovascular risk in them. Additionally, it remains unclear whether or not WCH is associated with target organ damage (TOD). Currently available quantitative markers of TOD of HT are echocardiographically determined left ventricular hypertrophy, retinal microvascular changes, ultrasonographically determined carotid intima-media thickness, and microalbuminuria.

Although the whole afferent vasculature is probably affected due to HT, one of the obvious results can be seen in eyes, and funduscopic examination is regularly performed to diagnose HT and to evaluate efficacy of antihypertensive therapy. Keith, Wagener, and Barker's (KWB) classification of hypertensive retinopathy (HR) has been used since 1939 to assess retinal damage of HT (1). By this method, besides evaluation of efficacy of treatment, we can also catch some overlooked

Grade I	Arteriolar diameter less than 50% of venous diameter		
Grade II	Arteriovenous crossing changes situated at more than one papillary diameter from the papilla		
Grade III	Retinal hemorrhages or exudates		
Grade IV	Papillary edema accompanied by retinal hemorrhages or exudates		

Table 1: Keith, Wagener, and Barker classification of hypertensive retinopathy

cases of HT. We tried to understand whether or not the WCH has any effect on the retinal vasculature in the present study.

#### Material and Methods

Consecutive patients with WCH and sustained normotension (NT) at and over the age of 50 years were studied among check up patients applying to the Internal Medicine Polyclinic of the Dumlupinar University between September 2005 and February 2006. Patients at and above the age of 50 years were studied just to catch long term effects of WCH on eyes, since the WCH probably has a long term nature. Clinical BP was measured by the same internist and a 10-day twice daily measurement of BP at home was obtained after a 10 minute education session about proper BP measurement techniques. The education included recommendation of upper arm devices, while discouraging wrist and finger devices, using a standard adult cuff with sizes of 12 x 26 cm for arm circumferences up to 33 cm in length and a large adult cuff with sizes of 12 x 40 cm for arm circumferences up to 50 cm in length, and taking a rest for a period of 5 minutes in the sitting position before measurement. HT is defined as BP of > 135/85 mmHg for systolic and/or diastolic on average home BP measurements (2). WCH is defined as an office BP of ? 140/90 mmHg for systolic and/or diastolic but average home BP of <135/85 mmHg, and sustained NT as an average home BP of <135/85 mmHg and an office BP of <140/90 mmHg, so the white coat effect is defined as the difference between the office and mean home BP values. Masked hypertension (MHT) is defined as an office BP of <140/90 mmHg, but an average home BP of > 135/85 mmHg. Funduscopic examination

was performed via +90D lenses containing biomicroscope by the same ophthalmologist who was blind about the patients' subclassification to prevent observer bias with or without dilatation of pupil according to severity of cases. HR was assessed according to KWB classification (Table 1). Results were compared between the WCH and sustained NT groups. Independent-Samples T Test and comparison of proportions were used as the methods of statistical analyses.

#### **Results**

Fifty-six patients with WCH and 51 with sustained NT were studied. Mean ages were 61.2 and 59.7 years in the WCH and sustained NT cases, respectively (p>0.05). Female ratio was significantly higher in the WCH group (82.1% vs 68.6, p<0.05). No case of grade III or IV HR was detected in either group. Eight cases (six females) of grade I HR (14.2%) were detected in the WCH group, whereas this ratio was 9.8% (three females) in the sustained NT group. Similarly, although three cases (one female) of grade II HR (5.3%) were detected in the WCH group, this ratio was 3.9% (one female and one male) in the sustained NT group (Table 2 - page 44). So, the differences between the two groups according to grade I and II HRs were statistically nonsignificant (p>0.05 for both).

#### Discussion

WCH is a pathology characterized by elevated BP measurements in medical settings combined with normal ambulatory recorded or home BP values. However, it is unknown whether or not it represents a transient state in the development of HT. It was reported in the Ohasama study that WCH is a risk factor for the development of home HT (3). As a parallel result to that, 46.9% of cases with WCH and 22.2% of cases with sustained NT progressed to the home HT in an 8-year follow up study (4). The results demonstrated that WCH is a transitional pathology eventually terminating with the home HT. But in a previous study, we observed very high prevalences of WCH in society, 33.3% in the second, 46.6% in the third, 50.0% in the fourth, 48.9% in the fifth, 36.9% in the sixth, 19.2% in the seventh, and 8.3% in the eighth decades of life, and prevalence of HT initially started to be higher than 40.0% in the sixth decade and it reached up to the prevalence of 75.0% in the eighth decade of life (5). The high prevalence of WCH in society was also shown in some other reports (6,7). On the other hand, the prevalence of HT was detected only as 3.0% in the third, 8.0% in the fourth, and 21.2% in the fifth decades of life (Table 3 - page 44) (5). So as a hypothesis all hypertensive patients, 75.0% in the eighth decade, may arise from the previously WCH cases, but this process takes a very long period of time reaching up to the normal life span of a human being. On the other hand, although HT affects both sexes equally, number of hypertensive females are higher than males in society as a result of longer life span of females (8). Similarly, we detected in the previous study (5) that although 60.0% of all WCH cases were males as an opposite finding to another report (9), 65.3% of all HT cases were females (p<0.001), which may indicate different etiopathogenesis of the WCH from HT.

