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Self-isolation during the COVID-19 pandemic is associated with increased risk of burnout among physician trainees: A cross sectional study page 112

Editorial

In this issue a number of papers dealt with common eye problems in primary care and cardiovascular issues in addition to other areas of interest to family physician.

Basheikh A., et al., Conducted a cross-sectional study among visitors of the awareness campaign about amblyopia, which took place in the Red Sea Mall, Jeddah. The authors aimed to assess the prevalence of astigmatism among the pediatric population in Jeddah, Saudi Arabia, and to assess the rate of newly detected cases (incidental astigmatism) and the associated risk factors. They examined the eyes of 347 children. The overall prevalence of astigmatism was 41.5%, whereas the prevalence of incidental astigmatism was 40.6% among 342 children without apparent astigmatism. The prevalence of incidental astigmatism was associated with a previous diagnosis of amblyopia. The authors concluded that astigmatism is highly prevalent among children in Western Saudi Arabia, with majority being undiagnosed before this screening campaign. These findings urge for further nationwide,

Almari et al., looked at the did a descriptive cross-sectional survey looking at the use of eye drops self-medication in Aseer region, Southern Saudi Arabia. A total of 209 participants completed the study questionnaire. Participants ages ranged from 18 to 65 years old with mean age of 32.9 ± 11.6 years. About persons who advised participants to use eye drops, the most reported was the person himself (34.4%; 72) followed by family and friends (29.2%), pharmacist (20.6%). The authors concluded that there is a large portion of Aseer region population practice self-medicating behavior based on their own concept or advice from friends and family most of the time, without consulting a specialized physician.

Aldhabaan W.A., et al., did a descriptive cross-sectional survey was conducted focus on all adults in Aseer region. Looking at the awareness and attitudes toward common eye diseases. A total of 1014 participants in southern region completed the survey. 23.1% of participants defined cataract as change in lens colour and 17.8% reported that it is age related disorder. Glaucoma was defined as disease that causes optic nerve damage by 22.2% of the participants while 18.6% defined the disease as condition causing diminished peri-ocular vision. In conclusion, the study revealed that overall public awareness regarding common eye diseases was very poor especially among old aged and females. The main source was family member or friend who had the disease

Basheikha, M et al., did a chart review of medical records of patients followed at King Abdul-Aziz University Hospital and diagnosed with dementia with at least one echocardiogram completed after the diagnosis of dementia. The study aimed to identify the prevalence of heart failure in patients diagnosed with dementia. A total of 200 patients met the inclusion criteria, with a mean age of 76.28 years. In 10.5% of the participants, the ejection fraction was less than 40%. The dominant type of dementia in the participants was mixed/unspecified type (78.5%). The authors concluded that the prevalence of systolic heart failure seems to be higher in patients with dementia when compared to similar age group populations reported in other studies. Multiple limitations are present in this study, and additional research is needed to further assess this possible correlation.

Farsi et al., present an excellent study on self isolation and increased burnout among physicians trainees. The authors stressed that the COVID-19 pandemic emerged in late 2019. Previous research has shown a significant prevalence of burnout among physician trainees, with concern that the pandemic will increase burnout. We aimed to assess this risk among trainees at a large academic hospital. We performed a cross-sectional study during the pandemic using a survey that included the Maslach Burnout Inventory. The response rate was 94.7%. Among trainees, 58.5% changed their living arrangements to protect family. Psychological well-being was negatively affected in 81.7% and clinical performance in 64.3%; 13.8% were at high risk of burnout. Emotional exhaustion (EE) scores were high in 50% and depersonalization (DP) scores in 28.8%; a sense of personal accomplishment was low in 41.9%. Increased risk of burnout was associated with male gender and increased exposure to suspected COVID-19 cases. Risk of high EE correlated with an increased number of children and risk of high DP with male gender. High EE and DP score correlated with increased exposure to suspected and confirmed COVID-19 patients. Trainees who self-isolated to protect family were more likely to experience high DP and burnout. Trainees in surgical specialties were more likely to feel their clinical performance was negatively affected. The results suggest that a significant percentage of trainees are at high risk of burnout during the pandemic especially those that attempted self-isolation. Training programs should incorporate methods to maintain well-being and coping, including adequate time off between shifts. Future research should evaluate other aspects of trainee well-being in relation to self-isolation and/or changed living arrangements.

AlJohani et al., reviewed the diagnostic therapeutic option of Covid-19. The global pandemic of coronavirus has resulted several manifestation of respiratory diseases. The mild common cold like illness is one of the major symptom that represents the clinical presentation of the respiratory infection. Some patients can be asymptomatic while some might have characteristic symptoms in the form of coughs, dyspnoea, and fever. Mostly it affects people aged between 30 to 79 years. major risk factors are people residing or travelling in the areas where risk of transmission is quite high, old age, and presence of comorbidities. In order to control the spreading there is four different ways quarantine the contact for at least 14 days, screening of the travellers, drive through screening centres, and temperature screening. Isolation, infection management, and the symptom management can be the most useful therapeutic approaches. Covid-19 is on a verge of constant increase and is impacting a lot of people around the globe. Currently, there is no proper treatment of covid-19 available as a result of which everyday preventive actions and vaccination are the best things that an individual can do in order to prevent the flow of covid-19.

Alsabi et al., conducted a cross sectional study included 260 female students at the King Khalid University. The aim is to know the impact of acne among female university students on their quality of life. Prevalence of acne among participant students was 87%. Its severity among 48% of participants was mild, 39.6% was moderate, while 12.3% had severe acne. The authors concluded that prevalence of facial acne is very high among students and significantly affects their QOL. During management of acne patients, health care professionals should consider its psychosocial aspect.

Hassan, A.A., et al., did a cross-sectional study was conducted at primary healthcare centers, to assess the levels of knowledge and practice regarding foot care among recently diagnosed diabetic patients.

Generally, 66% of patients had poor knowledge regarding diabetic foot, whereas only 13.6% of them had good knowledge. Good foot care practice was

observed among 52% of patients. Less than half of patients (45.2%) received health educational brochures about foot care. The authors concluded that most recently diagnosed diabetic patients in Muhayil City, Aseer Region, KSA have inadequate knowledge and poor practices regarding foot care. Intensive health education regarding diabetic foot care is highly recommended.

Alshahrani,et al., did a cross-sectional study conducted among male secondary school students in Abha City, to examine the relationship between obesity and negative emotional states among male secondary school students. The standardized Arabic version of Depression Anxiety Stress Scale (DASS-21) was used by the researchers. There were statistically significant associations between obesity and symptoms of depression, anxiety and stress ($p<0.001$ for all). 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.

Javed et al., did a multi-institutional prospective cross-sectional study at Oncology department, JPMC and Atomic Energy Medical Centre, Karachi to determine the frequency of Esophageal Carcinoma and to identify factors responsible for late stage diagnosis of this malignancy. A frequency of 3.83% of esophageal cancer was recorded. Squamous cell carcinoma as the most common (80.6%) subtype, moderately differentiated grade in 67.7% & lower 1/3rd involvement was noted in 53.8% cases. The authors concluded that Esophageal carcinoma is a common malignancy with squamous cell carcinoma as the most common subtype. Initial diagnosis of most of the patients was made in late stage. Important contributing factors of late diagnosis were unawareness of patients, delayed initial diagnostic workup, poor socioeconomic status and late referrals to oncologists by General Physicians. No significant association was observed between ethnicity and grading or staging of tumor.

Alqahtani, et al ., did a descriptive cross-sectional survey using a a self-administered questionnaire looking at the perception of food allergy among mothers. Descriptive and inferential statistics were obtained. Out of 980 mothers, 49% were suffering from food allergy, while 28.6% of their children were suffering from food allergy. Shellfish was the most common cause of food allergy (38%). The management of FA in children is improving through the acquisition of new knowledge in diagnosis and treatment. Education of physicians and food-allergic patients about FA and its treatment is becoming recognized as an unmet need

Shaheen et al., look at quality improvement project on minor head injury. The authors stressed that future management, follow up and final outcome of the injury depends on initial consultation and its clear and effective documentation. Quality of documentation after the introduction of the template was compared against the quality of previous documentation before the introduction of the template. Using NICE guidance on head injury (Jan 2014), 9 salient points in history and 8 in examination were chosen to be audited and given a tabulated form. Retrospectively, 15 medical notes were retrieved using ''System One'' (the electronic system for recording medical notes in UK). All notes were studied and audited against the chosen salient points in history and examination. Quality of notes was analysed collectively as well as individually. After 12 months, again a sample of 15 notes was collected randomly, in retrospective manner and again the clinicians' grades were kept indiscrete. Data analysed again and a remarkable improvement was demonstrated. Suggestions were made to further improve the documentation in other important areas of the clinical practice as well.

Yousuf & Mansouri attempt to define the best practice guidelines for primary prevention of cardio-vascular diseases in middle age individuals as well as the elderly. The authors reviewed RCT, clinical trials and systematic review studies published in English language from 2003-2018; in middle age individuals as well as the elderly. The total numbers of study search were 2020 studies. The authors concluded that Statin is beneficial for primary prevention of cardiovascular disease in middle age individuals as well as the elderly, who had dyslipidemia or diabetic aged 40-75years, or 10-years CVD risk =>7.5% according to AHA/ACC, or =>10% in accordance with the guidelines for both NICE and USPSTF, there is no definite evidence for non-statin therapy benefit for primary prevention of CVD but it can be used in hypercholesterolemia patients or high CVD risk patients who do not tolerate statins or not responded to the maximum dose of statins. No evidence for aspirin benefit in primary prevention of CVD in diabetics. Immediate blood pressure control is important in the primary prevention of CVD in hypertensive patients with high cardiovascular risk.

Almusa et al., did a correlational cross-sectional to assess prevalence of internet addiction with its association with insomnia and scholastic achievement among secondary school females in Abha city, Saudi Arabia. Self-administered questionnaire sheets were distributed to students in their classes. the study included 3 female students whose ages ranged from 15 to 22 years old with mean age of 16.9 ± 1.1 years. Regrading father education, 214 students' fathers were university graduated (61.5%) and 108 (31%) had secondary level of education. Regarding frequency of using social internet, 85.3% of the students reported usual use. The authors concluded that more internet addiction was a significant problem among secondary school female students affected their scholastic achievement and their life due to high stress.

Alshahrani et al., conducted cross-sectional study was conducted at primary healthcare centers to identify difficulties and barriers facing primary health care physicians in rural areas of Aseer Region, Saudi Arabia. Female physicians constituted 43.3% of respondents, age of 58.2% was 30-35 years, 54.5% were married, Only 34.3% had opportunities for on-the-job continuing medical education, 33.6% were satisfied with medical equipment and resources, and 50% were dissatisfied with their salary. Participants were less satisfied regarding several social factors, such as internet connectivity, isolation from family and relatives; received support from rural people, difficult schooling for children, but were not satisfied regarding PHCC infrastructure, their residential facilities, or earning more money. The authors concluded that serving within the rural healthcare system provides young physicians with an opportunity to build up their experience and to increase their confidence as physicians. However, important difficulties that they face are mainly social and financial. Hence, creating a health policy to safeguard the serving physicians' career and providing facilities to promote personal and social well-being needs to be considered.

Dr Patel A, conducted a cross-sectional study on a stratified proportional allocation sample, to estimate the proportion of households consuming iodized salt in the Aseer region, southwestern Saudi Arabia, and assess salt iodization's adequacy. The study included 3038 samples of table salt. Insufficient iodized table salt samples (less than 15 ppm based on the WHO/UNICEF ICCIDD classification) were observed in 22.3% (95% CI: 20.8% – 23.8%) of the samples. The study showed that the use of insufficient iodized salt in the region is still common. The accessibility of iodized salt can be achieved through iodized salt's marketing and sales. Authorities in the Aseer region should play an influential role in forbidding non-iodized salt in the local markets in the Aseer region.

Prevalence of Systolic Heart Failure in Patients with Dementia in Saudi Arabia: Single-center retrospective data review

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Abstract

Background: Dementia is one of the most common neurological diagnoses in older patients. Previous reports have proposed that heart failure could be a risk factor for dementia. Other studies have suggested that cardiovascular function could have a critical role in the pathogenesis of dementia.

Aim: This study aimed to identify the prevalence of heart failure in patients diagnosed with dementia.

Method: This was a chart review of medical records of patients followed at King Abdul-Aziz University Hospital and diagnosed with dementia with at least one echocardiogram completed after the diagnosis of dementia. Demographic variations and comorbidities of these patients were collected.

Result: A total of 200 patients met the inclusion criteria, with a mean age of 76.28 years. In 10.5% of the participants, the ejection fraction was less than 40%. The dominant type of dementia in the participants was mixed/unspecified type (78.5%).

Conclusion: The prevalence of systolic heart failure seems to be higher in patients with dementia when compared to similar age group populations reported in other studies. Multiple limitations are present in this study, and additional research is needed to further assess this possible correlation.

Key words: Systolic heart failure, dementia, Saudi Arabia

Introduction

Heart failure (HF) and dementia are prevalent medical issues in older adults [1]. HF is a complex clinical syndrome in which patients have many symptoms and signs resulting from any structural or functional cardiac issues that can give rise to the failure of the heart to provide adequate blood flow to other organs in the body [2]. It is a central issue in public health, and its prevalence is predicted to progressively increase due to aging of the overall population [3].

Of cardiovascular diseases, HF is considered the leading cause of morbidity and mortality worldwide [4, 5], and it negatively impacts quality of life, healthcare costs, and longevity [5]. The prevalence of HF in adults ranges from 1% to 2% in developed countries, with significantly higher incidence in older individuals [6]. Unfortunately, data on HF in the Arab population and developing countries in general are limited and largely absent [7].

Dementia is a common neurological diagnosis in older patients, defined as set of related symptoms that are caused by progressive brain damage in response to brain pathology. These symptoms mainly consist of progressive impairments of memory, thinking, language, and behavior, which lead to impairment of the ability to perform daily activities, and loss of independence [8, 9].

Research conducted in Sweden proposed that heart failure could be a risk factor for dementia [10]. Furthermore, previous studies have suggested that cardiovascular function in general could play a critical role in the pathogenesis of dementia [11]. However, to the best of our knowledge, little is known about the exact relationship between heart failure and dementia.

This study aimed to identify the prevalence of systolic heart failure among patients of King Abdul-Aziz University Hospital (KAUH) who were known to have dementia.

Methodology

Study Design and Setting

This retrospective correlational study was conducted by reviewing the medical records of 231 patients with dementia under the care of the Home Health Care Unit of KAUH, a tertiary referral hospital in Jeddah in the western region of Saudi Arabia.

Participants

A total of 231 medical records of patients diagnosed with dementia were identified and reviewed. Any patients with echocardiography performed after they were diagnosed with dementia were included in the study. Those without echocardiography performed after they were diagnosed with dementia were excluded.

Data Collection

Data were collected from the electronic medical record system used in KAUH and categorized into three sections: (1) demographic data (age, gender, nationality, and body mass index (BMI)), (2) clinical features (type of dementia, ejection fraction, diabetes mellitus, hypertension, and dyslipidemia), and (3) other information (smoking status and family history of dementia).

Confidentiality and Ethical approval

Ethical clearance was obtained from the Institutional Review Board of KAUH (Reference No 363-19). Access to the data was available only to one investigator. To ensure privacy and confidentiality of participants, all identifying variables were removed. Consent was waived given that no personally identifiable data were required in this survey. The survey data used to generate the findings of this study are available upon request from the corresponding author.

Data Analysis

Data were coded, checked, and entered using SPSS version 22. Categorical variables were described using frequency of occurrence. Continuous variables, including age and BMI, were described using mean and standard deviation.

Results

A total of 200 eligible patients were identified in this study, with a mean age of 76.28 years (± SD 9.556 years). The youngest patient was 52, and the oldest was 102 years old. Female patients represented 51.5%, and male patients were 48.5%.

Comorbidities were as follows: 133 (66.5%) participants were diabetic, 146 (73%) were hypertensive, 45 (22.5%) had dyslipidemia, and 11 were smokers. Table 1 shows the demographics and comorbidities of the participants.

As shown in Table 2, there were 21 patients (10.5%) with ejection fraction below 40% on at least 1 echocardiogram performed after their diagnosis with dementia.

In general, the types of dementia were as follows: 31 patients (15.5%) had Alzheimer disease, 12 (6%) had vascular dementia, and 157 (78.5%) had unspecified/mixed dementia.

There was no statistically significant evidence that the type of dementia had a true effect on development of HF, as 2 (6.5%) of the patients diagnosed with Alzheimer disease had HF, 1 (8.3%) with vascular-related dementia had HF, and 18 (11.6%) with unspecified type were found to have HF. Table 3 and Figure 1 show more detail about types of dementia and their association with HF.

Table 1: Demographic variations and comorbidities

Age		
N	200	
Mean	76.28	
Median	77.50	
Std. Deviation	9.556	
Minimum	52	
Maximum	102	
Gender	Number	Percent
male	97	48.5
female	103	51.5
Total	200	100
Comorbidities	Number	Percent
Diabetes Mellitus	133	66.5
Hypertension	146	73.0
Smoking	11	5.5
Dyslipidemia	45	22.5

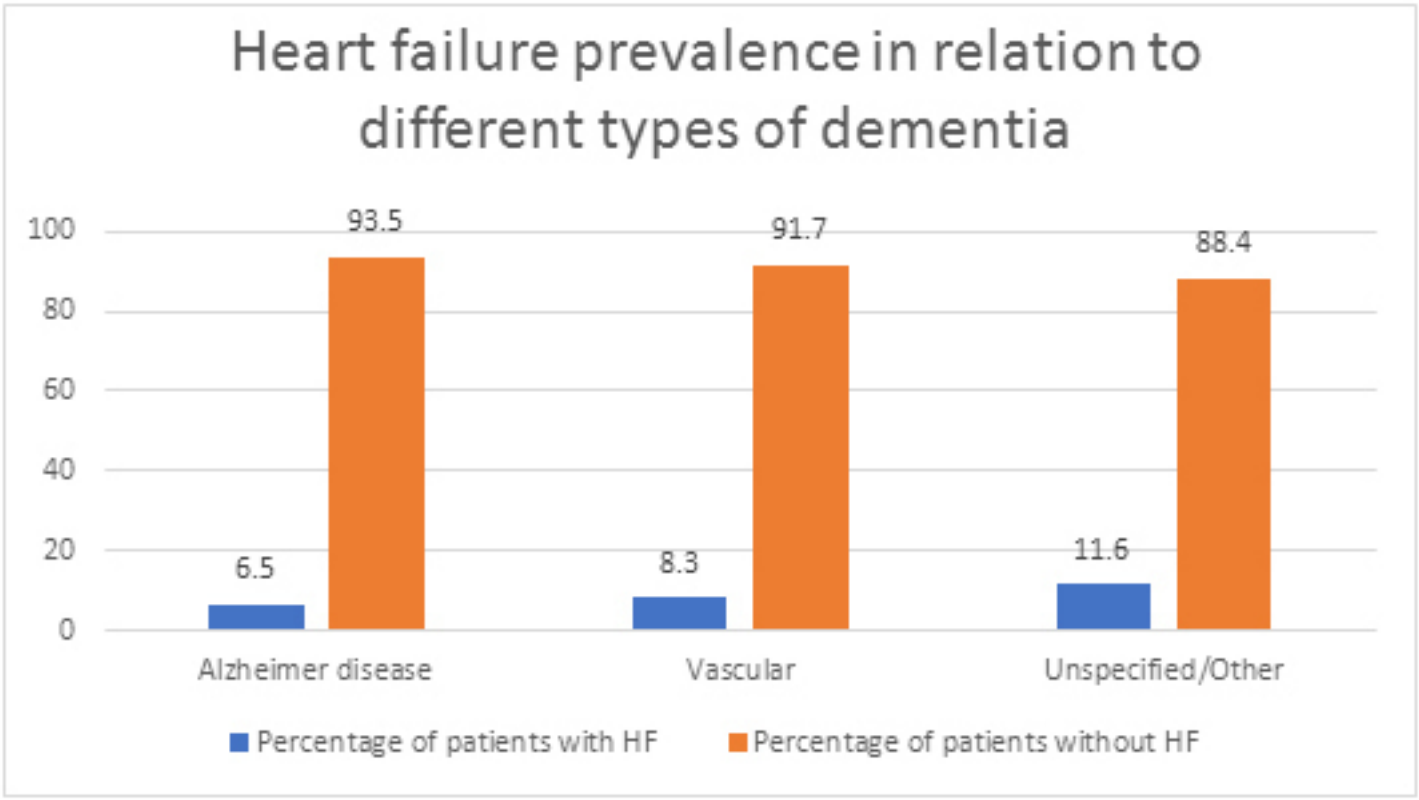
Table 2. Prevalence of HF in patients with dementia

Ejection Fraction	Frequency	Percent
Less than 40%	21	10.5
Above 40%	179	89.5
Total	200	100.0

Table 3. Heart failure prevalence in relation to different types of dementia

	Alzheimer disease	Vascular	Unspecified/mixed
Number of patients	31	12	157
Number of patients with HF	2	1	18
Number of patients without HF	29	11	139
Percentage of HF	6.5%	8.3%	11.6%

Figure 1. Relationship between HF and different types of dementia



Discussion

Heart failure is one of the main causes of morbidity, mortality, and rising public health costs [12]. Furthermore, prevalence of HF can be estimated at 1%–2% in the western world, and the incidence is approaching 5–10 per 1000 persons per year. Estimates of the occurrence of HF in the developing world are largely absent [13].

The leading cause of dementia is a topic of debate, with Alzheimer disease considered to be the leading cause in some reports [15], while in other reports, vascular dementia is reported be more prevalent [10]. This can be explained by different diagnostic criteria for each diagnosis.

Of the participants in this study, unspecified/mixed dementia was the most common (78.5%), with Alzheimer in 15.5%, and vascular-related dementia in 6%. This contrasted with a study done in Stockholm where vascular dementia was found to be the most common. It was found in 35.7% of the study population, with mixed dementia in 20.0%, and Alzheimer in 15.7% [10].

The current study found that HF was present in 10.5% of the patients diagnosed with dementia. In this study there was no control group; however, multiple reports have looked at the epidemiology of HF. One large population-based study estimated the prevalence of HF to be 8.4% in the population aged 75 years or more [6]. Although this study included an older age group compared to our group, the incidence was found to be lower.

Some studies showed that cognitive impairment and dementia were associated with a range of cardiovascular conditions, including hypertension, coronary artery disease, and atrial fibrillation [16]. Previous population-based studies suggested a possible relationship between chronic HF and cognitive impairment, independent of vascular disorders (like hypertension) and other potential confounders [17, 18].

Two other studies reported that low diastolic blood pressure (i.e., < 70 mm Hg) and a clinically significant decrease in systolic pressure were correlated with development of dementia and Alzheimer disease [19, 20]. Based on these findings, they assumed that HF could be correlated with dementia, as low blood pressure in extremely old people could be associated with poor functional status, cardiac insufficiency, and more importantly, cognitive impairment [21].

The presence of dementia in adults with chronic HF is known to be a factor that adds to the complexity of care for these patients [12]. The presence of cognitive impairment has been linked to an increase in the risk of re-hospitalization and mortality in patients with HF [22].

The type of dementia does not have a clear association with the prevalence of HF in our study, most likely due to the small number of patients diagnosed with Alzheimer and vascular dementia in comparison to mixed/unspecified type. Therefore, the association of heart failure with different types of dementia needs further assessment.

This study has some limitations. First, this is a retrospective chart study without a control group. Another limitation is incomplete documentation, as the hospital regularly accepts new patients who have not previously been seen in the clinic. Also, inaccurate data and lack of ethnicity data in medical records are unavoidable limitations.

Conclusion

The prevalence of systolic HF seems to be higher in patients with dementia when compared to similar age group populations reported in other studies. Multiple limitations in this study show the need for further detailed study in the future to assess possible correlations between different types of dementia and HF.

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Astigmatism among children in Jeddah, Saudi Arabia: prevalence and associated factors

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Abstract

Background: Undiagnosed astigmatism among children may result in multiple unfavourable consequences, such as poor performance on cognitive and language tasks, reduced oral reading fluency, behavioural disorders, and amblyopia development. In contrast, astigmatism is easily correctable in young children, which highlights the need for periodic assessment of its prevalence among pediatric populations.

Purpose: This study aimed to assess the prevalence of astigmatism among the pediatric population in Jeddah, Saudi Arabia, and to assess the rate of newly detected cases (incidental astigmatism) and the associated risk factors.

Patients and methods: This cross-sectional study was conducted among visitors of the awareness campaign about amblyopia, which took place in the Red Sea Mall, Jeddah, Saudi Arabia, on January 29–30, 2016. Children aged 2–15 years were enrolled in the study to undergo noncycloplegic eye examination using an autorefractometer for measuring cylindrical refractive error (Cyl). The calculated sample size for the studied age group of the population of Jeddah, Saudi Arabia was 291. Astigmatism was defined as Cyl ≥1 diopter in either eye. Multivariate binomial regression was used to analyze the predictors of incidental astigmatism.

Results: We examined the eyes of 347 children, mean age = 7.788 (standard deviation = 2.69) years, females = 53.3%. The overall prevalence of astigmatism was 41.5%, whereas the prevalence of incidental astigmatism was 40.6% among 342 children without apparent astigmatism. The prevalence of incidental astigmatism was associated with a previous diagnosis of amblyopia, having a sibling known to have amblyopia, and wearing spectacles. However, only wearing spectacles was shown to predict incidental astigmatism in the multivariate analysis.

Conclusion: Astigmatism is highly prevalent among children in Western Saudi Arabia, with the majority being undiagnosed before this screening campaign. These findings urge for further nationwide, population-based studies to address the burden of refractive errors among children in Saudi Arabia.

Key words: amblyopia, incidental, population, refractive error, risk factors, Saudi

Introduction

Owing to its impact on various aspects of the visual system, there has been a great deal of research concerning astigmatism since the early reports of Thomas Young and George Airy in the early 1800s (1). Astigmatism is a common type of refractive error characterized by unequal curvature of one or more refractive surfaces leading to the formation of 2 distinct focal lines of light, rather than a single focal ray on the retina. The disorder can occur at the level of the 2 principal meridia of the anterior cornea (corneal astigmatism), the posterior corneal surface and the surfaces of the crystalline lens (internal or residual astigmatism), or a combination of both entities, involving all of the ocular system (total astigmatism) (2).

Notwithstanding the significant advances in ophthalmological instrumentation and technologies that enable effective and accurate measurements of optical and shape properties, the typical etiologies of astigmatism remain elusive. The contribution of genetic factors is mostly evident in studies that reported the impact of heritable corneal power characteristics and increased risk of astigmatism in monozygotic twins compared with dizygotic twins (3). However, these results were conflicting in the literature. Therefore, environmental triggers may play a role in astigmatism development through the modulation of the mechanical interaction between the cornea and the eyelids or extraocular muscles (2). Conducting future investigations may improve our knowledge about the potential risk factors and causes of astigmatism.

Noteworthy, high degrees of astigmatism can lead to the development of amblyopia, whereas others reported correlations between myopia and astigmatism (4,5). Besides, the impact of severity and subtypes of uncorrected astigmatism on different developmental aspects is still unclear. Despite the scarcity of available investigations, astigmatic effects on visual acuity seem to start as early as the year after the first year of life (6). Therefore, children with uncorrected astigmatism would experience multiple unfavorable consequences, such as poor performance on cognitive and language tasks, reduced oral reading fluency, and increased prevalence of behavioral disorders (7,8,9).

Therefore, because astigmatism is easily correctable in young children, periodic assessment of its prevalence among pediatric populations is necessary. In addition, given that astigmatism can be compounded by the existence of multiple risk factors that increase severity degrees, it is important to get deeper insights into the risk profile and the associated triggers. This would ensure the safety of children by developing suitable interventions targeting the vulnerable risk factors to assist in reducing the burden of such a preventable disorder. In this context, this study aimed to investigate the prevalence of astigmatism among the pediatric population in Jeddah, Saudi Arabia, taking advantage of screening children while conducting a local awareness campaign about amblyopia. In addition, we aimed to assess the rate of newly detected cases (incidental astigmatism) and the associated risk factors.

Materials and Methods

Design and settings

This cross-sectional study was conducted among children who visited the awareness campaign about amblyopia, which took place in the Red Sea Mall, in Jeddah, Western region of Saudi Arabia, on January 29–30, 2016. The campaign was conducted by a group of specialized optometrists and ophthalmologists, including consultants and residents, supported by medical students and nurses. The campaign aimed to raise awareness about amblyopia among parents and companions to prompt voluntary screening and improve early detection. It was followed by a free examination of the children's eyes to screen for astigmatism or any other detectable eye disease. Written informed consent was obtained from all parents. The study was approved by the Biomedical Ethics Research Committee at King Abdulaziz University, Jeddah, Saudi Arabia.

Sampling

Sample size was calculated to determine the prevalence of astigmatism, ranging between 3.6% and 25.3%, per review of the national data,(10-15) among a target population of 850,000 children (aged 2–15 years) in Jeddah according to its most updated census conducted in 2010 by The Saudi Authority for Statistics in Saudi Arabia (www.stats.gov.sa), with 80% statistical power, 95% confidence interval, and 0.05 type I error. The largest sample size (N = 291) was considered, corresponding to the detection of highest prevalence (25.3%) (15). The sample size was increased to 400 to adjust for eventual incomplete participation or dropouts.

Using a convenience sampling method, all children aged 2–15 years were enrolled by approaching their parents or companions. The study aims and procedure were explained, and the consenting companions were invited to submit the accompanied child to an ophthalmological screening examination. Children with multiple eye surgeries or with severe chronic eye diseases (e.g. cataract, glaucoma, and congenital eye malformations) were excluded.

Data collection procedure

Two stands equipped with autorefractor KR-8900 (Topcon Corp., Tokyo, Japan) were set up in one of the mall's lobbies. Moreover, 2 consultant ophthalmologists, 2 optometrists, and 3 ophthalmology residents performed the noncycloplegic eye examination. Cylindrical refractive error (Cyl) were measured. Findings were reported in an individual sheet for each child.

Other study data were collected in the same individual datasheet and comprised the child's sociodemographic and clinical characteristics such as age; gender; spectacle wearing; history of amblyopia, myopia, astigmatism, or hyperopia; amblyopia in a sibling; and the mother's and father's ages, educational level, profession and nationality. These data were analyzed as factors and predictors of incidental astigmatism.

Outcome definition

Astigmatism was defined as Cyl of ≥1 diopter (D), and a child screened positive if astigmatism was found in any of the 2 eyes, whereas mild levels of Cyl (0–0.75 D) were considered nonastigmatism. The severity of astigmatism was further categorized into moderate (Cyl = 1.00–2.00), severe (Cyl = 2.25–3.00), and extreme (Cyl > 3.00). Where both eyes of a given child were astigmatic, the eye with the highest Cyl (more severely affected eye) was considered to determine the severity level. Incidental astigmatism was defined as positive screening for astigmatism in a participant with unknown astigmatic status, that is, by exclusion of children who are already known astigmatic.

Statistical methods

The Statistical Package for Social Sciences version 21.0 for Windows (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. The participants' characteristics and Cyl measurements were analyzed using descriptive statistics. Categorical variables were summarized as frequency and percentage, and numerical variables were summarized as mean ± standard deviation (SD), and eventually median, centile (P75), and range. The prevalence of astigmatism was calculated as the percentage of children who screened positive for astigmatism during the campaign; the results are presented with 95% confidence interval (CI). The factors associated with incidental astigmatism (Cyl≥1 D) were analyzed using chi-square test or Fisher's exact test, as appropriate, for categorical variables and independent t-test for discrete variables, including the child's and parents' ages. Multivariate binomial regression was used to analyze the predictors of incidental astigmatism; results are presented as odds ratio (OR) with 95% CI. $P < 0.05$ was considered statistically significant.

Results

Participants' characteristics

A total of 401 parents or companions participated, of whom 347 (86.5%) allowed their children to undergo ophthalmological assessments. Children and parents' characteristics related to the 347 participations are presented in Tables 1 and 2. The mean age of the participating children was 7.788 (SD = 2.69) years, wherein a majority (57%) were classified in the age group 5–<10 years and 53.3% were female. Clinical data revealed that 15.6% of the children wore spectacles, with a history of amblyopia (8.1%), myopia (2.7%), and astigmatism (1.4%). A history of amblyopia in a sibling was found in 50 cases (14.4%).

Astigmatism levels as measured by cylinder curvature

Measurements of the cylinder curvature (Cyl) in pooled right (n = 317) and left (n = 307) eyes of the participating children revealed mean of 0.98 and 1.02 D, respectively, with median of 0.75 and range of 0.25–5.00 D in both eyes. By considering the worst eye in each child, the overall prevalence of moderate to extreme astigmatism was 41.5% (95% CI = 36.3–46.9), distributed as follows: moderate (26.5%), severe (8.4%), and extreme (6.6%) astigmatism. After excluding children with known astigmatism, the prevalence of incidental astigmatism was 40.6% (95% CI = 35.4–46.1%), distributed as moderate (26.3%), severe (8.5%), and extreme (5.8%) (Table 3).

Factors and predictors of incidental astigmatism

After excluding children with known diagnosis of astigmatism, the prevalence of incidental astigmatism was higher among children with a history of amblyopia (72.0% vs 38.2%, P = 0.001), those who wore spectacles (70.0% vs 32.5%, P < 0.001), and those who had a sibling afflicted with amblyopia (55.1% vs 38.2%, P = 0.026) compared with their counterparts, respectively. However, no significant difference in astigmatism detection rates was found across the age categories.

Regarding the parents' factors, low maternal educational level was associated with a higher prevalence of incidental astigmatism (51.9%) vs high educational level (38.2%), albeit not statistically significant (P = 0.063) (Table 4).

Multivariate binary regression model including significant factors indicated that incidental astigmatism was independently associated with spectacle wearing (OR = 3.60, P = 0.003) (Table 5).

Discussion

Refractive error testing during vision screening is of great diagnostic utility to identify children with visual disorders. That is, school children with mere screening results of 20/20 are still vulnerable to be diagnosed as having astigmatism and hyperopia as sources of visual discomfort (16). Therefore, this study investigated diagnostically confirmed and newly incident cases of astigmatism. The prevalence of incidental astigmatism among children was 40.6%, and it was associated with a previous diagnosis of amblyopia, having a sibling known to have amblyopia, and wearing spectacles. Furthermore, low maternal educational level was relatively associated with a higher prevalence of astigmatism. However, only wearing spectacles was shown to predict incidental astigmatism in the multivariate analysis.

The prevalence rate of astigmatism in children in our study, defined as Cyl of ≥1 D, is higher than other rates reported in the literature among the Saudi population. A review of these studies revealed prevalence rates of 20%, 3.6%, and 11% in Riyadh, Dammam, and Jazan, respectively (10,11,12). Considering astigmatism diagnosis at ≥0.75 D, Aldebasi found a 9.8% prevalence among 5,176 primary school children in Qassim province, whereas Al Wadaani et al reported a 24.5% rate in Al Hassa region (13,14). A study conducted in Medina, which defined astigmatism as >2 D in children aged 3–6 years and >1 D in children aged 6–10 years, found a prevalence of 25.3% with significant variation by age, increasing among older children (15).

The Vision in Preschoolers Study, which is a multicenter study that enrolled 4,040 participants, conducted in the United States, and defined astigmatism as ≥1.5 D, found the prevalence of astigmatism as 17% (17). They found

Table 1: Participants' characteristics (N = 347)

Parameter	Category	Frequency	Percentage
Child's data			
Age	Mean, SD	7.78	2.69
	0–<5	44	12.7
	5–<10	198	57.0
	10–15	105	30.3
Gender	Male	162	46.7
	Female	185	53.3
Has spectacles	No	266	76.7
	Yes	54	15.6
Previously diagnosed with amblyopia	No	319	91.9
	Yes		
Ophthalmological history§	None	262	75.5
	Amblyopia	28	8.1
	Myopia	9	2.7
	Astigmatism	5	1.4
	Strabismus	5	1.4
Amblyopia in a sibling	No	297	85.6
	Yes	50	14.4
Guardian	Mother	180	51.9
	Father	145	41.8
	Other	22	6.3

Because of missing data, some values do not sum up to the total.
SD, standard deviation.
§A participant may have >1 condition.

Table 2: Participants' parents characteristics (N = 347)

Parameter	Category	Frequency	Percentage
Mother's data			
Age	Mean, SD	34.53	5.58
Educational level	Illiterate	3	0.9
	Primary	16	4.6
	Secondary	35	10.1
	Diploma/college	8	2.3
	University	278	80.1
	Not specified	7	2.0
Profession	Housewife	201	57.9
	Employed	90	25.9
	Retired	1	0.3
	Not specified	55	15.9
Nationality	Saudi	176	50.7
	Non-Saudi	130	37.5
Father's data			
Age	Mean, SD	40.53	6.54
Educational level	Illiterate	3	0.9
	Primary	6	1.7
	Secondary	32	9.2
	Diploma/college	21	6.1
	University	281	81.0
	Not specified	4	1.1
Profession	Unemployed	1	0.3
	Employed	337	97.1
	Retired	3	0.9
	Not specified	6	1.7
Nationality	Saudi	174	50.1
	Non-Saudi	133	38.3

Because of missing data, some values do not sum up to the total.
SD, standard deviation.

Table 3: Assessment of astigmatism in the study population

Parameter/Statistics	Population			
	Right eye (n = 317)	Left eye (n = 307)	Child§ (Overall, N = 347)	Child§ (Incidental, N = 342)
Cyl (diopter)				
Mean	0.98	1.02	-	
SD	0.90	0.91	-	
Median	0.75	0.75	-	
P75	1.25	1.25	-	
Range	0.25, 5.00	0.25, 5.00	-	
Astigmatism (Cyl, diopter)				
None (0.00)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)
Mild (<1.00)	202 (63.7)	187 (60.9)	203 (58.5)	203 (59.4)
Moderate (1.00–2.00)	72 (22.7)	75 (24.4)	92 (26.5)	90 (26.3)
Severe (2.25–3.00)	26 (8.2)	29 (9.4)	29 (8.4)	29 (8.5)
Extreme (>3.00)	16 (5.1)	15 (5.0)	23 (6.6)	20 (5.8)

§The eye with the worst level of astigmatism was considered per child. Values in the lower part of the table are frequency (percentage); percentages were calculated by the specified number in each population.

that the risk of astigmatism varies by ethnicity, being higher in Hispanic, African American, and Asian races than non-Hispanic white Americans. They also found that astigmatism was higher in older children. Moreover, Hashemi et al.(18) did a systematic review and meta-analysis to estimate the global prevalence of refractive errors. They estimated the global astigmatism prevalence in children as 14.9% with considerable variation among different studies (0.3% to 91%). When the estimated pooled prevalence was calculated according to the World Health Organization regions, the highest was seen in the Americas (27.2%), followed by the Eastern Mediterranean region (20.4%), and the lowest was seen in Southeast Asia (9.8%). They reported that astigmatism was the most common refractive error in children.

The variation in astigmatism prevalence figures in children across different global and local studies may be attributed to the differences in cutoff definitions of astigmatism, ethnic variations, socioeconomic conditions, and environmental factors. We used a cutoff astigmatism definition of 1 D according to a study conducted by Wang et al.(19) which found that visual acuity impairment occurred with astigmatism at ≥1.00 D and suggested a cutoff Cyl of ≥1.00 D for clinically significant astigmatism. Because astigmatism prevalence increases with age, the inclusion of older children in our study (the majority being aged ≥5 years) may partly explain the higher prevalence than those reported in local studies with younger pediatric populations (13,15,17). Another possible explanation is that our study was conducted in Jeddah, Saudi Arabia, wherein most residents come from different ethnic backgrounds compared with other regions in Saudi Arabia. Another factor that might explain this high prevalence is the presence of a selection bias, that is, the awareness campaign might have been more attractive to parents who have children with eye complaints and/or eye diseases.

In this study, a tabletop autorefractor was used to measure astigmatism in children without cycloplegia. This will not likely affect the results of measured astigmatism prevalence than that measured by cycloplegic retinoscopy, as there are many studies that have suggested that noncycloplegic autorefraction may have a role as a screening tool for astigmatism among young children (20,21,22,23). These studies found that there is minimal difference between the cylinder power when measured with noncycloplegic autorefraction (tabletop or handheld) and that measured with cycloplegic retinoscopy. This is likely explained by the fact that accommodation, which is triggered by the autorefractor near stimulus, does not affect the cylinder magnitude.

In the current study, astigmatism was associated with a personal history of amblyopia, which is consistent with the literature documenting astigmatism as a risk factor of developing amblyopia. Sjostrand and Abrahamsson (24) found that children with constant or increased astigmatism between 1 and 4 years of age were more likely to develop amblyopia. Similarly, in more recent cross-sectional investigations, astigmatism has been considered a risk factor of subsequent amblyopia (25,26). It was suggested that astigmatism during early visual development (>2 years of age) may lead to a specific form of meridian visual deprivation (meridional amblyopia) and visual cortex alterations. Based on the magnitude of astigmatism and the following meridional variations, patients may experience reductions in Vernier acuity, grating acuity, and contrast sensitivity (27). Therefore, young infants with astigmatism who do not undergo emmetropization

Table 4: Factors associated with incidental astigmatism (N = 342)

Factor	Category	Astigmatism				*P* value
		None or mild		Yes (moderate+)		
		Frequency	%	Frequency	%	
Child's factor						
Age category	0–<5	22	51.2	21	48.8	
	5–<10	118	60.2	78	39.8	
	10–15	63	61.2	40	38.8	0.452
Gender	Male	94	59.1	65	40.9	
	Female	109	59.6	74	40.4	0.934
Previously diagnosed with amblyopia	No	196	61.8	121	38.2	
	Yes	7	28.0	18	72.0	0.001*
Has spectacles	No	179	67.5	86	32.5	
	Yes	15	30.0	35	70.0	<0.001*
Sibling afflicted with amblyopia	No	181	61.8	112	38.2	
	Yes	22	44.9	27	55.1	0.026*
Mother's factors						
Age	Mean, SD	34.42	5.93	34.82	4.98	0.545
Educational level	Low	25	48.1	27	51.9	
	High	175	61.8	108	38.2	0.063
Professional status	Housewife	121	60.2	80	39.8	
	Employed	55	64.7	30	35.3	0.474
Nationality	Saudi	100	58.1	72	41.9	
	Non-Saudi	83	63.8	47	36.2	0.315
Father's factors						
Age	Mean, SD	40.45	6.54	40.70	6.57	0.756
Educational level	Low	25	64.1	14	35.9	
	High	176	58.9	123	41.1	0.531
Nationality	Saudi	100	58.8	70	41.2	
	Non-Saudi	81	60.9	52	39.1	0.714

Because of missing data, some values do not sum up to the total.
SD, standard deviation.
*Statistically significant result (P < 0.05).

Table 5: Predictors of incidental astigmatism (N = 342)

Predictor	OR	95% CI		*P* value
Previously diagnosed with amblyopia	1.17	0.36	3.79	0.796
Has spectacles	3.60	1.55	8.35	0.003*
Sibling afflicted with amblyopia	1.43	0.70	2.93	0.325

Multivariate binary regression; dependent variable: presence of incidental astigmatism.
*Statistically significant result (P < 0.05).
CI, confidence interval
OR, odds ratio

during the first years of life would typically develop meridional amblyopia.

Spectacle wearing was another significant factor and the only predictor of incidental astigmatism. Actually, this was not surprising because spectacle lens correction is the most common method used for the clinical correction of astigmatic eyes. However, an intriguing finding in our study is that corrective spectacles predicted incidental astigmatism, which may be explained by the fact that some parents might not know the nature and type of refractive error that the glasses were dispensed to correct, owing to either lack of understanding or poor education by the ophthalmologist or optometrist who prescribed the glasses.

The functional and clinical implications of uncorrected astigmatism during a specific critical period (early childhood) underscore the importance of targeting the factors that may influence the lack of correction of these visual problems. First of all, it is imperative to enhance knowledge among families and in the community to support regular vision screening in infants and children. Notably, we found that low maternal educational level was associated with relatively higher percentage of newly diagnosed incident astigmatism, and the result approached statistical significance. This indicates that mothers with a higher educational level and subsequently who are more knowledgeable are more likely to consult an ophthalmologist and detect visual problems in their children at an earlier age. Therefore, it is necessary to establish suitable interventional programs to raise awareness and knowledge levels among low-educated parents, to screen children for astigmatism and other refractive errors at easily correctable ages. Besides, late detection of refractive errors, for example, in children older than 10–12 years, would result in poorer prognosis, because the children may have developed incurable amblyopia (15). Other factors that should be considered for optimal refractive error correction include facilitating affordable corrective lenses, enhancing adherence to wearing spectacles, and promoting affordable refractive services.

In this cross-sectional study, we were unable to investigate other potential confounders that might have affected the outcomes. Parent-reported outcomes are subject to bias or misunderstanding, which could affect the associated factors of astigmatism. Because of the study design where data was collected from participants at a mall during a 2 days awareness campaign concerning amblyopia, there is potential selection bias, which adds to this study's limitations. Therefore, conducting further studies would overcome such limitations and help reveal the potential relationships between a comprehensive panel of genetic and environmental factors and the development of astigmatism. Besides, in line with the scarce studies in Saudi Arabia, the impact of compliance to prescribing guidelines about spectacle use and need should be thoroughly investigated on the local level.

Conclusion

Astigmatism was highly prevalent among screened children in Jeddah, Saudi Arabia, and was associated with a history of amblyopia, wearing spectacles, and having a sibling with amblyopia. The reported rate (41.5%) was higher than most figures reported at the local, regional, and international levels. Besides, newly detected children with astigmatism represented 40.6% of children without apparent astigmatism. This underscores the importance of conducting additional population-based screening campaigns to address the prevalence and associated risk factors of astigmatism at a national level and to explore the levels of compliance to spectacle prescribing guidelines. Regular vision screening and educational campaigns are required to increase awareness and knowledge levels of parents and teachers at schools regarding the functional and clinical consequences of uncorrected astigmatism during visual development in children.

Ethics approval and consent to participate

Written informed consent was obtained from all parents. The study was approved by the Biomedical Ethics Research Committee at King Abdulaziz University, Jeddah, Saudi Arabia, and conducted in accordance with the ethical standards of the Declaration of Helsinki (Reference No 216-16).

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Iodine in Table Salt in the Aseer Region, Southwestern Saudi Arabia

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Abstract

Background: Iodine, a micronutrient that plays a significant role in thyroid hormone synthesis, is essential for normal neurological development. Universal Salt Iodization is a plan advocated by the WHO to ensure sufficient iodine intake by all individuals. No accurate data was available about household coverage with iodized salt and salt iodization adequacy in the Aseer region, southwestern Saudi Arabia.

Objectives: To estimate the proportion of households consuming iodized salt in the Aseer region, southwestern Saudi Arabia, and assess salt iodization's adequacy.

Methods: The study was a cross-sectional study on a stratified proportional allocation sample. The household of each child was requested to bring a teaspoonful of table salt consumed in their kitchen. The salt samples were taken in standard, small, self-sealed plastic bags. The Iodine concentration of salt was determined spectrophotometrically.

Results: The study included 3038 samples of table salt. Insufficient iodized table salt samples (less than 15 ppm based on the WHO/UNICEF ICCIDD classification) were observed in 22.3% (95% CI: 20.8% – 23.8%) of the samples. Similarly, insufficient iodized table salt samples (less than 70 ppm based on Saudi Standards, Metrology and Quality Organization "SASO" classification) were observed in 75.7% (95% CI: 74.1% – 77.2%) of the study samples. The present study showed that rural areas significantly had higher insufficient table salt samples than urban areas.

Conclusions: The study showed that the use of insufficient iodized salt in the region is still common. The accessibility of iodized salt can be achieved through iodized salt's marketing and sales. Authorities in the Aseer region should play an influential role in forbidding non-iodized salt in the local markets in the Aseer region.

Key words: Iodine; Table salt; Saudi Arabia

Introduction

Iodine (atomic weight 126.9 g/atom), a micronutrient that plays a significant role in thyroid hormone synthesis, is essential for normal neurological development [1]. Iodine is critical for healthy brain growth in the fetus and young baby. Iodine deficiency harmfully influences the well-being of females, as well as economic productivity and quality of life. It is the most widespread cause of preventable mental impairment throughout the world [2]. Despite the scarcity of necessary public figures on iodine deficiency in Saudi Arabia, the two nationwide surveys, carried out nearly two decades apart, have shown that the Saudi population has adequate iodine nutrition at the public level; however, both surveys and other regional reports showed a grade of mild to moderate iodine deficiency especially in the southern regions based in goiter prevalence [3-5].

Universal Salt Iodization (USI) is a plan advocated by the WHO and UNICEF Joint Committee on Health Policy since 1994 to ensure sufficient iodine intake by all individuals. It indicates that all food-grade salt used in home and food handling should be strengthened with iodine as a harmless and effective strategy for preventing and controlling iodine deficiency disorders in populations living in stable and emergency settings[6]. This policy has been implemented in more than 120 countries worldwide; many have virtually eradicated iodine deficiency disorders or created substantial progress in their control. Saudi Arabia adopted this strategy to recommend the first national survey about iodine deficiency disorders among the Saudi population in 1994–1995 [3]. Salt iodization starts first at the level 70–100 ppm [7], then is subsequently adjusted to a level of 15–40 ppm responding to WHO recommendation [7].

No data was available about household coverage with iodized salt and salt iodization adequacy in the Aseer region, southwestern Saudi Arabia. The current study aimed to estimate the proportion of households consuming iodized salt in the Aseer region, southwestern Saudi Arabia, and assess salt iodization's adequacy.

