



Trends and Emerging Practices in Healthcare Project Management: The Role of Corona Crisis Management Room to Control COVID-19 Spread in Aseer Region, Saudi Arabia

## Editorial

Dr. Abdulrazak Abyad

## Regional Covid Issues

- 6 Trends and Emerging Practices in Healthcare Project Management: The Role of Corona Crisis Management Room to Control COVID-19 Spread in Aseer Region, Saudi Arabia  
Saeed Al Moslih, Ahmad Al Harbi, Ali Al-Mousa, Mushabab Al-Asmri, Haitham Bahaitham  
DOI: 10.5742/MEWFM.2021.94131
- 16 Attitude and practice of pregnant women living in Saudi Arabia, about COVID-19 in relation to pregnancy outcome  
Rehab Alsaleh, Fatima Mohammed Faraj, Ahlam Ahmed Aldcgha, Bashair Mohammed Omar, Elaf Hussein bin Mahfouz, Amjad Zaki  
DOI: 10.5742/MEWFM.2021.94132
- 21 Quarantine COVID-19 compliance in families with an allergic and immunological diseased child and its psychological impact in KSA  
Ghaida T Alrabaiai, Abeer H. Alharthi, Jawaher SH. Alotaibi, Nada E. ALgethami, Bushra F. Alshehri, Aymen A. Atalla  
DOI: 10.5742/MEWFM.2021.94146

## Special Editorial

- 32 The Scar is your Signature – Announcing details of FREE Skin Surgery Skills ZOOM Webinars for our readers  
Lesley Pocock

## Original Contribution

- 34 Awareness of General Population of Saudi Arabia toward Diabetic Complications  
Mansuor Ahmed Alanazi, Abdullah Ibrahim Almutaz, Saleh Essa Aldhwain, Bassam Ali Alasmari, Shoug Mohammad Alfarhan, May Yahya Barakat, Yahya Hassan Almalki, Reem Abdullah ALmoussa  
DOI: 10.5742/MEWFM.2021.94134
- 42 Etiologies of Lumbar Puncture Refusal in Pediatric Patients in Children’s Hospital, Taif City, Saudi Arabia. A Cross-Sectional Study  
Sara Safar Alrebaiee, Jamal Samear farahat  
DOI: 10.5742/MEWFM.2021.94135
- 50 Improving patient centered care by documenting their contribution in the plan of care at west bay health center, Qatar  
Wafaa Musallam, Hisham Abdulmoniem, Salma Elnour, Rouba Alkadi, Alawiya Gadallah, Azher Abbas Syed, Wafaa Yousuf  
DOI: 10.5742/MEWFM.2021.94136
- 54 Pathological factors and associated clinical outcomes of patients with urothelial neoplasms treated at King Adulaziz University Hospital : a single center experience  
Marwan Al-Hajeili, Reem K. Ujaimi, Omar Iskanderani, Mohammad Attar, Ehab Ahmed, Maha A. Safhi, Wejdan T. Almrzouqi, Bashaer A. Alsaati  
DOI: 10.5742/MEWFM.2021.94137
- 62 Impact of inhalation therapy on occurrence of oral manifestations in patients with bronchial asthma, in Jeddah, Saudi Arabia  
Fathi El-Gamal, Asim Rashid, Heetaf Saeed, Hind Alluheibi, Rotana Qari, Rahaf Baziyad  
DOI: 10.5742/MEWFM.2021.94138

## Population and Community Studies

- 74 Association between obesity and mental disorders among male secondary school students in Abha, Kingdom of Saudi Arabia: A Predictor based Cross-Sectional Study  
Mubarak M.A. Alshahrani, Mohammed Al-Masoudi, Eman M. Alshahrani, Abdulrahman M. Alshahrani, Khalid M. Alshehri, Suliman A. Asiri, Ahmed M. Asiri, Ahmed A. Asiri, Ahmed H. Alabdali  
DOI: 10.5742/MEWFM.2021.94139
- 83 Knowledge and practice among primary care physicians in Najran (south west region), Saudi Arabia regarding Maturity Onset Diabetes of the Young (MODY)  
Mohammed Ayed Huneif  
DOI: 10.5742/MEWFM.2021.94140
- 89 Level of Parental Awareness Regarding Aerodigestive Pediatric Foreign Bodies, Western Region, Saudi Arabia  
Nada E. Algethami, Abeer I. Alsulaimani, Wahaj A. Altalhi, Layla M. Alkhalidi, Eman S. bayoumy  
DOI: 10.5742/MEWFM.2021.94141
- 97 Prevalence of dry eye symptoms and risk factors in Saudi Arabia  
Abdulrahman Al-Amri, Sultan Mohammed Abdullah Alkorbi, Abdulrahman Nasser Alqahtani, Bandar Mohammed Mushabbab Asiri, Abdullah Fahad Alahmari, Turki bjad alotaibi  
DOI: 10.5742/MEWFM.2021.94144
- 105 Prevalence of Generalized Anxiety Disorder among Adults in Primary Health Care in Qatar: A Cross-Sectional Study  
Hani Abdalla, Hassan Tawfik, Ahmed Alnuaimi, Ibtihal Elzaki, Mustafa Mohamed, Tasnim Mobayed, Fatima Alshibani, Safa Zain, Eman Abdelkarim, Nagham Alsmady, Muna Taher  
DOI: 10.5742/MEWFM.2021.94148

## Education and Training

- 117 Epley's Maneuver in Primary Care: A Quality Improvement Project  
Muhammad Hameed, Shabana Shaheen, M Imran Malik, Yousef Essam Hassan Qabeel  
DOI: 10.5742/MEWFM.2021.94142

## Review

- 124 A Review on the Clinical Potential of Lorcaserin in the Treatment of Obesity  
Muhammad Danial bin Daud  
DOI: 10.5742/MEWFM.2021.94143
- 129 Evaluation and Approach of a Painful Quiet (Non-Red) Eye: A Comprehensive review for Primary Health Care Physicians  
Shahd A. Al Mahfud, Abdulrahman F. Algwaiz, Lujain S. Alfayez, Ali A. AlSaeed, Turki A. Bin Dakhil  
DOI: 10.5742/MEWFM.2021.94149
- 136 Knowledge of school teachers regarding Asthma in Aseer region of Saudi Arabia  
Zeinh Hussein Fardan, Abdulbari Ahmed Alzahrani, Sara Abdullah Althumairy, Hana Saeed Al Malih, Shahad Awad AlQahtani, Wijdan Saleh Quraishi, Hasnaa Abdullah Althumairy, Fajr Abdulhadi Alnaami, Wafaa Sulaiman Alhifzi  
DOI: 10.5742/MEWFM.2021.94151

## Editorial

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In this issue a number of authors from the region discussed important issues in primary care, in addition to the usual interest in the Covid epidemic in the MENA area.

Al Moslih, et al., attempted establishing the trends and emerging practices in health-care project management with a concerted interest in determining the role played by the CCMR in controlling and stopping the spread of the virus in Aseer region. The study adopted the exploratory research approach which sought to investigate the research phenomenon. The CCMR formed the focus of the study. 17 participants working in the CCMR were selected using the purposive sampling technique. Data were collected using in-depth interviews where a clear and detailed description of the phenomenon under research was obtained. The collected data were subjected to thematic analysis and classified into three thematic areas. The findings of the study established that the CCMR had a critical role in coordinating government activities within Aseer region. New management practices were based on the experiences of the pandemic and ranged from evidence-based decision making, use of modern technology, and collaboration of various entities. The pathological spectrum was key in risk assessment.

Alrabaia, et al., did a cross-sectional study conducted between June-August 2020 via a self-reported online questionnaire that includes fear of COVID-19 scale for parents, Revised children's anxiety and depression scale to assess Quarantine's psychological effect, fear of getting the infection, and also to know the family's attitude towards COVID-19 and public health measures. The authors concluded that the Quarantine impacted psychologically and financially on some parents, Children are also more vulnerable to psychological effects resulting

from the commitment of families to Quarantine, so we see that special attention and care is needed to prevent these effects on them, especially children with allergic or immune diseases.

Al-Hajeili, et al., did a retrospective study to evaluate the operative and pathologic factors associated with long-term survival and local recurrence in patients treated for urothelial tumors. In this study, 89.36% of patients had bladder tumors, and most were diagnosed based on transurethral resection of bladder tumor (TURBT). The histological grade was high in 74.47% of patients; in patients who underwent surgery, 17.39% had positive margins, 45.45% had perineural invasion, and 38.10% had lymphovascular/perivascular invasion. The median recurrence time was 40.2 months, and recurrence-free survival rates were 85.5%, 71.6%, and 44% for one, two, and five years, respectively. The authors stressed that their outcomes are comparable to those in the literature; however, more accurate data collection and future national collaboration are essential to improve patient outcomes.

Alsaleh, et al., aims to assess knowledge, attitude and practice toward covid-19 pandemic among pregnant women living in Jeddah, Saudi Arabia. A considerable number of pregnant women have been affected by the current pandemic.

Al-Amri, et al., did a descriptive cross-sectional survey looking at prevalence of dry eye symptoms and risk factors in Saudi Arabia. Data was collected using structured questionnaire included person's socio-demographic data, addition on that we will use OSDI (ocular surface disease index) combined by questions have relevant to the target of our research ((the repetitive habitual/behavioral factors leading to Dry eye disease (DED). Out of 2527 total respondents, 694 (27.5%) have no issues related to eye, while 1833(62.5%) have eye related issues. The mean (SD) of age was 29.4(8.9) Years. 67.0% were females while 33.0% were males. 22.9 % exposed with air conditioner, 22.9% used contact lenses, 7.36 % used lubricant drops, while 6.3% living in dry weather area. The authors concluded that dry eye illness is a prevalent ophthalmological condition with a number of clinical predictors, including the use of electronic devices and other risk factors. Teachers and health professional should teach the students and nation about the awareness regarding dry eye problems

Al Mahfud, et al., did a cross sectional study to assess the misunderstanding regarding LP among parents in Taif city. The study was done on 687 of parents of children who required LP procedure from birth till the age of 18 in Taif Children Hospital 15.7% of parents were asked to take a

sample of the cerebrospinal fluid of one of their children, of them, 61.2% agreed, with the average age of the child at the LP being  $2.24 \pm 3.28$  years. A consultant discussed the LP technique to 37.8% of them, and 86.5% and 56.2% said the doctor clarified the nature and complications of the treatment to them. For parents not asked for LP before, 41.4% will not agree for it in the future. For parents who refused LP when indicated and hose refusing it in the future, the most common causes were the side effects as paralysis (60.6%), pain (11.3%) and no trust in HCWs and fear of medical errors (10.9%). For them, the most common sources of refusal were information from friends and relatives (41.2%).

Hameed et al., discussed training of general practitioner to be able to do Epley's maneuver. The most effective and non-invasive treatment for BPPV is Epley's Maneuver which is usually performed by trained ENT specialists or consultants in secondary care settings. Based on this study, the following conclusions can be drawn:

1. The efficacy of the Epley's maneuver proves it the treatment of choice for BPPV.
2. This treatment can be safely given in primary care set up.
3. Performing this procedure in primary care is very much cost effective and can save significant sum of money and reduce the referral rate to secondary care.
4. Primary care doctors felt confident with this training and the project and gave an overall better work satisfaction to all the participants.
5. Pre-medication with Prochlorperazine and Betahistidine reduced the discomforting vertiginous feeling in all patients during the procedure.

Alanazi, et al., did a cross-sectional study was conducted among the general population

to study the level of awareness among general population towards diabetic complications and explore the relationship between level of awareness and different socio-demographic factors. A total of 508 participants completed the study of whom 67.5% were males. We found that 91.1% of the participants had good awareness about diabetic complications. The majority of the participants (93.9%) were diagnosed with DM or knew someone diagnosed with it. This study revealed that the general level of awareness about diabetic complications among the general population of Saudi Arabia was good.

Huneif et al., did a cross-sectional study among primary care physicians (PCPs) looking at knowledge and practice among primary care physicians in Najran (south west region), Saudi Arabia regarding Maturity Onset Diabetes of the Young (MODY).

The questionnaire was created following a series of conversations between a panel of experts, which included subject specialists, researchers, and language experts. 12% responding completely regarding definition of MODY, 55.5% have knowledge regarding mode of inheritance of Mody, 9% were aware about the type of the MODY, 60% were about typical symptoms of MODY, Diagnostic tools of MODY (45%). The authors concluded that clinicians should maximize alternative therapy in the era of CF modulators and correctors to improve outcomes and prevent long-term morbidity and mortality.

Dr. Musallam, did a quality improvement project on improving patients centered care by documenting their contribution in the plan of care at west bay health center, Qatar. Our project showed remarkable improvement, in physician's documentation of patient contributions in their plan of care. We found that, physician documentation of patient contributions in their plan of care, improved from 50% to 89.3% and that exceeds our aim by 39.3%. The strength of our project, is that, the project was applied to the family medicine clinic, which is the most busy clinic in our health centre, compared to other speciality clinic. On the other hand, the limitation of our project is small sample size, the total number of physician contributions checked was 300, which is relatively small number. The authors concluded that Their intervention showed remarkable improvement in the percentages of physician's documentation of patient contribution in their plan of care.

El-Gamal, et al., did a cross sectional study to explore the oral manifestations associated with the use of inhalation therapy among patients with asthma in Jeddah city. Data were collected using interview questionnaire, the standard 5th ed. WHO survey on oral manifestations, measurement of vital signs and anthropometric parameters, as well as clinical oral examination. The majority of patients with asthma (95%) used inhalation therapy, without use of spacers. The authors concluded that use of inhalation therapy in patients with asthma was significantly associated with increased occurrence of oral health problems. Health education programs about proper use of inhalers and oral hygiene should be implemented by primary health care personnel.

Dr Daud, reviewed the Clinical Potential of Lorcaserin in the Treatment of Obesity. He stressed that obesity is a chronic disease characterized by excessive fat accumulation and associated with impaired metabolism and cardiovascular disease. The high global prevalence of obesity has resulted in the production of anti-obesity drugs over the last couple of decades, normally to be used in combination with

lifestyle modifications such as physical activity and diet. One such medication is Lorcaserin, a selective serotonin 5-hydroxytryptamine<sub>2C</sub> (5-HT<sub>2C</sub>) receptor agonist approved by the FDA in 2012 as a drug therapy for weight management in conjunction with lifestyle modifications. This review addresses Lorcaserin's therapeutic potential for the treatment of obesity, considering the pre-clinical and clinical trials describing its efficacy in weight loss along with its adverse carcinogenic effects to ultimately determine the likelihood of its reintroduction into the market.

Fardan et al., looked at the Knowledge of school teachers regarding Asthma in Aseer region of Saudi Arabia. The data for this cross-sectional study was acquired using a specially designed questionnaire. Out of total 759 respondents, the mean (S.D.) of the respondents were 31.6(12.8). 14.2% were male while 85.8% were females. The Cronbach alpha of the questionnaire was 0.79. We have observed that age and education have a significant impact over the prevalence of the Asthma. The authors concluded that we should train our teachers by conducting series of seminars, webinars, workshops. We will also incorporate training for trainer sessions for teaching staff to enhance their skills to deal with asthma.

Algethami, et al., did a descriptive cross-sectional survey to assess parental knowledge and practices toward aerodigestive paediatric foreign bodies ingestion or inhalation, Saudi Arabia. A total of 611 child care givers completed the study questionnaire. Exact of 508 (83.1%) respondents were children's mothers and 103 (16.9%) were their fathers. Exact of 93.1% of the study parents heard of swallowing or inhaling foreign objects and 77.3% reported that children aged 1-5 years are more likely to swallow or inhale foreign objects while 20.5% reported for children aged less than 1 year. The authors concluded that the study revealed that parental knowledge and practices toward FBA were on average (but not satisfactory) especially for the correct actions for swallowed objects and timing to visit ER even for asymptomatic ingested FB. On the other hand, safe practice especially keeping small objects out of children reach was high but observing young aged children while playing was unsatisfactory.

Alshahrani et al., did a cross-sectional study conducted among male secondary school students to examine the relationship between obesity and negative emotional states among male secondary school students. Three hundred and ninety eight students participated in the study. Their mean age ( $\pm$ SD) was 16.98 $\pm$ 0.93 years. Overweight and obesity was present among 44.2% and 38.4% of participants,

respectively. The overall prevalence rates for symptoms of depression, anxiety and stress among participants were 57%, 64.6% and 39.4%, respectively. The authors concluded that the burden of overweight and obesity are high among the male secondary school students. Overweight and obesity are associated with symptoms of depression, anxiety and stress. Therefore, there should be emphasis on implementing interventions to raise awareness about maintaining normal body mass index among the school students and thereby reducing the risk of mental disorders.



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# Trends and Emerging Practices in Healthcare Project Management: The Role of Corona Crisis Management Room to Control COVID-19 Spread in Aseer Region, Saudi Arabia

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## Abstract

In response to the Covid-19 pandemic, the Emirate of Aseer Province, Saudi Arabia, has established the Corona Crisis Management Room (CCMR) to help support the health affairs and eliminate all the risks associated with the virus within the region. The study aimed at establishing the trends and emerging practices in healthcare project management with a concerted interest in determining the role played by the CCMR in controlling and stopping the spread of the virus in Aseer region. The study adopted the exploratory research approach which sought to investigate the research phenomenon. The CCMR formed the focus of the study. 17 participants working in the CCMR were selected using the purposive sampling technique. Data were collected using in-depth interviews where a clear and detailed description of the phenomenon under research was obtained. The collected data were subjected to thematic analysis and classified into three thematic areas. The findings of the study established that the CCMR had a critical role in coordinating government activities within Aseer region. New management practices were based on the experiences of the pandemic and ranged from

evidence-based decision making, use of modern technology, and collaboration of various entities. The pathological spectrum was key in risk assessment.

**Key words:** Covid-19; Corona virus; risk management; project management; crisis management; healthcare; qualitative research; Emirate of Aseer Province; Saudi Arabia

## Introduction

The ongoing spread of COVID-19 Virus presents major healthcare challenges worldwide. According to the World Health Organization (WHO), stopping the spread of the virus has become difficult, with countries using different measures to mitigate the viruses' impact. Saudi Arabia stands as the second-largest Arab country, with a population of approximately 34 million. The majority of the population are middle-aged (15-65 years), and those below 14 years and above 65 years make up 32.4% and 2.8%, respectively [1].

Provision of healthcare services in the Saudi Kingdom is free to the public under the supervision of the Ministry of Health (MoH). The private sector entails a network of for-profit hospitals across the region. With the growing need for healthcare services in Saudi Arabia, the Crown Prince launched the Kingdom's "2030 Vision" that considered fundamental structural changes in the healthcare sector. Likewise, during the pandemic, the Emirate of Aseer Region, Saudi Arabia, and on the generous initiative of His Royal Highness Prince Turki Bin Talal Bin Abdulaziz, the Prince of Aseer Region, has taken measures to establish the Corona Crisis Management Room (CCMR) to effectively support health affairs and eliminate all the health risks associated with the virus.

The MoH applies methodologies and practices of project management to help achieve the vision of the Kingdom. Project management as a body of knowledge, recognizes the importance of crisis/risk management. The pandemic has triggered governments at all levels to operate in a context of radical uncertainty. The impact of the virus, both local and international, is heterogeneous, with important implications for policy responses and crisis management. The COVID-19 crisis has immensely triggered several pre-existing trends in healthcare project management, especially in the aspects of digitalization, quality, risk management, and improvement programs. The spread of the virus has shaken the world, triggering a range of possible trajectories across the globe. It is the different trajectories that have prompted the different approach mechanisms to fight the virus [2].

According to Allain-Dupre et al. [2], there is strong evidence that implicates a detailed territorial approach to the COVID-19 crisis. Governments, and sub-governments are all at the forefront of crisis management and recovery from the virus, despite the asymmetric economic, health, and social impact. In addressing the impact to the health sector, various countries are adopting the differential approach, such as policies relating to the use of masks and execution of lockdowns. On the socio-economic front, governments are making available significant fiscal support to protect individuals and firms from the effect of COVID-19. Some countries have put in place large investment recovery packages that focus on public investment with a major focus on strengthening the health systems. Like many other countries, Saudi Arabia's response has been immense with the sole commissioning of the CCMR to

address the pandemic in the Kingdom. Therefore, the aim of this study was to establish the trends, and emerging practices in healthcare project management with a specific interest in determining the role played by the CCMR in stopping the spread of COVID-19 in Aseer Region, Saudi Arabia.

### Statement of the Problem

In 2020, the novel COVID-19 has negatively affected all countries, with more than 50 million people around the world being impacted. The COVID-19 has set up governments operating in a context of radical uncertainty raising health, economic, and social challenges. During the pandemic, the world has faced spontaneous containment measures and a series of lockdowns in various countries. Beyond the human and health tragedy caused by the virus, it is now evident that the pandemic has triggered a serious economic crisis since World War II [2]. Several economies are set not to recover their 2019 output levels at least until after 2022 [3]. A rebound of the crisis through 2021 is increasing uncertainty, calling for more containment measures to curb the spread of the virus. Recently, the WHO acknowledged the rise of a new variant that is more contagious [4].

The nature of the crisis seems unprecedented. Apart from the short-term reoccurring economic and health shocks, the long-term effects of COVID-19 on human capital, behavior, and productivity may turn out to be long-lasting. The pandemic has accelerated some pre-existing trends, especially in project management within the healthcare sector. The virus has taken the world by surprise, setting up waves of change accompanied by a range of unexpected trajectories in risk management [3].

Several governmental and non-governmental organizations are actively involved in the frontline of crisis management, and they are constantly being faced by the COVID-19 asymmetric economic, social, and health impact within and out the countries. The disparities in terms of infection of some populations are evident with the Western nations hit more than the African nations [4]. Large urban areas have been hit, but within them, the more deprived areas have been strongly affected. The health impact is now spreading toward the less populated regions, an example being the US, where the rural counties have experienced more deaths. Such disparities show that the risks vary depending on where one lives [2].

Taking that into account, the regional differences in disease impact call for a territorial approach to policy responses on the economic, health, fiscal, and health fronts coupled with strong inter-governmental cooperation and coordination.

Saudi Arabia has been quick in terms of implementing disease containment measures and working toward meeting the demands and needs of the community within the shortest time possible [5]. Despite the presence of the vaccines, not everyone has access to vaccination at this stage [4]. Therefore, it is evident that Saudi Arabia is being faced with a burden of how to prevent the spread of

the virus. To mitigate the risks involved with the spread, immediate measures, such as social distancing and city and state lockdowns continue to be the only solutions to containing the pandemic [6]. However, there is a need to try other management measures within the Kingdom.

As a result, the study sought to determine the role of the CCMR to control the spread of COVID-19 in Aseer Region, Saudi Arabia. Moreover, findings of this study are expected to establish whether the CCMR is efficient in preventing the spread of the virus and whether the regional-based approach to policy response is having an impact to curb the spread.

### Research Objectives

This study's main objective is to establish the trends and emerging practices in healthcare project management during COVID-19 pandemic through:

- determining the role of the CCMR in managing the spread of COVID-19 in Aseer Region,
- identifying the project management practices adopted in the management of COVID-19, and
- establishing the risk assessment approach adopted by the CCMR in fighting the virus.

### Research Scope

This study was conducted in Aseer Region, Saudi Arabia, with a special focus on the CCMR. The authors restricted themselves to the geographical scope of Aseer Region and within the confines of the CCMR.

### Literature Review

The Emergence of COVID-19: The Case of Saudi Arabia  
Coronaviruses (CoV) are important animal and human pathogens, which present an enormous public health and economic challenge. The viruses are known to cause gastrointestinal and respiratory infections [7]. Within the human body, Coronaviruses are known to affect the respiratory tract resulting in diseases that range from mild common cold to fatal pneumonia [8]. Four variants of human Coronaviruses are associated with the common cold, but a new variant of novel human Coronavirus was discovered in China between 2002-2003 and was associated with a severe respiratory disease referred to as Severe Acute Respiratory Syndrome-CoV (SARS-CoV) [9]. The SARS-CoV spread globally, causing a SARS epidemic affecting more than 8000 individuals with approximately 800 deaths [1]. Evidence suggests that there has been active research on the CoVs, but in 2012, a new zoonotic CoV identified as the Middle East Respiratory Syndrome-CoV (MERS-CoV) broke out in Saudi Arabia and spread to 27 nations resulting in approximately 2500 confirmed cases and 860 deaths with a majority in Saudi Arabia [10].

Recently, on January 7, 2020, a new variant of human Coronavirus, identified as Severe Acute Respiratory Syndrome-CoV-2 (SARS-CoV-2), was determined to be a causative agent of Coronavirus Disease 2019 (COVID-19) [11]. The virus was first reported in Wuhan, a Chinese city, and within weeks the virus quickly spread to different

Chinese cities and eventually outside of China, reaching almost all countries. The WHO declared a global pandemic because of the rapid and continuous spread of the SARS-CoV-2 by the end of January 2020. As on February 18, 2021, the virus has caused approximately 110 million cases, 61.9 million recoveries, and 2.43 million deaths, with several countries reporting high cases, including the USA, UK, Spain, Italy, China, Iran, France, Turkey, and Germany [1]. On March 2, 2020, the first case of COVID-19 was reported in Saudi Arabia, having been detected in a traveler coming back from Iran [1]. As of February 18, 2021, Saudi Arabia has reported 373,702 confirmed cases and 6,445 deaths, with June 2020 being the worst month of infection and deaths [12].

Since the start of the pandemic, the Kingdom has taken various measures ranging from restrictions, suspension of Umrah, closure of the two Holy Mosques in Makkah and Madinah and the shifting of learning to remote forms and virtual classrooms. The measures were followed by travel restrictions to affected countries and the execution of mandatory quarantine for individuals who had already arrived in the country. In addition to the domestic measures, Saudi Arabia has played a big role in the global efforts to control and fight the virus with a \$10 million pledge to the WHO [1].

## Crisis and Risk Management of COVID-19

The COVID-19 pandemic presents a complex global public health crisis resulting in not only clinical but also organizational and system-wide challenges to healthcare project management. Management and monitoring of the crisis require different research perspectives ranging from healthcare research, sociology, public health, epidemiology, management, and economics. According to Kringos et al. [13], the application of performance intelligence in addressing the COVID-19 crisis is critical since it demands the use of different research perspectives that support health systems' decision-makers to come up with policies that are based on well-informed choices aimed at enhancing the wholesome system. In line with the argument, the management of COVID-19 becomes an integral component of governing healthcare systems and does not make it a separate entity with its own rationale.

Since the start of the pandemic, Saudi Arabia has initiated and based its decisions on the risk assessment of the COVID-19 spread at both the local and international levels. According to the Saudi MoH report, the Kingdom largely relied on global statistics and the Saudi Center for Disease Prevention and Control's travel assessment tool to issue warnings against movements in and out of the Kingdom [2]. According to Algaissi et al. [1], the experience derived from the MERS-CoV in relation to risks that arise from having large crowds at Umrah and Hajj pilgrims helped shape the Kingdom's response to COVID-19. Risk management is an important component of project management practice, and the Kingdom's approach to risk assessment is testament enough to the role project management practice played in its measure.



Several risk assessment tools were under application by the Kingdom. According to the MoH [14], the “Jeddah Tool” for risk assessment helped to carry out a strategic assessment of the health risks associated with Hajj and Umrah during the pandemic. The findings of the tool indicated that the risk level was extremely high, and based on the result, Umrah was suspended. Another tool, “Salem COVID Tool” was applied in assessing the risks associated with mass gatherings. The two tools are scientific and developed with the supervision of the WHO making the results reliable. Therefore, the crisis and risks associated with COVID-19 can be well managed using scientific assessment tools that base results on factual data.

## Healthcare Project Management during the Pandemic

During the advent of COVID-19, almost all industries have been hit. The healthcare sector has suffered the most and continues to experience the strain. With the continuing pandemic, there exist opportunities for improvement, with healthcare project management playing a critical role. According to Moira [15], project managers are professionals who are used to working under pressure, be it financial, schedule-related, or quality control. Therefore, project management experts can easily help resolve crisis situations and lead the post-crisis reform agenda. Evidence suggests that the healthcare industry has been faced with challenges related to labor, scheduling, quality control, supply, and finance at the onset of the pandemic, thus requiring a well-organized project management office PMO [15]. The PMO’s responsibility lies in continuously monitoring the enterprise environmental factors that may affect projects and portfolios of organizations [16]. In coordination with other areas of management, the PMO assesses the threats and opportunities with the aim of developing a fallback plan.

## Materials and Methods

### Research Design

The authors adopted an exploratory approach to the study. According to Thomas and Lawal [17], exploratory research aims at investigating a research phenomenon that is not clearly defined. The study adopted a case study research design through conducting in-depth interviews. A case study design focuses on one organization as the source of information.

In this study, the CCMR in Aseer Region was used as the case study to understand its role in the larger Saudi Arabia. The application of the design is ideal in the current situation since it followed qualitative data collected through interviews. According to Hammarberg, Kirkman, and de Lacey [18], the qualitative methods are ideal in answering questions about a phenomenon and help in collecting factual data. The qualitative data were considered appropriate owing to its ability to reveal the emerging trends and practices in healthcare project management.

The qualitative design presents an inductive research that can be used to get the perspectives about the problem at hand and how it is being addressed. The collection of non-numerical data is only possible using qualitative research [19]. The design entailed the formulation of general research questions and the selection of specific targets within the CCMR, followed by a collection of data and data analysis to address the study objectives.

### Sampling Technique

For this research study, 17 individuals (34%) working at the CCMR in Aseer Region were selected out of 50 workers. Only individuals working in the Room were considered because of the focus of the study. The selection of study participants was through purposive sampling. According to Robinson [20], purposive sampling is the intentional selection of study participants based on the ability to elucidate a specific phenomenon, theme, or concept. In qualitative research, purposive sampling entails an iterative process of selecting the respondents instead of starting with a predetermined sampling frame from the larger study population. Therefore, the process involves the selection of the participants in line with the theme under study. The research applied purposive sampling out of convenience to help minimize movement during the pandemic and to align to the COVID-19 restriction measures put in place by the authorities.

### Data Collection Method

Data collection is a critical method during research. The study made use of in-depth interviews to collect data from the respondents. The major reason for conducting interviews was for the research to draw a clear and detailed description of the phenomenon under study. Interview questions were prepared, and the nominated respondents were taken through the direct interview or using a phone call interview. Respondents could respond in detail. The collected data were recorded and stored for analysis.

### Interview Questions

1. What is your role in the Crisis Management Room?
2. Has the COVID-19 pandemic impacted on crisis management practices? If yes, to what extent has your organization applied the practices?
3. What are some of the functions of the CCMR as per your understanding?
4. The CCMR aims at controlling the spread of COVID-19. What are some of the response strategies adopted to address this?
5. What are the current management practices in terms of project, program, and portfolio management that are applied during the pandemic?
6. Do you believe that crisis management is effective in controlling the spread of COVID-19 or reacting to its effects on the population?
7. Do you think that the CCMR has taken all the necessary measures to keep the public safe?
8. What are some of the risk assessment methods that are used in the Room to determine the effects and extent of the spread of the virus?
9. Has the pandemic changed the aspect of management

within the healthcare sector? If yes, what are some of the new insights?

**10.** From the experience of the pandemic and the anticipation of fundamental changes, has the management devised new practices to combat the spread of the pandemic?

**11.** On the global platform, how does the Room address the risk of global spread of the virus?

### Data Analysis Approach

The collected qualitative data were taken through thematic analysis. The NVivo software was used to find similarities in the collected data, which were unstructured and text-based. The interview transcripts were systematically arranged, and the data were coded and categorized [21].

## Results

The purpose of this qualitative case study was to explore and determine the trends and emerging practices in healthcare project management during the COVID-19 pandemic with a major focus on the CCMR in Aseer Region, Saudi Arabia, as the case study. Specifically, the study sought to determine the role of the CCMR in managing the spread of COVID-19 in Aseer Region and identify the project management practices adopted in the management of COVID-19 in the region. The study also established the risk assessment approach adopted by the CCMR in fighting the virus. To explore the topic, the authors targeted a total of 10 participants but managed to include 17 respondents (R1-R17), who were taken through the interview sessions to collect the relevant data to answer the study's objectives. To be considered for the study, the participants had to be working in the CCMR since its inception at the onset of the pandemic.

The unstructured interview data were subjected to thematic analysis. Three thematic areas were identified. The first thematic area was the role of the CCMR, and this was related to how the Room manages the spread of the virus within Aseer Region. The second thematic area was the project management practices adopted in managing COVID-19. The third thematic area was on risk assessment, where the risk assessment approaches adopted by the CCMR were analyzed based on the data collected.

### **Thematic Category 1: Role of the CCMR in Managing the Spread of COVID-19**

All the respondents in the study provided their views on this theme. The relative importance of this category was high in addressing the objectives of the study. The collected data showed strong evidence for the theme. The role of the CCMR strongly came out as one to control the virus and mitigate the effects of the pandemic. When asked to shed light on the functions of the CCMR, a variety of responses was attained, but the role of controlling the spread of the virus and mitigating the effects of the pandemic was strong. For example, Respondent 9 (R9) alluded that

*"...the most basic function of the CCMR, in my view, is to control the epidemic and mitigate the pandemic. This is done through a range of general functions of the Room and other specific tasks of specialized units. The general functions of the Room include ensuring follow-up and implementation of State directives regarding government decisions within the overall direction of the State in controlling the epidemic; close coordination between the various entities for the implementation of these directives; ... and the overall objective is to flatten the epidemiological curve and raise the capacity of the health sector."*

The arguments presented by R9 agreed with what R5, R7, R10, and R15 provided. It was evident across all the respondents that the major role of the CCMR was to control the epidemic and mitigate the pandemic. However, R2 provided different thoughts on the role played by CCMR. R2 divided the roles into what he termed as "field stages." The arguments were based on his role in data collection within the crisis management organization structure. He opined that

*"...I can divide roles by field stages to: phase 1 (preventive) which entails monitoring of non-proliferation hotspots, phase 2 (processing), which is the preparing of ICU rooms and increasing their capacity, phase 3 (treatment), which is the reception and treatment of cases at designated hospitals, phase 4 (preventive) which includes education and compliance with precautionary measures, and phase 5 (preventive) which entails vaccination of citizens and residents after the discovery of vaccines."*

The responses by R2 can be summarized into the preventive and treatment of COVID-19 role, which falls under the overall role of control and mitigation of the pandemic. There were notable similarities in R2 and R3 responses, but of notable interest, R3 opined that the CCMR had a role in "...vertical and horizontal coordination of all the healthcare stakeholders to make the mission against the Corona pandemic a success." The aspect of horizontal and vertical coordination agreed with the responses given by R5, who listed several functions that he believes define the role of the CCMR. R5 pointed out that

*"... the CCMR is responsible for collection and follow-up of government decisions, collection, and analysis of scientific information on the pandemic, dissemination of information and awareness-raising material to target groups, development of hypotheses for the worst-case scenarios and their respective implementation, monitoring of outlets and screening of passengers in accordance with the definition of suspected cases, ensuring approved standards are applied, and development of appropriate preventive measures together with their implementation follow ups."*

The similarities in responses acquired on the role of the CCMR suggested that the communication of the Room's scope was well understood by the respondents who are working at the organization. The CCMR in Aseer Region is mandated to "flatten the epidemiological curve and raise the absorptive energy of the health sector with the

*initiation of the Aseer Nashama Initiative program intended to reduce the effects of the pandemic in the region and its citizens (R7)."* However, the CCMR management works under the discretion of the Saudi Arabian Government, where it is mandated with supervising and implementing the Government's directives regarding the containment of the virus.

### **Thematic Category 2: Project Management Practices Adopted in Managing COVID-19**

Project management during the COVID-19 pandemic can be a challenge to many organizations. The number of activities that need to be coordinated and mobilized during this period can be overwhelming. Therefore, a combination of the best practices is needed to achieve results. According to [22], the COVID-19 pandemic has shown that the working environments are characterized by uncertainty, ambiguity, complexity, and volatility. Therefore, the application of project management strategies and practices is essential to ensure the success of the implementation and operation of various organizational activities. To answer the objectives of the study, the respondents were asked several questions, which targeted the project management strategies applied within the CCMR to control the spread of COVID-19.

### **Response Strategies**

The study participants were asked to respond to whether the COVID-19 pandemic has impacted on crisis management practices at the CCMR and how the organization is applying the practices in managing the spread of the virus. R1 alluded.

*"... Yes (the pandemic has impacted crisis management practices) and it has a clear impact on the working system in terms of restructuring the network of contact with those involved in dealing with the pandemic."*

R2 pointed out that the pandemic has influenced the *"... crisis management and working mechanisms"* of the organization. The sentiments of R1 and R2 were all like the other respondents who indicated that the pandemic had changed the way crisis management practices were executed.

With response to practices such as communication and risk management, R3 indicated that the pandemic has had a positive and tangible influence on crisis management practices. The Respondent said,

*"...the pandemic has certainly influenced some of the past practices in crisis management and has had a positive and tangible impact such as restructuring and improving the network of communication with stakeholders where they have been identified, and their requirements and impacts defined. Effective communication with stakeholders has been enhanced to address their needs and achieve the objectives of the Room. Risks have also been classified, analyzed, and prioritized with the necessary response plans developed if the risks occur. A number of precautionary and preventive measures have been modeled and coordinated to ensure safety, validity, and speed of the procedures."*

According to R3's response, it is evident that COVID-19 has changed the way communication management is carried out, significantly, and has influenced crisis management practices in a positive way.

In determining the various project management strategies under use by the CCMR to respond to COVID-19, the respondents were asked to point out some of the response strategies adopted. Several strategies were pointed out to indicate integration of various entities such as the management, security, oversight, and the public. R3, who is the commander of the Prevention Platform, responded as follows to the question:

*"...the pandemic response strategies under the administration of the Room are already entailed in the risk plan. They include escalation, avoid, mitigation, transfer of risks, exploitation of opportunities, digital transformation, increase in the number of ICU rooms, and development of regional laboratories where samples are sent to for testing during the crisis."*

The escalation strategy involves bottom-up communication in the event threats are difficult to solve within the limits of the CCMR. The avoid strategy involves the restriction of movements through traveling, while mitigation entails the response to various active cases and the risks they pose. Of interest, the Saudi Arabian Government, through the MoH, has heavily invested in digital transformation through the development of various applications that control crowds during religious gatherings.

In relation to the response strategies, R4 indicated that the strategies underuse includes the suppression strategy that makes use of non-therapeutic measures to control the virus based on seven key components, namely state-level control, health education, detection and isolation, community cleansing, health resources, physical distancing, and economic aspects. State-level control included the central coordination and control from the national prevention center with a clear participation and dissemination of information across the board regarding the pandemic. The health education campaign involved sensitization of the public on preventive measures. The detection and isolation components were made possible through the expansion of the medical examinations to be available to all and the treatment of active cases through isolation and medication. Surface contamination was controlled through community cleansing. The health resources were expanded to increase on the capacity of hospital beds and the provision of personal protection tools. Social distancing was also coordinated from the control room and through the use of digital applications. The economic component entailed providing material assistance to those affected by the pandemic and provision of assistance to professionals and healthcare workers. Other notable response strategies identified by R5 included implementation of Government resolutions on COVID-19, and monitoring of readiness in all Government and private establishments. The most common strategy among the majority of the respondents was the suppression strategy that relies on non-therapeutic measures.

In terms of projects and programs, R17 identifies the expansion of the healthcare facilities to increase capacity, establishment of field hospitals in Aseer Region, and equipping of vaccine centers in the region as some of the active undertakings. R15 identifies the "Aseer Nashama Initiative" as one of the programs started to target entrepreneurs in the region and cushion them against the adverse effects of the pandemic.

## Management Practices

Healthcare is one of the largest service industries in the world, and project management plays a vital role. Healthcare projects intend to improve access to healthcare, empower vulnerable groups during crises, and strengthen human resources [23]. The project management practices are conditions, characteristics, or variables that, if sustained and managed correctly, can result in significant success. In determining the various project management practices currently at play in the CCMR during the pandemic, the respondents were asked to respond to some questions during the interviews. The respondents had their say and shared the experiences on what they thought were the current management practices in terms of projects, programs, and portfolios management applied during the pandemic. R1 alluded that "...one of the most important practices is effective risk management at the highest level." In addition to that, R2 indicated that "monitoring of the epidemiological situation and periodic monitoring of all operational indicators" formed part of the management practices at play during the COVID-19 period. The responses by R2 agreed with R5 experiences, who said that "monitoring of standard implementations by regulators and the periodic evaluations" form part of the management practices exercised at the CCMR.

To establish the efficiency of the management practices at the CCMR, the respondents were tasked to respond to "Do you believe crisis management is effective in controlling the spread of COVID-19 or reacting to its effects on the population?" All the respondents were affirmative that crisis management has been very effective in curbing the spread of the virus. R5 responded by saying, "certainly, the Aseer Region has been proactive in implementing many of the initiatives that have come resulting in reduced cases and an increase in the absorptive capacity of the health facilities." R10 believes that the crisis management practices have been effective through the provision of guidance from the Room's leadership and the centralized decision-making approach adopted. The majority of the responses showed firm attainment of effectiveness and efficiency through crisis management of the COVID-19 pandemic in Aseer Region. Other responses received from some of the respondents are listed below.

*"It has certainly been very effective in controlling the spread of the epidemic because of policy follow up and coordination among stakeholders reflected in the curve of situations in the region (R16)."*

*"I believe that they are effective through the dissemination, application, and promotion of precautionary measures, whether recommendations or influential orders for the*

*application of divergence and control of the spread of the pandemic. However, there is still a lack of community awareness campaigns (R14)."*

*"Yes, crisis management is effective. Through the CCMR, facilitation and promotion of effective communication among different sectors (health, military, and services industry) have seen the suppression of the virus (R3)."*

*"It has been very effective in controlling the spread of the epidemic through careful implementation of guidance and close coordination between units and stakeholders (R17)."*

Based on the responses above it is evident that for implementation of new project guidelines within a given health situation, it is critical to have strategic and effective management practices. According to Njeri [23], project management practices are poised to have a positive impact on the success of a project. The inputs that are put into the process through the management practices are vital to ensure the delivery of the set objectives. In this case, the management of the CCMR is applying effective management practices in controlling the spread of the virus.

## New Management Practices

The experiences derived from the management of the COVID-19 pandemic have led to the introduction of new management practices. The Aseer Region is expected to experience the need for new management strategies regarding healthcare. The interviewees were asked to respond to whether the pandemic has changed the aspect of management within the healthcare sector. The majority of the responses were in the affirmative, indicating a shift to new management strategies based on the experience derived from the pandemic. Some of the responses have been listed.

*"...yes, the pandemic has changed the management approach not only in the health sector but also on the general level in terms of information-based decision making and not speculation or cognitive backgrounds (R2)."*

*"...yes, the epidemic has had a positive change in aspects of health management about administration and governance. Most of these changes are attention to risk assessment and better preparedness for health crises, decision making based on statistics and data collection, promotion of preventive aspects and public health, qualifying and training specialized cadre to face the crisis, making maximum use of modern technology for epidemiological investigation, and improved effectiveness of vertical and horizontal coordination (R4)."*

*"...yes, application of flexible working time and division of taskforce into groups, and adoption of remote working for staff who are most at risk (R13)."*

From the responses, it is evident that the pandemic has changed the management approach and way of working for a majority of people in the region. Every decision is made based on evidence with the aim of preventing further spread of the virus or having new infections.

New management practices have also been devised based on the experience of the pandemic and the anticipation of fundamental changes. The respondents identified some measures such as promotion of the concept of teamwork, use of modern technology, and remote working as the new practices across all the sectors. The Saudi Arabian Government has been active in ensuring digital transformation to support all the sectors of the economy to adapt to the new norms. Other notable new practices identified with the respondents included proactive professional media management of the crisis to combat rumors and raise awareness in the society, devising technical solutions to ensure optimal continuity of service such as having virtual clinics, and application of various hypotheses to measure performance and upgrade preparedness and response to any risks.

### **Thematic Category 3: The Risk Assessment Approach Adopted by the CCMR**

Governments and institutions are constantly being faced by an increasing number of crises. The crises may spread beyond national borders, thus triggering economic knock-on effects owing to the interconnected nature of the global economy [24]. The complexity of managing and controlling a pandemic entails the involvement of many actors that go beyond emergency services which demand effective risk assessment and coordination for a successful outcome. In relation to the risk assessment approaches adopted by the CCMR during this pandemic in Aseer Region, the interviewees were asked to respond to several questions regarding risk assessment methods and the contribution of the Room towards averting the risks caused by the global Virus.

In reference to the risk assessment methods used in the Crisis Management Room, the theory of a pathological spectrum was mentioned as the main strategy used to address the risks. The spectrum of pathological findings of the Coronavirus was key in addressing the risks of COVID-19. The pathological spectrum helps identify the COVID-19 pathophysiology, molecular pathology, diagnostics, and immunology with the aim of understanding the development of the disease and how it is spread [25]. In the CCMR, the spectrum has been key in the facilitation of scientific decision-making based on the facts of the pathogenesis of the disease. R14, in responding to the risk assessment methods question, pointed out that; *“...one of the most important methods used in the Room for risk assessment is the theory of pathological spectrum of the pandemic, with assumptions based on scientific studies to predict the numbers of potential cases by drawing epidemiological curves. This helps to determine the expected need and has helped make informed decisions on increasing the bed capacity in hospitals, intensive care units, and health quarries. The theory has also contributed to raising the capacity of the ICU beds from 470 to 920 in the region. A risk management team has also been established within the teams and units of the Room to assess potential risks and activate approved response plans.”*

Risk assessment makes a critical contribution towards crisis management. In the region and across the world, individuals are in constant risk of contracting the virus. The risk assessment based on the established pathological spectrum goes a long way in informing the decisions of the (CCMR). In response to the global risks regarding international travel, the CCMR has made contributions that were notable to the interviewees. R16 argued that;

*“...the wise leadership of the Kingdom has implemented strict preventive and remedial protocols that have contributed to reducing the spread of the virus. Strict precautionary measures were applied to ensure that crowd flashpoints do not arise during the Hajj and Al Umra seasons as a global starting point. The Kingdom has applied strict measures to the Kingdom's border entry points, which have contributed to the control of the epidemic. It is from this application of the precautionary measures that Aseer Region has ensured all its terrestrial and airport entry points are monitored to prevent the entry of infected individuals.”*

The CCMR in Aseer Region has been proactive in the implementation of the Government's measures to curb the emergence of new cases from outside the region. The control of movement has been effective in ensuring that the active cases are treated, and the chances of having new cases are reduced.

## Discussion

The efforts to build robust systems and project management structures are fundamental to avert the dangers caused by emergencies and crises that continue to ravage the world. The failure to detect the virus early enough to prompt preventive measures in many of the countries shows that building crisis management capacities deserves primary attention.

The CCMR in Aseer Region is a strategic measure that aims to address the Coronavirus pandemic as it continues to unfold. Its primary mandate is to control and avert the spread of the virus through providing a supervisory role to the Government directives in the region about containment measures and personal hygiene, for which the establishment of the CCMR in Aseer Region has spearheaded new developments in healthcare project management.

The CCMR management has focused on openness and transparency relating to its decision-making strategy and communication, where all decisions are based on scientific evidence and collected data. Moreover, management practice has also conformed to new measures informed by the experiences encountered in the management of the pandemic. The CCMR has opted for the adoption of modern technology in executing its duty. Other new management practices include effective horizontal and vertical coordination of health activities, strategic decision making, and teamwork.

Crisis management comprises phases, including preparedness before crisis, response to reduce damage, and feedback after the crisis. As a result, the CCMR is actively involved in sensitization of the society and creating awareness on the Coronavirus. The Room ensures that the community in Aseer implements the Government directives and has the knowledge to deal with any new cases and prevent the occurrence of other cases through personal hygiene and social distancing.