As another face of the subject, prognostic significance of WCH is unknown and there are various reports about this issue. For instance, intima-media thickness and cross-

	WCH*	Sustained NT†	<i>p</i> -value
Number	56	51	
Mean age (year)	61.2 ± 6.4 (50-75)	59.7 ± 6.5 (50-73)	ns‡
Female ratio	82.1% (46)	68.6% (35)	<u>&lt;0.05</u>
Prevalence of grade1 HR§	14.2% (8)	9.8% (5)	ns
Prevalence of	5.3% (3)	3.9% (2)	ns
grade II HR			

\*White coat hypertension †Normotension ‡Nonsignificant (p>0.05) §Hypertensive retinopathy **Table 2: Comparison of cases with white coat hypertension and sustained normotension** 

	Number	Prevalence	Prevalence	Prevalence	Prevalence
Decades	of cases	of NT*	of WCH†	of MHT‡	of HT§
2 <sup>nd</sup>	27	66.6%	<u>33.3%</u>	0.0%	<u>0.0%</u>
3rd	133	50.3%	<u>46.6%</u>	0.7%	<u>3.0%</u>
4 <sup>th</sup>	100	42.0%	50.0%	0.0%	<u>8.0%</u>
5 <sup>th</sup>	94	29.7%	<u>48.9%</u>	3.1%	<u>21.2%</u>
6 <sup>th</sup>	46	19.5%	<u>36.9%</u>	4.3%	<u>43.4%</u>
7 <sup>th</sup>	26	15.3%	<u>19.2%</u>	7.6%	<u>65.3%</u>
8 <sup>th</sup>	12	16.6%	<u>8.3%</u>	16.6%	<u>75.0%</u>

\*Normotension †White coat hypertension ‡Masked hypertension §Hypertension

Table 3: Prevalence of normotension, white coat hypertension, masked hypertension, and all hypertension cases in decades

sectional area of carotid arterv were found as similar in patients with WCH and sustained HT, which are significantly higher than the NT cases (10). So authors concluded that there was a TOD in WCH, and WCH should not be considered as an innocent trait (10). Whereas we couldn't detect any significant difference between the WCH and sustained NT cases according to HR in the present study. We particularly studied patients at and above the age of 50 years to be able to catch, if found, the long term effects of WCH on eyes, since according to the results of our previous study (5), the WCH cases probably have had this feature in the early decades of their lives. As a parallel result to ours, there was no evidence that WCH exhibits a clearly higher risk for cardiovascular events in a 7.4year follow up study (11). Similarly, complication risk of the WCH was not found as different from sustained NT in another study (12).

Recent HT guidelines propose self measurement of BP at home as an important means to evaluate response to antihypertensive therapy, to improve compliance with therapy, and most importantly, as an alternative to ambulatory BP measurement to confirm or refute the WCH (13). Additionally, elder individuals tend to have an abnormal circadian rhythm, and home BP measurements are also useful to determine such a pathophysiological condition. Home BP measurements are useful not only for diagnosis of HT but also for choice and titration of antihypertensive therapies. A minimal antihypertensive effect and duration of action can be determined by home BP measurements. So the latter is established by comparison of the antihypertensive effect of a drug in the morning with the evening, i.e. morningevening ratio. Appropriateness of home BP measurements to quide antihypertensive treatment was only tested in one largescale randomized trial: the THOP (Treatment of Hypertension Based on Home or Office Blood Pressure) trial, in which it was shown that antihypertensive treatments based

on home instead of office BP led to a less intensive drug treatment, but also to less effective BP control with no difference in general wellbeing and left ventricular mass (14). In another study, both ambulatory and home BP measurements appeared to be appropriate methods for detection of MHT (15) as another handicap of the office BP measurements. Additionally, home BP measurements can provide a greater number of readings and, when automatic devices are used, an absence of observer bias. It may also increase compliance with antihypertensive therapy and reduce the number of patient visits. Patients can use this method several times by themselves in a year without requiring any ambulatory device. It is also a less expensive method of monitoring. Furthermore, self measurement can also reveal therapeutic effects more reliably and has a greater predictive value for TOD.

As a conclusion, the high prevalence of HT in elders may be a sequela of previous WCH, but this process takes a very long period of time reaching up to the normal life span of a human being. So as a result of the absence of any difference between WCH and sustained NT cases according to funduscopic findings, and the already known high prevalences of WCH in society even in very early decades, WCH should be considered as a response of the body against some metabolic stresses.