Subjects and Methods

Design

The study was a cross-sectional study on a representative sample of schoolchildren in the Aseer region, southwestern Saudi Arabia.

Target population

Children of the age category 8–10 years living in the Aseer region were the target group for IDD screening because of their high vulnerability [8]. WHO recommends adding a community-based sample if the proportion of children attending schools is less than 50 % [9]. In Saudi Arabia, school registration is exceeding 90%. Consequently, there was no necessity to obtain samples from external school surroundings.

Sampling and field activities

Using the WHO manual Sample Size Determination in Health Studies [10], at a 95 % confidence interval with a conservative estimate of the expected population proportion of 45 % [3], and with an absolute precision of 2 %, the smallest sample size required for the study was calculated to be 2,377 children. To counteract for a probable loss of cases, a sum sample of 3,000 children was intended to be involved. A stratified proportional allocation sample of schools was chosen. Private letters were sent to their parents, explaining the study's purpose and asking for their written consent. Children lacking parental consent were omitted. The letters also asked parents to bring a sample of table salt used in their home with their children. Likewise, the letter included a simple questionnaire to be filled in by parents regarding their children's sociodemographic conditions. Two days later, the school was reexamined for field activities.

Iodine content in table salt

The household of each child was requested to bring a teaspoonful of table salt consumed in their kitchen. The salt samples were taken in standard, small, self-sealed plastic bags. The technique mentioned by WHO [11] for salt was followed.

Determination of Iodine concentration

Inductively Coupled Plasma Mass Spectrometry (ICP-MS) is commonly used to analyze Iodine content in drinking water, clinical laboratories, and pharmaceutical sectors. In our study, the Iodine concentration was determined spectrophotometrically using Sandel-Kolthoff reaction as it has shown similar results compared to the ICP-MS method. However, ICP-MS was more sensitive [12, 13]. This assay is performed in two steps: an initial digestion step followed by a Sandell – Kolthoff reaction [14]. The digestion step involves the removal of substances that may hinder the activity of Iodine. It is achieved by treating the sample with a strong acid or a base at a high temperature. The digesting agent used in this assay was ammonium persulfate, a non-explosive, and less hazardous chemical than traditional chloric acid [15]. The Sandell-Kolthoff reaction involved reducing the yellow-colored ceric ions by arsenic ions in iodide to form a colorless ion and elemental iodine. This is time-bound to decrease in yellow color intensity measured using a spectrophotometer (Novaspec II, Biochrom Ltd. UK) at 420 nm and is plotted against a standard curve to determine iodine concentration.

Preparation of standard Iodine

The standard stock solution of iodine with a concentration of 100 µgm/mL was prepared by dissolving 0.168 gm Potassium Iodate (KIO3) in distilled water and made up to 1 L. The working standard was prepared by diluting 0.5 mL of standard stock iodine to 100 mL of distilled water in a volumetric flask. The concentration of this operating standard was 0.5 µgm/mL

Determination of Iodine content in table salt

The iodine content in the table salt was determined using the WHO recommended titration method with sodium thiosulphate and starch as an external indicator [16, 17]. A spoonful of table salt was provided from each child's family in a small self-sealed plastic bag. The titration assay involved free iodine from the salt by treating it with sulphuric acid—the free iodine released is then consumed by sodium thiosulphate while titrating. The loss of blue color is considered as the end-point. The volume of sodium thiosulphate used is then used to calculate the concentration of iodine in the salt.

Quality control of iodine measurements

A precision study was done using two samples with different iodide levels analyzed twenty times in duplicate in a single batch (intra-assay) in additional days (inter-assay). The CV measures (which ranged from 5 % to 7 %) were well inside the acceptable limits, denoting reasonable intra- and inter-assay precision. A recovery study was carried out to measure accuracy. The recovery was 97 %, ranging from 92•3 % to 102•8 %. Similarly, precision and accuracy studies were done for salt, and similar results were obtained.

Results

The present study included 3,038 samples of table salt. The present study included 2,646 samples (86.9%) from high altitude areas, and the rest (400) were from low altitude areas. Similarly, the study included 466 samples (15.3%) from rural areas, and the rest (2,576) were from urban areas.

Overall, table salt samples' iodine content ranged from 0 to 112 ppm, with an average of 47•8 ± 27•9 ppm and a median of 55.1 ppm.

Table 1 shows the distribution of table salt samples based on the WHO/UNICEF ICCIDD classification. Insufficient iodized table salt samples (less than 15 ppm) were observed in 22.3% of the study samples (95% CI: 20.8% – 23.8%). Similarly, Table 2 shows the distribution of table salt samples based on Saudi Standards, Metrology and Quality Organization "SASO" classification. Insufficient iodized table salt samples (less than 70 ppm) were observed in 75.7% of the study samples (95% CI: 74.1% – 77.2%).

Table 3 shows the factors associated with insufficient salt iodization in the region (in a binary logistic multivariable regression). The table shows that rural areas significantly had higher insufficient table salt samples by ICCD classification (aOR=4.834, 95% CI: 2.555 – 9.147) or SASO classification (aOR=2.531, 95% CI: 1.231 – 5.319). On the other hand, altitude has no significant role.

Discussion

The present study showed that insufficient iodized table salt samples (less than 15 ppm based on the WHO/UNICEF ICCIDD classification) were observed in 22.3% (95% CI: 20.8% – 23.8%) of the study samples. Similarly, insufficient iodized table salt samples (less than 70 ppm based on Saudi Standards, Metrology and Quality Organization "SASO" classification) were observed in 75.7% (95% CI: 74.1% – 77.2%) of the study samples.

The present study showed that rural areas significantly had higher insufficient table salt samples by ICCD classification (aOR=4.834, 95% CI: 2.555 – 9.147) or SASO classification (aOR=2.531, 95% CI: 1.231 – 5.319). The rural-urban difference in the present study can be explained because people use rock salt as a source of table salt being very cheap compared to other types of table salts in the market.

Iodization of salt was proposed to combat iodine deficiency disorders. Salt was selected because it is widely available, and the cost of iodization is meager, besides being useful, simple, and does not cause adverse chemical reactions. A systematic review showed that in 2000–2006, 64% of households consume adequately iodized salt throughout the Eastern Mediterranean Region. In Egypt, Lebanon, Oman, and the Syrian Arab Republic, household consumption of adequately iodized salt is at least 50%. Nevertheless, challenges remain for about 1% of Sudan's population, 28% of Iraq, and 30% in Yemen [18]. Based on the Sudan Household Health Survey (SHHS) dataset, a sample of 24,507 families was examined, and 18,786 cooking salt samples were tested for iodine levels with rapid salt-testing kits. The percentage of families using adequately-iodized salt increased from less than 1% in 2000 to 14.4% in 2012 [19].

A study in Jazan studying 311 households showed that 89.4% used insufficient table salt samples (based on SASO classifications), and the figure was 10% for WHO/UNICEF ICCIDD classification. The study showed no urban-rural differences [20].

A Saudi national study, included 4,242 salt samples. Samples were screened for iodine content using a rapid test kit (RTK). The study showed that 68.7% (95% CI: 67.3–70.1%) were found to be iodized using the RTK, the rest 31.3%, were found to be not correctly iodized. The study showed significant regional differences [7].

A study examined twenty-five data sets from eighteen population surveys which assessed household iodized salt by both the RTK and a quantitative method (i.e., titration or WYD Checker) were obtained from Asian (nineteen data sets), African (five), and European (one) countries. It showed that using RTK in assessing salt iodization is a questionable practice. The study concluded that the RTK is not suited for the assessment of adequately iodized salt coverage.

Table 1. Assessment of salt iodization in Aseer region, Saudi Arabia (based on WHO/UNICEF/ICCIDD Classification)

The iodine content of salt (ppm)	Number	%	Interpretation
<15 ppm	677	22.3	Insufficient
14-40 ppm	193	6.4	Adequate
>40 ppm	2168	71.3	Excessive
Total	3038	100	

Total 3038 100

WHO (World Health Organization), UNICEF (United Nations Children's Fund), ICCIDDs (International Council for Control of Iodine Deficiency Disorders).

Table 2. Assessment of salt iodization in Aseer region, Saudi Arabia (Saudi Standards, Metrology, and Quality Organization "SASO" Classification)

The iodine content of salt (ppm)	Number	%	Interpretation
<70 ppm	2299	75.7	Insufficient
70-100 ppm	724	23.8	Adequate
>100 ppm	15	0.5	Excessive
Total	3038	100	

Table 3. Binary logistic multivariable analysis to show factors associated with insufficient salt iodization in Aseer region, Saudi Arabia.

Factor	WHO/UNICEF ICCIDD Classification	Saudi Standards, Metrology and Quality Organization "SASO" Classification
	aOR (95% CI)	aOR (95% CI)
High vs. low altitude	0.858 (0.464 - 1.586)	0.711 (0.324 – 1.559)
Rural vs. urban	4.834 (2.555 – 9.147)	2.531 (1,203 – 5.319)

WHO (World Health Organization), UNICEF (United Nations Children's Fund), ICCIDDs (International Council for Control of Iodine Deficiency Disorders).

Quantitative assessment, such as titration or WYD Checker, is necessary to estimate adequately iodized salt coverage [21].

Conclusion

The present study results showed that the use of insufficient iodized salt in the region is still common. To tackle this problem, recommendations should stress promoting advocacy and communication and guaranteeing adequately iodized salt. Advocacy and communication play a vital part in eradicating iodine deficiency by urging and educating people at all levels about the value of iodine and iodized salt. Fruitful communication efforts need to reach out to particular audiences, including community heads, the media, schoolteachers, the general public, and schoolchildren's fathers. Universal access to iodized salt is compulsory for IDD eradication. The accessibility of iodized salt can be achieved through iodized salt's marketing and sales. Authorities in the Aseer region should play an influential role in forbidding non-iodized salt in the local markets in the Aseer region.

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Foot care among recently diagnosed diabetic patients in Muhayel, Aseer Region, Saudi Arabia

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Abstract

Background: Amputations and ulcers of foot are the main causes of disability, morbidity, physical and emotional costs among diabetics. Management of their risk factors and early recognition can delay or prevent the beginning of any adverse outcomes.
Objectives: To assess the levels of knowledge and practice regarding foot care among recently diagnosed diabetic patients.

Subjects and Methods: A cross-sectional study was conducted at primary healthcare centers belonging to the Ministry of Health, Muhayil city, Aseer Region, Kingdom of Saudi Arabia (KSA) among recently diagnosed (i.e., before two years) diabetic patients. A study questionnaire (in a simple Arabic language) was used to collect data related to personal characteristics, present history related to diabetes, fasting blood sugar control (mg/dL), provided medical care, assessment of knowledge about foot self-care and prevention of diabetic foot and assessment of patient's daily practices related to foot self-care.

Results: The study included 250 recently diagnosed diabetic patients. Males represented 55.6% of them. Only 14.8% had glycemic control, based on HbA1c level <7%. Generally, 66% of patients had poor knowledge regarding diabetic foot, whereas only 13.6% of them had good knowledge. Good foot care practice was observed among 52% of patients. Young patients (20-30 years old) were more likely to have good foot care practice than those aged over 60 years, p=0.026. Patients with heart diseases were significantly less likely to have good foot care practice compared to those without cardiac diseases, p=0.039. Patients with HbA1c<7% were significantly more likely to express good foot care practice than those with HbA1c ≥7%, p=0.006. There was a significant association between patients' knowledge about foot care and their practice, p<0.001. Regarding provided foot-related health care, 90.8% of patients reported undergoing feet examination by their physicians, 63.2% reported that physicians explained to them the importance of foot care and how to perform it (60.0%). Less than half of patients (45.2%) received health educational brochures about foot care

Conclusion: Most recently diagnosed diabetic patients in Muhayil City, Aseer Region, KSA have inadequate knowledge and poor practices regarding foot care. Intensive health education regarding diabetic foot care is highly recommended.

Key words: Diabetes mellitus, diabetic foot, foot care, knowledge, practice, Saudi Arabia.

Introduction

Diabetic foot ulceration (DFU) is one of the major common complications related to diabetes. Approximately 85% of amputations associated with diabetes are preceded by ulcerations. DFU affects about 6% of patients of diabetes and it involves ulceration, infection or destruction of foot tissues. This complication impairs the quality of life of patients and can affect their life and social participation. Almost 0.03% to 1.5% of diabetic patients undergo amputations. However, most of their foot ulcers are preventable through effective screening and sufficient foot care(1).

According to Edmonds et al., (1) foot ulcerations in diabetic patients are common and costly, and make up approximately half of hospital amputation admissions. Although there is not enough evidence that shows whether foot care education plays a key role in reducing ulceration risks, a detailed understanding of ulceration etiopathogenesis is crucial in reducing foot lesion incidence and ultimately amputations.

The International Diabetes Federation reported that between 9 to 26 million diabetic people develop foot ulcers each year (2). Diabetic foot is a foot that is affected by ulceration associated with peripheral arterial disease and neuropathy of the lower limb of diabetic patients.

Hanson (3) pointed out that risk factors in diabetic foot development include cigarette smoking, diabetic neuropathy, previous ulceration of foot or amputation, peripheral vascular disease, ischemia of both large and small blood vessels, and diabetic nephropathy. The beginning of foot ulcer may cause swelling, pain, numbness, gangrene forms and deformity. Standard treatment of diabetic foot involves wound debridement, infection management, revascularization procedures and off-loading of ulcer.

Feet are the most common body parts that receive the least importance in daily care. Amputations and ulcers of foot are the main cause of disability, morbidity, physical and emotional costs of diabetic people. Diabetics are highly prone to serious foot complications which are a leading cause of their hospitalization. About 15% of diabetics are likely to develop serious foot complications. Good practice and knowledge concerning diabetic foot care will reduce and prevent the risks of complications of diabetic foot and ultimately amputation. Knowledge deficiency of foot care and poor foot care practices are among the major risk factors for foot complications (1).

Most diabetic patients admitted for foot complications are known to have inadequate knowledge and poor practice for diabetic foot care. Shearman (2) recommended that health education about strategies of foot care should be given emphasis and must be able to empower patients of diabetes. Diabetic foot complications are the leading cause of mortality, particularly in developing countries (4).

Aim of study

To assess the levels of knowledge and practice regarding foot care among recently diagnosed diabetic patients in Muhayel City, Aseer Region, KSA.

Methodology

This study was conducted during the period between January and June 2020. Following a cross-sectional study design, a total of 250 diabetic patients, registered at 26 primary healthcare centers belonging to the Saudi Ministry of Health, Muhayil City, Aseer Region, were included. The inclusion criteria were: being Saudi, adults, recently diagnosed (since two years or less) type 2 diabetics, and aged 20 years or more.

In each selected primary healthcare center, recently diagnosed diabetic patients were recruited consecutively. The number of patients chosen from each center was proportional to the total number of new cases registered in the center. The patients were interviewed and examined while they were waiting for their physician`s appointment at the “Chronic Diseases” clinics.

For data collection, the researchers used the study questionnaire of Al-Asmary et al (5).

It includes the following parts (in a simple Arabic language):

A- Personal characteristics: age, sex, occupation, educational and smoking status.

B- Present history related to diabetes: Duration of diabetes, associated comorbidity (e.g., obesity, hypertension, dyslipidemia), and foot-related symptoms.

C- Fasting blood sugar control (mg/dL): Fasting blood sugar control was classified as follows:

- Good (<126 mg/dL)
- Acceptable (126-180 mg/dL)
- Bad (>180 mg/dL)

D- Provided medical care: provision of health education, foot examination, referral to a podiatric clinic.

E- Assessment of knowledge about foot self-care and prevention of diabetic foot: This part included 13 questions, which covered the necessary knowledge related to foot self-care. Patients’ responses were given a score of (1) if correct, or a score of (0) if wrong or unknown. Then the total score and percentage were calculated for the knowledge part. Percentage scores of 75% or above were considered “good” knowledge level, 50-74.9% were considered as acceptable, while percentage scores <50% were considered as “bad” level of knowledge.

F- Assessment of patient’s daily practices related to foot self-care: This part included nine practice statements related to foot self-care. Patients’ responses were scored as follows: (always=4, often=3, sometimes= 2, rarely=1 or never=0). Then the total score and percentage were calculated for the practice part. Percentage scores below 50% were considered as “poor” practice, whereas scores >50% were considered as “good” practice.

The Statistical Package for Social Sciences (IBM, SPSS version 25.0) was used for data entry and analysis. Descriptive statistics were calculated using frequency and percentage for qualitative variables, or mean and standard deviation for quantitative variables. Pearson`s chi-square test was utilized to test for the association between qualitative variables, Fischer Exact test was applied instead of Chi-square test in case of small frequencies, student t-test to compare mean of a quantitative continuous variable between two different groups and one-way analysis of variance (ANOVA) test was used to compare means between more than two groups. Statistical significance was determined at p-values less than 0.05.

All the necessary official and ethical approval permissions were fully secured before data collection. Collected data were kept strictly confidential and were used only for research purposes. The ethical approval of this study was obtained from the Ethical Committee of Scientific Research-King Khaled University (ECM#2020-141)-(HAPO-06-B-001) dated 02/01/2020.

Results

Table 1 shows that 55.6% of participants were males. The age of 34.4% exceeded 60 years, whereas that of 29.2% ranged between 51 and 60 years. More than half of participants (56%) were not employed, while only 17.6% were employed. More than one-third (36.4%) were illiterate, whereas 6.4% were university graduates and above. Most participants (82.8%) were married. Prevalence of smoking among the participants was 12.4%; associated diabetes-related complications were heart disease (4%), nephropathy (4%) and retinopathy (11.2%)
Associated chronic diseases were hypertension (46%), dyslipidemia (30%) and obesity (19.6%). Diabetes control (as indicated by fasting blood sugar levels) was good among 12% of participants, acceptable among 51.2% and bad among 36.8%. Glycemic control (<7%) was fulfilled by 14.8% of patients.

Table 2 shows that among recently diagnosed diabetics, numbness, hotness and tingling, were reported by 24%, 20.8%, and 15.6%, respectively. Pain or cramps during walking were reported by 26.4% and 17.6%, respectively. Foot cracks were reported by 14.4% of patients, 4% had wounds, 2.4% had foot ulcers, while 1.2% underwent amputation.

Table 3 shows that the highest correctly known cause for diabetic foot was uncontrolled blood sugar (56.4%), whereas the lowest known was delayed diagnosis of diabetes mellitus (24.4%). The highest known diabetic foot complication was foot cracks and ulcers (48%). Most participants (74.4%) knew that diabetic foot is very dangerous. More than half of patients (58%) could recognize that they should visit a physician in case of finding a foot wound. Regarding what should be checked daily, diminished sensation, change in foot color and appearance of wounds/cracks were mentioned by 54.4%, 38.8% and 36.4%, respectively. Only 21.2% of patients knew that trimming toe-nails decreases incidence of diabetic foot.

Figure 1 shows that knowledge of 66% of patients regarding diabetic foot was bad, whereas only 13.6% had good knowledge.

Table 4 shows that patients' knowledge levels about diabetic foot did not differ significantly according to their personal characteristics.

Table 5 shows that patients' knowledge levels about diabetic foot did not differ significantly according to their disease characteristics.

Table (6) shows that 48.4% of patients reported that they examine their feet some days , whereas only 5.2% reported that they always examine their feet daily. Approximately half of patients (50.4%) reported washing their feet daily. More than one-third of patients (38.4%) reported drying their feet sometimes, especially between their toes immediately after washing, whereas only 8.4% of them always did that. More than one third of patients (36.4%) rarely apply a moisturizing agent to their skin feet, while only 6.4% always did that. Trimming of toe-nails, carefully and regularly was done sometimes by 46.4% and always by 13.2% of patients. Avoiding walking with bare-feet was done sometimes by 47.2% of patients and always by 12.8%. Checking water temperature by elbow before washing feet was always done by 6.4% of patients and rarely by 48%. Making sure that the shoes do not contain any harmful objects was rarely performed by 42.8% of patients and was always done by 10%. The choice of the proper type of shoes was always or often done by 46.8% of patients.

Figure 2 shows that good foot care practice was performed by 52% of participant diabetic patients.

Table 7 shows that diabetic patients' practices regarding foot care differed significantly according to their age groups (p=0.026), with those aged 20-30 years having the highest good level of practice and those aged over 60 years having the lowest good level of practice (71.4% and 39.5%, respectively). However, patients' practices regarding foot care did not differ significantly according to other personal characteristics.

Table 8 shows that patients with heart diseases were significantly less likely to have good foot care practices compared to those without heart diseases (53.3% versus 20%, respectively, p=0.039). Patients with HbA1c <7% were significantly more likely to express good foot care practices than those whose HbA1c ≥7% (73% versus 48.4%, respectively, p=0.006). However, other studied disease characteristics did not differ significantly regarding foot care practices according to their disease characteristics.

Table 9 shows a statistically significant association between levels of knowledge about foot care and its practice (p<0.001). Patients with good knowledge level

had the highest good level of practice, while those with bad knowledge had the lowest practice level (76.5% and 41.8%, respectively).

Table 10 shows that almost all diabetic patients were examined by their physicians for their peripheral pulses (99.6%), intact peripheral nerves (99.6%) and foot cleanliness (98.8%). However, less than half of them were examined for feet dryness (40.4%), shoes suitability (37.2%), foot ulcer/wounds (36%) or fungal infection between toes (26.8%).

Table 11 shows that, regarding provided foot-related healthcare to recently diagnosed diabetic patients among diabetic patients, the majority (90.8%) reported their feet examination being examined by physicians. Almost two-thirds (63.2%) reported that physicians explained to them the importance of foot care and how to perform it (60.0%). Less than half of them (45.2%) received health educational brochures about foot care and only 10.4% were referred for diabetic foot care in the hospital.

Discussion

In the present study, the highest known cause for diabetic foot among participants was uncontrolled blood sugar, whereas the lowest known was delayed diagnosis of diabetes mellitus. Also, the highest known complication of diabetic foot was foot cracks and ulcers and most participants knew that diabetic foot is very dangerous. Regarding the signs, diminished sensation, change in foot color and appearance of wounds/cracks were mentioned by about one-third to half of patients. However, only one-fifth of patients knew that trimming toe-nails decreases rate of diabetic foot. Overall, 66% of the recently diagnosed diabetics had bad knowledge regarding diabetic foot and only 13.6% had good knowledge.

Similar findings were observed in a recent study carried out in Iran, where 84.8% of patients had poor knowledge regarding diabetic foot (6). Also, deficient knowledge regarding foot care was observed in other studies carried out in Iraq (mean score: 6.1±2.6, out of 11),(7) Nigeria (30.1%),(8) Nepal (12.3%),(9) Iran (23.3%),(10) Thailand (mean score: 8.63±2.5 out of 15),(11) South Africa (32.4%),(12) and Malaysia (42%) (13). On the other hand, some other studies reported acceptable levels of knowledge regarding diabetic foot care(14-20).

The differences among various studies regarding reported diabetic patients' knowledge levels about foot care could be attributed to using different tools in assessing levels of knowledge or applying different training programs on diabetic foot care by healthcare professionals in various settings (16) and also the educational level of the studied subjects.

In the present study, participants' levels of knowledge did not differ significantly according to their personal or diabetes-related characteristics.

In Iraq, Saber and Daoud (7) found that diabetic patients who were obese, smoker, or with improper glycemic control had higher knowledge level about diabetic foot. In India (17) as well as another Saudi study(18), patients` educational level and duration of diabetes were significant predictors for patients' knowledge about diabetic foot.

In the present study, only 5.2% of patients reported always doing feet examination and approximately half of them reported daily washing of their feet. About one-third of patients reported drying of feet sometimes, especially between toes immediately after washing, whereas a minority of them did this always. More than one-third of patients rarely applied a moisturizing agent to the skin of their feet and sometimes trimmed their toe-nails carefully and regularly by 46.4% and always by 13.2% of them. Checking water's temperature by their elbow before washing their feet was rarely done by half of patients. Making sure that the shoes do not contain any harmful objects was done always by only 10% of patients and choice of the proper type of shoes was always or often done by half of them.

Among all these practices, finding that only half of patients reported washing of feet daily is lower than expected since people in Saudi Arabia are Muslims and have to wash their feet 5 times daily for their daily prayers. May be they considered washing feet as a separate issue from washing for praying. Also, in the present study and in accordance with another Iraqi study(7) one of the most neglected practices was drying their feet, particularly between toes after washing them.

Overall, in the present study, good foot care practice was observed among 52% of participant diabetics. Close to that, in Iran(21) 50.4% of diabetic patients expressed good performance regarding diabetic foot care. Also in accordance with the same study and others conducted in Iraq,(7) South Africa,(12) Bangladesh,(22) Tanzania,(23) and Sri Lanka,(24) there was a reported significant association between good knowledge of foot care and good level of practicing it. In a study carried out in Malaysia, 61.8% of diabetic patients had poor diabetic foot care practice (13). In Iraq,(7) moderate practice score was observed among 40% of type 2 diabetic adult patients. In Thailand(11) 60% of the patients expressed poor diabetic foot care practice.

It would be difficult to compare results of the present study with those of other studies as a result of variation between them regarding the nature of the study populations and the applied measures to assess practice.

In the current survey, younger patients, those without heart diseases and those with glycemic control (HbA1c <7%) were more likely to express good foot care practices.

In a recent Iranian study(6) history of hospital admission due to diabetic foot was a determinant of foot care good practice. In Thailand(11) gender, family history of diabetes, socio-economic status and marital status were significantly associated with levels of diabetic foot care practice among patients.

Table 1: Characteristics of recently diagnosed type-2 diabetic participants (n=250)

Characteristics	Values
Sex	
• Male	139 (55.6%)
• Female	111 (44.4%)
Age (years)	
• 20-30	7 (2.8%)
• 31-40	20 (8.0%)
• 41-50	64 (25.6%)
• 51-60	73 (29.2%)
• >60	86 (34.4%)
Occupation	
• Employee	44 (17.6%)
• Not employee	140 (56.0%)
• Retired	66 (26.4%)
Education	
• Illiterate	91 (36.4%)
• Able to read and write	61 (24.4%)
• Primary school	26 (10.4%)
• Intermediate school	25 (10.0%)
• Secondary school	31 (12.4%)
• University	16 (6.4%)
Marital status	
• Single	13 (5.2%)
• Married	207 (82.8%)
• Divorced	5 (2.0%)
• Widow	25 (10.0%)
Smoking status	
• Smoker	31 (12.4%)
• Non-smoker	219 (87.6%)
Duration of diabetes (Mean±SD)	14.3±7.3 months
Diabetes-related complications	
• Heart disease	10 (4.0%)
• Renal disease (Nephropathy)	10 (4.0%)
• Eye disease (retinopathy)	28 (11.2%)
Associated comorbidity	
• Hypertension	115 (46.0%)
• Dyslipidemia	75 (30.0%)
• Obesity	49 (19.6%)
Blood sugar control	
• Good	30 (12.0%)
• Acceptable	128 (51.2%)
• Bad	92 (36.8%)
Glycemic control (<7%)	37 (14.8%)

Table 2: Clinical findings among recently diagnosed diabetic patients

Clinical findings	No. (%)
Symptoms	
• Numbness	60 (24.0%)
• Hotness	52 (20.8%)
• Tingling	39 (15.6%)
• Pain during walking	66 (26.4%)
• Cramps during walking	44 (17.6%)
Signs/complications	
• Cracks	36 (14.4%)
• Wound	10 (4.0%)
• Ulcers	6 (2.4%)
• Amputation	3 (1.2%)

‘

Table 3: Participants’ correct responses regarding knowledge statements about diabetic foot

Knowledge statements	No.	%
Causes of diabetic foot		
- Uncontrolled blood sugar (Yes)	14	56.4
- No regular foot check-up (Yes)	100	40.0
- Delayed diagnosis of diabetes mellitus (Yes)	61	24.4
Complications of diabetic foot		
- Hotness of feet and painful sensation (Yes)	116	46.4
- Foot cracks and ulcers (Yes)	120	48.0
- Foot gangrene (Yes)	88	35.2
What is the degree of dangerousness of diabetic foot (very dangerous)	186	74.4
What to do in case of finding a foot wound? (visiting a physician)	145	58.0
What should you check daily in your feet?		
- Diminished sensation (Yes)	136	54.4
- Change in foot color (Yes)	97	38.8
- Change in foot temperature (Yes)	37	26.8
- Appearance of wounds/cracks (Yes)	91	36.4
To what extent toe-nail trimming decreases rate of diabetic foot? (always)	53	21.2

Figure 1: Levels of knowledge of recently diagnosed diabetic patients about diabetic foot

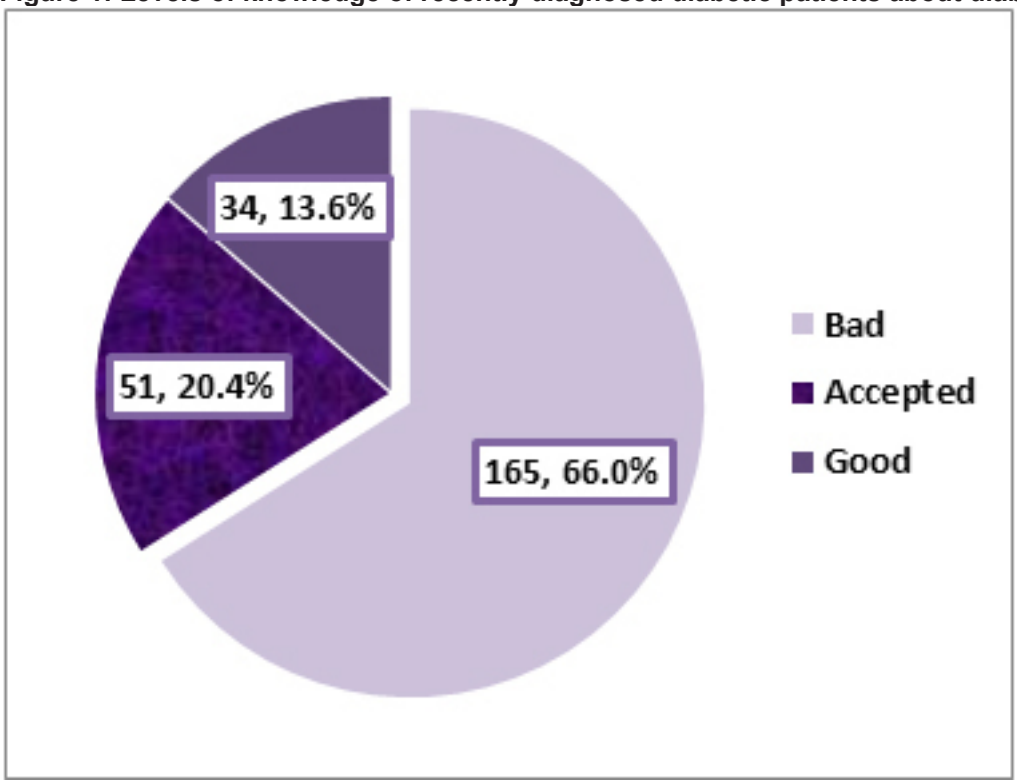

Figure 2: Levels of foot care practice by recently diagnosed diabetic patients

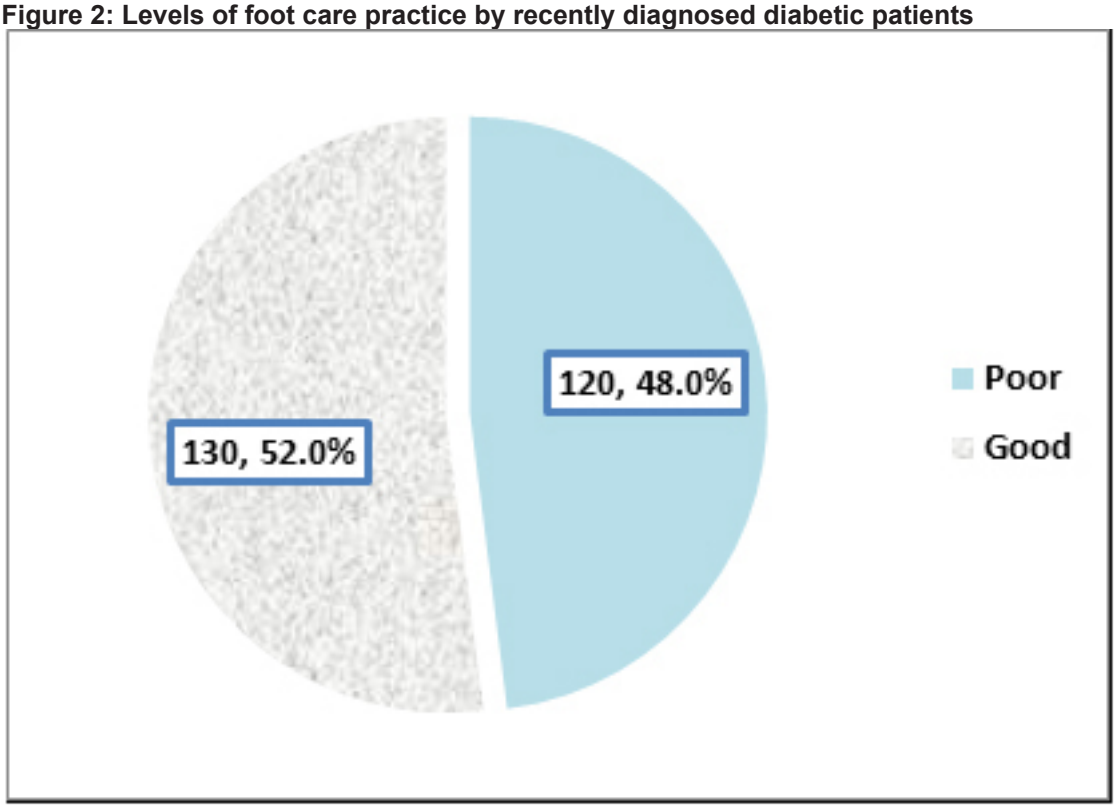

Table 4: Diabetic patients' knowledge levels about diabetic according to their personal characteristics

Personal characteristics	Levels of knowledge about diabetic foot			P value
	Bad (n=165)	Acceptable (n=51)	Good (n=34)	
Sex				
• Male (n=139)	92 (66.2%)	23 (16.5%)	24 (17.3%)	
• Female (n=111)	73 (65.8%)	28 (25.2%)	10 (9.0%)	0.068
Age (years)				
• 20-30 (n=7)	5 (71.4%)	2 (28.6%)	0 (0.0%)	
• 31-40 (n=20)	16 (80.0%)	2 (10.0%)	2 (10.0%)	
• 41-50 (n=64)	36 (56.3%)	13 (20.3%)	15 (23.4%)	
• 51-60 (n=73)	53 (72.7%)	15 (20.5%)	5 (6.8%)	
• >60 (n=86)	55 (64.0%)	19 (22.0%)	12 (14.0%)	0.168
Occupation				
• Employee (n=44)	28 (63.6%)	8 (18.2%)	8 (18.2%)	
• Not employee (n=140)	95 (67.9%)	31 (22.1%)	14 (10.0%)	
• Retired (n=66)	42 (63.6%)	12 (18.2%)	12 (18.2%)	0.452
Education				
• Illiterate (n=91)	60 (65.9%)	20 (22.0%)	11 (12.1%)	
• Able to read and write (n=61)	40 (65.6%)	11 (18.0%)	10 (16.4%)	
• Primary school (n=26)	19 (73.1%)	5 (19.2%)	2 (7.7%)	
• Intermediate school (n=25)	19 (76.0%)	5 (20.0%)	1 (4.0%)	
• Secondary school (n=31)	18 (58.1%)	7 (22.6%)	6 (19.4%)	
• University (n=16)	9 (56.2%)	3 (18.8%)	4 (25.0%)	0.759
Marital status				
• Single (n=13)	9 (69.2%)	2 (15.4%)	2 (15.4%)	
• Married (n=207)	135 (65.2%)	44 (21.3%)	28 (13.5%)	
• Divorced (n=5)	4 (80.0%)	1 (20.0%)	0 (0.0%)	
• Widow (n=25)	17 (68.0%)	4 (16.0%)	4 (16.0%)	0.960
Smoking status				
• Smoker (n=31)	21 (67.7%)	7 (22.6%)	3 (9.7%)	
• Non-smoker (n=219)	144 (65.7%)	44 (20.1%)	31 (14.2%)	0.779

Table 5: Diabetic patients' knowledge levels about diabetic foot according to their disease characteristics

Disease characteristics	Knowledge levels about diabetic foot			P Value
	Bad (n =165)	Acceptable (n =51)	Good (n=34)	
Duration of diabetes (Mean±SD)	14.1±7.5	14.9±6.6	14.2±7.2	0.789
Associated diseases				
-Hypertension				
• Yes (n=115)	75 (65.2%)	25 (21.7%)	15 (13.0%)	
• No (n=135)	90 (66.7%)	26 (19.3%)	19 (14.1%)	0.880
-Dyslipidemia				
• Yes (n=75)	50 (66.7%)	17 (22.7%)	8 (10.7%)	
• No (n=175)	115 (65.7%)	34 (19.4%)	26 (14.9%)	0.620
-Obesity				
• Yes (n=49)	37 (75.5%)	9 (18.4%)	3 (6.1%)	
• No (n=201)	128 (63.7%)	42 (20.9%)	31 (15.4%)	0.177
-Cardiac diseases				
• Yes (n=10)	7 (70.0%)	2 (20.0%)	1 (10.0%)	
• No (n=240	158 (65.8%)	49 (20.4%)	33 (13.8%)	0.939
-Renal diseases				
• Yes (n=10)	8 (80.0%)	1 (10.0%)	1 (10.0%)	
• No (n=240)	157 (65.4%)	50 (20.8%)	33 13.8%)	0.619
-Eye diseases				
• Yes (n=28)	18 (64.3%)	4 (14.3%)	6 (21.4%)	
• No (n=222)	147 (66.2%)	47 (21.2%)	28 (12.6%)	0.366
Fasting blood sugar				
• Bad (>180 mg/dL) (n=92)	57 (62.0%)	21 (22.8%)	14 (15.2%)	
• Acceptable (126-180 mg/dL) (n=128)	86 (67.2%)	25 (19.5%)	17 (13.3%)	
• Good (72-126 mg/dL) (n=30)	22 (73.3%)	5 (16.7%)	3 (10.0%)	0.828
Glycemic control				
• HbA1c<7% (n=37)	20 (54.1%)	10 (27.0%)	7 (18.9%)	
• HbA1c ≥7% (n=213)	145 (68.1%)	41 (19.2%)	27 (12.7%)	0.249

Table 6: Frequency of recently diagnosed patients` practice of foot care

	Always	Often	Sometimes	Rarely	Never
Daily examination of feet	13 (5.2%)	59 (23.6%)	121 (48.4%)	49 (19.6%)	8 (3.2%)
Washing feet daily	126 (50.4%)	87 (34.8%)	27 (10.8%)	10 (4.0%)	0 (0.0%)
Drying feet, especially between toes immediately after washing	21 (8.4%)	43 (17.2%)	96 (38.4%)	77 (30.8%)	13 (5.2%)
Regularly applying a moisturizing agent to the foot skin	16 (6.4%)	41 (16.4%)	80 (32.0%)	91 (36.4%)	22 (8.8%)
Trimming toe-nails carefully and regularly	33 (13.2%)	72 (28.8%)	116 (46.4%)	29 (11.6%)	0 (0.0%)
Avoiding walking with bare feet	32 (12.8%)	50 (20.0%)	118 (47.2%)	43 (17.2%)	7 (2.8%)
Checking water's temperature by elbow before washing feet	16 (6.4%)	25 (10.0%)	64 (25.6%)	120 (48.0%)	25 (10.0%)
Making sure that the shoes do not contain any harmful objects	25 (10.0%)	39 (15.6%)	47 (18.8%)	107 (42.8%)	32 (12.8%)
Choice of proper type of shoes	18 (7.2%)	99 (39.6%)	61 (24.4%)	36 (14.4%)	36 (14.4%)

Table 7: Diabetic patients' practice levels about diabetic foot according to their personal characteristics

Personal characteristics	Level of foot care practice		P value
	Poor N=120	Good N=130	
Sex			
• Male (n=139)	66 (47.5%)	73 (52.5%)	
• Female (n=111)	54 (48.6%)	57 (51.4%)	0.854
Age (years)			
• 20-30 (n=7)	2 (28.6%)	4 (71.4%)	
• 31-40 (n=20)	11 (55.0%)	9 (45.0%)	
• 41-50 (n=64)	23 (35.9%)	41 (64.1%)	
• 51-60 (n=73)	32 (43.8%)	41 (56.2%)	
• >60 (n=86)	52 (60.5%)	34 (39.5%)	0.026*
Occupation			
• Employee (n=44)	20 (45.5%)	24 (54.5%)	
• Not employee (n=140)	76 (54.3%)	64 (45.7%)	
• Retired (n=66)	24 (36.4%)	42 (63.6%)	0.052
Education			
• Illiterate (n=91)	48 (52.7%)	43 (47.3%)	
• Able to read and write (n=61)	31 (50.8%)	30 (49.2%)	
• Primary school (n=26)	10 (38.5%)	16 (61.5%)	
• Intermediate school (n=25)	13 (52.0%)	12 (48.0%)	
• Secondary school (n=31)	12 (38.7%)	19 (61.3%)	
• University/+ (n=16)	6 (37.5%)	10 (62.5%)	0.564
Marital status			
• Single (n=13)	5 (38.5%)	8 (61.5%)	
• Married (n=207)	103 (49.8%)	104 (50.2%)	
• Divorced (n=5)	3 (60.0%)	2 (40.0%)	
• Widow (n=25)	9 (36.0%)	16 (64.0%)	0.482
Smoking status			
• Smoker (n=31)	14 (45.2%)	17 (54.8%)	
• Non-smoker (n=219)	106 (48.4%)	113 (51.6%)	0.735

* Statistically significant

Table 8: Diabetic patients' practice levels about diabetic foot according to their disease characteristics

Disease characteristics	Level of foot care practice		P Value
	Poor N=120	Good N=130	
Duration of diabetes (Mean±SD)	14.3±7.6	14.3±7.1	0.977
Associated diseases			
- Hypertension			
• Yes (n=115)	58 (50.4%)	57 (49.6%)	
• No (n=135)	62 (45.9%)	73 (54.1%)	0.477
- Dyslipidemia			
• Yes (n=75)	34 (45.3%)	41 (54.7%)	
• No (n=175)	86 (49.1%)	89 (50.9%)	0.581
- Obesity			
• Yes (n=49)	24 (49.0%)	25 (51.0%)	
• No (n=201)	96 (47.8%)	105 (52.2%)	0.878
- Heart diseases			
• Yes (n=10)	8 (80.0%)	2 (20.0%)	
• No (n=240	112 (46.7%)	128 (53.3%)	0.039*
- Renal diseases			
• Yes (n=10)	5 (50.0%)	5 (50.0%)	
• No (n=240)	115 (47.9%)	125 (52.1%)	0.897
- Eye diseases			
• Yes (n=28)	15 (53.6%)	13 (46.4%)	
• No (n=222)	105 (47.3%)	117 (52.7%)	0.531
Fasting blood sugar			
• Bad (>180 mg/dL) (n=92)	5(54.3%)0	42 (45.7%)	
• Acceptable (126-180 mg/dL) (n=128)	57 (44.5%)	71 (55.5%)	
• Good (72-126 mg/dL) (n=30)	13 (43.3%)	17 (56.7%)	0.307
Glycemic control			
• HbA1c <7% (n=37)	10 (27.0%)	27 (73.0%)	
• HbA1c ≥7% (n=213)	110 (51.6%)	103 (48.4%)	0.006*

* Statistically significant

Table 9: Association between knowledge regarding foot care and its practice among recently diagnosed diabetic patients

Knowledge of foot care	Level of foot care practice		P value
	Poor N=120	Good N=130	
Bad (n=165)	96 (58.2%)	69 (41.8%)	
Acceptable (n=51)	16 (31.4%)	35 (68.6%)	<0.001*
Good (n=34)	8 (23.5%)	26 (76.5%)	

* Statistically significant

Table 10: Frequency of clinical feet examination items of recently diagnosed diabetics by physicians

Items of foot examination	No. (%)
Cleanliness	247 (98.8%)
Dryness	101 (40.4%)
Shoes suitability	93 (37.2%)
Fungal infection between toes	67 (26.8%)
Ulcers/wounds	90 (36.0%)
Existence of peripheral pulse	249 (99.6%)
Intact peripheral nerves	249 (99.6%)

Table 11: Provided foot-related healthcare among recently diagnosed diabetic patients

Foot-related healthcare items	No. (%)
The physicians explain the importance of foot care	158 (63.2%)
The physicians explain how to perform foot care	150 (60.0%)
Receiving health educational brochures about foot care	113 (45.2%)
Feet have been clinically examined by the physicians last year	227 (90.8%)
Referral for diabetic foot care in the hospital	26 (10.4%)

A point of strength in the present survey was that it is the first to explore this important issue in Muhayel City, Aseer Region, KSA. Nevertheless, this study has some limitations that should be declared. First, it followed a cross-sectional design, which cannot determine the direction of causal relationships. Second, the study recruited patients from primary healthcare centers belonging to the Ministry of Health, which limits the generalizability of results over other healthcare disciplines in Muhayel City.

Conclusion

Inadequate knowledge and poor practice of foot care are common among recently diagnosed diabetic patients in Muhayel City, Aseer Region, KSA and they are associated with each other. Younger patients (20-30 years), patients without cardiac diseases and those with HbA1c <7% are more likely to express good foot care practice than their counterparts. Most patients get their feet examined by a physician and most of them receive health education from their physicians regarding the importance of foot care and how to perform it. However, less than half of patients receive health educational brochures about foot care.

Recommendations

It is necessary to organize educational programs at primary healthcare centers, diabetes centers and hospitals for recently diagnosed diabetic patients focusing on aspects of diabetic foot care in order to reduce the burden of diabetic foot complications. Physicians, particularly those at primary care centers, nurses and health educators need to be encouraged, to play an active role in the health education program. Diabetic patients should receive regular check-up for their feet in order to early detect and manage any abnormality and to prevent diabetic foot. This check-up should be done at home and hospitals, based on evidence-based guidelines. Effective control of diabetes, as it is associated with better foot care practice.

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Minor Head Injury: Quality Improvement Project

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Abstract

The aim of this paper was to provide a Quality Improvement Tool for head injury patients.

Using NICE guidance on head injury (Jan 2014), 9 salient points in history and 8 in examination were chosen to be audited and given a tabulated form.

Key words: Quality Improvement, Head Injuries, NICE Guidelines

Background

There were 348,453 admissions to UK hospitals with acquired brain injury (ABI) in the year 2016-17 (Headway statistics, 2017). That is 531 admissions per 100,000 population. Most cases seek advice from first point of contacts, such as GP surgery (primary care), out of hours GP service, walk-in centres and minor injury unit of emergency department of nearest hospitals. Due to the ease of accessibility of primary care physicians, naturally more cases present to them first.

Aims and Objectives

The future management, follow up and final outcome of the injury depends on initial consultation and its clear and effective documentation. Hence, we felt the need to audit and improve the documentation of consultation by various primary care physicians based in two of the biggest GP practices in the Nottinghamshire area.

Standards

Quality of documentation after the introduction of the template was compared against the quality of previous documentation before the introduction of the template.

Methods

Using NICE guidance on head injury (Jan 2014), 9 salient points in history and 8 in examination were chosen to be audited and given a tabulated form.

Retrospectively, 15 medical notes were retrieved using ''System One'' (the electronic system for recording medical notes in UK). This data was found within a 3 months' time period (March - May 2017). A mixture of physicians was randomly selected which included ANPs (Advanced Nurse Practitioners), GP registrars and senior GPs (Consultants in family medicine). Clinicians' grades were kept indiscrete.

All notes were studied and audited against the chosen salient points in history and examination. Quality of notes was analysed collectively as well as individually.

Collective analysis revealed the overall trend of documentation pertaining to head injury and the individual analysis exhibited the trend of some clinicians as ''good documentation'' and ''poor documentation.''

Based on NICE and SIGN guidelines, a template was generated in ''System One'' and education delivered to all 25 clinicians in both practices. They were encouraged to document minor head injury notes using this template which would automatically appear on typing the word ''head injury'' and would prompt the clinician to use this template. The template included all the above 9 points in history and 8 in examination.

After 12 months, again a sample of 15 notes was collected randomly, in a retrospective manner and again the clinicians' grades were kept indiscrete. Data was analysed again and a remarkable improvement was demonstrated. Suggestions were made to further improve the documentation in other important areas of the clinical practice as well.

Basic knowledge

First we'll discuss the selected salient points in history and examination and their importance in documentation.

History

A large number of articles have suggested the importance of documenting a careful history of minor head injury on first consultation, including time, mechanism of injury, loss of consciousness (LOC), vomiting, bleeding from ear, nose or throat (E.N.T.) and excessive sleepiness, etc (Kerr J et al, 2005). Taking the lead from these studies, we drew the following points:

1. Time: Documenting time of head injury is extremely important to understand the clinical picture of the patient, lucid interval and for follow up management.
2. Mechanism: This depicts the severity of injury and the risk of brain injury. Any discrepancies in the history may also alert the clinician to think about non-accidental injury (safeguarding issues).
3. Loss of Consciousness (LOC): This is important to know if the patient remained alert throughout the incident or lost consciousness; even briefly. This would predict the severity of injury as well as define if there was any lucid interval.
4. Vomiting: In children 2 or more vomiting episodes since the time of injury were considered important, however, in adults even a single episode of vomiting should be considered important. This indicates early signs of raised intra-cranial pressure (NICE guidance, 2014).
5. Sleepiness: Excessive sleepiness after a head injury may indicate a severe injury and potential brain damage or intra-cranial collection.
6. Bleeding from Ear, Nose or Throat: This usually indicates fracture of base of skull and depicts a severe injury.
7. Headache: Some mild headache is not uncommon after even a minor head injury due to concussion. However, severe headache indicates a severe injury.
8. Safeguarding issues: A clinician should always be mindful of safeguarding issues while consulting any injuries, both in children and dependable adults as well as the elderly. If suspected NSI (non-accidental injury), they must follow the local protocol to deal with safeguarding concerns. We have a team called ''MASH (multi-agency safeguarding hub).
9. Anti-coagulants: It is very important to find out in the history if patient is taking anti-coagulants, such as Warfarin, DOACs, etc. Because if a patient is already on anti-coagulants, even with a subtle head injury there is always

a risk of intra-cranial bleeding, hence, they are referred straight to the emergency department for immediate CT scan. So the case will follow a different pathway.