The involvement of the CCMR in risk assessment is evident, with a great deal of success. In response to the pandemic in the Aseer Region, the CCMR actively applies the response phase of crisis management. This involves detection of the virus, monitoring of the developments, selection of appropriate contingency plans (both medical and non-medical), coordination of responses, and application of standard procedures. For this activity to work, flexibility and application of adaptable capacities for responses are critical for achieving a more holistic and dynamic approach to risk assessment.

For future studies, it would be necessary to explore the levels of crisis preparedness both in planning scenarios and preparing for the unknown. The application of project management practices, especially risk assessment regarding risk knowledge among Government and private entities, needs to be determined to allow for early preparedness. It is recommended that a broader and shared view of risk, both at the local and national levels, through a multi-threat and multi-hazard approach be put in place to include new and emerging potential threats.

Moreover, risk assessment should be shared widely with appropriate limitations to emergency response stakeholders, such as health agencies, security and police, local emergency services, non-governmental organizations, volunteer organizations, critical infrastructure operators, media, and the public. A cooperative strategy should exist between different stakeholders and disciplines to allow a multi-sector response to future pandemics.

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# Attitude and practice of pregnant women living in Saudi Arabia, about COVID-19 in relation to pregnancy outcome

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## Abstract

In December 2019, the outbreak of a new disease was reported in Wuhan, China (1).

**Key words:** Pregnancy, knowledge, attitude, practice, Covid 19

The given name was COVID-19), and is caused by corona virus (1). On 12th March 2020 WHO classified the current condition as pandemic status. Recorded cases worldwide is over 221 (September 8, 2021) million of with more than 4.5 million fatalities documented so far(2) . A considerable number of pregnant women have been affected by the current pandemic. As per literature review there were studies looking at concerns, attitudes and knowledge of pregnant women regarding Covid 19 in nearby countries, e.g. Iran and Turkey ( 3,4). This study aimed to assess knowledge, attitude and practice toward the Covid-19 pandemic among pregnant women living in Jeddah, Saudi Arabia.



## Introduction

Infectious diseases can play a significant role in pregnancy, particularly by affecting maternal and fetal outcomes (1). Prenatal respiratory infections may also result in stillbirth, miscarriage, and preterm delivery (1).

Pregnant women are more susceptible to developing severe cases of COVID-19. Prevention is superior to therapy, so knowledge, attitude and practice of pregnant women towards Covid 19 has a vital role in preventing infection transmission.

Our study looked at knowledge of a sample of pregnant women living in Jeddah during January and February 2021.

## Materials and Method

A cross sectional study, convenient non-probable sample, was used after collecting approval of ethical committee at the Research center of Ibsina national college for medical studies (no:021MP10022021). A validated website-based questionnaire was used. The sample size used software G power(3.1.9.4). It was found that minimal acceptable sample size is around 150 subjects. That number was based on G power software with alpha equal to 0.05 and power equal to 0.08 plus effect size of 0.3 plus differentiation factor of 5. The inclusion criteria was pregnant women living in KSA at the time of collecting data. Exclusion criteria was males, children and non-pregnant women.

**Data analysis.** In this study, the data were analyzed using IBM SPSS Statistics software (version 22). The relationship between qualitative variables was further assessed via the chi-square test. T test was used to compare numerical variables. Level of significance was <0.05.

**Data collection description:** The data collection instrument in this study was an online self-administrated questionnaire, composed of 4 main parts: sociodemographic characteristics information, knowledge, practice and attitude toward

**COVID-19.** The first 6 questions addressed area of residence, educational level, employment status. Question 7 was a direct question asking about if the pregnant lady had been diagnosed recently with Covid 19. Questions (7 -19) explored practice of participants towards preventive measures implementation (wearing mask, sanitizing hands, sanitizing surfaces, practice frequent hand washing, implementing social distancing, sleeping well, drinking plenty of water, practicing physical activity, ingesting supplements). These questions were given 3 options (yes, no, I do not know)

The attitude section was covered by questions (20-28). The questions discussed the participants attitude towards travelling, following Covid news, discussing Covid issues with family, social network and attending physician. Also participants were asked about their attitude towards breast feeding postpartum.

## Results

A total of 150 participants received the questionnaires. Their answers were complete and included in our study. Table 1 shows demographic characteristics of our study group. Most of the participants were Saudis living in Makkah region. 74% of the study sample had a university degree. Most members of our sample are from the age group (25-36 years old). Furthermore, 49% of the mothers had one child and they are currently housewives. Most of the participants were free from active Covid-19 infection at the time of the survey (Table 1).

Table 2 shows that most of the study group were using a face mask, while 57% of the participants used hand sanitizer strictly. Most of the study group always wash their hands regularly. In addition half of the group claimed that they avoid touching their nose and mouth with their hands. Most of the study group practice social distancing and continuous disinfection of surfaces.

In regards to measures for boosting self-immunity 7.3% never got adequate sleep, while 73.3% were always eating healthy foods and 56% were drinking water. A small portion of the group were always taking supplements and practiced physical activity on a regular basis. (Table 2).

Most of the participants avoided following up news and updates related to the current pandemic. They also did not share news with others. 83.3% of the study group claimed that they did not travel recently and they avoided attending social gatherings. However 28.7% went to work while most of the sample implemented distance working. 50% of our participants have had contact with someone with flu like symptoms.

In addition 71.3% of the sample did not discuss with their attendants impact of Covid-19 on pregnancy, or intra and postpartum care. A good finding was 80% of them plan to breast feed their babies (Table 3).

There was no significant relation between demographics and other questions except between education level and hand sanitizers using P-value 0.003.

### Limitation of study:

The limited number of cases involved may act as a limitation. It is recommended to perform the study on a wider scale with a larger number of participants.

<b>Table 1</b>	<b>Demographics</b>	
<b>Age Groups</b>	<b>Frequency</b>	<b>Percentage %</b>
15-25	55	36.7
26-35	66	44.0
more than 35	29	19.3
<b>Nationality</b>		
non-Saudi	32	21.3
Saudi	118	78.7
Total	150	100.0
<b>Level of Education</b>		
High School or less	29	19.3
Bachelor	111	74.0
Higher degree	10	6.7
<b>Employment Status</b>		
Employed	59	39.3
House wife	73	48.7
Unemployed	18	12.0
<b>Number of Children</b>		
one	73	48.7
2-4	65	43.3
more than 4	12	8.0
Total	150	100.0
<b>Diagnosed with Covid-19</b>		
No	123	82.0
Yes	27	18.0

<b>Table 2</b>		
<b>8- How often do you wear a face mask?</b>	<b>Frequency</b>	<b>Percentage %</b>
Always	105	70.0
Sometimes	39	26.0
Never	6	4.0
<b>9- How often do you use hand sanitizer?</b>		
Always	85	56.7
Sometimes	61	40.7
Never	4	2.7
<b>10- How often do you wash your hands with soap and water?</b>		
Always	126	84.0
Sometimes	24	16.0
<b>11- Limit groups, meeting to no more than 5 people</b>		
Always	51	34.0
Sometimes	93	62.0
Never	6	4.0
<b>12- Put space-distance between you and people</b>		
Always	88	58.7
Sometimes	57	38.0
Never	5	3.3
<b>13- Avoid touching your eyes, nose, and mouth</b>		
Always	73	48.7
Sometimes	69	46.0
Never	8	5.3
<b>14- How often do you clean and disinfect surfaces?</b>		
Always	82	54.7
Sometimes	65	43.3
Never	3	2.0
<b>15- Eating healthy food</b>		
Always	29	19.3
Sometimes	110	73.3
Never	11	7.3
<b>16- Take your supplements</b>		
Always	55	36.7
Sometimes	68	45.3
Never	27	18.0
<b>17- Drinking lots of water</b>		
Always	84	56.0
Sometimes	59	39.3
Never	7	4.7
<b>18- Sleep at least 7 hours a day</b>		
Always	66	44.0
Sometimes	73	48.7
Never	11	7.3
<b>19- Do you practice any form of exercise?</b>		
Always	21	14.0
Sometimes	82	54.7
Never	47	31.3

Table 3		
Follow the news on latest COVID-19 updates	Frequency	Percentage %
Always	55	36.7
Sometimes	68	45.3
Never	27	18.0
Share the latest facts and news of COVID-19 with other pregnant women		
Always	19	12.7
Sometimes	58	38.7
Never	73	48.7
Did you travel recently?		
No	125	83.3
Yes	25	16.7
Do you attend large gatherings?		
Always	6	4.0
Sometimes	55	36.7
Never	89	59.3
Do you go to work?		
No	107	71.3
Yes	43	28.7
Have you been in contact with someone who has cold or flu-like symptoms?		
No	75	50.0
Yes	75	50.0
Do you seek immediate care when feeling sick?		
Always	66	44.0
Sometimes	67	44.7
Never	17	11.3
Have you discussed the impact of COVID-19 on your pregnancy with your doctor?		
No	107	71.3
Yes	43	28.7
Are you planning to breastfeed your child?		
No	10	6.7
Yes	120	80.0
Maybe	20	13.3

## Conclusion

Our sample showed quite good practice and response towards preventing Covid 19 cross infection. It shows the impact of team work done by authorities at KSA.

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# Quarantine COVID-19 compliance in families with an allergic and immunological diseased child and its psychological impact in KSA

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## Abstract

**Background:** With the onset of the spread of the Coronavirus around the world, the Saudi Ministry of Health has taken protective measures early to prevent the spread of the disease in the region, and the most effective of these measures is Quarantine and home isolation, which can have an impact on the individual's mental health. The purpose of this study is to assess the compliance of Quarantine in a family with an allergic and immunologically diseased child and its psychological impact on them.

**Methods:** A cross-sectional study conducted between June-August 2020 was conducted via a self-reported online questionnaire that includes fear of COVID-19 scale for parents, Revised children's anxiety and depression scale to assess Quarantine's psychological effect, fear of getting the infection and also to know the family's attitude towards COVID-19 and public health measures.

**Results:** This study included 4,436 participants, and the findings revealed that (13.3%) of participants had a child with allergies or immune diseases, (30.2%) had children between 6-10 years of age, the mean fear score was  $18.74 \pm 6.48$  (7- 35) which is nearly moderate; the mean values of the Child Anxiety and Depression Sub- Scale for Parents (RCADS) were 4.81 5.61 and  $18.74 \pm 6.48$ , respectively. This study

showed a highly statistically significant positive relationship between the mean values for fear of COVID-19 Score scale and mean scores for child anxiety and depression ( $P = <0.001$ ), and also showed that 73.8% of the families thought that quarantine is a necessary action that should continue until the end of the Pandemic.

**Conclusion:** The Quarantine impacted psychologically and financially on some parents. Children are also more vulnerable to psychological effects resulting from the commitment of families to Quarantine, so we see that special attention and care is needed to prevent these effects on them, especially children with allergic or immune diseases.

**Key words:** COVID-19, Quarantine, Saudi, children.

## Introduction

The Pandemic of coronavirus disease (COVID-19) is an ongoing pandemic discovered firstly in Wuhan, China, in December 2019, and subsequently declared by WHO as a global concern on March 11, 2020 (1, 2).

This virus has high transmission power because of its long incubation period, which ranges from 2 days to 14 days and its vague symptoms, which mimic a common cold symptoms and leads to increased transmission between people (3 4).

Up to May 2020, there were 80,185 cases in Saudi Arabia including 441 deaths. Furthermore, 85% of them were adults, 4% old aged, and 11% of them children (5).

Children usually exhibit less severity of the disease (6). Indeed most of them have mild clinical manifestations. Children are exceptional groups due to the immaturity of the immune system (7 8). Therefore, the child who has comorbidities and chronic diseases such as asthma and immunodeficiency should be given special attention since they are considered one of the most common non-communicable chronic diseases. More importantly, it increases the risk of developing more severe COVID-19 (6, 9).

To date, there is no current specific treatment or even vaccine to prevent COVID-19 (10). As a result, there are many preventive efforts taken by public health officials around the world to contain and reduce the spread of the virus, such as social distancing, isolation and quarantine (11, 12). However, quarantine is often a heavy experience for those who undergo it and their families and, could lead to dramatic effects on the psychological health of children, but it is the most effective and oldest measure to control contagious disease, and it will not work if there is no compliance with it (12, 13).

A study suggests that the majority of people exhibit their agreement toward quarantine as one of the public health actions during the outbreak (14). On the other hand, another study concludes that compliance of people depends on complex behavior related to their perception toward contract or spread the virus, such as their own risk to get the infection, ethical reasons, and social pressure (15).

Regarding psychological issues, recent research showed that fear is a normal response toward new viruses, and it consistently predicts compliance with public health recommendations (16). Furthermore, another study concludes that anxiety, and feeling anger are the most common psychological outcomes on quarantined people (17).

Moreover, a recent survey study showed that people with higher education levels and self-awareness of their health tended to have more psychological distress (18).

However there has been no recent studies in the Kingdom of Saudi Arabia (KSA) about factors that might influence quarantine compliance and its possible psychological effects on children and their parents. Therefore, we aimed in this study to assess quarantine COVID-19 compliance in families who had an allergic and immunological diseased child and its psychological impact, in KSA.

## Method

A cross-sectional study aimed to assess Quarantine COVID-19 compliance in families who had an allergic and immunological diseased child and its psychological impact on children and their family was conducted on the general population in Saudi Arabia during the period between June 2020 – August 2020. Ethical approval was taken from the research ethics committee at Taif University.

The inclusion criteria were all families lived in KSA who had a child between the ages of 0-15 years. The exclusion criteria were any family that refused to answer the questionnaire or who left an incomplete survey, and any participant who had COVID-19 infection either alone or with their family, was excluded. Participants were divided into two groups. Group 1 are those participants who had an allergic child or a child who had an immunological disease, and group 2 was those participants who had not. Eligible participants numbered 4,436 participants; 229 (7.6%) of them had an allergic child and 253 (5.7%) had a child with an immunological disease.

This study focused on collecting information by specifically designed Google form questionnaire from a large random sample of the Saudi population who have children from as many as possible. The questionnaire included multiple choice question, open ended questions, and rating scale questions. The survey included items on the participants' demographics: (sex, number of family members, nationality, education level of parents, region, the income of the family, number of children with an allergy and immunological disease, and age of the diseased child). Items on the parents' perceptions about Coronavirus, Quarantine, child risk of acquiring the infection, their own risk of infection, family attitude toward public health instruction in general and quarantine especially, the source they prefer to get information from, family history of getting coronavirus infection or being isolated compulsorily, were included.

Assessment of parents' fear of COVID-19 was done using fear of COVID-19 Scale (19) and evaluation of the child anxiety and depression was done using the Revised Children's Anxiety and Depression scale (RCADS) (20).

Data were coded, tabulated, and analyzed using (SPSS) version 20 (Armonk, NY: IBM Corp.). Qualitative data were expressed as numbers and percentages, and the Chi-squared test ( $\chi^2$ ) was applied to test the relationship between variables.

Quantitative data were expressed as mean and standard deviation (Mean  $\pm$  SD), where Mann-Whitney and Kruskal Wallis Tests were applied for non-parametric variables. Correlation analysis using Spearman's test was done, and a p-value of  $<0.05$  was considered as statistically significant.

## Results

There were a total of 5055 participants. Six hundred and nineteen of them were excluded because they did not meet the inclusion criteria. The 4436 remaining were further reviewed.

Participants were divided into two groups. Group 1, was those participants who had an allergic child or a child that had an immunological disease representing 229 (7.6%), 253 (5.7 %) of the total participants, respectively. And group 2 was those participants who had not.

Table 1 shows that 66.8% of the participants of this study were mothers, 95.4% were of Saudi nationality, 39.7% had an income that ranges from 10000-< 20000 SR, 78.9% had a bachelor's degree of education or higher and most of them (43.8%) were from Mecca region. About a third of the participants (30.2%) had children with age that ranges from 6-10 years; the mean number of family members was  $6.22 \pm 2.6$  members.

Table 2 shows that of the participants who had an allergic child (No.: 299), 72.6%, 23.5%, 3%, and 0.9% had asthma, allergic rhinitis, drug, and food allergy, respectively. Most of the participants (54.3%) saw that Coronavirus is dangerous and could lead to death. 73.8% of the families thought that it is necessary action should continue until the end of the Pandemic, and 76.7% reported that they always wear masks. Only 35.6% of the participants reported that they are more likely to be in danger of infection if their child got infected, and 79.3% preferred to get their information regarding COVID-19 from the official spokesperson of the Ministry of Health (MOH).

The mean values of the child anxiety and depression scale and the mean value of fear of COVID-19 scale for parents were  $4.93 \pm 4.04$ , and the mean values of Revised Children's Anxiety and Depression subscale for parent (RCADS) were  $4.81 \pm 5.61$  and  $18.74 \pm 6.48$  respectively (Table 3).

Table 4 shows that a non-significant difference was found between the two groups according to parents' perceptions about Coronavirus and parents' perceptions about Quarantine if they are more likely to be in danger of infection if their child got infected, if they can protect their family from COVID-19 disease, family attitude toward public health instruction in general and Quarantine especially, and preferred source of information ( $p \geq 0.05$ ).

Spearman correlation analysis shows a non-significant positive correlation between the mean values of fear of COVID-19 scale scores and the mean number of family members and the mean number of allergic children ( $r = 0.01$ ,  $p = 0.44$ ,  $r = -0.01$ ,  $p = 0.44$ ) respectively.

On the other hand, a highly significant positive correlation was found between the mean values of fear of COVID-19 scale scores and the mean child anxiety and depression scores ( $r = 0.35$ ,  $p < 0.001$ ,  $r = 0.25$ ,  $p < 0.001$ ) respectively (Table 9).

Table 1. Distribution of the studied participants according to their characteristics (No.: 4436)

Variable	No (%)
<b>Gender</b>	
Male	1471 (33.2)
Female	2965 (66.8)
<b>Income</b>	
< 5000 SR	618 (13.9)
5000-<10000 SR	1287(29)
10000-< 20000 SR	1791(39.7)
>20000 SR	770(17.4)
<b>Education</b>	
Bachelor and higher	3498 (78.9)
Secondary	676 (15.2)
Basic	170 (3.8)
Illiterate	92 (2.1)
<b>Nationality</b>	
Saudi	4234 (95.4)
Non-Saudi	202 (4.6)
<b>Age of child ≤ 15 year</b>	
<1	406 (9.2)
1-5	1211 (27.2)
6-10	1341(30.2)
11-14	964 (21.7)
15	514 (11.6)
<b>Number of family members (mean ± SD)</b>	6.23 ± 2.61
<b>Number of allergic children (mean ± SD)</b>	1.8 ± 0.9
<b>Region</b>	
Riyadh region	770 (17.4)
Mecca region	1942 (43.8)
Al-Madinah region	96(2.2)
Qassim region	64 (1.4)
Eastern region	485 (10.9)
Assir region	527 (11.9)
Tabuk region	38 (0.9)
Hail region	15 (0.3)
Northern region	165 (3.7)
Jazan region	216 (4.9)
Nagran region	59 (1.3)
Baha region	27 (0.6)
Jouf region	32(0.7)



Table 2. Distribution of the studied participants according to the type of allergy in their children and their situation from COVID-19 (No.: 4436)

Variable	No. (%)
<b>Type of allergy (No.: 229)</b>	
asthma	166 (72.6)
allergic rhinitis	54 (23.5)
Drug	7 (3)
Food	2 (0.9)
<b>Parents' perceptions about Coronavirus</b>	
I think coronavirus is a simple virus like seasonal influenza.	257 (4.8)
I think Coronavirus is dangerous and could lead to death.	2777 (54.3)
I think coronavirus is a simple virus in the young but dangerous in old age.	949 (17.9)
I have no idea about its virulence, but I am afraid to get the infection.	453 (5.5)
<b>Parents' perceptions about Quarantine</b>	
I think it is an essential action and should continue until the end of the Pandemic.	3274 (73.8)
I think there is no benefit from Quarantine.	132 (3)
I think quarantine time has an effect on psychology	828 (18.7)
I have no idea if it works or not	74 (1.7)
<b>More likely to be in danger of infection if my child got infected:</b>	
Yes	1577(35.6)
No	2859 (64.3)
<b>Family attitude toward public health instruction in general and Quarantine especially</b>	
Always wearing the mask	3426 (76.7)
Always keeping social distance	132(3)
Always washing hands	832 (18.6)
	74 (1.7)
<b>Preferred source of information: I like to hear news from :</b>	
The official spokesperson of the ministry of health.	3516 (79.3)
Official doctor's accounts on twitter.	687 (15.5)
Social media on general (what's app, twitter, Instagram)	80 (1.8)
I think information is not clear and enough yet for me	153 (3.4)

Table 3. Distribution of the mean scores of fear of COVID-19 scale for the participants and the mean scores of anxiety and depression scores of their children

Scale	Mean $\pm$ SD
<b>Anxiety scale</b>	4.93 $\pm$ 4.04
<b>Depression scale</b>	4.81 $\pm$ 5.61
<b>Fear of COVID-19 scale</b>	18.74 $\pm$ 6.48

Table 4. Difference between the two studied groups according to their situation from COVID-19 (No.: 4436)

Variable	Group 1	Group 2	$\chi^2$	p- value
	No. (%)	No. (%)		
<b>Parents' perceptions about Coronavirus</b>				
I think coronavirus is a simple virus like seasonal influenza.	27 (10.5)	230 (89.5)	0.6	0.89
I think Coronavirus is dangerous and could lead to death.	308 (11.1)	2469 (88.9)		
I think coronavirus is a simple virus in young but dangerous in old age.	97 (10.2)	852 (89.8)		
I have no idea about its virulence, but I am afraid to get the infection.	50 (11)	403 (89)		
<b>Parents' perceptions about Quarantine</b>				
I think it is an essential action and should continue until the end of the pandemic.	352 (10.3)	3050 (89.7)	4.36	0.22
I think there is no benefit from Quarantine.	16 (12.1)	116 (87.9)		
I think quarantine time affects the psychology	106 (12.8)	722 (87.2)		
I have no idea if it works or not	8 (10.8)	66 (89.2)		
<b>More likely to be in danger of infection if my child got infected:</b>				
Yes	177 (11.2)	1400 (88.8)	0.32	0.56
No	305 (10.7)	2554 (89.3)		
<b>I can protect my family from COVID-19 infection</b>				
Yes, by following methods of prevention	359 (11.2)	2855 (88.8)	1.11	0.29
	123 (10.1)	1099 (89.9)		
<b>Family attitude toward public health instruction in general and quarantine especially</b>				
Always wearing the mask	367 (11.2)	2907 (88.8)	3.6	0.3
Always keeping social distance	32 (11.1)	255 (88.9)		
Always washing hands	65 (11.9)	661 (91.1)		
<b>Preferred source of information: I like to hear news from:</b>				
The official spokesperson of the Ministry of Health	382 (10.9)	3134 (89.1)	0.19	0.97
Official doctor's accounts on Twitter.	74 (10.8)	613 (89.2)		
Social media on general (what's app, twitter, Instagram)	8 (10)	72 (90)		
I think information is not clear and enough yet for me.	18 (11.8)	135 (98.2)		

Table 5. Distribution of the mean scores of fear of COVID-19 scale for the participants and the mean scores of anxiety and depression scores of their children

	Group 1	Group 2	Test <sup>a</sup>	p-value
Scale	Mean ± SD			
Anxiety scale	4.98 ± 4.04	4.56 ± 4.03	2.31	0.02
Depression scale	4.84 ± 5.6	4.58 ± 5.68	1.27	0.2
Fear of covid-19 scale	18.57 ± 6.37	18.76 ± 6.49	0.73	0.46

Table 6. Relationship between the mean values of fear of COVID-19 score and participants' income and their opinion about conditions related to COVID-19 Quarantine

Variable	Fear of COVID- 19 scores (Mean ± SD)	Test	p-value
<b>Income</b> < 5000 SR 5000-<10000 SR 10000-< 20000 >20000	18.89 ± 7.14 18.69 ± 6.45 18.65 ± 6.26 18.88 ± 6.46	3*	0.65
<b>Parents perceptions about Coronavirus</b> <i>I think coronavirus simple virus-like seasonal influenza.</i> <i>I think Coronavirus dangerous and could lead to death.</i> <i>I think coronavirus simple virus on young but dangerous on old age.</i> <i>I have no idea about its virulence, but I am afraid to get the infection.</i>	18.67 ± 6.33 16.81 ± 7.04 19.39 ± 6.82 17.81 ± 7.49	3*	< 0.001
<b>Parents perceptions about Quarantine</b> <i>I think it is essential action should continue until the end of the Pandemic.</i> <i>I think there is no benefit from Quarantine.</i> <i>I think quarantine time affects the psychology</i> <i>I have no idea if it works or not</i>	18.78 ± 6.59 18.54 ± 6.07 19.17 ± 6.19 16.08 ± 5.53	3*	< 0.001
<b>More likely to be in danger of infection if my child got infected:</b> Yes No	18.88 ± 6.6 18.36 ± 6.13	2.2**	0.02
<b>Family attitude toward public health instruction in general and Quarantine especially</b> <i>Always wearing the mask</i> <i>Always keeping social distance</i> <i>Always washing hands</i>	18.42 ± 6.96 17.68 ± 6.41 18.82 ± 6.39	2*	0.07
<b>Preferred source of information:</b> I like to hear news from : <i>The official spokesperson of the ministry of health.</i> <i>Official doctor's accounts on Twitter.</i> <i>Social media on general (What's App, Twitter, Instagram)</i> <i>I think information not clear and enough yet for me</i>	18.76 ± 6.54 18.59 ± 6.23 20.02 ± 6.46 18.14 ± 6.61	3*	0.23

N.B.: \* Kruskal Wallis test

\*\* Mann-Whitney test

**Table 7. Relationship between the mean values of anxiety scores and participants' income and their opinion about conditions related to covid-19 Quarantine**

Variable	Anxiety score (Mean ± SD)	Test	p-value
<b>Income</b> < 5000 SR 5000-<10000 SR 10000-< 20000 >20000	4.95±4.04 4.91±4.04 5.26±4.55 4.47 ±3.82	3	0.25
<b>Parents perceptions about Coronavirus</b> I think coronavirus is a simple virus like seasonal influenza. I think Coronavirus is dangerous and could lead to death. I think coronavirus is a simple virus in young but dangerous in old age. I have no idea about its virulence, but I am afraid to get the infection.	5.22±3.7 4.86 ±3.96 5.11±4.22 4.83 ±4.36	3	0.001
<b>Parents' perceptions about Quarantine</b> I think it is an essential action and should continue until the end of the Pandemic. I think there is no benefit from Quarantine. I think quarantine time affects the psychology I have no idea if it works or not	4.92 ±4 5.04 ±4.16 5.15 ±4.26 3.78 ±3.37	3	0.007
<b>More likely to be in danger of infection if my child got infected:</b> Yes No	5.15±4.17 4.34±3.64	1	< 0.001
<b>Family attitude toward public health instruction in general and Quarantine,</b> Always wearing the mask Always keeping social distance Always washing hands	5.24±4.1 5.33 ±4.23 4.87 ±4.03	2	0.04
<b>Preferred source of information:</b> I like to hear news from : The official spokesperson of the Ministry of Health. Official doctor's accounts on Twitter Social media on general (What's App, Twitter, Instagram) I think information not clear and enough yet for me	4.95 ±4.04 4.91±4.04 5.26 ±4.55 4.47 ±3.82	3	0.61

N.B.: \* Kruskal Wallis test

\*\* Mann-Whitney test

Table 8. Relationship between the mean values of depression scores and participants' income and their opinion about conditions related to covid-19 Quarantine

Variable	Depression score (Mean ± SD)	Test	p-value
<b>Income</b> < 5000 SR 5000-<10000 SR 10000-< 20000 >20000	5.28 ±5.78 4.71±5.55 4.76 ±5.48 4.71 ±5.82	3	0.7
<b>Parents perceptions about Coronavirus</b> I think coronavirus is a simple virus like seasonal influenza. I think Coronavirus is dangerous and could lead to death. I think coronavirus is a simple virus in young but dangerous in old age. I have no idea about its virulence but I am afraid to get infection.	4.63 ±5.5 4.37±5 5.61 ±5.9 4.83 ±6.37	3	< 0.001
<b>Parents' perceptions about Quarantine</b> I think it is an important action and should continue I think there is no benefit from Quarantine. I think quarantine time has effect on psychology I have no idea if it works or not	4.81±5.57 5.06 ±5.51 4.93±6 3.83±4.422	3	0.35
More likely to be in danger of infection if my child got infected: Yes No	4.963 ±5.75 4.42 ±5.2	2.54	0.01
<b>Family attitude toward public health instruction in general and Quarantine especially</b> Always wearing the mask Always keeping social distance Always washing hands	5.51 ±5.6 6.37 ±7.25 4.65 ±5.54	2	< 0.001
<b>Preferred source of information: I like to hear information from :</b> Official spokesperson of ministry of health. Official doctor's accounts on twitter. Social media on general (Whats App, Twitter, Instagram) I think information not clear and enough yet for me	4.84±5.64 4.52 ±5.36 5.78±6.31 4.88 5.42	3	0.32

N.B.: \* Kruskal Wallis test      \*\* Mann-Whitney test

Table 9. Spearman correlation between the mean fear of covid-19 scale scores and mean child anxiety and depression scores

Variable		
	r	p-value
<b>Number of family members</b>	0.01	0.44
<b>Child anxiety scores</b>	0.35	< 0.001
<b>Child depression scores</b>	0.25	<0.001

## Discussion

Recently quarantine compliance and its possible psychological effects on children and their parents have been questioned a lot. Therefore, we aimed in this study to assess Quarantine COVID-19 compliance in families who had an allergic and immunological diseased child and its psychological impact, in KSA.

As long as, identify self-risk and individual health differences determine responses toward quarantine. Our results show that most of the families who had allergic and immunological diseased children thought that quarantine is a necessary action that should continue till the end of the Pandemic by 73.8% and 18% of the remaining saw that Quarantine has a psychological impact. Also, most of them comply with public health preventive measures such as wearing masks, social distancing and Quarantine. Likewise, a study by Li et al. 21 and Wise et al. 22 concluded that feeling at risk promotes self-saving behavior by adherence to public health actions.

Even though, the more surprising result of our research , showed there is no significant difference between the two-family groups in their perception about Coronavirus and their attitude toward Quarantine by p-value > 0.05. It is most likely due to the unpredictable situation at the begging of the pandemic, obligatory closure, and Quarantine in KSA from our view.

Furthermore, there are 79.3% of our population who prefer an official spokesperson from the ministry of health as a favorite source of information, which reflects a high level of trust in Saudi MOH and adherence to their instructions. Likewise, a recently published study by Bodas, M found similar results(23).

Fear of getting the infection, anxiety, and depression are all expected psychological outcomes to the new Pandemic and obligatory Quarantine. By using fear of COVID- 19 scale, we evaluated the amount of fear among the participants. The score ranged from 7 to 35 and, the mean of fear score among our respondents was 18.74 - 6.48 which is nearly moderate. One possible reason for such results among the participants could be the time the study was conducted because at that time obligatory Quarantine was still active, and most of the normal life activities were suspended, and the pandemic was still new. A study that was conducted in 2003 by Cava, M et al. (24) on individuals affected by SARS showed that fear regarding one's health and other people around from getting the infection was among the psychological impact of SARS back then. Likewise, a review article written by Brooks, S. K et al. (25) showed that fear during COVID-19 Quarantine was one of the psychological stressors reported.

Fear is a negative emotion that leads to psychological distress, which may reflect on children's mental health wellbeing, in addition to quarantine stress burden on parents. We found that there is a highly significant positive correlation between parent's fear of COVID-19 scores and the mean child anxiety and depression scores. Similarly to a recently published paper by Spinelli, M et al. (26), which

concludes a significant association between parent's stress and children's psychological impact during the COVID-19 Pandemic.

School closure and sudden unpredicted change in life routine could lead to a challenging situation and chronic stress, which in turn may affect mental health and weaken the immune system. So we investigated the psychological impact on a special children group, those who had an allergic and immunological disease and found that the mean values of Revised Children's Anxiety and Depression subscale for parent (RCADS) were  $4.56 \pm 4.03$  and  $4.58 \pm 5.68$  respectively. Also a study published by Imran, N et al. (27) showed that anxiety, irritability, anger, and withdrawal all had manifested on children during COVID-19 quarantine.

Moreover, we found a non-significant positive correlation between the mean values of fear of COVID-19 scale scores and the mean number of family members and mean the number of allergic children.

In our results, there is a significant relationship between fear, anxiety, and depression, and parent's perception regarding getting the infection if their child becomes infected. Likewise, a study done in Japan by Shigemura J et al. (28) showed that fear of getting infected increases anxiety. Also some children were concerned about infecting others as a result of infection. Saurabh, K et al. (29). Additionally found there is 54.3% of participants who believe that Coronavirus is dangerous and can lead to death. Since the majority of our population have a bachelor's degree or a higher degree, they have more knowledge of the disease in our hypothesis.

From our view, adverse health effects are likely to be much worse if children are confined to their homes without physical activity for a long time. Parents should observe their children's attitudes and feelings during home quarantine and assist them by initiating a direct conversation related to COVID-19 news to help alleviate their fear and anxiety, as well as performing recreational and educational activities among family members, which will enhance and improve family bonds.

A major limitation is that studies on compliance with quarantine and its psychological impact in children on Saudi Arabia are still not many, and this study could be more accurate if there was an accurate assessment of mental health by physicians rather than an online questionnaire. So our recommendation for further researcher compliance factors of Quarantine and its impact on children should have exceptional attention to minimize long term effects.

## Conclusion

In conclusion, compliance to quarantine during COVID-19 pandemic may lead to loss of communication between relatives and friends, causing psychological consequences such as fear response, depression, and anxiety in children and their families. They need care and attention, especially those children who have an allergic and immunological disease.

## Acknowledgment

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### About Professor Brygel



Maurice is a general surgeon trained & working in Melbourne, Australia.

He is the founder of the Melbourne Hernia clinic & Melbourne Haemorrhoid and rectal bleeding Clinic. He has performed over 10,000 hernia operations.

He conducts accredited online & hands on workshops for general practitioners & trainees in collaboration with the Royal Australasian College of Surgeons, several universities, and private institutions

He encourages General Practitioners with suitable training to utilize their skills where appropriate to manage lacerations, skin cancers, lipomata, sebaceous cysts & the many other surgical related problems which can be capably dealt with in the office.

His publications include the Video Book of Surgery & Exploring Essential Surgery. Many of the topics & videos are pertinent to GP training in office surgery.

He is a regular contributor to the World Journal of Family Medicine with GP related articles such as the Management of ingrowing toenails. Sebaceous cysts & lipomas, Ano rectal conditions, hernias.

His website [www.hernia.net.au](http://www.hernia.net.au) provides a useful tool for the General Practitioner

#### Testimonial:

I attended all the lectures of Prof Brygel for GPs "Hands-On" workshops in the Corona era which was announced by ARMGSAS on Alan Roberts facebook page. They are AMAZING lectures that you all should not miss. Prof Brygel chose the most AMC popular subjects and explained them in depth. He talked about hernias: types, assessment, examination, ways of treatment, surgery types, when to treat. He showed us photos of real patients before operation and during operation.

He also gave lecture about all types of skin cancers, and precancerous lesion, how to differentiate between these lesions, lots and lots of photos of real patients with different skin lesion and he quizzes us with those cases. I think after his lecture I can tell which lesion is this or that with confidence. It was AMAZING lecture that you can't miss.

Third lecture I attended was about leg ulcers, all types, DDs, real patients, assessments, treatment. Prof Brygel invited one of his colleague who also talked in depth about this important subject. The fourth lecture was about skin suturing techniques--also very amazing and informative! Dr. Ethar Hussain, Iraq

# Awareness of General Population of Saudi Arabia toward Diabetic Complications

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## Abstract

**Objectives:** Diabetes mellitus (DM) is a medical condition that induces hyperglycemia due to the lack of insulin production or intervention. With high prevalence of DM in Saudi Arabia, it is essential for the population to have adequate information and understanding of DM. We aimed to study the level of awareness among the general population towards diabetic complications and explore the relationship between level of awareness and different socio-demographic factors.

**Methods:** A cross-sectional study was conducted among the general population of Saudi Arabia in different regions between May – July 2021. Total enumeration method was used for including all the adult males and females who agreed to answer the questionnaire in this study. Self-administered questionnaire was used for data collection.

**Results:** A total of 508 participants completed the study of whom 67.5% were males. We found that 91.1% of the participants had good awareness about diabetic complications. The majority of the participants (93.9%) were diagnosed with DM or knew someone diagnosed with it. Approximately 78.4% of the participants thought that DM is a lifestyle disease and a higher percentage of them (84.1%) agreed that DM is a disease which needs to be monitored every 3-6 months. The most common identified complication was retinopathy (41.9%). We found that level of awareness of diabetic complications was significantly related to age ( $P=0.011$ ), and also it was significantly related to the occupation ( $P=0.001$ ).

**Conclusion:** This study revealed that the general level of awareness about diabetic complications among the general population of Saudi Arabia was good.

**Key words:** Diabetes mellitus, Complications, Saudi Arabia, Awareness

## Introduction

Diabetes mellitus (DM) is a medical condition characterized by the persistent elevated level of blood glucose in a person due to underlying metabolic dysfunctions related to either insulin secretory pathways, aberrations in insulin mediated pathways or both (1,2). The disease is divided into five different types including type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM), gestational diabetes mellitus (GDM), monogenic diabetes mellitus and secondary diabetes mellitus. Among these types, the most commonly prevailing types are T1DM, T2DM and GDM (1).

According to the American Diabetes Association (ADA), DM can lead to risk of developing certain serious medical conditions including neurological disorders, eye diseases, skin problems, kidney disorders, cardiovascular conditions, hypertension, and stroke. The onset of these diabetic complications can be stopped or delayed with early diagnosis and with prompt treatment as early as possible (1,3).

The incidence and prevalence of DM have been observed in increasing trends as suggested by global reports estimating that more than 400 million people were living with DM in the year 2015. The prevalence of DM is expected to increase further and it is predicted that more than 600 million people will be affected with the condition by the year 2040 (4). Increasing trends in prevalence of DM would lead to an elevated global health burden because the prevalence of DM complications will also be increased. Moreover, health burden and quality of life may get significantly affected due to morbidity and mortality ratio associated with acute and chronic DM complications including coronary heart disease, end-stage renal disease (ESRD), retinopathy, lower extremity amputations and other neuropathies (5).

Most of the scientific literature regarding DM and associated complications is available for the developed countries. Despite the rising incidence of DM in developing countries, not much data is available regarding the prevalence, diagnostic markers, underlying causes, guidelines to measure the complications and mitigating practices for DM associated complications. It is necessary to collect and interpret the information regarding the DM complications in these regions of the world in order to design and implement policies for efficient control of DM prevalence and reduction of associated health burden (5,6).

In Saudi Arabia, the incidence of DM is worrisome as Saudi Arabia has been ranked to be seventh highest country in terms of DM prevalence. Around 7 million people in Saudi Arabia are estimated to be affected with DM while 3 million have been suspected with pre-diabetes (7). Despite the high prevalence of DM and associated risk of DMA complications in Saudi Arabia, poor public knowledge, attitude and practices have been reported in the Saudi population (8,9). Therefore, more efforts are required to gather the adequate information for designing policies and interventions for a better public response and behaviors towards DM and the risk of associated complications.

This study aimed to investigate the awareness of the general population of Saudi Arabia towards DM complications and their awareness of the relationship with different socio-demographic factors.

## Methods

This cross-sectional study was conducted in different regions in Saudi Arabia during the months of May to July 2021. The study population was recruited from the general public population. Both male and female adult Saudi residents from any nationality who agreed to participate in the study, who can read, and who have a social media account, were recruited. EPI info program was used to calculate the sample size, based on 95.0% confidence interval, 5.0% margin of error and the total population of Saudi Arabia. The estimated sample size calculated was 384 and was adjusted to 422 to compensate for 10.0% non-response rate. The study was conducted using an online self-administered questionnaire via Google Form. The generated link was shared randomly on social media (namely, Facebook, WhatsApp, Telegram, and Twitter). The aim of this study was clearly explained in the user interface. A validated questionnaire was used which was prepared based on previous studies. The questionnaire contained socio-demographic characteristics of the participants like age group, gender, nationality, and residence. The questionnaire also included questions regarding public awareness towards diabetic complications in Saudi Arabia. A common grading method was used for each variable in the questionnaire: 2 points for correct option, 0 for the incorrect answer and 1 for neutral. After data collection, a participant who correctly answered 75.0% or more of the questions (12 or more points out of 16) was considered as having good awareness and practice about DM and its complications while a participant who correctly answered less than 75% of the questions (less than 12 points out of 16) was considered as having poor awareness and practice about DM and its complications.

The questionnaire was validated in a pilot study over a sample of 20 participants whose responses were not included in this study. Some modifications were carried out accordingly to ensure clarity and easy understanding of the questions. A convenience non-probability sampling technique was employed to collect the data from the participants. Data was coded, entered, and analyzed using the IBM's statistical package for social science (SPSS) version 23. Categorical variables were expressed in the form of number and percentage (No. & %). Chi-square ( $\chi^2$ ) test was used to examine the association between level of awareness and practice about DM and its complications and different socio-demographic characteristics of the study participants.

Ethical approval was obtained from the research ethics committee of Qurayyat Health Affairs under registration number H-13-s-071. All the participants were volunteers who were asked to do their best. All data was kept confidential, used only for research purposes and only anonymous aggregated data is released.

## Results

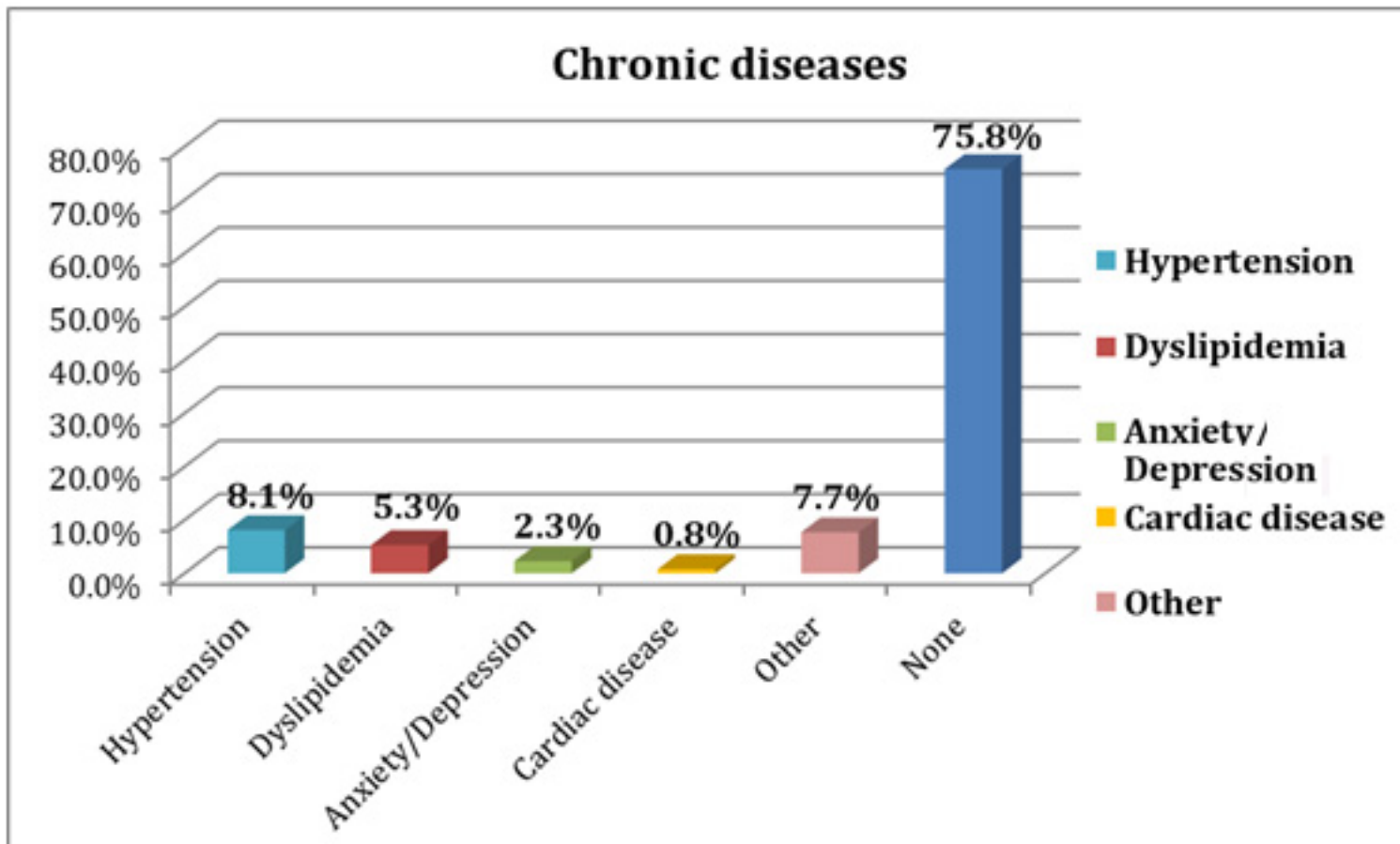
A total of 508 participants took part in our study; the majority of them were males (67.5%) and the rest were females (32.5%). The distribution of their age was as follows: 18 to 25 years (18.3%), 26 to 35 years (30.3%), 36 to 45 years (18.5%) and > 45 years (32.9%). Most of the participants were Saudi Arabian nationals (94.7%) and only 27 (5.3%) of them were other nationalities. Regarding their highest level of education, 322 (63.4%) of the participants had completed their bachelor's degree, 129 (25.4%) had completed their secondary school studies, 31 (6.1%) had other educational qualifications, 17 (3.3%) had completed their intermediate school studies and 9 (1.8%) had primary education. The majority of the participants were employed (50.2%), 98 (19.3%) had other occupation, 73 (14.4%) were retired, 71 (14%) were unemployed and only 11 (2.2%) had a private business. The characteristics of the participants are shown in Table 1.