Thus its follow up about progression to HT should be performed with regular home BP measurements.

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## CME Quiz #2



Ahmad is a 52 year old executive in a tool factory. You have just completed a company instigated medical check. Ahmad states that he has had no significant illness and is on no medication.

There is no family history of significance, and in fact both his parents are in their 70's and as far as he knows are still well and active. He himself plays golf twice a week, and the only negative item is that Ahmad continues to smoke 15 cigarettes a day.

On reflection he recalls that a few years ago he had indigestion for a few weeks. Gastroscopy was performed, results are unknown, but he has had no further indigestion problems since and is on no medication.

#### **Physical Examination**

On general inspection Ahmad looks healthy and alert, and is not overweight. - Vital signs: Pulse, regular rhythm, with a rate 88/min.

- Blood Pressure 146/91 mmHg
- Examination of his neck reveals a systolic bruit on the left side.
- There was no bruit on the right side.

No other abnormal findings.

#### **Question 1**

Which of the following statements to be given to Ahmad about the level of his blood pressure is/are true?

Select as many as you wish. (Answers and feedback are on next page)

- 1. Tell Ahmad that he has mild essential hypertension
- 2. Advise Ahmad to commence non drug treatment for blood pressure
- 3. Tell Ahmad that his blood pressure is normal
- 4. Suggest that Ahmad should return in 4-6 weeks for blood pressure review
- 5. Tell Ahmad that his blood pressure is at the upper limits of normal and arrange 2 further readings before proceeding

# 1. Tell Ahmad that he has mild essential hypertension.

#### The authors disagree.

#### Feedback

This is the likely diagnosis but he requires repeated measurements on 2 or 3 occasions to confirm the diagnosis.

#### 2. Advise Ahmad to commence non drug treatment for blood pressure.

#### The authors disagree.

#### Feedback

Advise Ahmad to commence non drug treatment for blood pressure.

# 3. Tell Ahmad that his blood pressure is normal.

#### The authors disagree.

#### Feedback

He likely has mild hypertension but needs to have this confirmed by further measurements

# 4. Suggest that Ahmad should return in 4-6 weeks for blood pressure review

#### The authors agree.

#### Feedback

Ahmad should have a repeat visit in 4-6 weeks

#### 5. Tell Ahmad that his blood pressure is at the upper limits of normal and arrange 2 further readings before proceeding.

#### The authors disagree.

#### Feedback

He likely has mild hypertension but needs to have this confirmed by further measurements.

#### **Continuing history**

After history and examination you discuss the results and their implications with Ahmad. You advise him: "Ahmad, you are still a heavy smoker and have mildly elevated blood pressure that puts you in the high risk category for heart disease and stroke. You have an additional problem in that when I listen to your neck I can hear a noise called a 'bruit' which could suggest some narrowing or blockage of the arteries."

Ahmad asks: "What causes that?"

You advise Ahmad:

"Well I'm not sure at this stage without doing any tests. I intend to do some tests, particularly an ultrasound, which will tell me the extent of the narrowing of the vessel. It is quite painless. I also want a repeat estimation of your cholesterol levels."

You talk further to Ahmad about other risk factors.

#### Question 2 What are the recognised risk factors for stroke which may be relevant in *Ahmad's* case.

Write down your answers in the box in the next column, then view the author's answers and feedback on the back page.

#### Your answers

## CME Quiz #2

### Author's Answer and feedback

Age	The authors agree. The risk of stroke certainly does increase with increasing age. Though it must be remembered that approximately 40% of strokes occur before the age of 65.		
Hypertension	The authors say it is possible. Ahmad should have a repeat visit in 4-6 weeks to confirm that hypertension is not present. If present after follow-up this should be treated.		
Smoking	The authors agree. This risk can be reduced. Stroke risk is increased 6 fold in smokers.		
Anticoagulant therapy	The authors disagree. Not relevant in this case.		
Carotid stenosis	The authors agree. The presence of the neck bruit may indicate this to be present. If the stenosis is greater than 75% then endarterectomy may be indicated.		
Anti platelet therapy e.g. aspirin	The authors disagree. Ahmad is not on any drugs, however taking drugs like aspirin may not be perceived as a drug by some and this may have to be specifically asked about.		
Elevated cholesterol	The authors disagree. This is generally accepted as a stroke risk factor and recent studies have confirmed this.		
Diabetes	The authors disagree. 20% of stroke patients have diabetes. This requires a blood glucose measurement.		
Obesity	The authors disagree. Ahmad is not overweight.		
Lack of exercise	The authors disagree. Ahmad plays golf regularly twice a week and this is a reasonable amount. Adequate exercise is 2 1/2 modest or 1 1/2 hours vigorous exercise a week which can be taken in bursts as short as 10 minutes.		
Excessive alcohol	The authors disagree. There is no indication of this. Such a question can be assumed to be part of the health check.		
Atril fibrillation	The authors disagree. No indication of this.		