Examination

Similarly, in examination, 7 salient points were chosen. These were also inferenced from NICE and SIGN guidelines.

1. GCS (Glasgow Coma Score): This should be readily evident if patient is alert and talking to the clinician and obeying clear commands. So, it does not require a formal evaluation of 15 points. Just overall impression of the patient or any deterioration in orientation or alertness should alert the consulting physician. However, it is expected to mention GCS as 15, if no concerns were found.
2. Mechanism: This is a very important point, as it determines the severity of injury plus it can indicate any signs of safeguarding issues as well.
3. Pupils: Pupil reactions to light and accommodation must be documented as unilaterally non-reactive, dilated or fixed pupil may indicate an intra-cranial collection.
4. C-Spine: It is often forgotten when clinician is too focussed on head injury. However, it must be kept in in mind that any head injury does have some impact on cervical spine. Hence, it is important to document if C-spine was normal or any findings.
5. Local: Examination of impact of injury must be documents, as open laceration, contusion, bruise etc. Skull must be examined for coup and counter-coup injuries and evidence of skull fracture.
6. ENT: As mentioned in history, any bleeding from ear, nose or throat should be asked, and then examination must be performed to confirm the findings.
7. Fundoscopy: We noticed, it was rarely done by physicians. However, it is still important to try and view the fundus if possible for any signs of raised intra-cranial pressure and be clearly documented in the notes.
8. Focal Neurology: It is important to mention if any focal neurological findings were determined by the consulting physician or not for completion purposes and for the reference for follow ups.

FIRST ANALYSIS (Mar – May 2017):

History:

NOTES: →	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	%AGE
1.Time	√		√			√	√		√	√	√	√		√		60
2.Mechanism		√	√		√		√			√	√		√	√		53.3
3.LOC	√	√	√	√	√	√		√	√	√	√	√			√	80
4.Vomiting	√			√	√	√		√			√		√	√		53.3
5.Sleepiness			√			√		√			√			√	√	40
6.Bleeding E, N, T		√	√		√					√			√	√		40
7.Headache			√		√						√			√		26.6
8. Safeguarding			√								√			√		20
9. Anti-coagulants			√		√	√		√			√			√		40
OVERALL																45.9

Examination:

NOTES: →	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	%AGE
1.GCS	√	√	√	√	√		√			√	√	√		√		66.6
2.PUPILS	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	100
3. C-SPINE			√		√						√			√		26.6
4. LOCAL			√		√						√			√		26.6
5.ENT	√	√	√	√	√	√	√		√		√	√		√	√	80
6.FUNDOSCOPY			√		√						√					20
7.OTHER INJURIES																0
8. FOCAL NEUROLOGY			√		√											13.3
OVERALL																47.6

Discussion

A clear below standards overall documentation was noticed in most of the consultations. Overall accuracy of notes hitting most points in the history section was only 45.9% while in examination section it was 47.6%. No notes mentioned if there were any other injuries or not. We assume that may be there were no other injuries hence the clinician did not like to mention any.

The quality of documentation of a few clinicians was way better than others. Those clinicians, individually, showed an overall good quality of documentation. However, they were few in number.

Physicians scored points in a wide variable range of 0 to 100%. The majority ranged between 40 - 80%.
We aimed to get the documentation to above 90% accuracy.

The Template

With the help of out IT team, using ''System One'' we created a template for consultation of minor head injury and incorporated it into the system. This triggers and pops up when a clinician types the words ''head injury'' or one of these two words. This way the clinician is automatically prompted to follow the template and record the documentation through this template.

If a clinician, at times gets distracted or forgets to evaluate any point in history or examination, the template would prompt him/her again.

The templated included all the points mentioned in the tables above as well as a few more points inferenced from NICE and SIGN guidelines and other published articles (Garcia-Rodroguez and Thomas, 2014).

SECOND ANALYSIS (Mar – May 2018):

Second analysis was conducted with an interval of 12 months to see the persistence of compliance. After 12 months, again a sample of 15 notes was collected randomly, in retrospective manner and again the clinicians' grades were kept indiscrete. The number of the notes audited again kept as random 15 for ease of comparison and calculations with the previous audit.

History:

NOTES: →	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	%AGE
1.Time	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	100
2.Mechanism	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	100
3.LOC	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	100
4.Vomiting	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	100
5.Sleepiness	√	√	√	√	√	√		√	√	√	√	√	√	√	√	93.3
6.Bleeding E, N, T	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	100
7.Headache	√	√	√	√	√	√		√	√	√	√	√	√	√	√	93.3
8. Safeguarding	√	√	√	√	√	√		√	√	√	√	√	√	√	√	93.3
9. Anti-coagulants	√	√	√	√	√	√		√	√	√	√	√	√	√	√	93.3
OVERALL																97

Examination:

NOTES: →	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	%AGE
1.GCS	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	100
2.PUPILS	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	100
3. C-SPINE	√	√	√	√	√	√		√	√	√	√	√	√	√	√	93.3
4. LOCAL	√	√	√	√	√	√		√	√	√	√	√	√	√	√	93.3
5.ENT	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	100
6.FUNDOSCOPY	√	√	√	√	√	√		√	√	√	√	√	√	√	√	93.3
7.OTHER INJURIES	√	√	√	√	√	√		√	√	√	√	√	√	√	√	93.3
8. FOCAL NEUROLOGY	√	√	√	√	√	√		√	√	√	√	√	√	√	√	93.3
OVERALL																95.8

Just at a glance, both tables look densely populated on second analysis. Almost all clinicians scoring 100% accuracy individually. However, one set of notes showed a trend of missing a few points. On investigation, it was revealed, the clinician was a locum who came to cover a shift and preferred documenting notes as free text instead of following the template. However, they still did a good job by covering most points, albeit not 100%.

This showed compliance of all regular clinicians in both practices and overall accuracy of 97% in history section and 95.8% in examination section.

Conclusion

So, the aims and objectives, set for this quality improvement activity (as >90%) of the audit were achieved successfully and further suggestions were made.

Using templates for accurate documentation is a good way and improves the quality of documentation.

Suggestions

1. Continue to show compliance with the template for minor head injury for better quality of documentation.
2. Suggestions to create more simple templates for other common consultations as well, for example, chronic disease monitoring, medication reviews, chest infection etc.
3. Continually keep auditing the quality of notes with the aim to improve practice regularly.
4. The suggestions were extended to the local CCG to be forwarded to other practices as well in the region.

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Difficulties and Barriers of Primary Health Care Physicians in Rural Areas of Aseer Region, Saudi Arabia

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Abstract

Aim of Study: To identify difficulties and barriers facing primary health care physicians in rural areas of Aseer Region, Saudi Arabia.

Methods: This cross-sectional study was conducted at primary healthcare centers (PHCCs) belonging to the Saudi Ministry of Health, in rural areas of Aseer Region. A total of 134 physicians participated in the study. A validated study questionnaire was adapted and used for data collection.

Results: Female physicians constituted 43.3% of respondents, age of 58.2% was 30-35 years, (Mean±SD: 32.8 ± 7.0 years), 54.5% were married, the salary of 76.1% was <10,000 SR, and the place of residence of 43.3% was in urban areas. Only 34.3% had opportunities for on-the-job continuing medical education, 33.6% were satisfied with medical equipment and resources, and 50% were dissatisfied with their salary. Internet service was present for 83.6% of participants. The social life of 83.6% was negatively affected, and 16.4% were exposed to violence at the workplace. Most participants had a favorable attitude toward working in rural areas, mainly in the form of professional satisfaction, pursuing postgraduate academic studies, building confidence as a clinician and provision of opportunities to upgrade knowledge and skills. Participants were less satisfied regarding several social factors, such as internet connectivity, isolation from family and relatives; received support from rural people, difficult schooling for children, but were not satisfied regarding PHCC infrastructure, their residential facilities, or earning more money.

Conclusion: Serving within the rural healthcare system provides young physicians with an opportunity to build up their experience and to increase their confidence as physicians. However, important difficulties that they face are mainly social and financial. Hence, creating a health policy to safeguard the serving physicians' career and providing facilities to promote personal and social well-being needs to be considered.

Key words: Primary healthcare, rural health, difficulties, barriers, Saudi Arabia

Introduction

Early intervention is the best approach to reduce the burden of diseases. However, healthcare access remains unequal, with rural populations having the poorest access to, and utilization of, primary healthcare centers and consequently the poorest health outcomes (1). In Saudi Arabia, there are 2,282 primary healthcare centers (PHCCs) that provide preventive and curative services for more than 23 million people, with almost 60% of these PHCCs located in rural areas and villages (2).

In Riyadh, Saudi Arabia, Alshammari (3) examined the factors influencing access to and use of PHCCs in urban and rural areas. The findings highlighted important differences between urban and rural populations. For rural patients these factors included the distance to the PHCC, its cleanliness, understanding the treatment and receiving health prevention and promotion services. Alfaqeeh (4) noted that due to inequalities in access and utilization of healthcare services, health outcomes between people living in rural and urban areas differ significantly.

Nielsen (5) argued that there are several challenges that face healthcare providers in rural areas. Rural physicians treat patients that tend to be older, sicker, and less well insured. Populations in rural communities are increasingly elderly; the average age for hospital admissions in rural settings is over 65, and these older patients comprise one-half of all admissions. In contrast, older patients in urban settings account for just 37% of hospital admissions.

Turisco and Metzger (6) added that physicians may experience negative impacts due to the low number of healthcare practitioners in rural areas as well as in the distance factor, which results in limitations on productivity, communication and ongoing education. Research notes that there is more difficulty for the rural providers in communication with other providers of health care. There is much less in the way of opportunities to attend conferences and training due to the requirements of travel, which limits access to medical knowledge and research work. Lower efficiency results from travel time involved in visiting patients in hospitals and nursing homes as well as in fewer face-to-face visits, and more time on the telephone with other providers and with patients.

Mumenah and Al-Raddadi (7) reported that the main problems faced by primary care physicians in rural areas are related to difficult transportation, unavailability of radiology technicians and radiologists, X-ray and ultrasound equipment, unavailability of laboratory services, reagents, insufficient laboratory tests, absence of internet and computer access, and poor building maintenance.

The present study aimed to identify difficulties and barriers facing primary health care physicians in rural areas of Aseer Region, Saudi Arabia.

Methods

Following a cross-sectional research design, the present study was conducted during the period from January to March 2020, in rural PHCCs belonging to the Ministry of Health of Aseer Region, at the southwestern part of the Kingdom of Saudi Arabia.

Using the single proportion equation in Raosoft software package (8), at 95% confidence intervals, a primary healthcare physicians' population size in rural areas of 204, 5% margin of accepted error, and 50% response distribution, the sample size was calculated to be 134 physicians.

A study questionnaire was constructed by the researchers that was adapted from the validated questionnaire of Singh et al. (9). The first part of the questionnaire comprised participants' personal and work data, while the second part included 15 statements about physicians' attitudes toward work in rural areas. Some questions were negatively phrased and others were positively phrased. Participants were asked to respond on a five-point Likert scale, ranging "from strongly agree" to "strongly disagree", to indicate the extent to which they agreed or disagreed to the statements. Numerical scores were assigned to each level of agreement, such as strongly disagree (1), disagree (2), neutral (3), agree (4), and strongly agree (5), for positively framed statements. For the statements framed negatively, scores were reverse coded, such as strongly disagree (5), disagree (4), undecided (3), agree (2), and strongly agree (1). Therefore, the maximum attitude score for each statement is 5, while the minimum is 1. Higher scores (i.e., 3 or more) indicate a positive (i.e., favorable) attitude toward working in a rural area, while scores less than 3 reflect a negative (i.e., unfavorable) attitude.

The Statistical Package for Social Sciences (IBM, SPSS version 25.0) was used for data entry and analysis. Descriptive statistics were applied (frequency and percentage for qualitative variables and Mean±SD for quantitative variables).

Results

Table 1 shows that 43.3% of respondents were females, age of 58.2% was 30-35 years, (Mean±SD: 32.8 ± 7.0 years), 54.5% were married, the salary of 76.1% was <10,000 SR, and the place of residence of 43.3% was in urban areas.

Table 2 shows that 34.3% of participants had opportunities for on-the-job continuing medical education, 33.6% were satisfied with medical equipment and resources, and 50% were dissatisfied with their salary. Internet service was present for 83.6% of participants. The social life of 83.6% was affected by working in rural areas, and 16.4% were exposed to violence in the workplace.

Table 3 shows that most attitude mean scores of primary health care physicians toward working in rural areas were above 3 (i.e., favorable), mainly in the form of professional satisfaction (4.8±1.8), pursuing postgraduate academic studies (4.4±1.5), building confidence as a clinician (4.4±2.8) and provision of opportunities to upgrade knowledge and skills (4.2±1.7). Moreover, participants were less satisfied regarding several social factors, such as internet connectivity, isolation from family and relatives; received support from rural people, difficult schooling for children (3.7±1.5; 3.4±2.1; 3.4±2.4, and 3.3±1.2; respectively). However, participants were not satisfied regarding PHCC infrastructure (2.9±1.5), their residential facilities (2.5±1.1) or earning more money (1.9±1.0).

Table 1: Personal characteristics of rural primary health care physicians in Aseer Region

Personal characteristics	No.	%
Gender		
• Female	58	43.3
• Male	76	56.7
Age (in years)		
• <30	22	16.4
• 30-35	78	58.2
• >35	34	25.4
• Mean±SD	32.8±7.0	
Salary (in SR)		
• ≤10,000	102	76.1
• Above 10,000	32	23.9
Marital status		
• Married	73	54.5
• Single	61	45.5
Place of residence		
• Rural	76	56.7
• Urban	58	43.3

Table 2: Work characteristics of rural primary health care physicians in Aseer Region

Work characteristics	No.	%
Opportunities for on-the-job continuing medical education		
• No	88	65.7
• Yes	46	34.3
Satisfaction with medical equipment/resources in the center		
• No	89	66.4
• Yes	45	33.6
Satisfaction with salary		
• No	67	50.0
• Yes	67	50.0
Use of Internet/e-mail in practice		
• No	22	16.4
• Yes	112	83.6
Was your social life negatively affected by working in rural are		
• No	22	16.4
• Yes	112	83.6
Were you exposed to any sort of violence at your work place		
• No	112	83.6
• Yes	22	16.4

Table 3: Rural primary healthcare physicians' attitude scores toward working in rural areas of in Aseer Region (Mean±SD)

Attitude toward working in rural areas	Mean	SD
Working in rural areas gives more professional satisfaction	4.8	1.8
Pursuing post-graduate academic studies after working in rural areas for a considerable time	4.4	1.5
Helps to build confidence as a clinician	4.4	2.8
Provides opportunities to upgrade knowledge and skills	4.2	1.7
Provides higher recognition among medical fraternity	3.9	2.9
Professional growth is limited	3.8	2.5
Provides an opportunity for independent working	3.8	1.5
Internet connectivity	3.7	1.5
Provides a good exposure of general practice	3.4	1.8
Isolation from family and relatives	3.4	2.1
People in rural areas are more supportive	3.4	2.4
Difficult schooling for children	3.3	1.2
PHCC infrastructure is adequate	2.9	1.5
Residential facilities are good	2.5	1.1
Helps in earning more money	1.9	1.0

Discussion

Various literature available has pointed out the differences between the facilities in urban and rural areas in both developed and developing countries. It has been noted that advances in healthcare systems is first seen in urban areas. However, the World Health Organization (WHO) stressed on providing healthcare services in rural areas and provided the guidelines to achieve this. Nevertheless, the majority of newly graduated physicians still prefer to work in urban areas rather than rural areas (10).

In our study we observed that the majority of the participant physicians in rural areas of Aseer were males aged 30-35 years, with an average age of 32.8 ± 7.0 years.

The relatively young age of participants in our study is attributed to the fact that most newly graduated physicians in Saudi Arabia become assigned to posts to serve in rural areas (11). However, this may constitute a difficulty for those who live in urban areas (43.3%).

It is to be noted that rural PHCCs are managed mainly by general practitioners. Specialists and consultants are exclusively present in secondary and tertiary healthcare hospitals in urban areas. This can provide a good opportunity for young physicians to start working independently and build valuable experience (11).

In our study, we observed that most primary care physicians were professionally satisfied (with a high mean score of 4.8±1.8) and helped them become more confident as a physician (with a high mean score of 4.4±2.8). However, they were not so happy with their residential facilities or their salary.

These findings are in accordance with those reported by several national and international studies. Al Asmri et al. (12) reported that the main difficulties facing physicians at PHCCs in rural areas of Riyadh, Saudi Arabia, include the distance to reach PHCCs, and residential facility cleanliness. They added that key areas to improve primary health care systems include the scope, structure, and infrastructure. Moreover, financial securities are essential factors and can have a positive effect on physicians' professional career.

Rohatinsky and Ferguson et al. (13), in the Canadian Province of Saskatchewan, reported that cross-professional mentoring enabled healthcare staff in rural areas to understand team member roles and established collaborative work environments. They concluded that inter-professional mentorship can assist with the challenges of socializing new employees to rural workplaces by offering a means to encourage collaborative relationships and ultimately foster positive patient outcomes.

Our participants were less satisfied socially, with the main encountered difficulties being schooling for children, connectivity with others, isolation from family and relatives; and received support from rural people.

It is to be noted that although schools are present everywhere throughout Saudi Arabia, there is a general perception that urban schools are always bigger and better. Therefore, schooling of physicians' children was cited as a reason for their lesser satisfaction. Rural schools often face difficulties that urban and suburban schools are much less likely to encounter. These difficulties may be attributed to that rural families live relatively far from the public schools, and the schools are relatively far from each other. As a result, there are considerable expenses for transporting children to and from schools (14).

It is to be noted that remote rural PHCCs constitute a real difficulty, especially for urban place of residence, who become separated from their family members and relatives, and may have the feeling of a stranger within rural people, especially when exposed to violence at their workplace.

In 2013, Al-Sareai et al. (15) reported that approximately one-third of primary healthcare teams in rural areas of Aseer Region, Kingdom of Saudi Arabia, face significant difficulties and barriers that affect provision of essential primary healthcare programs. In addition, most physicians are not very happy about serving in rural areas. Poor incentives including delayed disbursal of salary, lack of growth opportunities, delayed or no promotion, and absence of a system for professional development affect their motivation substantially. Besides, the absence of basic facilities like housing and good schools for children negatively affects their motivation. They advocated that a multi-sectoral integrated approach is mandatory to overcome these difficulties and introduce good quality care.

In conclusion, serving within the rural healthcare system provides young physicians with an opportunity to build up their experience and to increase their confidence as physicians. However, there are some important difficulties that face them, mainly social and financial barriers. Hence, creating a health policy to safeguard the serving physicians' career and providing facilities to promote personal and social well-being needs to be considered.

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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 (±SD) was 16.98±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 Gariepy 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 participanting 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)

BMI (Kg/m2) = Weight (Kg) / Height (m2)

Students were classified based on their BMI as: Normal (BMI = 18.5-24.9 Kg/m2); Overweight (BMI = 25-29.9 Kg/m2); or Obese (BMI = ≥ 30 Kg/m2). (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 (≥ 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 (≥ 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 (≥ 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±0.93 years. Regarding students' body mass index, 17.3% had normal body mass index (<25 kg/m2), while 44.2% were overweight (25-29.9 kg/m2) and 38.4% were obese (>30 kg/m2), as shown in Figure 3. Students' mean BMI was 29.15±5.84 kg/m2.

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±6.5 kg/m2), while the highest was observed among those aged >18 years (30.2±5.7 kg/m2). 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

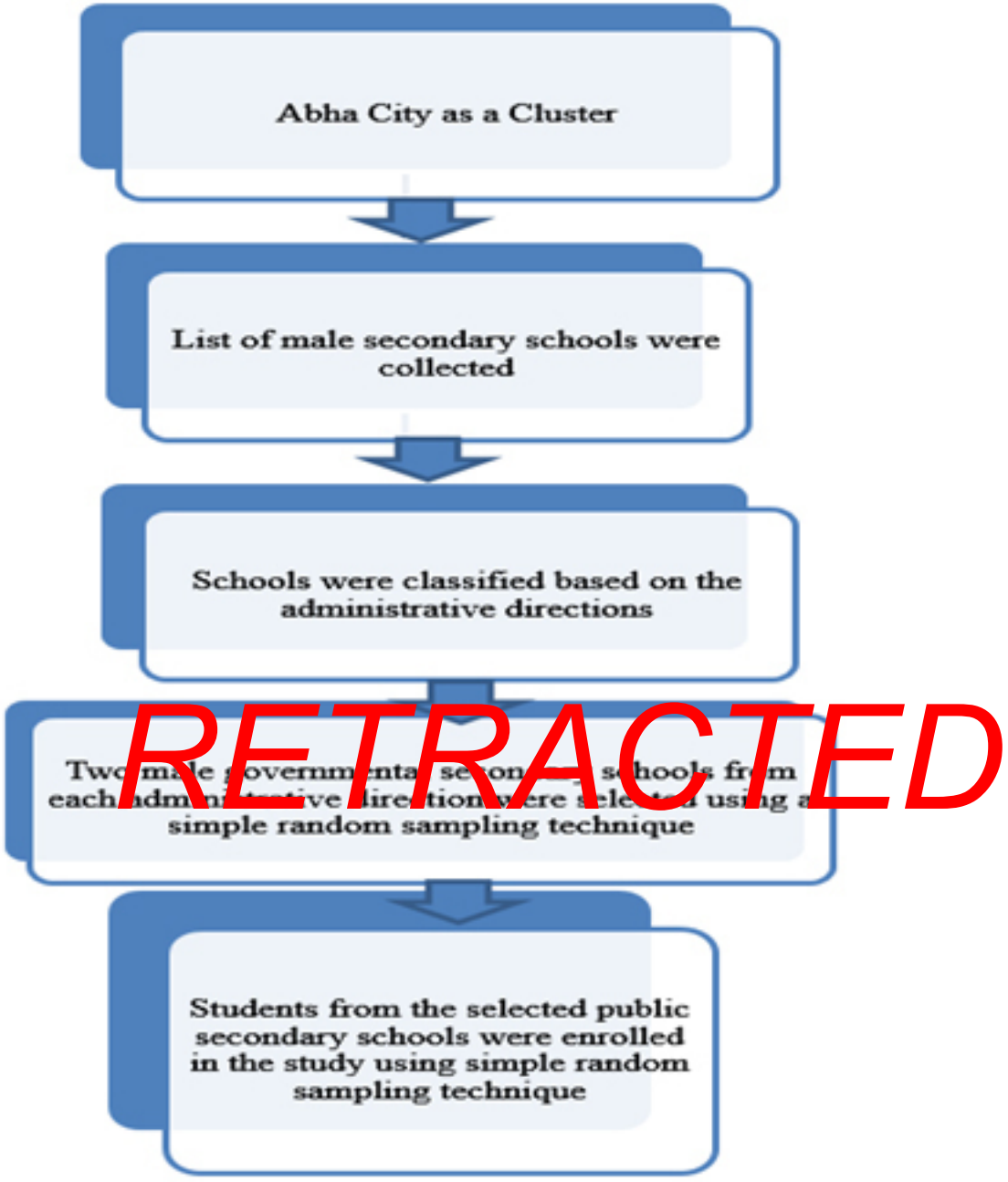

Table 1: Personal characteristics of participant students (n=398)

Characteristics	No. (%)
Age groups	
• <17 years	80 (20.1%)
• 17 years	217 (54.5%)
• ≥ 18 years	101 (25.4%)
• Mean±SD	16.98±0.93
Body mass index	
• Normal (<25 kg/m²)	69 (17.3%)
• Overweight (25-29.9 kg/m²)	176 (44.2%)
• Obese (≥30 kg/m²)	153 (38.4%)
• Mean±SD	29.15±5.84

Figure 2: Age groups of participant male secondary school students

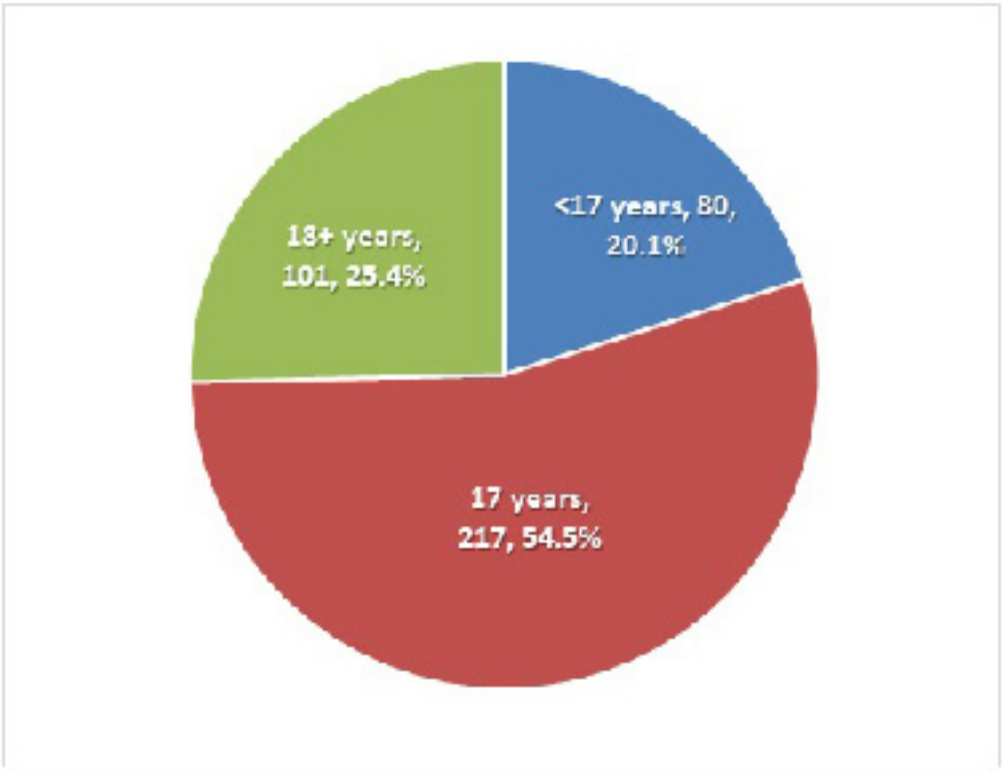

Figure 3: Body mass index groups of participant students

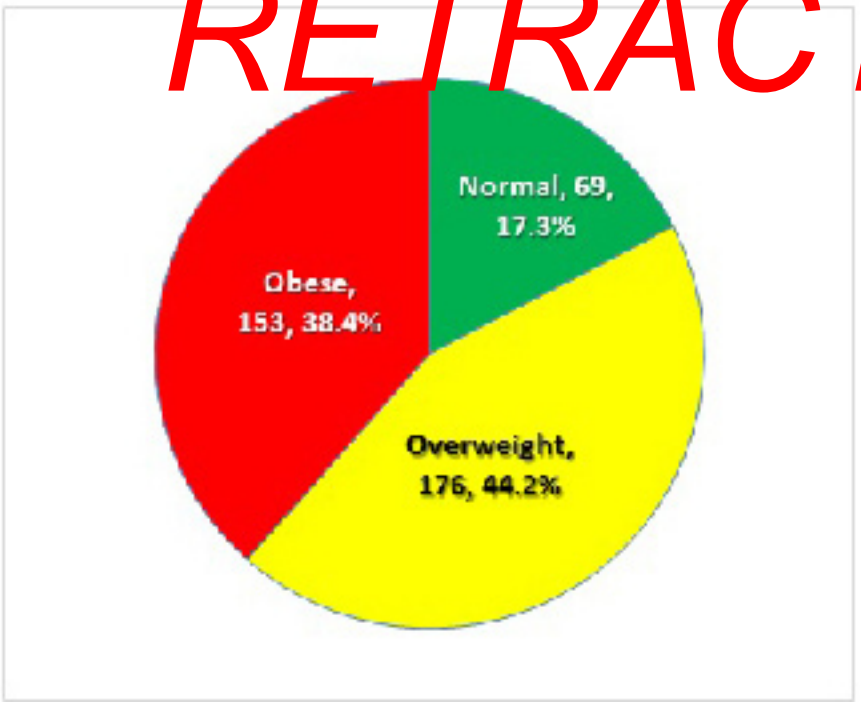

Table 2: Responses of participant students to DASS-21 (n=398)

	Never	Sometimes	Often	Always
DASS-21 items	No. (%)	No. (%)	No. (%)	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%)	[illegible]	[illegible]2.1%)	31(7.8%)
I felt I was close to panic	25[illegible](6[illegible].1%)	7[illegible](19.[illegible]%)	43(10[illegible].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. (%)
Symptoms of Depression	
• 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%)
Symptoms of Anxiety	
• 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%)
Symptoms of Stress	
• 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. (%)	
Depression				
• 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%)	<0.001*
• Severe	10 (14.5%)	12 (6.8%)	18 (11.8%)	
• ExtremelySevere	26 (37.7%)	6 (3.41%)	8 (5.2%)	
Anxiety				
• 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%)	<0.001*
• Severe	7 (10.1%)	28 (15.9%)	25 (16.3%)	
• ExtremelySevere	3 (4.3%)	48 (27.3%)	46 (30.1%)	
Stress				
• 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%)	<0.001*
• 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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Use of eye drops self-medication in Aseer region, Southern Saudi Arabia

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Abstract

Background: Self-medication is defined as the use of drugs to manage a self-diagnosed disease or complaint, or the intermittent or continued use of a prescribed drug for chronic or recurrent disease or symptoms. Self-medication includes getting medications without a prescription, resubmitting old prescriptions to buy medicines, sharing medicines with relatives or members of one's social circle, or using leftover medicines stored at home. Risks are related to many factors including not only the possible severe side effects of the drug itself, but also hazardous because of improper treatment.

Methodology: A descriptive cross-sectional survey was used targeting all population in Aseer region. The study was conducted during the period from May 2020 to August 2020. Data were collected using structured questionnaire which was developed by the researchers after intensive literature review and expert's consultation. The questionnaire data included person's socio-demographic data such as age, gender, and education. The second section of the questionnaire covered eye drops self-medication data. The questionnaire was uploaded online using social media platforms by the researchers and their relatives and friends to be filled in by all population in Aseer region.

Results: A total of 209 participants completed the study questionnaire. Participants' ages ranged from 18 to 65 years old with mean age of 32.9 ± 11.6 years. Exactly 152 (72.7%) participants were females and 158 (75.6%) had educational level of university or more. Regarding persons who advised participants to use eye drops, the most reported was the person themself (34.4%; 72) followed by family and friends (29.2%), and pharmacist (20.6%). As for causes of using unprescribed eye drops, 105 (50.2%) participants used the eye drops for itching in the eye, followed by eye redness (47.4%), eye pain (22.5%). Regarding side effects of used drops, the most reported was excessive lacrimation (5.7%), followed by blurred vision (5.7%), and eye inflammations (4.3%),

Conclusions: In conclusion, the study revealed that there is a large portion of Aseer region population practicing self-medicating behavior based on their own concept or advice from friends and family most of the time, without consulting a specialized physician.

Key words: Eye drops, self-medication, unprescribed, use, population, causes, practice

Introduction

The World Health Organization defined self-medication as the selection and use of medicines by individuals to treat illnesses or relieve symptoms [1, 2]. Self-medication covers purchasing drugs without consulting a physician or having a prescription, using leftover doses from previous prescriptions, sharing medications with other family members, or abusing the medical prescription either by prolonging, interrupting or modifying the dosage and the administration period [3-6].

Self-medication practice was reported for a wide spectrum of symptoms and pathologies and eye conditions are one of these conditions. It is well known that this kind of attitude and practice has pharmacological and toxicological hazards [7]. Risks are related to many factors including not only the possible severe side effects of the topical drug itself, but is also hazardous as a result of improper treatment or failure to obtain prompt medical care, thus leading to a delay in diagnosis, assessment and, in turn to accidental consequences [8].

Several over the counter (OTC) drugs are available to the public without prescription, which include usual pharmacy preparations and medications that have been liberalized from their previous classification as prescription medications. Policies regarding these OTC pharmaceuticals are different worldwide. Nonetheless, these substances are available for traditional use and commonly available without medical restrictions or a prescription in pharmacies or even in supermarkets. Not only OTC medications can be used as a resource for self-medication, but also non-prescribed drugs achieved without a prescription can be another common resource for patient's self-medication in different countries all over the world. There have been consistently high rates of use of non-prescribed drugs found in different developed countries, ranging from 22% to 67% for all ages [9-11]. The current study aimed to identify practices of self-medication in the treatment of ocular conditions and to identify causes and outcome of patients who self-medicate with eye drops in Aseer region, Southern Saudi Arabia.

Methodology

A descriptive cross-sectional survey was used targeting all population in Aseer region. The study was conducted during the period from May 2020 to August 2020. All those below the age of 18 years and those who were not permanently living in Aseer region (or for at least 1 year) were excluded. Data were collected using structured questionnaire which was developed by the researchers after intensive literature review and expert's consultation. The questionnaire data included person's socio-demographic data such as age, gender, and education. The second section of the questionnaire covered eye drops self-medication data including reasons for using the eye drops, persons who advised the participant to use the drops, side effects of using the eye drops, and medical consultation through reporting to OPD. The questionnaire was uploaded online using social media platforms by the researchers and their relatives and friends to be filled in by all the population in Aseer region. A consecutive convenience sampling method was used due to the current COVID-19 pandemic. All participants fulfilling the inclusion criteria who received the electronic questionnaire during the study period were invited to participate through filling out the questionnaire.

Data analysis

Online data were extracted, revised, coded, and fed to 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. Descriptive analysis based on frequency and percent distribution was done for all variables including participant's demographic data, reasons for using unprescribed eye drops, types of used drops, and reported side effects. Distribution of unprescribed eye drops use according to participant's age and gender was displayed by crosstabulation. Significant associations were tested using exact probability test due to small frequencies.

Results

A total of 209 participants completed the study questionnaire. Participants' ages ranged from 18 to 65 years old with mean age of 32.9 ± 11.6 years. Exactly 152 (72.7%) participants were females and 158 (75.6%) had educational level of university or more (Table 1).

Table 2 illustrates patterns of use of eye drop self-medication in the Aseer region. Regarding persons who advised participants to use eye drops, the most reported was the person themself (34.4%; 72) followed by family and friends (29.2%), pharmacist (20.6%), optic technician (11%), and physician the person knew (4.8%). Considering causes of using unprescribed eye drops, 105 (50.2%) participants used the eye drops for itching in the eye, followed by eye redness (47.4%), eye pain (22.5%), excessive lacrimation (16.3%), blurred vision (15.3%), eye dryness (9.1%), and eye discharge (5.3%). As for types of used eye drops, most respondents used moistening drops (68.9%) followed by antiallergic drops (11%), anti-inflammatory drops without cortisone (3.8%), antibiotic drops (2.9%), and saline drops (1.9%). Regarding side effects of used drops, the most reported was excessive lacrimation (5.7%), followed by blurred vision (5.7%), eye inflammations (4.3%), and increased pain (2.9%), while 80.4% had no side effects. On asking participants if they seek medical consultation (reasons for reporting to OPD), 76.6% did not report to the OPD while 14.8% reported to the clinic to have the appropriate treatment, and 7.2% reported to the clinic due to failed improvement.

Table 3 shows distribution of use of eye drop self-medication by participants' age. The most reported cause of using unprescribed eye drops among young aged group (18-30 years) were itching (61.4%) followed by eye dryness (59.6%), eye pain (28.9%) compared to

42.9%, 25%, and 25% among old aged respondents (> 50 years), respectively. These differences were found to be statistically significant (P=.001). As for types of used eye drops, the most used among the young age group were moistening drops (72.8%) compared to 57.1% of old aged group. The second most reported type was antiallergic drops (7%) compared to (14%) for those aged more than 50 years (P=.001).

Table 4 demonstrates distribution of use of eye drop self-medication by participants' gender. The most reported cause of use among males was itching (63.2%) followed by eye dryness (57.9%) compared to 45.4% and 43.4% of females with no statistical significance (P=.231). As for types of eye drops used, the most reported among males were moistening drops (70.2%) followed by antibiotic drops in comparison to 68.4% and 1.3% of females while antiallergic drops were used among 13.2% of females with no statistical significance (P=.126).

Discussion

The current study aimed to assess self-medication practices in the treatment of ocular disorders and to recognize causes and outcome of patients who self-medicate eye drops in Aseer region, Southern Saudi Arabia. The majority of ophthalmic acute or chronic disorders often necessitates the use of eye-drops or some systemic medication. Even though guidelines recommend the physician as the official source for these treatments, many patients with eye complaints treat themselves before, or instead of, seeking medical care [12, 13]. The overspread of this phenomena can be explained by many factors including economic, cultural and political factors [14–16] Nowadays, self-medication has become a habit worldwide, [17] in particular in the developing countries [18–20] where informal convenience of a large range of drugs without prescription, the growing number of over-the-counter (OTC) medicines, careless publicity, unavailable health care services, contribute to its spread.

The current study revealed that self-medication with eye drops among the study participants was recorded among all age groups from 18 to 65 years old, among males and females and among all, regardless of educational level. The main motive behind using eye drops without prescription was the person themself while family and friends' advice especially those who had previous eye diseases and used certain drugs were the second most reported encouraging group followed by regional pharmacists during consultation and optic technicians while a very small portion of the participants reported for physicians they know. Eye dryness with itching was the most reported causes of use (by more than half of the sample) in all age groups while pain appeared as a cause of use among old aged participants (> 50 years). The study results also revealed that moistening eye drops were used by more than two thirds of the participants and this matches the dryness that was reported as the main cause. Other types including anti allergic drops (for itching), and anti-inflammatory drops were also reported but with lower proportions. The surprising finding was that more than 80% of the participants did not experience any complications due to the eye drops use but this may be accepted as eye drops are a local treatment with low or even minimal systemic side effects. Few participants reported lacrimation (which may be due to itching or dryness but not due to the eye drops), pain, and eye inflammation. The main types of used eye drops (moistening drops and antiallergic drops) were more used among young, aged participants. This may be due to being outdoors most of the day or due to the use of eye contact lens. Causes of using eye drops or types of used eye drops, was not dependent on the participants' gender. As for seeking medical consultation, more than three quarters of the participants did not seek medical consultation and did not visit the clinic. Among those who did, seeking appropriate treatment was the main motive due to failed improvement (less than 10%).

In Argentina, Marquez GE et al [21] used a questionnaire to assess the magnitude of ocular self-medication, with commercial eye drops in patients seen in a private ophthalmology unit. Self-medication was reported among 25.6% of the participants, showing that one in four patients self-medicates before seeking medical advice. Omolase CO et al in Nigeria studied Ocular Self Medication in Owo city [22]. The authors reported that nearly 79% of the participants performed ocular self-medication. The factors reported for using self-medication were their perception that they had a minor eye disorder flexible to self-care (41.1%). The other reasons included non-readily available ophthalmic services (17.4%), financial restraints to achieve medical care (14.6%), lack of knowledge regarding the potential drawbacks of self-medication (12.7%), and assurance of the efficacy of self-medication used (11.5). In Saudi Arabia, Bifari I et al [23] assessed self-medication among the population of Taif City. Nearly one third of the participants reported self-medication for eye problems. Eye redness, watery eye, eye discharge, and burning sensation were the most reported causes of using eye self-medication. These are all consistent with the current study reported cause of use. A second study was conducted by Al-Ghamdi S et al to assess self-medication practices in the Kingdom of Saudi Arabia [24]. The study revealed that about 35% of the study participants used unprescribed eye drops. The most reported reasons were difficulty reaching the hospital, lack of the service in the primary health care centres, and no medical insurance.

Conclusions and Recommendations

In conclusion, the study revealed a large portion of Aseer region population practice self-medicating behaviour based on their own concept or advice from friends and family most of the time, without consulting a specialized physician. Eye self-medication was mainly for dryness or itching specially at a young age group while pain was reported among old, aged participants. It is recommended to clarify for the public the association between different factors promoting self-medication and assess the changing trends in order to help derive strategies for lowering drug-related health risks among the population. Health education targeting

Table 1: Personal data of study participants, Aseer region, Saudi Arabia

Personal data	No	%
Age in years		
18-30	114	54.5%
31-50	67	32.1%
> 50	28	13.4%
Gender		
Male	57	27.3%
Female	152	72.7%
Educational level		
Below university	51	24.4%
University	158	75.6%

Table 2. Pattern of use of eye drop self-medication in the Aseer region, Saudi Arabia

Unprescribed eye drops use		No	%
Who advised you to have unprescribed eye drops	Myself	72	34.4%
	Family/ friends	61	29.2%
	Pharmacist	43	20.6%
	Optic technician	23	11.0%
	Physician I know	10	4.8%
Causes of using unprescribed eye drops	Itching	105	50.2%
	Eye redness	99	47.4%
	Eye pain	47	22.5%
	Excessive lacrimation	34	16.3%
	Blurred vision	32	15.3%
	Eye dryness	19	9.1%
	Eye discharge	11	5.3%
	Peri-orbital oedema	5	2.4%
Types of used eye drops	Moistening drops	144	68.9%
	Anti allergic drops	23	11.0%
	Don't remember	22	10.5%
	Anti-inflammatory without cortisone	8	3.8%
	Antibiotic drops	6	2.9%
	Saline drops	4	1.9%
	Anti-inflammatory with cortisone	2	1.0%
Side effect of used drops	None	168	80.4%
	Excessive lacrimation	12	5.7%
	More pain	6	2.9%
	Eye inflammation	9	4.3%
	Blurred vision	12	5.7%
	Eye discharge	2	1.0%
Seek for medical consultation	No need	160	76.6%
	Failed improvement	15	7.2%
	To have appropriate treatment	31	14.8%
	Follow-up	3	1.4%

Table 3. Distribution of use of eye drop self-medication by participants' age

Eye drops use	Age in years						P-value
	18-30		31-50		> 50		
	No	%	No	%	No	%	
Causes of using unprescribed eye drops							
Eye redness	68	59.6%	24	35.8%	7	25.0%	.001*
Itching	70	61.4%	23	34.3%	12	42.9%	
Eye pain	33	28.9%	7	10.4%	7	25.0%	
Blurred vision	12	10.5%	13	19.4%	7	25.0%	
Excessive lacrimation	24	21.1%	9	13.4%	1	3.6%	
Eye discharge	6	5.3%	4	6.0%	1	3.6%	
Eye dryness	11	9.6%	7	10.4%	1	3.6%	
Peri-orbital oedema	2	1.8%	1	1.5%	2	7.1%	
Types of used eye drops							
Moistening drops	83	72.8%	45	67.2%	16	57.1%	.008*
Antiallergic drops	8	7.0%	11	16.4%	4	14.3%	
Antibiotic drops	4	3.5%	1	1.5%	1	3.6%	
Saline drops	4	3.5%	0	0.0%	0	0.0%	
Anti-inflammatory without cortisone	4	3.5%	1	1.5%	3	10.7%	
Anti-inflammatory with cortisone	0	0.0%	0	0.0%	2	7.1%	
Don't remember	11	9.6%	9	13.4%	2	7.1%	

P: Exact probability test
* P < 0.05 (significant)

Table 4. Distribution of use of eye drop self-medication by participants' gender

Eye drops use	Gender				P-value
	Male		Female		
	No	%	No	%	
Causes of using unprescribed eye drops					
Eye redness	33	57.9%	66	43.4%	
Itching	36	63.2%	69	45.4%	
Eye pain	15	26.3%	32	21.1%	
Blurred vision	9	15.8%	23	15.1%	.231
Excessive lacrimation	10	17.5%	24	15.8%	
Eye discharge	4	7.0%	7	4.6%	
Eye dryness	4	7.0%	15	9.9%	
Peri-orbital oedema	1	1.8%	4	2.6%	
Types of used eye drops					
Moistening drops	40	70.2%	104	68.4%	
Antiallergic drops	3	5.3%	20	13.2%	
Antibiotic drops	4	7.0%	2	1.3%	
Saline drops	0	0.0%	4	2.6%	.126
Anti-inflammatory without cortisone	3	5.3%	5	3.3%	
Anti-inflammatory with cortisone	0	0.0%	2	1.3%	
Don't remember	7	12.3%	15	9.9%	

P: Exact probability test

the general public and imposing regulations on the non-prescription use of drugs could help reduce the challenge of the self-medication practice.

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Impact of acne on quality of life among university students

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Abstract

Objective: To know the impact of acne among female university students on their quality of life.

Methodology: A cross sectional study conducted included 260 female students at the King Khalid University. A self-administered questionnaire was used in Arabic for data collection. It consisted of personal data, practices and conditions related to health, specific questions on acne vulgaris and the Acne Quality of Life (QOL) questionnaire.

Results: Prevalence of acne among participant students was 87%. Its severity among 48% of participants was mild, 39.6% was moderate, while 12.3% had severe acne. Its prevalence did not differ significantly according to participants' personal characteristics. The mean score for self-perception was 18.4+8.0, for role emotional was 14.4+8.8, for role social was 14.4+6.4, for acne symptoms was 13.4+5.2, while mean overall score was 60.5+24.4. Acne QOL scores for all domains were significantly lower among students who have acne. Scores for all domains and overall scores were lowest among students having severe acne. Students' acne QOL scores differed significantly according to their family monthly income regarding "self-perception" (p=0.005), role emotional (p=0.037) and overall (p=0.012).

Conclusions: Prevalence of facial acne is very high among students and significantly affects their QOL. During management of acne patients, health care professionals should consider its psychosocial aspect.

Limitations: Generalizability of the results is limited to female university students only and limited personal characteristics were assessed in the present study.

Conflict of interest: There is no conflict of interest involved with this study

Key words: Acne, quality of life, female university students.

Introduction

Acne vulgaris is one of the commonest dermatological problems. In adolescent age group its prevalence is about 80% (1). It is a disease of the pilo-sebaceous glands and its clinical manifestations range from seborrhea, comedones, papules, pustules, nodules and in some severe cases it can even cause scarring (2).

Acne effects mostly adolescent people, and it has multiple effects on patients which include not only physiological and social impacts but also psychological. Literature shows that psychological effects of acne on patients can be drastically significant. The relationship of acne and psychosocial issues is very complex among adolescents; it is highly associated with body image, socialization and also sexuality (3). Previous studies showed that acne causes dissatisfaction with appearance, embarrassment, self-consciousness, and lack of self-confidence among patients (3). Social dysfunction has also been observed among acne patients which has different aspects such as hesitation with their interactions with opposite gender, low feeling about personal appearances in public, avoiding interaction with strangers, and lack of employment opportunities (4-6). Furthermore, related to psychological issues acne is directly associated with anxiety, depression (7), anger (8) and lower self-esteem (9). Psychological impact affects female patients more than male patients (7). Because of their avoiding behavior and low confidence level these patients have low tendency or intention to participate in sports and exercise as compared to those who don't have acne (10).

Among acne patients depression is common although depression has also found to be associated with the medications which are being used for the treatment of acne, such as Accutane. A study in Norway found that acne is associated with serious mental disorders itself. They discovered that depression and suicidal thoughts were two to three times more common among teenagers with severe acne than in those who did not have any kind of skin problem (11). Even suicidal ideation was found to be around 6-7% in acne patients (12).

Therefore this study aims to examine the impact of acne among female university students on their different domains of QOL.

Methodology

A cross sectional study design was followed and included 260 female students at King Khalid University (KKU), Abha City, Saudi Arabia. The sample was almost equally distributed between the academic years (1st – 6th) according to the selected colleges. Through a simple random sampling technique, students were selected from a list obtained from the university clinic for the girls who had an appointment to diagnose their acne and its stage.

A self-administered questionnaire was constructed by the researcher in simple Arabic language and was used for data collection. It consists of:

1. Personal data: age, scholastic year, marital status, family income.
2. Condition and practices related to health: smoking, obesity and menstrual problems.
3. Specific questions on acne vulgaris (history of acne, duration, treatment and severity).
4. Acne QOL questionnaire: It contains 19 questions organized into four domains (self-perception, role-social, role-emotional, and acne symptoms) which refer to facial acne. For all domains, higher scores reflect better rate for quality of life. The total "overall" score varies from zero to 114, distributed as follows: 0-30 (self-perception), 0-24 (role-social), 0-30 (role-emotional), and 0-30 (acne symptoms). It is to be noted that all questions of the Acne-QOL questionnaire are framed to be disease-specific ('. . . because of your facial acne'), which means that the effect on the QOL is unlikely to be due to other factors (13). An Arabic version was translated first by the researcher which has been translated back to original English language again to validate the Arabic version.

Scoring of the Acne-QOL was done in the following manner:

1. Each response was coded. Responses were numbered starting with '0' in ascending order (i.e. extremely=0, very much=1, quite a bit=2, a good bit=3, somewhat=4, a little bit=5, not at all=6). This coding scheme is adopted so that higher scores for each domain in Acne-QOL reflects increased health related quality of life, i.e. less negative self-perception, social, emotional and symptomatic effects associated with acne.
2. Missing values were identified and any missing value was replaced with the mean of the given sub-score. However, if there was less than 3 questions answered in a given domain then the sub-score was not calculated.
3. The scores for each domain were calculated by summing the coded responses to each question in the domain. The sub-scores for different QOL domains were calculated.
4. The overall score for QOL was calculated by summing the total scores for all four domains.