**Table 1: characteristics of the participants (n = 508)**

Variable	Categories	Frequency	Percent
Gender	Male	343	67.5%
	Female	165	32.5%
Age in Years	18-25	93	18.3%
	26-35	154	30.3%
	36-45	94	18.5%
	More than 45	167	32.9%
Nationality	Saudi	481	94.7%
	Non-Saudi	27	5.3%
Educational Level	Primary	9	1.8%
	Intermediate	17	3.3%
	Secondary	129	25.4%
	Bachelors	322	63.4%
Occupation	Other	31	6.1%
	Employed	255	50.2%
	Unemployed	71	14%
	Retired	73	14.4%
	Private business	11	2.1%
Are you a diabetic patient?	Other	98	19.3%
	Yes	86	16.9%
If yes, which type of DM do you have?	No	422	83.1%
	Type 1 DM	21	24.4%
	Type 2 DM	51	59.3%
	Gestational DM	2	2.3%
	Others	12	14%

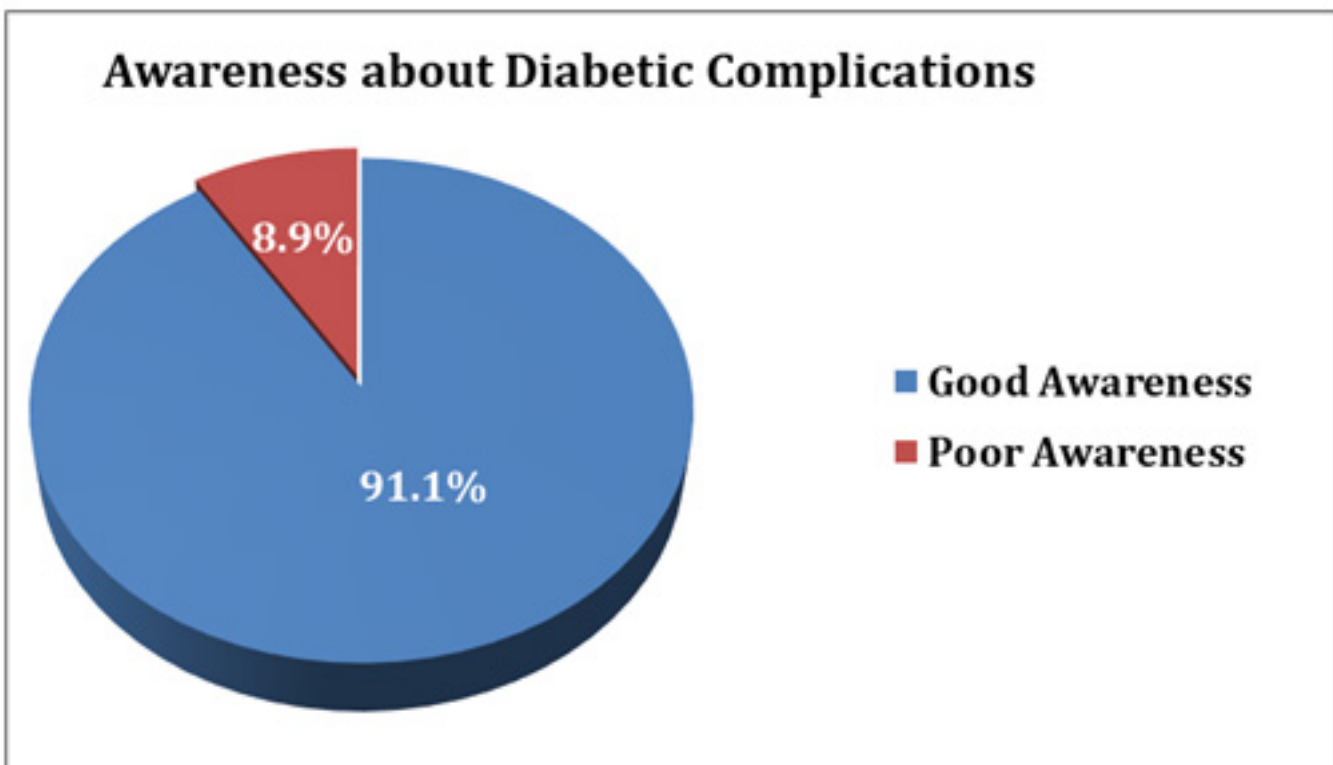
A total of 86 (16.9%) participants were diabetic patients of whom 24.4% were type 1 and 59.3% were type 2. The remaining had gestational diabetes (2.3%) and other types of diabetes (14%). Comorbidities among the study participants included: hypertension (8.1%), other diseases (7.7%), dyslipidemia (5.3%), anxiety depression (2.3%) and cardiac disease (0.8%) while 385 (75.8%) had no chronic disease, as shown in Figure 1.

Figure 1: History of chronic diseases (N = 508)



The mean awareness score was  $13.6 \pm 1.8$  points. We found that 463 (91.1%) participants had good awareness about diabetic complications while only 45 (8.9%) had poor awareness as shown in Figure 2.

Figure 2: Awareness about Diabetic Complications (N = 508)



Out of the 508 participants, 93.9% were diagnosed with diabetes mellitus or knew someone diagnosed with it. About 78.4% of the participants thought that diabetes is a lifestyle disease and a higher percentage of them (84.1%) agreed that DM is a disease which needs to be monitored every 3-6 months.

In addition, 84.3% knew that DM can affect multiple systems (namely a multi-systemic disorder). "Uncontrolled DM can cause multiple complications", the vast majority of the participants (96.1%) agreed with this statement and a similar proportion of the participants (96.7%) knew that monitoring DM can help to reduce the chance of these complications' occurrence. Participants were asked to identify Diabetic complications; only 184 (36.2%) of them correctly identified them without adding any other wrong answers. Retinopathy was the most selected (41.9%) followed by erectile dysfunction (35.8%), kidney disease (35.6%), foot ulcer (35.4%), myocardial infarction (22.6%), neuropathy (22%) and stroke (13.6%). Few participants thought that liver failure and pneumonia (16.5% and 5.7% respectively) could occur as a complication of diabetes. Furthermore, the majority of the participants (89.8%) agreed that diabetics should at least check complications of diabetes once every year. 373 (73.5%) of the participants thought that there is a lack of awareness regarding diabetic complications in Saudi Arabia.

**Table 2: Awareness about Diabetic Complications (n = 508)**

Awareness	Yes	No	
Do you know someone diagnosed with diabetes mellitus	477 (93.9%)	31 (6.1%)	
	Agree	Disagree	I don't know
Do you think diabetes is a lifestyle disease?	398 (78.4%)	57 (11.2%)	53 (10.4%)
DM is a disease which needs to be monitored every 3-6 months.	427 (84.1%)	21 (4.1%)	60 (11.8%)
DM is a multi-systemic disorder which can affect multiple systems.	428 (84.3%)	35 (6.9%)	45 (8.8%)
Uncontrolled DM can cause multiple complications.	488 (96.1%)	3 (0.6%)	17 (3.3%)
Monitoring DM can help to reduce the chance of the complications.	491 (96.7%)	2 (0.4%)	15 (2.9%)
Diabetic patients should at least check for diabetic complications once every year.	456 (89.8%)	22 (4.3%)	30 (5.9%)
Do you think we have lack of awareness regarding Diabetic complications here in Saudi Arabia?	373 (73.5%)	84 (16.5%)	51 (10%)

3.

The level of awareness of diabetic complications was significantly associated with age ( $P = 0.011$ ), participants aged more than 45 years had higher level of awareness compared to other age groups, and it was significantly related to the occupation ( $P = 0.001$ ). A higher percentage of participants with other than the stated occupations had good awareness when compared to the remaining occupational groups. On the contrary, gender, nationality and educational level did not have any significant impact on diabetic complications awareness, as the calculated  $P$  values were recorded 0.837, 0.333 and 0.911 respectively, as shown in Table

**Table 3: Factors associated with awareness about diabetic complications (the percentages were calculated within each studied group)**

Variable		Level of Awareness				P value
		Good		Poor		
		N	%	N	%	
Gender	Male	312	91%	31	9%	0.837
	Female	151	91.5%	14	8.5%	
Age in Years	18-25	85	91.4%	8	8.6%	0.011
	26-35	131	85.1%	23	14.9%	
	36-45	88	93.6%	6	6.4%	
	More than 45	159	95.2%	8	4.8%	
Nationality	Saudi	437	90.9%	44	9.1%	0.333
	Non-Saudi	26	96.3%	1	3.7%	
Educational Level	Primary	8	88.9%	1	11.1%	0.911
	Intermediate	16	94.1%	1	5.9%	
	Secondary	117	90.7%	12	9.3%	
	Bachelors	295	91.6%	27	8.4%	
	Other	27	87.1%	4	12.9%	
Occupation	Employed	232	91%	23	9%	0.001
	Unemployed	56	78.9%	15	21.1%	
	Retired	70	95.9%	3	4.1%	
	Private business	10	90.9%	1	9.1%	
	Other	95	96.9%	3	3.1%	

## Discussion

The past studies indicate the ever increasing threat of diabetes in Saudi Arabia (10,11). According to the Saudi Arabian Ministry of Health, DM was reported to affect 0.9 million people in 1992 (10). This number increased dramatically to 2.5 million people in 2010, which constitutes a 2.7 times increase in the incidence rate within 18 years only (10). According to a study done in 2013, Saudi Arabia comes in the Top 10 countries with a higher prevalence of DM (23.9%) (10). Due to the increased incidence and prevalence rates of diabetes in Saudi Arabia more attention and awareness are needed especially about recognizing the early symptoms of DM complications. It is important in order to help us in early identification of diabetic complications. Findings of our study will help assess overall awareness and to shed light on areas of awareness deficiency and misconception which help in targeting health education efforts and is helpful for health educators to plan for future awareness programs which will prevent the onset of diabetes or postpone the complications in the population.

The prevalence of diabetes mellitus among the study participants was found to be 16.9%. The same result was obtained in a study conducted in Saudi Arabia among the Riyadh population by Alanazi et al.(11) and in another study conducted among the Tabuk population by Mirghani et al.12, which were 16.7% and 16.5% respectively.

In the current study, the mean awareness score was  $13.6 \pm 1.8$  points. We found that 463 (91.1%) participants had good awareness about diabetic complications while only 45 (8.9%) had poor awareness. A lower level of awareness was reported among type 2 diabetic patients in Alahsa, Saudi Arabia by El Sheikh et al.(10) who found that 54.6% of the patients had good awareness level regarding diabetes and its complications. This difference in level of awareness may be attributed to the difference in the used assessment tool and types of questions used in the questionnaire. Due to the rapid increase in the number of people with type II diabetes worldwide, which comprises 90%-95% of all cases of DM(11), more attention and awareness are needed especially for those patients to help in curbing the crisis.

Regarding the statement "Uncontrolled DM can cause multiple complications", the vast majority of the participants (96.1%) agreed with the statement. A lower percentage was reported by Aljofan et al.(13) who found that 47.0% of the respondents knew that uncontrolled diabetes will lead to affect other organs; however, the remainder either did not believe (20.0%) or did not know that uncontrolled diabetes can affect other organs (33.0%).

Most of the participants agreed that diabetes is a lifestyle disease (78.4%) and 96.7% knew that monitoring DM can help to reduce the chance of these complications' occurrence. A similar result was obtained by El Sheikh et al.(10) who reported that 91.5% of the study's participating patients agreed that lifestyle and dietary modifications

reduce DM complications, while 87.7% said that DM control reduces its related complications.

Our study showed that when participants were asked to identify diabetic complications, retinopathy was the most selected (41.9%) followed by erectile dysfunction (35.8%), kidney disease (35.6%), foot ulcer (35.4%), myocardial infarction (22.6%), neuropathy (22%), and stroke (13.6%). Relatively similar results were obtained by Aljofan et al.(14) who found that 24.5% of those who knew the effect of diabetes on health, thought that diabetes will lead to eye disease, 28.0% believed it affects the kidneys, 26.0% listed foot ulcers and 20.0% only believed that diabetes can cause heart problems. A higher level of awareness about diabetic complications was reported in another two studies carried out by El Sheikh et al.(10) and Fatani et al. (14). El Sheikh et al.(10) reported that the most known diabetic complications by patients were diabetic retinopathy (91.6%), vision loss (90.8%), peripheral neuropathy (80.2%), and chronic renal diseases (36.9%). Fatani et al.(14) found that the mostly recognized complications of diabetes mellitus were as follows in order: eye disease (72.9%), diabetic foot (71.2%), renal disease (56.2%), peripheral neuropathy (53.8%), sexual impairment (42.5%), heart disease (40.1%), high blood pressure (33.1%), sudden death (20.4%), and cerebrovascular disease (18.7%). This difference in the recognition of the diabetic complications may be attributed to the difference in study populations since our study was carried out among the general population while the other two studies were among diabetic patients.

The level of awareness of diabetic complications was significantly related to age ( $P = 0.011$ ); participants aged > 45 years had the highest level of awareness. The result we found goes in line with the study carried out by Alanazi et al.(11), in Riyadh, Kingdom of Saudi Arabia (KSA), which found that there was a significant statistical relationship between the age and level of knowledge regarding the complications of T2DM ( $p$ -value = 0.028). Younger participants had a higher level of awareness regarding complications of DM type 2 than older age groups.

Furthermore, level of awareness of diabetic complications was significantly related to the occupation ( $P = 0.001$ ); a higher percentage of participants with other than the stated occupations had good awareness when compared to the remaining occupational groups. Gender, nationality, and educational level did not have any significant impact on diabetic complications awareness, as the calculated  $P$  values were recorded as 0.837, 0.333 and 0.911, respectively. This result was contrary to a study carried out by El Sheikh et al.(10) who reported that good awareness was detected among 61.2% of patients with a university level of education compared to 42.7% of those with an educational level below secondary, with recorded statistical significance ( $p = 0.011$ ).

This study provides informative data about awareness of diabetic complications and included a large sample size as the estimated sample size was 384 and the included



sample was 508, thus we can generalize the result for the general public. However, one of the limitations for this study is there is no question about the region of residence of the participants so the sample may not be representative of the studied region.

## Conclusion

This study revealed that the general level of awareness about diabetic complications among the general population of Saudi Arabia was good. The majority of the participants (91.1%) correctly completed more than 75.0% of the awareness questions. We noticed that there is a knowledge gap in the recognition of organs that may be affected by diabetes mellitus. Health authorities should employ special efforts to improve the level of knowledge and awareness toward diabetic complications which in turn may help diabetic patients to improve self-knowledge and recognition of early signs and symptoms of DM complications, and this will prevent further deterioration, which will improve life quality and increase life expectancy for those patients.

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# Etiologies of Lumbar Puncture Refusal in Pediatric Patients in Children's Hospital, Taif City, Saudi Arabia. A Cross-Sectional Study

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## Abstract

**Background:** Lumbar Puncture (LP) is a medical emergency operation in which a needle is inserted into the lower back's spinal canal for diagnostic and therapeutic purposes. Even though LP has a high diagnostic and therapeutic value, many parents refuse to have their children tested.

**Objectives:** to assess the misunderstanding regarding LP among parents in Taif city.

**Methods:** A cross sectional study was done on 687 parents of children who required LP procedure from birth till the age of 18 in Taif Children Hospital from January 2020 to May 2020. Data about participants demographics, ever been asked to take a sample of the cerebrospinal fluid (LP) of the child, circumstances related to this event were collected. For those who were not asked a question of "if it was needed to take a sample of the cerebrospinal fluid of one of your children, will you agree? was added.

**Results:** 15.7% of parents were asked to take a sample of the cerebrospinal fluid of one of their children, of whom, 61.2% agreed, with the average age of the child at the LP being  $2.24 \pm 3.28$  years. A consultant discussed the LP technique to 37.8% of them, and 86.5% and 56.2% said the doctor clarified the nature and complications of the treatment to them. For parents not asked for LP before, 41.4% will not agree to it in the future. For parents who refused LP when indicated and those refusing it in the future, the most common causes were the side effects such as paralysis (60.6%), pain (11.3%) and no trust in HCWs and fear of medical errors (10.9%). For them, the most common sources of refusal were information from friends and relatives (41.2%).

**Conclusion:** There is a need for health education of parents about the importance and nature of LP to overcome barriers that lead to LP refusal.

**Key words:** etiologies, LP, refusal, pediatric, Taif, Saudi.

## Introduction

Lumbar Puncture (LP) is a medical emergency procedure that involves inserting a needle into the spinal canal in the lower back for diagnostic and therapeutic purposes [1]. In cases of suspected meningitis, the most common reason for a lumbar puncture is to collect cerebrospinal fluid [2,3,4]. However, it may be used to diagnose other neurological issues including subarachnoid hemorrhage and hydrocephalus and benign intracranial hypertension [5].

LP is contraindicated in patients with an intracranial mass or other indications of elevated intracranial pressure; hemodynamic dysfunction, such as respiratory compromise, status epilepticus, any underlying spinal cord anatomic defects, coagulopathy, or spinal or epidural abscess; or an inflammation of the superimposing lumbar region, such as cellulitis or skin or subcutaneous abscess [6,7].

Use of a small gauge, 22G atraumatic needle to obtain adequate CSF on the first attempt with minimal pain and without any trauma, CSF must contain 1000 red blood cells per high powered area, and to reduce the risk of complications such as post-LP headache and cerebral herniation [8].

The procedure and risks should be explained to the patient and informed consent should be obtained. There has never been a study that looked at the effect of patient positioning [9,10,11]. Spinal hematomas and post-lumbar puncture headache are uncommon complications of LP [12]. However, it's still unclear if there are certain factors that increase the likelihood of these events, or if surgical intervention improves outcome.

In 2016, a report was conducted to assess the literature for cases of spinal hematoma and subsequent intervention after 1974. Patients with coagulopathy have a worse prognosis than healthy people, according to this report [13]. Another prospective study examined local rates of LP complications and risk factors, especially post-dural puncture headache (PDPH). The findings revealed that these complications are uncommon in Singapore. This could be due to the audit enhancing adherence to best practices [14], or it could be setting specific.

Research published in 2019 looked at the risk factors for the occurrence of post-lumbar puncture headaches, as well as the treatments used to avoid and alleviate them [15]. It also found that using an atraumatic needle decreased total costs when compared to traditional needles [16]. While LP has a high diagnostic and therapeutic value, many parents refuse to have it done on their children. According to a study conducted in Kuwait, 78.1 percent of parents believe the LP is a risky procedure, 14.2 percent believe it is healthy, and 6.4 percent are unsure [17].

In KSA, 44.3 percent of parents in a study conducted in Makkah, Abha, and Riyadh, Saudi Arabia, declined to have their children undergo the LP treatment. Fear of side effects such as paralysis, as well as a lack of knowledge

about the utility of LP in the diagnosis and treatment of infants, were the key reasons for refusal. In the therapy for such diagnostic tests, it is important to educate parents [18]. According to a previous study conducted in Dammam, Saudi Arabia, 24% of parents believe LP is not permissible in society [19]. The aim of this study is to assess the misunderstanding regarding LP among parents in Taif city. As there has been no similar study done in Taif city, KSA, this study aimed to assess the misunderstanding regarding LP among parents in Taif city.

## Methods

**Study design:** a cross sectional study done.

**Study participants:** The inclusion criteria were all parents of children who required LP procedure from birth till the age of 18 in Taif Children Hospital from January 2020 to May 2020. And the exclusion criteria were anyone who refused to share their data in this research.

**Data collection instrument:** a questionnaire was used for data collection and consisted of two parts. The first part included items about participants' demographic information and the second part included items about ever been asked to take a sample of the cerebrospinal fluid (LP) of one of parents' children and circumstances related to this event. In addition, parents were asked the following two questions: "have you ever been asked to take a sample of the cerebrospinal fluid of one of your children?", and "If you were not asked before, if it was needed to take a sample of the cerebrospinal fluid of one of your children, will you agree?"

**Ethical considerations:** ethical approval for the study was obtained from the research ethics committee of Taif university.

**Statistical analysis:** Data were analyzed using the SPSS6. Qualitative data was expressed as numbers and percentages and Chi-squared test ( $\chi^2$ ) was used to test the relationship between variables. Quantitative data was presented as mean and standard deviation (Mean  $\pm$  SD) and Mann-Whitney was applied for non-parametric variables. A p-value less than 0.05 was considered as statistically significant.

## Results

Table 1 shows that 66.3% of those who filled out the questionnaires were children's mothers and 67.4% had Saudi nationality. For fathers, their mean age was  $40.17 \pm 9.55$  years and 62.5% had a university level of education. For mother, the mean age was  $37.26 \pm 9.54$  years and 78.6% had a university level of education.

Table 2 shows that only 15.7% (No.108) were asked to take a sample of the cerebrospinal fluid of one of their children, of whom, 61.2% (No. 66) agreed to it. For those who agreed, the mean age of the child at the LP was

2.24 ± 3.28 years. For 37.8% of parents a consultant explained this procedure to them and 86.5% and 56.2% reported that the doctor explained the nature and the complications of LP procedure to them.

Figure 1 illustrates that 15.7% of the participants were asked to take a sample of the cerebrospinal fluid of one of their children and 61.2% agreed to it. For those who were not asked before, 41.4% reported that they will not agree to do LP if indicated in the future.

Figure 2 shows that for those who disagreed to do LP to their children when it was indicated and those who will disagree if indicated in the future, the most common causes of refusal were: Side effects such as paralysis (60.6%), followed by pain (11.3%) and no trust in HCWs and fear of medical errors (10.9%). For them, the most common sources of refusal were information from friends and relatives (41.2%), and data from the social media and internet and personal experience (19.8%) (Figure 3).

Tables 3 and 4 shows that a non-significant relationship was found between previous agreement to do LP or future agreement to do LP if indicated and participants' characteristic ( $p \rightarrow 0.05$ ).

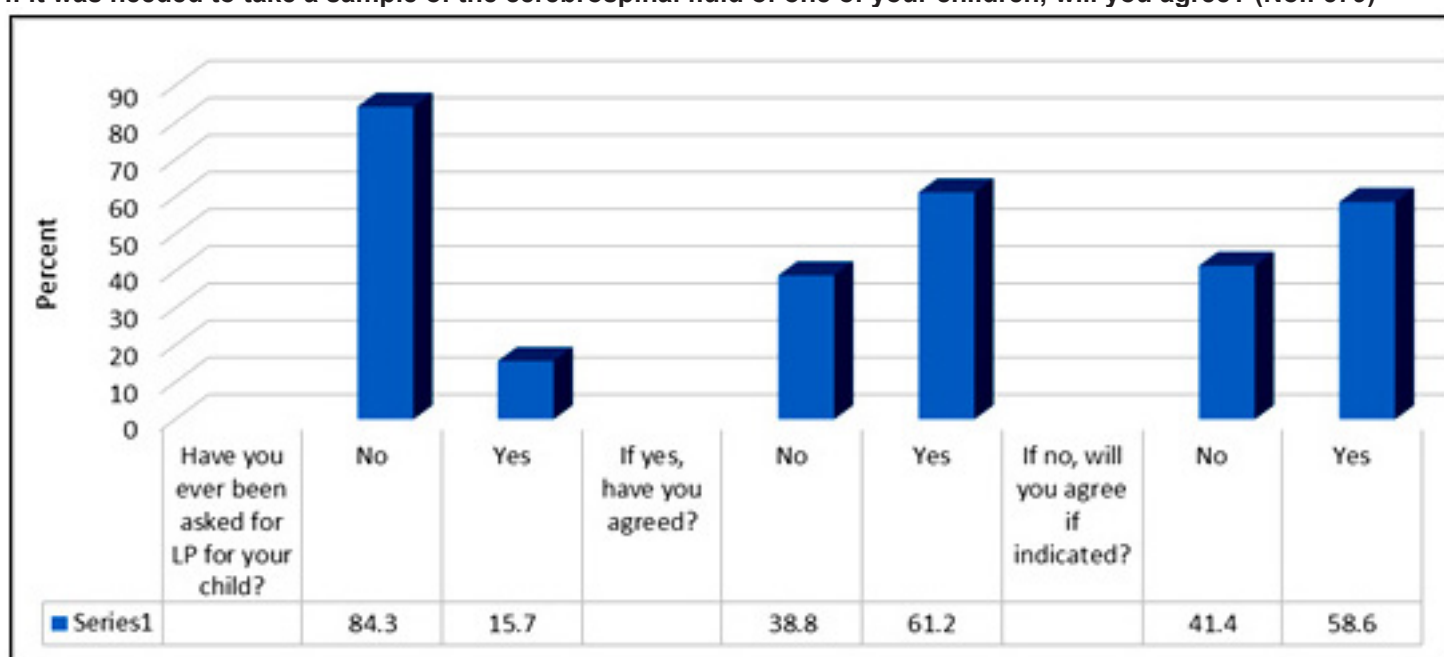
**Table 1. Distribution of the studied participants according to their characteristics (No.:687)**

Variable	No. (%)
Guardian	
Father	232 (33.7)
Mother	455 (66.3)
Nationality	
Saudi	446 (67.4)
Non-Saudi	12 (48)
<b>Fathers' information</b>	
Age (mean ± SD)	40.17 ± 9.55
Educational level	
Elementary	5 (2.1)
Middle	8 (3.4)
Secondary	28 (12)
University	145 (62.5)
Postgraduate	46 (20)
Nationality	
Saudi	216 (32.6)
Non-Saudi	13 (52)
<b>Mothers' information</b>	
Age (mean ± SD)	37.26 ± 9.54
Educational level	
Elementary	9 (1.9)
Middle	2 (0.4)
Secondary	62 (13.6)
University	358 (78.6)
Postgraduate	27 (5.5)

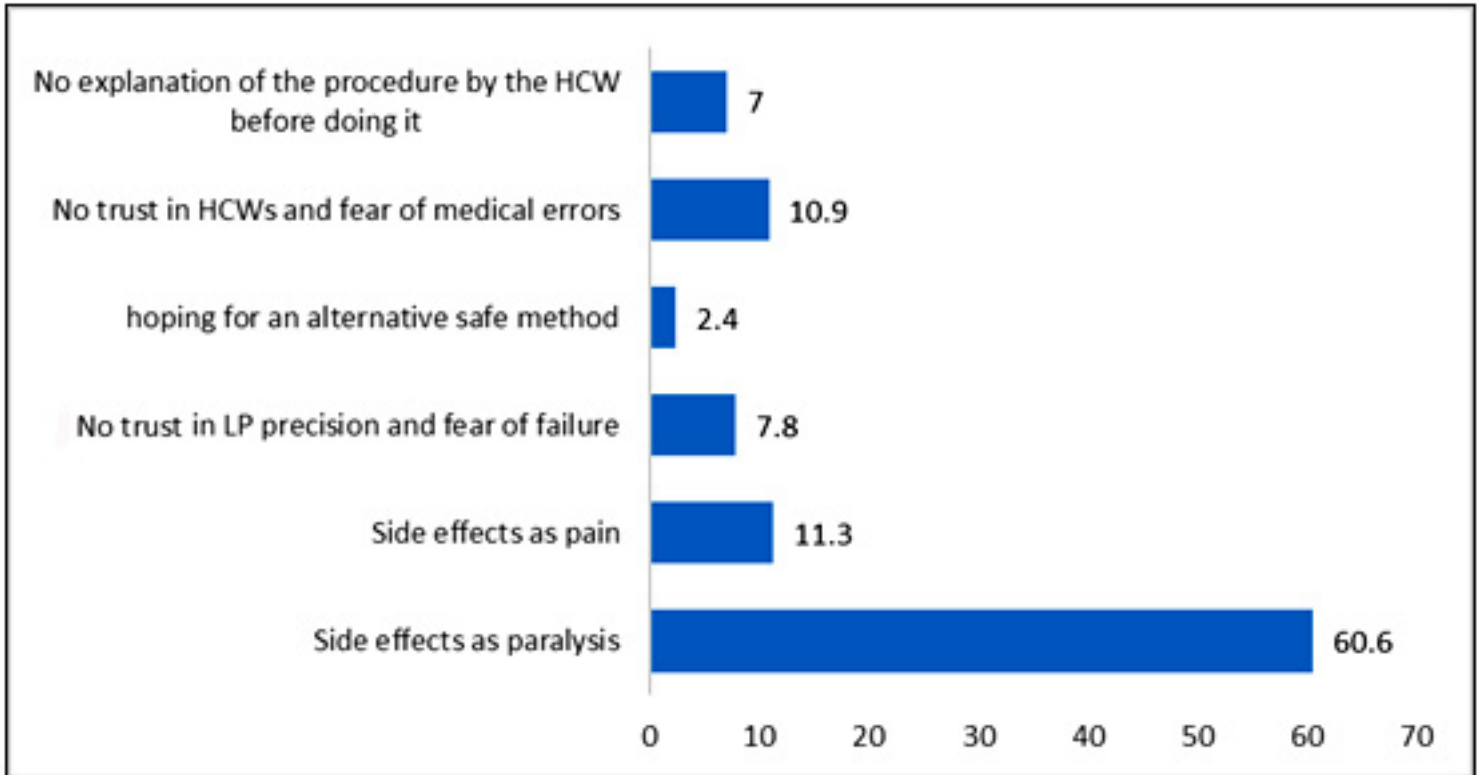
**Table 2. Distribution of the studied participants according to ever been asked to take a sample of the cerebrospinal fluid (LP) of one of their children and circumstances related to this event**

Variable	No. (%)
Have you ever been asked to take a sample of the cerebrospinal fluid of one of your children? (No.:687)	
No	579 (84.3)
Yes	108 (15.7)
If you were asked to, have you agreed? (No.:108)	
No	42 (38.8)
Yes	66 (61.2)
For those who were asked to take a sample of the cerebrospinal fluid of one of their children and agreed (No.:66)	
Child age at LP (mean $\pm$ SD)	2.24 $\pm$ 3.28
Qualification of the doctor who explained this procedure to you (No.:66)	
Specialist	24 (36.3)
Consultant	25 (37.8)
Resident	3 (4.5)
I do not remember	14 (21.4)
Did the doctor explain to you the nature of the LP procedure? (No.:66)	
No	5 (7.5)
Do not remember	4 (6)
Yes	57 (86.5)
Has the doctor explained to you the complications of this procedure <sup>‡</sup> (No.:66)	
No	24 (36.3)
Do not remember	5 (7.5)
Yes	37 (56.2)

**Figure 1. Percentage distribution of the participants according to their response to: “have you ever been asked to take a sample of the cerebrospinal fluid of one of you children? (No. 687)”, and “If you were not asked before, if it was needed to take a sample of the cerebrospinal fluid of one of your children, will you agree? (No.: 579)”**



**Figure 2. Percentage distribution of the cause of LP refusal for those who disagreed to do LP to their children when it was indicated and those who will disagree if indicated in the future (No:282)**



**Figure 3. Percentage distribution of the sources of LP refusal for those who disagreed to do LP to their children when it was indicated and those who will disagree if indicated in the future (No:282)**

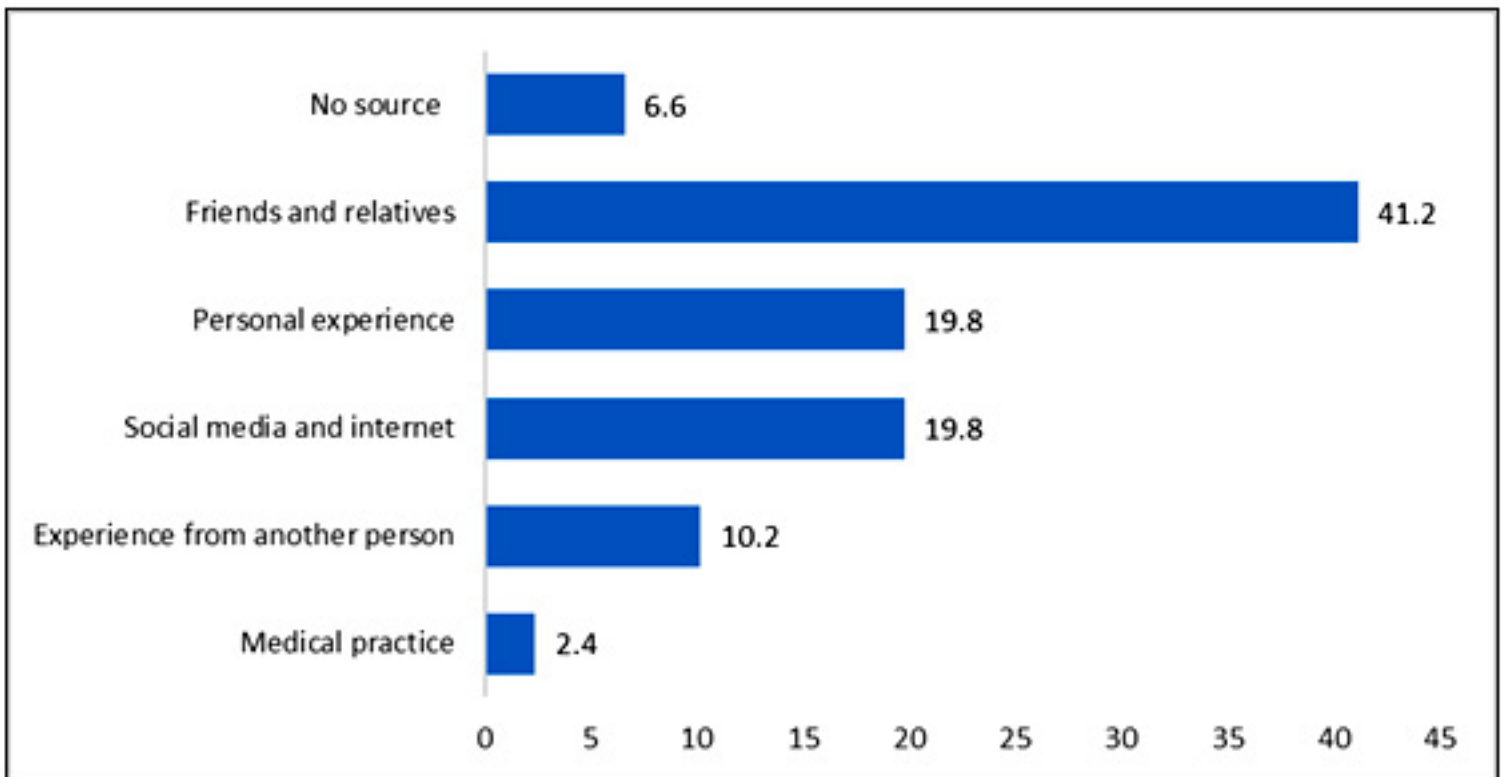


Table 3. Relationship between previous agreement to do LP and participants' characteristics

Variable	Agreed No. (%)	Did not agree No. (%)	$\chi^2$	p-value
<b>Fathers' information</b>				
Age	43.5 ± 10.74	41.25 ± 8.83	0.5	0.521
<b>Educational level</b>				
Elementary	3 (100)	0 (0.0)	7.46	0.188
Middle	2 (50)	2 (50)		
Secondary	0 (0.0)	3 (100)		
University	16 (66.7)	8 (33.3)		
Postgraduate	3 (50)	3 (50)		
<b>Mothers' information</b>				
Age	39.29 ± 9.49	37.71 ± 8.69	0.77	0.439
<b>Educational level</b>				
Elementary	3 (100)	0 (0.0)	8.28	0.141
Middle	0 (0.0)	1 (00)		
Secondary	8 (80)	2 (20)		
University	31 (58.5)	22 (41.5)		
Postgraduate	0 (0.0)	2 (100)		

Table 4. Relationship between future agreement to do LP if indicated and participants' characteristics

Variable	Will agree No. (%)	Will not agree No. (%)	$\chi^2$	p-value
<b>Fathers' information</b>				
Age	40.34 ± 9.87	38.56 ± 8.57	0.91	0.362
<b>Educational level</b>				
Elementary	2 (100)	0 (0.0)	8.74	0.12
Middle	2 (50)	2 (50)		
Secondary	8 (72)	7 (28)		
University	68 (56.2)	53 (43.8)		
Postgraduate	30 (75)	10 (25)		
<b>Mothers' information</b>				
Age	37.41 ± 9.92	36.4 ± 9.09	0.9	0.368
<b>Educational level</b>				
Elementary	2 (33.3)	4 (66.7)	8.11	0.15
Middle	1 (100)	0 (0.0)		
Secondary	33 (63.5)	19 (36.5)		
University	173 (56.9)	131 (43.1)		
Postgraduate	10 (40)	15 (60)		

## Discussion

In numerous neurological disorders, the LP procedure is a useful diagnostic tool, as well as an important aesthetic and therapeutic indication. It's frequently utilized in emergency rooms to detect CNS diseases [20,21].

The purpose of this study is to determine whether parents in Taif have any misconceptions about LP. Because no analogous study had been conducted in Taif, Saudi Arabia, this study sought to determine the extent to which parents in Taif were misinformed about LP.

Even though LP is commonly performed in the pediatric population, patient caregivers refuse 30 percent of LPs [22]. In the current study, 38.8% of parents who were requested to collect a sample of their child's cerebrospinal fluid refused.

The most common reasons for LP refusal, according to the study, were adverse effects such as paralysis (60.6 %), pain (11.3 percent), lack of faith in HCWs, and fear of medical errors (10.9 %). Previous research has revealed a wide range of reasons for the procedure's refusal. Most of the denials were due to misunderstandings that had propagated throughout the society [23,24].

A prior survey conducted in Dammam, Saudi Arabia, found that 24% of parents felt LP is not acceptable in society [19].

This research investigated the knowledge, attitude, and perception to find the gap from where these misconceptions arise. Of the study participants, 37.8% of parents reported that the consultant explained this procedure to them and 86.5% and 56.2% reported that the doctor explained the nature and the complications of LP procedure. Previous studies on this issue in different settings have found that the public lacks an appropriate level of knowledge about LP [25].

### Limitations

Being a cross-sectional study revealed the association between studied variables but not the causal relationships.

## Conclusion

Only 15.7% of parents were asked to collect a sample of their child cerebrospinal fluid, of them 61.2 % accepted. A consultant discussed the LP technique to 37.8% of them, and 86.5% and 56.2% said the doctor clarified the nature and complications of the treatment. The main causes of LP refusal were the side effects such as paralysis, pain, and lack of trust in HCWs and fear of medical errors. To remove the hurdles that contribute to LP refusal, parents must be educated about the importance and nature of LP. HCWs should have a role in this education to overcome the knowledge gaps and can provide a better awareness of the dangers involved, the key indications, and the treatment options.

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# Improving patient centered care by documenting their contribution in the plan of care at west bay health center, Qatar

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## Abstract

### Introduction

In our health center, we found only 50% of our physicians documenting patient contributions in their plan of care, which reflects the need for improving patient contributions and physician documentations. Therefore, this project was conducted to improve the percentage of physician 'documentation from 50% to 60 % over 5 weeks, to be completed by thirteenth of January 2021.

**Key words:** Patient centered care

## Methodology

To start our project, we got the approval from our physician lead and from our health center manager. We then introduced our project to the physicians through the corporation mail and through what's work group. Then we created a reminder card and we fixed it in all physician's clinic tables. Then, we started to mail all physicians, to remind them to document patient engagement and their contribution in their plan of care. In addition, we keep monitoring the physicians and we keep checking our intervention availability in all clinics. The team was updated about the progress through face-to-face meeting and through emails. The data were collected weekly, by the team members and then were analyzed by one of the team members.

## Results

Our project showed remarkable improvement, in physician's documentation of patient contributions in their plan of care. We found that, physician documentation of patient contributions in their plan of care, improved from 50% to 89.3% and that exceeds our aim by 39.3%.

**Table1: Shows the number of physician documentation over 5 weeks, week zero, representing our base line data which is 50 %.**

weeks	Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	total
number	25	49	48	48	50	48	268
total	50	50	50	50	50	50	300
percentage of documented care plan	50%	98%	96%	96%	100%	96%	89.3%

Chart 1: Percentage of physician Documentation of Patient contribution In Their Plan of Care Over 5 weeks

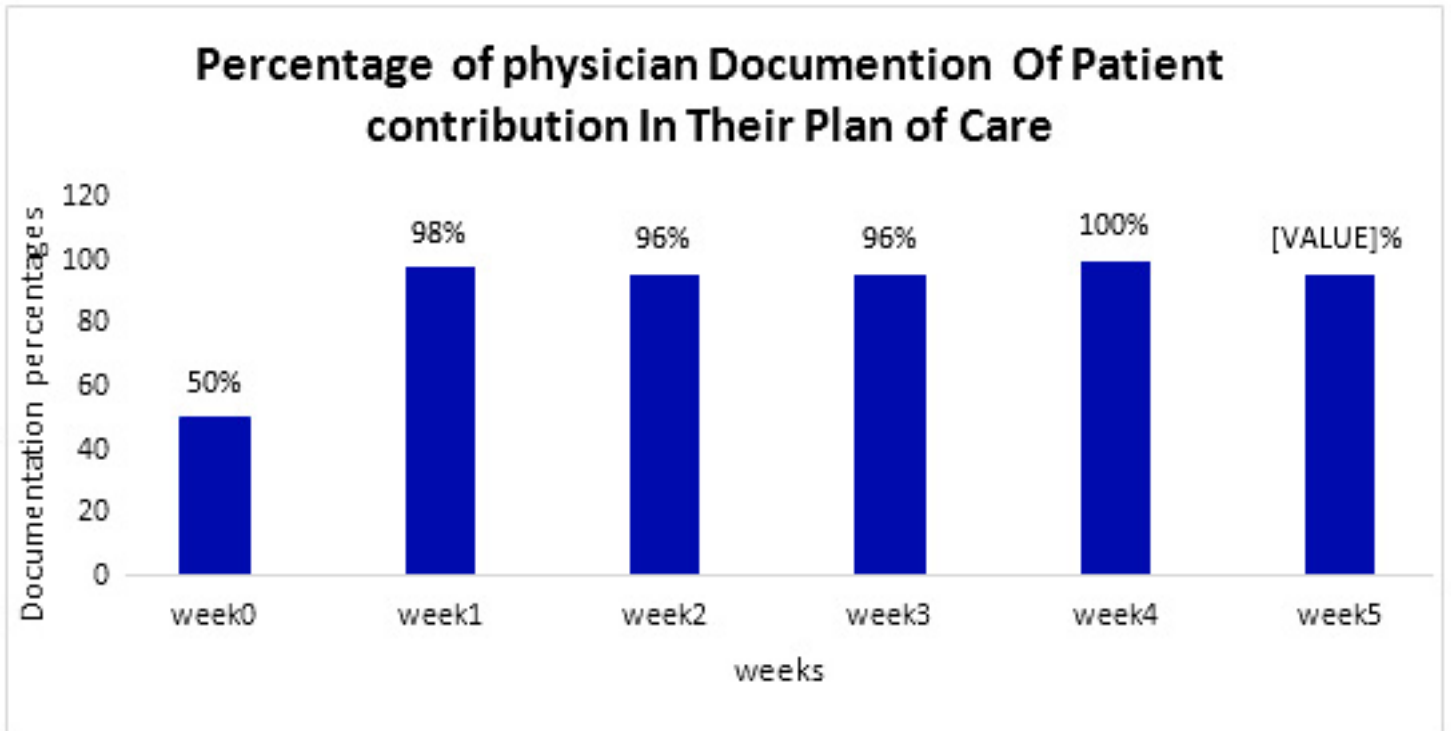
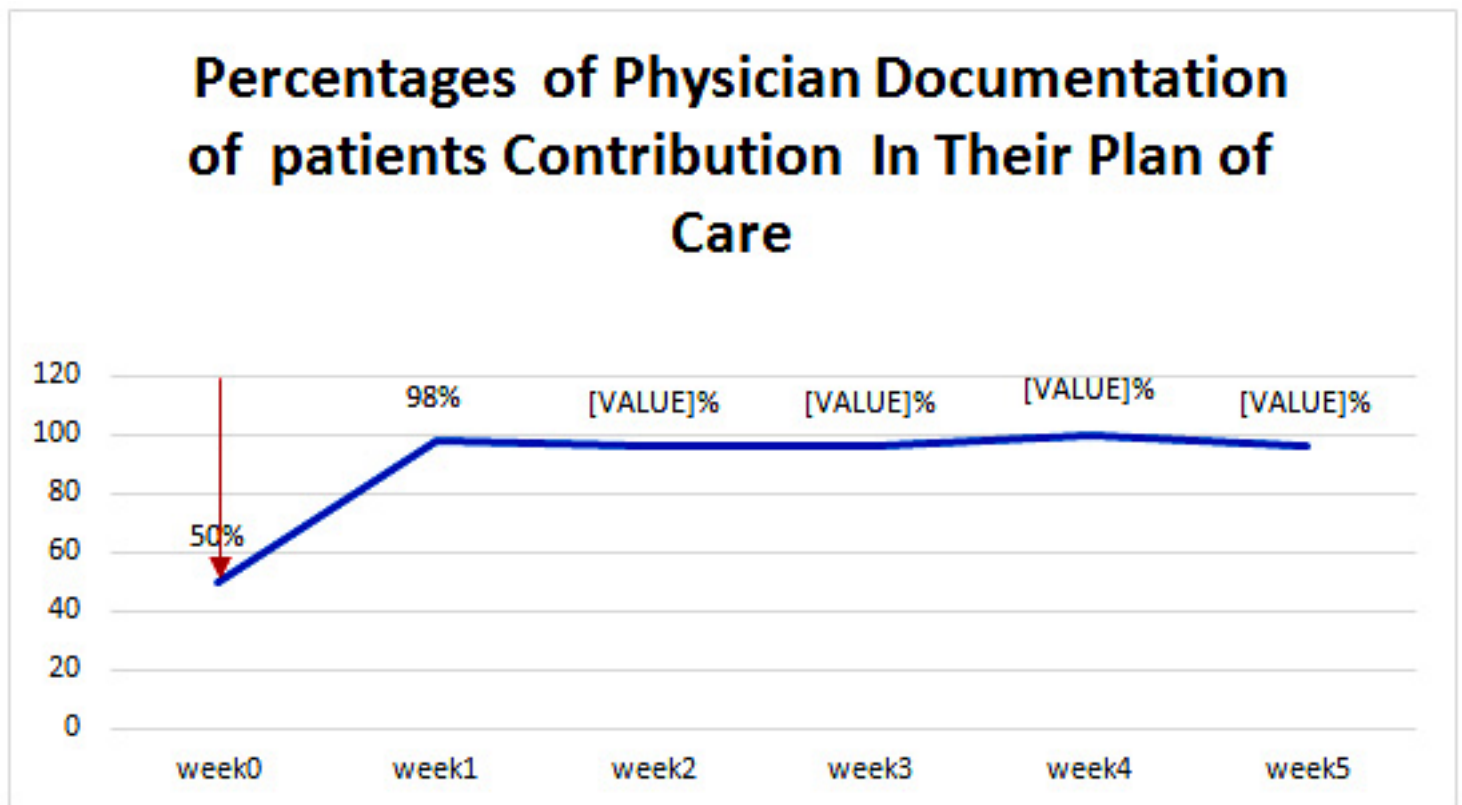


Chart 2:



## Discussion

Our project showed 49.3% improvement in physician documentation of patient contribution in their plan of care. These changes will serve to improve patient centred care, which is one of the top priorities in my institution, primary health care.

The strength of our project, is that the project was applied to the family medicine clinic which is the most busy clinic in our health centre, compared to the other speciality clinic. On the other hand, the limitation of our project is small sample size, and the total number of physician contributions checked was 300, which is a relatively small number.

## Conclusion

To conclude, our intervention showed remarkable improvement in the percentages of physician's documentation of patient contribution in their plan of care.

We will adopt the change, as the results of pre- and post-intervention analysis clearly showed improvement in physician documentation of patient contribution in their plan of care. We will generalize our intervention to other health centers specialty clinics and will keep reminding our physicians about the importance of patient centered care. The subsequent step will proceed to the second cycle. Documentation of patient contributions in their plan is very important as it not only helps the patient to receive better quality care but also improves the health care settings.

# Pathological factors and associated clinical outcomes of patients with urothelial neoplasms treated at King Abdulaziz University Hospital : a single center experience

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## Abstract

**Objectives:** To evaluate the operative and pathologic factors associated with long-term survival and local recurrence in patients treated for urothelial tumors.

**Methods:** A retrospective study was performed that included 47 patients with resected urothelial tumors at King Abdulaziz University Hospital, Jeddah, Saudi Arabia from 2009 to 2017.

**Results:** In this study, 89.36% of patients had bladder tumors, and most were diagnosed based on transurethral resection of bladder tumor (TURBT). The histological grade was high in 74.47% of patients; in patients who underwent surgery, 17.39% had positive margins, 45.45% had perineural invasion, and 38.10% had lymphovascular/perivascular invasion. The median recurrence time was 40.2 months, and recurrence-free survival rates were 85.5%, 71.6%, and 44% for one, two, and five years, respectively.

**Conclusion:** Our outcomes are comparable to those in the literature; however, more accurate data collection and future national collaboration are essential to improve patient outcomes.

**Key words:** long-term, survival, recurrence, urothelial, tumors, Saudi Arabia

## Introduction

Bladder cancer is the 11th most common cancer in Saudi adult men and 12th in women according to the 2020 Cancer Registry Report(1). Urothelial carcinoma, also known as transitional cell carcinoma, is the most common histological variant of bladder cancer. It most commonly involves the bladder, however, other urinary tract sites lined by transitional epithelium, namely the renal pelvis, ureters, and urethra, could also be involved (2,3).

Less common variants of bladder cancer include adenocarcinomas, squamous cell carcinomas, mixed histologies, neuroendocrine tumors, and sarcomas. Collectively, these cancers account for less than 5%–10% of all bladder cancers in the United States (4). Tumors of the upper urinary tract are almost twice as common in men compared to women, with a mean age of 73 years at diagnosis (5). The age-adjusted annual incidence rates of ureteral and renal pelvis cancer in the Surveillance, Epidemiology, and End (SEER) database was 0.91 and 1.15/100,000 person-years during the period from 1997 to 2005 (6).

The most commonly used staging system is the tumor, node, and metastasis (TNM) staging system by the The American Joint Committee on Cancer (AJCC). Treatment recommendations for urothelial carcinoma of the bladder are based on many factors, but the most important is the presence or absence of muscle invasion, which is categorically divided into non-muscle-invasive disease (Ta, T1, and Tis) and muscle-invasive disease ( $\geq$ T2 disease). Other factors affecting management include histology, grade, and depth of invasion, and this information can be obtained through biopsy and TURBT specimens. These factors are used to estimate the probability of recurrence and progression to a more advanced stage. Patient bladder function, comorbidities, and life expectancy are also important considerations (7).

For muscle invasive bladder cancer (MIBC) with limited or no nodal metastasis, the standard of care is to offer neoadjuvant cisplatin-based chemotherapy (NAC) followed by radical cystectomy (RC) and lymph node dissection(8). The addition of NAC has been shown in multiple randomized prospective trials and a large meta-analysis to improve survival as well as complete response rate in MIBC (9). The role of lymph node dissection at the time of RC has been controversial. Multiple retrospective trials have found that lymph node dissection plays an important prognostic and therapeutic role. A recent review of the SEER database and the database of the Changhi Tenth People's Hospital in China demonstrated that the number of lymph nodes dissected was independently associated with prolonged survival (10). However, a European trial has recently failed to prove the advantage of extended lymphadenectomy over a limited lymphadenectomy in all oncologic outcomes measured (11). An ongoing large phase 2 randomized trial by the Southwest Oncology Group (SWOG) examining the role of extended lymph node dissection at the time of RC is currently underway (12).

Since bladder cancer is a common malignancy in old age with comorbid diseases and potential renal impairment, the standard approach with NEC and RC may not be feasible.

Treatment options for patients with MIBC who are not candidates for NAC or RC or who refuse the RC approach include RC alone; bladder preservation with radiation therapy, with or without chemotherapy and/or prior TURBT; and, for select patients, TURBT alone (7). There is an increasing interest in organ preservation approaches with trimodal therapy (TURBT, radiation, and chemotherapy), even for RC candidates (13).

For non-muscle invasive bladder cancer (NMIBC), the management of choice is TURBT. Depending on the tumor grade, the clinical stage (T0, Ta, Tis, or T1), presence of residual tumor, a combination of the above, intravesical chemotherapy, Bacille Calmette-Guerin (BCG), or even cystectomy could be recommended (14).

The risk of recurrence in patients with non-muscle invasive urothelial bladder carcinoma depends on multiple factors. Tumor grade is the most important prognostic factor for progression. T category, tumor size, tumor number, concurrent CIS, intravesical therapy, response to bacillus Calmette–Guerin at 3- or 6-month follow-up, prior recurrence rate, age, sex, lymphovascular invasion, and depth of lamina propria invasion are other important clinical and pathological parameters to predict recurrence and progression in patients with NMIBC (15).

For most patients with upper urinary tract urothelial cancers, nephroureterectomy with excision of a cuff of normal bladder and bladder mucosa is the preferred procedure; the frequent occurrence of synchronous or metachronous multifocal tumors makes a less extensive resection contraindicated (16,17,18).

Open and laparoscopic surgical approaches appear to be equally safe and effective, assuming adequate expertise is available and complete resection of the intramural ureter with bladder cuff is performed (19). Some patients with particular conditions may benefit from renal-sparing surgery, such as those with a single kidney, impaired renal function, bilateral lesions, or other nephropathies (20). In addition, those with low-grade, low-stage tumors of the ureter or renal pelvis may also be candidates for this approach (19). Treatment options in these settings include retrograde uretero-pyeloscopy alone or in conjunction with antegrade percutaneous resection (21,22,23).

This study aimed to identify the operative and pathologic factors affecting long-term survival and local recurrence in a tertiary center in Jeddah, Saudi Arabia, for urothelial tumors.

## Subjects and Methods

**Study design and time frame:** A retrospective study was conducted at King Abdulaziz University Hospital (KAUH), Jeddah, Saudi Arabia during 2018-2020.

**Sampling methodology:** We collected data for all patients treated at our center between 2009 and 2017.

**Study instrument:** Data were obtained from the electronic medical records through a data collection sheet for every patient that included items about sex, date of birth, death

and date of death, site of tumor, date of first pathological diagnosis, method of diagnosis, metastasis, site of metastasis, transurethral resection of bladder tumor procedure and the date, the presence of muscle invasion, any procedures (nephrectomy, urethrectomy, Ureterectomy, cystectomy), chemotherapy treatment and the date of first cycle, cytology and histological type and grade, margin, perineural invasion, lymphovascular or perivascular invasion, recurrence or progression and the date, TNM staging, and last follow-up date.

**Ethical considerations:** Ethical clearance was obtained from the research ethics committee of KAUH, Saudi Arabia.

**Data analysis:** Stata SE, version 15.0, (StataCorp LLC, TX) was used for data analysis, and survival analysis was performed using the Kaplan–Meier method.

## Results

### Patients' demographics

A total of 47 patients with resected urothelial tumors were identified and included in this study. The mean age was  $62.97 \pm 2.1$  years, with a predominance of male patients (85.11%). Most patients (89.36%) had a bladder tumor, and the majority were diagnosed based on transurethral resection of bladder tumor (TURBT), with only 4.26% diagnosed via biopsy. Of those who underwent TURBT, 85.11% were curative. The number of patients who underwent other surgical procedures was 62.5% (29), of which 36.96% underwent cystectomy. The other patient characteristics are shown in Table 1.

### Tumor characteristics and treatment

Cytology was performed in 34 patients, 21 of whom showed atypical cells, and nine patients had clear malignant changes. Moreover, the histological grade was high in 35 patients (74.47%). Among those who underwent surgery, 17.39% had positive margins, 45.45% had perineural invasion, and 38.10% had lymphovascular/perivascular invasion.

Data from 31 patients documented muscle invasion by the tumor. Of these, 20 patients underwent TURBT as a curative modality of management, 11 underwent TURBT for biopsy purposes, and 8 underwent cystectomy. For those who underwent TURBT, none of the patients who received TURBT as curative management had muscle invasion, while 10 of 11 patients who received TURBT for diagnostic purposes had muscle invasion. In contrast, the majority (7 of 8 patients) who underwent cystectomy had muscle invasion.

Regarding neoadjuvant and adjuvant treatment, unfortunately, a significant amount of data was missing, and no correlation between outcomes and adjuvant therapy could be performed.

### Recurrence and survival data

The data showed that the overall median recurrence time was 40.2 months. Recurrence-free survival (RFS) was 85.5% for one year, 71.6% for two years, and 44% for five years (Figure 1). The univariate analysis results showed a higher risk of death with increased age (hazard ratio, 1.089; 95% confidence interval;  $p$  value = 0.014), and further analysis revealed no significant difference between mortality risk and sex, tumor site, histopathology details, and invasion (Table 2).



Table 1: Patient demographics and clinical information

	Summary statistics
<b>Characteristics</b>	
Total number of patients	47 (100%)
Age (mean $\pm$ SD), years	62.97 $\pm$ 2.1
<b>Sex</b>	
Female	7 (14.89%)
Male	40 (85.11%)
<b>Clinical information</b>	
<b>Site of tumor</b>	
Pelvic ureter	5 (10.64%)
Bladder	42 (89.36%)
<b>Method of diagnosis</b>	
TURBT	40 (85.11%)
Biopsy	2 (4.26%)
Surgical resection	5 (10.64%)
<b>TURBT</b>	
Yes	39 (82.98%)
No	8 (17.02%)
<b>TURBT type</b>	
Curative	21 (53.85%)
Biopsy	18 (46.15%)
<b>Nephrectomy</b>	
Yes	6 (12.77%)
No	41 (87.23%)
<b>Ureterectomy</b>	
Yes	5 (10.64%)
No	42 (89.36%)
<b>Cystectomy</b>	
Yes	17 (36.96%)
No	29 (63.04%)
<b>Urethrectomy</b>	
Yes	1 (2.13%)
No	46 (97.87%)
<b>Cytology</b>	
Malignant	9 (19.15%)
Atypical	21 (44.68%)
No malignancy	4 (6.38%)
Not done	14 (29.79%)
<b>Histological grade</b>	
Low grade	12 (25.53%)
High grade	35 (74.47%)
<b>Margin</b>	
Positive	4 (17.39%)
Negative	19 (82.61%)
<b>Perineural invasion</b>	
Yes	5 (45.45%)
No	6 (54.55%)

(continued next page)

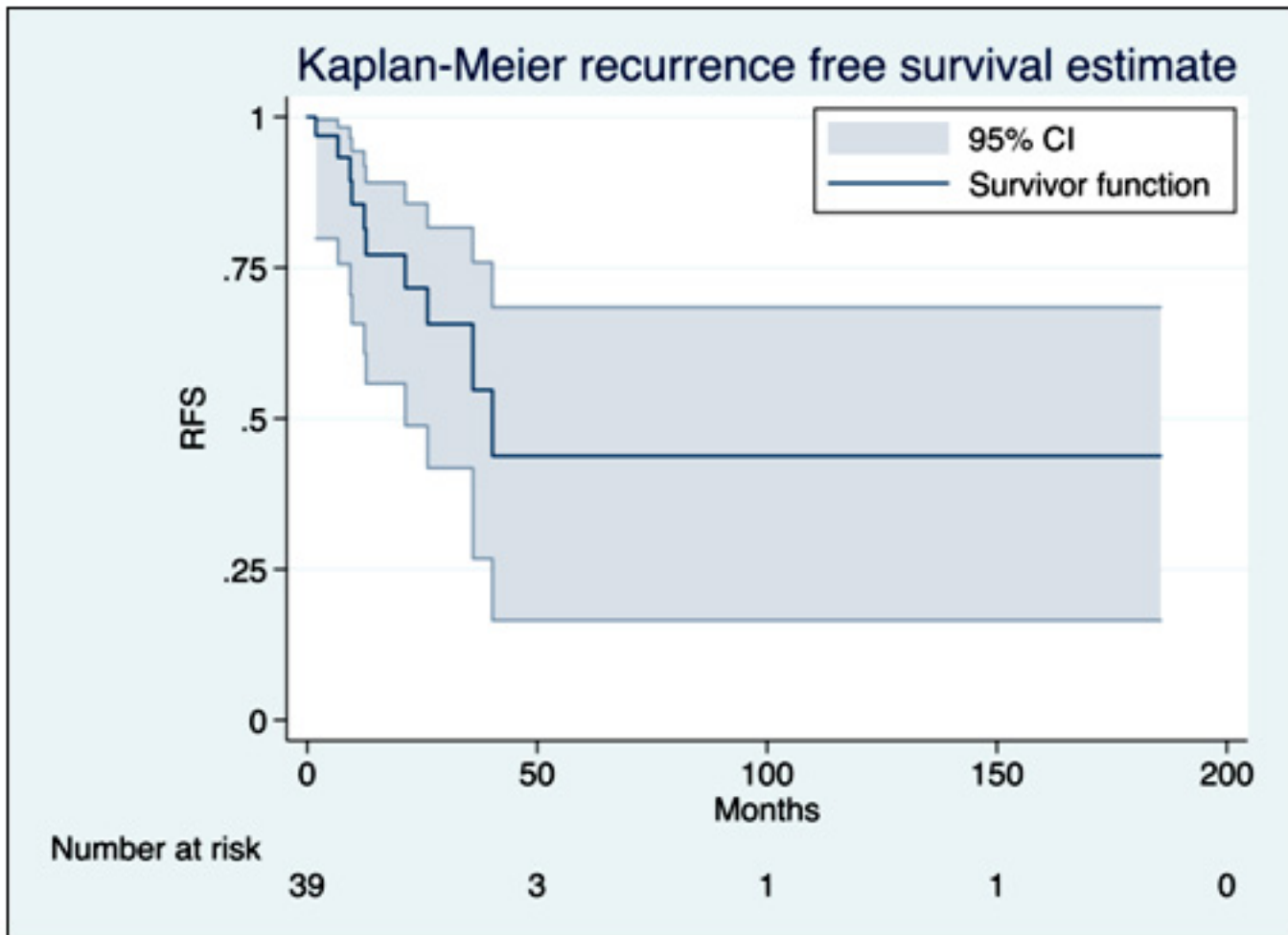
**Table 1: Patient demographics and clinical information (continued)**

Lymphovascular/Perivascular invasion	
Yes	8 (38.10%)
No	13 (61.90%)
Muscle invasion	
Yes	10 (32.26%)
No	21 (67.74%)
TNM staging	
T staging	
T1	9 (45%)
T2	5 (25%)
T3	4 (20%)
T4	2 (10%)
N staging	
N+	5 (23.81%)
N0	15 (71.43%)
Unknown	1 (4.76)

**Table 2: Univariate analysis for variables related to recurrence in patient with resected bladder tumor**

Variable	Hazard Ratio (95% CI)	P-value
Age	1.089 (1.017–1.166)	0.014
Sex	0.6991 (0.179–2.718)	0.605
Site of tumor	0.972 (0.120–7.871)	0.980
Histological grade	1.220 (0.314–4.735)	0.773
Margin	0.756 (0.073–7.830)	0.815
T stage	1.119 (0.3625–3.4530)	0.845
N stage	0.4553 (0.0844–2.456)	0.360
Perineural invasion	2.392 (0.2134–26.82)	0.479
Lymphovascular/Perivascular invasion	4.699 (0.4854–45.48)	0.182

Figure 1: Kaplan- Meier recurrence free survival estimate



## Discussion

This study was performed to evaluate operative and pathologic factors associated with long-term survival and local recurrence in patients treated for urothelial tumors in a tertiary center in Jeddah, Saudi Arabia. The data of patients who were treated for urothelial tumors in our cohort showed that the mean age at diagnosis was 63 years. This finding is consistent with those of another study, in which the median age of patients was 66 years (24). While urothelial tumor can occur at any age, it is generally a disease in middle-aged and elderly people. Not surprisingly, age is now widely accepted as the greatest single risk factor for developing urothelial bladder cancer (UBC) (25). Various descriptive studies have shown that individuals aged  $\geq 65$  years have 11 times the incidence of cancer in general. In fact, the median age at diagnosis is approximately 70 years (26).

There was a male predominance (85%) in our study. Fajkovic et al. found that men have up to a four-fold higher UBC incidence than do women (27). A retrospective study of the Netherlands Cancer Registry spanning the period 1989–1994 identified 20,541 patients diagnosed with UBC, of whom 80% were male and 20% female (28).

Another study was conducted in 17 Spanish hospitals with 615 patients with newly diagnosed UBC and found

a 6.7-fold greater risk of diagnosing UBC in men than in women for both non-muscle-invasive and muscle-invasive disease (29). While there is no uniform theory to explain the sex differences in UBC presentation and behaviors, a suggested explanation could be related to excessive environmental exposure to carcinogens such as tobacco and industrial chemicals in men compared to that in women(30). Moreover, the historically lower smoking prevalence in women may also play a role(31).

Most of our patients underwent TURBT for initial diagnosis and treatment. TURBT is the 'gold standard' for the diagnosis and therapy of non-muscle-invasive bladder cancer (32). The aim of TURBT in bladder cancer is twofold. On the one hand, TURBT aims to provide a potential cure of selected bladder tumors. On the other hand, TURBT is important for accurate staging of high-risk tumors and particularly muscle-invasive lesions, which require additional therapy including radical cystectomy or radio-chemotherapy(33). Successful surgical therapy for low-risk, non-muscle-invasive tumors depends on the completeness of the performed TURBT. However, despite all surgical efforts aimed at achieving complete tumor removal, the high recurrence rate (35%–70%) and thus the propensity of these lesions to eventually progress (10%–50%) represent the major obstacles of TURBT(32).

As for the recurrence of cancer, the median time of recurrence for our patients was more than 3 years. In comparison to previous studies, a retrospective review demonstrated a 5-year disease-free survival reaching up to 50%–60% when using TURBT (33). The 2-years RFS for our patients was 71.6%, which agrees relatively well with a study conducted in Germany that found the overall recurrence rate after TURBT was 14.4% (33). In addition to tumor cell implantation, insufficient resection has also been discussed as a cause of relapse, particularly at the primary resection site. Numerous trials investigating routine re-TURBT, as a diagnostic approach, have reported detection rates of 30%–75% of residual tumor cells across all tumor stages (34).

In a previous Korean study, the median bladder recurrence-free survival, disease progression-free survival, and cancer-specific survival values were 19.0 months, 38.5 months, and 67.0 months, respectively (35).

The univariate predictor for survival showed a higher risk of death with increased age, which is consistent with the findings of other studies that predicted a longer survival in patients younger than 65 years (36). The ratio of cancer-specific mortality to incidence for men and women in the USA aged 65–69 years is 14% and 18%, respectively, whereas that for men and women aged 80–84 years is 30% and 37%, respectively (26). There have been several studies on the biological and clinical aggressiveness of UBC in young and old patients, but these have been relatively inconclusive (26).

Studies have found that cigarette smoking is significantly associated with advanced disease stages, recurrence, and survival among patients who underwent RNU for UTUC (37). This can be explained by the effect of aromatic amine-like chemicals that promote carcinogenesis, causing recurrence and progression, and reducing survival (38). In a previous Saudi study, pathological tumor stage and lymph node metastasis were the only independent predictors of survival following radical cystectomy (14).

### Limitations

Because of the retrospective nature of our study, certain data elements were not available, as were some missing data in the old medical records. In particular, limitations in the data regarding neoadjuvant and adjuvant therapies have limited the possibility of correlating the clinical outcomes with the treatment received.

### Conclusion

Limited data are available pertaining to the management of urothelial neoplasms in Saudi Arabia. Future prospective data collection, institutional and national data registries, and research collaboration are needed to improve the clinical outcomes of our patients and to dictate future management approaches.

### Acknowledgements

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# Impact of inhalation therapy on occurrence of oral manifestations in patients with bronchial asthma, in Jeddah, Saudi Arabia

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## Abstract

**Background:** Inhalation therapy for asthma includes cortisol and bronchodilators. High dosage and long duration of inhalation therapy has been linked with several adverse effects on the oral tissues.

**Objectives:** To explore the oral manifestations associated with the use of inhalation therapy among patients with asthma in Jeddah city.

**Method:** This was a cross sectional study; the non-probability convenient sampling method was used to select 215 subjects (99 with Doctor diagnosed asthma and 116 without asthma), from the outpatient clinics of two private hospitals. Data were collected using interview questionnaire, the standard 5th ed. WHO survey on oral manifestations, measurement of vital signs and anthropometric parameters, as well as clinical oral examination. Data were analyzed using SPSS version 22, and Logistic multinomial regression was used to study the Odds ratio and its 95% confidence interval between the variables. Level of significance for the study was 0.05. Results: The majority of patients with asthma (95%) used inhalation therapy, without use of spacers. Ulceration, pigmentation and candidiasis of the tongue, buccal mucosa and palate were

significantly more encountered among patients with asthma compared to those without asthma ( $p < 0.001$ ,  $0.002$  and  $0.046$  respectively). Xerostomia and salivary gland affection, also, were significantly more encountered among patients with asthma compared to those without asthma ( $p < 0.000$ , and  $0.002$  respectively). Patients with asthma were 7.7 times more likely to develop tongue disorders (OR: 7.7,  $p < 0.013$ ), 3 times more likely to develop buccal mucosal disorders (OR: 3,  $p < 0.039$ ), and 15 times more likely to develop palate disorders (OR: 15,  $p < 0.004$ ) compared to subjects without bronchial asthma.

**Conclusion:** Use of inhalation therapy in patients with asthma was significantly associated with increased occurrence of oral health problems. Health education programs about proper use of inhalers and oral hygiene should be implemented by primary health care personnel.

**Key words:** Inhalation therapy, Asthma, Oral manifestations, Jeddah.

## Introduction

Asthma is a chronic inflammatory airway disorder, (1) where its occurrence is linked to several factors, such as sociodemographic constitution, environmental and occupational exposure, personal and genetic characteristics, and the morbid condition of the patient (2 - 10). Asthma is characterized by episodic attacks of cough, shortness of breath and wheezing (11, 12). Headache, body aches, vomiting and nasal symptoms are also reported by patients with asthma (13-18). Symptoms of insomnia and tremors were reported by uncontrolled asthma patients, who were put on high doses of systemic medications (19 – 22). Beta2 agonists, and cortisol (mainly inhalation therapy), are the standard treatment for asthma, in addition to anticholinergic drugs and antileukotrienes (23– 32). The health of the oral cavity is essential for good general health (33). Growth of bacteria in the oral cavity, on the teeth and mucosa, is affected by the variety of surfaces it provides bacteria with. These different bacterial populations are influenced by the integrity of the soft-tissues, oral hygiene, saliva, diet, and the host's immune and inflammatory responses (34). Bronchial asthma is one of the major systemic diseases which produces dental caries. Salivary production and secretion are associated with the prolonged use of  $\beta_2$  agonists, inhaled corticosteroids, and antihistamines. The reduction in saliva can affect the natural process by which the mouth maintains its chemical balance and the protective function of cleaning the mouth. Reduced salivary flow provides a favorable environment for the growth and multiplication of microorganisms, such as Lactobacilli and Streptococcus mutans, causing dental caries (35). Ig E-mediated allergic reactions are typical in asthma, and thus the increase in salivary Ig E values could reflect the extent of these reactions on the oral mucosa. Similar reactions are also assumed to be a pathogenic mechanism in periodontal disease.(36). Candida Albicans causes deep-seated or superficial infections in patients under treatment with antibiotic or corticosteroid drugs (37). The present study was conducted to explore the clinical patterns of asthma, and its treatment regimens, and explore the impact of inhalation therapy on the occurrence of oral health problems.

## Subjects and Methods

It was a cross sectional study, and the sampling method was a non-probability convenient one.

Sample size was determined using G\*power software, where  $\alpha = 0.05$ , Power = 0.95 effect size = 0.3, and degree of freedom= 5 (38). The minimal sample size required was 194 subjects; thus, 215 subjects were enrolled in the present study (99 with Doctor diagnosed asthma and 116 without asthma), from the outpatient clinics of two private hospitals. Data were collected using interview questionnaire which provided information on the personal and clinical aspects of the subjects. Each subject was asked a medical history questionnaire to know if he/she was diagnosed by a doctor as having asthma or not. Each subject was asked the standard 5th ed. WHO survey on oral manifestations (39). Measurement of vital signs and anthropometric parameters, as well as clinical oral examination was done on every subject. Data were analyzed using SPSS version 22, and Logistic multinomial regression was used to study the Odds ratio and its 95% confidence interval between the variables. Level of significance for the study was 0.05.

**Availability of the data:** the raw data is available at the research center of ISNC and all results of the data are included in the paper.

## Results

Total number of patients with doctor diagnosed asthma was 99, while those without asthma were 116 subjects. The mean age of patients with asthma was 50 years (SD: 10.2), while mean age of the control subjects was 48.2 years (SD: 7.4). This difference was not statistically significant ( $t = - 1.47$ ;  $p < 0.143$ ). No significant differences were found between normal subjects and patients with asthma in gender or educational level ( $p > 0.05$ ). A greater proportion of patients with asthma were unemployed compared to the normal subjects (52.5% and 31.0% respectively;  $p < 0.006$ ). A greater proportion of patients with asthma were smokers compared to the normal subjects (41.4% and 27.6% respectively;  $p < 0.033$ ). A lower proportion of patients with asthma used to rinse their mouth frequently compared to the normal subjects (73.7% and 86.2% respectively;  $p < 0.022$ ). A greater proportion of patients with asthma suffered from diabetes, hypertension and ischemic heart diseases (33.3%, 38.4%, and 14.1% respectively), compared to the normal subjects (19.8%, 13.8%, and 3.4% respectively);  $p < 0.025$  (Table 1).

**Table 1: Distribution of studied subjects by having asthma and personal and clinical characteristics**

Variable	Categories	Doctor diagnosed asthma				Total		X <sup>2</sup> (p-value)
		No		Yes		N	%	
		N	%	N	%			
Gender	Female	47	40.5	47	47.5	94	43.7	1.051 (0.305)
	Male	69	59.5	52	52.5	121	56.3	
Educational Level	< University	65	56	71	71.7	136	63.3	5.652 (0.17)
	≥ University	51	44	28	28.3	79	36.7	
Occupational	Unemployed	36	31.0	52	52.5	88	40.9	10.206 (0.006)
	Manual	49	42.2	29	29.3	78	36.3	
	Clerical	31	26.7	18	18.2	49	22.8	
Smoking habit	Non-Smoker	84	72.4	58	58.6	142	66.0	4.554 (0.033)
	Smoker	32	27.6	41	41.4	73	34.0	
Rinse the mouth frequently	No	16	13.8	26	26.3	42	19.5	5.284 (0.022)
	Yes	100	86.2	73	73.7	173	80.5	
Brush teeth frequently	No	32	27.6	42	42.4	74	34.4	5.210 (0.022)
	Yes	84	72.4	57	57.6	141	65.6	
Use dental floss 2 times day	No	92	79.3	70	70.7	162	75.3	2.128 (0.145)
	Yes	24	20.7	29	29.3	53	24.7	
Use mouth wash 2 times per day	No	76	65.5	68	68.7	144	67.0	0.243 (0.622)
	Yes	40	34.5	31	31.3	71	33.0	
Use of fluoride	No	36	31.0	40	40.4	76	35.3	2.052 (0.152)
	Yes	80	69.0	59	59.6	139	64.7	
Suffer from Diabetes Mellitus	No	93	80.2	66	66.7	159	74.0	5.058 (0.025)
	Yes	23	19.8	33	33.3	56	26.0	
Suffer from Hypertension	No	100	86.2	61	61.6	161	74.9	17.173 (0.000)
	Yes	16	13.8	38	38.4	54	25.1	
Suffer from Ischemic heart disease	No	112	96.6	85	85.9	197	91.6	7.962 (0.005)
	Yes	4	3.4	14	14.1	18	8.4	
Suffer from GERD	No	106	91.4	84	84.8	190	88.4	2.217 (0.136)
	Yes	10	8.6	15	15.2	25	11.6	

Table 2 reveals the oral manifestations of the studied subjects having bronchial asthma. Angular stomatitis was significantly more encountered among patients with asthma compared to those without asthma ( $p < 0.001$ ). Ulceration, pigmentation and candidiasis of the tongue, buccal mucosa and palate were significantly more encountered among patients with asthma compared to those without asthma ( $p < 0.001$ ,  $0.002$  and  $0.046$  respectively). Xerostomia and salivary gland affection were significantly more encountered among patients with asthma compared to those without asthma ( $p < 0.000$ , and  $0.002$  respectively).



Table 2: Distribution of studied subjects by having asthma and oral Manifestations (continued next page)

Variable	Categories	Doctor diagnosed asthma				Total		X <sup>2</sup> (p- value)
		No		Yes		N	%	
		N	%	N	%			
Arrhythmia	YES	1	.9	5	5.1	6	2.8	3.454 (0.063)
	NO	115	99.1	94	94.9	209	97.2	
Angular stomatitis	YES	116	100	90	90.9	206	95.8	11.006 (0.001)
	NO	0	0.0	9	9.1	9	4.2	
Tongue	No	113	97.4	80	80.8	193	89.8	22.439 (0.001)
	Ulceration	0	0.0	2	2.0	2	.9	
	Pigmentation	0	0.0	8	8.1	8	3.7	
	Candidiasis	0	0.0	5	5.1	5	2.3	
	Geographical tongue	0	0.0	2	2.0	2	0.9	
	Taste changes	1	0.9	0	0.0	1	0.5	
	Fissured tongue	2	1.7	2	2.0	4	1.9	
Buccal mucosa	No	110	94.8	82	82.8	192	89.3	8.062 (0.045)
	Ulceration	3	2.6	8	8.1	11	5.1	
	Pigmentation	2	1.7	6	6.1	8	3.7	
	Candidiasis	1	0.9	3	3.0	4	1.9	
Periodontium	No	25	21.6	18	18.2	43	20.0	14.450 (0.002)
	Gingivitis	69	59.5	43	43.4	112	52.1	
	Bleeding Gum	0	0.0	7	7.1	7	3.3	
	Recession of the gum	22	19.0	31	31.3	53	24.7	
Palate	No	114	98.3	84	84.8	198	92.1	14.961 (0.002)
	Ulceration	2	1.7	4	4.0	6	2.8	
	Pigmentation	0	0.0	1	1.0	1	0.5	
	Candidiasis	0	0.0	10	10.1	10	4.7	
Teeth	No	4	3.4	7	7.1	11	5.1	7.240 (0.299)
	Caries	25	21.6	15	15.2	40	17.6	
	Attrition	0	0.0	2	2.0	2	0.9	
	Pockets	4	3.4	1	1.0	5	2.3	
	Missing	2	1.7	2	2.0	4	1.9	
	Staining	1	0.9	0	0.0	1	0.5	
	More than one defect	80	69.0	72	72.7	152	70.7	

(Table 2: Distribution of studied subjects by having asthma and oral Manifestations continued)

Pockets	No	53	54.7	32	32.3	85	39.5	40.543 (0.000)
	Mild	50	43.1	24	24.2	74	34.4	
	Moderate	13	11.2	16	16.2	29	13.5	
	Severe	0	0.0	27	27.3	27	12.6	
Teeth affected	No	4	3.4	9	9.1	13	6.0	6.968 (0.138)
	UA	29	25.0	20	20.2	49	22.8	
	UP	47	40.5	50	50.5	97	45.1	
	LA	10	8.6	6	6.1	16	7.4	
	LP	26	22.4	14	14.1	40	18.6	
Lips	No	114	98.3	90	90.9	204	94.9	7.095 (0.069)
	Cheilosis	1	0.9	6	6.1	7	3.3	
	Candidiasis	0	0.0	2	2.0	2	0.9	
	Ulceration	1	0.9	1	1.0	2	0.9	
Xerostomia	NO	116	100	87	87.9	203	94.4	14.892 (0.000)
	YES	0	0.0	12	12.1	12	5.6	
Salivary glands	No	116	100	91	91.9	207	96.3	9.736 (0.008)
	Inflammation	0	0.0	7	7.1	7	3.3	
	Stones	0	0.0	1	1.0	1	0.5	

Table 3 displays that the majority of the patients with asthma (71.7%) used systemic and inhalation medicine; 22.2% used inhalation medicine only. About one third of the patients (34.3%) used both bronchodilators and cortisol as systemic drugs; while 23.2% used SABA alone as systemic drugs. About one fifth of the patients (22.2%) did not use systemic drugs for treatment of asthma. About 94% of the patients received inhalation therapy for asthma; SABA was the medicine usually used in the inhalation therapy (76.8%). The majority of the patients did not use spacers with the inhalers (96%); and the majority of the patients use the inhalers PRN (72.7%). Most of the patients used the inhaler once or twice per day (45.5% and 37.4% respectively). About 86% of the patients did not receive health education by the treating doctor about oral hygiene, and the majority of the patients did not practice regular oral hygiene measures after using the inhalers (79%). Headache and cough were commonly encountered among patients with asthma.

Table 3: Clinical characteristics of patients with asthma (continued next page)

Variable	Categories	Number	Percent
Medication used	Nothing	2	2.0
	Systemic	2	4.0
	Inhalation	22	22.2
	Systemic and inhalation	71	71.7
Systemic drugs	No	22	22.2
	Cortisol syrup	9	9.1
	Cortisol lab	3	3.0
	Cortisol injection	2	2
	SABA	23	23.2
	LABA	3	3
	Cortisol and bronchodilator	34	34.3
	LTA	3	3
Inhalation therapy	No	6	6.1
	MDI	37	37.4
	Powder	25	25.3
	Nebulizer	31	31.3
Medicine in the inhalation Therapy	No	3	3
	Budesonide	1	1
	Fluticasone	2	2
	LABA	13	13.1
	SABA	76	76.8
	LAMA	2	2
	SAMA	2	2
Dose of cortisol	No	13	13.1
	Mild	51	51.5
	Moderate	32	32.3
	High	3	3
Use of spacer	No	96	96
	Yes	4	4
Use of the inhaler	Regular	27	27.3
	PRN	72	72.7
Frequency of administration	00	4	4.0
	1,00	45	45.5
	2,00	37	37.4
	3,00	10	10.1
	5,00	1	1.0
	6,00	1	1.0
	20,00	1	1.0
Advised by Doctor on oral hygiene	No	85	85.9
	Rinse mouth	13	13.1
	Brush teeth	1	1.0

Table 3: Clinical characteristics of patients with asthma (continued)

<b>Practice oral hygiene after inhalation</b>	No	78	78.8
	Rinse mouth	17	17.2
	Brush teeth	2	2.0
	Mouth wash	2	2.0
<b>Complaint</b>	No	27	27.3
	Headache	16	16.2
	Dizziness	5	5.1
	Insomnia	5	5.1
	Cough	25	25.3
	Hoarseness of voice	4	4.0
	Sore throat	2	2.0
	Runny or stuffy nose	9	9.1
	Nausea	1	1.0
	Vomiting	3	3.0
	Dry mouth and throat	1	1.0
	Diarrhea	1	1.0

Table 4 reveals that patients with doctor diagnosed asthma were 7.7 times more likely to develop tongue disorders (OR: 7.7,  $p < 0.013$ ), and 3 times more likely to develop buccal mucosal disorders (OR: 3,  $p < 0.039$ ) compared to subjects without bronchial asthma.

**Table 4: Multinomial Logistic regression of tongue disorders and buccal mucosal disorders and bronchial asthma and other personal and clinical characteristics**

Variables	Tongue disorders			Buccal mucosa disorders		
	B	P	Exp (B)	$\beta$	P	Exp(B)
Intercept	6.031	.000		.959	.472	
Age in years	-.068	.013	934	.021	.424	1.021
Doctor diagnosed asthma (yes=1, no=0)	2.044	.004	7.724	1.111	.039	3.036
Gender (male=1, female=0)	-.453	.461	.636	-.517	.334	.596
Educational level (yes=1, no=0)	-1.448	.078	.235	.104	.842	1.110
Smoking habit	.183	.776	1.200	.705	.189	2.023
Rinse the mouth frequently (yes=1, no=0)	-1.077	.144	.341	-.844	.182	.430
Brush teeth frequently (yes=1, no=0)	1.181	.126	3.258	.007	.991	1.007
Use dental floss $\geq 2$ times/day (yes=1, no=0)	-.157	.823	.854	.161	.790	1.175
Use mouth wash $\geq$ 2 times/day (yes=1, no=0)	1.105	.102	3.019	-.009	.988	.991
Use of fluoride (yes=1, no=0)	-1.171	.085	.310	-1.010	.070	.364

Table 5 shows that patients with doctor diagnosed asthma were 15 times more likely to develop palate disorders (OR: 15,  $p < 0.004$ ) compared to subjects without bronchial asthma.

**Table 5: Multinomial Logistic regression of periodontium disorders and palate disorders, and bronchial asthma and other personal and clinical characteristics**

Variables	Periodontium disorders			Palate disorders		
	B	P	Exp (B)	$\beta$	P	Exp (B)
Intercept	- .856	.454		7.188	.000	
Age in years	-.010	.651	.90	-.056	.072	.945
Doctor diagnosed asthma (yes=1, No=0)	.084	.821	1.088	2.711	.004	15.038
Gender	-.019	.961	.981	1.252	.110	3.499
Educational level (yes=1, No=0)	-.228	.545	.796	-1.738	.081	.176
Smoking habit	.547	.192	1.728	-1.756	.055	.173
Rinse the mouth frequently (yes=1, No=0)	-.907	.115	.404	-2.303	.007	.100
Brush teeth frequently (yes=1, No=0)	.501	.244	1.650	1.688	.072	5.408
Use dental floss 2 times per day or more (yes=1, No=0)	-.214	.638	.807	.260	.760	1.297
Use mouth wash 2 times per day or more (yes=1, No=0)	-.175	.676	.839	.913	.329	2.491
Use of fluoride (yes=1, No=0)	-.173	.668	.841	-2.296	.013	.101

## Discussion

The purpose of this study was to explore the impact of use of inhalation therapy in patients with asthma on the health of the oral cavity. Previous studies revealed that women had increased occurrence of bronchial asthma compared to men, educational level may influence asthma control, and (4) asthma is a common occupational lung disease (3-5). However, in the present study no significant associations were found between asthma and gender, educational level, or occupation of the subject. Air pollution, and second-hand smoking (SHS) exposure represents significant risk factors for asthma (6). In the present study, we found a significant link between smoking and occurrence of asthma. Growth of bacteria in the oral cavity, on the teeth and mucosa, is affected by the variety of surfaces it provides bacteria with. These bacteria are affected by the condition of the oral hygiene, soft-tissues, diet and saliva, as well as the host's immune and inflammatory responses (33, 34). The present study revealed that patients with asthma are significantly less likely to brush their teeth, rinse the mouth, use dental floss or use fluorides. This is consistent with findings from a previous study. (40). Previous studies reported significant association between asthma and occurrence of diabetes mellitus, hypertension and coronary heart disease. (7 – 9). This is consistent with findings from the present study. Gastro-esophageal reflux disorder (GERD), is significantly associated with asthma (10). However in the present study asthma was not significantly associated with GERD. Asthma should be considered as a potential etiology in any patient with chronic cough, because asthma is a common condition that is commonly associated with cough (12). In addition, migraine-type and tension-type headaches are more common in patients with asthma, compared to the overall population (11-13). The present study revealed that headache and cough were commonly encountered among patients with asthma. This is in line with another study (11). The present study revealed that ulceration, pigmentation and candidiasis of buccal mucosa and palate; as well as bleeding gum and gingival recession were significantly more common in patients with asthma compared to those without asthma. This was in line with a previous study, which revealed that, the amount of *Candida* organisms was found to be high in the oral cavity of patients with asthma due to the immunosuppressive effect of the inhaled cortisol (43).

High doses of systemic medications for asthma lead to salivary glands affection with resultant xerostomia, inflammation and stone formation which may increase dental caries (19 – 22). Beta2 agonists, and inhaled cortisol reduce secretion of saliva and increase dental caries, attrition and dental erosion (45, 46). This is consistent with findings from the present study.

ICSs, the mainstay of asthma treatment, lead to a reduction in both airway inflammation and airway hyper-responsiveness (29). In the present study the majority of the patients with asthma (71.7%) used systemic medication and inhalation of cortisol, while 22.2% used

inhalation medicine only. Patients diagnosed with asthma should be prescribed a short-acting, beta-2 agonist "rescue" inhaler (29). This is consistent with findings from the present study. Previous studies revealed that the use of spacer with the MDI (an additional reservoir placed between the mouthpiece of the MDI and the mouth of the patient) or a valved holding chamber (VHC) (a reservoir with a one-way valve permitting airflow into, but not out of, the patient's mouth) prior to inhalation increased the amount of inhaled medicine to different generations of the airways (31). However, in the present study, the majority of the patients did not use spacers with the inhalers (96%); and the majority of the patients use the inhalers PRN (72.7%). Previous studies revealed that clinical trials have shown that the "as-required," or PRN, use of inhaled combinations of a corticosteroid and a rapid-onset  $\beta_2$ -agonist provides clinical advantages over the traditional PRN inhaled rapid-onset  $\beta_2$ -agonists alone in patients with different degrees of asthma severity (32). In the present study most of the patients used the inhaler of  $\beta_2$ -agonist only, once or twice per day (45.5% and 37.4% respectively). Dental practitioners should be aware of the correlation between asthma and oral health. They should educate their patients to follow precautionary measures to prevent adverse effects on oral tissues (42). In the present study we found that 85% of the doctors did not advise the asthmatic patients to maintain oral hygiene.

## Conclusions

The majority of patients with asthma use inhalation therapy, but they do not use inhalers. Oral clinical disorders e.g. ulceration, pigmentation and candidiasis, in the tongue, buccal mucosa, and palate as well as xerostomia are significantly associated with inhalation therapy for asthma. Oral hygiene practice by patients with asthma was low. The health care practitioners should focus on health education of patients with inhalation therapy, about importance of proper practice of oral hygiene.

### Limitations of the study:

This study was a convenient non-probability one, and used an online questionnaire so the representation of the data to the population can't be assured. However, this was an exploratory study and showed no marked variations in the characteristics of the studied subjects, and the results are similar to those obtained globally.

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# Association between obesity and mental disorders among male secondary school students in Abha, Kingdom of Saudi Arabia: A Predictor based Cross-Sectional Study

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## Abstract

**Background:** Obesity-related morbidity continues to increase in Saudi Arabia, especially among school students, who constitute a vulnerable population since they can be highly influenced by the western culture and rapid globalization.

**Aim of Study:** To examine the relationship between obesity and negative emotional states among male secondary school students.

**Methodology:** This was a cross-sectional study conducted among male secondary school students in Abha City, Saudi Arabia during the academic year 2019-2020. A multistage cluster sampling technique was followed by the researchers, in order to recruit participants. The standardized Arabic version of Depression Anxiety Stress Scale (DASS-21) was used by the researchers for determining prevalence and levels of depression, anxiety and stress symptoms among participants.

**Results:** Three hundred and ninety eight students participated in the study. Their mean age ( $\pm$ SD) was 16.98 $\pm$ 0.93 years. Overweight and obesity was present among 44.2% and 38.4% of participants

respectively. The overall prevalence rates for symptoms of depression, anxiety and stress among participants were 57%, 64.6% and 39.4%, respectively. There were statistically significant associations between obesity and symptoms of depression, anxiety and stress ( $p < 0.001$  for all).

**Conclusions:** The burden of overweight and obesity are high among the male secondary school students. Overweight and obesity are associated with symptoms of depression, anxiety and stress. Therefore, there should be emphasis on implementing interventions to raise awareness about maintaining normal body mass index among the school students and thereby reducing the risk of mental disorders.

**Key words:** Obesity, Mental disorders, Depression, Anxiety, Stress, School students, Saudi Arabia.

## Introduction

Obesity has become a major public health problem, with several associated physical and psychosocial complications. Although it is increasing in all age groups and among all racial groups and educational levels, young adults aged 18 to 29 years experience the highest rate of increase (1). Obesity during adolescence carries with it important psychosocial sequelae. The experience of weight stigma or perceived weight discrimination is associated with several negative emotional states (2).

Obesity has an impact on psychological well-being, which can lead to several mental disorders, e.g., depression, anxiety, stress, eating disorder, or distorted body image (3). As per the research carried out in childhood obesity, anxiety is considered to be both a symptom and a disorder that has been more commonly reported among the child population (4).

Adolescent age group is one of the highly significant stages in human life. At this stage, multifactorial changes that include biological, physiological and psychological changes occur, which mainly cause depression that can affect the academic performance of the students in the school and the colleges. It can also make the adolescents vulnerable to substance abuse which further can increase the risk of suicides among the adolescents (5).

Depression among adolescents is the major public health issue throughout the world in the last few years (6). Prior evidence suggests that depression is often under-diagnosed in a variety of health care organizations inclusive of primary health care centers. Depression among the youth and the teenagers in schools is quite frequently underdiagnosed which further increases the burden of depression in the country (7).

The prevalence rate of depression has severely increased over a period of years across the world and in the developing countries the prevalence rate has sharply increased to 44% (8). Prevalence of depression is quite alarming in the Kingdom of Saudi Arabia (KSA). The predisposing factors that increase the level of depression among the population includes stress, chronic diseases, sedentary life style, social isolation and social stigmas in terms of psychiatric illnesses (9).

A study carried out in the KSA using the 'Depression, Anxiety and Stress Scale (DASS) reported that 59.4% of students had symptoms of at least one of the above-mentioned negative emotional states (10).

Generally, students, especially those at secondary schools, are more prone to have stress mainly due to the heavy academic burden and fears about the future. The students may come across a huge amount of stress due to lack of relaxation time and competitive examinations at the end of the school education (11).

A positive association has been observed between obesity and psychological well-being of the population. Obese persons may be more prone to depression, anxiety, stress, eating disorders and low self-esteem due to disorientation of their body shape (12). However, the association between obesity and mental health problems is very complex in nature and difficult to understand. There are several theories that were framed mainly to link obesity with mental health problems (13).

The systematic review of Luppino et al. described a bidirectional relationship between obesity and depression. They reported that obese individuals were at risk of developing depression, and depressed persons had 58% of increased risk of becoming obese (14). Likewise Garipey et al. found a positive association between obesity and the anxiety disorders (15).

Obesity during adolescence carries with it important psychosocial sequelae, in addition to the medical complications. In KSA, prevalence of obesity continues to increase steadily among adolescents (16). Mouzan et al. (17) reported that the prevalence rate for overweight and obesity was as high as 37.2%. However, there is still limited information on overweight and obesity and its psychosocial impact among Saudi children and adolescents.

Research on the association between obesity and mental disorders among Saudi male secondary school students is so scarce. Therefore, the present study aimed to find the association between obesity and mental disorders among male secondary school students in Abha City, KSA.

## Materials and Methods

Following a cross-sectional research design, this study was conducted during the period from August to December 2019 and included 398 male secondary school students in Abha City, KSA.

A multistage cluster sampling technique was applied. Lists of governmental secondary schools for boys in the Abha City were obtained from the Directorate of Education in Aseer Region. Abha city was geographically divided into: central, east, west, north and south administrations and the schools were listed based on these five administrative locations. Two male public secondary schools from each location were randomly selected. To fulfill the required sample size from the 10 randomly selected secondary schools, about 40 students were randomly selected in the study from each selected school (Figure 1).

Inclusion criteria were being a student, aged less than 20 years in the selected governmental secondary schools. On the other hand, students with special needs were excluded. Each participating student was interviewed using a structured self-administered questionnaire, which was developed by the researchers. It contains information about students' socio-demographic characteristics and the anthropometric measurements, including height, weight and body mass index (BMI). Students' weight was

measured using a digital scale and their height was taken by a stadiometer. Students' BMI was calculated by using the formula: (18)

$$\text{BMI (Kg/m}^2\text{)} = \text{Weight (Kg)} / \text{Height (m}^2\text{)}$$

Students were classified based on their BMI as: Normal (BMI = 18.5-24.9 Kg/m<sup>2</sup>); Overweight (BMI = 25-29.9 Kg/m<sup>2</sup>); or Obese (BMI =  $\geq$  30 Kg/m<sup>2</sup>). (18)

The Depression, Anxiety and Stress, 21-item Scale (DASS-21) was used in the present study to assess the common negative emotional states that include depression, anxiety and stress. Depression was classified based on the scores obtained from the depression anxiety stress scale and it is classified as Normal (0-9), Mild (10-13), Moderate (14-20), Severe (21-27) and extremely severe ( $\geq$  28). Similarly, anxiety was classified based on the scores obtained from the depression anxiety stress scale and it is classified as Normal (0-7), Mild (8-9), Moderate (10-14), Severe (15-19) and extremely severe ( $\geq$  20). Likewise, stress was classified based on the scores obtained from the depression anxiety stress scale and it is classified as Normal (0-14), Mild (15-18), Moderate (19-25), Severe (26-33) and extremely severe ( $\geq$  34). The Arabic version of DASS-21 questionnaire has been already validated as per the Arabic culture (19).

Ethical approval was obtained from the Research Ethics Committee, King Khalid University, Abha, Kingdom of Saudi Arabia. Moreover, verbal consent was obtained from the concerned class teacher and overall head of the school for collecting the data about obesity and mental disorders.