Diagnosis of acne was based on presence of whitehead comedone and blackhead comedone, papule, pustule, pseudocyst and scar. It was done by a trained dermatology female resident. Acne is categorized into three degrees according to its severity into mild, moderate and severe. Mild acne has less than 20 non-inflamed blackheads or whiteheads, or a moderate number of small, mildly irritated pimples. Blackheads are characterized by small bumps with small black dots at their centers. Whiteheads have a similar appearance to black heads but lack the dark or black dots in center. Pimples have a pus filled white center surrounded by a small area of erythema around it. Moderate acne is characterized by more comedones and pimples. Severe acne have more larger, red, painful pus-filled lumps (nodules) that sometimes even join together under the skin into giant, oozing abscesses or cystic lesions (14).

The researcher distributed the self-administered questionnaire to the target population by direct contact with target population with permission from the college administrators. Care was taken to not disturb the student lectures. The researcher and the dermatology resident first diagnosed the students who have acne by arranging with the college clinic to make an appointment for the girls who were suspected to have acne to come to the clinic on specific days to meet the researcher and the dermatology resident to make the diagnosis. Both the researcher and the dermatology resident were always available to clarify any issues and the questionnaires were distributed and collected immediately. Appreciation was used to encourage the participants to participate in the study

A pilot study was conducted on 30 volunteers from the College of Medicine who were excluded from the study. The internal consistency of the questionnaire at all and every domain were assessed by Cronbach's α coefficient. The test-retest reproducibility was assessed by the intra-class correlation coefficient (ICC) for each domain and by comparison between subjects' answers at baseline and second visit (an average of two weeks in between). Content validity was assessed by three consultants (one in Family Medicine, one in Psychiatry and one in Dermatology).

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Collected data were verified by hand and then coded before computerized data entry. The statistical Package for Social Sciences (IBM, SPSS version 22) was used for data entry and analysis. Descriptive statistics (e.g., number, percentage, mean, range, standard deviation) and inferential statistics, using chi-square test ($\chi 2$), t-test, analysis of variance (ANOVA) and correlation analysis were applied. P-values less than 0.05 were considered as statistically significant

Results

Table (1) shows that more than two thirds of participants were aged 20-24 years, while 18.1% were <20 years old and 12.3% were > 24 years old. Participants' scholastic years were almost equally represented, but only 13.8% of them belonged to the sixth year. The majority of participants were non-smokers, however, 3.1% were smokers. More than one quarter of students (26.2%) were overweight and 4.2% were obese, while 16.9% of students had a chronic disease. About one quarter of participants (26.9%) had menstrual problems. Most participants were single (84.2%), while 15.8% were married and 8.8% had children, while 6.2% used contraceptive pills.

The monthly family income of 38.1% of participants was less than 5,000 SR, that of 23.1% was 5,000-9,999 SR, 18.1% had 10,000-14,999 SR and 20.8% had ≥15,000 SR.

Prevalence of acne was found to be 227(87%) among participants. Severity of acne among 48% of participants was mild, that of 39.6% was moderate, while 12.3% had severe acne. Treatment for acne was not received by 42.7% of participants while 41% received a local treatment. Oral treatment was received by 5.7% of participants while 10.6% received both oral and local treatment for acne.

Table 2 shows that the students attained acne QOL scores (Mean+SD) for all its four domains including self-perception, role emotional, role social and acne symptoms. Mean score (+SD) for self-perception was 18.4+8.0, for role emotional was 14.4+8.8, for role social was 14.4+6.4, for acne symptoms was 13.4+5.2, while for the overall score was 60.5+24.4

Table 3 shows that acne QOL scores for all domains, especially the "role emotional" and "role social" were significantly lower among female university students who have acne. Similarly, acne QOL scores for all 4 domains and overall scores (Mean+SD) were lowest among female university students who have severe acne. Differences were statistically significant for all domains and the overall score. However, acne QOL scores did not differ significantly according to received treatment modality.

Table 4 shows that students' acne QOL scores were not significantly significant for age, scholastic years, smoking, BMI, marital status and menstrual problems. While students' acne QOL scores only differed significantly according to their family monthly income regarding "self-perception" (p=0.005), role emotional (p=0.037) and overall (p=0.012). For all domains, students with high monthly family income had higher acne QOL scores.

Table 1: Personal and disease characteristics of participants (n=260)

Personal characteristics	No.	%
Age groups		
• <20 years	47	18.1
• 20-24 years	181	69.6
• >24 years	32	12.3
Scholastic year		
• First	49	18.8
• Second	44	16.9
• Third	46	17.7
• Fourth	44	16.9
• Fifth	41	15.8
• Sixth	36	13.8
Smoking status		
• Smoker	8	3.1
• Nonsmoker	252	96.9
Grade of body mass index		
• Normal weight	181	69.6
• Overweight	68	26.2
• Obese	11	4.2
Menstrual problems		
• Yes	70	26.9
• No	190	73.1
Marital status		
• Single	219	84.2
• Married	41	15.8
Monthly family income		
• <5000 SR	99	38.1
• 5000-9999	60	23.1
• 10000-14999	47	18.1
• ≥15000	54	20.8
Presence of acne		
• Yes	227	87.3
• No	33	12.6
Severity of acne (n=227)		
• Mild	109	48.0
• Moderate	90	39.6
• Severe	28	12.3
Receiving treatment for acne (n=227)		
• Nothing	97	42.7
• Local treatment	93	41.0
• Oral treatment	13	5.7
• Both oral and local treatment	24	10.6

Table 2: Students' attained acne QOL scores (Mean+SD) for its four domains

Acne QOL Domains	Maximum score	Mean±SD
Self-perception	30	18.4±8.0
Role emotional	30	14.4±8.8
Role social	24	14.4±6.4
Acne Symptoms	30	13.4±5.2
Overall	114	60.5±24.4

Table 3: Students' acne QOL scores (Mean+SD) according to disease characteristics

Acne-related characteristics	No.	Self perception	Role emotional	Role Social	Acne symptoms	Overall
Having acne						
• Yes	227	18.1±8.0	13.5±8.5	14.1±6.4	12.8±5.0	58.5±23.7
• No	33	20.3±7.7	20.2±8.5	16.7±6.2	17.4±4.8	74.5±25.0
P-value		0.141	<0.001*	0.029*	<0.001*	<0.001*
Severity of condition						
• Mild	109	20.3±7.8	15.8±8.8	15.2±6.3	14.1±5.2	65.4±23.8
• Moderate	90	17.4±6.9	12.6±7.5	13.8±6.0	12.2±4.1	55.9±19.7
• Severe	28	11.8±8.6	7.8±7.4	10.7±6.7	9.4±5.4	39.6±24.0
P-value		<0.001*	<0.001*	0.003*	<0.001*	<0.001*
Received treatment for acne						
• Nothing	97	19.4±7.9	14.2±8.8	14.9±6.5	12.6±5.2	61.1±23.6
• Local	93	17.3±7.4	13.1±7.9	13.3±6.3	13.3±4.9	57.0±22.5
• Oral	13	18.8±10.9	11.6±7.4	14.5±6.7	14.1±4.9	58.9±26.6
• Oral and local	24	15.5±8.7	13.7±10.3	13.3±6.1	10.6±4.9	53.1±26.6
P-value		0.105	0.684	0.332	0.081	0.425

Table 4: Acne QOL scores (Mean+SD) according to participant's sociodemographic characteristics

Personal characteristics	No.	Self perception	Role emotional	Role Social	Acne symptoms	Overall
Age groups						
• <20 years	47	18.1±7.7	14.1±8.7	14.4±6.1	12.7±5.5	59.4±22.4
• 20-24 years	181	18.5±8.3	14.8±9.1	14.5±6.5	13.6±5.2	61.5±25.5
• >24 years	32	18.2±7.2	12.2±6.4	13.7±6.1	12.8±5.1	56.8±20.5
P-value		0.937	0.292	0.801	0.444	0.573
Scholastic year						
• First	49	17.8±7.5	14.7±8.2	14.7±6.0	13.0±5.4	60.1±22.7
• Second	44	19.3±8.8	15.2±10.6	14.4±7.2	12.8±5.3	61.8±27.5
• Third	46	19.8±8.1	14.2±8.5	15.3±6.3	14.3±5.3	63.5±23.9
• Fourth	44	17.4±8.2	14.0±8.8	13.8±6.7	13.6±4.8	58.8±25.2
• Fifth	41	18.5±8.1	15.4±8.9	14.3±6.2	13.9±5.3	62.1±25.1
• Sixth	36	17.4±7.4	12.3±7.3	13.6±6.3	12.6±5.5	55.9±22.3
P-value		0.640	0.680	0.847	0.644	0.778
Smoking status						
• Smoker	8	18.5±10.0	14.1±5.9	12.4±6.4	10.9±6.4	53.3±25.3
• Nonsmoker	252	18.5±7.9	14.4±8.9	14.5±6.4	13.4±5.2	60.7±24.4
P-value		0.369	0.936	0.367	0.172	0.384
BMI						
• Normal weight	181	18.5±7.9	15.1±8.7	14.6±6.4	13.9±5.4	62.1±24.6
• Overweight	68	17.3±8.2	12.5±8.7	13.3±6.5	12.0±4.4	55.1±23.0
• Obese	11	22.6±7.9	14.5±10.4	17.3±5.2	13.5±6.5	67.9±25.9
P-value		0.105	0.120	0.118	0.135	0.075
Marital status						
• Single	219	18.4±8.0	14.7±8.8	14.6±6.4	13.5±5.3	61.2±24.5
• Married	41	18.1±8.2	12.7±8.7	13.4±6.4	12.6±4.6	56.9±23.7
P-value		0.836	0.193	0.301	0.286	0.300
Menstrual problem						
• Yes	70	18.4±8.4	13.7±9.1	14.2±6.9	13.1±5.3	59.4±25.2
• No	190	18.4±7.9	14.6±8.7	14.5±6.3	13.4±5.2	60.9±24.2
P-value		0.973	0.437	0.770	0.683	0.650
Family monthly income (SR)						
• <5000	99	15.7±7.7	11.5±8.8	14.7±6.1	13.6±5.1	51.6±23.5
• 5000-9999	60	17.2±8.2	14.2±9.3	14.6±6.4	12.9±5.7	58.8±25.7
• 10000-14999	47	19.4±7.3	15.2±6.7	12.3±6.5	12.1±5.3	63.0±22.0
• ≥15000	54	19.9±8.3	15.2±9.3	15.5±6.7	14.5±4.7	65.1±24.7
P-value		0.005*	0.037*	0.066	0.118	0.012*

P-value significant= <0.05*

Discussion

There are many factors that contribute to the confidence level of a person about his/her physical appearance. Healthy and glowing skin is one of the leading factors influencing how a person feels regarding his/her perceived attractiveness towards others (15). This study aimed to examine the impact of acne among female university students on their different domains of QOL.

Results of this study showed that the majority of female university students were non-smokers. In addition, more than one quarter of students (26.2%) were overweight and 4.2% were obese. A study conducted at King Abdul-Aziz University Saudi Arabia among non-medical female students showed prevalence of smoking about 4.2% (16) whereas prevalence of cigarette smoking at King Saud University Saudi Arabia was reported as 4.3% among female students (17). Over weight and obesity was reported in up to 47.9% among female students of Princess Nora Bint Abdul Rahman University, Riyadh, KSA (18).

The present study found that the prevalence of acne among female university students in KKU was 87%. Almost 48% of participants had mild acne, 39.6% had moderate while 12.3% had severe acne. Around 42.7% of participants were not taking any treatment while 41% received a local treatment. Those findings are consistent with other studies as well. Tasoula et al (19) found that acne vulgaris is a common skin disease affecting up to 80% of adolescents and many adults at some stage in their life. Yolac et al. (20) reported that acne, once thought to be an ailment of teenagers, affects more than 85% of the population.

Several studies have reported that acne is a complex disorder that requires individualized treatment (21). Samanthula and Kodali stated that acne has a wide range of treatment modalities starting from non-pharmacological measures including modifying lifestyle factors and psychosocial support to pharmacological management including topical creams, systemic medications, and laser treatments as well (22). Our study showed that 41%, 5.7% and 10.6% of participants were on topical treatment, oral treatment and combined treatment respectively. The present study showed that scores for acne symptoms (which represent the severity of acne) correlated significantly with all other domains of acne QOL index. This finding is similar to that reported by Al-Shidhani who reported a significant association between scores for acne symptoms and those for all other domains. They explained this finding by any increase in acne severity would subsequently lead to an increase in the negative effects on the patients' feelings, self-perception, and socialization as the lesions became more prominent and especially if scarring occurred (23).

Results of the present study revealed that prevalence of acne increased with some personal characteristics of participants, (e.g., age, scholastic year, and smoking status, body mass index and presence of associated chronic diseases). However, differences were not statistically significant. Moreover, prevalence of acne among participants increased with some gynecological and obstetric characteristics, (e.g., married and those with menstrual problems). However, differences in prevalence rates of acne were not statistically significant. In addition, prevalence rates of acne among participants did not differ significantly according to their monthly family income.

The lack of significant differences in acne QOL domains according to personal variables is due to the fact that all questions of the acne-QOL questionnaire are framed to be disease-specific, which means that the effect on the QOL is unlikely to be due to other factors (13, 23). Epidemiological studies can be a helpful tool to identify risk factors for acne in a community, to quantify its burden and contribute to health care planning (18). Acne among adolescent females is becoming more and more common. Its prevalence is estimated to range from 40% to 50% (24). Therefore it is required to assess and treat the causes of acne among females as well. Acne is very widespread worldwide, affecting 75-80% of adolescents. Its risk factors are not always the same in the various populations, and the treatments proposed are also not always well tolerated by all individuals. In Senegal it is found that around 75% of acne cases were young women, 76.3% of whom were single (25).

Results of the present study showed that acne QOL scores did not differ according to their personal characteristics or their gynecological and obstetric characteristics. Moreover, according to family-related characteristics, there were significantly higher (i.e., better) acne QOL scores among students with higher monthly family income. Previous study reported the prevalence of acne is 58.6% in Chinese adolescent females, and showed that increased age was related to higher prevalence of acne vulgaris (26).

The significantly better acne QOL scores among participants with higher family income may reflect more healthy nutrition. Some studies analyzed socioeconomic levels as well, and showed that individuals with lower income categories were more prone to develop acne because of difficulty to buy medications because of low income (27).

Results of the present study showed that acne QOL scores were lower among female university students who have acne. Moreover, their scores were lowest among those who have severe acne. These results are consistent with several studies worldwide, which reported that the impact of acne on quality of life was proportional to acne severity. Those patients who have severe acne reported more burden on their QOL than those with mild acne or no acne. This indicates that the impact of acne on QOL is influenced by perceived severity of acne (28-31). Some studies reported significant psychological impact of acne for example anxiety, depression, low self-esteem, fragile emotions, low self-confidence, and even suicidal thoughts and tendency (29; 30). However more severe acne has been shown to be associated with more symptoms of

anxiety and depression and more negative impact on their lives (31). The association between social inhibition and phobia with acne is also reported (33). Moreover degree of severity of acne is highly correlated with more stress (34).

This study showed that treatment for acne was not received by almost half of participants (42.7%). Moreover, although acne QOL scores were significantly associated with severity of acne, these scores did not differ significantly according to received acne treatment modality. This finding reflects the fact that acne is frequently undertreated because it is often regarded as a simple disease by family physicians and primary care physicians. This information can be very helpful for doctors and other health care professionals for better understanding of the psychological and social impact of acne on patients' lives (28-29).

Although acne can have major effects on the patients' QOL, perhaps these effects are sometimes not fully appreciated and recognized by the treating physician and even not considered as a cosmetic concern (30).

QOL is defined by four important domains: self-perception, role-social, role-emotional, and acne symptoms. Moreover literature shows a similar impact on quality of life with acne than that of asthma, epilepsy, diabetes, back pain, arthritis, and coronary heart diseases (32).

This study found that there is worst impact on emotional and social aspect of QOL compared to self-perception and acne symptoms (23). There is a significant impact of acne on patients' emotions in terms of self-embarrassment, low self-esteem, low self-confidence, feeling of selflessness and disturbance in daily life due to acne symptoms such as pain and itching, and discomfort from the side effects of the treatment itself (18).

Conclusion

In conclusion, this study showed that prevalence of facial acne is very high among female university students and acne significantly affects their quality of life. Moreover, results of the present study indicate that prevalence of overweight and obesity is quite high among female university students, while their physical activity and practice of exercise are low and some students are cigarette smokers. Therefore, it is recommended that family physicians and other health care professionals should consider the psychosocial aspect of acne during the management of patients with acne. Health education programs should focus on healthy lifestyle practices, including proper healthy nutrition and physical activity to prevent obesity as well as measures to quit smoking. Further studies, using a larger sample size representing the general population are needed to address the extent of the problem among the acne patients.

Strengths and limitations of this study

Perhaps a point of strength in the present study is that it was conducted on female university students, whose age group is early adulthood, during which acne is highly prevalent and when the effects of any health problem on their quality of life would have greater effects on their future. Another point of strength, is that this study used a self-administered questionnaire with fulfilled confidentiality and anonymity, thus minimizing participants' response bias.

However, the study group included only female university students who were relatively homogenous regarding their age group and educational level. Consequently, they constitute only a special subgroup within the community. Therefore, generalizability of the results is limited to female university students not the whole population. In addition, limited personal characteristics were assessed in the present study. Nevertheless, the scope of this study was mainly focused on acne vulgaris and all differences in prevalence and severity of acne attributed to personal characteristics proved to be not statistically significant. Moreover, this limitation might not have significant effects as the acne QOL index which was used in this study is disease specific, i.e., the questions contained the statement "because of your facial acne".

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Frequency of Esophageal Carcinoma and Delay in Diagnostic Workup; A Multi-centre Experience from Southern Pakistan

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Abstract

Objective: Esophageal carcinoma is one of the most lethal and yet least studied malignancies in South Asian region. The aim of our study was to determine the frequency of Esophageal Carcinoma and to identify factors responsible for late stage diagnosis of this malignancy.

Methods: A multi-institutional prospective cross-sectional study was conducted at Oncology department, JPMC and Atomic Energy Medical Centre, Karachi. Association between risk factors of delayed diagnosis with ethnic groups, grade and stage of tumour was statistically assessed.

Results: A frequency of 3.83% of esophageal cancer was recorded. Squamous cell carcinoma as the most common (80.6%) subtype, moderately differentiated grade in 67.7% and lower 1/3rd involvement was noted in 53.8% cases. Representation of Sindhi speaking ethnicity was 33.3%. First visit to a general physician was within a month of onset of symptoms in 54.8% patients. In 21.5%, first visit was delayed by more than 2 months. Biopsy was delayed in 19.4% cases. Significant association was found between delayed diagnosis and late referral to oncologist (P 0.003), non-availability of laboratory (P 0.018), location of tumour (P 0.000), age and size of tumour (P 0.001).

Conclusion: Esophageal carcinoma is a common malignancy with squamous cell carcinoma as the most common subtype. Initial diagnosis of most of the patients was made in the late stage. Important contributing factors of late diagnosis were unawareness of patients, delayed initial diagnostic workup, poor socioeconomic status and late referrals to oncologists by General Physicians. No significant association was observed between ethnicity and grading or staging of tumour.

Key words: Esophageal carcinoma,
Esophageal Squamous Cell Carcinoma (SCC),
Adenocarcinoma of Esophagus (AC),
Southern Pakistan

Introduction

Esophageal carcinoma is one of the most lethal cancers worldwide, and has not been extensively studied in the Pakistani population. It is very aggressive in nature, usually diagnosed in late stages and has a poor prognosis. Esophageal Squamous cell carcinoma (SCC) and Esophageal Adenocarcinoma (AC) are its two major histological types [1, 2]. According to GLOBOCAN 2018, there are dramatic increases in the incidence of esophageal carcinoma and it is the sixth common cause of mortality, worldwide [3]. A high prevalence of this malignancy has been recorded in the Asian Belt of Esophageal cancer. This belt region expands from northern Iran to north-central China. Intermediate risk for developing Esophageal cancer exists in areas including southeast Africa, parts of South America and Western Europe. According to data, 90% of cases of esophageal cancer in the developing countries are histologically SCC [4]. Annual cancer registry report-2018, of The Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC), Pakistan showed that esophageal cancer is the 10th most common malignancy in Pakistan, with a frequency of 3.2% [5].

A report published in 2004 showed that only 1/4th of patients had early stage malignancy at the time of diagnosis with locally invasive and metastatic tumours to be 41% and 34% respectively. Furthermore, statistics from the same report showed SCC is 4 times more frequent than adenocarcinoma (AC) with a median survival of 7 months [6]. Similarly, a study from Thailand reported a high frequency of late diagnoses of esophageal cancer [7].

Risk factors for esophageal carcinoma include smoking, tobacco, alcohol consumption, hot beverages. Human papilloma virus and certain driver genetic mutations are other possible factors for this malignancy. Barrett's esophagus is an important precancerous disease in which there is 50 to 100 times increased risk of developing esophageal adenocarcinoma. The association of western diet, polycyclic aromatic hydrocarbons in charcoal and mutagenic heterocyclic amines in roasted red meat with the development and progression of esophageal cancer has also been established. Diet lacking in zinc and selenium has been linked with increased risk for developing this malignancy. Common clinical features of this malignancy include dysphagia, weight loss, vomiting, dyspepsia, chest pain and hematemesis [1, 3, 7, 8, 9] .

Extensive literature review showed that substantial information regarding the possible factors contributing to delayed diagnostic workup of this malignancy is lacking in the region. Karachi is a densely populated cosmopolitan city in Southern Pakistan, where people from different regions of the country belonging to various ethnic groups, reside. They do not only differ in race and language, but also have varying dietary habits and lifestyles. The current study is an attempt to determine the frequency of esophageal cancer in different ethnic groups presenting to a public sector tertiary care hospital of Karachi. This study will also identify the possible factors involved in delayed diagnosis of esophageal carcinoma.

Patients and Methods

A multi-institutional prospective cross sectional study was conducted at Department of oncology Jinnah Post Medical Centre (JPMC) and Atomic Energy Medical Centre (AEMC) Karachi from 1st March 2018 till 28th February 2019. The study was approved by Institutional Review Boards (JSMU/IRB/2017/93) of Jinnah Sindh Medical University, AEMC and JPMC Karachi. Non-Probability convenient sampling technique was implemented to select the study participants. The sample size was calculated using Open Epi software. Considering the annual registered number of patients at both institutes, the population size = 125, anticipated frequency = 50%, Confidence level = 95 %, confidence level as +/- percent of 100 = 5, design effect =1, the minimum sample size calculated was 95. Complete history and investigations were not available for two patients, so the final number of patients included in the study was 93.

Biopsy proven cases of esophageal carcinoma of either gender, registered in JPMC and AEMC who agreed to participate in our study after taking written or verbal consent were included in the study. Subjects who refused to participate, metastatic malignancy to esophagus or recurrent esophageal tumours cases were excluded. Data were collected using a self-structured validated questionnaire. The questionnaire was developed after extensive literature review using PubMed and Google Scholar. It was comprised of multiple choice, open and close-ended questions. The questionnaire was divided into four sections. The first part inquired about demographics, ethnicity and place of presentation. The second section included clinical features at presentation and all the possible factors leading to late diagnosis. The third and fourth sections were comprised of CT scan and biopsy findings including subtypes of cancer, grading, staging, extent, possible metastasis etc. American Joint Committee of Cancer (AJCC) criteria were followed to stage the carcinoma [10]. Stage 3 and 4 were considered late stages.

Data analysis was performed using IBM Statistical Package for the Social Sciences (SPSS), Version 25.0. Descriptive statistics were used to determine mean and standard deviation for numerical variables. Categorical variables were expressed in frequency and percentages. Chi-square/ Fisher Exact test was applied to assess the statistical difference in distribution of cases among different ethnic groups as well as to observe any association between risk factors of delayed diagnosis and ethnic groups, grade and stage of esophageal carcinoma. A P value of < 0.05 was considered significant.

Results

A total of 95 esophageal carcinoma patients presented to both institutes during the study duration. Due to incomplete data, two of them were excluded and the final number of patients remained at 93. They included 41 males and 52 females, aged between 18 to 80 years, mean age was 45.45, with Standard deviation ±14.504, (Figure 1). Out of these 93 patients, 82 were registered in Oncology ward JPMC and 11 in AEMC. SCC was the most common histological type 75 (80.6%) followed by AC 14 (15.1%) cases. Other morphological types included small cell carcinoma, signet ring cell carcinoma and large cell variety of Adenocarcinoma. Location of tumour was Upper one third in 17 (18.3%), middle one third in 26 (28%) and lower one third 50 (53.7%) cases (Table 1).

Most common presenting symptom was dysphagia in 89 (95.7%) followed by weight loss in 70 (75.3%) and Odynophagia in 41(44.1%) cases. There was significant association of dysphagia with weight loss (P=0.017), history of chronic cough (P =0.001) and history of dyspnea (P =0.000). Lack of awareness was an important contributing factor in delayed diagnosis as 87(93.5%) patients never heard about esophageal cancer before being diagnosed with it.

Positive family history of various malignancies was observed in 20 (21.5%). Sindhi population was the most commonly affected ethnic group 31 (33.3%) as shown in (Table 2). This was followed by Urdu speaking 26 (28%), Pathan and Baloch 10 (10.8%) each, respectively. Endoscopy report of only 15 patients were available where 13/15 (86.6%) patients showed an ulcerated lesion. Moderately differentiated was the most common 63 (67.7%) histologic grade. Association of grading and staging with ethnic groups is presented in detail in (Table 2).

Approximately half of the patients, 51 (54.8%) visited a physician within a month of the occurrence of first symptoms. About 26 (28%) had an appointment with a physician immediately, while 25 (26.9%) visited after 15 days. However, 20 (21.5%) patients saw a doctor about two or more months after the initial symptom. Almost all patients, 90 (96.8%) properly followed investigations and treatment as prescribed by the doctors. Biopsy of 18 (19.4%) patients was delayed. Important contributors were low socioeconomic status and unavailability of diagnostic laboratory within nearby location. (P = 0.000). Total number of patients diagnosed at late stage was 58(62.2%) [Stage 3: 26(27.8%), stage 4 31(34.4%)]. (Table 3) Significant association was found between various factors and late stage diagnosis as explained in Table 3. The majority of patients (86%) had delayed referrals by general physicians. The second most significant contributor to late diagnosis was non availability of a good diagnostic laboratory facility in the nearby vicinity in about 32% patients.

Figure 1: Bar chart representing number of esophageal cancer cases in association with age groups and gender

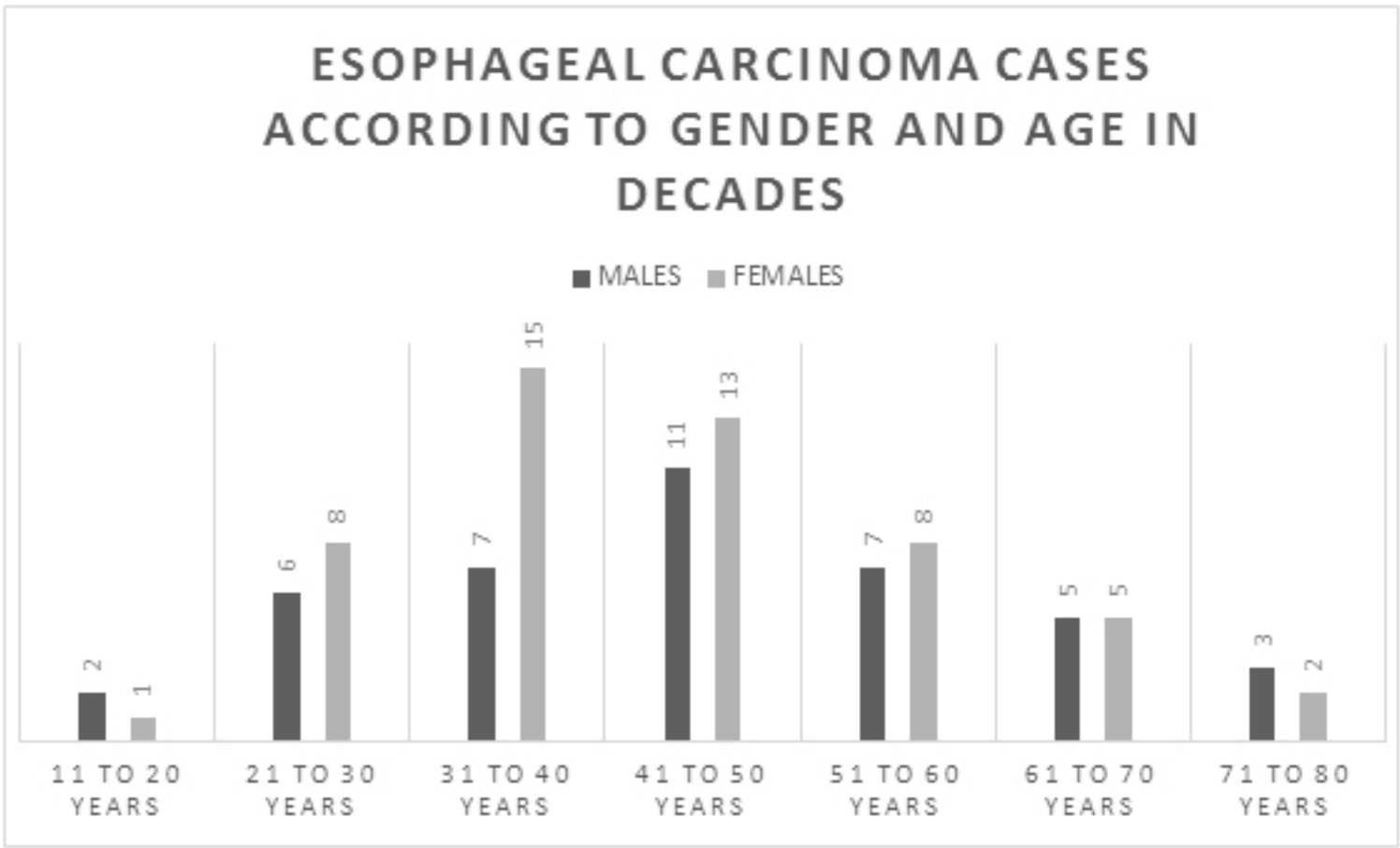

Table 1: Frequency of Esophageal Cancer according to morphological types & location

Location of Tumor	AC	SCC	Small cell carcinoma	Others	Total N (%)	P value±
Upper 1/3rd	1	14	1	1	17 (18.3%)	0.080
Middle 1/3rd	1	25	0	0	26 (28%)	
Lower 1/3rd	12	36	1	1	50 (53.8%)	
Total	14 (15.1%)	75 (80.6%)	2 (2.2%)	2(2.2%)	93 (100%)	

Table 1 shows frequency of Esophageal Adenocarcinoma (AC), esophageal squamous cell carcinoma (SCC), small cell carcinoma and other variants of esophageal cancer according to location.
±Fisher Exact Test

Table 2: Staging & Grading of Esophageal Cancer at the time of diagnosis according to ethnicity. (N=93)

Grading of esophageal cancer at the time of diagnosis according to ethnicity								
Grade at diagnosis	Sindhi	Pathan	Baloch	Punjabi	Urdu Speaking	Others	Total n(%)	P value
Well Differentiated	8	1	2	1	5	0	17 (18.2%)	0.806
Moderately Differentiated	21	7	7	3	15	10	63 (67.7%)	
Poorly Differentiated	2	2	1	1	6	1	13 (13.9%)	
Total	31 (33.3%)	10 (10.7%)	10 (10.7%)	5 (5.3%)	26 (27.9%)	11 (11.8%)	93 (100%)	
Staging of esophageal cancer at the time of diagnosis according to ethnicity								
Stage at Diagnosis	Sindhi	Pathan	Baloch	Punjabi	Urdu Speaking	Others	Total n(%)	P value
1A	1	0	2	0	0	0	3 (3.2%)	0.249
1B	3	0	1	0	2	2	8(8.6%)	
2A	9	1	2	0	5	3	20 (21.5%)	
2B	4	0	0	0	1	0	5 (5.4%)	
3A	2	1	3	1	6	2	15 (16.1%)	
3B	2	4	1	1	2	1	11 (11.8%)	
4A	5	3	0	0	7	3	18 (19.4%)	
4B	5	1	1	3	3	0	13 (14.0%)	
TOTAL	31 (33.3%)	10 (10.7%)	10 (10.7%)	5 (5.3%)	26 (27.9%)	11 (11.8%)	93 (100%)	

Table 2 shows distribution of Grades and Stage I to IV of esophageal cancer cases according to ethnicity. Stage 3 and 4 are considered advanced stage of the disease. ±Fisher Exact Test

Table 3: Possible Association of various factors with delayed diagnostic workup and late stage diagnosis of esophageal carcinoma.

Factors leading to delayed diagnosis	Number of patients n (%)	P value*
Referral by General Physician (GP) to a medical specialist		
Late Referral by GP	80 (86%)	0.003
Delayed diagnosis due to late referral	48/80 (60%)	
Availability of Diagnostic laboratory in the vicinity		
No laboratory in nearby location	30 (32%)	
Delayed diagnosis due to unavailability of early diagnostic facility	12/30 (40%)	0.018
Location of tumor in esophagus		
Upper 1/3rd	17 (18.3%)	
Middle 1/3rd	26 (28%)	0.000
Lower 1/3rd	50 (53.8%)	
Late stage diagnosis in lower 1/3rd	36/50 (72%)	
Age at diagnosis		
No. of patients in 5th, 6th, 7th decade	61 (65.6%)	
Late stage diagnosis among older age group	41/ 61 (67.2%)	0.044
Size of tumor in largest dimension (2.1 – 8 cm)	68 (73.1%)	
Late stage diagnosis according to tumor size	42/68 (62%)	0.001

Table 3 shows association of various possible factors with late stage diagnosis of EC.
*Pearson Chi-square test

Discussion

Carcinoma of esophagus is a less studied entity in the local population. The current study was designed to observe the pattern of this malignancy in a tertiary care hospital in the hub of the city. To the best of our knowledge, similar research has not been reported from this region.

A frequency of 3.83% of esophageal cancer was recorded in the current series. It is close to the annual cancer registry report 2018 of SKMCH&RC (3.2%) [5]. Most of the patients were in either 4th or 5th decade, constituting 23.6% and 25.8% respectively. Mean age was found to be 45.45 with Standard deviation ±14.504. A slight female preponderance was observed in our study (55.9% female and 44.1% male). Male to female ratio was 1:1.2. On the contrary, another tertiary care facility from Karachi reported a male majority (59%) [6]. This is an interesting finding from the subcontinent region as the GLOBOCAN 2018 also showed 70% cases of esophageal cancer in male population of Eastern and Southern Africa [3]. Sindhi and Urdu speaking were the most common ethnicities. Interestingly, no significant association was found between ethnic groups and grading (P= 0.806), and staging (P=0.249) of tumour. The reason could be the similar dietary habits, exposure to similar environmental exposure and unvarying socioeconomic conditions of all ethnic groups.

SCC was the predominant morphological type. Other studies support our finding. Smoking and Betel quid chewing are regarded as important causes of increased frequency of SCC in the Western world and subcontinent respectively [3, 6, 13]. A study conducted in rural Southern province of Sindh showed frequency of SCC to be 95%, affirming 80.6% in our study [11]. Histologically, moderately differentiated tumour (Grade 2) was found in a significant number (67.7%) of patients. Well differentiated (Grade 1) and poorly differentiated morphologies (Grade 3) were 18.3% and 14% respectively. This is comparable with the findings of a German study observing grade 2 (50%) as the most frequent, followed by grade 1 (41.7 %) and grade 3 (8.3%) respectively [12]. These facts emphasize on the frequency of morphological grades of similar types, regardless of regional differences as well as higher possibility of late diagnosis of this malignancy. Lower 1/3rd of the esophagus was found to be the most common location overall as well as for both major histological types, followed by middle and upper thirds respectively (Table 1). Similar statistics regarding highest frequency of malignancy in lower third of esophagus have been reported from the region [6]. One of the possibilities of frequent involvement of lower one third of esophagus could be its association with Gastroesophageal Reflux Disease (GERD).

Most common presenting complaints of patients were dysphagia (95.7%) and weight loss (75.3%). In the majority of patients, dysphagia developed initially for solids and

subsequently for liquids. Odynophagia was the third most common symptom (44.1%), commonly in the 4th and 5th decade of life (P = 0.043). Hoarseness was found in 28%, most common with lower 1/3rd involvement. (P= 0.009). These observations are in agreement with a previous study of this region [6]. The increased severity of symptoms with time is indicative of progression to advanced stage of malignancy. This finding again indicates the fact that the delayed diagnosis of esophageal cancer is not an uncommon event.

About 61.2% patients were diagnosed either at stage 3 or 4. Table 2.0. A study conducted in Thailand reported more than 90% of the cases presented at late stage. Advanced stage disease is reported to have a poor prognosis and low survival rate [7]. Decreased awareness among masses regarding symptoms of esophageal malignancy was an important contributor to late diagnosis in the current series. Approximately 87(93.5%) of our patients did not have previous information about symptoms and signs of this disease until diagnosed. This is indicative of lack of awareness in the general population related to this ailment. Routine annual check-ups are not being offered at public sector tertiary care hospitals of the region. General physicians in the locality usually offer symptomatic treatment instead of advising early diagnostic workup including endoscopy, biopsy or referring the patients timely to medical specialists. Furthermore, this finding is supported by another study stating that the primary care physicians in the largest city of Pakistan are deficient in practicing World gastroenterology organization (WGO) practice guidelines [13]. All these factors contribute to the advancement of the disease at the time of diagnosis. In the present study, 53.8% of patients were investigated for endoscopic histological sampling after remaining on symptomatic treatment for approximately two months, by general physician (P = 0.003).

Genetic alteration is another significant contributor in development of esophageal carcinoma. Although it is not well understood but repeated chromosomal gains, losses and amplification have been reported [1, 14]. In the current study 21.5% patients had a positive family history of various malignancies at different sites. Supporting our observation, a Chinese cohort revealed 34.7% of esophageal cancer cases who had first-degree relatives suffering from cancer. Individuals with both parents affected by this malignancy were 8 times more likely to develop esophageal carcinoma. A positive family history of other types of malignancies were also found to be associated with an increased risk of this malignancy [15].

Limitation:
Loss of follow up of patients is one of the limitations of this study. No official cancer registry of the Southern province of Sindh was available for comparative analysis. Factors associated with late stage diagnosis were not compared because of lack of data in published studies.

Recommendation:
We recommend public awareness programs to spread information regarding symptoms of esophageal carcinoma. Symposiums for General physicians should be organized to increase the rate of early referrals.

Conclusion

Esophageal carcinoma is a fairly common malignancy in the region. SCC is the most common histological type. Initial diagnosis of most of the patients was made in the late stage of the disease. Important contributing factors of late diagnosis were inadequate awareness of patients, delayed initial diagnostic workup, poor socioeconomic status and late referrals to oncologist by general physicians. No significant association was observed between ethnicity and grading or staging of esophageal carcinoma.

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Awareness and Attitudes towards Common Eye Diseases among the General Population of Southern region of Saudi Arabia

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Abstract

Background: Globally, the number of visually impaired persons still increases; this will increase demand for more eye care services, programmes, and treatment for the visually disabled individuals. Consequently, the first step is to map the size of the problem. Detection of the related factors of visual loss and blindness is vital to build appropriate treatment, rehabilitation, and service programmes. Public awareness regarding these eye related health conditions is the first step for mapping the problem and public concern for early detection and management.

Methodology: A descriptive cross-sectional survey was conducted focused on all adults in Aseer region. The study was conducted during the period from May 2020 to September 2020. Data were collected using pre-structured online questionnaire established by the researchers after intensive literature review and expert's consultation. The questionnaire data included participants' socio-demographic data, awareness regarding eye diseases was evaluated and its main domains included glaucoma related awareness, cataract awareness, diabetic retinopathy awareness, refractive errors awareness, and eye dryness.

Results: A total of 1,014 participants in the southern region of Saudi Arabia completed the survey. Participants' ages ranged from 18 to 75 years with mean age of 33.8 (12.2%) years old. Exactly 641 (63.2%) participants were males. Exactly 23.1% of participants defined cataract as a change in lens colour and 17.8% reported that it is an age related disorder. Glaucoma was defined as a disease that causes optic nerve damage by 22.2% of the participants while 18.6% defined the disease as a condition causing diminished peri-ocular vision. DR was defined as retinal vascular lesion disorder by 23.6% of the participants and 42.9% classified the disease as one of the DM complications. In total, good awareness regarding cataract was detected among 13.4% of the participants and 10% had good awareness regarding glaucoma.

Conclusions & recommendations: In conclusion, the study revealed that overall public awareness regarding common eye diseases was very poor especially among the old aged and females. The main source of information was a family member or friend who had the disease.

Key words: Eye diseases, disorders, cataract, glaucoma, diabetic retinopathy, awareness, population

Introduction

Globally, ocular disorders, including diabetic retinopathy, glaucoma, and cataract are judged prominent causes of blindness (1, 2). Recently, the World Health Organization reported that about 285 million people of all age are visually impaired globally constituting about 80% of the total health burden (3). A joint program of the WHO and the International Agency for the Prevention of Blindness (IAPB) initiated VISION 2020: The Right to Sight in 1999, to eliminate avoidable blindness by the year 2020 (4).

Awareness of eye diseases not only aimed for better awareness of the disease but also to promote the global population to properly use the available eye care services. Proper utilization of eye care services performs a major role in the prevention of blindness due to ocular diseases (5). Nowadays, there are 2.2 billion people around the world who have a vision impairment, of whom at least 1 billion have a reversible vision impairment due to temporary causes or is yet to be addressed (6). Consequently, improving public awareness regarding the most frequent ocular diseases has a significant role in the early detection and management of these conditions to minimize the burden of visual impairment (7, 8). Many studies have assessed the level of public awareness of common ocular diseases worldwide (9, 10). Studies have revealed many determinants which may modulate the level of awareness and knowledge regarding ocular diseases. Those include age, gender, education level, socioeconomic level, and type of disease (11, 12). Knowing the level of public awareness concerning eye health and the factors that impact eye disease consequences could help to reduce public and economic burden due to visual impairment (13, 14). Poor health awareness of these conditions and their complications causes a delay in seeking medical care and chances of early intervention and prevention. Therefore, raising public awareness of ocular diseases plays a significant role in the early diagnosis and treatment of such conditions and thus reduces the burden of visual impairment. The current study aimed to evaluate the public awareness and attitudes towards common eye diseases and their related factors in Southern region, Saudi Arabia.

Methodology

A descriptive cross-sectional survey was conducted focused on all adults in Aseer region. The study was conducted during the period from May 2020 to September 2020. All persons aged less than 18 years, besides others who were not permanently living in the southern region (or for at least 1 year) were excluded. Data were collected using pre-structured questionnaire established by the researchers after intensive literature review and expert's consultation. The questionnaire data included participants socio-demographic data such as age, gender, nationality, monthly income, and education. Adults' awareness regarding eye diseases was evaluated including its main domains which included glaucoma related awareness, cataract awareness, diabetic retinopathy awareness, refractive errors awareness, and eye dryness. A panel of 3 experts reviewed the questionnaire separately for content validity and all reported changes and modifications were applied till the final tool was attained. The questionnaire was uploaded online using social media platforms by the researchers and their relatives and friends, to be filled in by all the population in Aseer region. A consecutive convenience sampling method was used due to the current situation of the COVID-19 pandemic. All adults fulfilling the inclusion criteria who received the electronic questionnaire during the study period were invited to participate through filling in the questionnaire. A pilot study was conducted to assess tool applicability and reliability. The tool reliability coefficient (Alpha Cronbach's) was assessed and equalled 0.77.

Data analysis

After data was 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 correct answer was scored one point and total summation of the discrete scores of the different items at each eye disease type was calculated. A patient with score less than 60% of the maximum score was considered to have poor awareness while good awareness was considered if they had a score of 60% of the maximum or more. Descriptive analysis based on frequency and percent distribution was done for all variables including demographic data and awareness items. Crosstabluation was used to assess distribution of awareness according to participants' personal data. Relations were tested using Pearson chi-square test.

Results

A total of 1014 participants in the southern region completed the survey. Participants' ages ranged from 18 to 75 years with mean age of 33.8 12.2 years old. Exactly 641 (63.2%) participants were males. Saudi were 987 (97.3%) and 819 (80.8%) were university graduated and 35 (3.5%) had educational level below secondary. Regarding monthly income, 381 (37.6%) participants had monthly income less than 5000 SR and 20.7% had income of 15000 SR or more (Table 1).

Table 2 shows awareness regarding cataract among general population. Exactly 23.1% of participants defined cataract as a change in lens colour and 17.8% reported that it is an age related disorder. As for risk factors, the most reported was age (46.9%) followed by DM and hypertension (41.6%), systemic disorders (10.7%), and drugs (9.9%). As for treatment methods, surgery was reported by 78.7% of the participants. Exactly 51.8% of the participants agreed that vision can return to normal after treating cataract. Regarding source of information, 19.5% of the participants had their information from a diseased family member or friend and 17.9% reported from health care provider while 17% learned about it from mass media and social media.

Table 3 demonstrates awareness regarding glaucoma among the general population. Glaucoma was defined as a disease that causes optic nerve damage by 22.2% of the participants while 18.6% defined the disease as a condition causing diminished peri-ocular vision. With regard to risk factors, 37.1% of the participants reported increased intra-ocular pressure, followed by age (29.6%), history of having cataract (23.7%), and family history of glaucoma (10.2%). Surgery as treatment modality was reported by 59.6% of the participants and 23.1% reported treatment by drugs. Vision can return to normal after treating cataract was reported by 41.8% of the participants. As for source of information, 19.5% of the participants reported Family member/ friend have the disease followed by learned from a health care provider (17.9%), and by social media and mass media (17%).

Table 4 illustrates awareness regarding diabetic retinopathy among the general population. DR was defined as retinal vascular lesion disorder by 23.6% of the participants and 42.9% classified the disease as one of the DM complications. The most reported risk factors for DR was DM and hypertension (50%) followed by age (25.4%), dietary habits (15.8%), and systemic diseases (11.4%). Exactly 39.9% of the participants agreed that vision can return to normal after treating DR. Regarding frequency of eye examination for diabetic patients, 10.9% of the participants reported it should be annually while 51.8% selected every 6 months. As for source of information regarding DR, Social media and mass media was selected by 20.3% of the participants followed by health care provider (20.1%), and family member/ friend have the disease (18.8%).

Table 5 shows awareness regarding refractive errors among the general population. Short vision was defined as focused image front of retina by only 5 participants (0.5%) and 56.8% reported that it means you cannot see far objects. As for long vision, it was defined as Focused image behind retina by 14.5% of the participants and 53.6% said that it means inability to see near objects. Exactly 76.8% of the participants agreed that excess TV watching/ mobile use can cause refractive error while only 10.1% denied that refractive error can be avoided. As for source of information, 32.1% were told by family member/ friend who has the disease, 24.3% had their information from health care provider, 15.7% from social media and mass media.

Table 6 illustrates awareness regarding dry eye among the general population. Exactly 60.3% of the participants defined dry eye as insufficient lacrimation. As for treatment methods, 71.8% reported moistening drops, 29.5% said drugs, and 5.2% know about other methods. As for complications of dry eye, the most identified were unclear vision (37.7%) followed by eye ulcers (35%), and eye infections (18.2%). About source of information regarding dry eye, 26.1% had their information from health care providers followed by gamily member/ friend who have the disease (22.9%), social and mass media (13%), and 14.1% had other sources.

In total, good awareness regarding cataract was detected among 13.4% of the participants and 10% had good awareness regarding glaucoma. On the other hand, 9.5% of the participants had good awareness regarding dry eye, 7% had good awareness regarding DR, and 3.5% had good awareness regarding refractive errors (Figure 1). Totally, 5.3% of the participants had good awareness regarding common eye diseases.

Table 7 demonstrates distribution of participants' awareness regarding common eye diseases by their personal data. Good awareness was detected among 8.3% of young age group (<25 years) in comparison to 0.8% of those who were aged 45 years or more with statistical significance (P=.001). Also, 7.2% of male participants had good awareness compared to 2.1% of females (P=.001). Good awareness was detected among 15.5% of participants with high income compared to 6.3% of those who had monthly income of less than 5000 SR (P=.001).

Discussion

The current study focused to assess public awareness and attitude regarding common eye diseases and their related factors in Aseer region, Southern Saudi Arabia. Globally, the numbers of visually impaired persons still increases; this will increase demands for more eye care services, programmes, and treatment for the visually disabled individuals (15). Consequently, first step is to map the size of the problem. Detection of the related factors of visual loss and blindness is vital to build appropriate treatment, rehabilitation, and service programmes. Public awareness regarding these eye related health conditions is the first step for mapping the problem and public concern for early detection and management (16).