Collected data were analyzed using the Statistical Package for Social Sciences (IBM, SPSS (version 16.0, SPSS Inc. Chicago, IL, USA). Frequency tables were used to describe the socio-demographical characteristics of participants. To test significance of differences the Chi square test was applied for categorical variables. Pearson's correlation between two quantitative variables was applied. Tests of significance were two-tailed and were set at  $p < 0.05$ .

## Results

Table 1 shows that age of 20.1% of students was <17 years, 54.5% were 17 years old, while 25.4% were 18 years old or more (Figure 2). The mean age of the participant students was  $16.98 \pm 0.93$  years. Regarding students' body mass index, 17.3% had normal body mass index (<25 kg/m<sup>2</sup>), while 44.2% were overweight (25-29.9 kg/m<sup>2</sup>) and 38.4% were obese (>30 kg/m<sup>2</sup>), as shown in Figure 3. Students' mean BMI was  $29.15 \pm 5.84$  kg/m<sup>2</sup>.

Table 2 shows participant students' responses regarding DASS-21.

Table 3 shows that secondary school students' average BMI showed a slightly increasing positive trend with their age. The lowest BMI was observed among those aged <17

years ( $28.5 \pm 6.5$  kg/m<sup>2</sup>), while the highest was observed among those aged >18 years ( $30.2 \pm 5.7$  kg/m<sup>2</sup>). However, differences in BMI according to students' age groups was not statistically significant ( $p = 0.100$ ).

Table 4 shows that 57% of participant students had symptoms of depression, with varying severity grades: mild (14.8%), moderate (20.1%), severe (10.1%) or extremely severe (12.1%). About two-thirds of participant students (64.6%) had symptoms of anxiety, with varying severity grades: mild (7.5%), moderate (17.6%), severe (15.1%) or extremely severe (24.4%), while 60.6% had symptoms of stress, with varying severity grades: mild (12.6%), moderate (11.8%), severe (10.3%) or extremely severe (4.8%).

Table 5 shows that prevalence and severity of negative emotional states (depression, anxiety and stress) among male secondary school students differed significantly according to their body mass index ( $p < 0.001$  for all comparisons).

## Discussion

The present study showed high prevalence rates of overweight and obesity among male secondary school students in Abha City (44.2% and 38.4%, respectively).

This finding is in agreement with those reported by other studies in Saudi Arabia among male students. Farshori et al. (20) in Hail City, reported that prevalence rates of overweight and obesity among male students aged 13-18 years were 48% and 29%, respectively, while Shaikh et al., (21) in Qassim Region, reported that prevalence of overweight and obesity among Saudi intermediate school students, between 12-14 years of age were 55.8% and 21.7%, respectively. However, lower prevalence rates were also reported in Saudi Arabia by Al-Hussaini (22) among male school children aged 6-16 years in Riyadh City (12% and 18.4%), and Abdalla et al. (23) in Majmaah City among primary school students aged 6-14 years (11.2% and 17.6%, respectively).

The lower prevalence rates for overweight and obesity among male secondary school students reported in some studies in Saudi Arabia compared to results of our study may be due to regional or socio-demographic variations.

The present study found that more than half of male secondary school students (57%) had symptoms of depression, while about two-thirds of them had symptoms of anxiety (64.6%) and 60.6% had symptoms of stress. All these three negative emotional states among participants were of variable grades of severity from mild to extremely severe.

This finding is in accordance with that of Hakamy et al. (24) in Jizan, Saudi Arabia, who reported that 50% of secondary school students had symptoms of depression, of whom 17.3% had mild depressive symptoms, 16.5% had moderate symptoms, while severe and extremely severe

Figure 1: Flowchart showing the adopted sampling method in this study

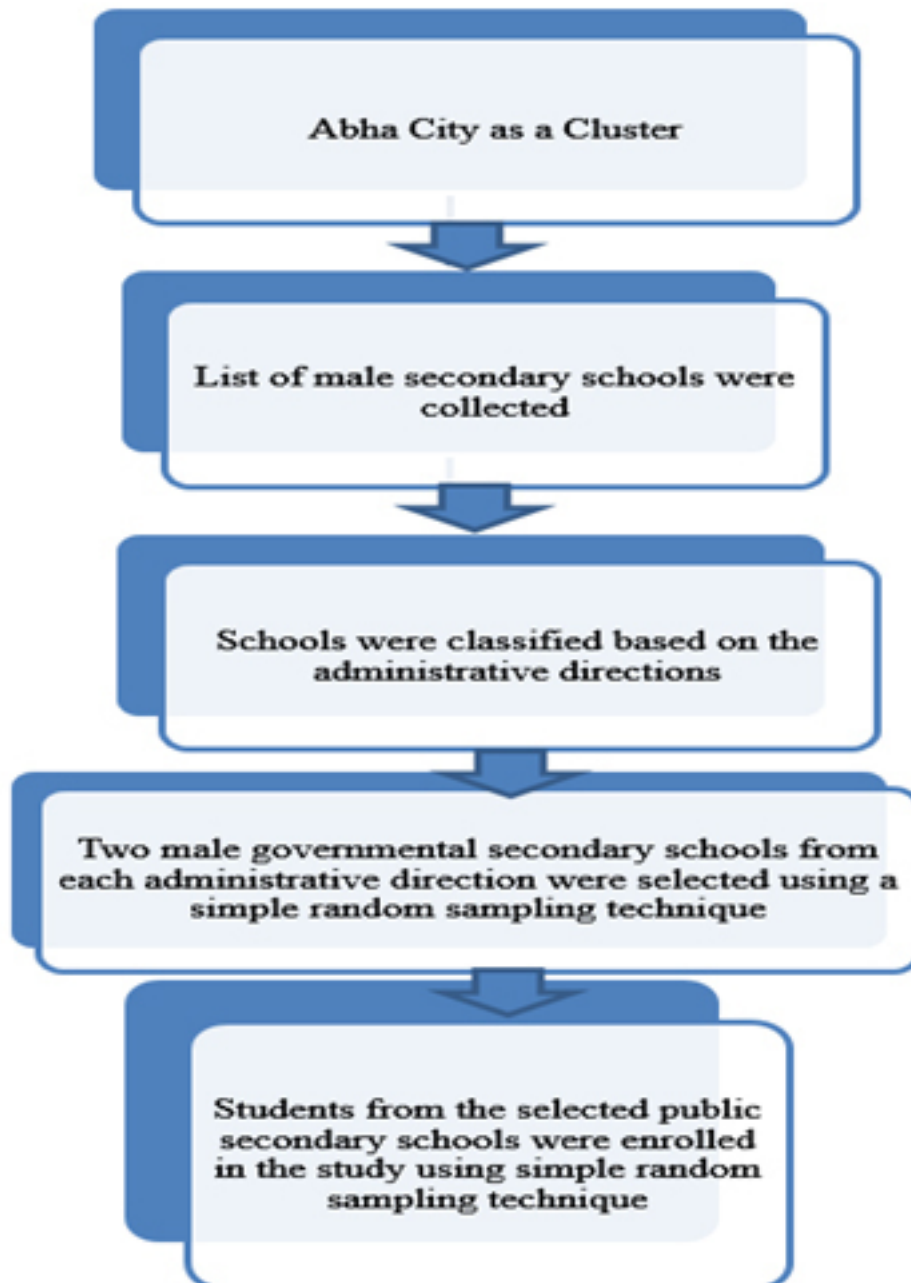


Table 1: Personal characteristics of participant students (n=398)

Characteristics	No. (%)
Age groups	
• <17 years	80 (20.1%)
• 17 years	217 (54.5%)
• $\geq 18$ years	101 (25.4%)
• Mean $\pm$ SD	16.98 $\pm$ 0.93
Body mass index	
• Normal (<25 kg/m <sup>2</sup> )	69 (17.3%)
• Overweight (25-29.9 kg/m <sup>2</sup> )	176 (44.2%)
• Obese ( $\geq 30$ kg/m <sup>2</sup> )	153 (38.4%)
• Mean $\pm$ SD	29.15 $\pm$ 5.84

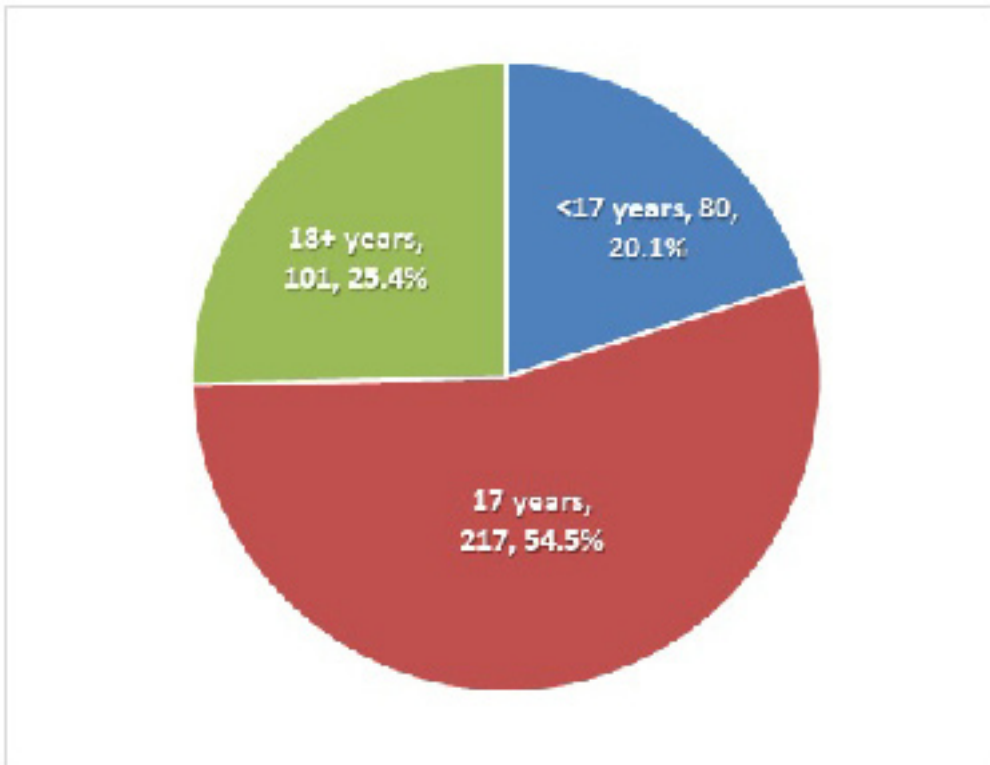
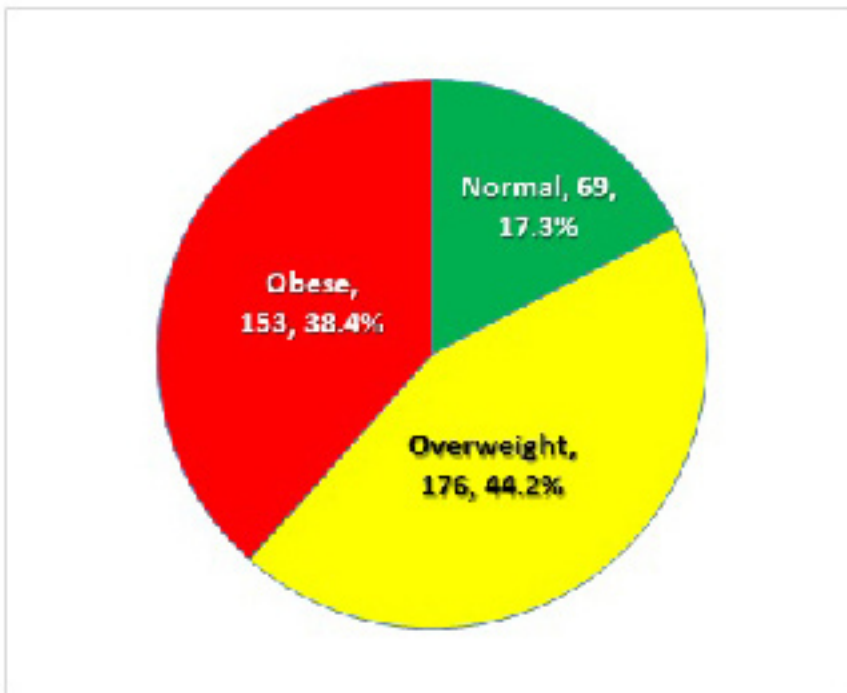
**Figure 2: Age groups of participant male secondary school students****Figure 3: Body mass index groups of participant students**

Table 2: Responses of participant students to DASS-21 (n=398)

DASS-21 items	Never No. (%)	Sometimes No. (%)	Often No. (%)	Always No. (%)
I found it hard to wind down	196(49.2%)	134(33.7%)	47(11.8%)	21(5.3%)
I was aware of dryness of my mouth	222(55.8%)	123(30.9%)	40(10.1%)	13(3.3%)
I couldn't seem to experience any positive feeling at all	245(61.6%)	85(21.4%)	50(12.6%)	18(4.5%)
I experience breathing difficulty in the absence of physical exertion	255(64.1%)	75(18.8%)	46(11.6%)	22(5.6%)
I find it difficult to work up the initiative to do things	181(45.5%)	123(30.9%)	66(16.6%)	28(7.0%)
I tended to over-react to situations	214(53.8%)	106(26.6%)	43(10.8%)	35(8.8%)
I experienced trembling (e.g. in the hands)	198(49.7%)	106(26.6%)	58(14.6%)	36(9.0%)
I felt that I was using a lot of nervous energy	170(42.7%)	103(25.9%)	77(19.3%)	48(12.1%)
I was worried about situations in which I might panic and make a fool of myself	175(44%)	89(22.4%)	81(20.4%)	53(13.3%)
I felt that I had nothing to look forward to	233(58.5%)	100(25.1%)	42(10.6%)	23(5.8%)
I found myself getting agitated	189(47.5%)	133(33.4%)	54(13.6%)	22(5.5%)
I found it difficult to relax	217(54.5%)	114(28.6%)	35(8.8%)	32(8.0%)
I felt down-hearted and blue	171(43.0%)	116(29.1%)	57(14.3%)	54(13.6%)
I was intolerant of anything that kept me from getting on with what I was doing	206(51.8%)	113(28.4%)	48(12.1%)	31(7.8%)
I felt I was close to panic	259(65.1%)	78(19.6%)	43(10.8%)	17(4.6%)
I am unable to become enthusiastic about anything	202(50.8%)	102(25.6%)	58(14.6%)	36(9.0%)
I felt I wasn't worth much as a person	270(67.8%)	70(17.6%)	42(10.6%)	16(4.0%)
I felt that I was rather touchy	219(55%)	104(26.1%)	41(10.3%)	34(8.5%)
I was aware of the action of my heart in the absence of physical exertion	244(61.3%)	75(18.8%)	51(12.8%)	28(7.0%)
I felt scared without any good reason	245(61.6%)	85(21.4%)	42(10.6%)	26(6.5%)
I felt that life was meaningless	230(57.8%)	88(22.1%)	39(9.8%)	41(10.3%)

Table 3: Participant students' body mass index (Mean±SD) according to their age

Age of students	No.	Mean±SD	P-value
• <17 years	80	28.5±6.5	0.100
• 17 years	217	29.1±5.0	
• ≥18 years	101	30.2±5.7	

**Table 4: Grades of negative emotional states (depression, anxiety and stress) according to DASS-21 among participant students**

Grades of negative emotional states	No. (%)
<b>Symptoms of Depression</b>	
• Absent	171 (43.0%)
• Present	227 (57.0%)
• Mild	59 (14.8%)
• Moderate	80 (20.1%)
• Severe	40 (10.1%)
• Extremely severe	48 (12.1%)
<b>Symptoms of Anxiety</b>	
• Absent	141 (35.4%)
• Present	257 (64.6%)
• Mild	30 (7.5%)
• Moderate	70 (17.6%)
• Severe	60 (15.1%)
• Extremely severe	97 (24.4%)
<b>Symptoms of Stress</b>	
• Absent	241 (60.6%)
• Present	157 (39.4%)
• Mild	50 (12.6%)
• Moderate	47 (11.8%)
• Severe	41 (10.3%)
• Extremely severe	19 (4.8%)

**Table 5: Distribution of participant students' body mass index according to their grades of negative emotional states**

Grades of Negative Emotional States	Body mass index (BMI)			P Value
	Normal (n=69) No. (%)	Overweight (n=176) No. (%)	Obese (n=153) No. (%)	
<b>Depression</b>				<0.001*
• Absent	13 (18.8%)	98 (55.7%)	64 (41.8%)	
• Mild	7 (10.1%)	18 (10.2%)	34 (22.2%)	
• Moderate	13 (18.8%)	42 (23.9%)	25 (16.3%)	
• Severe	10 (14.5%)	12 (6.8%)	18 (11.8%)	
• ExtremelySevere	26 (37.7%)	6 (3.41%)	8 (5.2%)	
<b>Anxiety</b>				<0.001*
• Absent	42 (60.9%)	68 (38.6%)	35 (22.9%)	
• Mild	4 (5.8%)	12 (6.8%)	14 (9.2%)	
• Moderate	13 (18.8%)	20 (11.4%)	33 (21.6%)	
• Severe	7 (10.1%)	28 (15.9%)	25 (16.3%)	
• ExtremelySevere	3 (4.3%)	48 (27.3%)	46 (30.1%)	
<b>Stress</b>				<0.001*
• Absent	24 (34.8%)	117 (66.5%)	104 (68.0%)	
• Mild	7 (10.1%)	26 (14.8%)	17 (11.1%)	
• Moderate	8 (11.6%)	23 (13.1%)	16 (10.5%)	
• Severe	22 (31.9%)	8 (4.5%)	11 (7.2%)	
• ExtremelySevere	8 (11.6%)	2 (1.1%)	5 (3.3%)	

\* Statistically Significant



grades were present in 11.3% and 4.9% of students, respectively. More than half of students had symptoms of anxiety (59.7%), of whom 22.7% had moderate grade, while severe and extremely severe grades were present in 13.2% and 14.6% of students, respectively. Symptoms of stress were present among 39% of students, with most students having either mild or moderate grades (13.7% for both), while severe and extremely severe grades were present in 9.7% and 1.9% of students, respectively. Similarly, Alenazi et al. (25), in Arar City, Saudi Arabia, reported that prevalence rates of depression, anxiety and stress among male secondary school students were 56.3%, 56%, and 41.9%, respectively.

However, prevalence of depression, anxiety, and stress symptoms among secondary school students in Imphal, Manipur, India, were much lower than those reported in Saudi Arabia (19.5%, 24.4%, and 21.1%, respectively). These reported low prevalence rates of negative emotional states among school students in India may be due to different cultures and traditions practiced in that country, as well as the variations in the socio-demographic features of study samples.

The present study revealed that both prevalence and severity of studied negative emotional states (i.e., depression, anxiety and stress) among male secondary school students differed significantly according to their body mass index.

This finding is in agreement with those reported by several studies. In Abha City, Saudi Arabia, AlQahtani et al. (26) reported a significant association between obesity and levels of depression, anxiety, and stress ( $p < 0.001$ ;  $p < 0.001$ ; and  $p = 0.003$ , respectively). Moreover, in Amsterdam, Netherlands, von Vuuren et al. (27) reported significant associations between overweight and mental health problems among adolescents. They found that adolescents who were overweight or obese were more likely to suffer from mental health problems in comparison with those with normal body weight. They concluded that overweight and obesity are significantly associated with mental health problems among adolescents. They recommended that mental health should be integrated into prevention programs that address healthy weight development.

### Limitations

The present study followed a cross-sectional design, and is based on a self-reported questionnaire. Therefore, there may be some degree of response bias. Moreover, this study has taken place only in selected secondary schools of males in Abha City. Consequently, the generalization of our results cannot be generalized to the wider population of Saudi Arabia.

### Conclusions

Prevalence of overweight and obesity among secondary school male students is quite high. Obesity is associated with higher prevalence and more severe negative emotional states. There is a pressing need for having a healthy public policy related to obesity for designing and implementing suitable interventions to control and reduce the burden of obesity among school students. Schools should provide a supportive environment to students for improving their physical activity, which further helps them maintain a normal BMI. The high prevalence of negative emotional states among secondary school students prioritizes the need of planning and implementing counselling sessions to students. Further prospective research is needed, involving both genders and covering a wider range of schools for better understanding the relationship between the obesity and mental disorders.

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# Knowledge and practice among primary care physicians in Najran (south west region), Saudi Arabia regarding Maturity Onset Diabetes of the Young (MODY)

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## Abstract

**Background:** Maturity Onset Diabetes of the Young (MODY) is a disease that is caused by a single gene. This indicates that it is the result of a single gene mutation. MODY can be caused by a variety of gene mutations. When a family member who has MODY, relatives are at a higher risk of developing the disease. Maturity Onset Diabetes of the Young is a kind of diabetes mellitus that is inherited. A mutation in one of eleven genes causes it. MODY could be the cause of up to 5% of all diabetes cases. MODY patients, like other diabetics, have difficulty controlling their blood sugar levels.

**Methods:** This was a cross-sectional study among primary care physicians (PCPs) in the Najran region (13). The questionnaire was created following a series of conversations between a panel of experts, which included subject specialists, researchers, and language experts. Pilot study with 15 respondents was also conducted to observe the clarity of the content of the questionnaire and its validity. The questionnaire's Cronbach alpha was computed. It was created in English and disseminated through Google as well as on printed forms. The forms had two main sections, one for knowledge and the other for practice regarding MODY.

**Results:** 12% responding completely regarding definition of MODY, 55.5% have knowledge regarding mode of inheritance of Mody, 9% were aware about the type of the MODY, 60% were about typical symptoms of MODY, Diagnostic tools of MODY (45%), Possible presentations of MODY (6%), Therapeutic modalities of MODY (39%), Complications of MODY (20%) Differences between Mody and T1DM and T2DM 6.80 while overall knowledge score was 53.8%

**Conclusion:** Clinicians should maximize alternative therapy in the era of CF modulators and correctors to improve outcomes and prevent long-term morbidity and mortality.

**Key words:** knowledge, practice, primary care physicians, Maturity Onset Diabetes of the Young (MODY)

## Background

Maturity Onset Diabetes of the Young (MODY) is a disease that is caused by a single gene. This indicates that it is the result of a single gene mutation. MODY can be caused by a variety of gene mutations. When a family member who has MODY, relatives are at a higher risk of developing the disease. Maturity Onset Diabetes of the Young is a kind of diabetes mellitus that is inherited. A mutation in one of eleven genes causes it. MODY could be the cause of up to 5% of all diabetes cases. MODY patients, like other diabetics, have difficulty controlling their blood sugar levels(1-3).

MODY is a type of familial diabetes with an early onset (in childhood, adolescence, or young adulthood) and an autosomal-dominant mode of transmission (shown by the existence of three generations of the same afflicted lineage) linked to anomalies in the insulin secretion sphere (2-5).

When compared to type 1 and type 2 diabetes, MODY is extremely rare; scientists believe that only 1–2% of people with diabetes (20–40,000 people) in the UK have it. Because MODY is so uncommon, doctors may be unaware of it, and it is estimated that 90% of patients with it are initially misdiagnosed with type 1 or type 2 diabetes (6-8).

The two most common types of monogenic diabetes are neonatal diabetes mellitus (NDM) and maturity-onset diabetes of the young (MODY). NDM is a condition that affects neonates and infants. MODY is far more frequent than NDM, and it usually begins in adolescence or early adulthood (9-10).

Stefan S. Fajans, an American researcher, described for the first time in 1960 a group of non-obese children and adolescents with a strong family history of diabetes mellitus who had mild diabetes mellitus and achieved good metabolic control with the use of sulfonylurea after several years of observation. MODY has been confirmed through the use of genome scanning strategies, carried out in several families with a clinical diagnosis of MODY (9).

A study reported that MODY accounts for up to 2% of all diabetes cases in people aged 20 and under in the United States. MODY is caused by a variety of distinct gene mutations, all of which restrict the pancreas' ability to make insulin. This causes high blood glucose levels, which can harm bodily tissues such as the eyes, kidneys, neurons, and blood vessels over time. GCK-MODY (MODY2) and HNF1A-MODY (MODY3) are the two most prevalent causes of MODY, accounting for 30 percent to 60 percent of all MODY cases. GCK-MODY is expected to affect one out of every 1,000 people (11-12).

The prevalence of MODY has not yet been defined, but it is estimated that 2-5% of individuals considered to have DM2 are actually MODYs. The prevalence of GCK-MODY is higher in some countries (the United States, Germany, Italy, France, and Spain) than in others (most likely due to biased assessment of children versus adults) (11-12).

For illness prevention, early diagnosis and treatment, and public knowledge of genetic disorders is critical. Furthermore, institutions must be made aware of the importance of providing the finest possible healthcare, social, and environmental amenities for patients, their families, and care managers. Due to a lack of knowledge and practice and likely a lack of awareness of the disease at the level of primary care physicians, any disease including MODY will increase.

The aim of this study is to determine the knowledge and practice of primary care physicians about MODY and to make recommendations.

## Methods

This was a cross-sectional study among primary care physicians (PCPs) in the Najran region of Saudi Arabia. Primary healthcare centers (PHCCs) are regarded as the patient's primary point of contact with the healthcare system. Many countries use health indicators to assess the quality and operation of their primary healthcare systems. Saudi Arabia has been working to integrate preventative and primary curative healthcare services into PHCs, which now provide a wide range of treatments. Najran is a city in Saudi Arabia's southwest, close to the Yemeni border. It is the provincial capital of Najran. Najran, which has been designated as a new town, is one of the kingdom's fastest-growing cities, with a population that has increased from 47,500 in 1974 to 90,983 in 1992 to 246,880 in 2004 and 505,652 in 2017 (13). The questionnaire was created following a series of conversations between a panel of experts, which included subject specialists, researchers, and language experts. A pilot study with 15 respondents was also conducted to observe the clarity of the content of the questionnaire and its validity. The questionnaire's Cronbach alpha was computed. It was created in English and disseminated through Google as well as on printed forms. The form had two main sections, one for knowledge and the other for practice with MODY. There were 8 knowledge questions and three practice questions that examined various aspects of MODY. Each question had correct and incorrect responses, as well as the possibility of selecting more than one option. For each question, there were three options: complete answer, incomplete response, and incorrect answer. Complete implies the respondent selected all correct answers, incomplete meant the responder selected some correct and some incorrect answers, and wrong means the responder selected all incorrect answers. The total knowledge score was computed based on all correct answers to all questions, and each respondent's total score was calculated based on his or her correct responses. Age, gender, years of experience after graduation and in a primary care setting, nationality, job nature (resident, specialist, family medicine consultant), and whether the responder had ever attended the yearly educational pediatric club meeting were all included in the first section of the questionnaire. We used a convenient sampling method. After collection of data, data was coded and entered in the SPSS Ver. 20 software for analysis; descriptive statistics were computed. The

median and percentage out of the total scores were used to compute the total knowledge and practice scores. The sum of all correct answers was used to calculate the total knowledge score, while the practice score was out of five points.

The study was approved by the research ethical committee of the Najran University; informed consent was obtained from the respondents, and the questionnaire was anonymous.

## Results

45 respondents successfully completed the questionnaire out of 54, so the response rate was 83.3%. Cronbach alpha of the questionnaire was 0.79. Out of 45 respondents 25 (55.5%) were of age group less than 40 years. The male doctor respondents were 88.8% and females were 11.2%, out of 45 respondents. 77.7% had been performing their duties in the PHCC for less than 5 years while 13.3% had been working for more than 10 years with professional responsibilities. 77.7% were working as a general practitioner while others were specialists (11.11%) and family medicine consultant (11.1%); 13.4% attended a training course or a conference on management of MODY while only 12.2% prescribed sulfonylureas (Table 1).

Table 2 shows that 12% responded completely regarding definition of MODY, 55.5% have knowledge regarding mode of inheritance of MODY, 9% were aware about the type of the MODY, 60% were aware of typical symptoms of MODY, diagnostic tools of MODY (45%), possible presentations of MODY (6%), therapeutic modalities of MODY (39%), complications of MODY (20%), differences between MODY and T1DM and T2DM 6.80, while overall knowledge score was 53.8% (Table 2).

The overall practice score percentage was 48% with a mean of 5.4 and maximum and minimum scores were 5 and 1, respectively. Regarding the practice of PCPs about when to refer suspected

MODY patients, 18.6% responded correctly and the remaining either answered incorrectly or incompletely. More than 40% of the responders answered correctly about treatment of MODY. On the other hand, 47.8% knew the standard of care to follow up with children who are known to have the diagnosis of CF (Table 3).

## Discussion

This is the first study in Najran to analyze PCPs' knowledge and practice about MODY in Saudi Arabia's southwest region. Misconceptions, gaps, and inaccuracies in MODY knowledge could lead to inadvertent non-adherence to treatment, which could affect the disease's course and outcome.

MODY was found to be responsible for 2.4 percent of diabetes cases in children under the age of 15 in Saxony, Germany. The most frequent type of monogenic diabetes is MODY. Adults have a prevalence of about 1/10,000,

whereas children have a prevalence of about 1/23,000. There has been no mention of any ethnic preferences. It is estimated that about 80% of cases are misdiagnosed as type 1 or type 2 diabetes, confounding estimates of prevalence and incidence (14-16).

MODY is the final diagnosis in 1%–2% of patients who have been diagnosed with diabetes. The prevalence is 70–110 persons per million. The identical mutation will be inherited by 50% of first-degree relatives, putting them at a greater than 95% lifetime risk of getting MODY. As a result, proper diagnosis of this illness is critical (17-19).

Apart from glucokinase, all types of MODY carry a risk of long-term diabetes complications, so patients should eat a healthy balanced diet and stay physically active to help maintain good blood glucose and cholesterol levels, which reduces the risk of complications (19).

This research emphasized the importance of guidelines that are clear and defined across the country for diagnosis of the problem and initiating the necessary treatment. However, we need a true and reliable baseline before creating such treatment centers for MODY (20).

Affected individuals and families should receive genetic counseling to learn about the nature, mode(s) of inheritance, and implications of genetic abnormalities so they can make informed medical and personal decisions. According to one study conducted in Kenya, the total prevalence of MODY is estimated to be 1–5 per 10,000 people, accounting for 1–5% of all diabetes mellitus cases. Among Western Australians, however, the prevalence of MODY in diabetic individuals under the age of 35 years is 0.24 percent, equating to an estimated minimum prevalence of 89 instances per 1,000,000 for the entire Australian population (22-23).

In our study we have observed the lack of information and misconceptions regarding MODY. We need a series of seminars and educational activities to educate doctors regarding MODY.

## Conclusion

This study emphasizes the importance of PCPs participating in intensive teaching programs in order to promote early detection of MODY and begin proper treatment of MODY. Clinicians should maximize alternative therapy in the era of CF modulators and correctors to improve outcomes and prevent long-term morbidity and mortality.

Defective transcriptional regulation, aberrant metabolic enzymes, protein misfolding, malfunctioning ion channels, and impaired signal transduction are all involved in the etiology of MODY. In order to effectively identify patients, individualize patient therapy and follow-up, and screening of family members of afflicted individuals for diabetes mellitus is required. Clinicians need to have a complete grasp of the epidemiology and etiology of MODY.

Table 1: Demographic characteristics of the responding physicians

<ul style="list-style-type: none"> <li>• <b>Age in years</b></li> <li>• Less than 30 years old</li> <li>• 30-40 year</li> <li>• 41-50 years</li> <li>• More than 50 year</li> </ul>	<p>25 (55.5%)</p> <p>15 (33.3%)</p> <p>2 (4.3%)</p> <p>3 (6.67%)</p>
<ul style="list-style-type: none"> <li>• <b>Gender</b></li> <li>• Female</li> <li>• Male</li> </ul>	<p>5 (11.2 %)</p> <p>40 (88.8 %)</p>
<ul style="list-style-type: none"> <li>• <b>Qualification</b></li> <li>• MBBS</li> <li>• Diploma</li> <li>• Master</li> <li>• Doctorate/PhD/Fellowship</li> <li>• Others</li> </ul>	<p>40 (88.8%)</p> <p>0 (0%)</p> <p>4 (8.8%)</p> <p>1 (2.4)</p> <p>0 (0.0%)</p>
<ul style="list-style-type: none"> <li>• <b>Years of experience in the primary health care field</b></li> <li>• 5-10 years</li> <li>• Less than 5 years</li> <li>• Over 10 years</li> </ul>	<p>4 (8.8%)</p> <p>35 (77.7%)</p> <p>6 (13.3%)</p>
<ul style="list-style-type: none"> <li>• <b>Nationality</b></li> <li>• Arabic other than Saudi</li> <li>• Non-Arabic</li> <li>• Saudi Arabia</li> </ul>	<p>2 (4.4%)</p> <p>8 (17.7%)</p> <p>35 (77.7%)</p>
<ul style="list-style-type: none"> <li>• <b>Job nature</b></li> <li>• Consultant</li> <li>• General practitioner</li> <li>• Specialist</li> </ul>	<p>5 (11.11%)</p> <p>35 (77.7%)</p> <p>5 (11.11%)</p>
<ul style="list-style-type: none"> <li>• <b>Have you ever attended conference meeting in Diabetes?</b></li> <li>• No</li> <li>• Yes</li> </ul>	<p>20 (45%)</p> <p>25 (55%)</p>
<ul style="list-style-type: none"> <li>• <b>Attending a training course or a conference on management of MODY?</b></li> <li>• No</li> <li>• Yes</li> </ul>	<p>39 (86.6%)</p> <p>6 (13.4%)</p>
<ul style="list-style-type: none"> <li>• <b>Have you ever prescribed sulfonylureato your patients during the last year?</b></li> <li>• No</li> <li>• Yes</li> </ul>	<p>40 (88.8%)</p> <p>5 (12.2%)</p>

Table 2: Responses about MODY knowledge among primary care physicians

Items	Responding completely	Responding Incompletely	Responding wrongly
Definition of MODY	12%	45%	33%
Mode of inheritance MODY	55.50%	10%	34.50%
Awareness regarding types of MODY	09%	40%	51%
Typical symptoms of MODY	60%	10%	30%
Diagnostic tools of MODY	45%	19%	36%
Possible presentations of MODY	6%	45%	49%
Therapeutic modalities of MODY	39%	40%	21%
Complications of MODY	20%	25%	55%
Differences between MODY and T1DM and T2DM	6.80%	25%	68.20%
Overall knowledge score (percent)	53.80%		

Table 3: Responses about MODY practice among primary care physicians

Items	Responding completely	Responding Incompletely	Responding wrongly
Referring suspected cases of Mody to specialized center	18.6%	20.0%	61.4%
Treating of Mody	42.0%	32.0%	26.0%
Regular follow-up of patients with Mody	47.8%	32.0%	20.2%
Overall practice score	48.0%	20.0%	32.0%

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# Level of Parental Awareness Regarding Aerodigestive Pediatric Foreign Bodies, Western Region, Saudi Arabia

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## Abstract

**Background:** Foreign body aspiration (FBA) is a life-threatening condition with a high mortality rate, especially in children less than three years of age. Delayed diagnosis is often due to the non-specific presentation of symptoms and the absence of a witness to the aspiration event.

**Aim:** This study aimed to assess parental knowledge and practices toward aerodigestive paediatric foreign bodies ingestion or inhalation, in Saudi Arabia.

**Materials and Methods:** A descriptive cross-sectional survey was conducted among Saudi parents in western region, Saudi Arabia during the period between 1st To 20th August. A pre-structured validated self-administered questionnaire containing 11 questions of awareness and 4 questions of practices toward aerodigestive pediatric foreign bodies, was distributed online via various Social Media platforms. The questionnaire was initiated after literature review for similar articles and after experts' consultation for validity and reliability.

**Results:** A total of 611 child caregivers completed the study questionnaire. Exactly 508 (83.1%) respondents were children's mothers and 103 (16.9%) were their fathers. Exactly 93.1% of the study parents heard of swallowing or inhaling foreign objects

and 77.3% reported that children aged 1-5 years are more likely to swallow or inhale foreign objects while 20.5% reported for children aged less than 1 year. About 69% of the parents buy children toys that contain small parts but to different degrees. As for protective actions, keeping small items out of children's reach was reported by 95.4% of the parents.

**Conclusion:** In conclusion, the study revealed that parental knowledge and practices toward FBA were on average (but not satisfactory) especially for the correct actions for swallowed objects and timely visits to ER even for asymptomatic ingested FB. On the other hand, safe practice, especially keeping small objects out of children's reach, was high, but observing young aged children while playing was unsatisfactory.

**Key words:** Children, foreign body aspiration, knowledge, parents, practices

## Introduction

By Jackson, the foreign body is described as a substance or items foreign to the place(1). Aero-digestive foreign bodies are one of the common clinical issues that can cause serious consequences or sudden death(2). Children who are under three years old are at a higher risk of FBA (3). This is due to many factors, including the lack of molar teeth, limiting their ability to effectively break foods like peanuts or melon seeds, narrow airways and immature defensive mechanisms (4)(5). FBA is the 4th leading cause of death in children less than three years old and the 3rd in infants less than one-year-old (6). Children have a tendency to put foreign objects in their mouths, such as coins which tend to be the most common problem worldwide and other objects such as buttons, marbles, crayons, toy pieces, and so on (1)(7). Button battery used for watches, hearing aids, and some toys is one of the life-threatening foreign bodies usually. In addition, the tiny, smooth, and bright appearance of the battery attracts most children who notice it. But, unfortunately, it includes strong enough materials to cause rapid liquefaction necrosis of tissue, leading to severe consequences such as mediastinitis, perforation, or even death (2).

About 90% of foreign bodies can move through the GIT easily without causing any harm; others cause trouble and show symptoms when they are stuck in the tonsils, the base of the tongue, crico-pharynx, or further down which may require intervention to avoid consequences (1)(3).

Cough, wheeze, and reduced breath sounds are the typical diagnostic triad found in about 40% of patients and recorded by several authors (5)(8). Also, when the foreign body is esophageal it can cause dysphagia, gagging, choking, drooling, and regurgitation (1). Because of the vague history, non-characteristic clinical features, radiological results, or parent-related concerns such as parent's lack of knowledge of clinical signs suggesting FBA, such as sudden choking and coughing, the diagnosis might be difficult or delayed (1)(9). Rigid bronchoscopy is considered the gold standard for locating and removing aspirated foreign bodies (4). Delayed diagnosis is associated with increased complications like atelectasis, pneumonia, bronchiectasis, asphyxia, and death (2). Foreign bodies are an important and preventable cause of mortality and morbidity in children and a cause of psychological distress for both the children as well as the parents (10). Improving the parent's awareness is one of the most helpful strategies to avoid FBA. To obtain this goal, it is essential to assess what parents think and how they react to FBA. That has led to reduce the risk of FBA and its complications (3). Unfortunately, no research in the western region discusses parental beliefs and actions regarding Aerodigestive Foreign Bodies. As a result, we are conducting this research to assess the beliefs and practices of Parents in this region to hopefully raise awareness.

## Methodology

A cross-sectional study was done to assess parental awareness regarding aerodigestive pediatric foreign bodies among Saudi parents from different cities of the Western region, Saudi Arabia, over the period from 1st to 20th August. A total sample size of 611 participants were involved from only Saudi parents who have children, who agreed to participate in the study, while participants other than the parents, non-Saudi parents and those who disagreed to participate were excluded.

### Data collection instrument:

We used a predesigned questionnaire. The questionnaire was designed in Arabic including, parent of child, age of child, whether the parent has knowledge about the problem or not. Also, it included twelve questions about the awareness of the risks of aerodigestive foreign bodies. This questionnaire was distributed among participants preceded by brief explanation of the aim of the study. After the validation, the questionnaire was sent to the participants through various Social Media platforms (WhatsApp, Twitter, etc.).

### Ethical considerations:

Ethical approval was obtained from the research ethics committee of Taif University application NO: (43-007 ).

### Data analysis

After data were extracted, it was revised, coded, and fed into statistical software IBM SPSS version 22(SPSS, Inc. Chicago, IL). All statistical analysis was done using two tailed tests. P value less than 0.05 was statistically significant. For awareness items, each parent's answer was displayed for different situations. Descriptive analysis based on frequency and percent distribution was done for all variables including parents' personal data, children's age, awareness regarding aerodigestive paediatric foreign bodies, and parents practice to avoid child swallowing or inhaling of foreign bodies.

## Results

A total of 611 child caregivers completed the study questionnaire. Exactly 508 (83.1%) respondents were children's mothers and 103 (16.9%) were their fathers. As for educational level, 409 (66.9%) parents had university level of education or above while only 51 (8.3%) had a low level of education (below secondary). Exactly 115 (18.8%) parents had a child below 1 year while 132 (21.6%) had children aged 1-3 years and 275 (45%) had children aged above 5 years (Table 1).

Table 2 illustrates distribution of parental awareness regarding aerodigestive paediatric foreign bodies, Saudi Arabia. Exactly 93.1% of the study parents heard of swallowing or inhaling foreign objects and 77.3% reported that children aged 1-5 years are more likely to swallow or inhale foreign objects while 20.5% reported for children aged less than 1 year. As for subjects more inhaled or

ingested by children, 4.9% talked about coins, 4.3% for plastic games, 3.9% for nuts and 2.5% for batteries while 83.6% selected all of them. As for the correct action if child swallows a foreign object such as batteries, 91.8% reported for the child is in danger and I will take him to the emergency immediately but only 5.2% think that the child is not in danger and they will observe the child at home. Back blows and chest presses were the most reported behaviour for a child less than 1 year and exposed to swallowing or inhaling a foreign object (30.4%), followed by going to ER (28.6%), Abdominal compression (while lying down) (15.4%), while 14.9% will try to remove it and 2.9% don't know what to do. As for the correct behaviour for a child less than 5 years and exposed to swallowing or inhaling a foreign object, 28.2% selected going to ER, 27.8% will do back blows and chest presses, 14.2%v selected Abdominal compression (while standing) and a similar portion will try to remove it. Regarding the correct behaviour for a child more than 5 years and exposed to swallowing or inhaling a foreign object, going to ER was the most known among 27.3% parents, followed by Abdominal compression (while standing) (24.5%), and do back blows and chest presses (24.5%) while 11.1% will try to remove it. Exactly 52.2% of the parents said that they must go to the emergency in all cases when their

child has swallowed or inhaled a foreign object, but 32.7% will go to ER according to the type of foreign body even if there are no symptoms and 10.8% will go if there are symptoms. Regarding the correct action that parents will do if the child suffocates and his airway is completely blocked, 48.9% will do first aid (CPR), while 47% go to ER immediately and 4.1% don't know what to do. Exactly 32.9% of the parents agreed that not suffocating is a sure sign that the FB is disappearing while 15.2% agreed on delaying FB removal if the foreign body does not cause any symptoms.

Table 3 illustrates distribution of parental practice regarding aerodigestive paediatric foreign bodies swallowing, in Saudi Arabia. Exactly 69.2% of the parents buy children's toys that contain small parts but in different degrees (29.5% said sometimes). As for protective actions, keeping small items out of children's reach was reported by 95.4% of the parents (which was usually among 63.7%). Also, 43.3% of the parents reported that they never let their children under 5 years old eat alone without adult supervision, and only 28.8% never let their children under the age of 5 play on their own without adult supervision.

**Table 1. Personal data of study respondents, Western region, Saudi Arabia**

Personal data	No	%
<b>Respondent</b>		
Mother	508	83.1%
Father	103	16.9%
<b>Educational level</b>		
Below secondary	51	8.3%
Secondary	151	24.7%
University/ above	409	66.9%
<b>Youngest child age (years)</b>		
< 1	115	18.8%
1-3	132	21.6%
3-5	89	14.6%
> 5	275	45.0%

**Table 2. Distribution of parental awareness regarding aero-digestive paediatric foreign bodies, Western region, Saudi Arabia**

Awareness items		No	%
Have you ever heard of swallowing or inhaling foreign objects?	Yes	569	93.1%
	No	42	6.9%
At what age are children more likely to swallow or inhale foreign objects?	< 1	125	20.5%
	1-5	472	77.3%
	6-10	10	1.6%
	> 10	4	.7%
Which of the following items may be at risk of being inhaled or ingested by children?	None	5	.8%
	Coins	30	4.9%
	Plastic games	26	4.3%
	Nuts	24	3.9%
	Batteries	15	2.5%
	All of them	511	83.6%
If your child swallows a foreign object such as batteries, what is the correct action to do?	The child is in danger and I will take him to the emergency immediately	561	91.8%
	The child is not in danger and I will observe the child at home	32	5.2%
	I don't know	18	2.9%
The correct behaviour for a child less than 1 year and exposed to swallowing or inhaling a foreign object	Go to ER	175	28.6%
	Abdominal compression (while lying down)	94	15.4%
	Abdominal compression (while standing)	47	7.7%
	I'll do back blows and chest presses	186	30.4%
	I will try to remove it	91	14.9%
	I don't know	18	2.9%
The correct behaviour for a child less than 5 years and exposed to swallowing or inhaling a foreign object	Go to ER	172	28.2%
	Abdominal compression (while lying down)	76	12.4%
	Abdominal compression (while standing)	87	14.2%
	I'll do back blows and chest presses	170	27.8%
	I will try to remove it	87	14.2%
	I don't know	19	3.1%
The correct behaviour for a child more than 5 years and exposed to swallowing or inhaling a foreign object	Go to ER	167	27.3%
	Abdominal compression (while lying down)	54	8.8%
	Abdominal compression (while standing)	150	24.5%
	I'll do back blows and chest presses	150	24.5%
	I will try to remove it	68	11.1%
	I don't know	22	3.6%
When should you go to the ER when your child has swallowed or inhaled a foreign object?	You must go to the emergency centre in all cases	321	52.5%
	Depends on the type of foreign body even if there are no symptoms	200	32.7%
	If there are symptoms	66	10.8%
	No need at all	11	1.8%
	I don't know	13	2.1%
What is the correct action that you will do if the child suffocates and his airway is completely blocked?	I will do first aid (CPR)	299	48.9%
	Go to ER immediately	287	47.0%
	I don't know	25	4.1%
Not suffocating is a sure sign that the FB is disappearing	Agree	201	32.9%
	Disagree	410	67.1%
If the foreign body does not cause any symptoms, it is okay to delay its removal	Agree	93	15.2%
	Disagree	518	84.8%

**Table 3. Distribution of parental practice regarding aero-digestive paediatric foreign bodies swallowing, Western region, Saudi Arabia**

Parents practice	No	%
<b>Do you buy your children toys that contain small parts?</b>		
Never	188	30.8%
Rarely	195	31.9%
Sometimes	180	29.5%
Always	33	5.4%
Usually	15	2.5%
<b>Are small items out of children's reach?</b>		
Never	28	4.6%
Rarely	21	3.4%
Sometimes	49	8.0%
Always	124	20.3%
Usually	389	63.7%
<b>Do you let your children under 5 years old eat alone (without adult supervision)?</b>		
Never	263	43.3%
Rarely	143	23.5%
Sometimes	143	23.5%
Always	42	6.9%
Usually	17	2.8%
<b>Do you let your children under the age of 5 play on their own (without adult supervision)?</b>		
Never	176	28.8%
Rarely	176	28.8%
Sometimes	175	28.6%
Always	69	11.3%
Usually	15	2.5%

## Discussion

The current study aimed to assess parental knowledge and practices toward foreign body ingestion or inhalation in children in Saudi Arabia. Foreign body aspiration (FBA) is a serious condition with a high mortality rate, chiefly if management is delayed. Children who are below the age of three years are at a higher danger of FBA (11). Late diagnosis is frequently due to the non-specific clinical presentation with no witness to the aspiration event (12). Seeing of aspiration events, frequently by parents or caregivers, with succeeding in telling the treating physician is helpful for early detection and intervention (13, 14). Many types of foreign bodies have been reported in the literature; mostly, aspirated foreign bodies are toys, sweets, jewels, batteries, rocks, and magnets (15). The obstruction triggered by foreign bodies may cause impaired oxygenation and ventilation, ending with morbidity or mortality. Hypoxic–ischemic brain injury is the main mechanism of death followed by pulmonary haemorrhage (16, 17). Recurrent pneumonia, neuro-skeletal disability, pulmonary abscess, and bronchiectasis were also reported complications (18-20).

The current study revealed that nearly all the parents (93%) knew about swallowing or inhaling foreign objects. Also, the majority of the study parents know about the most reported age more likely to swallow or inhale foreign objects (97.8% reported less than 5 years). As for the items that may be at risk of being inhaled or ingested by children, more than three quarters of the parents selected all mentioned subjects including coins, plastic games, nuts, and batteries which are consistent with literature findings (15, 17). Also, more than 90% of the parents know that the child is in danger and they will take them to the emergency immediately in case of swallowing a foreign object such as batteries. Regarding the correct actions if the child is exposed to swallowing or inhaling a foreign object, going to ER was the most reported if the child is aged less than 5 years or more than 5 years (28.2% and 27.3%, respectively) while doing back blows and chest presses was the most reported for children aged less than 1 year (30.4%). Doing back blows and chest presses was reported by about one quarter of the parents if the child is aged less than 5 years but it was combined with Abdominal compression (while standing) in children aged 5 years or more. Going to ER in all cases was reported by more than half of the parents while one third of them said

said that going to ER depends on the type of foreign body even if there are no symptoms and 10% will go to ER if there are symptoms. This explains high morbidity and mortality rates due to late complications for asymptomatic ingested or inhaled foreign bodies especially those not witnessed by parents or children's caregivers. The surprising finding was that less than half of the parents will do first aid (CPR) for suffocated children but authors did not ask if they know the correct mechanism of doing this procedure. Also, another disappointing finding was that a very low percentage (15%) of the parents think that they could delay foreign body removal if there are no associated clinical symptoms which means more likelihood for developing complications with higher mortality rate. Also, one third of the parents considered absence of child suffocation is a sure sign that the FB is disappearing, which is not correct. Other studies showed similar findings. Fatimah A et al. (21) conducted a similar study and found that about 60% of participants were aware of aerodigestive foreign bodies. In regard to the management of child with aerodigestive foreign bodies in different age groups, for children of age group 1 year and less, about (34.9%) of participants were aware of the management. However, there is misunderstanding of managing child aged 5 years and less where only 5.6% of participants were aware of the management in this age group. As regards children more than 5 years old, only 36.2% of parents were aware of the management. Almutairi AT et al. (22) reported that parents with poor and good knowledge regarding foreign body aspiration in children were 61.3% and 36.9% and those with poor and good practices were 55.3% and 44.7%, respectively. El Bahnasawy (23) found that 59% of mothers had poor knowledge, 28% were average, and only 13% had good knowledge regarding FBA. On the other hand, AlShakhs et al. (24) had different findings. Their study showed that the awareness toward aero-digestive paediatric foreign bodies was high (60.3%) though, only 36.2% reported to have awareness regarding its management. These assessments and similar findings have been validated by many studies (25-28).

Regarding safe practices, the current study showed that more than 70% of the parents buy children toys that contain small parts but the majority of them (more than 95%) keep small items out of children's reach and about half of them never let their children under 5 years old eat alone.

## Conclusion

In conclusion, aero-digestive foreign bodies can have serious consequences. Our study revealed that parental knowledge and practices toward FBA were on average (but not satisfactory). On the other hand, safe practice especially keeping small objects out of children's reach was high but observing young aged children while playing was unsatisfactory.

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- 17th November 2021-Skin Cancer 7pm
- 1st December 2021-Head and neck 7pm
- 15th December 2021-Leg Ulcers and PVD 7pm



# Prevalence of dry eye symptoms and risk factors in Saudi Arabia

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## Abstract

**Background:** Dry eye is a multifactorial condition of the tears and ocular surface that causes discomfort, visual disruption, and tear film instability, as well as the risk for ocular surface injury. It is accompanied by an increase in the osmolality of the tear film as well as ocular surface inflammation. Dry eye is a prevalent ocular disease that leads to ophthalmologist appointments. The prevalence of the disease varies greatly between epidemiological studies, depending on how the sickness is characterised and diagnosed, as well as depending on the sector of the population surveyed. It is expected to be between 7.4% and 33.7 percent

**Methods:** A descriptive cross-sectional survey was used targeting all groups of population in Aseer region. The study was conducted during 2021. Data was collected using structured questionnaire which included person's socio-demographic data, and the OSDI (ocular surface disease index) combined with questions relevant to the target of our research ((the repetitive habitual/behavioral factors leading to Dry eye disease (DED)), and also using SAS-SV (smartphone addiction scale) in the context of users of smart phones.

**Results:** Out of 2,527 total respondents, 694 (27.5%) have no issues related to eyes, while 1,833 (62.5%) have eye related issues. The mean (SD) of age was 29.4 (8.9) years. 67.0% were females while 33.0% were males. 22.9 % were exposed to air conditioners, 22.9% used contact lenses, 7.36 % used lubricant drops, while 6.3% live in a dry weather area.

**Conclusion:** Dry eye illness is a prevalent ophthalmological condition with a number of clinical predictors, including the use of electronic devices and other risk factors. Teachers and health professionals should teach the students and nation about the awareness of dry eye problems.

**Key words:** Dry eye, electronic devices, risk factors, diseases

## Background

Dry eye is a multifactorial condition of the tears and ocular surface that causes discomfort, visual disruption, and tear film instability, as well as the risk for ocular surface injury. It is accompanied by an increase in the osmolarity of the tear film as well as ocular surface inflammation [1]. Despite the fact that this ailment rarely results in visual loss, it can have a negative impact on one's quality of life when symptoms arise.

Dry eye is a prevalent ocular disease that leads to ophthalmologist appointments. The prevalence of the disease varies greatly between epidemiological studies, depending on how the sickness is characterised and diagnosed, as well as which sector of the community is concerned. It is expected to be between 7.4% and 33.7 percent [2, 3, 4]. Because symptom-based dry eye definitions are more reproducible and accurate than objective clinical tests in identifying dry eyes, they are frequently used to define dry eye prevalence in population-based investigations [5]. A frequently used and useful technique to identify the presence of dry eye is the validated six-item questionnaire of ocular symptoms related to dry eye [6, 7].

Some environmental and epidemiological risk factors are suggested to increase the likelihood of dry eye in the Al-Ahsa community. Al-Ahsa, like the rest of Saudi Arabia, has a hot desert environment with temperatures reaching over 50°C in the summer [8]. To cope, practically everyone in the country uses air conditioning in their houses and cars. Trachoma was endemic in this Saudi Arabian district, with a prevalence of 100% in surveys conducted between 1955 and 1970 [9].

Researchers have become increasingly interested in investigating dry eye as the description of the condition has been refined over the previous few decades. As a result, dry eye is no longer regarded a component of Sjögren syndrome, but rather a distinct clinical entity [2]. Depending on the research, diagnostic methods employed, and demographics analysed, the prevalence of dry eye symptoms is estimated to range from 7% to 34% [3],[4],[5],[6].

Aqueous deficit, excessive lacrimal film evaporation, or a combination of the two causes eye dryness. When the lacrimal gland's function is compromised, tear volume is reduced, resulting in aqueous deficit. The tear volume is typical in evaporative dryness, but the tear film is abnormal due to fast evaporation. The evaporative type could affect up to 86 percent of patients with dry eye symptoms [7],[8]. About 14% of those over the age of 65 experience dry eye symptoms [9]. Aside from age, other individual and environmental factors have been identified as risk factors for dry eye, including being a woman, smoking, depression, or having LASIK surgery [4],[10],[11],[12].

These symptoms were found to be common and linked to chronic diseases in studies conducted in Saudi Arabia (Riyadh, Jeddah, and Al-Ahsa) [13],[14],[15]. The goal

of this study was to establish the prevalence of dry eye symptoms among the people of Taif, Saudi Arabia, as well as the most common risk factors for the disease.

Dry eye is a condition in which a person's tears aren't good enough to lubricate and feed the eye. Tears are required for the health of the front surface of the eye as well as for clear vision. Dry eyes are a widespread and often persistent condition, especially among the elderly [1]. DE's epidemiology has been studied in multiple major population-based studies in the United States and elsewhere, with a wide range of frequencies recorded for DE symptoms (6 percent - 50%), signs (16 percent - 85 percent), and symptoms with signs (73 percent - 93 percent) [2-4]. In Pakistan, the prevalence of dry eye is 3.3 percent in patients aged 10 to 30, 20 percent in patients aged 30 to 40, 33.3 percent in patients aged 40 to 50, 23.3 percent in patients aged 50 to 60, and 6.6 percent in patients aged 60 to 70. Dry eye was caused by keratitis in 30% of cases, bacterial and viral conjunctivitis in 20% of cases, and pterygium in 10% of cases [5]. In an aged Korean population, a study with 85 percent symptom frequency of dry eye ascertained indications by positive tear film break-up time (TBUT) [6,7]. Dry eye is reported to affect a wide range of people, with rates ranging from 14.4% to 33% of the population in questionnaire-based surveys. Dry eye prevalence rates have been reported to be lower in studies that include measures of tear function, such as Schirmer's test, tear film break up time, and fluorescein staining [8].

Keratitis, allergies, contact lenses, numerous medications, thyroid disease, Lasik, Pterygium, and smoking are all risk factors for symptomatic dry eye illness. Keratitis is an inflammation of the cornea, which covers the pupil and iris and is the outermost component of the eye. Infection and damage are the most common causes of keratitis. Keratitis can be caused by bacterial, viral, parasitic, or fungal infections. After a corneal injury, infectious keratitis can develop. However, damage to the cornea might cause inflammation without causing a subsequent infection. Infectious keratitis is more common in people who wear contact lenses. If a person suspects that he or she is getting an eye infection, contact lenses should be removed immediately [9]. When something allergic irritates the conjunctiva, it is an eye allergy. Contact lenses can amplify the symptoms of dry eyes [11]. Discomfort from contact lenses is common, but is typically easy to fix [12]. The patient's usage of systemic drugs is one component in dry eye, which is a multi-factorial illness of the tears and ocular surface [1]. Many common systemic drugs can influence ocular tissues, and medicines that cause dry eye symptoms can be found in a wide range of pharmaceutical categories. Thyroid eye illness is an autoimmune disorder that causes swelling, irritation, and occasionally vision issues in the eyes. Itching, watering, or dry eyes, as well as a grittiness in the eyes, are early signs of thyroid eye disease. LASIK (laser-assisted in situ keratomileusis) is a common corneal refractive procedure that produces excellent refractive results. Dry eyes are the most prevalent LASIK consequence, with nearly all patients experiencing some degree of dryness in the

immediate postoperative period [13]. Pterygium is an eye ailment that commonly affects persons who spend a lot of time outside. It's also known as surfer's eye because it frequently affects surfers. Even youngsters who do not wear sunglasses outside can be affected [14]. Tobacco smoking irritates the eyes and exacerbates dry eye. Smokers are roughly twice as likely to suffer from dry eyes [15]. The main aim of this study is to find out the prevalence of dry eye problems and their risk factors.

Eye is one of the most important organs in the human body, therefore any injury or limitation in its function will affect the quality of life. There are many systems that protect the eye and maintain its function; one of them is the lacrimal system which makes the eye moist and humid to keep the eye at its optimal function. There are repetitive habitual and behavioral factors which contribute in affecting the function of lacrimal system and therefore may develop as dry eye disease (DED), such as: exposure to , contact lenses wearing [4,9] smart phone addiction, environmental factors, and living in dry weathers areas. Published data, according to the Saudi Arabia: Jeddah Regional Climate Center [8] found the DED to be highly prevalent in Saudi Arabia. Measuring and increasing the awareness of population about these factors helps in understanding how these factors are related to this (DED) and hopefully will help in reducing the prevalence of the effects of dry eye syndrome in the future.

## Methodology

A descriptive cross-sectional survey was used targeting all groups of population in Aseer region. The study was done during 2021. Data was collected using structured questionnaire and included person's socio- demographic data, and the OSDI (ocular surface disease index) combined with questions relevant to the target of our research (the repetitive habitual/behavioral factors leading to Dry eye disease (DED)), and SAS-SV (smartphone addiction scale) in the context of smart phone addiction being one of the most relevant causes of DED as previous studies have shown.

The Smartphone Addiction Scale-Short Version (SAS-SV), which was initially developed from an older version called SAS, was used to assess the participants' addiction to smartphones. It consists of 10 questions that are based on a self-reporting system using a 6- point Likert scale (1: "strongly disagree" and 5: "strongly agree"). On the other side: the OSDI contains a 12-item questionnaire designed to assess symptoms consistent with DED. The 12 items of the questionnaire were graded, using a self-reporting system, from 0 to 4 (0: "none of the time" and 4: "all of the time").

SPSS ver.20 was used for analysis, Chi-square test was used to compare the variables at 5.0% level of significance

**Inclusion criteria:** All the population aged from 18 to 65 healthy individuals who were not from the mentioned groups in the exclusion criteria.

**Exclusion criteria:** Exclusion criteria included patients who had undergone refractive surgery procedures and those with an active ocular surface disease and any other conditions that may interfere with development of DED. Subjects with a previous diagnosis of DED were excluded from the study.

## Results

Out of 2,527 total respondents, 694 (27.5%) had no issues related to the eye, while 1,833(62.5%) have eye related issues. The mean (SD) of age was 29.4(8.9) years. 67.0% were females while 33.0% were males.

## Results

Out of 2,527 total respondents, 694 (27.5%) had no issues related to the eye, while 1,833(62.5%) have eye related issues. The mean (SD) of age was 29.4(8.9) years. 67.0% were females while 33.0% were males.

**Table 1: Frequency distribution related to Eye Problems**

Are your eyes exposed to direct air conditioner or fan for long periods of time?		
	Frequency	Percent
No	1413	77.1%
Yes	420	22.9%
Have you used contact lenses now or in the previous short period?		
	Frequency	Percent
No	1413	77.1%
Yes	420	22.9%
Do you use eye drops other than lubricant drops?		
	Frequency	Percent
No	1698	92.64%
Yes	135	7.36%
Do you live in a city dominated by dry weather?		
	Frequency	Percent
No	673	36.7%
Yes	1160	63.3%

Table 1 depicts that 22.9 % were exposed to air conditioner, 22.9% used contact lenses, 7.36 % used lubricant drops, while 6.3% are living in a dry weather area.

Table 2: Eye problems

Do you have blurry vision in your eyes?			
		Frequency	Percent
	Every time	58	3%
	Half the time	132	7%
	Most of the time	123	7%
	Never	827	45%
	Sometimes	693	38%
Do you have a lack of vision?			
		Frequency	Percent
	Every time	173	9%
	Half the time	126	7%
	Most of the time	106	6%
	Never	933	51%
	Sometimes	495	27%
Are your eyes sensitive to light?			
		Frequency	Percent
	Every time	25	1%
	Half the time	78	4%
	Most of the time	141	8%
	Never	791	43%
	Sometimes	798	44%
Do you feel a sandy feeling inside your eyes?			
		Frequency	Percent
	Every time	11	1%
	Half time	57	3%
	Most of the time	83	5%
	Never	1139	62%
	Sometimes	543	30%
Have you had problems with your eyes that reduced your ability to (drive at night)?			
		Frequency	Percent
	Every time	44	2%
	Half the time	50	3%
	Most of the time	40	2%
	Never	1462	80%
	Sometimes	237	13%
Have you had problems with your eyes that reduced your ability to (read)?			
		Frequency	Percent
	Every time	73	4%
	Half the time	94	5%
	Most of the time	88	5%
	Never	1095	60%
	Sometimes	483	26%

(continued next page)

**Table 2: Eye problems (continued)**

Have you had problems with your eyes that reduced your ability to (watching TV and reading ATMs)?			
		Frequency	Percent
	Every time	65	4%
	Half the time	85	5%
	Most of the time	73	4%
	Never	1208	66%
	Sometimes	402	22%
Did you feel pain in your eyes last week?			
		Frequency	Percent
	Every time	28	2%
	Half time	127	7%
	Most of the time	131	7%
	Never	924	50%
	Sometimes	623	34%
Do you feel discomfort (in your eyes) when you are in low humidity (dry) places?			
		Frequency	Percent
	Every time	55	3%
	Half the time	107	6%
	Most of the time	107	6%
	Never	1094	60%
	Sometimes	470	26%

Table 2 depicts that 3% have blurry vision all the time, 9% have lack of vision all the time, 1% have sensitivity to light all the time, 1% have sandy feeling inside their eyes all the time, 4% have difficulties watching TV and reading ATM's all the time, and 3% feeling difficulties in eyes every time when they are in dry weather

**Table 3: Likert scale analysis**

Likert scale analysis		
	Mean	S.D
Feeling impatient and anxious when I'm not holding my smartphone	3.3	8.6
Feeling pain in the wrist or in the back of the neck while using the smartphone	3.8	7.5
Having my smartphone on my mind even when I'm not using it	3.1	7.4
I can't stand the thought of not owning a smartphone	3.2	7.6
I check my smartphone frequently so I don't miss conversations between other people on Facebook or Twitter	4.4	7.4
I will never give up using my smartphone even when my daily life is greatly affected by it	3.2	6.5
People around me tell me that I use my smartphone a lot	3.9	5.5

Table 3 depicts that all items (Feeling impatient and anxious when I'm not holding my smartphone, Feeling pain in the wrist or in the back of the neck while using the smartphone, Having my smartphone on my mind even when I'm not using it, I can't stand the thought of not owning a smartphone, I check my smartphone frequently so I don't miss

Table 3 depicts that all items (Feeling impatient and anxious when I'm not holding my smartphone, Feeling pain in the wrist or in the back of the neck while using the smartphone, Having my smartphone on my mind even when I'm not using it, I can't stand the thought of not owning a smartphone, I check my smartphone frequently so I don't miss conversations between other people on Facebook or Twitter, I will never give up using my smartphone even when my daily life is greatly affected by it, People around me tell me that I use my smartphone a lot) having average value above 3.00 means all of them are significant items.

**Table 3: Comparison between smartphone and concentration in class:**

Use my smartphone for longer than I intended \* Difficulty concentrating in class, on tasks, or at work due to smartphone use

		Difficulty concentrating in class, on tasks, or at work due to smartphone use					Total
		Strongly disagree	Disagree	Neutral	Agree	Strongly Agree	
Use my smartphone for longer than I intended	Strongly disagree	96	33	15	24	42	210
	Disagree	48	27	42	26	37	180
	Neutral	70	55	55	29	63	272
	Agree	37	46	61	53	72	269
	Strongly Agree	133	90	132	141	406	902
<b>Total</b>	<b>Agree</b>	<b>384</b>	<b>251</b>	<b>305</b>	<b>273</b>	<b>620</b>	<b>1833</b>

P=0.00001

Table 3 depicts that we have observed significant differences while comparing smart phones and concentration in classes

## Discussion

The frequency and risk factors for symptomatic dry eye disease were assessed in this cross-sectional investigation. In this study, the prevalence of dry eye was reported to be 2.4 percent. In comparison to certain other Asian areas and countries, the prevalence of Dry Eye Syndrome (DES) in this region and country is rather low. There were 100 patients in this study, 65 of whom were female and the rest were male. According to a study conducted in the United States [17], 41.0 percent of dry eye patients were female and 16 percent were male. According to a study, 33.7 percent of people over the age of 65 in the United States are diabetic. Taiwan was symptomatic, as defined by the reporting of one or more dry eye symptoms occurs frequently all of the time [18]. There was a disparity in prevalence between our data and findings in other Asian regions and nations in this investigation. However, a recent study discovered that 10% of people over the age of 60 have dry eyes as a result of pterygium, posterior blepharitis, and age. In our study other diseases also have a significant relationship with eye problems.

The cornea contains a lot of innervation and is one of the most sensitive regions of the human body (12). The DED is

attributed to a lack of corneal pain tolerance. DED lowers quality of life, and it affects 6–34 percent of the world's aged population. In our study, dry eyes were diagnosed in 30.3 percent (486) of patients who presented to the eye unit. This is in line with the findings of the international dry eye workshop (DEWS) 2007, which found that the global prevalence of DED is around 17 percent, with a greater prevalence of roughly 30 percent in Asia.

Dry eyes have two risk factors: older age and feminine sex. The frequency of DED rises with age, particularly in the sixth decade. According to the research, the majority of our patients were above the age of 50. Females have a 1.56-1.85 times higher risk of DED than males, according to previous studies. However, contrary to 15 other studies, males were more symptomatic than females in this study. In this study, 286 women (58.8%) were postmenopausal. The hormonal effect on the tear (16) film and ocular surface can be seen here. Menopause and female sex are common risk factors for DE and depression, implying that sex hormones are involved. Inflammation also plays a role in the onset of DED. Similar to another study in South Korea (17) that found a higher frequency of DED in urban areas, the majority of our patients were from cities rather than rural areas.

Smoking causes an unstable tear film and aggravates allergy illness in people (18). According to the findings, 33 percent of the patients had been smoking for at least ten years. In our study, DE symptoms such as dryness, irritation, and fatigue were the main reasons for decreased daily activities and quality of life (19). In other studies, females had a higher rate of depression than men, with rates ranging from 4.0 percent to 9.3 percent for women and 2.8 percent to 20.69 percent for men. In our study, female DE patients had a rate of depression of 68.7%, which was higher than male DE patients (31.3%) [18-22]. Long-term usage of smartphones has been demonstrated in multiple studies to be harmful to eye health. Extensive smartphone use was found to raise the frequencies of ocular symptoms, such as eye dryness, in a study focusing particularly on the adolescent age group, which is in line with our study [22].

## Conclusion

Dry eye illness is a prevalent ophthalmological condition with a number of clinical predictors, including the use of electronic devices and other risk factors. Teachers and health professionals should teach the students and nation awareness regarding dry eye problems.

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# Prevalence of Generalized Anxiety Disorder among Adults in Primary Health Care in Qatar: A Cross-Sectional Study

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## Abstract

**Background:** Generalized Anxiety Disorder (GAD) has distinctive features of excessive anxiety, worries, and tension. People with GAD have a considerable degree of impairment and often have a poor quality of life besides increased health care costs. Our aim is to determine the prevalence of GAD among adults and the associated factors.

**Subjects and methods:** A cross-sectional study with a sample size of 385 was conducted on adults aged 18 - 65 years at Primary Health Care Corporation in Qatar. We used probability, cluster sampling technique and written consents were secured from participants who met inclusion and exclusion criteria. Considering the COVID-19 current pandemic, measures were considered at interviews to complete GAD-7 questionnaire which is a seven-item instrument that is used to measure the severity of GAD. A total score ranges from 0 to 21. Scores of 5, 10, 15 represent cut-points for mild, moderate, and severe anxiety respectively. Moderate and severe anxiety are considered worthy of clinical attention. We used SPSS version 23 for data analyses. Approval notice was obtained from the Research Committee.

**Results:** The prevalence of clinically significant GAD (moderate to severe) in the study sample was 5.2%. One half of the group with moderate to severe anxiety felt that their life is tough (very or extremely difficult). One third of the participants diagnosed with clinically significant GAD related it to COVID-19 pandemic. A multiple logistic regression model used to predict GAD showed association with: female gender, Northern Africa/South-eastern Asia nationalities, having a positive family history of anxiety disorders, age less than 30 years, illiterate/primary education level, a very high income, and being a smoker. The primary model that included all the explanatory variables was statistically significant with a 95.6% overall predictive accuracy for the outcome.

**Conclusion:** This prevalence highlights the importance of regular screening of GAD, especially for those at high risk. The study was conducted during the COVID-19 pandemic.

### Key words:

Generalized anxiety disorder, prevalence, Qatar.

## Introduction

Generalized Anxiety Disorder (GAD) is a mental disorder with distinctive features of excessive anxiety, worries and tension. The intensity, duration, and frequency of symptoms are disproportionate to the actual likelihood or impact of the anticipated event according to DSM 5th edition (1). Anxiety disorders are one of the leading causes of non-fatal health loss worldwide and are among the major causes of years lost due to disability (YLD) (2). People with GAD have a considerable degree of impairment and often have a poor quality of life (3). Also, such patients incur significant healthcare costs that are directly related to both healthcare utilization and absence from work (4).

The etiology of GAD has not been well established, but many sociodemographic factors were linked to GAD such as middle age, female gender, low-income and those who are widowed or divorced (5). Diagnosis of GAD is frequently missed as patients may present with physical symptoms rather than verbalizing stress or worry (6). Nevertheless, it can be satisfactorily treated by primary care physicians (7). Hence, it is essential that primary care physicians are aware of the burden of GAD in the community. The GAD-7 questionnaire is considered a valid screening tool for GAD (10).

Prevalence of GAD in Asian countries is variable. South Korea had a 8.7% lifetime prevalence and 12-month prevalence of 6.8% (8), while Japan recorded lifetime prevalence of 1.6% and 12-month prevalence of 0.6% (9). Canada demonstrated 8.7% lifetime prevalence and 12-month prevalence of 2.6% (10). A national study in the United States estimated the lifetime prevalence of GAD as 5.1% (11). A study among five primary care health centers across Europe reported the prevalence as 22% (12). At national level, Qatar had a prevalence rate of 10.3% of "any anxiety disorder" in a study that was done at the primary care level (13). Another study included 1475 participants attending primary care in Qatar and described the prevalence as 10.4% (14).

Despite that GAD is frequently seen in primary care in Qatar; studies in Qatar were performed mainly on "any anxiety disorders" and depression, with a minimum focus on GAD. This is the first-ever study performed exclusively on GAD to the best of our knowledge. Mental health is one of the top priorities according to Qatar National Health Strategy and Primary Health Care Corporation Strategic Plan. Improving access to mental health services and delivering 40% of care within the primary and community sectors by 2022 is the main objective (15)(16). Determining the prevalence of GAD will contribute in raising awareness of the community and motivate physicians to achieve the target goals. Furthermore, GAD is often associated with chronic diseases (13), so specifying these comorbid conditions and how they relate to GAD may help in developing an approach to target and screen high-risk groups in the community. The severity of GAD is the highest contributing factor to the healthcare cost, so diagnosis may alleviate such burden from the health care system (4).

## Materials and Methods

### 1. Study Design

A cross-sectional study.

### 2. Setting and Quality Control Measures

The Primary Health Care Corporation (PHCC) in Qatar operates 28 primary health care centers. This study was conducted on a random sample recruited from random multiple health centers representing the three regions (Western, Northern, and Central) of Qatar served by PHCC. The data collection phase of the study extended from January to March 2021. The data included sociodemographic variables and GAD-7 questionnaire. The English, or a PHCC approved Arabic version of GAD-7 were used according to the participants' preference.

GAD-7 is a valid and reliable tool. It is a seven-item instrument that is used to measure the severity of GAD. Each item rates the severity of symptoms over the past two weeks. Response options include "not at all", "several days", "more than half the days" and "nearly every day". GAD-7 score is calculated by assigning scores of 0, 1, 2, 3 to the response categories of "not at all," "several days," "more than half the days," and "nearly every day," respectively, and then adding together the scores for the seven questions. GAD-7 total score for the seven items ranges from 0 to 21. Scores of 5, 10, 15 represent cut-points for mild, moderate, and severe anxiety respectively. Moderate and severe anxiety are considered worthy of clinical attention.

The study protocol was approved for ethics and science by the Research Subcommittee of PHCC. Informed written consent was secured from all participants. A personal (face to face) interview was used to complete the questionnaire forms. Considering the COVID-19 current pandemic, measures were considered by allowing 2 meters social distance during interviews, and both participant and investigator were wearing masks. Patients diagnosed with GAD were treated according to PHCC guidelines following the step-by-step model, offering the least intrusive, most effective interventions first.

### 3. Participants

Adults of all nationalities, males and females of 18-65 years old were eligible for this study. Elderly people more than 65 years may tend to express anxiety symptoms as medical or somatic problems rather than psychological distress (17). Also, in this age group, anxiety symptoms often overlap with medical conditions.

Patients with known active psychiatric disorders were excluded due to the possibility of having cognitive problems or other comorbid psychiatric conditions such as depression which is closely associated with an anxiety disorder and therefore this may play as a confounder (18). Other groups excluded from sampling included people with physical disabilities, people with learning difficulties, pregnant and postnatal women, and those diagnosed with cancer or any terminal illness.

#### 4. Sampling Technique

Probability, cluster sampling technique.

#### 5. Study Size

The calculation of sample size was based on a formula for estimating a single proportion, which was suitable for a cross-sectional study (19).

The formula:

$$x = Z(c/100)2r(100-r)$$

$$n = N x / ((N-1) E^2 + x)$$

$$E = \text{Sqrt} [(N - n) x / n(N-1)]$$

N is the population size, r is the fraction of responses that we are interested in (estimated proportion), and  $Z(c/100)$  is the critical value for the confidence level c. The population size (N) is 1035000. This is the number of adults of all nationalities, males and females, aged 18 - 65 years registered under PHCC at the time of the study. This information was obtained from the Business and Intelligence Department at PHCC. The fraction of responses that we are interested in was set at 50%. The calculated sample size was 385 for estimating the proportion of those with GAD with a 5% margin of error (95% confidence level). By the end of data collection, 385 fully answered questionnaires were included in analysis.

#### 6. Statistical Analysis

After data were translated into a computerized database structure, the database was examined for errors using range and logical data cleaning methods, and inconsistencies were remedied. Statistical analyses were done using IBM SPSS version 23 computer software (IBM Statistical Package for Social Sciences) in association with Microsoft Excel. P value less than 0.05 was considered statistically significant.

To measure the strength of association between a dichotomous independent variable (a specific group compared to reference group) and a dichotomous outcome variable (like having clinically significant GAD) the prevalence ratio (PR) was used. PR equals the ratio between prevalence of outcome (GAD) among those with risk factors divided by prevalence rate among those negative for the risk factor (comparison group). The logarithm method was used in calculation of confidence intervals for PR.

A multiple logistic regression model with selected factors as independent variables and having GAD as the dependent variable was used. The model assessed the risk of having depression for each explanatory variable after adjusting for the effect of other confounders included in the model. The model provides the following parameters:

- P value for the model: In order to generalize the results obtained, the model should be statistically significant.
- Predictive power of the model: The overall predictive power is expressed as percentage of study subjects being classified correctly based on calculated parameters.
- Adjusted OR (odds ratio): the risk of having the outcome in the presence of a specific risk factor. Each OR is adjusted for the effect of other explanatory variables included in the

model, to represent a net effect of each factor on the risk of having the outcome. The OR for different explanatory variables in a subject is additive, in other words the risk of having the outcome in a specific subject is the sum of the OR for the whole set of explanatory variables.

- P value for OR: reflects the statistical significance of the calculated OR.

## Results

The results presented here were based on the analysis of a sample of 385 respondents. The description of the study sample by sociodemographic variables is shown in Table 1.

As shown in Table 2, diabetes mellitus and hypertension were the two most common comorbidities reported in the study sample (18.2% and 16.1%, respectively). One-third (33.5%) of individuals declared at least one chronic comorbidity (out of a list of six items).

More than a third (35.6%) agreed that they practice the recommended duration of 150 minutes of physical exercise per week. 17% were smokers, 5.5% consumed alcohol, and 2.6% had a family history of anxiety disorders, (Table 3).

As shown in Table 4, one third (33.3%) of the participants diagnosed with clinically significant GAD (moderate and severe) related GAD to COVID-19 pandemic.

The relative frequency of moderate to severe anxiety in the study sample was 5.2%, while mild anxiety constituted 15.1% of individuals, (Table 5). Additionally, half (50%) of the group with moderate to severe anxiety felt that their life is tough (very or extremely difficult) because of their concern, (Table 6).

As shown in Table 7, 5.2% of the total sample were classified as having clinically significant anxiety (GAD7=10+). The risk of having this outcome was significantly increased by 3.19 (with a 95% confidence interval of 1.25 - 8.12) in females compared to males. The Southern Asia nationality was associated with the lowest rate of clinically significant anxiety (0.9%). Only the Northern Africa nationality was associated with a statistically significant increase in risk of 9.3 times compared to Southern Asia. The other nationalities were associated with an obvious increase in having the outcome but failed to reach the level of statistical significance.

As shown in Table 8, a multiple logistic regression model was used to assess the net and independent effect of a set of sociodemographic explanatory variables on the risk of having clinically significant GAD. The primary model that included all the explanatory variables was statistically significant with a 95.6% overall predictive accuracy for the outcome. Because of the small sample size and the limited number of individuals with a positive outcome, most of the explanatory variables failed to reach the level of statistical significance for the calculated adjusted Odds Ratio (OR) for having the outcome (clinically significant

anxiety). Female gender significantly increased the risk of the outcome by 9.4 times compared to males after adjusting for the remaining confounders included in the model. Gender was among the important explanatory variables for predicting the outcome that was retained by the backward selection model also. Nationality was also an important predictor in the general model and the backward selection one. Both the Northern Africa and South-eastern Asia nationalities significantly increased the risk of having the outcome compared to Southern Asia nationality after adjusting for the effect of other explanatory variables included in the model. The other two nationalities were also associated with an obvious increase in risk compared to Southern Asia nationality, but the calculated adjusted OR was not significant statistically. The third important factor that retained its position in the backward selection model was having a positive family history of anxiety disorders which significantly increased the risk of having clinically significant anxiety after adjusting for the remaining variables in the model

Age less than 30 years was associated with an obvious increase in risk of the outcome compared to old age (50-64 years) after adjusting for other explanatory variables, but the calculated OR estimate was not significant statistically. Marital status, crowding index, BMI, Alcohol consumption and practicing the recommended physical activity (150 minutes per week) were unrelated to the outcome. A higher educational level was associated with an obvious (but statistically insignificant) reduction in risk of having the outcome compared to illiterate / primary education after adjustment for other explanatory variables in the model. A very high income compared to the lowest (more than 15000 QAR monthly compared to less than 5000 QAR monthly) was associated with an obvious increase in risk of the outcome after adjusting for other explanatory variables, but the calculated OR estimate was not significant statistically. Having at least one comorbid condition had no important or statistically significant association with the outcome after adjusting for other explanatory variables included in the model. Being a smoker was associated with an obvious, but statistically insignificant increase in the risk of having clinically significant anxiety after adjusting for effect of other explanatory variables included in the model.

**Table 1: Frequency distribution of the study sample by selected variables**

	N	%
<b>Gender</b>		
Female	162	42.1
Male	223	57.9
Total	385	100.0
<b>Nationality categories</b>		
Northern Africa	95	24.7
South-eastern Asia	43	11.2
Southern Asia	113	29.4
Western Asia	116	30.1
Miscellaneous others	18	4.7
Total	385	100.0
<b>Age (years)</b>		
<30	76	19.7
30-39	139	36.1
40-49	87	22.6
50-64	83	21.6
Total	385	100.0
<b>Marital status</b>		
Single	89	23.1
Married	284	73.8
Separated / divorced / widowed	12	3.1
Total	385	100.0
<b>Educational level</b>		
Illiterate	4	1.0
Primary	17	4.4
Intermediate	20	5.2
Secondary	96	24.9
University	248	64.4
Total	385	100.0
<b>Occupation</b>		
Not working	79	20.6
Manual worker	51	13.3
Professional	219	57.0
Self-employed	19	4.9
Army/Police	16	4.2
Total	384	100.0
<b>Crowding index-categories</b>		
Lowest (First quartile) $\leq 1.1$	97	25.2
Average (interquartile range) 1.2 - 2.0	206	53.5
Highest (Fourth quartile) 2.1+	82	21.3
Total	385	100.0
<b>BMI (Kg/m<sup>2</sup>)-categories</b>		
Acceptable (18.5 through to 24.9)	80	20.8
Overweight (25-29.9)	167	43.4
Obese Grade I (30-34.9)	85	22.1
Obese Grade II-III (35+)	53	13.8
Total	385	100.0
<b>Income (QAR)</b>		
Less than 5000 QAR	92	24.0
5000 – 9999 QAR	97	25.3
10,000 – 15,000 QAR	85	22.1
More than 15,000 QAR	110	28.6
Total	384	100.0

**Table 2: The relative frequency of selected comorbidities in the study sample**

Comorbidities (N=385)	N	%
Diabetes Mellitus	70	18.2
Hypertension	62	16.1
Thyroid disease	31	8.1
Chronic Lung conditions	14	3.6
Ischemic Heart Disease	9	2.3
Rheumatoid arthritis	6	1.6
At least one chronic comorbid condition	129	33.5

**Table 3: The relative frequency of selected risk factors in the study sample**

Positive risk factors (N=385)	N	%
Recommended physical activity (150 minutes per week)	137	35.6
Smoking	66	17.1
Alcohol consumption	21	5.5
Family History of anxiety disorders	10	2.6

**Table 4: The relative frequency of reported/perceived reasons for anxiety**

Reported/perceived reasons for Anxiety (N=18*)	N	%	95% confidence interval
COVID19 Pandemic	6	33.3	(15.3 to 56.3)
Total	18	100.0	

\*Note: two individuals with clinically significant GAD were non-respondents to these items.

**Table 5: The relative frequency of different grades of anxiety according to GAD score**

GAD7 categories	N	%	95% confidence interval
Minimal anxiety (<5)	307	79.7	(75.5 to 83.5)
Mild Anxiety (5-9)	58	15.1	(11.8 to 18.9)
Moderate Anxiety (10-14)	18	4.7	(2.9 to 7.1)
Severe Anxiety (15-21)	2	0.5	(0.1 to 1.7)
Total	385	100.0	

**Table 6: Perceived quality of life for individuals with moderate to severe anxiety**

	N	%	95% confidence interval
GAD related quality of life for those with moderate to severe anxiety	N	%	
Not difficult at all	2	10.0	(2.1 to 28.4)
Somewhat difficult	8	40.0	(21.1 to 61.6)
Very Difficult	7	35.0	(17.2 to 56.8)
Extremely difficult	3	15.0	(4.4 to 34.9)
Total	20	100.0	

**Table 7: The relative frequency and the prevalence ratio estimates for having a clinically significant anxiety (GAD7=10+)**  
(continued next page)

	Clinically significant Anxiety (GAD17=10+)						PR	95% Confidence Interval
	Negative		Positive		Total			
	N	%	N	%	N	%		
<b>Gender</b>								
Male	217	97.3	6	2.7	223	100	Ref	
Female	148	91.4	14	8.6	162	100	3.2	(1.25 - 8.12)
Total	365	94.8	20	5.2	385	100		
<b>Nationality categories</b>								
Southern Asia	112	99.1	1	0.9	113	100	Ref	
Northern Africa	87	91.6	8	8.4	95	100	9.3	(1.19 - 73.27)
South-eastern Asia	40	93	3	7	43	100	7.8	(0.83 - 72.77)
Western Asia	109	94	7	6	116	100	6.7	(0.83 - 53.35)
Miscellaneous others	17	94.4	1	5.6	18	100	6.2	(0.41 - 95.07)
<b>Age (years)</b>								
50-64	80	96.4	3	3.6	83	100	Ref	
40-49	80	92	7	8	87	100	2.2	(0.59 - 8.3)
30-39	133	95.7	6	4.3	139	100	1.2	(0.31 - 4.63)
<30	72	94.7	4	5.3	76	100	1.5	(0.34 - 6.36)
<b>Marital status</b>								
Single	85	95.5	4	4.5	89	100	Ref	
Ever married	280	94.6	16	5.4	296	100	1.2	(0.41 - 3.5)
<b>Educational level</b>								
Illiterate / Primary	20	95.2	1	4.8	21	100	Ref	
Intermediate	19	95	1	5	20	100	1.04	(0.07 - 15.53)
Secondary	92	95.8	4	4.2	96	100	0.88	(0.1 - 7.48)
University	234	94.4	14	5.6	248	100	1.2	(0.16 - 8.47)
<b>Occupation</b>								
Manual worker	50	98	1	2	51	100	Ref	
Not working	77	97.5	2	2.5	79	100	1.3	(0.12 - 13.43)
Professional	204	93.2	15	6.8	219	100	3.4	(0.46 - 25.15)
Self-employed	18	94.7	1	5.3	19	100	2.7	(0.17 - 40.28)
Army/Police	15	93.8	1	6.3	16	100	3.2	(0.21 - 47.55)
<b>Crowding index-categories</b>								
Lowest (First quartile) <=1.1	93	95.9	4	4.1	97	100	Ref	
Average (Interquartile) 1.2 - 2.0	195	94.7	11	5.3	206	100	1.3	(0.42 - 3.95)
Highest (Fourth quartile) 2.1+	77	93.9	5	6.1	82	100	1.5	(0.41 - 5.37)
<b>BMI (Kg/m2)-categories</b>								
Acceptable (18.5 thru 24.9)	77	96.3	3	3.8	80	100	Ref	
Overweight (25-29.9)	159	95.2	8	4.8	167	100	1.3	(0.34 - 4.62)
Obese (30+)	129	92.9	9	7.1	85	100	1.9	(0.52 - 6.71)
<b>Income QAR</b>								
Less than 5000 QAR	89	96.7	3	3.3	92	100	Ref	
5000 – 9,999 QAR	93	95.9	4	4.1	97	100	1.2	(0.29 - 5.39)
10,000– 15,000 QAR	82	96.5	3	3.5	85	100	1.1	(0.22 - 5.11)
More than 15,000 QAR	101	91.8	9	8.2	110	100	2.5	(0.69 - 8.89)

Table 7: The relative frequency and the prevalence ratio estimates for having a clinically significant anxiety (GAD7=10+) (continued)

<b>Diabetes Mellitus</b>								
Negative	296	94	19	6	315	100	Ref	
Positive	69	98.6	1	1.4	70	100	0.23	(0.03 - 1.69)
<b>Hypertension</b>								
Negative	306	94.7	17	5.3	323	100	Ref	
Positive	59	95.2	3	4.8	62	100	0.91	(0.27 - 3.01)
<b>Ischemic Heart Disease</b>								
Negative	357	94.9	19	5.1	376	100	Ref	
Positive	8	88.9	1	11.1	9	100	2.2	(0.33 - 14.56)
<b>Chronic Lung conditions</b>								
Negative	354	95.4	17	4.6	371	100	Ref	
Positive	11	78.6	3	21.4	14	100	4.7	(1.54 - 14.04)
<b>Thyroid disease</b>								
Negative	336	94.9	18	5.1	354	100	Ref	
Positive	29	93.5	2	6.5	31	100	1.3	(0.31 - 5.22)
<b>Rheumatoid arthritis</b>								
Negative	360	95	19	5	379	100	Ref	
Positive	5	83.3	1	16.7	6	100	3.3	(0.53 - 21.07)
<b>At least one chronic comorbid condition</b>								
Negative	244	95.3	12	4.7	256	100	Ref	
Positive	121	93.8	8	6.2	129	100	1.3	(0.55 - 3.15)
<b>Family History of anxiety disorders</b>								
Negative	358	95.5	17	4.5	375	100	Ref	
Positive	7	70	3	30	10	100	6.7	(2.32 - 19.15)
<b>Recommended physical activity (150 min per week)</b>								
Negative	235	94.8	13	5.2	248	100	Ref	
Positive	130	94.9	7	5.1	137	100	0.98	(0.4 - 2.4)
<b>Smoking</b>								
Negative	303	95	16	5	319	100	Ref	
Positive	62	93.9	4	6.1	66	100	1.2	(0.42 - 3.53)
<b>Alcohol consumption</b>								
Negative	345	94.8	19	5.2	364	100	Ref	
Positive	20	95.2	1	4.8	21	100	0.92	(0.13 - 6.55)



**Table 8: Multiple Logistic Regression model with the risk of having clinically significant anxiety as the dependent (outcome) variable and selected explanatory variables**

	Adjusted OR	95% confidence interval adjusted OR	P
<b>All explanatory variables included</b>			
Female gender compared to male	9.40	(1.97 to 44.88)	0.005
<b>Nationality categories</b>			0.08[NS]
Northern Africa compared to Southern Asia	66.92	(2.5 to 1790.67)	0.012
South-eastern Asia compared to Southern Asia	40.70	(1.18 to 1408.35)	0.04
Western Asia compared to Southern Asia	12.60	(0.53 to 301.36)	0.12[NS]
Miscellaneous others compared to Southern Asia	22.91	(0.43 to 1209.66)	0.12[NS]
<b>Age (years)</b>			0.48[NS]
<30 compared to 50-64	3.70	(0.39 to 34.61)	0.25[NS]
30-39 compared to 50-64	0.94	(0.15 to 5.88)	0.94[NS]
40-49 compared to 50-64	1.76	(0.31 to 10.01)	0.52[NS]
Ever married compared to single	1.19	(0.22 to 6.31)	0.84[NS]
<b>Educational level</b>			0.25[NS]
Intermediate compared to Illiterate/primary	0.01	(0 to 2.42)	0.1[NS]
Secondary compared to Illiterate/primary	0.05	(0 to 1.32)	0.07[NS]
University compared to Illiterate/primary	0.05	(0 to 1.16)	0.06[NS]
<b>Occupation</b>			0.37[NS]
Not working compared to Manual worker	0.75	(0.03 to 21.03)	0.87[NS]
Professional compared to Manual worker	3.93	(0.18 to 85.5)	0.38[NS]
Self-employed compared to Manual worker	4.87	(0.11 to 217.68)	0.41[NS]
Army/Police compared to Manual worker	9.13	(0.22 to 379.95)	0.24[NS]
<b>Crowding index-categories</b>			0.98[NS]
Average (interquartile range) 1.2 - 2.0 compared to Lowest (First quartile) <=1.1	1.13	(0.25 to 5.16)	0.87[NS]
Highest (Fourth quartile) 2.1+ compared to Lowest (First quartile) <=1.1	1.03	(0.15 to 7.11)	0.98[NS]
<b>BMI (Kg/m<sup>2</sup>)-categories</b>			0.67[NS]
Overweight (25-29.9) compared to Acceptable (18.5 thru 24.9)	1.88	(0.33 to 10.56)	0.47[NS]
Obese (30+) compared to Acceptable (18.5 thru 24.9)	2.20	(0.39 to 12.32)	0.37[NS]
Being a smoker	3.36	(0.66 to 17.2)	0.15[NS]
Having a positive family history of anxiety disorders	201.71	(8.66 to 4695.59)	<0.001
Practicing the recommended physical activity (150 min per week)	1.63	(0.48 to 5.52)	0.43[NS]

Table 8: Multiple Logistic Regression model with the risk of having clinically significant anxiety as the dependent (outcome) variable and selected explanatory variables (continued)

Alcohol consumption	0.60	(0.05 to 7.06)	0.69[NS]
Income QAR			0.15[NS]
5000 - 9999 compared to Less than 5000 QAR	1.41	(0.16 to 12.37)	0.76[NS]
10,000– 15,000 compared to Less than 5000 QAR	1.22	(0.14 to 10.86)	0.86[NS]
More than 15,000 compared to Less than 5000 QAR	5.72	(0.74 to 44.37)	0.1[NS]
Having at least one chronic comorbid condition	1.28	(0.34 to 4.78)	0.71[NS]
Constant	0.0002		0.001
<b>Backward Selection Method</b>			
Female gender compared to male	2.83	(0.99 to 8.09)	0.05[NS]
Nationality categories			0.15[NS]
Northern Africa compared to Southern Asia	20.99	(1.93 to 228.77)	0.012
South-eastern Asia compared to Southern Asia	13.25	(0.99 to 177.58)	0.05[NS]
Western Asia compared to Southern Asia	9.93	(0.92 to 107.65)	0.06[NS]
Miscellaneous others compared to Southern Asia	8.14	(0.41 to 161.17)	0.17[NS]
Having a positive family history of anxiety disorders	26.14	(3.57 to 191.34)	0.001
Constant	0.003		<0.001

P (Model) = 0.03

Overall predictive accuracy = 95.6%

## Discussion

This study calculated the prevalence rate of GAD (moderate and severe) of 5.2%. WHO mental health surveys showed the disorder was especially common and impairing in high-income countries (5.0%), lower in middle-income countries (2.8%), and lowest in low-income countries (1.6%) (20).