The current study revealed that less than half of the participants correctly defined cataract as one of the most reported eye diseases (40.9%). Also, nearly the same portion reported cataract related risk factors especially age and diabetes. Surgery was the most identified treatment modality (more than three quarters of the participants) and about half of the participants agreed on the patient ability to return to normal visual ability after treating the disease which is a low percentage regarding cataract disease nature of being totally manageable after surgical intervention. These findings were consistent with Misra V et al in Delhi, India, (17) who estimated that 89.9% had heard of cataract but only 42% were aware of any symptom of cataract. White opacity in eyes and loss of vision were the most identified symptoms. Exactly 40.1% of the participants reported surgery as a treatment of cataract. A higher level of awareness was detected in Ethiopia by Alimaw YA (11). The authors found that about 67% (562) of respondents' adults were knowledgeable regarding cataract [95% CI, 63.8–70.2]. and 61.7% of them had good knowledge about cataract. In Saudi Arabia, the current study findings were higher than what reported by Moustafa S et al, (18) who reported that nearly 28% of the participants correctly defined cataract and 78% did

Table 1. Personal characteristics of survey participants, Southern region, Saudi Arabia

Personal data	No	%
Age in years		
<25 Yrs.	*351*	*34.6%*
25-34	*202*	*19.9%*
35-44	*213*	*21.0%*
45+	*248*	*24.5%*
Gender		
Male	*641*	*63.2%*
Female	*373*	*36.8%*
Nationality		
Saudi	*987*	*97.3%*
Non-Saudi	*27*	*2.7%*
Education		
Below secondary	*35*	*3.5%*
Secondary	*160*	*15.8%*
University/ more	*819*	*80.8%*
Income		
<5000 SR	*381*	*37.6%*
5000-10000 SR	*193*	*19.0%*
10001-15000	*230*	*22.7%*
15001-20000	*126*	*12.4%*
>20000	*84*	*8.3%*

Table 2. Awareness regarding cataract among general population, Southern region, Saudi Arabia

Cataract awareness	No	%
What is cataract		
Change in eye lens colour (opaque)	*234*	*23.1%*
White fluid in the eye	*425*	*41.9%*
Age related visual defect	*180*	*17.8%*
White coat on the eye	*165*	*16.3%*
Don't know	*161*	*15.9%*
Risk factors for cataract		
Age	*476*	*46.9%*
Smoking	*89*	*8.8%*
Dietary habits	*79*	*7.8%*
DM	*422*	*41.6%*
HTN	*422*	*41.6%*
Systemic diseases	*108*	*10.7%*
Drugs	*100*	*9.9%*
Don't know	*243*	*24.0%*
Treatment methods of cataract		
Drugs	*103*	*10.2%*
Surgery	*798*	*78.7%*
Others	*86*	*8.5%*
Don't know	*131*	*12.9%*
Vision can return to normal after treating cataract		
Yes	*525*	*51.8%*
No	*148*	*14.6%*
Don't know	*341*	*33.6%*
Source of information for cataract		
Health care provider	*182*	*17.9%*
Family member/ friend have the disease	*198*	*19.5%*
Family member/ friend free of the disease	*111*	*10.9%*
Social and mass media	*172*	*17.0%*
Don't know	*351*	*34.6%*

Table 3. Awareness regarding glaucoma among general population, Southern region, Saudi Arabia

Glaucoma awareness	No	%
What is glaucoma		
Increased intra-ocular pressure	*205*	*20.2%*
Blue fluid in the eye	*217*	*21.4%*
Optic nerve damage	*225*	*22.2%*
Diminished peri-ocular vision	*189*	*18.6%*
Age related disorder	*128*	*12.6%*
Don't know	*352*	*34.7%*
Risk factors for glaucoma		
Age	*300*	*29.6%*
Family history	*103*	*10.2%*
Increased intra-ocular pressure	*376*	*37.1%*
History of cataract	*240*	*23.7%*
Drugs	*75*	*7.4%*
Don't know	*371*	*36.6%*
Treatment methods of glaucoma		
Drugs	*234*	*23.1%*
Surgery	*604*	*59.6%*
Others	*95*	*9.4%*
Don't know	*276*	*27.2%*
Vision can return to normal after treating cataract		
Yes	*424*	*41.8%*
No	*140*	*13.8%*
Don't know	*450*	*44.4%*
Source of information for cataract		
Health care provider	*182*	*17.9%*
Family member/ friend have the disease	*198*	*19.5%*
Family member/ friend free of the disease	*111*	*10.9%*
Social and mass media	*172*	*17.0%*
Don't know	*351*	*34.6%*

Table 4. Awareness regarding diabetic retinopathy among general population, Southern region, Saudi Arabia

Diabetic retinopathy awareness	No	%
Diabetic retinopathy		
Increased IOP due to DM	*292*	*28.8%*
Retinal vascular lesion	*239*	*23.6%*
Diabetes complications	*435*	*42.9%*
Blindness	*4*	*.4%*
Don't know	*266*	*26.2%*
Risk factors for DR		
Age	*258*	*25.4%*
DM/ HTN	*507*	*50.0%*
Dietary habits	*160*	*15.8%*
Systematic diseases	*116*	*11.4%*
Drugs	*74*	*7.3%*
Smoking	*99*	*9.8%*
Don't know	*313*	*30.9%*
Vision can return to normal after treating DR		
Yes	*405*	*39.9%*
No	*217*	*21.4%*
Don't know	*392*	*38.7%*
Frequency of eye examination for DM		
Every 6 months	*525*	*51.8%*
Annually	*111*	*10.9%*
Every 2 years	*19*	*1.9%*
According to degree of vision defect	*110*	*10.8%*
Don't know	*249*	*24.6%*
Source of information for DR		
Health care provider	*204*	*20.1%*
Family member/ friend have the disease	*191*	*18.8%*
Family member/ friend free of the disease	*66*	*6.5%*
Social and mass media	*206*	*20.3%*
Don't know	*347*	*34.2%*

Table 5. Awareness regarding refractive errors among general population, Southern region, Saudi Arabia

Refractive errors awareness	No	%
Short vision		
Focused image on retina	*164*	*16.2%*
Focused image behind retina	*72*	*7.1%*
Cannot see far objects	*576*	*56.8%*
Cannot see near objects	*237*	*23.4%*
Focused image front of retina	*5*	*.5%*
Don't know	*129*	*12.7%*
Long vision		
Focused image on retina	*82*	*8.1%*
Focused image behind retina	*147*	*14.5%*
Cannot see far objects	*244*	*24.1%*
Cannot see near objects	*544*	*53.6%*
Focused image front of retina	*81*	*8.0%*
Don't know	*113*	*11.1%*
Excess TV watch/ mobile use can cause refractive error		
Yes	*779*	*76.8%*
No	*106*	*10.5%*
Don't know	*129*	*12.7%*
Refractive error can be avoided		
Yes	*652*	*64.3%*
No	*102*	*10.1%*
Don't know	*260*	*25.6%*
Source of information for refractive errors		
Health care provider	*246*	*24.3%*
Family member/ friend have the disease	*326*	*32.1%*
Family member/ friend free of the disease	*124*	*12.2%*
Social and mass media	*159*	*15.7%*
Don't know	*159*	*15.7%*

Table 6. Awareness regarding dry eye among general population, Southern region, Saudi Arabia

Dry eye awareness	No	%
Eye dryness		
Insufficient lacrimation	*611*	*60.3%*
Sand feel in eye	*290*	*28.6%*
Photosensitivity	*185*	*18.2%*
Don't know	*138*	*13.6%*
Treatment methods of dry eye		
Drugs	*300*	*29.5%*
Surgery	*73*	*7.1%*
Moistening drops	*783*	*71.8%*
Other methods	*54*	*5.2%*
Don't know	*128*	*12.6%*
Complications of dry eye		
Eye infections	*185*	*18.2%*
Eye ulcers	*355*	*35.0%*
Unclear vision	*382*	*37.7%*
Don't know	*297*	*29.3%*
Source of information for dry eye		
Health care provider	*265*	*26.1%*
Family member/ friend have the disease	*232*	*22.9%*
Family member/ friend free of the disease	*84*	*8.3%*
Social and mass media	*132*	*13.0%*
Others	*143*	*14.1%*
Don't know	*158*	*15.6%*

Figure 1. Overall awareness regarding common eye diseases among study participants

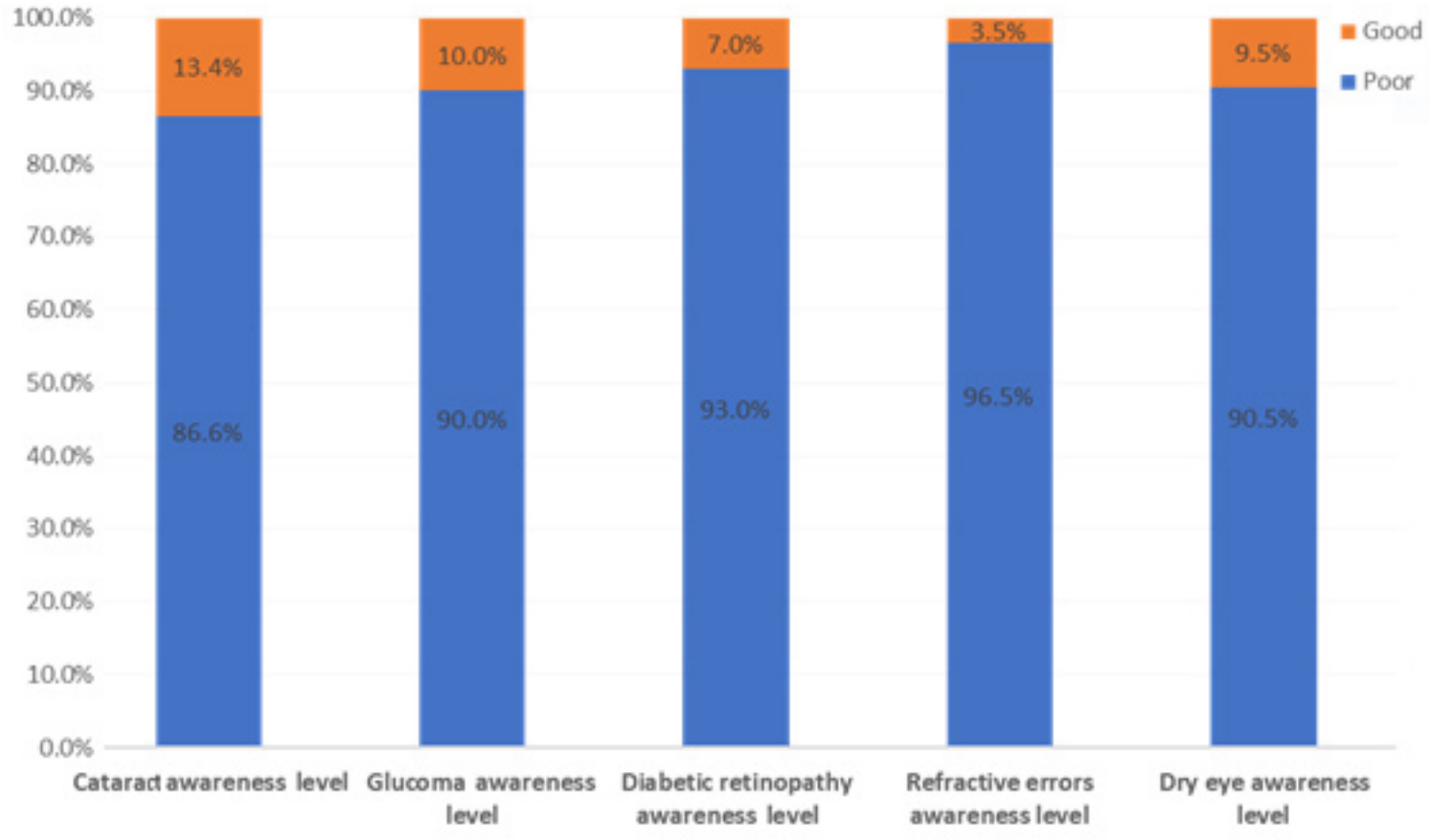

Table 7. Distribution of participants awareness regarding common eye diseases by their personal data

Personal data	Overall awareness level				P-value
	Poor		Good		
	No	%	No	%	
Age in years					
<25 Yrs.	322	91.7%	29	8.3%	.001*
25-34	188	93.1%	14	6.9%	
35-44	204	95.8%	9	4.2%	
45+	246	99.2%	2	0.8%	
Gender					
Male	595	92.8%	46	7.2%	.001*
Female	365	97.9%	8	2.1%	
Nationality					
Saudi	936	94.8%	51	5.2%	.175
Non-Saudi	24	88.9%	3	11.1%	
Education					
Below secondary	35	100.0%	0	0.0%	.343
Secondary	152	95.0%	8	5.0%	
University/ more	773	94.4%	46	5.6%	
Income					
<5000 SR	357	93.7%	24	6.3%	.001*
5000-10000 SR	190	98.4%	3	1.6%	
10001-15000	220	95.7%	10	4.3%	
15001-20000	122	96.8%	4	3.2%	
>20000	71	84.5%	13	15.5%	

not know that cataract can cause blindness. Also, 90% of participants were not aware regarding cataract risk factors and only 24% reported age as the main risk factor. Surgical treatment for cataract was identified by only 34% of the participants. Other researchers estimated public awareness regarding cataract between 24% to 79% and this was based on the nature of the community (urban vs. rural) and upon the nature of the tool used to assess public awareness (19-23)

.

As for glaucoma, the current study showed that only one third of the participants know of glaucoma and its nature (38.8%). Also, one third of the participants were aware of glaucoma related risk factors including intra-ocular pressure, age, and family history. Surgery was reported as the treatment modality among nearly two thirds of the participants and less than half of the participants know that the patient can return to their normal visual ability. These findings were consistent with that reported by Alemu DS et al, (24) who found that nearly 35% of the public participants were knowledgeable regarding glaucoma with good awareness among 49.6%. This estimated awareness level was mostly higher than a previous study in Riyadh, (25) which assessed awareness level among the general population with 14.8%, 7% in Bangladesh, 15.8% in Nigeria, and 8.3% in north India (26-28).

Considering diabetic retinopathy (DR), the current study revealed that more than two thirds of the participants were knowledgeable regarding DR (66.5%). The surprising finding was that only 50% of the participants reported diabetes as the main risk factors ignoring its name which indicated its association with diabetes. Also, only 10% of the participants reported the recommended interval for eye check-up for diabetic patients but more than half of them recommended it should be every 6 months instead of being annually. A study conducted in India by Venugopal D et al, (29) assessed that only 34.9% participants know about DR and 34.1% had an adequate knowledge level. Similar results regarding DR awareness were reported by Koshy et al (30) and Hussain et al (31).

Regarding refractive errors (RE) awareness, the current study findings recommended that more than half of the participants were aware of long and short vision disorders. These findings matched that previously reported in a Riyadh study by Al-Rashed et al, (25) who reported that 63% of the participants were aware of RE and by Alghamdi AH et al, (32) who assessed an awareness level of 53%.

With regard to dry eye, more than two thirds of the participants had good awareness level regarding dry eye and its treatment alternatives including moistening drops. These findings were consistent with other previous studies in Saudi Arabia which assessed awareness regarding dry eye among the population as between 38% to 86%

(25, 33, 34). In total, less than 10% of the participants had good awareness level regarding common eye diseases. The awareness level was higher among young, than aged participants, male group, and those with high income.

Conclusions and recommendations

In conclusion, the study revealed that overall public awareness regarding common eye diseases was very poor especially among the old aged and females. The main source was family member or friend who had the disease, but physicians and other health care staff had a minimal role as a source of information. This means that more effort should be paid from health care providers to provide more information regarding the disease's nature and their preventive measures. Also, there is urgent need to implement strategies to increase public awareness of ocular diseases to reduce the risk of visual complications through mass media, posters, health education sessions and other relevant methods. Provision of periodic screening campaigns may also play an important role in public awareness and concern.

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Perception of food allergy among mothers of allergic children in Southwestern Saudi Arabia

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Abstract

Background: Food allergy (FA) is increasingly recognized with the highest prevalence in preschool children; there has been a significant increase in hospital admissions for systemic allergic diseases with anaphylaxis and food allergies. Hospital admissions for food allergy were noticed to rise from 6 to 41 per million between 1990 and 2000 worldwide. The prevalence of food allergy is increasing over time with significant geographic variations. It is estimated to affect 6% of children in the United States (USA); according to a study conducted in Makkah, by AL Mokarmah, the prevalence of FA among children attending the well-baby clinic was 22.5% and in Riyadh is 6% among children who visit the allergy clinic at King Khalid University Hospital. FA in children is usually caused by milk (2.5%), egg (1.3%), peanut (0.8%), tree nuts (0.2%), fish (0.1%), as well as shellfish (0.1%), with an overall prevalence of 6%.

Methods: In this cross-sectional study, a self-administered questionnaire was used in the data collection. After data were collected, they were entered in the Statistical Software IBM SPSS version 22. Descriptive and inferential statistics were obtained.

Results: Out of 980 mothers, 49% were suffering from food allergy, while 28.6% of their children were suffering from food allergy. Shellfish was the most common cause of food allergy (38%).

Conclusion: The management of FA in children is improving through the acquisition of new knowledge in diagnosis and treatment. Education of physicians and food-allergic patients about FA and its treatment is becoming recognized as an unmet need.

Key words: Food allergy, mother, children, knowledge, prevalence, factors

Background

Food allergy (FA) is increasingly recognized with the highest prevalence in preschool children; there has been a significant increase in the hospital admissions for systemic allergic diseases with food allergies and anaphylaxis. The hospital admissions for food allergy rose from 6 to 41 per million between 1990 and 2000 [1-2]. FA has a great impact on the child's diet, care, and social life. Also, it is considered to be associated with parent anxiety. The death rate from FA was found to be 1 in 800,000. So, the diagnosis and consideration of FA is an important issue [3, 4]. FA among children requires good health care and specific instructions from their parents, family and school members. The correct diagnosis of FA should decrease the incidence of adverse food reactions resulting from true FA, and help to prevent the unnecessary exclusion of safe foods and should be eaten as part of a regular healthy diet [5-7].

The history-taking should help determine whether the mechanism of FA is IgE mediated or non-IgE mediated. In a study conducted in a large city in Saudi Arabia, there were 238 reported cases of anaphylaxis in a 2-year period. Food allergies are more common among children and adolescents, whereas insect and drug-induced allergies are more prevalent in adults [8]. A Turkish study reported that the most common cause of anaphylaxis in children was food [9].

There is no study that has estimated FA's prevalence among children in the southern region of Saudi Arabia. Regarding the lack of studies on this issue, this study investigates the epidemiological aspects of the commonest allergies tofood among children in Aseer region of Saudi Arabia.

The main aim of this study is to find out the perception of food allergy among mothers of allergic children in Aseer region, Saudi Arabia. We also discussed some relevant variables like commonest foods for FA, factors associated with developing FA, and parents' awareness about FA.

Methods

This is a cross-sectional study conducted at Abha Maternity and Children Hospital, in Abha, Saudi Arabia. The duration of the study was from the 1st of July 2019 to the 31st of October 2019. The sample was selected using convenience sampling. Mothers with children's age up to 15 years who visited Abha maternity and children hospita during the study duration were included in this study. A direct interview questionnaire was used in the data collection. The researchers developed the questionnaire based on the review of the literature of similar articles and with the help of experts from King Khalid University, College of Medicine. The questionnaire consists of three parts, including mothers and children demographic data, nutritional history, and mode of delivery. The second part included data regarding child history of developing food allergy, aggravating factors, signs and symptoms, and most reported food-initiated allergy among the children.

The third part included knowledge about food allergy and how the food allergic child affects family life. The questionnaire was then given to the mothers of the patients or filled in by researchers if they were illiterate. Mothers were included consecutively daily during the study period. and verified by hand, then coding for computerized data entry. The mothers signed a written consent; the study was approved by the Ethical Committee of our institute.

Data analysis

After data were collected, they were revised, coded and fed into Statistical Software IBM SPSS version 22. The given graphs were constructed using Microsoft Excel software. All statistical analysis was done using two-tailed tests and an alpha error of 0.05. A P-value less than 0.05 was considered to be statistically significant. Frequency and percent were used to describe the frequency distribution of each category for mother and child data while mean with standard deviation described numerical data. Chisquare/ Monte Carlo exact test and Fisher exact test were used to test for the differences between child data and food allergy.

Results

The study included 980 participating children and their mothers whose ages ranged from 19-52 years old with a mean age of 35.3 ± 7.2 years old. Most of the mothers were Saudis (95%; 931), and university level of education was reported among 614 (62.7%). Family history of allergy was reported among 96% of the participating mothers; the most reported were food allergy (49.1%), followed by eczema (35.6%), allergic rhinitis (30.8%0, and Asthma (28.1%) (Table 1).

The prevalence of food allergy (Figure 1) was detected among 280 (28.6%) children. Ages of children with a positive history of food allergy ranged from 1 to 16 years with a mean age of 10.3 ± 3.4 years. Exactly 143 (51.1%) children were males. The age of the first food allergy episode was the first two years among 44.2% and above the age of 6 years among 18.6%. Exactly 55% of the children with food allergies visited the ER during the last 12 months before the study date, and 21.8% of those children had brothers with a history of food allergy. The most-reported allergy mechanism was through eating food (73.6%) and eating or smelling food (9.6%). Among 77.9% of the children, it takes minutes to hours to develop allergy signs (Table 2).

Table 3 shows feeding data of children with food allergies. Breastfeeding was reported among 23.2% of the children with a food allergy, while 56.4% had both breastfeeding and formula. Among those who had formula, it was started immediately after birth among 60.5% of them. Exactly 54.4% of children with an allergy who had formula were given the formula once daily. First solid food was given for 39.5% of those children at the age of 6 months. About 23% of those who started solid food developed food allergy.

Table 4 illustrates FA manifestations as recorded for children by their mothers. The most reported food allergy manifestations were itching (51.8%), followed by a pinpoint rash (47.9%) and eyelid and lips swelling (26.8%). As for respiratory manifestations, 37.5% had dyspnea, 36.4% had a cough, and 30.4% had no respiratory symptoms. The itching was the most reported eye manifestation (28.2%) for food allergy, followed by redness (23.9%) and lacrimation (22.5%). Abdominal pain and nausea with vomiting were reported among 17.9% of children with food allergy. Rhinorrhea was reported among 28.6% of those children, followed by sneezing (24.3%) and congestion (20.7%) as a nasal manifestation for food allergy.

Figure 2 demonstrates the most common foods causing food allergy as recorded by mothers. Shellfish was the most identified (38%), followed by egg (21%), milk (19%), peanuts (11%), and banana (8%). Considering aggravating factors of allergy as recorded by children's mothers (Figure 3), having allergy stimulant food was the most reported factor (76.8%) followed by the presence of smoker at home (33.9%), abnormal birth (29.3%), overfeeding (24.3%), and heating food (18.2%) while effort was the least reported factor (8.6%).

Considering mothers' awareness regarding food allergy (Figure 4), it was reported that 56.6% of the respondent mothers agreed that food allergy includes the activity of the immune system, while 39.8% agreed that Asthma is an inducing factor for food allergy, and 32.7% agreed that food allergy can be diagnosed by laboratory test only.

Table 1: Personal data of screened mother, Aseer region, Saudi Arabia

Mother personal data		No	%
Age in years	19-	220	22.4%
	30-	454	46.3%
	40+	306	31.2%
Nationality	Saudi	931	95.0%
	Non-Saudi	49	5.0%
Education	Primary	106	10.8%
	Intermediate / secondary	260	26.5%
	University	614	62.7%
Family history of allergy	None	39	4.0%
	Food allergy	481	49.1%
	Eczema	[illegible]	[illegible]
	Allergic rhinitis	302	[illegible]
	Asthma	[illegible]	[illegible]
	Animal allergy	179	18.3%
	Eye allergy	155	15.8%
	Insect bite allergy	127	13.0%
	Plant allergy	119	12.1%
	Drug allergy	118	12.0%
	Eyelid edema	83	8.5%
	Touching allergy	74	7.6%
	Others	44	4.5%
	Urticaria	36	3.7%

Figure 1: Prevalence of food allergy among children as recorded by their mothers, Aseer region, Saudi Arabia

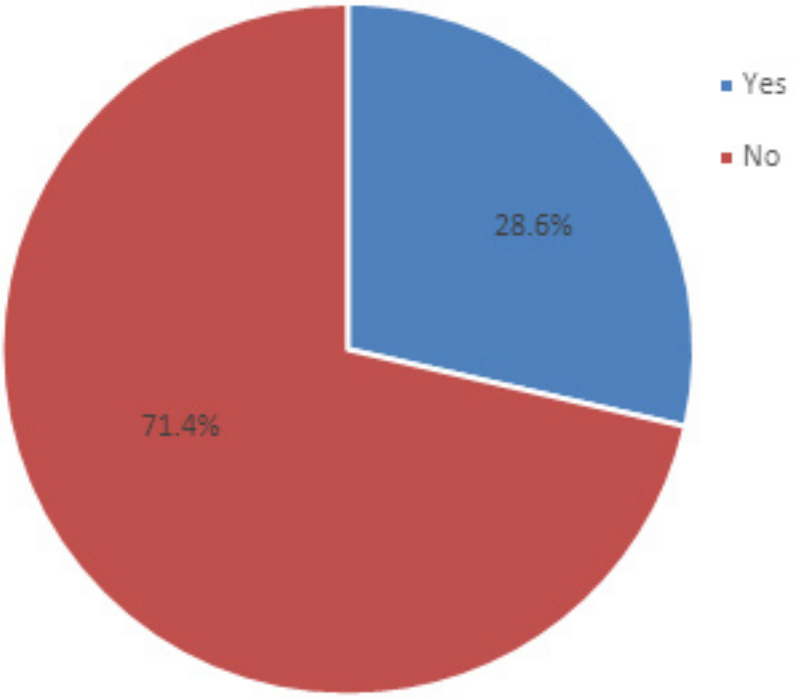


Table 2: Food allergy data for children of sampled mothers, Aseer region, Saudi Arabia

Food allergy data		No (280)	%
Age of the child in years	1-4	83	29.6%
	5-9	88	31.4%
	10-14	100	35.7%
	15+	9	3.2%
Age at first allergy in years	Before one year	39	13.9%
	1-2 years	113	40.4%
	3-6 years	76	27.1%
	Above six years	52	18.6%
Gender of child	Male	143	51.1%
	Female	137	48.9%
No of ER visits due to allergy at the last 12 months	None	126	45.0%
	1-2	111	39.6%
	3+	43	15.4%
Have other children with food allergy	Yes	61	21.8%
	No	219	78.2%
Mechanism of food allergy	Eating food	206	73.6%
	Smelling food	14	5.0%
	Touching food	13	4.6%
	Eating or smelling	27	9.6%
	All	20	7.1%
Duration till signs of allergy	Minutes to hours	218	77.9%
	Days	62	22.1%

Table 3: Feeding data of children with a food allergy, Aseer region, Saudi Arabia

Child feeding data		No (280)	%
Child feeding	Breastfeeding	65	23.2%
	Formula	57	20.4%
	Both	158	56.4%
Child had colostrum	Yes	199	71.1%
	No	81	28.9%
First artificial feeding (n=215)	Immediately after birth	130	60.5%
	Days to months after birth	85	39.5%
No of formula feeding per day (n=215)	On need	117	54.4%
	9-12	23	10.7%
	5-8	48	22.3%
	1-5	27	12.6%
Improved after formula (n=215)	Yes	69	32.1%
	No	146	67.9%
Changed formula milk (n=215)	Yes	164	76.3%
	No	51	23.7%
Age of first solid food	4 months	61	22.1%
	6 months	109	39.5%
	8 months	55	19.9%
	1 year	33	12.0%
	After1 year	18	6.5%
Allergy after solid food intake	Yes	64	23.1%
	No	213	76.9%

Table 4: Food allergy manifestations as recorded for children by their mothers, Aseer region, Saudi Arabia

Food allergy manifestations		No	%
Skin manifestations	None	24	8.6%
	Itching	145	51.8%
	Dryness	36	12.9%
	Pinpoint rash	134	47.9%
	Raised circular rash	43	15.4%
	Eyelid and lips swelling	75	26.8%
	Others	3	1.1%
Respiratory manifestations	None	85	30.4%
	Dyspnea	105	37.5%
	Heaviness	33	11.8%
	Wheezes	54	19.3%
	Cough	102	36.4%
Eye manifestations	None	102	36.4%
	Lacrimation	63	22.5%
	Itching	79	28.2%
	Redness	67	23.9%
	Eyelid swelling	52	18.6%
GIT manifestations	None	222	79.3%
	Abdominal pain	50	17.9%
	Diarrhea	26	9.3%
	Nausea and vomiting	50	17.9%
Nasal manifestations	None	103	36.8%
	Rhinorrhea	80	28.6%
	Sneezing	68	24.3%
	Congestion	58	20.7%
	Itching	40	14.3%
	Others	3	1.1%

Figure 2: Most common foods causing food allergy as recorded by mothers

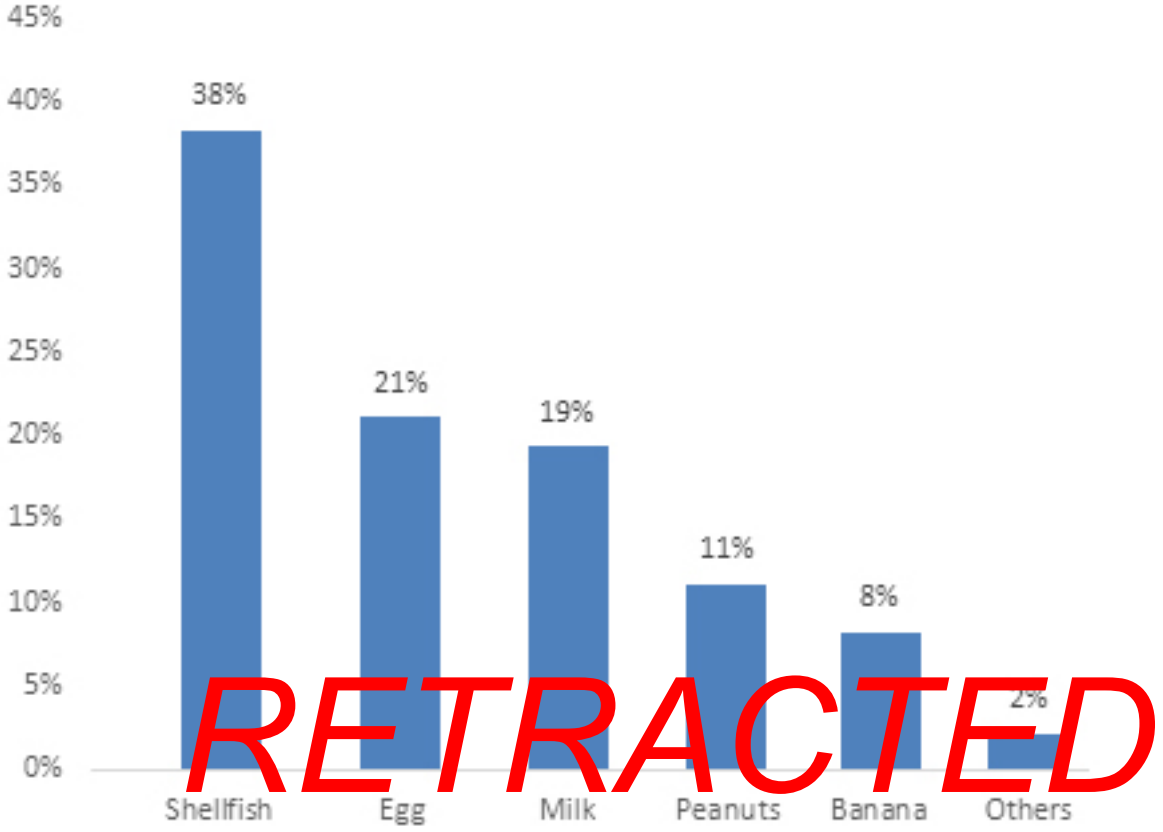


Figure 3: Aggravating factors of allergy as recorded by children mothers, Aseer region, Saudi Arabia

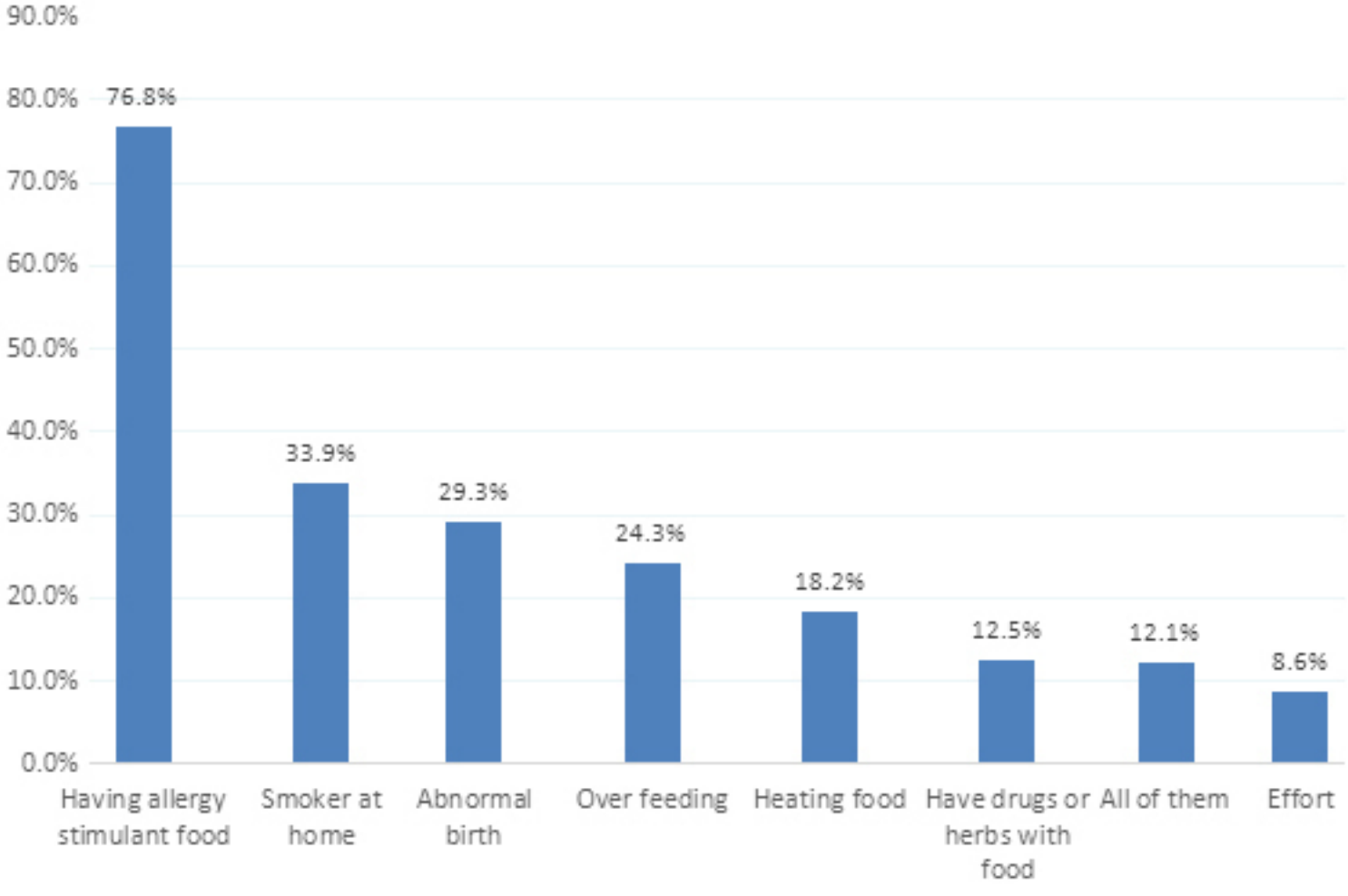
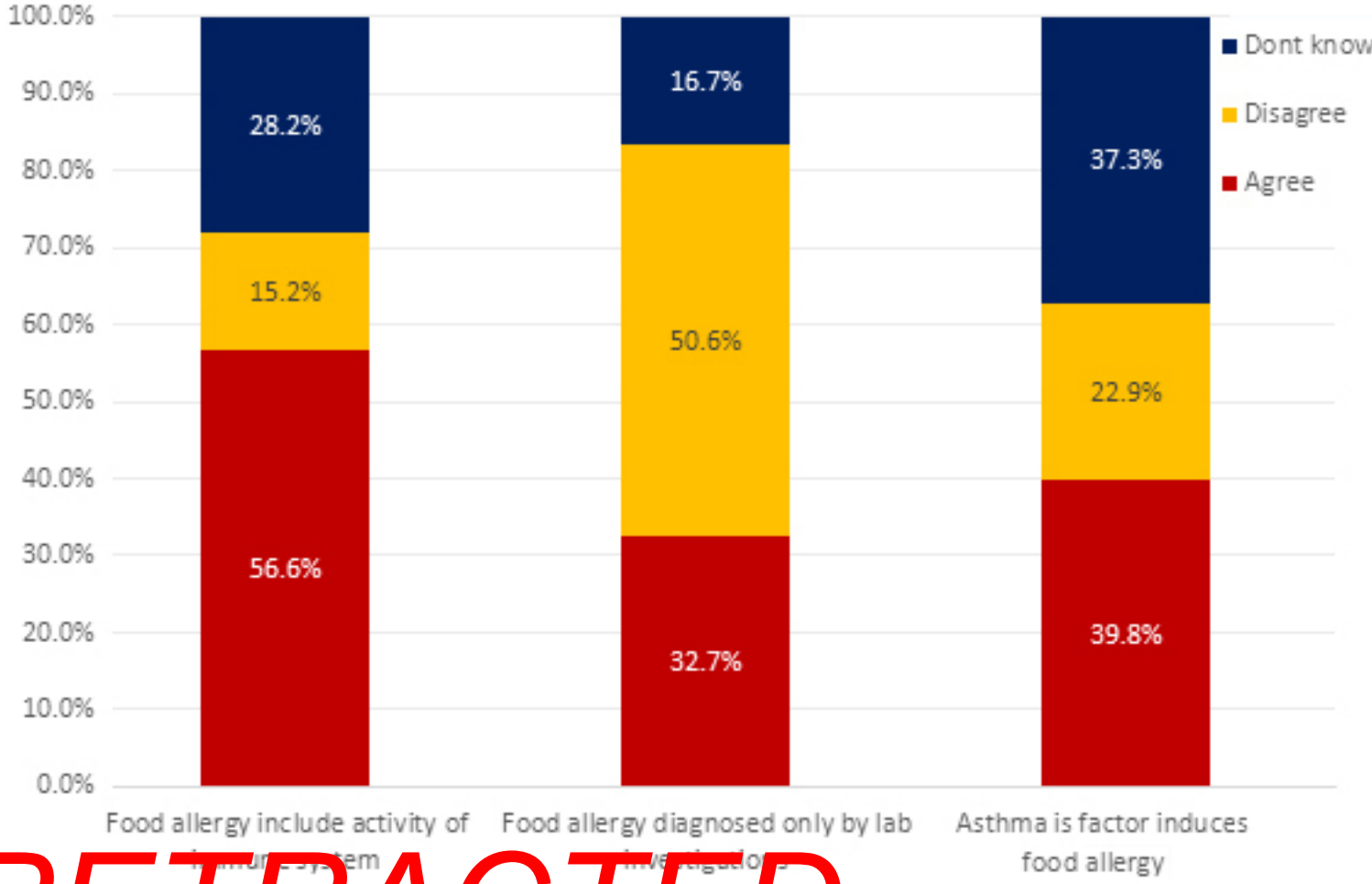


Figure 4: Mothers awareness regarding food allergy, Aseer region, Saudi Arabia



Discussion

The main objective of this study was to find out the perception of mothers of food allergic children in the Aseer region of the KSA. The natural history of a food allergy includes information on the acquisition of the allergy, the likelihood that it will be outgrown, and its usual duration.

Nearly 8% of US children (about 5.6 million) have food allergies, with almost 40% of those children allergic to more than one food, a study conducted by researchers from Ann & Robert Lurie Children's Hospital of Chicago determined [10]. According to a study conducted in Makkah, by AL-Mokarmah, the prevalence of FA among children attending the well-baby clinic was 22.5%, and in Riyadh, it is 6% (11), among children who visit the allergy clinic at King Khalid University Hospital. In our study, we found the prevalence (28.6%) higher than the Makkah Study, which may be due to the lack of awareness and training.

One USA study reported that peanut is the leading cause of Food allergy [12], but in our study, we found fish, egg and milk are the leading source of the food allergy which is in line with other studies that stated the most common food allergens responsible for about 90% of adverse reactions of this type are the proteins of cow's milk, eggs, peanuts, tree nuts (walnuts, hazelnuts, almonds, etc.), soy, wheat flour, fish and marine mollusks, crustaceans and cephalopods (shells, crabs, squids). Significant allergens include berries and citrus fruit, honey, sesame seeds, and many other foods and their additives [13]. According to the data from the USA and Western Europe, the leading causes of food allergy in childhood are cow's milk proteins (2.0–3.5%), eggs (1.3–3.2%), peanuts (0.6–1.3%), fish (0.4– 0.6%) and tree nuts (0.2%) [14].

A study published in the BMJ stated that Asthma is also a risk factor for food allergy; in our study, 40% of the mothers agreed that Asthma is one of the risk factors of food allergy. In our study, the Family history of FA was found in 49%, and 28.6% of their children had FA, which confirms the findings of other studies that the greatest risk of developing an allergy depends on genetic factors. It has been found that the risk of allergy development in children of healthy parents ranges from 5% to 15%; when one of the parents is allergic, it increases to 40%, and if both parents are affected, it reaches 60-80%.[15].

Conclusions and Recommendations

In conclusion, the study revealed that nearly 1 out of every four included children had a positive history of food allergy, most of them either during eating or just by smelling. The allergy attack lasts for less than 24 hours in most children with recorded history. Itching with the rash is the dominant clinical presentation of allergy among sampled children.

Fish and egg constituted more than half of the aggravating foods for the allergy attack. Health education for mothers to improve their awareness regarding allergy triggering factors, including behavior and foods, is a crucial recommendation. This can be achieved through GP staff in the PHCCs or during hospital visits. Social media can also play a significant role in improving the mother's awareness and modifying their behavior.

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Insomnia and social network use among secondary school female students in Abha Sector

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Abstract

Background: Internet addiction and other problematic internet use behaviors can dramatically affect sleep hygiene, resulting in sleeplessness and other sleep disturbances. Excess internet and social media use are mainly associated with insomnia and increased time spent on the internet leads to the important disturbance of sleep. One psychophysical mechanism that could help to clarify the negative influence of problematic internet use on sleeping habits can be that nighttime computer use causes a state of high arousal, therefore, interfering with the soothing procedures that are essential for sleep. Sleep disturbance may result in stress which in turn affects student's scholastic performance.

Aim: The current study aimed to assess prevalence of internet addiction with its association with insomnia and scholastic achievement among secondary school females in Abha city, Saudi Arabia.

Methodology: A correlational cross-sectional approach was applied for the current research. The research targeted all secondary school female students in Abha city. A multistage cluster sample was applied by selecting schools and students from the Directorate of Education in Abha. Self-administered questionnaire sheets were distributed to students in their classes. The questionnaire covered students' socio-demographic data like age, grade, parents' education, work, and living conditions. Also, the tool included scales for internet addiction and perceived stress. Scholastic performance was measured by grades in the last year with absenteeism.

Results: The study included 3 50 female students whose ages ranged from 15 to 22 years old with mean age of 16.9 ± 1.1 years. Regarding father's education, 214 students' fathers were university graduated (61.5%) and 108 (31%) had secondary level of education. Regarding frequency of using social internet, 85.3% of the students reported usual use. Also, 83.9% of the students spend more than three hours daily using social networks. Internet addiction was reported among more than one third of the sampled students.

Conclusions & recommendations: In conclusion, the study revealed that more internet addiction was a significant problem among secondary school female students and affected their scholastic achievement and their life due to high stress.

Key words:
Internet addiction, students. Secondary school, stress, school performance

Introduction

Internet use including social media has increased dramatically worldwide with more than 2.5 billion actual users [1, 2]. Adolescents and young people are the main groups using internet facilities especially social media [3]. With the rapid growth in internet use, there is an increased trend of internet addiction, especially among adolescents, gaining increased attention from the popular media, government authorities, and researchers [4, 5]. In the past ten years, the rate of internet use among adolescents has increased extremely; 93% of adolescents of ages 12–17 years old go online in the U.S, as do 93% of Japanese, 71.8% of Chinese, and 74.5% of Indian adolescents [6]. Also, internet addiction magnitude in Iranian high school students was 22.2%, in Indians 25.5%, in Tunisians 18.05%, in Taiwanese 10.6% and in Turkish 07.9% [6, 7]. The internet addicts had higher rates of psychopathy (65.0%), suicidal thoughts in a week (47.0%), history of suicide attempt (23.1%), and attempt for suicides in one year (5.1%) [8].

Insomnia and sleep deprivation can induce serious effects, such as more liability for having physical and mental problems [9]. Sleep deprivation may be higher among adolescents who are at the most important period of physical, cognitive, and psychosocial development. These changes have a high effect and impact on their subsequent development [10]. Insomnia is one of the most frequent sleep deprivation problems usually recorded in adolescents [11]. Insomnia is clinically defined as a subjective perception of dissatisfaction with the amount and/or quality of sleep, usually difficulties falling asleep in spite of being in bed, waking up often during the night and having trouble going back to sleep, waking up too early in the morning or having an unrefreshing sleep [12]. High social media use can aggravate the occurrence of anxiety, depression, and suicide [13]. Social media overuse can negatively affect moral development in students, such as increased incidence of cyber-bullying [14] and internet addiction, which could lead to social withdrawal [15, 16]. Social media overuse and insomnia can affect the physical, psychosocial, cognitive, moral, and social development of students. Insomnia results in decreased health status, increased weight, and increased risk of cardiovascular and cardio metabolic disorders [17]. Insomnia may also affect student's psychosocial development, such as depression, anxiety, withdrawal, and aggression. The current study aimed to assess prevalence of internet addiction and its association with insomnia and scholastic achievement among secondary school female students in Abha city, Saudi Arabia

Methodology

A correlational cross-sectional approach was applied in the current study. The study was conducted at the female secondary schools (private and governmental) in Abha sector during the period from 2018 to 2020. There are about 30 governmental schools having about 5,000 female students in the secondary stage and four private schools with about 200 female students. Inclusion criteria were being a female student, able to communicate, agreed to participate in the study. Students with clinically diagnosed psychological disease, and females who refused to participate in the study were excluded. A total sample of 350 female students from a total of 6,000 students were required to detect average sleep disorders rate among social network users of 32% [18] with precision of 5% at 95% confidence level. The sample size was calculated using PASS software. Sampled students were selected from private and governmental schools using probability proportionate to size. A stratified sampling technique was used for selecting female students. Schools were stratified into governmental and private and then female students within each selected school were included randomly using systematic sampling method including each 3rd student. The sample distribution among schools was based on probability proportionate to size method using the list of names obtained from the school after explaining the benefit and importance of the research. After obtaining permission from Institutional ethics committee, data collection started. Data were collected from students directly using pre-structured data collection tool covering the following data: Students socio-demographic data like age, family data, residence, parents' education, Social media use data including age of first use, duration of use, peak time for use, and sites visited. Scholastic achievement data included studying hours, days of absenteeism, and grades of last year. Social network use and addiction were measured using Kimberly's Internet Addiction Test (IAT) [19]. It comprises 20 questions based upon a five-point Likert scale, which measures the severity of internet addiction (weak, moderate, severe). The lowest and highest scores are 20 and 100 respectively. Higher score indicates more severe addiction to internet.

Scoring:

Score	*20-49*	*50-79*	*80-100*
The Severity of Internet Addiction	*No or little*	*Moderate*	*Severe*

Insomnia was measured using insomnia severity index (ISI) [20]. The ISI comprises seven items assessing the perceived severity of difficulties initiating sleep, staying asleep, and early morning awakening, satisfaction with current sleep pattern, interference with daily functioning, noticeability of impairment attributed to the sleep problem, and degree of distress or concern caused by the sleep problem.

Scoring:
0–7 = No clinically significant insomnia
8–14 = Sub threshold insomnia
15–21 = Clinical insomnia (moderate severity)
22–28 = Clinical insomnia (severe)

Data analysis

After data was extracted, it was revised, coded and fed to 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 considered to be statistically significant. For internet addiction and stress scales, discrete scores for each scale items were summed together and the total sum of scores was categorized according to scoring method in methodology section. Descriptive analysis based on frequency and percent distribution was done for all variables including demographic data, scholastic achievement variables and internet addiction with stress. Cross tabulation was used to assess distribution of students' internet addiction according to their personal data. Also, cross tabulation was done to test relations between internet addiction and student's scholastic achievement and stress. Relations were tested using Pearson exact probability tests. Scatter diagram was used to assess the correlation between student's internet addiction score and last year's grade.

Results

The study included 350 female students whose ages ranged from 15 to 22 years old with mean age of 16.9 ± 1.1 years. Regarding father's education, 214 students' fathers were university graduated (61.5%) and 108 (31%) had secondary level of education. As for fathers' work, 68.7% of the student's fathers worked at governmental jobs and 8.9% were not working. Considering mothers education, 56.6% of the student's mothers were university graduated while 44% were housewives. As for social level, it was reported as high by 130 students (37.4%) (Table 1).

Table 2 illustrates social internet use among the study students. Exactly 63.5% of the students used the internet for the first time at the age of 10-14 years. Regarding frequency of using social internet, 85.3% of the students reported usual use. Also, 83.9% of the students spend more than three hours daily using social networks. The most reported sites visited by the students were Facebook (39.4%), Snap Chat (25.6%), and What's App (7.2%). As for reasons for using social networks, entertainment was the most reported reason (53.4%) followed by following the current trend (24.7%), and search and share information (8.9%). Considering peak time spent on social media, 63.5% of the students reported before going to sleep.