Females had a higher prevalence for GAD (8.6%) compared to males (2.7%). Another study conducted in the United States among the age group 18 to 64 years revealed association between gender and GAD; the lifetime prevalence was 7.7% among females and 4.6% among males (21). Some factors may contribute to a higher rate of anxiety among females like monthly cycle, female hormones, and sexual abuse or violence. Females are more likely than males to seek help for anxiety, while males' testosterone hormone may help to relieve the anxiety symptoms (22).

The US National Comorbidity Survey showed the highest prevalence was among the age group 45 to 49 years (7.7%), and the lowest prevalence was among the age group of 60 years and older (3.6%) (23). Our study had a similar prevalence; 8% among the age group 40-49 years, and 3.6% among the age group 50-64 years. One study showed severity of anxiety symptoms decreased over time, as persons with GAD make some changes in their lives, so anxiety symptoms become less impairing over time (24).

Being separated, divorced or widowed had the highest prevalence (8.3%), compared to married and single participants (5.3% and 4.5% respectively). The US national comorbidity survey also revealed GAD was significantly correlated with being separated, widowed or divorced (11). This may be related to more stressors and lack of partner support among these groups. While low educational level in both genders increased the risk of GAD (25), our study showed a lower prevalence in the illiterate group compared to the educated groups (illiterate stratum involved only 4 participants out of 385). The prevalence increased with the increased crowding among households in our study.

Professionals and those who worked in army or police at the time of the study had a higher risk of GAD compared to others. A French prospective study demonstrated that working in jobs that had a psychological demand, emotional demand, job insecurity and jobs with low reward put the individual at a higher risk of GAD (26). Another study conducted in UK showed 2 to 3 times increased risk of GAD among men and women who were doing jobs that had a high psychological demand (27).

GAD was associated with obesity in our study; on the other hand participants with acceptable BMI had the lowest risk. Another study in Germany demonstrated a higher rate of GAD among the group of obesity compared to groups of overweight and normal weight (28).

Although GAD is associated with low income, our study showed an increased risk among high income participants. A study held in Canada showed prevalence of 10.3% among population with annual income of \$20,000 in comparison to prevalence 6.2% in population whose income equal to or more than \$70,000 (29).

GAD is more common among patients with chronic physical illness and conditions associated with chronic pain. Our study showed an increased risk of GAD among those with ischemic heart disease, rheumatoid arthritis and chronic lung disease. A review of the effects of worry and generalized anxiety disorder upon cardiovascular health and coronary heart disease in three studies reported GAD was associated with poorer prognosis in establishing coronary heart disease, GAD prevalence was 10.4% in 3,266 patients across 15 studies (30). A case control population-based study confirmed a higher proportion of anxiety in rheumatoid arthritis patients (31). In our study, although hypertension and thyroid disease showed association, diabetics had a lower risk.

Family history of anxiety disorders is a risk factor for developing GAD (32). Our study showed an increased risk (30% compared to 4.5%). Genetic factors may predispose to development of GAD; the serotonin transporter gene-linked polymorphic region SS genotype (short/short) was found to be more frequent in those with GAD (33). History of psychiatric conditions showed strong association with GAD (30% compared to 4.5%). The National Comorbidity Survey follow-up study showed persons with major depression and GAD were more likely to develop GAD 10 years later (34).

A systematic review supported cigarette smoking as being a risk factor for development of GAD (35). Although our study showed association with smoking, practicing the recommended physical activity or alcohol were not found to be related to GAD. Patients known to have comorbid alcohol or other substance use disorder, had a significantly low likelihood of recovery from generalized anxiety disorder, and even if they recovered from GAD, they are still at higher risk of recurrence (36).

Our study was conducted during the COVID-19 pandemic and the data collection phase of the study extended from January to March 2021. One third (33.3%) of participants with GAD related the COVID-19 pandemic as a cause. Future study after the era of COVID-19 may show a difference in the prevalence of GAD.

We believe our study represented different areas of PHCC in Qatar as it involved randomly selected multiple health centers from different regions (Western, Northern and Central). This prevalence of GAD of 5.2% highlights the importance of regular screening for those at high risk. Those who have GAD need interventions and follow up.

### Ethical Approval

We got an approval notice to conduct this study from the Independent Ethics Committee (IEC) and the Department of Clinical Research at Primary Health Care Corporation in Qatar.

### Conflict of Interest

The authors declare that there is no conflict of interest regarding publication of this paper.

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# Epley's Maneuver in Primary Care: A Quality Improvement Project

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## Abstract

Almost all health systems of the world are burning out of budgets, hence, activities need to be developed to save as much money as possible for health services. We chose a simple, effective and proven by research method "Epley's manoeuvre (EM)" as a diagnosis and treatment of "Benign Paroxysmal Positional Vertigo (BPPV)". We delivered training to primary care physicians and studied the effectiveness of the the treatment and the cost saved in this project. It was found that EM proved both highly effective treatment as well as saved a good sum of money along with other benefits, such as better job satisfaction, convenience for the patients, etc.

**Key Words:**Epley's manoeuvre, primary care, cost-effectiveness, ENT in primary care

## Introduction

Dizziness is a common presentation in primary as well as secondary care all over the world. The most common cause of dizziness in all types of vestibular vertigo is "Benign Paroxysmal Positional Vertigo (BPPV)" (von Brevern et al, 2007). The most effective and non-invasive treatment for BPPV is Epley's Maneuver which is usually performed by trained ENT specialists or consultants in secondary care settings. This causes a significant amount of clinical workload and financial burden on secondary care (Kovacs et al, 2019). We planned to train the primary care physicians to perform Epley's maneuver in primary care settings to see if this change of practice can reduce some financial burden on secondary care as well as reducing the unnecessary costs of consultations and investigations.

## Background

BPPV is a common vestibular disorder leading to significant comorbidity, psychological impact and medical costs (von Brevern et al, 2007). This phenomenon is prevalent throughout the world. An estimated incidence of BPPV is 107/100,000 per year (Froehling et al, 1991) with overall lifetime prevalence of 2.4% (von Brevern et al, 2007). This significantly increases the financial burden on secondary care for the cost of the treatment. Not only that, it also causes absenteeism from work on medical grounds and that inflicts extra economic burden on any country's economy (Kovacs et al, 2019).

In the UK, BPPV, is most often is diagnosed in secondary care in ENT clinics and is treated by ENT consultants and associate specialists. Once a patient is referred by his/her GP (General Practitioner or Family Doctor) to ENT, patients will have to wait for several weeks before they see the doctor. Followed by the initial consultation, often patients end up going through further investigations, such as imaging, audiometry and blood analysis, etc. This further increases the cost of the overall treatment. Many patients would require follow up appointments also. It has been proven by several studies all over the world that the most effective treatment of BPPV is Epley's manoeuvre (Mujeeb & Khan 2000, Moreno et al 2019). A meta-analysis of the studies on effectiveness of Epley's maneuver have been published by Prim-Epsada et al in 2010 showing the evidence of effectiveness of Epley's maneuver in treating BPPV in all age groups. As the incidence of BPPV increases in the elderly (around 50% of all vestibular vertigos), still Epley's maneuver remains the most effective treatment with positive outcome of around 70% or more (Balatsouras et al, 2018).

Based on the above facts, it was thought that if we train the primary care physicians to perform Dix-Hallpike (the first part of Epley's maneuver to diagnose BPPV) and Epley's maneuver in primary care settings, this might save a significant number of referrals to secondary care, which in turn will help reduce workload and financial costs

(Kovacs et al 2019) on secondary care providers, i.e, NHS UK. Moreover, if this project proves successful, it will be a great convenience as well for the patients as they will get the best treatment at their local family doctor, instead of waiting a long time to see an ENT specialist. The procedure improves the quality of life (Uz et al, 2019) in all age groups including the elderly, if performed according to the right technique (Woodhouse 2015).

## Materials and Methods

A general invitation was sent to all the primary care physicians (GPs) and to the trainee GPs working in all the GP Surgeries (primary healthcare centres) in the whole region of the area of local CCG (clinical commissioning group) in Nottinghamshire, UK to participate in the project.

A face to face training session was arranged for the volunteers. This session included a theory lecture, explaining the pathophysiology of BPPV and the mechanism of Epley's maneuver. Then in the practical part of the training session, one to one training was delivered to all the participating physicians. We used our weekly half-day release time in our deanery (East Midlands, Mansfield rotation) to train the GPs and the GP registrars for this. So, no extra money was spent for this training.

Data was collected from all the participating GP surgeries and the results were compared with the other studies.

An estimated savings of the cost of the treatment of BPPV was calculated based on the treatment tariffs in the private sector. It is assumed that the cost on NHS would be significantly high as compared to the private sector.

We gave "Prochlorperazine" 5mg three times daily along with "Betahistidine" 16mg three times daily, orally, to all patients 14 days prior to the planned Epley's manoeuvre. This reduced the discomfort to all the patients during the procedure, to a great degree.

## Training

Out of around 41 surgeries, 12 agreed to participate in the study. Out of all the volunteers 31 doctors were recruited into the training session. One of the monthly "half day local training sessions" was chosen to deliver this training to all the participants. In the assessment after training 25 doctors were found to be competent enough to perform Dix-Hallpike and Epley's manoeuvre confidently and accurately.

As mentioned above, the training was divided into two parts. Firstly, a lecture was delivered by the main author explaining the anatomy of the internal ear, pathophysiology of BPPV and the mechanics and dynamics of both Dix-Hallpike as well as Epley's manoeuvre were explained. Secondly, one to one practical training was delivered to each and every participant using real subjects. Every

participant was critically assessed both on theory as well as practical aspects of the procedure and the 25 best participants were selected.

Below, we will briefly go through the anatomy of the internal ear, pathophysiology of BPPV and the method of Epley's manoeuvre:

**Anatomy of Internal Ear and Pathophysiology of BPPV:**

The internal ear is a membranous organization of tubes and sacs filled with fluid called "Endolymph" and suspended in a different fluid called "Perilymph" within a similar shaped bony house. Endolymph is rich in salts while perilymph has the same composition as CSF (Cerebrospinal Fluid). See the figures below:

Figure 1

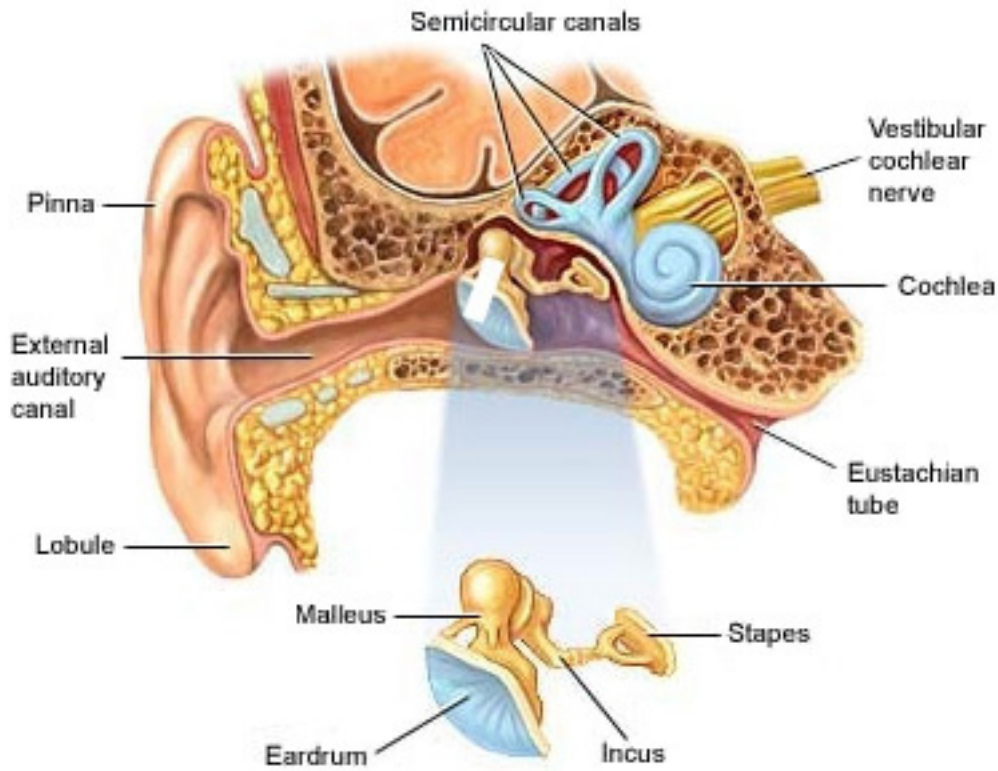
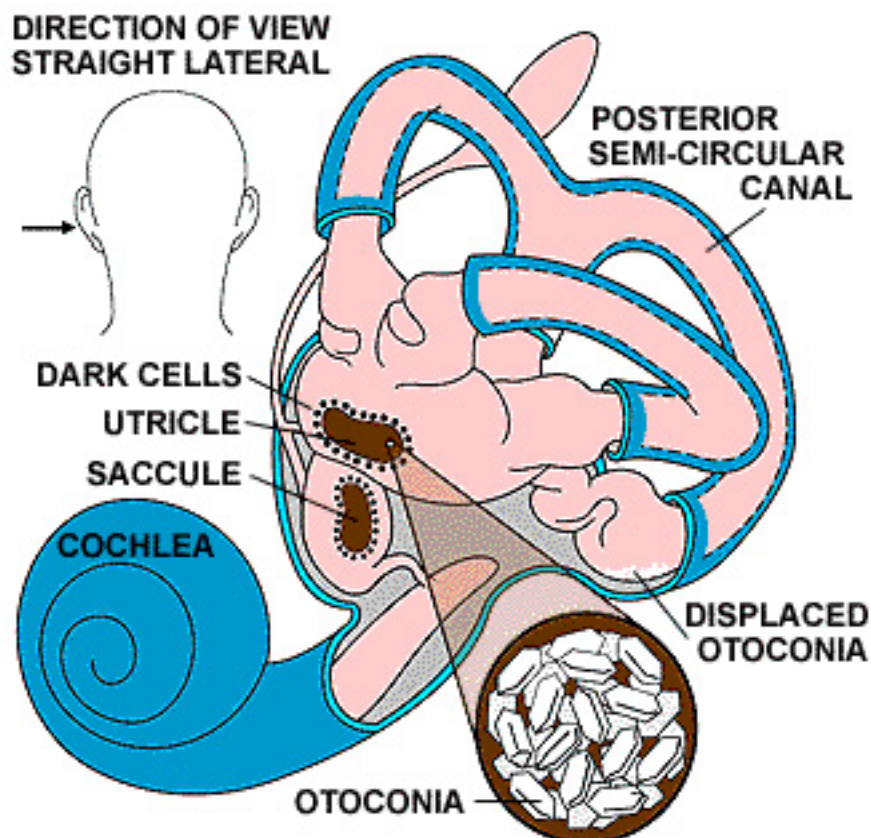


Figure 2



In summary, the calcium crystals called “otoconia” which normally are riding on a gelatinous membrane called “tectorial membrane” are confined in a membranous chamber of labyrinth called “Utricle” to which are attached three semi-circular canals via 5 openings instead of 6. That is because posterior and superior semi-circular canals join together to form a single tube called “crus communes” before opening into the utricle. This is the channel through which the dislodged otoconia pass through and enter the posterior semi-circular canal (90% of the times).

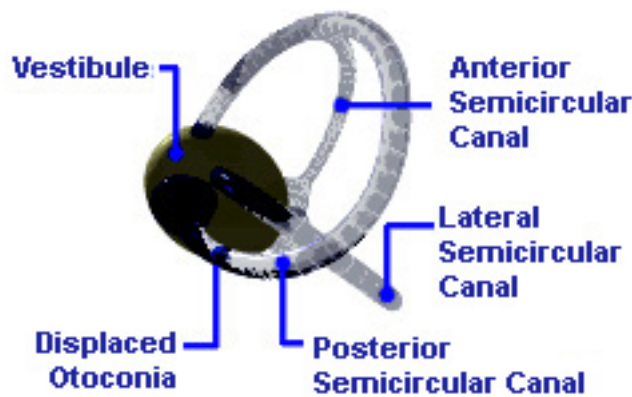
These misplaced otoconia then would create ripples in the endolymph on the movements of head and stimulate the balance organ lying in the ampulated end of the posterior semi-circular canal (SCC) which then produces the sense of imbalance. This usually happens when the head moves in the direction of the affected ear.

**Mechanics of Epley’s Manoeuvre:**

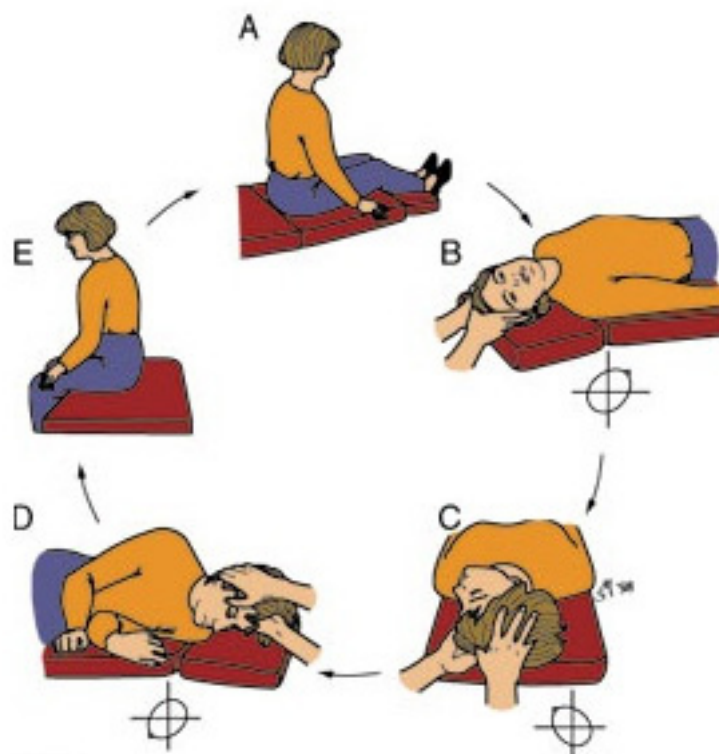
As mentioned above, there are misplaced otoconia in the posterior SCC which are responsible for stimulating the balance organ in its ampulated end. So, logically, to treat the condition, these otoconia need to be tracked down back to the utricle to allow them to lodge back onto the tectorial membrane. This is only possible via crus communes.

So, the head of the patient is moved in some specific directions to help these otoconia to fall back into the utricle. This procedure is called “Epley’s manoeuvre” and is illustrated by the diagram below:

**Figure 3**



**Figure 4**



Steps (Modified from Burgess L, Aug 30, 2017)



**Steps** (Modified from Burgess L, Aug 30, 2017)

The first step in the Epley's manoeuvre is called "Dix-Hallpike" test.

1. Ask the person to sit upright on an examination table, fully extending their legs out in front of them.
2. Rotate the person's head at a 45-degree angle towards the side they are experiencing the worst vertigo.
3. Quickly push the person back, so that they are lying down with their shoulders touching the table. The person's head is kept facing the side worst affected by vertigo but now at a 30-degree angle, so that it is lifted slightly off the table. The doctor holds the person in this position for between 30 seconds and 2 minutes, until their dizziness stops.
4. Rotate the person's head 90 degrees in the opposite direction, stopping when the opposite ear is 30 degrees away from the table. Again, the doctor holds the person in this position for between 30 seconds and 2 minutes, until their dizziness stops.
5. Next, they roll the person in the same direction that they are facing, onto their side. The side that they experience the worst vertigo on will be facing upwards. The doctor holds the person in this position for between 30 seconds and 2 minutes, until their dizziness stops.
6. Finally, the doctor brings the person back up to a sitting position.
7. The whole process is repeated up to three times, until the person's symptoms are relieved.

**Findings**

The data was then collected over a period of 8 months from the clinicians who were given the training. Because all the data was electronically recorded on a common medical records system called "System One", it was easy to retrieve all the patients treated over this period and their follow up appointments. A total of 144 patients were seen by these 25 trained doctors over a period from March to October. Rather than analysing the data on the basis of all individual 25 clinicians, we preferred to analyse the data as a joint effort from all. All ages were included in the study.

Those patients who attended again within a week with no relief in symptoms were considered as "misdiagnosis". Those cases were personally examined by the author and the most common condition which was misdiagnosed as BPPV was "cervical vertigo" which usually occurs with some arthritic changes in the cervical spine and causes transient vertiginous symptoms on moving cervical spine in almost any direction. We can see from the data, there are only a few misdiagnosed patients.

Table 1:

Total No. Patients	Required 2 <sup>nd</sup> treatment within 3 months	Misdiagnosed	Successfully treated	Unsuccessful
144	39	9	114	39
	27%	6.25%	79.16%	27.08%

In the first analysis, all 144 patients were included. The reason was to find out the number of misdiagnosed cases which were found to be 9. The total unsuccessful cases in the table also include the misdiagnoses. So after correction, the total true BPPV cases were found to be 135.

On the corrected analysis, all the misdiagnosed cases were excluded and the data was re-analysed, see Table 2.

Table 2:

Total No. Patients	Required 2 <sup>nd</sup> treatment within 3 months	Successfully treated	Unsuccessful
135	39	114	30
	28.88%	84.44%	14.58%

As a summary, overall 135 patients were correctly diagnosed with BPPV over an 8 month period and 114 of them were successfully treated. 39 patients out of 135 did require a second session of Epley's manoeuvre. 30 patients did not improve even after the second session. The reasons for this phenomenon can be theoretically proposed as follows:

1. The otoconia are present in lateral SSC instead of posterior SCC or may be in both.
2. The otoconia do not stick well onto the tectorial membrane after the procedure and hence keep coming back to the SSCs too early and too frequently.

#### Cost Effectiveness:

In the private sector, the initial consultation fee for an ENT patient is £150 and a follow up visit costs £120. So, based on this tariff the cost effectiveness yielded by this project is shown below:

**Table 3:**

	Total No. Patients	Required 2 <sup>nd</sup> treatment within 3 months	Successfully treated	Unsuccessful
	135	39	114	30
		28.88%	84.44%	14.58%
Cost	£20,925	£4,875		Total = £25,800.00

This small project in primary care saved £25,800.00 which is a considerable amount. As we can see in this calculation, all the misdiagnosed cases have not been counted which if presented in private practice, would have been charged at least the first visit fee. However, we only calculated the money saved on successful cases.

#### Results

1. The efficacy of Epley's manoeuvre remains unchallenged and in our study it was around 84.44%. This showed a better outcome than many other studies in secondary care which achieved a success rate of around 70% or more (Mujeeb & Khan 2000, Moreno et al 2019).
2. The rate of misdiagnosis was only 6.25% in the hands of family medicine doctors who were given training. This is almost negligible as compared to the overall achievement of the project.
3. A significant sum of money was saved by this project (Kovacs et al, 2019).

#### Conclusions

Based on this study, the following conclusions can be drawn:

1. The efficacy of the Epley's maneuver proves it the treatment of choice for BPPV.
2. This treatment can be safely given in the primary care set up.
3. Performing this procedure in primary care is cost effective and can save a significant sum of money and reduce the referral rate to secondary care.
4. Primary care doctors felt confident with this training and the project and showed overall better work satisfaction to all the participants.
5. Pre-medication with Prochlorperazine and Betahistidine reduced the discomforting vertiginous feeling in all patients during the procedure.

#### Recommendations

Drawn from the above study, we suggest the following recommendations:

1. Training primary care physicians in delivering the Epley's maneuver is very useful and carries lots of benefits, such as better work satisfaction, cost effectiveness, reducing referral rate to secondary care and convenient and quick for our patients.
2. Similar training should be given to more primary care physicians and the multicentre studies should be audited and presented from other regions.
3. If proven by multicentre studies, it should be made a national recommendation to train all primary care physicians in delivering the Epley's manoeuvre.
4. Growing health systems like in Qatar and other Middle Eastern countries, may adopt this practice nice and early in their system as it would be easy in the beginning to change a practice than later.
5. Pre-medication as mentioned in this study should be tried in all other studies as we found it extremely useful in our patients.

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# A Review on the Clinical Potential of Lorcaserin in the Treatment of Obesity

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## Abstract

Obesity is a chronic disease characterized by excessive fat accumulation and associated with impaired metabolism and cardiovascular disease. The high global prevalence of obesity has resulted in the production of anti-obesity drugs over the last couple of decades, normally to be used in combination with lifestyle modifications such as physical activity and diet. One such medication is lorcaserin, a selective serotonin 5-hydroxytryptamine<sub>2C</sub> (5-HT<sub>2C</sub>) receptor agonist approved by the FDA in 2012 as a drug therapy for weight management in conjunction with lifestyle modifications. Importantly, the FDA recently issued a request to withdraw lorcaserin from the market as it may promote certain types of cancers, including pancreatic, colorectal, and lung, but further clinical data is being collected and analyzed to assess its carcinogenic risk. This review will address lorcaserin's therapeutic potential for the treatment of obesity, considering the pre-clinical and clinical trials describing its efficacy in weight loss along with its adverse carcinogenic effects to ultimately determine the likelihood of its reintroduction into the market.

**Key words:** Lorcaserin, obesity, carcinogenic risk

## Introduction

Recent evidence through systematic analysis demonstrates that cardiovascular diseases such as myocardial infarction or stroke, along with cancer are the leading causes of death worldwide (1). These pathologies are highly associated with the obesity epidemic which plagues the globe today. In particular, obesity or overweight (as determined by body-mass index, BMI) strongly predicts and increases the risk for cardiovascular diseases (2,3). Obesity is also widely associated with at least 13 cancer types, including meningiomas, cancers of the liver and pancreas, and more, which make up 40% of all diagnosed cancers in the United States each year (4,5). Thus, a clear therapeutic need exists for obesity interventions aimed at improving both weight management and mitigating weight regain.

Generally, the current approach to reduce obesity and manage weight gain involves caloric restriction diets and increased physical activity (6). However, clinical studies indicate that without the use of pharmacological intervention in addition to these lifestyle changes, most individuals with obesity lose modest amounts of weight, and many of those who lose significant weight return to their original weight within a few years due to low rates of long-term adherence (7). Due to these weight management issues, many strategies to improve weight management in those who cannot achieve substantial weight loss through lifestyle alterations alone involve the use of anti-obesity medications (7).

Food intake and overall satiety are primarily controlled by central and peripheral hormonal signaling, which impact a variety of signaling pathways throughout the body. As such, modern pharmacology has targeted these pathways, such as increasing energy expenditure, reducing appetite, and decreasing fat and calorie absorption through the inhibition of lipases within the gastrointestinal system, to improve weight management in obese patients (7,8). The efficacy of these medications is mixed. While some of the drugs, such as phentermine, orlistat, and lorcaserin, do improve weight loss in obese individuals, they are associated with serious adverse effects (9).

The clinical potential of lorcaserin as an anti-obesity medication is of particular interest considering it was one of the most prescribed weight-loss drugs until early 2020 when the FDA revealed the drug may increase the risk of cancer and cancer-related mortality (10,11). Lorcaserin was approved by the FDA as a weight-loss medication on June 27th, 2012, but never gained approval from the European Medical Agency (EMA) due to its associated risks with breast cancer, psychiatric disorders, and valvulopathy. Specifically, the drug is a highly selective agonist to serotonin 2C (5-HT<sub>2c</sub>) receptors in the pro-opiomelanocortin (POMC) neurons of the central nervous system. The stimulation of these neurons results in the release of alpha-melanocortin-stimulating hormone (alpha-MSH) to suppress appetite (12,13).

The discovery of selective 5-HT<sub>2c</sub> agonists resulted in numerous pre-clinical and clinical trials on various drugs over the past two decades, and one showing the most promise as an anti-obesity drug was the serotonin releaser/reuptake inhibitor known as (dex)fenfluramine. (Dex)fenfluramine reduced appetite and helped obese individuals lose weight (14,15). However, the drug (along with other 5-HT<sub>2c</sub> agonists) was associated with various cardiovascular disease-related side effects, prompting its withdrawal from clinical use in the early 2000s (16). Despite the negative findings, testing of different selective 5-HT<sub>2c</sub> receptor agonists persisted throughout the early 2000, and lorcaserin was eventually discovered by Arena Pharmaceuticals.

Together with lifestyle modifications, lorcaserin is the only 5-HT<sub>2c</sub> receptor agonist that has been approved as an anti-obesity drug by the FDA. It has also been approved in Mexico, Taiwan, Israel, South Korea, while larger markets such as the EU and Japan have approved it for clinical use. Concerning lorcaserin's recent withdrawal from the market, this review will discuss its clinical potential, including its efficacy and adverse effects in recent clinical trials, along with the likelihood of it being reintroduced into the market as an anti-obesity medication.

## *In vivo* and pre-clinical pharmacology

Initial investigations on lorcaserin administration to rodents found the drug reduced alcohol intake and locomotor activity (17,18) and similar observations were observed with other 5-HT<sub>2c</sub> receptor agonists as well (19). Rodent motor activity was also affected when higher doses of lorcaserin were administered, indicating lower-dose lorcaserin administration may reduce exploratory drive in addition to impaired motor performance (20).

Increased brain serotonin levels and the activation of 5-HT receptors can trigger certain behaviors from rodents including yawning or penile grooming (YPG), a behavior specific to activation of the 5-HT<sub>2c</sub> receptor (21). In rats subcutaneously administered 0.3-10mg/kg lorcaserin, YPD was significantly induced at even the lowest dose (18). Additionally, when these animals were treated with SB-242084, a selective 5-HT<sub>2c</sub> receptor antagonist, along with 10mg lorcaserin, they exhibited a wet dog shake (WDS) behavior commonly associated with specific activation of the 5-HT<sub>2a</sub> receptor, suggesting lorcaserin may have off-target effects at higher doses (18,19).

*In vivo* investigations on the administration of lorcaserin in rodents on food intake, satiety, obesity, and type 2 diabetes have been described at length. Specifically, lorcaserin treatment reduces sugar consumption and promotes satiety in a dose-dependent manner at doses between 0.1-3.0mg/kg body weight (22). Further research has discovered these effects persist in obese, aged (12-14 month-old) mice as well, and that the appetite-reducing effects are specific to POMC activation (23). Interestingly, studies show lorcaserin administration and subsequent

activation of the 5-HT<sub>2c</sub> receptors of dopaminergic neurons inhibits binge-like eating behavior in mice as well (24).

Feeding studies that investigate the effects of lorcaserin treatment in diet-induced obesity (DIO) rodent models indicate the drug is effective at reducing body and fat mass in the acute term, but long-term investigations have less successful results. Two studies observed the effects of high oral-dose lorcaserin treatment (9-36mg/kg,(25) 4.5-18mg/kg(26)) on weight gain and body composition in rat (DIO) models, and identified dose-dependent reductions in body weight gain over 28-days, with the highest dose resulting in a 12% decrease. Despite the reduction in body weight observed over the 28 days, lorcaserin's ability to reduce food intake over the period was less effective. In particular, lorcaserin significantly reduced food intake during the first 2 days of oral administration, but this effect constantly diminished after a week (25,26). Moreover, once lorcaserin treatment was stopped, daily food intake increased and body weight levels rose to values similar to pre-lorcaserin administration levels (26). Additional 28-day lorcaserin investigations on DIO rats have been conducted as well, specifically on low-dose (1-2mg/kg subcutaneous) administration (27). The study found the 2mg/kg lorcaserin administration resulted in 5% less weight gained compared to control mice, and the disparity was due to reductions in fat mass relative to lean mass. The authors also showed that similar to previous studies, lorcaserin induced a robust reduction in food intake during the first few days of administration, but the effect wore off after the first week.

Subcutaneous lorcaserin administration (2mg/kg body weight) to rats also lowered blood cholesterol and glucose levels in a glucose tolerance test (GTT), indicating it may improve lipid profiles and glucose homeostasis as well (27) Similar results have also been observed in mice in a dose-dependent manner, where lorcaserin treatment significantly improved glucose control during a GTT, an effect that was completely diminished in POMC knockout mice. (28). Using insulin tolerance tests (ITT) and hyperinsulinemic/euglycemic clamps, the researchers also displayed lorcaserin treatment improves insulin sensitivity, suppresses hepatic glucose production, and enhances peripheral glucose disposal as well, providing further evidence of the drug's beneficial impact on glucose homeostasis and diabetic symptoms (28).

## Pharmacokinetics

Research has identified a single, 10mg/kg oral dose of lorcaserin in male, Sprague-Dawley rats resulted in rapid drug absorption from the gastrointestinal tract into the systemic circulation with a maximum mean drug concentration at 15 minutes (0.760 ug/mL), and maximal exposure in the brain at 1 hour after treatment. Together, these results demonstrate lorcaserin is rapidly absorbed, has high oral bioavailability, and a moderate half-life (25,26). Further studies investigating the pharmacokinetic properties of lorcaserin have been described as well. Specifically, lorcaserin levels measured in the plasma and

cerebrospinal fluid (CSF) after 0.3-6mg/kg subcutaneous injection in Sprague-Dawley rats were directly proportional to the dose injected (29). Additionally, Arena Pharmaceuticals also measured sex-specific differences in lorcaserin treatment in rats and found plasma drug levels were higher in females compared to males (30). Similar pharmacokinetics were also observed in reports on the cynomolgus monkey, where maximal absorption of lorcaserin was observed less than 3.5 hours after administration, along with high oral bioavailability in a dose-dependent manner (30).

Despite the inhibitory activity lorcaserin displays on human cytochrome P2D6, the potential for drug-drug interactions is low since numerous CYP enzymes are involved in the drug's metabolism (12). Evidence also indicates lorcaserin increases the expression of certain CYP enzymes, suggesting that long-term exposure to the drug may increase its metabolism. Furthermore, lorcaserin displays moderate protein-binding capabilities around 60-76%, and the major elimination route of the drug and its metabolites (primarily N-carbomoyl glucuronide lorcaserin) is through the urine. (12).

## Lorcaserin clinical trials

The initial submission of lorcaserin for FDA approval in 2009 was denied, as treatment of the drug to rats was associated with the increased risk of developing several types of cancers compared to placebo-treated rats (9). However, the drug was eventually approved by the FDA in 2012, and this approval was primarily due to a few studies from 2010-2011: the behavioral modification and lorcaserin for overweight and obesity management (BLOOM) study, behavioral modification and lorcaserin for overweight and obesity management in patients of diabetes mellitus type 2 (BLOOM DM) study, and the BLOSSOM investigation, which was a 1-year non-randomized clinical trial analyzing lorcaserin's effectiveness at improving weight loss in obese or overweight adults.

The BLOOM trial was a double-blind, placebo-controlled clinical trial measuring the effects of lorcaserin in weight management. 3,182 obese or overweight individuals were randomly chosen to receive 10mg of lorcaserin twice a day for 1 year. Notably, these patients also received diet and exercise counseling. After 52 weeks, patients in the lorcaserin group were reassigned either to continue receiving the medication or to switch to placebo (31). After 1 year, 47.5% of lorcaserin-treated individuals lost 5% or more of their body weight compared to 20.3% in the placebo group. The increase in body weight lost in the lorcaserin group persisted when comparing it with placebo-treated patients after 2 years as well. Finally, of the over 3000 patients observed, no serious effects (specifically, cardiac valvulopathy, which was previously reported) were attributed to lorcaserin administration, and the most frequently described side effects were headache, dizziness, and nausea (31). Results from the BLOOM study provided the initial clinical framework for lorcaserin's use as a promising weight loss medication together with lifestyle modifications.

The BLOOM-DM investigation evaluated the efficacy and safety of lorcaserin for weight loss in type 2 diabetic patients. Similar to the BLOOM trial, BLOOM-DM consisted of a 1-year randomized, placebo-controlled trial with over 600 patients (2). Patients (mean age of 52.7) were administered either placebo, 10mg of lorcaserin daily or 10mg lorcaserin twice/day. After the 1-year treatment period, more patients from the lorcaserin-treated groups lost at least 5% body weight compared to the placebo group (32). Furthermore, lorcaserin improved glycemic control in patients with type 2 diabetes, as demonstrated by the greater decrease in HbA(1c) levels in the lorcaserin-treated patients compared to placebo (32). Reports of adverse events were consistent with previous clinical trials as well and consisted of headaches, back pain, and nausea.

The BLOSSOM trial was a one-year randomized, placebo-controlled, double-blind clinical trial that included over 4,000 obese or overweight patients between 18-65 years old. The treatment groups were the same as in the BLOOM-DM trials (placebo, 10mg lorcaserin once/day, or 10mg lorcaserin twice/day) (33). Similar to previous observations, 47.2% of individuals given lorcaserin twice daily for a year lost at least 5% of their initial body weight compared to only 25.0% of patients given the placebo (33). Importantly, the group given lorcaserin once per day showed significant improvements in body weight loss compared to placebo as well (40.2% of patients). Along with the BLOOM and BLOOM-DM trials, the BLOSSOM study also reported adverse effects of headache, nausea, and dizziness, but no associations with valvulopathy as measured by echocardiography.

Together, these three trials led to FDA approval of lorcaserin as an anti-obesity medication. However, upon the FDA's review of the safety of lorcaserin, it has since been removed from the market. This review was announced after further analysis of the Cardiovascular and Metabolic Effects of Lorcaserin in Overweight and Obese Patients – Thrombolysis in Myocardial Infarction 61 (CAMELLIA-TIMI 61) clinical trial data indicated patients receiving lorcaserin were diagnosed with cancer more often compared to patients given the placebo (34). The CAMELLIA-TIMI 61 clinical trial was a randomized, double-blind, placebo-controlled trial of over 12,000 overweight or obese patients with a history of cardiovascular disease, and the major goal of the study was to evaluate any associations between lorcaserin and cardiovascular disease. Individuals were treated with 10mg of lorcaserin twice per day or given placebo, and the primary safety analysis indicated no differences between the groups concerning risk for cardiovascular events (34). However, upon further observation the trial displayed that 7.7% of lorcaserin-treated patients were diagnosed with cancer compared to only 7.1% in the placebo group. Furthermore, cancer-associated mortality rates were higher in the lorcaserin group as well, as 0.9% of the patients died from cancer compared to 0.6% of individuals given the placebo (34). Importantly, the cancer-causing effects were only observed with longer duration lorcaserin use (between 180-

900 days), as there were no differences in cancer risk after 180 days of use when compared with the placebo group. The study concluded that risk for developing specific types of cancers may be associated with lorcaserin use as well, including pancreatic, colorectal, and lung cancers (10).

## Concluding remarks

The CAMELLIA-TIMI 61 data indicates lorcaserin increases cancer development after long-term use, but finds no such association in the short term (namely, 180 days). These data suggest lorcaserin has some potential as an acute medication to help manage food intake and body weight in obese or overweight individuals struggling to lose weight. The risk for developing cancer and cancer-related mortality rates should not be ignored, nor should the adverse psychological effects, dizziness, and nausea commonly associated with lorcaserin use. Currently, the FDA has approved five drugs for weight management in obese/overweight individuals, including orlistat (Xenical, Alli), phentermine-topiramate (Qsymia), naltrexone-bupropion (Contrave), liraglutide (Saxenda), and semaglutide (Wegovy). However, reports have described adverse (and some serious) side effects associated with most of these medications as well, such as cancer, mental disorders, and cardiovascular events. Thus, while the past decade has seen a substantial increase in weight-loss research and medications to combat the obesity epidemic, there is still much more work to be done.

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# Evaluation and Approach of a Painful Quiet (Non-Red) Eye: A Comprehensive review for Primary Health Care Physicians

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## Abstract

Different eye signs or symptoms seen in primary health care clinics and emergency departments may indicate the urgency for advanced and specialized care from ophthalmologists. Eye pain is one of the commonest complains encountered in various age groups and for that it is essential for health care providers to be aware of alarming features of eye pain and how to deal with it plus knowing when referral to an ophthalmologist is indicated. In many cases, isolated pain with no other signs and clear examination may lead to underestimation or misdiagnose of critical situation in which vision-saving can be a matter of time. Subsequently, this review article is provided to primary health care physicians and non-specialized caregivers who might face similar cases. In this review, differential diagnosis of pain in clear quiet eyes have been discussed briefly pointing out most relevant history and examination points, risk factors, treatment options and expected outcomes or prognosis of each differential.

**Key words:** Quiet Eye, painful, differential diagnosis, Saudi Arabia, normal examination.

## Introduction

Eye pain is one of the most common complaints that present to primary care and family medicine clinics and emergency departments (1). Differential diagnosis of this kind of pain can be a true challenge, especially when the examined eye appears normal and with transient, mild, or no findings at all (1). A key important element in similar cases is taking a detailed history, which aids in reaching a proper diagnosis or at least recognizing critical cases that require immediate intervention or consultation from an ophthalmologist (1,2). Eye pain can also be a manifestation of a neurological problem or systemic disease; thus, practitioners are advised to thoroughly study the common causes of eye pain. (2,3). In this review, the discussion starts with covering the important items of history taking and physical examination for non-specialized doctors (3). Then, the most frequently encountered causes are divided into three main categories: orbital, ocular, neurological diagnoses, and other systemic diseases common in Saudi Arabia. A typical case from each division is presented, and key historical features of the disease are discussed. Additionally, important findings on examination and appropriate management are outlined according to national studies. The eye conditions presented in this review have been sorted based on their prevalence in Saudi Arabia since some similar articles were done in other foreign countries.

## Evaluation and Approach

Initial evaluation should include several questions about vision loss or change in vision, foreign body sensation, photophobia and headache or presence or absence of eye redness either intermittent or constant (4). In all cases, potential sight-threatening conditions should be identified and dealt with as soon as possible. A careful examination can uncover these serious conditions:

Determine if the pain is in or around the eye. If the vision has changed, assess visual acuity. Check if the apparently white eye has any signs of inflammation, e.g. eye congestion localization whether it is diffuse, ciliary flush, localized or sectoral. Carefully examine the external eye, including those parts of the globe under the lids, for signs of occult trauma (subconjunctival hemorrhage), conjunctivitis, or foreign bodies. Serious sight-threatening causes of eye pain in the inflamed eye, in which the vision may or may not be reduced at the time of examination, include occult trauma, anterior uveitis, optic neuritis, acute angle closure glaucoma and, rarely, chronic glaucoma. In checking for these conditions, ask the following:

- Is there a history of recent or past trauma? (Pain after cataract or laser refractive surgery may rarely persist for weeks to months.)
- Is there evidence of trauma to the external eye and lids, e.g., in the pupil shape and reactions to light or sectoral or total iris loss?

- Examine with a bright pen torch and a direct ophthalmoscope, including the region of the globe under the eyelid. Evert the upper eyelid with a cotton bud (a useful check for foreign bodies). A retained sub-tarsal, periocular, or corneal foreign body can cause pain in an uninflamed eye. Some of the retained intraocular foreign bodies for a long period may alter the color of the iris (heterochromia).

- Is the pain of a dull, persistent, occasionally throbbing nature with headache?

This suggests migraine headache, chronic angle closure glaucoma or neovascular glaucoma, for instance, secondary to retinal vein occlusion or diabetic eye disease. Angle closure may occur in patients with shallow chamber and narrow angle.

- Is the pain of sudden onset or acute, especially on eye movement, and/or associated with visual loss?

This set of symptoms is pathognomonic for optic neuritis. Non-sight-threatening ophthalmic causes of eye pain are the most likely to present to general practice(5). These include optical causes (refractive error, eye strain), ocular surface disease (dry eye disease, Sjogren's syndrome), and a range of eyelid diseases(6).

When assessing for keratitis, clinicians should ask about several predisposing factors such as trauma and contact lenses. A contact lens history includes wearing schedule; overnight wear; contact lens hygiene protocol; use of tap water to rinse contact lenses; and swimming, using a hot tub or showering while wearing contact lenses. Bacterial and Acanthamoeba keratitis is associated with inappropriate contact lens use or care(2). Orbital cellulitis presents as unilateral erythema, swelling, proptosis and ptosis of the eyelid with associated pain with eye movement and decreased visual acuity(8). The eyelid and surrounding region should also be inspected for rashes or vesicles. Conjunctival or eyelid vesicles occur in about one-half of patients with Herpes Simplex Virus keratitis whereas herpes zoster ophthalmicus leads to associated pain and vesicular lesions appearing on a larger dermatome in a horizontal midline pattern(7). In the functional assessment, all patients presenting with eye pain should be tested for vision loss. Having the patient read a Snellen chart at a distance of 20 ft. (6 m.) is the standard test to evaluate visual acuity. Gross visual deficits are assessed using confrontational testing. The kinetic red test is performed by taking a five mm. red-topped pen and moving it inward from the boundary of each visual quadrant. This test may be combined with the more common static finger wiggle test to improve sensitivity for detecting visual field loss. This combination is the most sensitive way to assess for visual field deficit in the primary care setting (8). Determining more subtle differences such as whether vision loss is diffuse, central, or peripheral may require an ophthalmology referral for more precise testing (7). Primary care physicians are expected to examine the patient using the Snellen chart, tonometer, penlight, and fluorescein stain (7).

## Ocular Causes

### Dry Eye Disease

Dry eye disease, also known as dry eye syndrome or keratoconjunctivitis sicca, is a disease of the eye surface caused by underproduction or changes in the composition of lacrimal fluid or by increased evaporation. A diagnosis of dry eye accounts for nearly 20% of eye pain, and it represents the most common cause of eye pain(9). Dry eyes may lead to bilateral eye pain, foreign body sensation, tearing, photophobia, and occasional redness. Common causes of this condition include environmental factors (e.g., dry rooms and looking at computer screens for a long period of time), usage of contact lenses, eyelid abnormalities, and the use of medications (e.g., antihistamines, estrogens, Isotretinoin capsules and anticholinergics). Deficiencies in one of the three layers of the tear film (lipid, aqueous, and mucin) can be identified using the tear breakup time (TBUT) test(10). The general treatment is to avoid triggers (e.g., dry air), changing the environment (e.g., use of humidifiers), and the use of ocular lubricants or artificial tears in cases of aqueous or mucin layer deficiency(10). As for an inadequate lipid layer, warm compresses and fish oil supplements (e.g., Omega-3) can be used. Topical steroids and/or cyclosporin can also be used if the cause of the dryness is inflammatory(11).

### Corneal Abrasion

A corneal abrasion is a scrape or a scratch on the surface of the corneal epithelium. Its symptoms can be eye pain, red eye, tearing, decreased visual acuity, photophobia, and/or a foreign body sensation (12). Corneal injuries can result from blunt force trauma or by sharp objects (e.g., with fingernails), wearing of contact lenses, foreign body entry, or chemical/radiation burns (12, 13). The patient's detailed history and an examination of the eye using fluorescein staining are the cornerstone for reaching the diagnosis of corneal abrasion(14). Fluorescein dye can aid in the visualization and properly estimate the depth and size of the suspected abrasion (15). Visual acuity should be checked with a Snellen chart(16). The goal of treatment is to prevent bacterial infections, speed up the process of healing, and provide symptomatic relief to the patient. Identifying such injuries and removal of any retained objects is crucial to the healing process. Antibiotic prophylaxis with lubricating ointments (e.g., erythromycin or bacitracin), topical drops (e.g., ofloxacin or moxifloxacin), or a combination of both therapies can prevent any pathogenic infections from growing on the epithelial defect. Pain relief options include oral analgesics and oral nonsteroidal anti-inflammatory drugs. Extended use of topical steroids is contraindicated on account of the risk of delaying stromal healing, especially in cases of HSV infection related abrasions, masking the development of a corneal ulcer, and causing toxicity to the corneal epithelium(13, 17). Also, topical steroids should be avoided in initial management. Recent studies have found that there is no advantage in using pressure eye patches or bandage contact lenses to reduce the abrasion area and pain. Small uncomplicated corneal abrasions should

heal within approximately 24–48 hours. Recurrent corneal erosions can occur as a complication(14).