Table 3 demonstrates scholastic achievement among the sampled female students. Good achievement was reported by 83.6% of the students and 1.7% reported excellent achievement. Studying for 1-2 hours was reported by 69.5% of the students and 44.3% reported rare absenteeism of school while 12.4% reported high absenteeism. Last year grades ranged from 85% to 100% with an average of 96%.

As for internet addiction among the surveyed students, it was clear that 31.6% of the students reported that they find themselves anticipating when they will go online again. Also, 31.3% reported they find that they stay online longer than intended. Besides, 28.7% said that they feel preoccupied with the Internet when off-line or fantasize about being online. And 28.4% reported that they block out disturbing thoughts about their life with soothing thoughts of the Internet. About 11.5% of the students try to hide how long they have been online. Figure 1 shows that 31% of the students in total had moderate internet addiction and 3.7% had severe internet addiction.

Table 4 shows the distribution of insomnia items among the surveyed students. About 28% of the students reported that they are highly dissatisfied with their sleep pattern. Also, 27% reported that sleep problems interfere severely with performing their daily activities. Besides, 26.8% had problems walking up too early and 24.7% were stressed due to sleep problems. In total, 25.6% of the students had moderate insomnia and 3.4% had severe insomnia while 33.3% had no insomnia (Figure 2).

As for predictors of students' internet addiction, Table 5 demonstrates that 40.4% of students who usually use social network had internet addiction compared to 2% of those who sometimes use the internet with recorded statistical significance (P=.001). Also, internet addiction was diagnosed among 39% of the students who spent more than three hours daily on internet compared to none of those who spent less than one hour (P=.001). As for reasons for internet use, addiction was recorded among 80% of those who use internet to find new friends and 45.2% of those using it for entertainment compared to 9.1% of those using it for studying with friends (P=.001). Table 6 illustrates the effect of internet addiction on having insomnia and student's scholastic achievement. Exactly 49.6% of the students who are addicted to internet use had severe insomnia compared to 18.1% of non-addict students (P=.001). Also, 78.5% of students addicted to internet study for 1-2 hours daily compared to 64.8% of non-addict group (P=.026). Good scholastic achievement was recorded among 74.4% of students who are addicted to internet use compared to 88.5% of non-addicted students (P=.003). Figure 3 demonstrates that there is a significant positive intermediate correlation between student's internet addiction score and their insomnia score.

Discussion

The current study aimed to assess the magnitude of internet addiction among the secondary school female students in Abha city, Southern Saudi Arabia. The study revealed that one third of the students had internet addiction or problematic internet use. This was mostly due to nearly one out of each four students starting social media use below the age of 10 years (too early) and nearly two thirds started at the age of 10-14 years which is the age of exploring all new fields for teenagers and being more involved without breakdown. More than 80% of the students reported that they always use social media platforms and for more than 3 hours daily without control. The most reported reason for using social media was not for study as expected or claimed to parents but

Table 1. Social internet use among secondary school females in Abha city, Saudi Arabia

Internet use		No	%
Age of first use of social media (years)	< 10 years	85	24.4%
	10-14 years	221	63.5%
	15-20 years	42	12.1%
Using social networks	Sometimes	51	14.7%
	Usually	297	85.3%
Hours spent on social media daily	< 1 hour	5	1.4%
	1-3 hours	51	14.7%
	> 3 hours	292	83.9%
Sites you visit on opening social network	WhatsApp	25	7.2%
	Facebook	137	39.4%
	Snap Chat	89	25.6%
	Instagram	1	.3%
	Others	96	27.6%
Reasons for using social network	Following the current trend	86	24.7%
	Find new friends	5	1.4%
	Search and share information	31	8.9%
	Means of communication	29	8.3%
	Entertainment purposes	186	53.4%
	Studying with my colleges	11	3.2%
Peak time spent on social media	Early morning	22	6.3%
	After back of school	105	30.2%
	Before going sleep	221	63.5%

Table 2. Scholastic achievement among sampled secondary school females in Abha city, Saudi Arabia

Scholastic achievement		No	%
Scholastic achievement	Good	291	83.6%
	Very good	51	14.7%
	Excellent	6	1.7%
Studying hours per day	1-2 hours	242	69.5%
	3-5 hours	69	19.8%
	> 5 hours	37	10.6%
Absenteeism of school due to fatigue	Rarely	154	44.3%
	Sometimes	151	43.4%
	Many times	43	12.4%
Last year grade	Range	85%-100%	
	Mean ± SD	96% ± 4%	

Table 3. Internet addiction among secondary school female students in Abha, Saudi Arabia

Internet addiction items	Rarely		Occasionally		Frequently		Often		Always	
	No	%	No	%	No	%	No	%	No	%
How often do you find that you stay online longer than you intended?	21	6.3%	54	16.1%	86	25.7%	69	20.6%	105	31.3%
How often do you neglect household chores to spend more time online?	56	17.9%	102	32.7%	68	21.8%	49	15.7%	37	11.9%
How often do you prefer the excitement of the Internet to intimacy with your partner?	59	18.7%	94	29.8%	64	20.3%	48	15.2%	50	15.9%
How often do you form new relationships with fellow online users?	103	41.7%	72	29.1%	33	13.4%	16	6.5%	23	9.3%
How often do others in your life complain to you about the amount of time you spend online?	71	24.8%	72	25.2%	68	23.8%	27	9.4%	48	16.8%
How often do your grades or schoolwork suffer because of the amount of time you spend online?	80	41.5%	62	32.1%	22	11.4%	19	9.8%	10	5.2%
How often do you check your e-mail before something else that you need to do?	111	50.2%	50	22.6%	23	10.4%	20	9.0%	17	7.7%
How often does your job performance or productivity suffer because of the Internet?	79	30.0%	86	32.7%	45	17.1%	26	9.9%	27	10.3%
How often do you become defensive or secretive when anyone asks you what you do online?	58	19.8%	79	27.0%	51	17.4%	47	16.0%	58	19.8%
How often do you block out disturbing thoughts about your life with soothing thoughts of the Internet?	43	13.6%	86	27.1%	65	20.5%	33	10.4%	90	28.4%
How often do you find yourself anticipating when you will go online again?	39	11.9%	99	30.1%	87	26.4%	0	0.0%	104	31.6%
How often do you fear that life without the Internet would be boring, empty, and joyless?	71	23.4%	79	26.0%	67	22.0%	37	12.2%	50	16.4%
How often do you snap, yell, or act annoyed if someone bothers you while you are online?	59	20.7%	83	29.1%	60	21.1%	39	13.7%	44	15.4%
How often do you lose sleep due to late-night logins?	82	37.1%	67	30.3%	34	15.4%	19	8.6%	19	8.6%
How often do you feel preoccupied with the Internet when off-line, or fantasize about being online?	31	9.8%	66	20.8%	86	27.1%	43	13.6%	91	28.7%
How often do you find yourself saying "just a few more minutes" when online?	56	20.0%	64	22.9%	67	23.9%	35	12.5%	58	20.7%
How often do you try to cut down the amount of time you spend online and fail?	75	31.6%	54	22.8%	40	16.9%	28	11.8%	40	16.9%
How often do you try to hide how long you've been online?	72	28.5%	78	30.8%	44	17.4%	30	11.9%	29	11.5%
How often do you choose to spend more time online over going out with others?	76	27.0%	60	21.3%	47	16.7%	34	12.1%	65	23.0%
How often do you feel depressed, moody, or nervous when you are off-line, which goes away once you are back online?	107	42.5%	97	38.5%	28	11.1%	20	7.9%	0	0.0%

Figure 1. Internet addiction level among secondary school female students in Abha city, Saudi Arabia

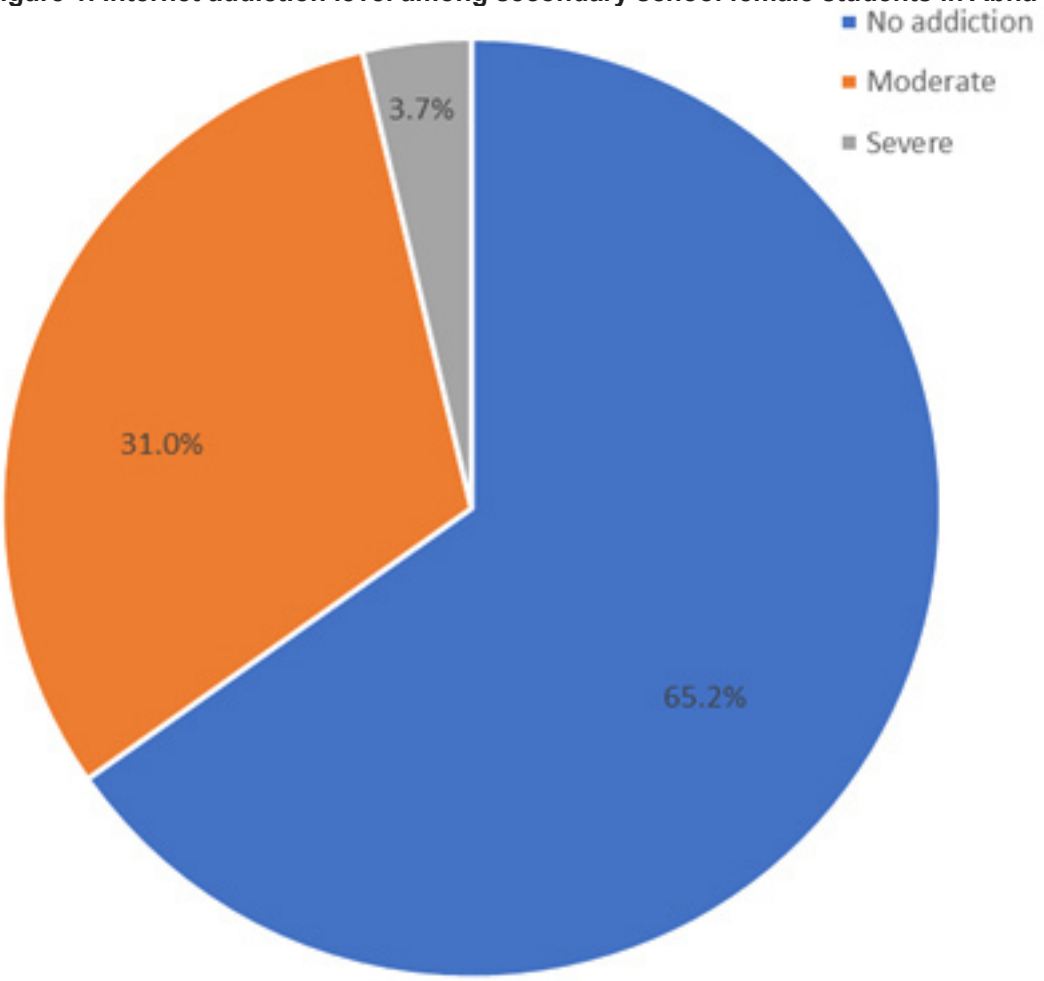

Table 4 Insomnia among secondary school female students in Abha city, Saudi Arabia

Insomnia items	None		Mild		Moderate		Severe		Very severe	
	No	%	No	%	No	%	No	%	No	%
Difficulty falling asleep	96	27.6%	107	30.7%	97	27.9%	28	8.0%	20	5.7%
Difficulty staying asleep	143	41.1%	81	23.3%	69	19.8%	32	9.2%	23	6.6%
Problems waking up too early	93	26.7%	72	20.7%	90	25.9%	50	14.4%	43	12.4%
How satisfied/ dissatisfied are you with your current sleep pattern	24	6.9%	87	25.0%	138	39.7%	59	17.0%	40	11.5%
How noticeable to others do you think your sleep problem is in terms of impairing the quality of your life	110	31.6%	77	22.1%	75	21.6%	46	13.2%	40	11.5%
How worried/ distressed are you about your current sleep problem	118	33.9%	77	22.1%	75	21.6%	41	11.8%	37	10.6%
To what extent do you consider your sleep problem to interfere with your daily functioning	74	21.3%	74	21.3%	106	30.5%	50	14.4%	44	12.6%

Figure 2. Overall insomnia level among secondary school female students in Abha city, Saudi Arabia

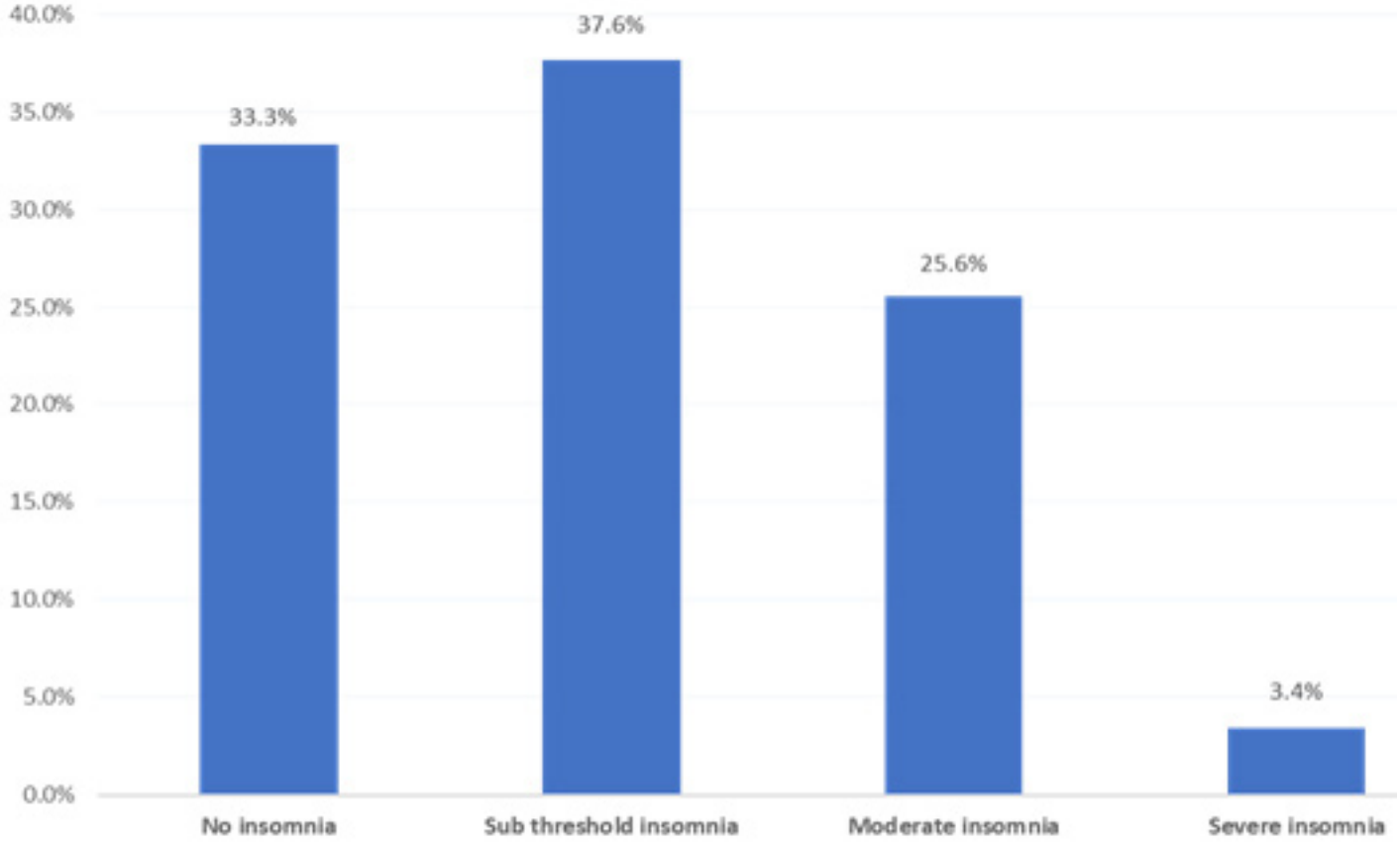

Table 5. Distribution of internet addiction by student's personal data, Abha city, Saudi Arabia

Personal data		Internet addiction level				P-value
		No addiction		Moderate/ severe		
		No	%	No	%	
Age in years	< 18 years	157	62.8%	93	37.2%	.128
	> 18 years	70	71.4%	28	28.6%	
Father education	Basic education	17	65.4%	9	34.6%	.547
	Secondary	66	61.1%	42	38.9%	
	University	144	67.3%	70	32.7%	
Father work	Not working	21	67.7%	10	32.3%	.747
	Governmental	158	66.1%	81	33.9%	
	Private	25	65.8%	13	34.2%	
	Free works	23	57.5%	17	42.5%	
Mother education	Illiterate	17	60.7%	11	39.3%	.745
	Basic education	29	72.5%	11	27.5%	
	Secondary	54	65.1%	29	34.9%	
	University	127	64.5%	70	35.5%	
Mother work	Housewife	98	64.1%	55	35.9%	.683
	Working	129	66.2%	66	33.8%	
Social level	Moderate	138	63.3%	80	36.7%	.328
	High	89	68.5%	41	31.5%	
Age of first use of social media (years)	< 10 years	57	67.1%	28	32.9%	.364
	10-14 years	139	62.9%	82	37.1%	
	15-20 years	31	73.8%	11	26.2%	
Using social networks	Sometimes	50	98.0%	1	2.0%	.001*
	Usually	177	59.6%	120	40.4%	
Hours spent on social media daily	< 1 hour	5	100.0%	0	0.0%	.001*
	1-3 hours	44	86.3%	7	13.7%	
	> 3 hours	178	61.0%	114	39.0%	
Reasons for using social network	Following the current trend	64	74.4%	22	25.6%	.001*
	Find new friends	1	20.0%	4	80.0%	
	Search and share information	28	90.3%	3	9.7%	
	Means of communication	22	75.9%	7	24.1%	
	Entertainment purposes	102	54.8%	84	45.2%	
	Studying with my colleagues	10	90.9%	1	9.1%	
Peak time spent on social media	Early morning	17	77.3%	5	22.7%	.470
	After back of school	68	64.8%	37	35.2%	
	Before going sleep	142	64.3%	79	35.7%	

P: Pearson X2 test
* P < 0.05 (significant

Table 6. Effect of internet addiction on student's scholastic achievement and insomnia, Abha city, Saudi Arabia

Scholastic achievement and stress		Internet addiction level				P-value
		No addiction		Moderate/ severe		
		No	%	No	%	
Scholastic achievement	Good	201	88.5%	90	74.4%	.003*
	Very good	23	10.1%	28	23.1%	
	Excellent	3	1.3%	3	2.5%	
Studying hours per day	1-2 hours	147	64.8%	95	78.5%	.026*
	3-5 hours	51	22.5%	18	14.9%	
	> 5 hours	29	12.8%	8	6.6%	
Absenteeism of school due to fatigue	Rarely	108	47.6%	46	38.0%	.109
	Sometimes	96	42.3%	55	45.5%	
	Many times	23	10.1%	20	16.5%	
Insomnia level	No/ subclinical	186	81.9%	61	50.4%	.001*
	Moderate/ severe	41	18.1%	60	49.6%	

P: Pearson X2 test
* P < 0.05 (significant

was for entertainment and this explains the long duration of enjoyment in using the platforms. The peak time for using social media was just before going to sleep which then caused lack of sleep with tiredness feeling. This can affect their ability for school attendance and teaching achievement. This can by the way explain their moderate scholastic achievement as the trend among students who recorded that they had good scholastic achievement and excellent grading was reported by very few numbers of the participants. This moderate achievement was due to insufficient studying hours as more than two thirds reported that they study for only 1-2 hours daily. Also, recurrent school absenteeism was reported among nearly half of the students. The study also revealed that there was a significant relation between internet addiction and high absenteeism, few studying hours daily, and lower scholastic achievement. Considering insomnia, the current study revealed that one third of the students had moderate to severe levels of insomnia (Figure 2). Nearly half of the students who had internet addiction had moderate to severe insomnia. On testing the direct and indirect effect of internet addiction on student's scholastic achievement (Figure 4), it was clear that higher internet addiction score was significantly inversely related with last year's grade, but insomnia wasn't related after adjusting for internet addiction effect, but internet addiction significantly affected student's insomnia (significant positive relation). Regarding social consequences, time-disruption was the most documented effect, which then disrupted regular social life, including academic, professional performance and daily practices [21]. Some studies also concluded that IAD can lead to interruption of social relationships among participants [22, 23]. It is, however, also noted by others that IAD is beneficial for peer relations in Taiwan [24]. Dr. Keith W. Beard (2005) states that "an individual is addicted when an individual's psychological state, which includes both mental and emotional states, as well as their scholastic, occupational and social interactions, is impaired by the overuse of [the Internet]" [25] Regarding physical symptoms, it includes a decreased immune system due to insomnia and insufficient sleep, lack of exercise, and increased the risk for musculoskeletal complaints. Symptoms of withdrawal might include agitation, depression, anger, and anxiety when the person is away from technology. These psychological symptoms might even turn into physical symptoms such as rapid heartbeat, tense shoulders, and shortness of breath [26, 27]. These findings were consistent with that reported by Siomos KE, 2008 in Greece [28]. The author reported that 70.8% of adolescents had access to the Internet. The most frequent type of Internet use is online games, representing 50.9% of Internet users, and information search, constituted 46.8%. The prevalence of Internet addiction among Internet users of Central Greece is 8.2%, especially the male students who play online games and visit Internet cafés. Also, Younes F et al, 2016 studied internet addiction and relationships with insomnia, anxiety, depression, stress, and self-esteem in university students [29]. Potential IAD prevalence was 16.8% (95% confidence interval: 13.81–19.79%), with a higher prevalence in males (23.6% versus 13.9%). Significant correlations were found between potential IAD and insomnia, stress, anxiety, depression, and self-esteem (p-value < 0.001); ISI and DASS sub-scores were higher and self-esteem lower in students with potential IAD. Sleep problems among internet addict group was assessed by Chen YL et al, 2016. Based on the results of used models, dyssomnias (odds ratio = 1.31), especially early and middle insomnias (odds ratio = 1.74 and 2.24), sequentially predicted internet addiction, and internet addiction sequentially predicted disturbed circadian rhythm (odds ratio = 2.40). A systematic review was conducted by Lam LT et al to address internet gaming

addiction, problematic use of the internet, and sleep problems [30]. Seven studies were included through a systematic literature search. Of these three focused on addictive Internet gaming and four on problematic Internet uses and sleep problems. Results of the review revealed that addictive gaming, especially massively multiplayer online role-playing games MMORPG, may be associated with poor quality of sleep. Results also indicated that problematic Internet use was associated with sleep problems including subjective insomnia and poor sleep quality.

Conclusions and Recommendations

In conclusion, the study revealed that nearly one third of the students had moderate to severe internet addiction, Internet use purpose was mainly for items other than studying. Also, more than one third of the students had significant insomnia due to lack of sleep hours. Scholastic achievement and attendance were moderately poor among the included students due to insufficient sleeping and few study hours, Internet addiction inversely affected students sleep and their scholastic achievement. Researchers recommended that students should learn the correct method and time for using internet by parents and schoolteachers. Students need periodic psychological assessment for early detection of any consequences of stress and health education sessions are crucial to improve their coping skills. Larger scale studies covering more areas and more schools (private and governmental) should be conducted to have better mapping of internet use and its consequences.

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Self-isolation during the COVID-19 pandemic is associated with increased risk of burnout among physician trainees: A cross sectional study

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Abstract

The COVID-19 pandemic emerged in late 2019. Previous research has shown a significant prevalence of burnout among physician trainees, with concern that the pandemic will increase burnout. We aimed to assess this risk among trainees at a large academic hospital. We performed a cross-sectional study during the pandemic using a survey that included the Maslach Burnout Inventory. The response rate was 94.7%. Among trainees, 58.5% changed their living arrangements to protect family. Psychological well-being was negatively affected in 81.7% and clinical performance in 64.3%; 13.8% were at high risk of burnout. Emotional exhaustion (EE) scores were high in 50% and depersonalization (DP) scores in 28.8%; a sense of personal accomplishment was low in 41.9%. Increased risk of burnout was associated with male gender and increased exposure to suspected COVID-19 cases. Risk of high EE correlated with an increased number of children and risk of high DP with male gender. High EE and DP score correlated with increased exposure to suspected and confirmed COVID-19 patients. Trainees who self-isolated to protect family were more likely to experience high DP and burnout. Trainees in surgical specialties were more likely to feel their clinical performance was negatively affected. The results suggest that a significant percentage of trainees are at high risk of burnout during the pandemic especially those that attempted self-isolation. Training programs should incorporate methods to maintain well-being and coping, including adequate time off between shifts. Future research should evaluate other aspects of trainee well-being in relation to self-isolation and/or changed living arrangements.

Key words:
Burnout, Medical education, pandemic, coronavirus, psychological wellbeing, medical residents

Introduction

The coronavirus pandemic emerged late in 2019, initially being reported in Wuhan, China, and referred to as coronavirus disease 2019 (COVID-19) (1). On March 11, 2020, it was declared a global pandemic by the World Health Organization (WHO) (2). By early July 2020, over 11 million patients across the world were infected and over 500,000 mortalities reported. Over 200,000 cases and over 1,000 mortalities were reported in Saudi Arabia (3).

Healthcare workers (HCW), physicians and medical trainees can experience high levels of burnout, and there is reason to believe that these levels may increase during the pandemic. The term "burnout" was first used by psychologist Herbert Freudenberger in 1974 when he described job dissatisfaction induced by work stressors (4). Recently, burnout has been defined as a state of physical, emotional, and psychological exhaustion; depersonalization; and a decreased sense of accomplishment. As an entity, burnout has been gaining much attention in the last decade (5-7). Prior to the pandemic, reviews showed that its prevalence among medical trainees ranged between 27% and 75% (5). Medical trainees in Saudi Arabia are no exception, with several studies showing a high risk of burnout among local trainees (9-11). Its risk factors among trainees include first-year residency, being single, and having social stressors, with some medical specialties having a higher risk than others (12).

High burnout has been reported among HCW during previous endemics and pandemics (5-8). Similarly, several studies have demonstrated a high incidence of burnout during the COVID-19 crisis among physicians and trainees (13-15), with much of the academic literature of late warning of the possible psychological impact of the COVID-19 pandemic on HCW (16-18). One study showed the prevalence of burnout among trainees during the COVID-19 crisis to be 76% (14). Because medical trainees are on the front line of healthcare, burnout among them can be attributed to the nature of their duties, work hours, the stress and frustration they face, time-management difficulties, high demands, and dealing with critical situations (8,19). In a pandemic, high burnout risk can be attributed to mental stress, physical exhaustion, safety concerns, prolonged wearing of personal protective equipment (PPE), and change in work routine (14). Burnout can lead to negative effects on the trainee's performance, psychological well-being, job satisfaction, and productivity (5,12,19).

In this study, we aimed to assess the degree of burnout and possible contributing factors among medical trainees from various specialties who work at a large tertiary academic center that was a COVID-19 referral center during the pandemic in Jeddah, Saudi Arabia.

Methods

1. Study design and setting

This cross-sectional survey was conducted during the month of May 2020. We obtained approval from the Biomedical Ethics Unit in the Faculty of Medicine at King Abdulaziz University. The principal investigator distributed the voluntary survey electronically to all trainees who were either affiliated with King Abdulaziz University Hospital or undergoing training there. Participants were licensed physicians pursuing specialist training in an accredited residency training program.

2. Covariates and outcomes

The first part of the questionnaire included demographic characteristics, residency training level, the training program they were enrolled in, and their current rotation. We asked whether they normally lived with family members and if they had changed their living arrangements or attempted self-isolation since the pandemic started in order to protect family members. We asked whether they felt that the COVID-19 pandemic had affected their psychological well-being or clinical performance. We asked how often they came in contact with suspected or confirmed COVID-19 patients. The second part of the questionnaire included the Maslach Burnout inventory – Human Services Survey for Medical Personnel (MBI-HSS (MP)) (20). This externally validated survey has 22 questions that assess three domains: emotional exhaustion (EE, nine questions), depersonalization (DP, five questions), and sense of personal accomplishment (PA, eight questions). Participants responded to the 22 questions by choosing one of the following according to the perceived intensity: everyday = 6, a few times a week = 5, once a week = 4, a few times a month = 3, once a month or less = 2, a few times a year or less = 1, and never = 0. High scores in the EE and DP domains are associated with a higher risk of burnout, whereas high scores in the PA domain are associated with a lower risk of burnout. High EE was defined as a score of 27 or over and high DP as a score of 13 or over. Low PA was defined as a score of 31 or under. A high risk of burnout was defined as co-existing high EE, high DP, and low PA.

3. Statistical analysis

Statistical analysis was performed with R studio version 3.6.2 (R Studio, Inc., Boston, MA, USA). Counts and percentages were used to summarize the participants' demographics. Continuous variables were summarized as means and standard deviations. Burnout dimensions and overall burnout were summarized as continuous and categorical (dichotomous) variables based on the previously mentioned criteria. Cronbach's alpha was used to assess the reliability of the tool used; a value of ≥ 0.7 was considered satisfactory. Univariate analysis was initially performed by using a chi-square test of impendence or an unpaired t-test to assess the association of demographic and work-related variables with the risk of burnout. The dichotomized versions of burnout dimensions were used as dependent variables. Four models were constructed, one for each of the three dimensions of burnout, as well as one for overall burnout (three dimensional). Independent variables included in the analysis were age, gender, marital status, training program level, and exposure to COVID-19.

Results

Table 1 : Descriptive statistics of the study sample

Characteristic	*n* (%) (*N* = 328)	Valid *N*
Gender		328
Female	169 (51.5)	
Male	159 (48.5)	
Age, mean ± SD	27.9 ± 2.25	326
Marital status		328
Single	181 (55.2)	
Married	140 (42.7)	
Divorced	7 (2.13)	
Number of children, mean ± SD	0.37 (0.71)	328
0	241 (73.5)	
1	60 (18.3)	
2	19 (5.79)	
3	8 (2.44)	
Normally live with family members		328
No	28 (8.54)	
Yes	300 (91.5)	
Training level		328
First year resident	81 (24.7)	
Second year resident	76 (23.2)	
Third year resident	76 (23.2)	
Fourth year resident	71 (21.6)	
Fifth year resident	24 (7.32)	
Hospital (current month)		328
KAUH (Base hospital)	306 (93.3)	
Outside KAUH	22 (6.71)	

Note. All values are n (%) except where otherwise indicated. KAUH = King Abdulaziz University Hospital.

The questionnaire was completed by 328 of the 346 trainees contacted to fill out the survey, a response rate of 94.8%. Demographic data can be found in Table 1. Males and females were almost equally represented. Approximately half of the included trainees were single (55.2%) and the great majority (91.5%) normally lived with family members.

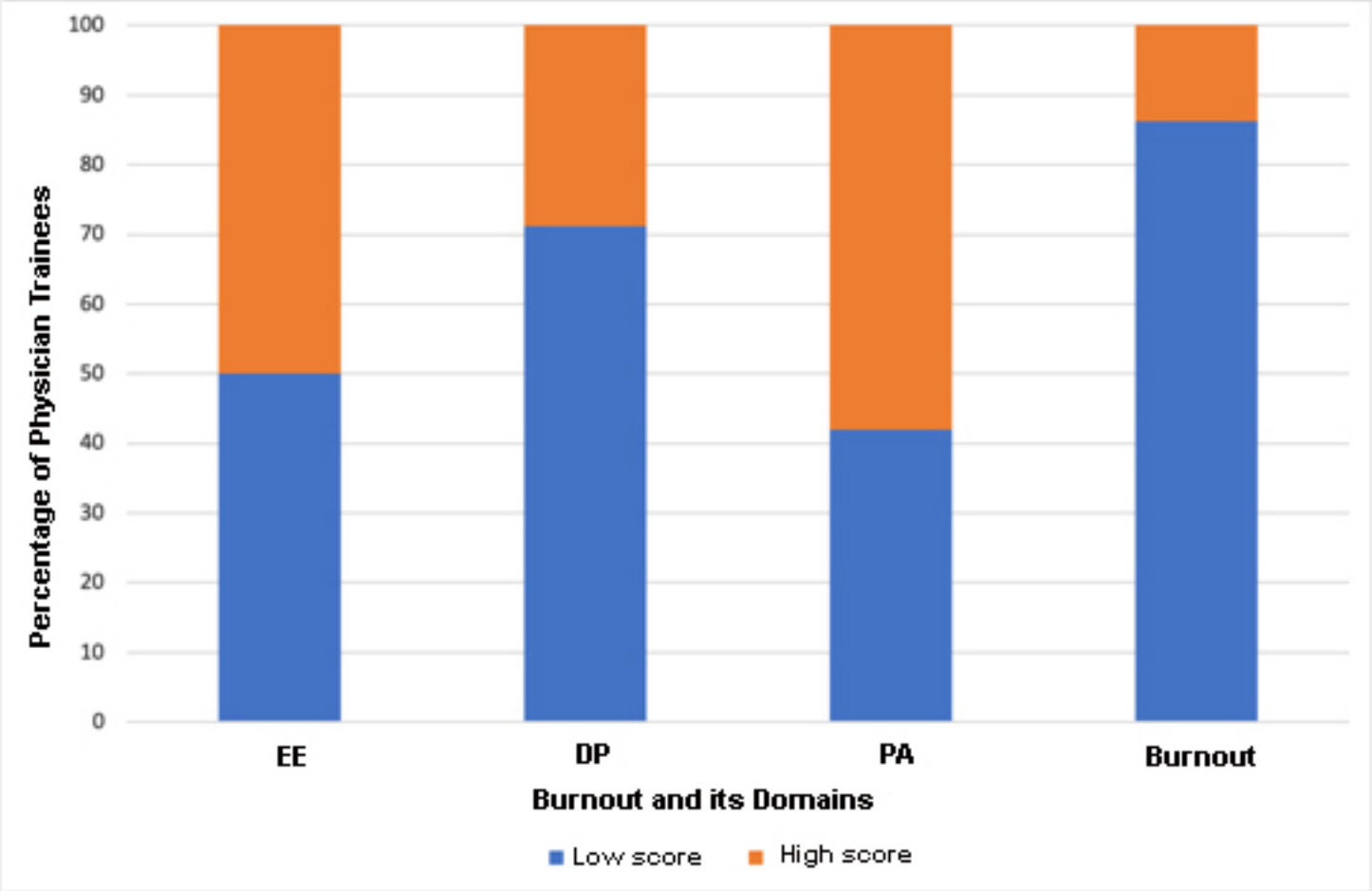
Table 2: Factors assessed in relation to the COVID-19 pandemic and burnout elements.

Factor	*n* (%)
Changed living arrangements and/or practiced self-isolation to protect family member from possible infection	
No	136 (41.5)
Yes	192 (58.5)
Exposure to *suspected* COVID-19 cases	
Less than once a week	115 (35.1)
A few times a week	134 (40.9)
Daily	79 (24.1)
Exposure to *confirmed* COVID-19 cases	
Less than once a week	220 (67.1)
A few times a week	66 (20.1)
Daily	42 (12.8)
Psychological well-being affected by the COVID-19 pandemic	
No	60 (18.3)
Yes	268 (81.7)
Clinical performance affected by the COVID-19 pandemic	
No	117 (35.7)
Yes	211 (64.3)
Burnout, mean ± SD	
EE score (α = 0.89)	27.8 (12.2)
DP score (α = 0.7)	9.50 (6.23)
PA score (α = 0.72)	33.5 (7.52)

Note. All values are n (%) except where otherwise indicated. EE = emotional exhaustion, DP = depersonalization, PA = personal accomplishment.

More than half of the trainees (58.5%) changed their living arrangements or practiced some form of self-isolation in order to protect family members from infection. COVID-19 negatively affected the psychological well-being of 81.7% of the trainees and the clinical performance of 64.3%. The average EE score was 27.8, the average DP score 9.5, and the average PA score 33.5. Cronbach's alpha was ≥ 0.7, which was considered satisfactory. These data can be found in Table 2.

Figure 1. Prevalence of burnout and its domains among physician trainees. EE = emotional exhaustion, DP = depersonalization, PA = personal accomplishment.



Fifty percent of the trainees had a high EE score, 28.8% had a high DP score, and 41.9% had a low PA score; these scores indicated a high risk of burnout, which was present in 13.8% of the trainees (Figure 1).

Table 3 Factors that affected burnout domain scores (EE, DP, and PA) in physician trainees.

Factor	EE Low *n* (%) (*N* = 161)	EE High *n* (%) (*N* = 161)	*P*-value	DP Low *n* (%) (*N* = 227)	DP High *n* (%) (*N* = 92)	*P*-value	PA High *n* (%) (*N* = 186)	PA Low *n* (%) (*N* = 134)	*P*-value
Gender			1.000			**0.005**[$]			0.722
Female	83 (49.7)	84 (50.3)		130 (78.3)	36 (21.7)		95 (56.9)	72 (43.1)	
Male	78 (50.3)	77 (49.7)		97 (63.4)	56 (36.6)		91 (59.5)	62 (40.5)	
Age, mean (SD)	27.8 (2.13)	28.1 (2.37)	0.215	27.9 (2.15)	28.1 (2.52)	0.424	28.0 (2.36)	27.9 (2.14)	0.987
Marital status			0.317			0.613			0.497
Single	94 (53.4)	82 (46.6)		124 (70.9)	51 (29.1)		97 (55.4)	78 (44.6)	
Married	63 (45.3)	76 (54.7)		99 (72.3)	38 (27.7)		84 (60.9)	54 (39.1)	
Divorced	4 (57.1)	3 (42.9)		4 (57.1)	3 (42.9)		5 (71.4)	2 (28.6)	
Number of children			**0.029**[$]			0.607			0.967
0	125 (53.0)	111 (47.0)		167 (71.7)	66 (28.3)		135 (57.7)	99 (42.3)	
1	29 (49.2)	30 (50.8)		43 (72.9)	16 (27.1)		35 (59.3)	24 (40.7)	
2+	7 (25.9)	20 (74.1)		17 (63.0)	10 (37.0)		16 (59.3)	11 (40.7)	
Normally live with family members			0.323			0.447			0.623
No	11 (39.3)	17 (60.7)		17 (63.0)	10 (37.0)		18 (64.3)	10 (35.7)	
Yes	150 (51.0)	144 (49.0)		210 (71.9)	82 (28.1)		168 (57.5)	124 (42.5)	
Training level			0.114			0.315			0.212
First year resident	46 (58.2)	33 (41.8)		59 (75.6)	19 (24.4)		47 (59.5)	32 (40.5)	
Second year resident	30 (40.5)	44 (59.5)		48 (65.8)	25 (34.2)		41 (56.2)	32 (43.8)	
Third year resident	33 (43.4)	43 (56.6)		49 (65.3)	26 (34.7)		43 (58.1)	31 (41.9)	
Fourth year resident	39 (56.5)	30 (43.5)		54 (78.3)	15 (21.7)		36 (51.4)	34 (48.6)	
Fifth year resident	13 (54.2)	11 (45.8)		17 (70.8)	7 (29.2)		19 (79.2)	5 (20.8)	
Exposure to *suspected* COVID-19 cases			**0.005**[$]			**<0.001**[$]			0.840
Less than once a week	67 (60.4)	44 (39.6)		84 (76.4)	26 (23.6)		61 (56.0)	48 (44.0)	
A few times a week	66 (49.3)	68 (50.7)		104 (78.2)	29 (21.8)		80 (59.7)	54 (40.3)	
Daily	28 (36.4)	49 (63.6)		39 (51.3)	37 (48.7)		45 (58.4)	32 (41.6)	
Exposure to *confirmed* COVID-19 cases			**0.003**[$]			**<0.001**[$]			0.401
Less than once a week	122 (56.5)	94 (43.5)		162 (76.1)	51 (23.9)		123 (57.5)	91 (42.5)	
A few times a week	26 (40.0)	39 (60.0)		47 (71.2)	19 (28.8)		36 (54.5)	30 (45.5)	
Daily	13 (31.7)	28 (68.3)		18 (45.0)	22 (55.0)		27 (67.5)	13 (32.5)	
Hospital (current month)			0.825			0.940			0.898
KAUH (base hospital)	149 (49.7)	151 (50.3)		212 (71.4)	85 (28.6)		174 (58.4)	124 (41.6)	
Other (please specify)	12 (54.5)	10 (45.5)		15 (68.2)	7 (31.8)		12 (54.5)	10 (45.5)	

Table 3

Note. All values are n (%) except where otherwise indicated. Statistical analysis was performed by using a chi-square test of independence or an unpaired t-test. EE = emotional exhaustion, DP = depersonalization, PA = personal accomplishment, KAUH = King Abdulaziz University Hospital.

* P value < 0.05.

Statistical analysis showed trainees with a higher number of children had an increased risk of EE (P < 0.05), the percentage at high risk rising with an increase in the number of children. Higher frequency of exposure to suspected or confirmed COVID-19 cases was associated with a higher risk of EE (P = 0.005 and P = 0.003, respectively). Males were at higher risk of DP than females were (36.6% vs. 21.7%, respectively, P = 0.005). Higher frequency of exposure to suspected or confirmed COVID-19 cases was associated with a higher risk of DP (P < 0.001 for both comparisons). None of the included factors was significantly associated with a low sense of PA. These data are shown in Table 3.

Table 4: Factors associated with high risk of burnout among physician trainees

	Burnout (three dimensional)		
Factor	Low *n* (%) (*N* = 276)	High *n* (%) (*N* = 44)	*P*-value
Gender			0.017*
Female	151 (91.0)	15 (9.04)	
Male	125 (81.2)	29 (18.8)	
Age, mean (SD)	27.9 (2.26)	28.1 (2.24)	0.604
Marital status			1.000
Single	150 (86.2)	24 (13.8)	
Married	120 (86.3)	19 (13.7)	
Divorced	6 (85.7)	1 (14.3)	
Number of children			0.823
0	203 (86.8)	31 (13.2)	
1	50 (84.7)	9 (15.3)	
2+	23 (85.2)	4 (14.8)	
Normally live with family members			0.556
No	25 (92.6)	2 (7.41)	
Yes	251 (85.7)	42 (14.3)	
Training level			0.832
First year resident	69 (88.5)	9 (11.5)	
Second year resident	61 (83.6)	12 (16.4)	
Third year resident	66 (86.8)	10 (13.2)	
Fourth year resident	58 (84.1)	11 (15.9)	
Fifth year resident	22 (91.7)	2 (8.33)	
Exposure to *suspected* COVID-19 cases			0.05*
Less than once a week	97 (89.0)	12 (11.0)	
A few times a week	118 (88.7)	15 (11.3)	
Daily	61 (78.2)	17 (21.8)	
Exposure to *confirmed* COVID-19 cases			0.142
Less than once a week	189 (88.7)	24 (11.3)	
A few times a week	55 (83.3)	11 (16.7)	
Daily	32 (78.0)	9 (22.0)	
Hospital (current month)			0.521
KAUH (Base hospital)	258 (86.6)	40 (13.4)	
Outside KAUH	18 (81.8)	4 (18.2)	

Table 4

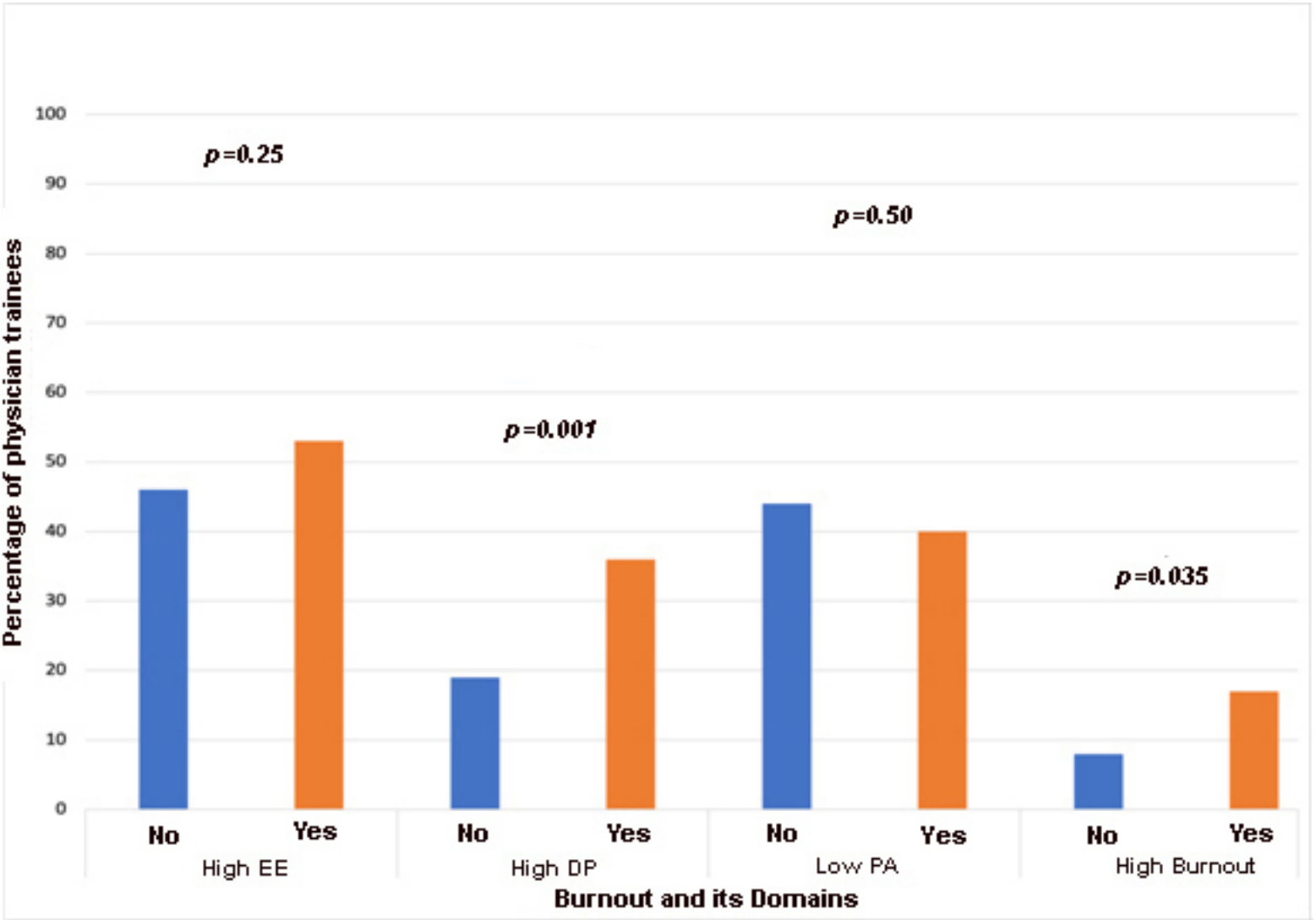
Note. All values are n (%) except where otherwise indicated. Statistical analysis was performed by using a chi-square test of independence or an unpaired t-test. KAUH = King Abdulaziz University Hospital.
* P value < 0.05.

Statistical analysis showed that males were at higher risk of burnout than females were (18% vs. 9%, P < 0.05). High risk of burnout was more prevalent in those who were exposed to suspected cases daily (21.8%) than in those who were exposed to suspected cases weekly or less than weekly (P = 0.05). The risk of burnout increased with increased exposure to confirmed COVID-19 cases, but this did not reach statistical significance. None of the remaining factors were significantly associated with a high risk of burnout. Table 4 shows the full details.

Living arrangements and burnout

Results showed trainees who changed their living arrangements and/or self-isolated to protect family members during the pandemic were more likely to have a high risk of both DP and burnout than were those who did not, and this was statistically significant (Figure 2).

Figure 2. Association between changed living arrangements and/or self-isolation and burnout. EE = emotional exhaustion, DP = depersonalization, PA = personal accomplishment.



Clinical specialty and burnout

Table 5 shows that the highest proportions of burnt-out trainees were neurosurgeons (37.5%), followed by psychiatrists (33.3%) and urologists (33.3%). Among critical care trainees, 72.2% had a high EE score, whereas 50% of neurosurgeons, 44.4% of urologists, and 37.9% of internal medicine trainees had a high DP score.

Table 5: Percentage of physician trainees with significant scores in overall burnout and its domains by clinical specialty.

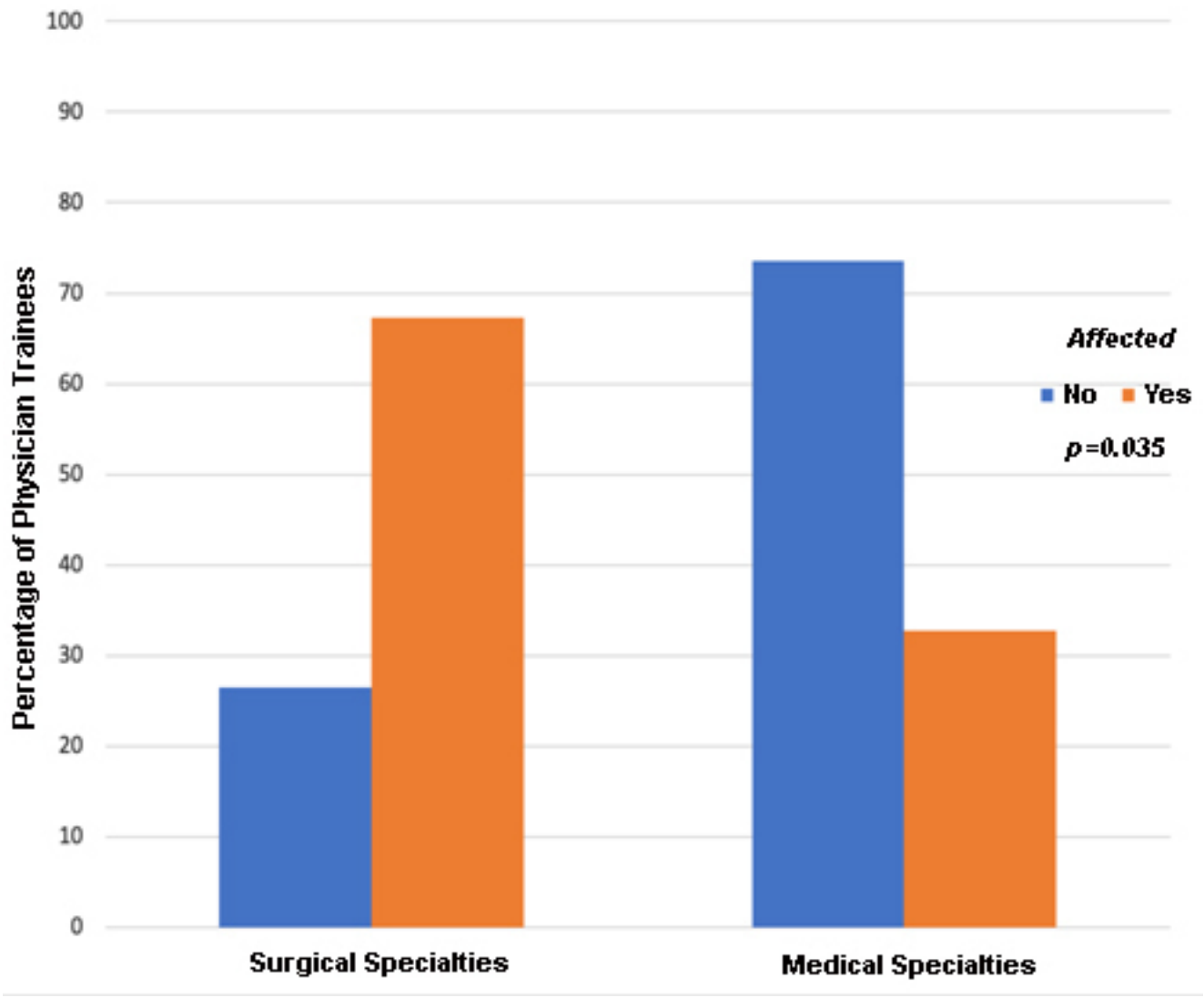
Clinical Specialty	*N*	EE High *n* (%) (*N* = 161)	DP High *n* (%) (*N* = 92)	PA Low *n* (%) (*N* = 134)	Burnout High *n* (%) (*N* = 44)
Anesthesia	16	7 (43.8)	2 (12.5)	6 (37.5)	0 (0.00)
Critical Care	18	13 (72.2)	6 (33.3)	7 (38.9)	2 (11.1)
Emergency Medicine	26	10 (38.5)	5 (20.0)	8 (30.8)	3 (11.5)
Otorhinolaryngology	13	7 (50.0)	5 (35.7)	6 (46.2)	3 (23.1)
Family Medicine	6	6 (85.7)	3 (50.0)	3 (42.9)	1 (16.7)
General Surgery	20	9 (45.0)	4 (20.0)	9 (45.0)	2 (10.0)
Internal Medicine	58	32 (56.1)	22 (37.9)	26 (44.8)	12 (20.7)
Neurology	6	3 (50.0)	1 (16.7)	3 (50.0)	0 (0.00)
Neurosurgery	8	4 (50.0)	4 (50.0)	4 (50.0)	3 (37.5)
Obstetrics and Gynecology	25	17 (65.4)	10 (40.0)	6 (23.1)	4 (16.0)
Orthopedics	17	6 (35.3)	4 (23.5)	7 (41.2)	1 (5.88)
Other	22	14 (63.6)	9 (40.9)	5 (23.8)	3 (13.6)
Pediatrics	48	18 (37.5)	6 (12.8)	20 (41.7)	2 (4.17)
Plastic Surgery	5	1 (20.0)	0 (0.00)	3 (60.0)	0 (0.00)
Psychiatry	3	1 (33.3)	1 (33.3)	1 (33.3)	1 (33.3)
Radiology	20	8 (40.0)	6 (30.0)	15 (78.9)	4 (20.0)
Urology	9	5 (55.6)	4 (44.4)	5 (55.6)	3 (33.3)

Note. EE = emotional exhaustion, DP = depersonalization, PA = personal accomplishment.

Clinical performance during the COVID-19 pandemic

Of the 328 physician trainees, 211 (64.3%) thought that their clinical performance had been compromised during the COVID-19 pandemic. The clinical performance of trainees in surgical specialties (otorhinolaryngology, general surgery, neurosurgery, obstetrics and gynecology, orthopedics, plastic surgery, and urology) was more likely to be affected than their fellow non-surgical trainees (p = 0.035), as depicted in Figure 3.

Figure 3. Impact of COVID-19 pandemic on the clinical performance of surgical and medical trainees.



Discussion

With the COVID-19 pandemic straining worldwide healthcare resources and creating an unprecedented burden on HCW, we set out to assess the prevalence of burnout among physician trainees at a tertiary academic hospital that was a referral center for COVID-19 patients in the region. We chose to focus on trainees because previous research had shown this period in their career to carry the highest risk of burnout, with high EE and high DP (21).

We found 13.8% of trainees were at a high risk of burnout. At first, this rate would seem to compare favorably with the results described in previous studies. In a systematic review of burnout among medical trainees by specialty, the authors reported its prevalence to vary between 9.9% and 73.4%. However, not all of the studies agreed on the definition of burnout, with burnout risk in some articles defined as high DP and/or EE (low PA was not an obligatory criterion) (22). Indeed, there is considerable disagreement within the literature as to the definition of burnout even when using a single instrument such as the MBI-HSS (MP). In a systematic review of burnout among consultant physicians (i.e., non-trainees), Rotenstein et al. (2018) found that there were 47 unique implementations of MBI versions, cutoff combinations, or both. This variation will inevitably lead to potential under- or overdiagnosis of burnout. Among studies that defined burnout as high levels of EE, high DP, and low PA, as we did, the prevalence of burnout among consultant physicians varied between 2.6% and 11.8% (23).

Another factor that could explain our seemingly low rate of burnout may be that during the time of our survey, the hospital had implemented a week-on, week-off system for clinicians in order to decrease the risk of cross-infection and burnout. The benefit of this may have been a lower rate of burnout, as time off work is one recognized way of decreasing the risk of circumstantial burnout (burnout resulting from self-limited circumstances and environmental triggers) (24-26). Thus, only 13.8% of trainees were found to be at high risk of burnout, but the trainees themselves identified changes in their well-being due to the pandemic, with 81.7% feeling that their psychological well-being had been affected by the COVID-19 pandemic and 64.3% indicating that their clinical performance had been affected. In addition, although medical specialties saw an increase in patient volume, there was a slowdown in many other specialties, as nonurgent clinic visits and elective surgeries were canceled. This change decreased some trainees' exposure to their own specialty, which was confirmed when we found that trainees in surgical programs were more likely to feel that their clinical performance had been affected by the pandemic than were those in nonsurgical programs.

Males and those who encountered suspected COVID-19 cases daily were at the highest risk of burnout, but not those who encountered confirmed COVID-19 cases daily. This unexpected result is similar to what Wu et al. (27) described when they found that frontline COVID-19 HCW had a lower burnout score than did those working on the usual wards. They attributed this finding to frontline workers having a potentially greater sense of control of the situation and being more involved in the new policies and procedures being implemented to protect physicians and patients. We would add that this finding may also be due to trainees who encountered confirmed COVID-19 cases daily having more training, as well as greater access to and stricter adherence to full PPE protocols when treating patients, which may have contributed to a greater sense of ease and less stress (14). Another possibility is that uncertainty about the patients' COVID-19 status could increase trainee anxiety. Although our study showed that the percentage of trainees reporting high burnout scores increased as their exposure to confirmed cases increased, this did not reach statistical significance. The finding that men were more likely to experience burnout is consistent with the results of a previous meta-analysis of burnout among physician trainees (28). This observation is concerning, as it has been shown that men are more likely than women to develop persistent burnout (29).

We found that 50% of trainees were at high risk of EE, with those with a higher number of children at greatest risk. The closures of schools and daycares creates a unique plight for parents. They face additional demands at work because of the crisis and at home because they have to take on the role of teacher or sitter during daytime hours. This situation creates an additional emotional burden, highlighting the importance of providing childcare services for HCW during the pandemic. We also found that increased exposure to suspected or confirmed COVID-19 cases was associated with a higher risk of EE.

Males and those with increased exposure to suspected or confirmed COVID-19 cases were at the highest risk of DP. In general, it has been suggested that with the increased use of masks and full PPE during the COVID-19 pandemic, physicians may be at increased risk of DP. The loss of the ability to read the facial expressions of both colleagues and patients, as well as the limitations on interactions imposed by physical distancing, could contribute to higher DP among HCW during the pandemic (14). This change in normal social interactions is not limited to work but extends to the home, as 58.5% of our study population stated they had changed their living arrangements and/or were practicing self-isolation to avoid infecting family. An important new finding is the association between this and the risk of DP and burnout among physician trainees. We hypothesize that attempts to physically self-isolate may contribute to psychological self-isolation, with trainees anxious about transmitting the infection to family and losing their normal support network around them in a time of increased need. Such drastic changes at both work and home gives some indication of the huge challenges facing trainees (and other HCW) during the pandemic. Previous research on premedical students showed they rank family as their most important source of support and coping (30). The average PA score in our cohort was 33.5, but none of the factors that we included were associated with it.

Our study has several limitations. As the COVID-19 pandemic was an unforeseen event, we did not have an opportunity to assess trainees' pre-pandemic responses to the MBI-HSS (MP); comparing their current responses to a "baseline". We had a high response rate, but it is unclear whether the results from our large academic institute are generalizable to trainees in other healthcare institutes. We also did not assess the degree to which trainees had changed their living arrangements or for how long.

Our study strengths are that we included all three domains in our definition of burnout in order to obtain a more global assessment of trainees' well-being and to avoid overestimated measures of diagnosing burnout while at the same time analyzing the three domains individually. We had a good response rate from a reasonably large population of trainees. We included all specialties that would be expected to have significant risk of exposure to COVID-19 patients. Ours is also the first study in the Middle East to examine the risk of burnout among medical practitioners during the COVID-19 outbreak and the first we know of to document the association of self-isolation and/or changed living arrangements in the increased risk of burnout.

In conclusion, we have shown that a significant percentage of trainees are at high risk of burnout during the COVID-19 pandemic. Changing living arrangements and/or self-isolation was associated with an increased risk of burnout. It is important that program directors and institutions work on preventing and treating symptoms of burnout by instituting support groups, hotlines, a specialized clinic, and work regulations. Program directors and institutional administrators should meet regularly with trainees to answer questions, provide reassurance, and update them with any changes in their training program. Attending physicians must remain vigilant for early signs of burnout and provide support proactively, as trainees may be reluctant to seek help for stress-related issues. It is important to reduce stigma by normalizing the feelings of EE and encouraging open discussions (31,32). Residency training programs should incorporate methods on maintaining psychological well-being and coping into their curricula, including adequate time off between shifts. The focus of future research should be on assessing the effectiveness of these steps, identifying coping mechanisms for trainees, and evaluating other aspects of trainee psychological well-being (such as depression, anxiety, and insomnia), especially in relation to changing living arrangements and/or self-isolation.

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Diagnostic and therapeutic option of Covid-19; A systematic review

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Abstract

Background: The global pandemic of coronavirus has resulted in it causing several respiratory diseases. The mild common cold like illness is one of the major symptoms that represents the clinical presentation of the respiratory infection. Some patients can be asymptomatic while some might have characteristic symptoms in the form of coughs, dyspnoea, and fever. Mostly it affects people aged between 30 to 79 years. Major risk factors are people residing or travelling in the areas where risk of transmission is quite high, old age, and presence of comorbidities. The origin of the virus was linked to the Southern China's Huanan wet market in Huanan. The pathophysiology has not yet been understood properly but the exudative diffuse alveolar is considered as the major reason behind the deaths due to respiratory failure. In order to control the spread there are four different ways currently: quarantine the contact for at least 14 days, screening of travellers, drive-through screening centres, and temperature screening. Isolation, infection management, and symptom management can be the most useful therapeutic approaches.

Methodology: During this research, the systematic review has been done by referring to several studies that showed the data related to the diagnostic and therapeutic approach against Covid-19. During the research it has been -ensured that only the data from thighly qualified authors was used to determine the effective diagnostic and therapeutic options of Covid-19. The inclusion criteria were articles available in English language, the most recent and highly rated studies, and articles having statistics. The exclusion criteria were data which is available without clear statistics, articles other than those in the English language, data of high risk and low quality, and the data not able to provide the basic diagnostic and therapeutic options of Covid-19. It has been ensured that the quality of data should be maintained in order to establish quality research.

Discussion: Covid-19 diagnostic options are oral and nasal PCR, rapid diagnostic test, serologic test, plain X-rays, Magnetic resonance imaging (MRI), CT scanning, ultrasonography, and nuclear scanning. The therapeutic options are pharmacological drugs (like chloroquine, hydroxychloroquine, corticosteroids, sirolimus, tocilizumab), airway assistance ventilation, and vaccination.

Conclusion: Covid-19 is on the verge of constant increase and is impacting many people around the globe. Currently, there is no proper treatment for covid-19 as a result of which everyday preventive actions and vaccination are the best things that an individual can do in order to prevent the spread of covid-19.

Key words: Covid-19, corona virus, SARS-CoV-2, diagnostic, therapeutic.

Introduction

The global pandemic of coronavirus has resulted in several respiratory diseases. The mild common cold like illness is one of the major symptoms that represents the clinical presentation of the respiratory infection (Yonker, et al, 2020). Some patients can be asymptomatic while some might have characteristic symptoms in the form of coughs, dyspnoea, and fever (Ellington, et al, 2020).

There are around 87% of confirmed cases in China that are aged between 30 to 79 years (Bi, et al, 2020). However, there are only 3% of people whose ages are above 80 years. In the case of Italy, the prevalence and the median age of the coronavirus cases were much higher than that of China. When it comes to the healthcare workers, the infection rate was different in different locations. For example, the infection rate in the healthcare workers in US was 18%, 9% in Italy and almost 6% in the Netherlands. However, the infection rate Saudi Arabia is 5.6% with a total of 347,000 cases till now (Sutcliffe, et al, 2016). As a comparison, the United States currently has over 24 million cases and in the UK, the total reported cases is over 3.4 million (Geldsetzer, 2020). Hence, there is an extensive need for epidemiology around the world. One of the major risk factors in the case of Covid-19 is linked with the people residing or travelling in the areas where risk of transmission is quite high. Along with this, old age is another major risk factor for infection (Liu, et al, 2020). The presence of comorbidities is another major risk factor for infection. Similarly, the environmental and the behavioural factors that are directly associated with the individual who is infected are also the risk factors (Hui, et al, 2018). The etiology can be used in order to find out different important aspects of covid-19. One of the major aspects is the origin of the virus. There are a number of patients who have been reported at the earlier stages of the coronavirus to be linked to Southern China's Huanan wet market . During the early stages, it was reported that around 55% out of 425 confirmed cases are from this wet market area (Li, et al, 2020). A wet market is a market in China where fish and meat are butchered and sold. This is the market from where the first few cases of Covid-19 were reported.

Pathophysiology in the case of coronavirus has not been understood properly but it is confirmed that the extra pulmonary manifestations are associated directly with this infection (Zheng, et al, 2020). The exudative diffuse alveolar is considered as the major reason behind the increase in numbers of the covid-19 patients who are dying due to respiratory failure (Menter, et al, 2020). The exudative diffuse alveolar is the global respiratory injury and the number of these types of injuries has increased since the outbreak of covid-19 (Menter, et al, 2020).

There are different classifications taken by the World Health Organization in order to know covid-19 disease's severity properly. Mild illness is among those and common symptoms in mild illness include fatigue, cough, myalgia, and fever. Along with this, there are some other nonspecific symptoms in the form of headache, nausea, loss of smell and taste, and throat infection. Similarly, in moderate disease the adults find different signs of clinical lung infection but not a single sign of severe pneumonia (Feng, et al, 2020). Most of the children find it hard to breathe and do not find any sign of severe pneumonia. Similarly, in cases of severe disease, the adults will find some clinical signs of pneumonia whereas the children also face the clinical signs of pneumonia in case of severe disease. However, in the case of critical disease the acute respiratory distress syndrome is present. Along with this, some other complications in the form of acute coronary syndrome and delirium are also present in cases of critical disease (Schwartz, et al, 2018). Screening includes four different methods. The first one is management of contacts. In order to manage the contacts properly, it is necessary to make sure that the contacts remain quarantined and properly monitored for at least 14 days. The second one is the screening of travellers. The screening of travellers is still recommended in some of the countries where the borders are open. Drive through screening centres are now set up in the majority of the countries for safer and efficient screening (Campbell, 2020). In cases of temperature screening, different temperature screening products and thermal cameras are used as reliable resources for efficient screening (Mitra, et al, 2020).

One of the major aspects of diagnosis of covid-19 is early recognition and timely diagnosis. Another major aspect of diagnosis is the higher index of clinical suspicion. The establishment of covid-19 pathways on local and national level is significant. The screening of patients is also one of the major diagnostic tehniques that can prevent covid-19 from further spreading (Zanardo, et al, 2020).

Isolation, infection management, and the symptom management are the most useful therapeutic approaches that can be helpful to use against an infection like Covid-19 (Hao, et al, 2020). Any vaccine for the cure of covid-19 has not yet been sufficiently tested in most parts of the world as a result of which these three are still the most appropriate therapeutic approaches available for reducing the incidence and prevalence of this infection (Zhu, et al, 2020).

The research aim for this paper was to evaluate and assess appropriate therapeutic approaches against Covid-19; hence, based on this aim, the research objectives are as follows;

- To outline and identify a wide range of diagnostic and therapeutic options for Covid-19.
- To analyse diagnostic and therapeutic options for Covid-19.
- To compare different types of diagnostic and therapeutic options for Covid-19.

Research Methodology

Search Strategy

During this research, the systematic review was done by referring to several studies that showed the data related to the diagnostic and therapeutic approach against Covid-19. For identifying the approaches which can be used to tackle the emerging uncertainties regarding Covid-19, search strategy was selected as the most appropriate strategy. Search strategy during this research has been of massive significance in order to find the accurate diagnostic and therapeutic options against Covid-19. The studies from different scholarly articles have been used to make sure that the most accurate data of highly authorized scholars was used. Along with this, the studies from the Web of Science, PubMed, and Research Gate have been retrieved to strengthen the research. Furthermore, search strategy has enabled the use of electronic database citations which are vital for gaining reliability and validity in this report (Torres, et al, 2019). Along with this, during the citation the snowball search strategy was used which has further strengthened the quality of data and has helped find and critique the efficient diagnostic and therapeutic option for Covid-19.

Study Selection and Screening

There are numerous studies available on the internet regarding the diagnostic and therapeutic options of Covid-19. However, during the research it has been ensured that only the data from the highly qualified authors was used to find out the effective diagnostic and therapeutic options of Covid-19. In order to do so, the duplicate studies have been removed just to maintain the quality of the research and to make the research more valuable. In this research, several investigators were used in order to screen the selected studies to maintain the quality of the data. Along with this, another major reason behind the screening of the selected data is to remove the effect of plagiarism. The screening was done in such a way that it has removed the plagiarism from the data which was selected from several scholarly articles. Moreover, the screening during the research was also significant in order to properly undertake the eligibility criteria for the selected studies. Undertaking the eligibility criteria of the selected studies is one of the best ways to maintain quality in the research.

Inclusion and Exclusion Criteria

The highly authorized data is included in this research to maintain the quality of the research. Along with this, the studies which are available in the English language are included in this research. The most recent and highly

rated studies are included in this research to determine the diagnostic and therapeutic options for Covid-19. Moreover, articles having statistics are mostly preferred and included so that a better insight into numbers and quantity of Covid-19 cases can be created. Furthermore, the data which is available without clear statistics were excluded. This was in order to find out the actual diagnostic and therapeutic options for Covid-19, as statistics play a major role, as an approach which can be used against a wide population of Covid-19 patients as the best option (Soler, et al, 2020). Furthermore, the data which was not able to provide the basic diagnostic and therapeutic option of Covid-19 was excluded.

Quality Assessment

Maintaining the quality of the research is one of the major focus of this research. While screening and the selecting of the data, it has been made sure that the quality of data should be maintained in order to establish the quality research. The data from certain authorized articles has been used in this research in order to maintain the quality of data. The ethical data has been selected to maintain the quality of the research. Different group members have been given the role of reviewing the research in order to review the research properly and also to avoid major confidential issues from the research as well.

Discussion

Molecular testing

The OraRisk Covid-19 is considered as the real-time test for the polymerase chain reaction (PCR). Usually, the OraRisk has been done for the qualitative detection of the nucleic acid in the form of oral and nasal swab specimens that are being collected in the universal transport media (Punyadeera, and Slowey, 2019). The paired sample study is used most of the times in order to collect data for both Oral and Nasal PCR, the data which is mostly collected for the asymptomatic and symptomatic patients of Covid-19.

The serologic test is another testing method that is used to detect the components of plasma and the serum of the blood. Most of the time, the serologic test is designed specifically to minimize the cross reactivity. Furthermore, in the case of the Covid-19 the serologic tests are designed in order to detect the diseases of less severe illness and the best example can be a common cold. The serologic tests have the sensitivity of around 96% and the specificity of more than 99% (Pallett, et al, 2020). This percentage of sensitivity and specificity of the serologic test is based completely on its performance evaluation. Moreover, the serologic tests can also be used in order to properly identify the infections in people that are infected within the time period of 1 to 3 weeks. Along with this, CDC is another major strategy that is being used by the doctors in the United States in the serologic testing of the Covid-19 patients. The CDC approach has been used by to better understand the number of people in the US who have been affected because of the widespread contagion of Covid-19. Moreover, CDC approach has also been of massive significance in order to find out the speed the corona virus is spreading and the people who are being infected due to Covid-19 in the United States (Zhang, et al, 2020).

Rapid diagnostic test is another major medical diagnostic test and is highly rated in the medical field. The rapid diagnostic test is a diagnostic test which is very quick and simple to perform. One of the main aspects of rapid diagnostic test is that it is available for every kind of emergency medical screening (Dinnes, et al, 2020). Similarly, you can easily utilize the rapid diagnostics test even with limited resources available. The rapid diagnostic test uses the cassette and the dipstick format which helps it to provide the result of the test within 20 minutes. This quick provision of results makes it different from other diagnostic tests. When it comes to Covid-9, the rapid diagnostics test is still not the perfect option for the medical staff. Many medical staff are using it, but the results are often reviewed again after the test in order to find out whether they are accurate or not.

The use of plain X-rays is mostly considered as the best way of chest imaging. However, there are other ways through which the chest imaging can be done and that includes the Magnetic resonance imaging (MRI), CT scanning, ultrasonography, and nuclear scanning. All the other procedures are non-invasive imaging procedures except the MRI. The presence of metallic objects during the MRI makes it different from the other methods and procedures of chest imaging (Caraiani, et al, 2018). Along with this, the presence of permanent pacemakers makes the MRI much more secure because whenever the gadolinium is used during MRI it increases risk as the kidneys of a patients can be under risk. So, the presence of permanent pacemakers makes the chest imaging through MRI much more effective and safer. In case of Covid-19, chest imaging is useful in order to find out whether the patient has respiratory symptoms or not.

Limitation of the diagnostic tests

The three major diagnostic tests for Covid-19 are the serologic test, Rapid diagnostic tests, and chest imaging. All of these three methods have a variety of significance but all of them have some limitations as well. The major limitation of the Serologic tests is that whenever the prevalence of the disease is low there is a massive risk in the accuracy of the results (Vodicar, et al, 2020). It becomes quite hard to find out whether the reports are true or false. Similarly, when it comes to the rapid diagnostic tests, the reliability of the rapid diagnostic tests in diagnosing the Covid-19 patients has a big question mark and it needs to be improved in order to strengthen its applicability towards Covid-19 diagnosis. Similarly, the major limitation of chest imaging is that it fails to diagnose every disease. . For example, in one study, 85% of the patients who tested positive for COVID-19 had negative chest x-rays, 50% of them were asymptomatic the other half had mild symptoms. Identifying patients with COVID-19 positive RT-PCR is essential in containing the disease by isolating the patients to prevent further spread of the disease.(Rousan LA et al, 2020).

Table 1 : Comparison between diagnostic tests

	Serologic test	Rapid diagnostic test	Chest imaging
Role	Detects the components of plasma.	Every kind of emergency medical screening	Pulmonary disease management and diagnosis
Importance	Minimizes cross reactivity	Provides the result of the test within 20 minutes	In properly determining infections
Importance in case of Covid-19	Detects the diseases of less severe illness e.g. cold	Not accurate in case of Covid-19	For detecting respiratory symptoms.
Limitation	During low prevalence, it lacks accuracy	Not reliable in case of Covid-19 diagnosis.	Fails to diagnose every disease

Table 2 : Comparison between the oral PCR and Nasal PCR

Oral PCR	Nasal PCR
Oral PCR is a real time test	Most used test in the clinical laboratories
It is polymerase chain reaction	Nasal PCR is very sensitive
The use of qualified clinical laboratory is mandatory for the Oral PCR testing	Nasal PCR is generally used to trace genetic material of the coronavirus.

Management of each stage with great emphasis on the management of pregnant women

The current pandemic of covid-19 has brought about intense respiratory conditions. It has introduced remarkable difficulties to the medical care frameworks in pretty much every nation around the globe. At present, there are no compelling immunization or strict medicine-based approach against the infection. Without conclusive and explicit vaccines, systems including early analysis, opportune detailing, disconnection, and strong medicines are significant lines of activities against COVID-19 diseases. Current social work including convenient arrival of epidemic data and support of social requests and individual practices, for example, improving individual cleanliness, wearing facial masks, sufficient rest, and keeping rooms ventilated are some of the first line activities against COVID-19 pandemic (Yin, et al, 2020). Under these circumstances of covid-19, managing the pregnant women is also a challenge and for that purpose a step by step guide to achieving better healthcare of pregnant women involves the usage and impact of therapeutic pharmacological drugs, airway assistance ventilation, and the vaccination strategy.

Therapeutic pharmacological drugs

Currently, there is no major vaccine available but in most parts of the world there are some therapeutic pharmacological drugs that can be of great significance in order to prevent and treat different sick covid-19 patients. However, in order to manage the pregnant women, therapeutic pharmacological drugs can be used. Therapeutic pharmacological drugs have also been approved by the FDA in the US and medical professionals are allowed to use these therapeutic pharmacological drugs to treat pregnant women even under the radar of being covid-19 patients (Drożdżal, 2020). Chloroquine and hydroxychloroquine are therapeutic pharmacological drugs with a long history of clinical use. In pregnancy it found that Hydroxychloroquine Fetal risk cannot be ruled out, Fetal ocular toxicity have been reported, Hydroxychloroquine use should be avoided during pregnancy, unless absolutely indicated and only after assessing maternal benefit and fetal risk. While Lactation No adverse effects of Hydroxychloroquine in infants exposed during the lactation period have been observed. Although the benefits of breastfeeding outweigh the theoretical risk to the infant, the nursing infant should always be monitored for adverse effects. Chloroquine in Pregnancy they found that Fetal risk cannot be ruled out. Fetal ocular toxicity have been reported. Administer chloroquine during pregnancy recommended only if the potential maternal benefit outweighs the potential fetal risk. While on Lactation American Academy of Paediatrics and the WHO consider chloroquine compatible during breastfeeding. WHO recommends against use in G6PD-deficient infants, and advises monitoring premature infants and neonates for side effects such as hemolysis and jaundice. Due to the potential for adverse events in the nursing infant, advise the nursing mother to either discontinue nursing or discontinue chloroquine therapy, considering the clinical benefit of the drug to the mother. (Saudi MOH Corona virus disease 19 guideline, 2020).

Alongside this, several supporting agents are also the therapeutic pharmacological drugs which can be helpful in order to manage the cases of pregnant women. Without the vaccine and any other medications there are different supporting agents which can be utilized for strong consideration for managing pregnant women during the global pandemic of covid-19 (Mhatre, et al, 2020). The different treatments in the form corticosteroids, sirolimus, tocilizumab etc. can be used in order to manage the corona infused pregnant women. A few of these treatments like that of tocilizumab can be regulated with an end goal to dull the cytokine storm regularly observed during the pregnancy of the women. The ideal planning of managing pregnant women during these kinds of challenging situations is yet to be recognized. Thoughtfully, impeding cytokine creation before it advances to an overstated level would appear to be therapeutic pharmacological drugs which can be utilized in order to manage the pregnant women who remain the most vulnerable in the covid-19 pandemic situations (de Almeida, et al, 2020).

Traditional herbal drugs are also therapeutic pharmacological drugs that can play a role in managing corona in pregnant women in the best possible way. One of the main challenges for the healthcare industry during this pandemic is the management of the pregnant women due to them being in the most vulnerable condition possible; however, countries like South Korea and China have used traditional herbal drugs to great use in order to provide relief and better treatment for pregnant women properly (Mirza, et al, 2020). The medical professionals in these countries believe that traditional herbal medicines have the ability to properly treat the pregnant patients. The best traditional herbal drugs used by the Koreans and the Chinese professionals for the treatment of the pregnant women during this pandemic situation are Radix platypodine, Chromium fortune and Astragalus membranous.

Airway assistance ventilation

Airway assistance ventilation plays a major role whenever airway difficulty is not recognized properly before choice of sedation. There are a few direct preoperative bedside tests that can be performed inside a few minutes to overview the airway course for a pregnant patient. These tests include mouth opening, thyromental distance, Mallampatiscore, atlanto-occipital augmentation, and capacity to extend the mandible. In order to manage pregnant patients in the best possible way, these Airway assistance ventilation tests play a significant role. No single test can continually predict a badly designed Airway ventilation. A blend of these tests is a basic need to enable Airway ventilation and to lessen the probability of adverse outcomes identified within the Airway ventilation. The Airway ventilation of pregnant women can be totally unpredictable (Cook, et al, 2020). It is not just an all-encompassing danger of irritating intubation, in addition there is trouble in keeping up satisfactory cover ventilation for pregnant women. Under the current pandemic situation of Covid-19, pregnant women can be at major risk. Even under the current situations, it is necessary to make sure that the emergency situation for the pregnant woman is planned in advance along with the availability of proper assistance ventilation.

Along with this, there are two principle airway assistance ventilation systems that play a vital role in order to manage pregnant women during this pandemic situation of covid-19. The principle of airway assistance ventilation systems are positive weight and negative weight ventilation (London, 2020). Positive weight airway ventilation is the overwhelming method of airway ventilatory that can be utilized in the ICU which is of massive significance in the proper management of pregnant women. Starting positive weight airway ventilation could prompt a decrease in preload because of diminished venous return, potentially decreased afterload, and a decrease in cardiovascular yield alongside decreased splanchnic blood stream. Lower cut off points of ordinary oxygen immersion combined with weakness could prompt decrease in oxygen conveyance. Non-obtrusive positive weight airway ventilation through a firmly fitting facemask is a well used ventilatory and oxygenating methodology in the overall ICU populace (Chiera, et al, 2020). It should be utilized uniquely for the proper management of pregnant patients.

Pregnancy is a high metabolic and physiologic state as mentioned earlier, but obese pregnant women are at double the risk during the emergence of covid-19. Anaesthesia for both elective and emergency situations should be planned in advance with a difficult airway cart readily available. If possible, regional anaesthesia with a good block should be the goal for caesarean section. General anaesthesia should be avoided due to difficulty with endotracheal intubation and rapid oxygen desaturation during induction tends to evoke apprehension in even the most competent anaesthesiologists when dealing with the airways in a pregnant woman; the most important reason being pregnancy-related altered anatomy and physiology impacting aesthetic management, the urgent nature of the obstetric practice leading to limited time for adequate aesthetic preparation, and the potential risk of impacting both.

Vaccination Strategy

Covid-19 is still spreading at a rapid pace and the effective vaccines against the coronavirus are still considered as the eventual solution to the different public crises. Most clinical professionals believe that safe and effective vaccines are the best way to beat the coronavirus and to return back to normal lifestyle before the emergence of this virus (Tibbetts, 2020). As a result, many medical professionals around the globe are making agreements with different pharmaceutical companies in order to come up with an effective vaccine that can help the world beat the coronavirus and return to what it was before the occurrence of this virus. The efficacy, safety, and the quality are considered as the cornerstones of any vaccine. Medical professionals have been advised to monitor the effectiveness of the vaccine. Alongside this, keeping the health of taffected covid-19 patients in mind is another major factor on which the medical professionals have been

Table 3 : Tabular Representation for management options

Therapeutic pharmacological drugs	Airway assistance ventilation
Clinical experts are permitted to utilize these therapeutic pharmacological drugs to treat pregnant patients.	No emanant setting is considered as the ideal examination of the airway assistance ventilation.
Hydroxychloroquine a) Pregnancy: - Fetal risk cannot be ruled out. Fetal ocular toxicity have been reported. - Hydroxychloroquine use should be avoided during pregnancy, unless absolutely indicated and only after assessing maternal benefit and fetal risk. b) Lactation: - No adverse effects of Hydroxychloroquine in infants exposed during the lactation period have been observed. Although the benefits of breastfeeding outweigh the theoretical risk to the infant, the nursing infant should always be monitored for adverse effects.	Preoperative bedside tests that can be performed inside a couple of months to outline the airway in a pregnant patient (Smit, et al, 2020).
Chloroquine a) Pregnancy: - Fetal risk cannot be ruled out. Fetal ocular toxicity have been reported - Administer chloroquine during pregnancy only if the potential maternal benefit outweighs the potential fetal risk b) Lactation: - American Academy of Paediatrics and the WHO consider chloroquine compatible during breastfeeding. - WHO recommends against use in G6PD-deficient infants, and advises monitoring premature infants and neonates for side effects such as hemolysis and jaundice. - Due to the potential for adverse events in the nursing infant, advise the nursing mother to either discontinue nursing or discontinue chloroquine therapy, considering the clinical benefit of the drug to the mother.	Airway ventilation lessens the probability of adverse outcomes identified while managing the pregnant women.
Best way of dealing with the pregnant ladies during this sort of a difficult circumstance is yet to be perceived; however, hindering cytokine creation is as yet the best therapeutic pharmacological drug accessible for the best possible management of pregnant women in the Coronavirus circumstance.	Emergency circumstances for pregnant women should be arranged ahead of time alongside the accessibility of the best possible airway assistance ventilation.
Radix platypodine, Chromium fortune and Astragalus membranous are the best traditional herbal drugs used to manage the pregnant women properly (Yang, et al, 2020).	Positive weight airway ventilation can be utilized in the ICU while managing the pregnant women during these crunch pandemic situations.

advised to monitor the effectiveness of the vaccine. Alongside this, keeping the health of taffected covid-19 patients in mind is another major factor on which the medical professionals have been asked to take note of during the vaccine development.

Under the current situation, the Americans and the Chinese have come up with different vaccination strategies that have somehow helped them in finding out the decrease incidence of the disease . America is one of those countries that has been affected badly by the global covid-19 pandemic. Hence, vaccine for covid-19 infection in United States is mandatory. As a result of which, Moderna a company in United States is developing avaccine considered as 94% effective and has the ability to ward off the virus completely . Yet we need to do more study after distributing the vaccine to large number of population. When it comes to China, the vaccine in China has already been tested and approved. The Chinese have come up with the Sinovac vaccine that they claim has the ability to kill different viral particles in order to completely expose the immune system of the body without even risking some of other serious disease response (Yamamoto, et al, 2020).

When it comes to the vaccination strategy, the first and the major strategy is the routine vaccination and the main goal of the routine vaccination is to eliminate and eradicate the virus (Alonge, 2020). Vaccination is actually the need of almost every country around the world at the moment in order to keep their daily routine on track and they have high expectations from it. However, some health institutions do prefer to observe the clinical trails more before approve the available vaccines now and before encouraging their population to get it. The number of cases in most parts of the world are continuously on a verge of increase and the main objective behind the development of vaccine is to reduce the number of covid-19 cases and in order to do so, response to the disease outbreak will play a an important role. Supplement immunisation activities is another vaccination strategy which can be of great significance in order to eliminate the disease where the routine vaccine has failed to make its mark. The strategy of supplement immunisation activities is useful for the development of the advanced vaccines which are applied when the routine vaccine fails.

Table 4: Tables for comparison between different vaccination approaches

Vaccine Strategies	Goals
Routine vaccination	To eliminate and eradicate the coronavirus completely from the human body.
Response to the disease outbreak	To reduce the coronavirus cases in a particular area.
Catch up vaccination	To prevent the individuals whose vaccination has been delayed
Supplemental immunisation activities	To eliminate the diseases that are not prevented by the routine vaccination.

Recommendations and Conclusion

Covid-19 is on the verge of constant increase and is impacting many people around the globe. Currently, there is no proper treatment of covid-19 available as a result of which everyday preventive actions are the best thing that an individual can do in order to prevent the spread of covid-19. The everyday preventive actions will play a vital role in stopping the spread of covid-19. Hence, it is recommended that the person who is sick should stay at home. Everyone should use masks to cover their faces. Covering the face with mask is still considered as the best and the most effective way of preventing the covid-19 disease from entering the human body (Liang, 2020). Alongside this, washing hands throughout the day is another preventive action that is recommended by the World Health Organization to stop the flow of covid-19. Furthermore, it is also recommended that touched surfaces and objects should be cleaned on a regular basis. These everyday preventive actions are mandatory under the current situation because of no proper vaccine yet discovered for the prevention of covid-19 (Kayrite, et al, 2020). Hence, it is mandatory for everyone to make sure that they are taking these everyday preventive actions to stop the spread of covid-19. However, for future benefits, the development of different drugs and vaccines are mandatory otherwise it is difficult to get rid of this global pandemic.

The worldwide pandemic of Covid-19 has brought about many cases of respiratory disease. A few patients can be asymptomatic while some may have trademark manifestations such as coughs, dyspnoea, and fever. One of the significant diagnosis of coronavirus is the early recognition and testing . Another significant aspect is a high index of clinical suspicion. The spread of coronavirus pathways on neighbourhood and public level is huge. The screening of patient is likewise one of the significant determinations that can stop firther spread. Isolation, infection management, and the symptom management can be the most valuable restorative strategies against a disease like Covid-19.

Most countries around the world have controlled the flow of covid-19 to some extent however, none of them have fully eradicated it. Most medical specialists believe that in order to end the pandemic vaccination is the best and the most appropriate option. There are different vaccination strategies that will be used during the development of vaccine that will play a massive role in order to eliminate the coronavirus from the human body. In the end, it can be concluded that, despite the fact that vaccination can help remove the coronavirus completely from the human body, everyday preventive actions is the best way to go ahead.

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Preference of final year medical students towards family medicine as a career choice: A comparative study from Pakistan

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Abstract

Introduction: Career choices by newly graduated doctors play an important role in the provision of health care and for the making of health policies. Family Medicine is not being recognized as a specialty of choice among the health care society. The objective of this study was to see the preference of final year medical students towards family medicine as a career choice and its associated factors.

Methodology: This was a cross sectional study conducted among final year medical students of private and government medical colleges who were exposed and not exposed to family medicine teaching, after taking informed consent.

Results: Out of a total of 175 students 158 planned to go for specialization. Among them a small number, 16 from government and 4 from a private university, planned to join family medicine residency. The majority (74) from private university believed that there is a difference between general practitioner and family physician. Nearly all of them (75) believed holistic care approach as a main domain of family physicians. All private and few government university students said that Family Medicine should be incorporated as a subject in the undergraduate medical curriculum.

Recommendations: Family Medicine is in its infancy stage and requires the dire need to increase its awareness through sessions and seminars among health care professionals.

Key words: Family medicine, career choice, medical students

Introduction

Family Medicine is a primary care medical specialty providing comprehensive health care to the individual and the family regardless of sex, age or type of problem(1). A family physician plays a major role in integrating and coordinating care provided to patients and their families. Family practitioners can themselves provide care for the majority of conditions encountered in the ambulatory setting and integrate all necessary health care services.

It is a well-known specialty throughout the world however its importance was overlooked in developing countries like Pakistan (2,3) until 2014 when the Pakistan Medical and Dental Council recognized its importance and incorporated Family Medicine as a subject in undergraduate curriculum (4). However, its status is still in infancy stage and only very few medical colleges have included this specialty as a formal subject in final year (2, 3).

Career choices of new graduate doctors play an important role for individuals and society in terms of provision of health care and health policy decisions. Undergraduates face challenges in making decisions about their career paths in their student life; hence after graduation they choose their career paths based on the influence of general trends of society and may end up in joining a specialty which may not be an appropriate choice for them (5).

The choices selected by newly graduated doctors are being influenced by many factors including exposure to the specialty as a subject during their undergraduate years, interest in the subject, peer pressure, monetary benefits, future prospects and job prestige. Unfortunately, family practice has not been a popular choice by the majority of the new graduates throughout the globe, perhaps due to perceived low monetary benefits, lack of awareness of its role in the community, poor exposure during student life etc(6).

In developing countries like Pakistan, Family Medicine still fails to get popularity as a career choice in medical students due to their limited exposure during their clinical years. A study done by final year medical students towards family medicine as a career showed only18% of students opting for family medicine as a career choice for similar reasons as described above (7).

The objective of this study is to compare the preference of final year medical students (exposed and not exposed to family medicine during their clinical years) regarding family medicine as a career choice and factors associated with it. The results of this study will help us understand student's views about career choices and can help to design modifications in the curriculum, to make it more relevant, interesting and inspiring for the students.

Methodology

This was a cross sectional study conducted among medical students of two medical colleges of Karachi a mega city of Pakistan from July to Sept 2019. One was a private medical university having an undergraduate Family Medicine curriculum and the other was a government medical university with no such curriculum. Students from final year MBBS belonging to both the medical institutes were invited to participate in the study as they were about to graduate and were fresh to make up their mind for career choices.

Sample Size:
Sample size was calculated using WHO sample size determination software. Since this was a comparative study limited data was available on this topic, therefore a prevalence of 50% (maximum variance) was obtained, with 95% confidence interval and 8% bound on error, a total of 151 students was estimated. The sample size was further inflated 15 % for non-responders yielding a sample size of approximately 175 participants.

Ethical consideration:
Written informed consent was obtained from the students after explaining the study objectives. The students were free to withdraw at any time without giving any reason. Strict confidentiality was maintained throughout the process of data collection, entry and analysis. The Ethics review committee of both the institutes reviewed and approved the study protocol and followed the principles of the Declaration of Helsinki.

Development of Questionnaire:
The questionnaire was formulated by consulting literature and peers. The language of the questionnaire was in English and there was no need for translating this questionnaire to Urdu. Questionnaire was pre tested on 10 students, to look at the flow and clarity of questions so that modifications were made accordingly. Overall, the questionnaire took 10-15 minutes to be completed.

Students of both sexes, who gave consent to participate were included in the study and those who were absent on the day of the data collection or did not provide consent to participate in the study were excluded.

Questionnaire:
The questionnaire was divided into two portions. The first part included questions related to students' age, gender, their career preference, reason for choosing a particular specialty, and factors influencing their choice of medical specialty. The second part included questions related to their exposure and their perception of Family Medicine as a career. It also assessed their opinion regarding inclusion of Family Medicine in the undergraduate curriculum. Most of the questions were single best type and students had to choose one option that fitted the best according to their opinion.

Analysis:
The analysis was performed on SPSS version 19. Students were divided and analysed within two groups (private and government). Their baseline information on demographics was analyzed using descriptive statistics. For continuous variables such as age, means and standard deviation were reported. For categorical variables such as gender, preferred specialization, reasons for choosing a particular entity et. proportions were obtained. Pearson γ2 and Fisher exact statistics was applied where appropriate for categorical variables. Results were considered statistically significant if the two-tailed p-value was less than 0.05.

Results

A total of 175 medical students were approached out of whom 164 participated in this study with a response rate of 94%. Out of these 164 students 75 were from private medical college and 89 from government medical college. The mean age range of the students was 22+ 7 years with a predominance of male 90 (55%) as compared to female 74 (45%.). The majority 155 (94%) of the students in both the groups had an intention to go for specialization in future.

Figure 1 clearly depicts future specialty choices preferred by these young students. The majority of the students in both groups preferred Internal Medicine as a career choice however Family Medicine was chosen by only (2%) of the students in both the groups.

Most common reason for choosing a particular type of speciality was interest in subject as stated by the majority 74% of the students followed by other reasons. Around 8% kept monetary benefits as a major reason while flexible working hours was a special area of interest for 7 % of the students. Approximately 6% were influenced by parents or friends while deciding speciality choice and only 5% of the students planned to choose a specialty after being inspired by a role model.

Table 1 demonstrates perception of students regarding Family Medicine and General Practice. Nearly all 73 (97%) of the students belonging to private medical college were familiar regarding Family Medicine specialty however more than half 55 (62%) of the students in Government College had also heard about family medicine. Nearly all 74 (99%) of the students in private medical college were able to differentiate services offered by family physicians as compared to specialists, however on the other hand a large number of students 57 (64%) of government medical college failed to identify any difference among two types of consultations.

On questioning about need of incorporation of family medicine as a formal subject in undergraduate curriculum all 75 (100%) of private medical college students and half 43 (48%) of the government college students gave a favorable response.

According to the students of the private medical college the most common reason for incorporation into the curriculum was for provision of basic medical knowledge 49 (65%) whereas seeing a large number of patients 25(58%) was cited as the main reason by students of the government college. When asked about their opinion regarding recognition of family medicine as a specialty in Pakistan, the majority from both the groups 75(100%), 72(81%) showed a positive response. Similarly, they also agreed to the fact that Family Medicine filter clinics should be present in every hospital of Pakistan.

Figure 2 represents Attributes of family physicians as perceived by medical students. The majority from private medical college agreed that they provide preventive care (63%), patient centered (56%) and holistic care (68%) to their patients which is a unique quality which differentiates them from specialists while only few from government college students agreed to this fact.

Discussion

Family Medicine is a distinct specialty providing holistic care for the whole family. It is an undisputed fact that this specialty has not been fully recognized as an important field in Pakistan. The focus of this study was to compare the preferences of final year medical students private and government medical university students (exposed and not exposed to family medicine during their clinical years) regarding family medicine as a career choice and factors associated with it.

Our study showed that the majority of the students preferred Medicine, Surgery, Pediatrics and Gynecology and Obstetrics as a specialty for career choice while Family Medicine was preferred by only few 4% of the students. These results are similar to a study done in Pakistan by Aslam M et al (8) and Khader Y et al (9) . The probable reason for this could be lack of awareness among students regarding Family Medicine as a distinct specialty as most of the students belonging to the government medical university were not exposed to family medicine during their clinical years (10,11). However surprisingly even those who were exposed to this specialty during their clinical years were not influenced to choose Family Medicine as a career choice, perhaps because of less monetary gain and lack of post fellowship opportunities (7).

The most common reason for choosing a particular type of specialty was interest in subject as stated by most of the students, followed by peer pressure, high income potential and flexible working hours. These findings are similar to a study done among medical students of a government college in Karachi by Rehman A et al (12). The most probable explanation for this might be less monetary reward which is assumed as a major motivating factor while choosing a medical specialty. This finding is thought provoking for higher authorities concerned with planning and organization of medical education in Pakistan, and they need to understand and remunerate this important specialty accordingly.