### Eye Strain

Eye strain is an emerging public complaint nowadays, especially with the digital devices being a part of daily life(18,19). A common presentation of patients is usually with an eye sore, frontal headache, and other ocular surface related symptoms like tearing and itchiness explained by the dryness of the eyes(1,18,19). Patients in some cases may suffer from other vision-related syndromes caused by viewing the computer display(18). Pains in eye strain were suggested to be muscular in origin by Duke-Elder and Tait and explained by the continuously overtaxing of the ciliary and extraocular muscles in order to maintain binocularity(19). However, other theories outweigh environmental and psychological factors(19).

Since dryness is a significant cause of eye strain, treatment options must include lubricating eye drops for mild cases(18). In some cases, oral supplements such as blueberry extract or omega-3 fatty acids can be used. Identifying any causative factors is important: in cases where eye strain is a result of computer vision syndrome or overuse of digital devices in general, it is important to initiate ergonomic practices as part of the management(18).

### Post-Refractive Surgical Pain

The relation between dry eye syndrome and refractive surgeries is well established(1). Usually patients complain of discomfort, especially in the first few months (up to 6 months) following surgery. This dissatisfaction is found in about 90% of cases and is caused by dryness (1). In LASER assisted in-situ keratomileusis (LASIK) and other refractive procedures, disturbance of tear film, which acts as a defense barrier against ocular dryness, is due to direct damage to either the lacrimal glands or the corneal nerve plexuses, responsible for blinking rate control (1). Both injuries lead to decreased lacrimal clearance and therapy dryness and discomfort(1,20). The neuropathic pain following refractive procedures is usually described as being persistent and burning in nature or compared to the sensation of a foreign body due to allodynia(1,20). Patients are usually prescribed pain control medications and lubricants to manage the discomfort(1).

### Intermittent Angle Closure

There are three types of primary angle closure glaucoma: intermittent, acute and creeping(1). Repeated episodes of rising intraocular pressure, which is characteristic of the intermittent subtype, can sometimes lead to chronic angle-closure glaucoma and other permanent complications of the anterior chamber if not identified early(21). Intermittent angle closure glaucoma is caused generally by the repeated papillary blockade and angle closure, which resolves spontaneously within 30–120 minutes and, thus, the usual physical examinations appear to be normal most of the time(1,21). An effective treatment option(21) appears to be a definitive surgical laser peripheral iridotomy with the

use of topical agents to decrease intraocular pressure. In some cases, selective laser trabeculoplasty may be used (21).

### Posterior Scleritis

This is a disease of an autoimmune inflammatory process that affects the sclera and is mainly localized to restore muscle insertions(1,22). Pain in posterior scleritis is aching in nature and frequently described as deep and significant upon eye movements or pressure applied to the eye(22). Other features of the disease include loss of visual acuity or blurred vision(2). It is a relatively rare diagnosis and has a variable presentation. Moreover, physical examination may be normal in mild cases, and the slit lamp may not show any optic disc edema or any other abnormalities(22). Therefore, imaging modalities, especially ultrasonography, should be considered in suspected cases. An ultrasonogram is a useful tool in diagnosing posterior scleritis by revealing posterior scleral thickening(22). Other concurrent autoimmune diseases may raise the suspicion of posterior scleritis in patients with similar complaints. Treatment options are limited to oral steroids in most cases; however, recurrence is common(2,22).

### Benign Essential Blepharospasm

This is a form of focal muscular dystonia that affects the co-inhibitory effect between protractor and retractor muscle groups in blinking and, thus, resulting in increased blink rate due to the continued spasms of the orbicularis oculi muscle(1,23,24). Patients usually complain of photophobia in the majority of cases accompanied by eye irritation or discomfort; women in their fifth to seventh decades are the most commonly affected individuals(23,24). The pathophysiology of the disease is still not well known; however, dysfunction of the thalamus, basal ganglia or brain stem is thought to play a part in this disease. Previously, botulism-type A toxin was used alone to treat benign essential blepharospasm. Nowadays, conservative measures like wearing sunglasses and dry eye treatments are effective in addition to oral medications prescribed for the underlying comorbidities, especially those of a psychological origin(24).

### Microbial Keratitis

Microbial keratitis is characterized by a corneal epithelial defect with underlying stromal inflammation caused by replicating microorganisms. Patients often feel significant pain and distress which is rapidly progressive(25). Microbial keratitis appropriates considerable resources in ophthalmic acute care and requires aggressive treatment to halt the disease process and limit the extent of corneal scarring, which can cause loss of vision(26). Wearing contact lenses and trauma is the most common causes of microbial keratitis among other causes associated with ocular surface disease, previous herpetic eye disease and systemic disease(25). Treatment varies depending upon the type of microbial keratitis. In initial treatment, 'shotgun therapy' a combination of antibiotics is used on the basis of local epidemiological information and an intensive treatment using a single antibiotic as directed by the results of microbiological investigation(27). Soft

contact lens and chloramphenicol is used widely in United Kingdom for conjunctival and corneal disease as prophylaxis against bacterial infection and is commonly available without prescription(28). In the United States, concern about the precipitation of aplastic anemia has led to widespread use of fluoroquinolones in such scenarios, despite the paucity of evidence linking topical chloramphenicol use to the hematologic disorder(29). Fluoroquinolones are bactericidal antibiotics and inhibit 2 bacterial enzymes required for deoxyribonucleic acid synthesis. Second-generation compounds (ciprofloxacin, ofloxacin) inhibit DNA gyrase in gram-negative organisms better than topoisomerase IV in gram-positive bacteria, leading to poorer gram-positive cover(30).

### Endophthalmitis

Endophthalmitis is a serious intraocular inflammatory disorder in result of an infection of the vitreous cavity. When infectious organisms gain entry to the eye by direct inoculation through intraocular surgery, penetrating trauma, or contiguous spread from adjacent tissues they cause exogenous endophthalmitis, whereas, endogenous endophthalmitis occurs when infectious agents are hematogenously disseminated into the eye from a distant focus of infection (31). Timing of therapy is an important factor in visual outcome of infectious endophthalmitis which can be diagnosed through various clinical presentations which helps to distinguish acute from chronic to determine an effective management plan (32). The prognosis in endophthalmitis is dependent on culture results (better prognosis for culture-negative cases), time of onset of the endophthalmitis (better prognosis for late-onset postoperative endophthalmitis), and the virulence of the pathogen (32) Patients receive either intravitreal antibiotics alone or in conjunction with steroids (33). The treatment modality is non-random in nature and based on the treatment preference of the various attending physicians (48). Intravenous antibiotics (maximum doses to allow intravitreal penetration) are considered mandatory in the treatment of endogenous endophthalmitis to treat both the eye infection as well as the original source of infection and bacteremia, if present (34). In general, intravenous antibiotics should be administered for 2 weeks for most infections, except in the case of endocarditis which usually requires at least 4 weeks of treatment (35). However, there has been considerable controversy over the use of more aggressive means in the treatment of endogenous endophthalmitis, in particular, intravitreal antibiotics and therapeutic vitrectomy (36,37).

## Orbital causes

### Graves' Ophthalmopathy

Graves' ophthalmopathy (GO) or orbitopathy is an autoimmune condition that is generally associated with Graves' disease (38). It is most associated with hyperthyroidism, but a state of euthyroid or hypothyroid may be present. Laboratory tests targeting thyroid malfunction as the cause may show decreased TSH, increased T3/T4, and, in the case of Graves' disease, increased TSH receptor antibodies (39). MRI or CT scan confirmatory

tests show exophthalmos, increased fat density and inflammation, and enlargement of the extraocular muscles. Photo documentation and imaging studies may also help in monitoring the progression of the disease. GO is usually a self-limiting disease, but intervention may be necessary in the case of severe symptoms (e.g., severe proptosis and lid retraction) or risk of complications (39,40). Treatment strategies for all patients include treating the underlying cause, e.g., hyperthyroidism, and conservative local measures such as eye protection and sleeping with the head of the bed elevated. In moderate to severe cases, high-dose IV steroids are used to reduce the production of glycosaminoglycans. Surgery is reserved for non-responders or if there is a threat to the vision of the patient (40).

### Preseptal Cellulitis

Preseptal cellulitis, also known as periorbital cellulitis, is an infection of the eyelid and periorbital soft tissue without involvement of the orbital contents (41). Most commonly, it can occur as a result of a complicated bacterial rhinosinusitis infection. Other causes include acute inflammation of the lacrimal sac (dacryocystitis), trauma, ophthalmic surgery, and even hematogenous spread from distant locations (28). Symptoms include ocular pain, eyelid swelling, and, less commonly, chemosis and fever. It is primarily a clinical diagnosis. Laboratory investigations may show leukocytosis and positive culture, though they are generally unnecessary. A CT scan will show eyelid swelling only. Treatment options include oral antibiotics and close follow-up for mild, afebrile, non-systemic cases. Generally, the incidence of complications, especially life-threatening ones, is rare (41).

### Orbital Cellulitis

Orbital cellulitis is an infection/inflammatory process that involves the tissues located posterior to the orbital septum within the bony orbit. The etiology is similar to preseptal cellulitis. The main symptoms are ptosis and ophthalmoplegia. Fever, malaise, eyelid swelling, and decreased visual acuity can also be seen. Clinical findings of reduced vision, diplopia, ophthalmoplegia, and ptosis make it distinguishable from preseptal cellulitis (42). It can affect all age groups. Like preseptal cellulitis, it is also primarily a clinical diagnosis. Laboratory investigations may show leukocytosis and positive culture results from the blood or tissue fluid. A CT scan of the orbit can confirm the diagnosis and unveil complications, e.g., orbital abscess or intracranial extension(42). Treatment options include empiric intravenous administration of antibiotics (vancomycin plus a third-generation cephalosporin or an aminopenicillin combined with a beta-lactamase inhibitor). Surgical drainage is indicated if there is an abscess(43).

### Orbital Inflammatory Pseudotumor

Orbital pseudotumor, also known as idiopathic orbital inflammation, is a clinico-pathological entity that can present as unilateral or bilateral eye pain. The cause may be inflammation of muscle (myositis), the lacrimal glands (dacryoadenitis), the sclera (scleritis), or the

trochlea (trochleitis). Symptoms include external signs such as conjunctival injection and chemosis, ptosis, ophthalmoplegia, or proptosis (44). However, patients with isolated conditions such as myositis may only present with acute or subacute orbital pain on eye movement (2). Also, patients with trochleitis may present with focal tenderness in the superonasal orbit. Direct inspection and palpation of the trochlea and lacrimal gland areas should be performed in cases of eye pain, especially when localized superotemporally or superonasally (45). The diagnosis of orbital inflammatory pseudotumor is usually not clinically difficult. Orbital ultrasound or orbital imaging (CT or MRI) may demonstrate the characteristic findings. The patient with orbital myositis has enlarged, irregular muscles usually with tendinous insertion involvement (44). Treatment includes non-steroidal anti-inflammatory agents or corticosteroids for mild and moderate-severe cases respectively. Local injection of corticosteroids may also be helpful in selected patients. The illness is often monophasic although recurrent episodes may occur. Failure to respond to medications or recurrence is a "red flag" for possible alternative etiology. Biopsy should be considered in these cases (46-50).

## Neurological causes

### Migraine Headache

Migraine is a neurological disturbance of the sensory integration of the central nervous system resulting in visual and auditory symptoms in addition to headache (9,51). The pathophysiological pathway that relates eyes to migraine is still not well-understood, but theories suggest that the eye resembles the trigeminal input to pattern the disorder. A mainstay of diagnosis is that patients usually experience transient, recurrent episodes of headaches that are disabling in the majority of cases (9). Visual signs include redness and lacrimation while symptoms are usually photophobia, light-sensitivity, and blurry vision(9). Ophthalmoplegic migraine (OM) is a rare entity that is known to combine visual symptoms with migraine headache; however, more severe complications such as oculomotor paresis are present. Thus, investigation is essential rather than relying on clinical diagnosis (51). Treatment options vary depending on trigger factors and any other underlying causes(51).

### Trigeminal Neuralgia

Trigeminal nerve transmission of direct and referred eye pain through its first branch, the ophthalmic, explains the eye involvement in many neurological conditions (9). Stabbing unilateral facial pain that is associated with numbness or other sensory symptoms is a typical presentation for patients with trigeminal neuralgia (9). Pain is usually episodic and severe and extends to involve other branches of the trigeminal nerve (9). Patients are in most cases treated with antiepileptics such as carbamazepine. If monotherapy fails, then a combination of two agents is preferred before surgical intervention (9).

### Elevated Intracranial Pressure

High intracranial pressure (ICP) can arise due to different causes like space-occupying lesions, e.g., tumor or mechanical obstruction of cerebrospinal fluid flow and many other pathologies (9,51). Bilateral eye pain or ophthalmoplegia, due to retrobulbar pain and pain with eye movement, is a distinguishing feature of high ICP diagnosis. Imaging is of great use to establish diagnosis in such cases (52). Other patients' complaints can be generalized like seizures, loss of consciousness, or symptoms indicating focal deficits (52). In some cases, the pathophysiology is unclear and thus referred to as idiopathic (9,52). Approach to patients with high ICP can be started by investigating the underlying cause and then lowering intracranial pressure through medical therapy (52).

### Optic Neuritis

Optic neuritis is an inflammation of the optic nerve that results in demyelination and can develop in patients with multiple sclerosis or be idiopathic (53). It is the most common neuropathy(53). Patients present with unilateral painful acute visual dysfunction complaining of poor color perception, central visual field defects, or relative afferent pupillary light defect (RAPD), which can be provoked or aggravated by eye movement. Treatment options vary depending on the cause (53). In cases where optic neuritis is a complication of multiple sclerosis, a neurological consultation is essential (53). In other cases, intravenous administration of steroids will aid in reducing optic disc edema and resolving the symptoms(53).

### Cluster Headache

A cluster headache is a primary headache that is neurovascular in origin and thought to be a result of the continuous activation of the trigeminal autonomic reflex (9,51). This disorder is characterized by short-lasting attacks of severe headache(41). Patients tend to present complaining of unilateral worsening headache that is localized mostly to the first division of the trigeminal nerve, which is the ophthalmic division. It is important to not misdiagnose cluster headaches as migraines since different management approaches are designed for each disorder (54,55). Other symptoms include unilateral ptosis, miosis and rhinorrhea or facial swelling. These patients are usually managed by high flow oxygen supplementation (55).

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# Knowledge of school teachers regarding Asthma in Aseer region of Saudi Arabia

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## Abstract

**Background:** Asthma is a leading cause of impairment, high health-care costs and poor quality of life for those who suffer from it. Asthma is the most prevalent chronic medical illness that schoolteachers must deal with in their students, impacting more than 10% of them. Teachers may be required to supervise inhaler administration and determine the necessity for additional treatment in acute attacks. Asthma prevalence varies greatly over the world, ranging from 1 to 20% for both children and adults.

**Methods:** The data for this cross-sectional study was acquired using a specially designed questionnaire. The questionnaire includes demographic questions as well as questions about asthma awareness and knowledge. After collection of data, it was coded and entered in the SPSS ver.20 software for analyses descriptive statistics (mean standard deviation, frequencies and percentages were computed), to measure the significance differences t test and chi-square test was used at 5% level of significance. Data was collected from the teachers of Aseer region of KSA. Ethical approval was obtained from King Khalid University, Saudi Arabia. The study duration was from January-2021 to April-2021.

**Results:** Out of a total 759 respondents, the mean (S.D.) of the respondents were 31.6(12.8). 14.2% were male while 85.8% were females. The Cronbach alpha of the questionnaire was 0.79. We have observed that age and education have a significant impact over the prevalence of Asthma awareness.

**Conclusion:** We should train our teachers by conducting series of seminars, webinars and workshops. We will also incorporate training the trainer sessions for teaching staff to enhance their skills to deal with asthma.

**Key words:** Asthma, diseases, teacher, knowledge, awareness



## Background

Asthma is a leading cause of impairment, high health-care costs, and poor quality of life for those who suffer from it. Asthma is the most prevalent chronic medical illness that schoolteachers must deal with in their students, impacting more than 10% of them (1). Teachers may be required to supervise inhaler administration and determine the necessity for additional treatment in acute attacks. Asthma prevalence varies greatly over the world, ranging from 1 to 20% for both children and adults. These significant variances are due to environmental differences between nations, as well as the use of different measurement methodologies and epidemiological definitions of asthma (2).

Asthma is one of the most frequent chronic respiratory diseases that affect children under the age of five. According to the International Study of Asthma and Allergies in Childhood, 14 percent of the world's youngsters have had asthmatic symptoms (ISAAC) (3). The prevalence of asthma in children and adolescents has been studied in Saudi Arabia. According to one study the prevalence of bronchial asthma in the southern part of Saudi Arabia is 19.5 percent at sea level and 6.9 percent at higher elevations (4-6).

A study was conducted in the United States (US) to look into asthma mortality in schools and the factors behind these deaths. It was discovered that some asthma deaths were caused by a delayed response or difficulties in deciding how to care a child with asthma symptoms by school workers.

In order to recognize the risk factors, symptoms of an exacerbation, and how to deal with an emergency; instructors play a critical role in the care of asthmatic school children (7).

Numerous studies from India, New York City, Spain, Turkey, and Bahrain revealed a lack of understanding and practice in the care of asthma in children. Training programs should enhance awareness in order to satisfy the needs of children and reduce school absence (8-10). Teachers play a critical role in recognizing and controlling asthma in schools, thus it is critical to assess their expertise in order to avoid asthma problems. The main aim of this study is to find out the awareness and knowledge of teachers regarding asthma and how to deal with it.

## Methods

The data for this cross-sectional study was acquired using a specially designed questionnaire. The questionnaire includes demographic questions as well as questions about asthma awareness and knowledge. After a series of meetings with the panel of experts, the questionnaire was created. This panel is made up of subject experts, researchers, and language experts. To measure the internal consistency of the questionnaire, Cronbach's alpha of the questionnaire was calculated. The study was conducted in the Aseer region of Saudi Arabia. The questionnaire included items related to the awareness regarding Asthma, and its symptoms, first aid, courses regarding asthma, demographic variables and awareness regarding the response to asthma.

After collection of data, data was coded and entered into SPSS ver.20 software for analyses descriptive statistics (mean standard deviation, frequencies and percentages were computed); to measure the significance differences t test and chi-square test was used at 5% level of significance. Data was collected from the teachers of Aseer region of KSA. Ethical approval was obtained from King Khalid University, Saudi Arabia. The study duration was from January-2021 to April-2021

## Results

Out of a total 759 respondents, the mean (S.D.) of the respondents were 31.6(12.8). 14.2% were male while 85.8% were female. The Cronbach alpha of the questionnaire was 0.79.

**Figure 1: Prevalence of Asthma**

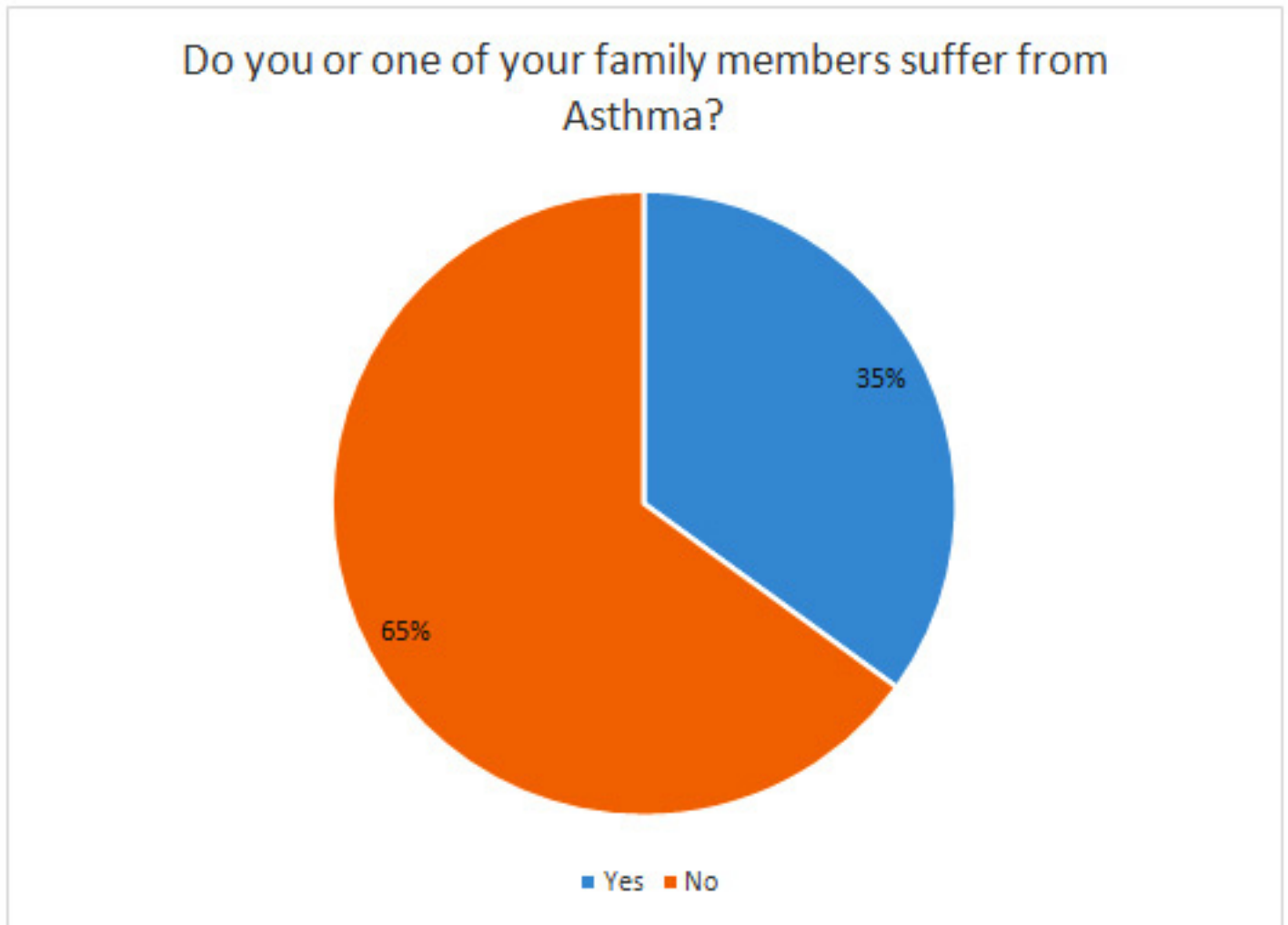


Figure 1 depicts that 35% (out of 759) of the respondents or their family members suffer from Asthma.

Table 1: Comparison between Asthma and demographical variables

Do you or one of your family members suffer from asthma?				Total
		No	Yes	
Do you live in	City	427	221	648
	Village	73	38	111
p=0.529				
Education	Bachelor's degree	411	197	608
	Certificate of Secondary Education	58	55	113
	Doctor degree	5	3	8
	Master's degree	26	4	30
p=0.001				
		No	Yes	
Age	25-34 Years	70	34	104
	35-45 Years	227	99	326
	46-55 years	170	95	265
	less than 25 years	4	1	5
	more than 55 years	29	30	59
p=0.036				
		No	Yes	
Gender	Female	425	236	661
	Male	75	23	98
p=0.10				
		No	Yes	
Income	5000-15000 SAR	320	174	494
	More than 15000 SAR	111	48	159
	up to 5000 SAR	69	37	106
p=0.499				
		No	Yes	
Married life	Married	454	229	683
	Separated	17	15	32
	Single	29	15	44
p=0.298				

In Table 1 we have compared the asthma patients with demographical variables and we have observed that age and education have a significant impact over the prevalence of the Asthma.

**Table 2: Statement about Asthma**

Which of the following is true about asthma?		
	Frequency	Percent
No response	134	17.7
A genetic disease that can be treated, a chronic disease that does not affect the heart	51	6.7
A hereditary disease that cannot be cured but that can be controlled, it is a chronic disease that does not affect the heart	54	7.1
A hereditary disease that cannot be cured, but it can be controlled	180	23.7
A hereditary disease that cannot be cured, but it can be controlled, Contagious disease, Chronic disease and no effect on the heart	1	.1
Chronic disease and no effect on the heart	116	15.3
Contagious disease	6	.8
Hereditary disease that can be cured	174	22.9
A hereditary disease that cannot be cured but that it can be controlled, it is a chronic disease that does not affect the heart	12	1.6
A hereditary disease that cannot be cured, but it can be controlled	31	4.1
<b>Total</b>	<b>759</b>	<b>100.0</b>

In Table 2, 23.7% stated that it is a hereditary disease that cannot be cured, but it can be controlled, 22.9% stated that it is a Hereditary disease that can be cured, while 15.3% stated that it is a Chronic disease and has no affect the heart

**Figure 2: Source of information regarding Asthma**

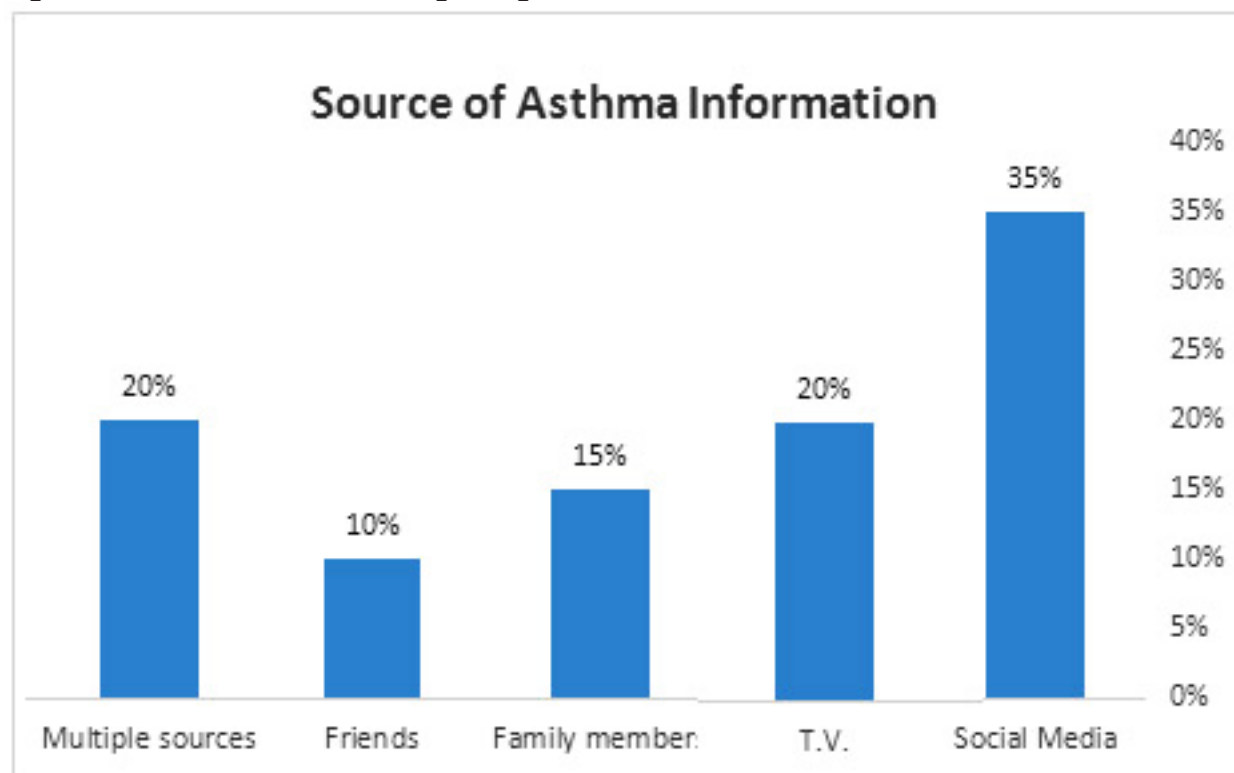
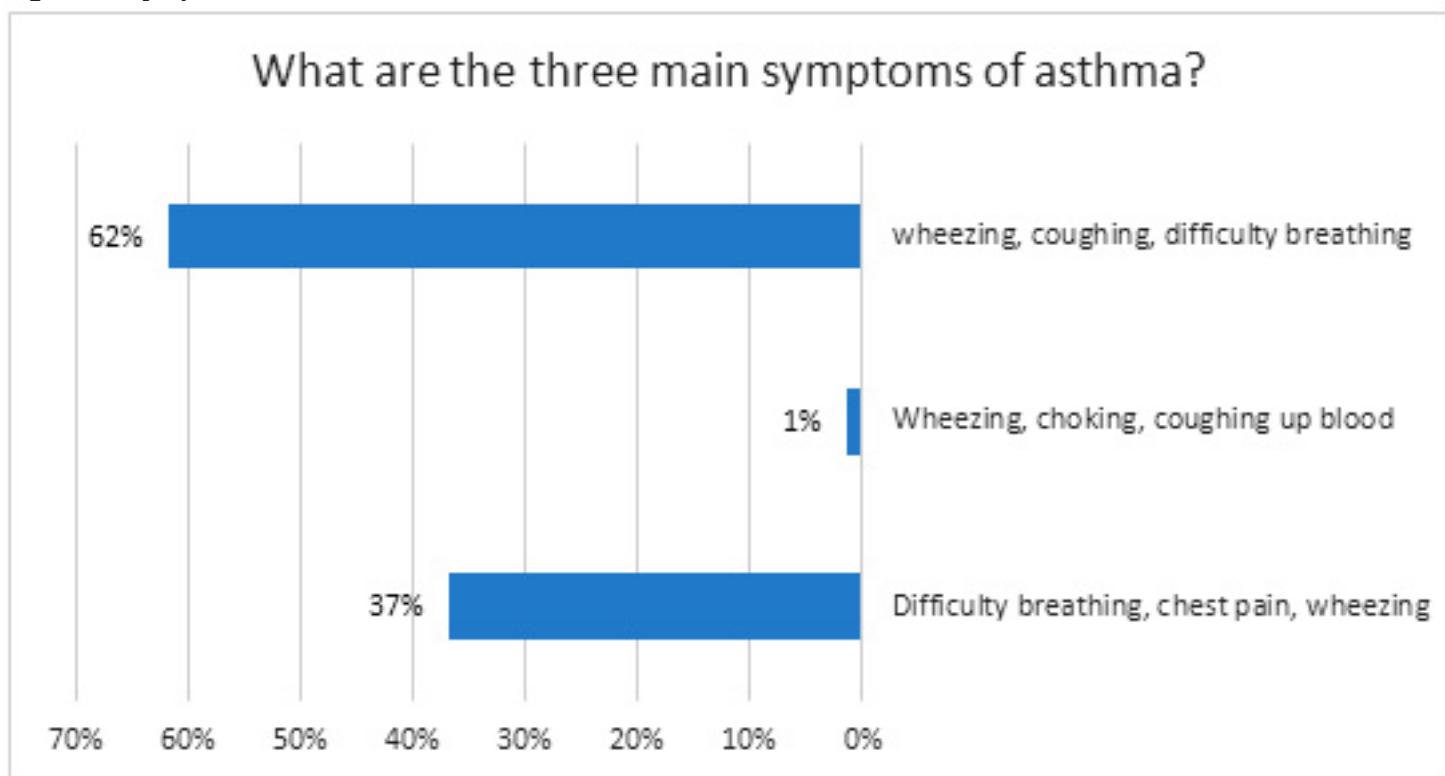


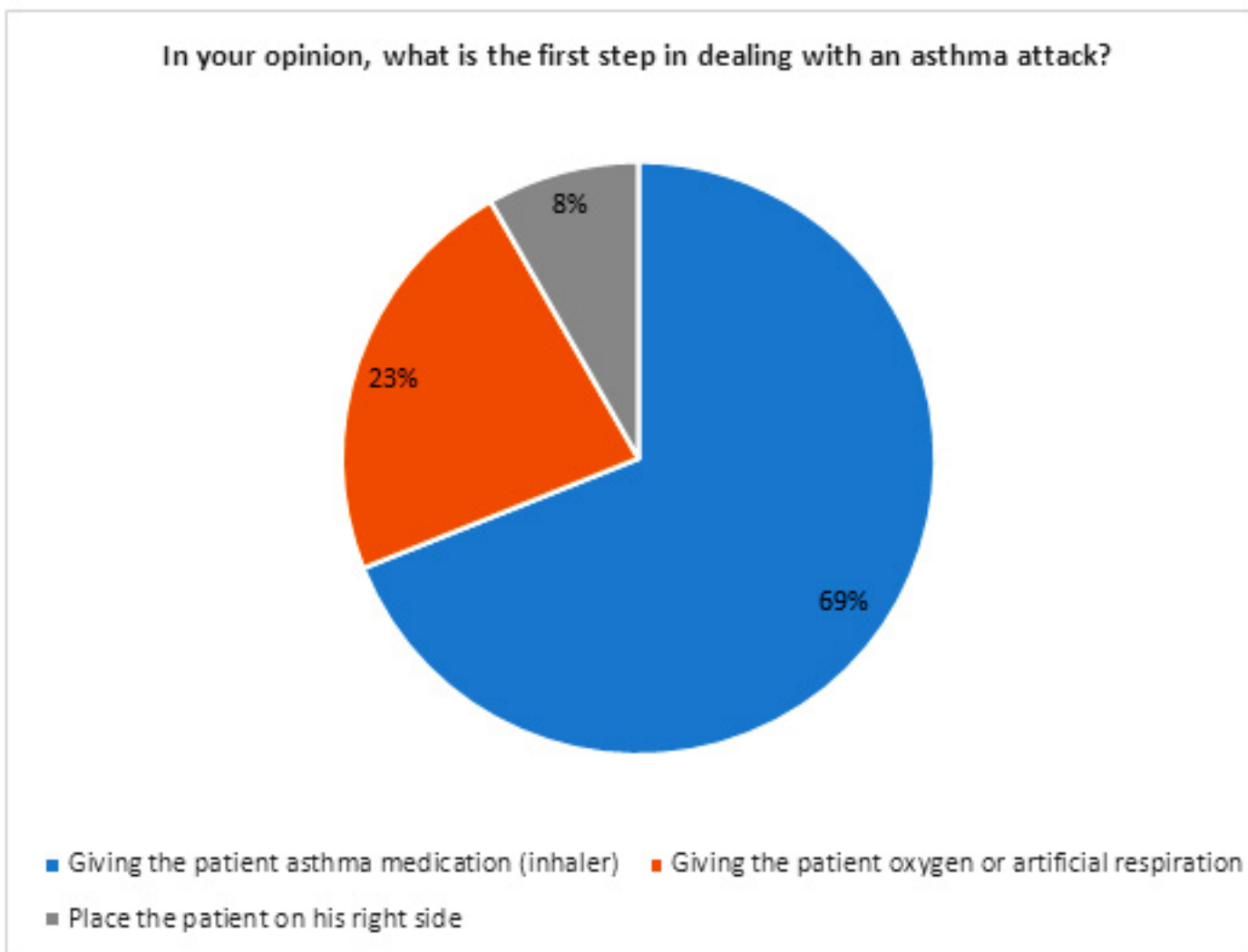
Figure 2 depicts that 35% got information regarding Asthma from social media, 20.% from TV, 20.% from multiple sources, and 15.0% and 10.% from family members and friends respectively.

Figure 3: Symptoms of Asthma



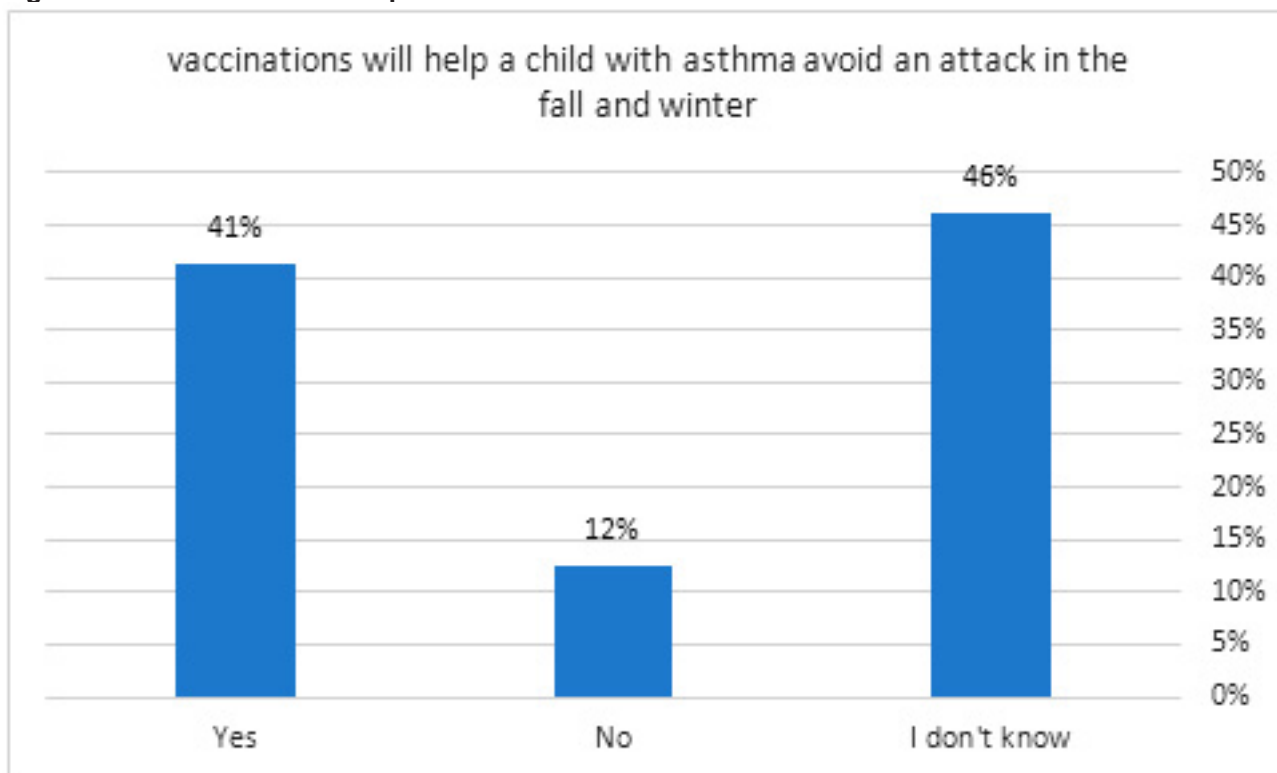
As per Table 3, wheezing, coughing, difficulty breathing were the major symptoms (62%), followed by difficulty breathing, chest pain, wheezing (37%).

Figure 4: First Aid for Asthma Attack



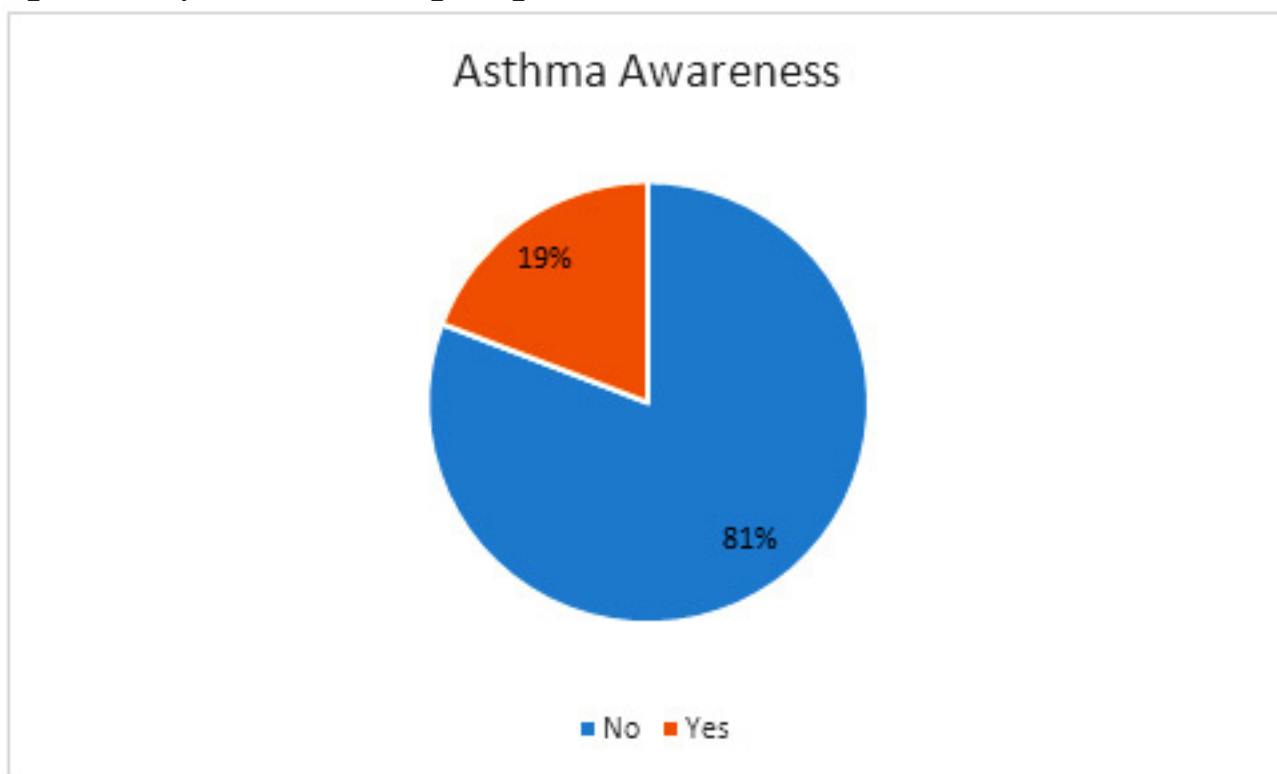
In Figure 4, we have observed that 69% of the respondents believed that inhaler is a major source of first aid, 23% believed that it was providing oxygen, while 8% believed that placing the patient on his right side is counted as a first aid option.

**Figure 5: Vaccinations will help a child with asthma avoid an attack in the fall and winter**



As per Figure 5, 41% opted yes, vaccinations will help a child with asthma avoid an attack in the fall and winter.

**Figure 6: Adequate information regarding Asthma**



As per Figure 6, only 19% had adequate information regarding asthma.

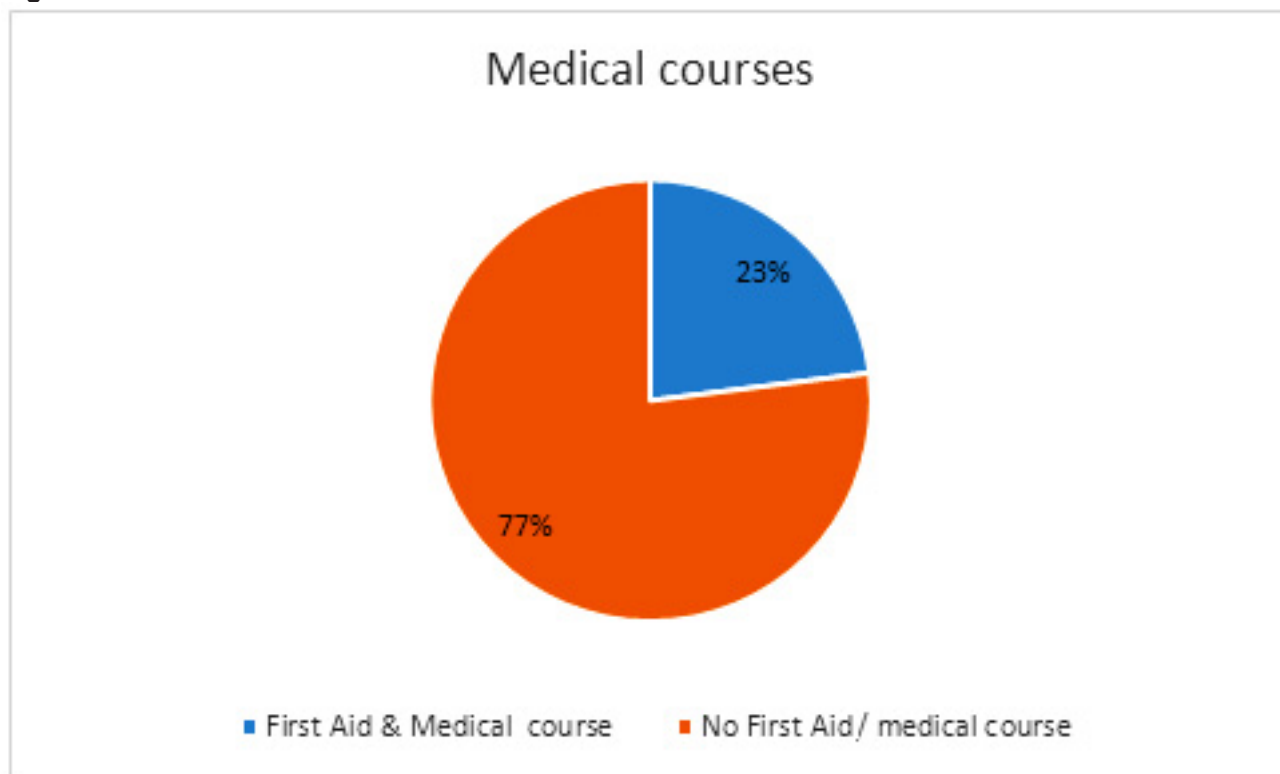
**Figure 7: Prevalence of medical / first aid courses**

Figure 7 showed that only 23% of the respondents received training regarding the medical / and first aid courses.

## Discussion

The main aim of our study was to find out the knowledge and perceptions of teachers regarding asthma. Around 300 million people worldwide suffer from asthma, with an additional 100 million expected to be impacted by 2025 (6-12). Asthma affects 5-10% of the population, or 23.4 million people, with 7 million of them being children. In our study we have also observed the prevalence of asthma diseases among teachers and their relatives was 35% out of 759 respondents, which is quite alarming; physicians and government officials should make an effort to overcome this situation (13-14).

In our study we have compared prevalence of asthma with socio-demographical variables and we have observed the significant impact of age and education on asthma knowledge while gender, income status and other demographical variables were insignificant. As mentioned in the report of American Lung Association that males (8.3% of youngsters) have current asthma at a higher rate than females (6.7 percent). However, among adults, females (9.8%) are more likely than males (5.5%) to suffer from asthma (15-16). We did not observe gender differences among asthma patients which is in contrast with the findings of the other studies. As per one study indoor allergen levels in urban households in low-income areas and those hosting numerous families are greater than in rural areas and suburbs, which is in contrast with our study findings as in our study we did not observe any significant differences among rural and urban areas. According to the 2018 American annual lung report, asthma rates were significantly higher (11.0 percent)

among those with a family income below the poverty line than those with a family income above the poverty line in 2018, which is matchable with our findings that income and asthma have a significant relationship(15-18).

A study stated that severe asthma risk increased with each year of life until the age of 45, after which it climbed at a significantly slower rate which is in line with our study.

In our study 19.% have adequate information regarding asthma, which is in line with other studies stated that up to 85% of teachers do not receive any formal asthma training during their formal education in preparation for teaching jobs (16-17).

In this study we also evaluated the knowledge regarding the symptoms of asthma among school teachers and first aid and immediate actions to overcome the panic situation and facilitate and provide relief to the patients, We have observed that there is still a lot of work required to enhance the awareness regarding the complete knowledge of asthma i.e. symptoms, first aid, how to react, and how to observe the asthmatic students.

## Conclusion

Asthma is increasing; we should train our teachers to fight it; a series of training and awareness sessions are the need of the day. We should train our teachers by conducting a series of seminars, webinars and workshops. We will also incorporate training the trainer sessions for teaching staff to enhance their skills to deal with asthma.

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