Figure 1

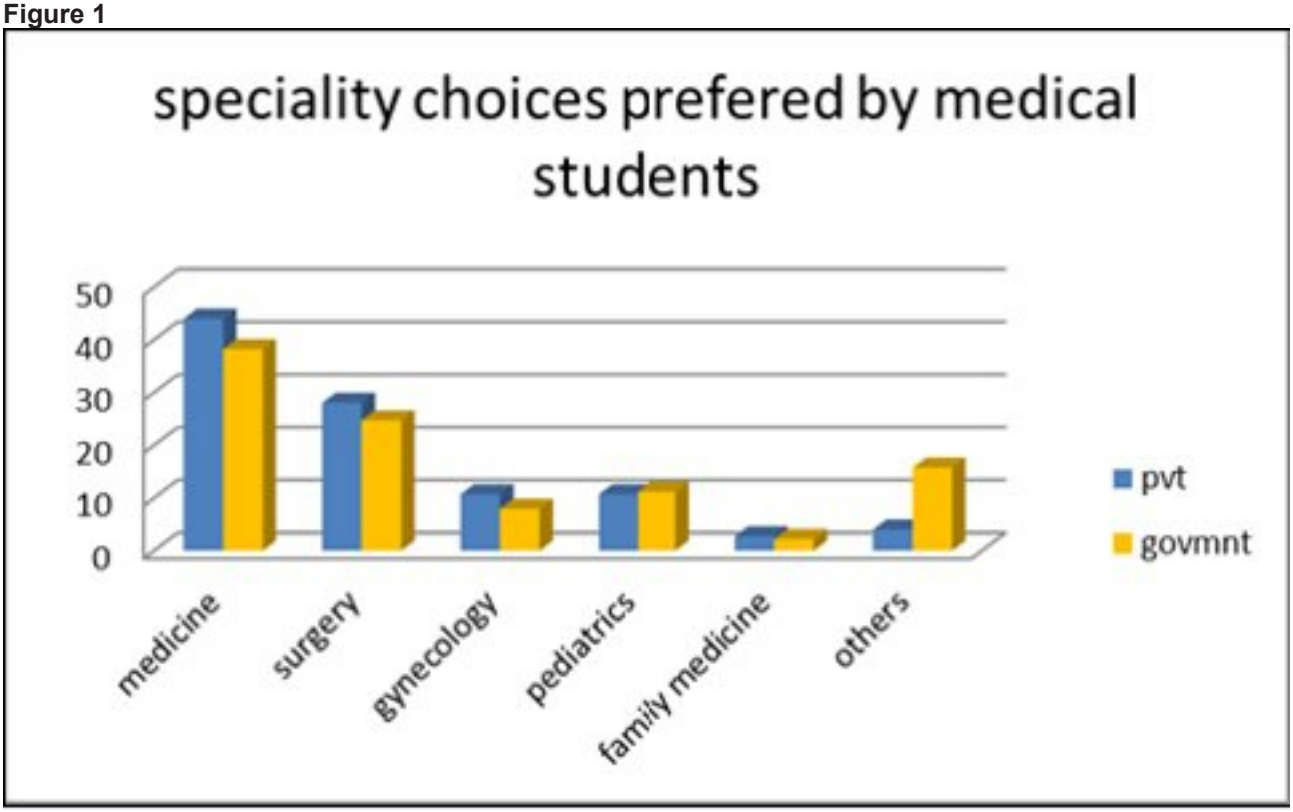
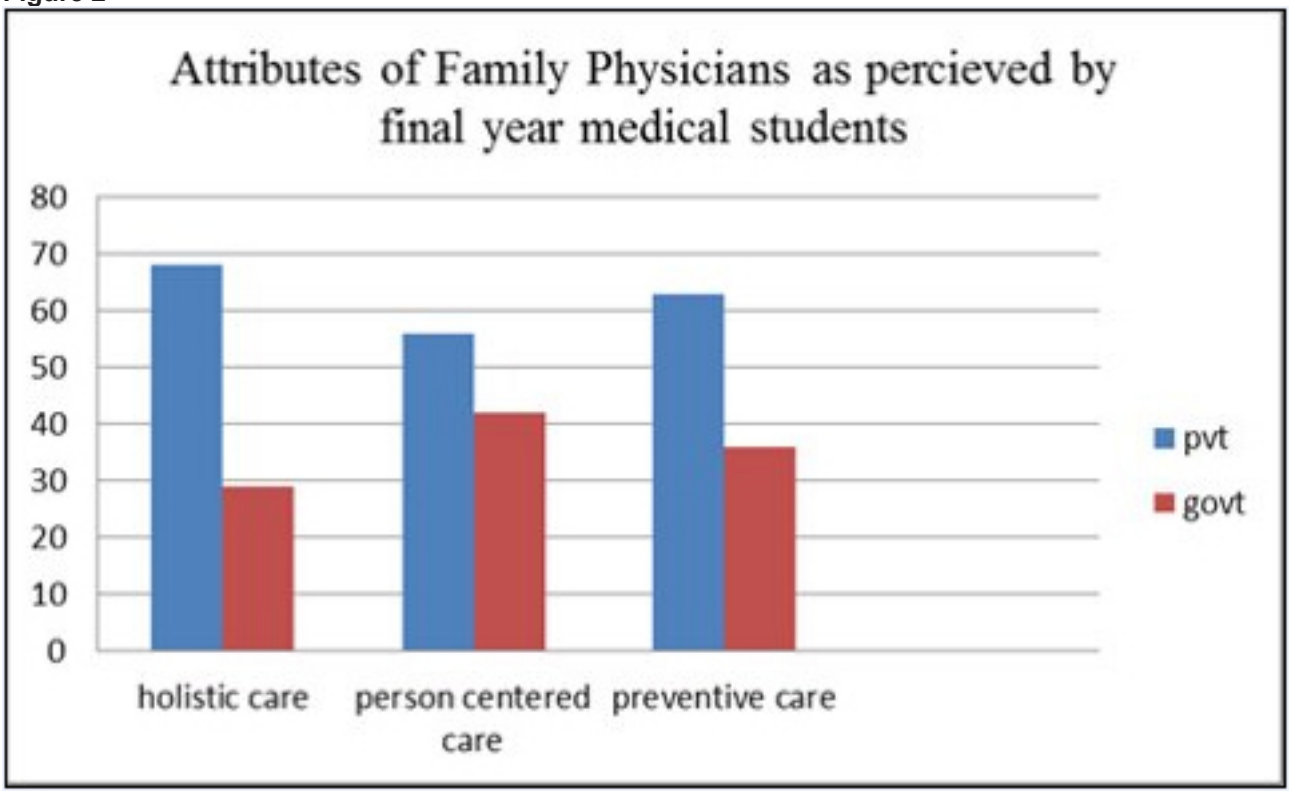


Table 1: Students' opinion regarding Family Medicine and General Practice

Variables		Private medical university N (%)	Government medical university N (%)	*p-value*
1. Do you have any idea regarding family medicine				
1.	Yes	73 (97)	55 (62)	0.00
2.	No	2 (3)	34(38)	
2.Did you find any difference between family physician and specialist				
1.	Yes	74 (99)	32 (36)	0.00
2.	No	1 (1)	57(64)	
3.Did you find any difference between family physician and general practitioner				
1.	Yes	18(24)	45(51)	0.00
2.	No	57(76)	44(49)	
4. Do you think family medicine should be part of under graduate curriculum				
1.	Yes	75(100)	43(48)	0.00
2.	No	0	46(52)	
5. Reason for family medicine as part of undergraduate curriculum				
1.	Provide Basic Knowledge	49(65)	13(30)	0.01
2.	Important for students	8(11)	5(12)	
3.	Seeing large number of patients	18(24)	25(58)	
6. Do you think family medicine should be approved as specialty in Pakistan				
1.	Yes	75(100)	72(81)	0.00
2.	No	0	17(19)	
7. Do you think each hospital in Pakistan should have family medicine filter clinics				
1.	Yes	74(99)	70(79)	0.00
2.	No	1(1)	19(21)	

Figure 2



When inquiring about perception of medical students regarding Family Medicine and General Practice, nearly all (97%) of the students from the private medical university and more than half (62%) from government medical university were familiar with Family Medicine specialty however they were unable to find any difference between Family Physician and General Practitioners' role and surprisingly this perception was more among medical students of private medical university who were exposed to Family Medicine rotation, however private university students were able to differentiate between family physicians and specialists.

The most likely reason for this behavior was duration of rotation as currently Family Medicine rotation was only for a few weeks in the private university which was not sufficient to give them an actual flavour of Family Medicine and allow them to understand and differentiate the distinct roles of Family Physician from General practitioners and specialists. This signifies the importance of duration of rotation which should be kept in mind by medical educators while designing curriculum.

In addition, role of mentorship or attachment with a Family Physician may help to improve clarity regarding Family Medicine specialty as seen by a study in Germany, where significant high rate of students agreed to consider Family Medicine as a professional career (32.7%) when they were attached with one family physician in the clinic thus giving them the opportunity to experience various aspects of family medicine(13).

The majority of the students from private medical university agreed that Family Physicians provide holistic care which differentiates them from specialists however only a few (9%) said that they are able to treat common disease as their knowledge is only limited to common diseases. These results are contrary to a study done among final year students at a University of Helsinki where students considered seeing multiple problems as a negative feature of GPs attributes (14). Similarly, studies done by Selva Olid A (15) et al considered treating common diseases as less challenging and as a negative factor for career choice.

Despite its under recognition as a specialty for career choice, the majority of the medical students from the private medical university and few from the government medical university considered Family medicine as a distinct specialty and according to them holistic care, and ability to treat common diseases prevalent in the community were the main positive attributes which differentiated a Family Physician from a specialist. The most probable reason for this response of private medical university students is related to their level of awareness and exposure which they have experienced during their rotations in Family Medicine. These results are similar to a study done in Finland among medical students by L. Kuikka (14). This shows that exposure to Family Medicine rotation can improve understanding about specialty and its importance and may further help to improve student's willingness to opt for it as a career.

All of the private medical university students and nearly half (48%) of the government university students agreed that it should be included in the undergraduate curriculum as it provides basic knowledge to students followed by holistic care for the patients, similar to a study done by Iqbal SP (16) at Shifa international Islamabad. However, this concept is still in its infancy stage as evident by the opinion of various other studies where students do not consider family medicine as a preferred choice for career.

This specialty is still trying to gain recognition and is facing various challenges. Medical students are still confused about the concept of Family Medicine and are unable to appreciate the crucial role of the specialty in improving and strengthening weak and compromised health care systems of developing countries like Pakistan. There is overall lack of prestige compared to other specialties, and poor level of satisfaction among General Practitioners (17) due to low monetary benefits and less support from government etc. All these factors may portray a negative picture of the specialty leading to lesser motivation to opt for it as a career choice.

For this purpose various means can be used including initiating and strengthening of Family Medicine departments in medical colleges as mandated by PMDC, introducing focused community based teaching to give students the actual flavor of pattern of disease burden in the community (18), mentorship by general practitioners (19), career counseling and guidance of medical students including promotional seminars by the faculty to enhance awareness especially for final year students as they are at a stage where they are about to make decisions regarding their future career and choose a path which is suitable for themselves (20). These interventions will improve the likelihood of students choosing Family Medicine as a career choice with a profound effect on delivery of quality health care in this country.

Strength/Limitations:
This study has several limitations, as it was conducted in two medical universities of one province, thus it may not reflect the whole country. Larger scale studies are required to make a conclusion however the result of this study can give an idea about perception of specialty among medical students and these results can be used to develop strategies to increase awareness regarding Family Medicine in the country.

Conclusion

This calls for a need of strengthening Family Medicine as an essential component of medical school curriculum. Medical educators should realize the relevance of the medical curriculum to the actual health needs of the community and should work together with the policy makers to produce doctors who can cater to this need of the country. Family medicine rotation as part of undergraduate medical curriculum may help in fostering an interest among medical students in this newly emerging subspecialty which could have a profound effect on delivery of quality health care in this country.

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Treatment of Hepatitis C with Glecaprevir/Pibrentasvir in a Patient with Concurrent Stricturing Crohn's Disease on Adalimumab

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Abstract

A 22-year-old male with long standing, active Crohn's disease on Adalimumab had presented with increasing levels of his transaminases. A full workup was conducted and the patient was found to have hepatitis C (HCV) based on a positive HCV antibody, polymerase chain reaction (PCR) and genotyping. He was started on a regimen of Glecaprevir/Pibrentasvir with excellent response defined by complete normalization of his transaminitis and an undetectable PCR at the end of 8 weeks of treatment and achieved sustained viral response at 12 weeks of treatment. This is the first case reporting the use of a combination of Glecaprevir/Pibrentasvir and Adalimumab in a patient with HCV and Crohn's disease.

Key words: Hepatitis C, Glecaprevir/Pibrentasvir, Crohn's Disease

Introduction

Inflammatory bowel disease (IBD) is a chronic illness with an underlying autoimmune process(1); it encompasses both ulcerative colitis (UC) and Crohn's disease (CD). The prevalence of hepatitis C virus (HCV) in patients suffering from IBD was found to be around 1-6% in the western world(2,3,4). Anti tumour necrosis factor (anti TNF) inhibitors such as infliximab and Adalimumab had been approved for the treatment of moderate to severe CD(5). Management of IBD and concomitant HCV has changed remarkably in the last few years, with many new lines of treatment being introduced. Initially, treatment of HCV was interferon based, which was shown to cause more IBD flares. Direct acting antivirals (DAA) were first introduced in 2011 and were used first in combination with interferon therapies(6,7).

Over the last ten years, newer agents have entered the market with improved efficacy and safety profiles resulting in the possibility of near future global disease elimination. However, despite the advancements in the field, treatment of HCV in IBD patients remains a difficult task. Drug metabolism and toxicity, drug-drug interactions and timing strategies are among the main challenges (6,8). Relatively older DAAs (Sofosbuvir alone or in combination with Ledipasvir, Simeprevir or Daclatasvir, Ritonavir-boosted Paritaprevir, Ombitasvir-Dasabuvir, Grazoprevir-Elbasvir and Ribavarin) have been used to treat HCV in patients with concomitant IBD. Glecaprevir plus Pibrentasvir have not been reported in these patients before(9).

This paper describes the case of a young man who was diagnosed with HCV while having active Crohn's disease and receiving Adalimumab. He was treated successfully with Glecaprevir/Pibrentasvir and achieved acceptable disease controll.

Case Report

In this article, we report the case of a 22-year-old male who was known to have colonoscopy proven Crohn's disease since 2011. The patient had recent active disease as evidenced by a high stool calprotectin (522) and a magnetic resonance small bowel enterorrhaphy which revealed terminal ilium strictures and a proximal bowel dilation. He was maintained on adalimumab 40 mg subcutaneous injection every two weeks. Whilst the patient was following with the gastroenterology and hepatology service, he was found to have increasing alanine aminotransferase (ALT) and upon further workup was diagnosed with type 4 HCV based on a positive HCV antibody, polymerase chain reaction (PCR) and genotyping. A fibroscan was conducted and ruled out the presence of cirrhosis. The patient was started on Glecaprevir 100 gram/Pibrentasvir 40 milligram combined tablet (MAVYRET, AbbVie) with a dosage of three tablets once daily for a total of 8 weeks (started on 13-1-2020 to 8-3-2020). This treatment resulted in PCR proven HCV clearance and the subsequent normalization of his ALT after conclusion of therapy at 8 weeks and sustained viral response at 12 weeks. (Table 1)

Discussion

We are reporting the successful treatment of a patient with long standing active Crohn's disease and a recent diagnosis of HCV with a therapy combination of Glecaprevir plus Pibrentasvir and Adalimumab. This line of management resulted in remission of both entities.

Combined DAA attacks specific proteins in the replication cycle of the virus leading to viral demise(10). Glecaprevir plus Pibrentasvir is a recently produced DAA that was introduced in 2017; it acts as a NS5A and a NS3/4A protease inhibitor. It is used to treat HCV genotypes 1-4 in patients with either early cirrhosis or without it. It has been shown to have good tolerability and a good safety profile with a sustained viral response (SVR) reaching 95%(11).

Table-1: HCV PCR And ALT Levels, before, at 8 and 12 weeks after therapy

	Before treatment	8 weeks after treatment	12 weeks after treatment
ALT	317 U/L	21	18
HCV PCR	2,843,352 IU/mL	Not detected	Not detected

HCV PRC : Hepatitis C Virus Quantitative Polymerase chain reaction , ALT: Alanine Transaminase

Glecaprevir plus Pibrentasvir use in Crohn's disease patients receiving Vedolizumab has been reported in literature with resolution of the infection and no remarkable adverse events on the IBD side. On the other hand, Infliximab, Adalimumab, Golimumab were all reported to be used in patients receiving older DAAs (Sofosbuvir based regimens or other older agents) but not with Glecaprevir plus Pibrentasvir(8,12). This report is therefore unique and shows an unprecedented medication regimen.

Concomitant, sequential or inverted sequential timing strategies have all been used in clinical practice and have shown nearly similar efficacy rates, however, the use of shorter therapy durations (8 weeks) increases the drug's administration feasibility. The choice between these different strategies should be made on an individual basis.

Although HCV screening prior to the use of biological therapy is a staple in treatment guidelines, it is not universally done in clinical practice. Biological therapy was not reported to be as strongly associated with reactivation of HCV as compared to hepatitis B, however, its immunomodulatory effect on viral dynamics might lead to treatment difficulties(14,15).

The prevalence of HCV in IBD patients is close to the numbers reported in the general population. Therefore, this presentation is not an uncommon occurrence and requires implementation of effective screening protocols and follow up guidelines. The recent medication surge (DAAs) in the management of HCV offers promising results even in the presence of active IBD disease.

Conclusion

The treatment of IBD with concomitant HCV is an area of research that is still evolving, with many DAA agents proving to be effective and safe. The combination of Glecaprevir plus Pibrentasvir and Adalimumab was used in this report with excellent outcomes.

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Primary prevention of Cardiovascular Diseases among the Middle aged and the Elderly

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Abstract

Aim: To define the best practice guidelines for primary prevention of cardiovascular diseases in middle age individuals as well as the elderly.

Study design and Methodology: Narrative review study for RCT, clinical trials and systematic review studies published in English language from 2003-2018; in middle age individuals as well as the elderly. Search was conducted in Pubmed and Google Chrome. Terms used for searching were (best practice guidelines) and (primary prevention of cardio-vascular disease).

Results: The total number of study search items was 2020 studies and after filtering them, the matching studies were 70: 38 studies were excluded whereas 32 studies were included. Six studies were about statins therapy in primary prevention of CVD in the elderly. Five studies were about statin benefits for primary prevention of cardiovascular disease in middle age individuals. Nine studies were about non-statin therapy. Five studies were about blood pressure control and primary prevention of cardiovascular disease. Seven studies were about aspirin for primary prevention of cardiovascular disease in diabetics.

Conclusion: Statins are beneficial for primary prevention of cardiovascular disease in middle age individuals as well as the elderly who had dyslipidemia or were diabetic aged 40-75 years, or 10-years CVD risk =>7.5% according to AHA/ACC, or =>10% in accordance with the guidelines for both NICE and USPSTF. There is no definite evidence for non-statin therapy benefit for primary prevention of CVD but it can be used in hypercholesterolemia patients or high CVD risk patients who do not tolerate statins or have not responded to the maximum dose of statins. There was no evidence for aspirin benefit in primary prevention of CVD in diabetics. Immediate blood pressure control is important in the primary prevention of CVD in hypertensive patients with high cardiovascular risk.

Key words: Cardiovascular diseases, middle aged, elderly, primary prevention

Introduction

Cardiovascular disease (CVD), of which coronary heart disease (CHD) and stroke are the prevailing components, is by far the leading cause of death in most developed countries and is rapidly becoming the leading cause of death in the world (Lim et al., 2010). Indeed, the World Health Organization estimates that annual global mortality due to CVD will approach 25 million by 2030, of which about 80 % will occur in developing countries (World Heart Organization. Atlas of heart disease and stroke 2015). Not only is CVD a leading cause of mortality, but it is the leading cause of loss of disability-adjusted life years globally (Perk et al. 2012). Emelia et al (2017) stated that CVD and stroke accounted for 14% of total health expenditure in 2012 to 2013, more than any major diagnostic group. The annual direct and indirect cost of CVD and stroke in the United States was an estimated $316.1 billion in 2012 to 2013. According to the same authors, taking into account nursing home care costs, the total direct medical costs of CVD between 2012 to 2030 are projected to increase from $396 billion to $918 billion. All these facts guide us to the importance of early detection of risk factors for CVD, so that we can identify and avoid these diseases. In addition, there is need to establish clear protocols and guidelines for primary prevention of CVD, of course, many countries do have them.

The INTERHEART study elucidated the effect of CVD risk factors including dyslipidemia, smoking, hypertension, diabetes, and abdominal obesity, whilst it demonstrated the protective effects of consumption of fruits and vegetables and regular physical activity. These risk factors were consistent throughout all populations and socioeconomic levels studied, helping to establish the viability of uniform approaches to CVD primary prevention worldwide (Yusuf et al., 2004).

Significant morbidity and mortality of CVD, in addition to its financial burden on health, led us to concentrate on the fundamental components of CVD primary prevention in the current study. The question remains what are the best practice guidelines for the primary prevention of CVD?

Study Aim

The main aim of this study to define the best practice guidelines for primary prevention of cardiovascular disease. In addition the other study objectives are:

1-To improve the practice for primary prevention of cardiovascular disease through following evidence based best practice guidelines recommendations.
2-To control cardiovascular disease risk factors mainly hypertension, hypercholesterolemia and diabetes.
3-To check the role of aspirin in primary prevention of cardiovascular disease in diabetic patients.

Study Hypothesis:

There is meaningful relationship between hypertension, hyperlipidemia, diabetes and cardiovascular disease so that the main hypothesis of the study is that the management of these diseases plays a vital role in primary prevention of cardiovascular disease.

Other hypotheses include:
Aspirin has no benefit in primary prevention of cardiovascular disease in diabetic patients.
Best practice guidelines recommendations had an important role in primary prevention of cardiovascular disease.

Methodology

The global burden of cardiovascular disease mortality, as it is classified as number one cause of mortality and the main reason for morbidity worldwide, requires the improvement of preventative strategies of cardiovascular disease and increased community and care provider awareness about best evidence strategies. Furthermore the World Health Organization (WHO) rating shows that above 75% of premature cardiovascular disease is preventable and improvement of risk factors is able to lower the increasing CVD load on both care providers and individuals (WHO 2016). While age is a recognized risk factor for CVD increase; autopsy evidence proposes that the process of CVD expansion in the last year is avoidable (Kannel et al 2020), so risk lowering is pivotal. Based on that the current study searched best practice guidelines for primary prevention of cardiovascular disease?

To answer this question properly, the study tried to review the most updated literature. The study used the RCT, systematic reviews and meta-analysis studies which have been published from 2003 to 2018 by using the Cochrane library, Pubmed, or Google Chrome.

The data did not use any studies with low evidence or old papers that were published more than 15 years. The study compared results of these studies with the current best practice guidelines mainly National Institute for Health and Care Excellence (NICE, 2016), American Heart Association (AHA) and American College of Cardiologists (ACC) (Eckel et al., 2013). The data reviewed a high number of studies around different aspects of CVD primary prevention and risk factors. The study formed a clear idea on the risk factors of CVD, the data then used the new-found knowledge to find a common reason why the cardiovascular system is susceptible to disease. Secondly ,it reviewed the most relevant protocols used to modify CVD risk factors to avoid CVD. Then the study tried to find common links between the most common types of CVD and formulate the best recommendations that are used to avoid all types of CVD.

Results

The total numbers of study search items were 2020 studies and after filtering them, the match studies were 70:
38 studies were excluded whereas 32 studies were included.
Six studies about statins therapy in primary prevention of CVD in the elderly.

Five studies about statin benefits for primary prevention of cardiovascular disease in middle age individuals.
Nine studies about non-statin therapy.
Five studies about blood pressure control and primary prevention of cardiovascular disease.
Seven studies about aspirin for primary prevention of cardiovascular disease in diabetic patients.

Discussion

The main concept in primary prevention of cardiovascular disease is to control risk factors.

Example: hyperlipidemia /hypertension /diabetes/ smoking/sedentary life-style etc.

Hyperlipidemia and primary prevention of cardiovascular disease:
Hyperlipidemia management in middle age individuals:
Statin therapy:
The Cholesterol Treatment Trialists' Collaboration provided evidence that statins are beneficial for primary prevention of ASCVD events. Meta-analyses of 27 studies (n = 174,149), using most of statin trials data as a source for participants, illustrated a reduction in main ASCVD events (e.g. stroke and non-fatal myocardial infarction). Associated with the use of statins in patients with low risk (five-year risk of less than 10%). The authors found that for each reduction of 39 mg per dL (1.01 mmol per L) in LDL-C, there were 11 fewer major vascular events per 1,000 persons treated for five years. (Mihaylova et al., 2012). Secondary analysis aiming at identifying mortality reasons did not find any effectiveness for statin treatment in low-risk groups (i.e., 10-year risk less than 10%). (Abramson et al., 2014).

According to RCT (Yusuf et al., 2016), statins use in intermediate-risk persons without cardiovascular disease, reduced cardiovascular risk events with clinically and statistically significance.

Statin use in persons without evidence of cardiovascular disease leads to clinically significant reduction in CVD events and all-cause mortality, based on systematic review study (Taylor et al., 2013).

Diabetic patients are at high risk of ASCVD events during their life, so high rank of evidence level A recommended moderate-intensity statin therapy for diabetic patients at age 40-75 years old (Stone et al2013). For those outside this range of age, statins therapy should be individualized depending on the benefits of statins, side effects, interaction, and patient priority.

Table 1: Statins therapy for lowering lipid level in middle age individuals:

Type of study	Sample size	Outcome	Type of patients.	Author/Year
Meta-analysis	174,149	reduction of major vascular event RR(0.79,95%CI 0.77-0.81)	low risk individuals	Mihaylova et al., 2012.
RCT	12,705	reduction of CVD related mortality HR (0.76, 95% CI 0.64-0.91) P0.002 Reduction of cardiovascular risk events HR (0.75, 95% CI 0.64-0.88) P0.001	Intermediate risk individuals	Yusuf et al., 2016.
Systematic review	56,934	Reduction of CVD related mortality OR (0.86, 95% 0.79-0.94), reduced combined fatal and non-fatal CVD RR0.75(95%0.70-.81)	People without evidence of cardiovascular disease. Some with specific cases (hyperlipidemia, DM, Albuminuria, HTN).	Taylor, et al., 2013.
Meta-analysis Systematic review/RCT		Reduced CVD risk events And all cause mortality	Diabetics aged 40-75 years/at high CVD risk	Stone, 2013
RCT		Reduced CVD risk events And all related cause mortality	Adults aged 40-75 years With 10-years CVD risk of 7.5% or more.	Jones, 2016

Stone et al., (2013), demonstrated that high intensity statin therapy may be recommended (evidence level B) for primary prevention of cardiovascular events in patients with or without diabetes and a 10-year ASVD risk of at least 7.5% according to the ACC and AHA guidelines, or at least 10% in accordance with the guidelines for both NICE and USPSTF.

Almost every panel list for the 2004 ACC/AHA guidelines, joined with the National Heart, Lung, and Blood Institute, (Grundy et al., 2004) had industry ties. The ACC/AHA committee worked hard to eliminate industry impact for the 2013 guideline, but seven of the 15 committee members still had ties to industry (Ioannidis 2014).

Furthermore, there are worries that the 2013 guidelines (ACC/AHA), underestimate adverse effects of the statins. Main side effects of statins are myopathy (incidence of 0.5 per 1,000 more than in the general population over five years) and rhabdomyolysis (incidence of 0.1 per 1,000 more than in the general population over five years), (Taylor et al., 2013). In addition to the side effect of diabetes, 0.1, other studies mentioned higher percentages of diabetes as a side effect of statins.

The limitations of AHA/ACC guidelines are: bias due to industry ties, underestimation of risks associated with statins use, furthermore limitation is that some of the recommendations depend on expert opinions and some of these recommendations had a low level of evidence in addition to conflicts between guidelines members.

CVD Risk calculation:
ACC/AHA guidelines mentioned new Pooled Cohort Equations risk calculator that is available at http://www.cvriskcalculator.com. (Pursnani et al., 2015). The NICE panel, however, advised using QRISK2 calculator, which is available at http://www.qrisk.org/ (Hippisley-Cox et al 2008). Physicians must use the Pooled Cohort Equations risk calculator, or QRISK2 calculator, or both to assess a patient's risk.

Non –Statins lipid-lowering drugs:
There is no potent evidence that routine use of non-statin lipid-lowering medications (i.e., fibrates omega-3 fatty acids, niacin and ezetimibe [Zetia]) are beneficial in the primary prevention of ASCVD (Sando and Knigh 2015). The addition of niacin demonstrated significant harm in a recent randomized controlled trial, and its use is no longer recommended (Landray et al., 2014).

Based on the SHARP study, a randomized double-blind control trial, enrolled 9270 patients with chronic kidney disease some 3023 on dialysis, with the rest no dialysis, without evidence of CVD. The patients were randomly assigned to simvastatin 20mg plus Ezetimibe 10mg versus placebo, and follow up for 5 years. The study found that simvastatin plus Ezetimibe group had clinically and statistically significant reduction in the incidence of atherosclerotic events versus placebo group.

According to IMPROVE-IT study, randomized double-blind control trial, including 18,144 acute coronary syndrome patients who had been hospitalized; randomly allocated them to either simvastatin 40mg and Ezetimibe 10mg or to simvastatin 40mg and placebo. They were followed for 6years. The results were a clinically significant reduction in LDL cholesterol with improving cardiovascular events outcome in Ezetimibe group compared to the placebo group.

Ezetimibe reduced atherosclerotic events in chronic kidney disease patients and lowering LDL and improved cardiovascular outcome in acute coronary syndrome as approved from above mentioned double-blind randomized control trials but no evidence about its role for primary prevention of cardiovascular disease.

Based on the systematic review study, involving 13,140 participants in the intervention group and 138,976 individuals in control group, comparing lipid-lowering intervention with placebo or diet/to assess Cardiac mortality, followed them for 6-months.The study found resins causes clinically significant reduction in cardiovascular mortality.

Table 2:1 -Ezetimibe studies SHARP/IMPROVE-IT:

Study type	Sample size	Outcome	Type of patients	Author/year
RCT (double-blind), (SHARPSTUDY)	9270	Reduced atherosclerotic events RR 0.83 95% CI 0.74-0.94 P0.0021	Patients with chronic kidney disease/no CVD	Baigent, 2011
RCT (double-blind) (IMPROVE-IT study)	18,144	Lowering LDL Improved cardiovascular events HR0.93,95%CI0.89 -099/po.o16	Hospitalized patients for an acute coronary syndrome	Christopher, 2015

Table 3:2-Bile acid sequestrates:

Type of study	Sample size	Outcome	Type of patients	Author/year
Systematic review	137140 intervention group 138976 Control group	Reduced cardiac mortality for: Resins (RR0.70 , 95% CI 0.50-0.99)	>90% no CVD event <10% with CHD	Studer et al., 2005

Table 4:3-PCSK9 inhibitors:

Study type	Sample size	Outcome	Type of patients	Author/year
Systematic review/meta-analysis/RCT	10159	Significant lowering: of LDL Mean difference-47, 49% (95% CI-69.64 to-25.35%) Myocardial infarction rate OR0.94 (95% CI0.26-039) p0.030 Serum creatinine kinase level increasing was reduced OR0.72 (95% CI 0.54 to 0.96)	Adult with hypercholesterolemia	Navarese 2015
Multicentre double-blind randomized control placebo trial (RUTHERFORD-2TRIAL)	329	Evolocumab 420mg once monthly reduced LDL-60 (95% CI-68to-52)	51 years (average) patients with heterozygous familial hypercholesterolemia	Oaks 2015 Raal et al., 2015
Multi-centre double-blind randomized control placebo trial (TESALA-B trial)	49	Mean reduction in LDL 31% (95% CI-44% to 18%) p<0.001	Homozygous hypercholesterolemia patients (aged13-57 years)	Oaks 2015 Raal 2015

According to a systematic review and meta-analysis study Navarese et al., (2015), for randomized trials comparing proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9 inhibitors) versus non PCSK9 inhibitors, in total 10,159 participants of hypercholesterolemic adults. The study found PCSK9 inhibitors significantly reduced LDL. MI rate and no increase on side effects. Study limitation is that the data was extracted from previous RCT study, not directly from patients, and with their short duration of follow up 2 months to 2 years. They are expensive, need an injection to apply, and more research is needed about safety, effectiveness, and cost-effectiveness before recommended for CVD primary prevention.

Based on multi-centre randomized control placebo trial (RUTHERFORD-2TRIAL) Evolocumab 420mg once monthly for patients aged 51 years with heterozygous familial hypercholesterolemia reduced LDL significantly compared to the placebo group after 12 weeks follow up period.

TESALA-B trial, double-blind randomized trial, randomly assigned homozygous familial hypercholesterolemia patients aged 13 to 57 years, to Evolocumab 420mg monthly versus placebo. Evolocumab significantly reduced LDL in the intervention group after 12 weeks compared to the placebo group.

Based on Studer et al., (2005) systematic review study for randomized control trial, comparing the effect of a fibrate in the intervention group versus placebo group using random allocation/follow up at 6 months/reported mortality rate/fibrate associated with increased non-cardiovascular mortality.

According to Jun et al., 2010 systematic review for trials including 45,058 participants, found that fibrates reduced risk of cardiovascular disease events, as well as coronary events, reduced progression of albuminuria, but increased serum creatinine without significant increase in serious drug-related side effects.

Table 5:4-Fibrates:

Study type	Sample size	Outcome	Type of patient	Author/year
Systematic review/RCT	137140 intervention group 138976 control group	The risk ratio for overall mortality 1.0 (95% CI 0.91-1.11) The risk ratio for non-cardiovascular mortality1.13 (95%CI 1.01 to 1.27)	Adult with hyperlipidemia >90% no CHD <10%with CHD event	Studer et al., 2005
Systematic review/meta-analysis	45058 participants Including2870 major Cardiovascular events 4552 coronary events 3880 deaths	Risk reduction: for major cardiovascular events10% (95% CI0-18) p0.048 For coronary events 13% (95%CI7-12) p<0.0001 Risk reduction of albuminuria progression14% (2-25,p0.028 A non-significant increase in serious drug-related side effects RR1.2 (0.9-1.6) P0.19/Increase serum creatinine1.9 (1.46-2.7) p<0.0001	Hyperlipidemia patients	Jun et al., 2010

Table 6:5-Omega-3fatty acids:

Study type	Sample size	Outcome	Type of patients	Author/year
Randomized open-label blinded endpoint analysis	18645	Relative reduction of 19% in major coronary events p0.011 LDL decreased by 25% Unstable angina/non fatal coronary events significantly reduced	Japanese hypercholesterolemia Patients	Yokoyama et al., 2007

According to Yokoyama et al., 2007 randomized trial, involving 18,645 Japanese hypercholesterolemia patients, randomly allocated to statin plus omega-3fatty acid 1800mg or statin only. At follow up of 4.6 years' study found a 19% relative reduction in major coronary events. A significant reduction in unstable angina and non-fatal coronary events.

ACC in 2016 issued an Expert Consensus Decision Pathway (ECDP) on the action of non-statin medications in the treatment of ASCVD risk (Lloyd-Jones et al., 2016). The ECDP's target is to provide practical advice for physicians and patients in situations which are not covered by the ACC/AHA 2013 guidelines. The consensus recommends the non-statin medications for individuals at risk who did not achieve expected statin Response (50% or greater LDL-C reduction with a high-intensity statin or 30% to 49% LDL-C reduction with a moderate-intensity statin), or who cannot tolerate recommended statin dose. ECDP recommends ezetimibe as first-line medication or bile acid sequestrants as second-line therapy (e.g., if a patient cannot tolerate ezetimibe and the triglyceride level is less than 300 mg per dL) for primary prevention in patients with or without diabetes, a 10-year ASCVD risk of 10% or greater, and a baseline LDL-C level of 70 to 189 mg per dl (Lloyd-Jones et al., 2016). These recommendations also apply to patients with baseline LDL level of190mg/dl or greater, without ASCVD.

Management of hyperlipidemia in the elderly (past the age of 65 years): is not ideal due to many reasons:

1- less potent statistical relationship between blood cholesterol level and cardiovascular disease, in comparison to middle-aged patients (Simons et al., 2003).

2- there are worries about the side effects of statins including myalgia and other side effects (Golomb 2005).

3- Calculators of cardiovascular disease risk are not accurate in the elderly, in whom clinicians may overestimate or underestimate the risk of cardiovascular disease (Yourman et al., 2012).

The risk of cardiovascular disease increases with age as demonstrated by previous epidemiological studies. Age is a crucial risk factor for cardiovascular disease, and the outcome of cardiovascular disease in the elderly is worse.

CVD risk estimation in the elderly:

Lately, the International Atherosclerosis Society (IAS), recommend using long term risk prediction; from age 50 years to 80 years for primary prevention through clinical intervention on atherogenic lipoproteins and low-density lipoproteins. Patients above the age of 80 years were not included due to deficiency of evidence and information. Long term risk for atherosclerotic CVD (age 50-80 years): <15 low, >45 high, in between is moderate risk.

Based on IAS/QRISK (for CVD prediction) seems to be credible for the UK and Western Europe (Hippisley-Cox et al., 2010). On the other hand, the IAS recommends for the general population the Framingham algorithm for calculating the absolute ASCVD risk (Berry et al., 2012). The calculated risk can be recalibrated established on coefficients specified by national arbitrage. If recalibration values are not available, then treatment should be individualized.

Coronary Calcium Score:

In the elderly, the Framingham equations overestimate CVD risk because they involve the age in the calculation. Numerous physicians do not use risk calculators, they use the impression of risk which they think is precise, and it is right to some limit (Jackson et al., 2013).

Coronary Calcium Score for mortality assessment in asymptomatic elderly individuals (age more than 75 years), has been established (Tota-Maharaj et al., 2012). A zero score is associated with 5.6 years' survival of 98%, similar to survival in other age groups with the same zero score, which is 99%. Participants in the study were 44,052 asymptomatic persons, in North America. High score predicted a high risk of all-cause mortality in all age groups. In the elderly (more than 75years), a score more than 400, was associated with 16 times mortality more than when the score is zero. The same study in North America, also CAC score, predicted all-cause mortality for those less than 45 years.

The CAC score is a vital predictor test for CAD and all-cause mortality, so based on this test some individuals will start treatment to reduce their CVD risk, while many of the elderly would not need medication treatment.

Statin therapy:

Table 7: The benefit of Statins for the elderly:

Type of study	Sample size	Outcome	Type of patients	Author/year
Meta-analysis	50,000	Reduced total mortality of 15% Reduced CHD mortality 23% Fatal and non-fatal stroke 24% Fatal or non-fatal MI 26%	Elderly aged >60 years with hyperlipidemia	Roberts et al., (2007)
Meta-analysis CTTC (27 trials)	134537 in 22 trials 39612 in 5 trials	Reduced risk of major vascular events (RR 0.79, 99% CI 0.77-0.81). Reduced major coronary events (RR 0.57, 99% CI 0.36-0.89) p0.0021 and (RR 0.61 99% CI 0.50-0.74) p<0.0001	low-risk vascular disease individuals 5-years risk of major vascular events<10%	Mihaylova et al., 2012
A multicentre randomized controlled trial ASCOT-LLA	19342	Atorvastatin 10mg reduced total cardiovascular events HR 0.79, 95% CI 0.69-0.90, p0.0005. Reduced total coronary events HR0.71, 95% CI 0.59-0.86, p0.0005. Reduced fatal and non-fatal stroke HR0.73 (95% CI 0.56-0.96), p0.024. Reduced death HR0.87 (0.71-1.06), p0.16. Reduced primary endpoint (non-fatal MI, fatal CHD) HR 0.64 (95% CI 0.50-0.83), p0.0005	Hypertensive patients aged 40-79 years with at least three other cardiovascular risk factors. 10305 had total cholesterol non-fasting 6.5mmol/l or less	Sever et al., 2003
Multicentre randomized placebo controlled trial CARDS	2838	Atorvastatin 10mg reduced major cardiovascular events 37% (95% CI-52 to -17), p0.001. Reduced acute coronary Heart disease events RR 37% (95% CI -55 to -9). Reduced coronary revascularisation RR31% (95% CI-59 to16). Reduced death rate by 27% (-48 to 1) p0.059. Reduced stroke by 48% (-69 to -11)	Diabetics aged 40-75 years/without Cardiovascular disease/had LDL 4.1mmol/l or less fasting TG 6.78mmol/l or less, and at least one of HTN, retinopathy, albuminuria/current smoking	Colhoun et al., 2004
Randomized controlled trial (prospective) (MEGA study)	3966 randomly assigned to a diet 3866 to diet and 10-20mg pravastatin	Reduced coronary heart disease HR 0.67 95% CI0.49-0.91, p0.01	Hypercholesteremic Japanese Patients/without CVD.	Nakamura et al., 2006

Table 7: The benefit of Statins for the elderly:(continued)

RCT (JUPITER)	17802	Reduced primary end point HR 0.56 (95% CI 0.46-0.69) p<0.00001. Reduced MI, HR0.46, 95% CI 0.30-0.70, p0.0002. Reduced stroke/HR 0.52 (95% CI0.34-0.79,p0.002 Reduced unstable angina HR0.53 (95%CI0.40-0.70, p0.00001. Reduced combined end point HR 0.53 (95% CI 0.40-0.69, p0.02.	Healthy men and women with normal LDL-C <3.4mmol/l, high sensitivity-C-reactive protein2mg/l or more	Ridker et al., 2008

Roberts et al., (2007) demonstrated decreased total mortality (15% reduction), fatal or nonfatal myocardial infarction (MI) (26% reduction), coronary heart disease (CHD) mortality (23% reduction), and fatal or nonfatal stroke (24% reduction), in a meta-analysis study including more than 50,000 patients > 60 years old, treated with statins. (Roberts et al., 2007) consummated, "statin treatment should be given to high-risk elderly patients", and "statin therapy is associated with obviously decreased mortality risk of cardiovascular in the elderly patients aged 75 years or more".

The Cholesterol Treatment Trialists' Collaboration data highly recommended statins use in the elderly for cardiovascular disease risk reduction (Mihaylova et al., 2012).

As Mihaylova et al., (2012) meta-analysis (CTTC) study of 27 trials, involving 22 trials of statin versus control (participants 134537, follow them for4.8years)/5 trials of more versus less statin (n39612, follow them for 5.1 years)/participants in control group was divided into 5 categories based on 5 years major vascular event risk, study found statin reduced major vascular and coronary events significantly without harm, but regarding low risk individuals' statin use is not suitable.

Server et al., 2003 multicentre randomized controlled trial, involving 19342 hypertensive patients with at least three other risk factors for cardiovascular disease, were randomly assigned to one of two antihypertensive regimens of the Anglo-Scandinavian Cardiac test results, 10305 of the patients with total non-fasting cholesterol of 6.5mol/L or less, randomly assigned to an additional atorvastatin 10mg or placebo. After 3.3 years, the study found atorvastatin group had clinically and statistically significant reduction in: the primary endpoint (non-fatal MI, fatal CHD), total cardiovascular events and total coronary events. In addition to a clinically significant reduction in fatal and non-fatal stroke but statistically not significant, versus the placebo group.

Colhoun et al., (2004) multicentre randomized placebo-controlled trial (CARDS), enrolled 2838 diabetics aged 40-75years/without CVD, had LDL 4.1mmol/l or less/fasting TG6.78mmol/l, with at least one of: HTN, current smoking, albuminuria, retinopathy, randomly assigned to Lipitor 10mg daily or placebo, after 3.9years, study found atorvastatin group had clinically significant reduction in first cardiovascular disease events and acute coronary events, compared to placebo group.

Nakamura et al., (2006) MEGA prospective randomized controlled trial, involving 3966 patients randomly assigned to diet group, 3866 to diet plus 10-20mg daily pravastatin. Japanese patients with hypercholesterolemia without CVD, after 5.3 years' study found significant risk reduction of coronary heart disease (HR0.67,95% CI 0.49-0.91, p0.01) in diet plus pravastatin group compared to diet only group. A study limitation is withdrawal of some participants before the end of the study which leads to bias; also reduction of CHD is statistically insignificant.

Ridker et al.,(2008) randomized trial (JUPITER), randomly allocated 17802 healthy women and men with normal LDL-C, but high Sensitivity-C-reactive protein to either rosuvastatin 20mg or placebo, after a 1.9-year study found clinically and statistically significant reduction in the incidence of major cardiovascular events in rosuvastatin group versus placebo group.

EPIC-Norfolk and Reykjavik studies for triglyceride as risk factors in the elderly aged from 70-74 years showed odds ratio (for the association of triglyceride with CHD) of 1.57 (95% CI, 1.10–2.24) and 1.76 (CI, 1.39–2.21) respectively, which is clinically significant. (Sarwar et al., 2007) meta-analyses of these, in addition to other studies, approve that triglycerides are distinct risk factors for cardiovascular disease. Fasting triglyceride level above 1.7mmol/l (150mg/dl) is associated with increased risk of CHD. About 33.3% of adults had the same range of previously mentioned fasting triglyceride (Kotseva et al., 2009). Lately meta-analysis of five prospective, randomized, placebo-controlled trials demonstrated the benefit of fibrates in reducing CHD events in elderly patients with elevated fasting triglycerides more than 2.3mmol/l (200mg/dl). OR =0.65 (0.54–0.78 [95% OR =0.65 (0.54–0.78 [95% CI}, (Jun et al., 2010) which is clinically significant.

The European Society of Cardiology/European Atherosclerosis Society (ESC/EAS) Guidelines recommend medication therapy to reduce triglycerides if still fasting triglycerides remaining high more than 2.3 mmol/L (≈200mg/dl) despite lifestyle intervention (Catapano et al., 2011). Treatment is intended to be for patients considered at "high total CV risk". High total CV risk is defined as either significantly raised single risk factors such as severe hypertension and familial dyslipidemia, or a calculated 10-year risk of fatal CVD SCORE ≥5% and <10%.

The risk of pancreatitis is clinically significant with very high fasting triglycerides more than 10mmol/l (500mg/dl), (Catapano et al., 2011). The ESC/EAS guidelines warrant "actions to prevent acute pancreatitis are compulsory".

ESC/EAS recommendations for medication therapy of high TGs are Class I/Level B for fibrates, Class IIa/Level B for n-3 fatty acids, Class IIb/Level B for fibrate and n-3 fatty acids and Class IIa/Level C for statin and fibrate (Catapano et al., 2011).

Guidelines summary for lipid management in the elderly: REF. Noaman et al., (2014):
1-Adult treatment panel III of national cholesterol education program recommended clinical judgment before using statins for primary prevention of CVD in the elderly due to unreliable CV risk calculators.
2-National collaborative centre for primary care recommended statin for primary prevention of CVD in the elderly aged 75 years and more/who are at high risk of CVD, put in consideration risk-benefit ratio.
3- European Society of Cardiology/European Atherosclerosis Society recommended clinical judgment in decision making for statin therapy in the very old >80-85 years.

American Heart Association/American College of Cardiology (AHA/ACC) recommend using pooled cohort equations for calculation of 10-year CVD risk which will help in treatment decision making in elderly patients aged from 76-79 years. (Stone et al., 2014) randomized control trials recommend continuing statins therapy in the elderly beyond 75years if they are already on statins and tolerating them. But we should consider the side effects of statins, safety, preferences of care and co-morbidities. AHA/ACC recommend discussion before starting statins for primary prevention in the elderly above 75 years, regarding side effects of statins, patient's priorities, drug interactions, and the statins benefit in reducing cardiovascular disease risk (Stone et al., 2014).

Evidence for treatment in the elderly aged from 80-85 years is very limited due to sparse data, and the treatment decision is based on clinical judgment (Catapano et al., 2011).

National Institute for Clinical Excellence (NICE): NICE guidelines for lipid management in the elderly for primary prevention of cardiovascular disease in primary care, an organized strategy should be done to define people aged from 40-75 years who are at high risk of CVD. Those aged 75 years and more are already at high risk of CVD, so they are likely to benefit from statins therapy. But the treatment should be guided by benefits and risks of treatment, side effects, informed preference and co-morbidities which may make the treatment unsuitable (NICE, 2010).

The International Atherosclerosis Society guidelines recommend calculating CHD risk in patients aged more than 65 years using Framingham scoring, recalibrated for country [1]. Total CVD can be calculated by adding the CHD risk by one-third, and the result should help in deciding on statin treatment.

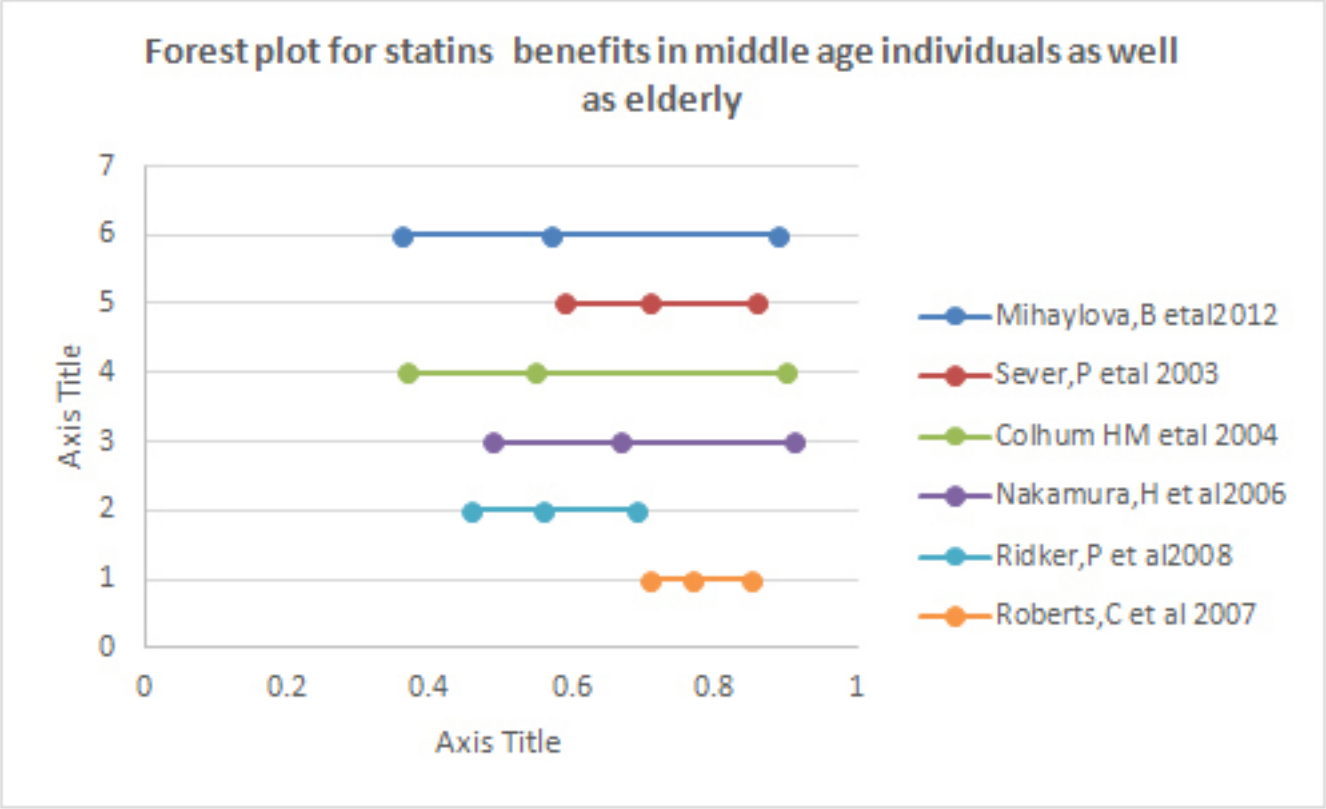
Abelhafiz et al (2012) revised the relationship between cholesterol levels and outcomes in the elderly patients with specific consideration to body weight and fragility, pointing out that low body weight and fragility are substantial determinants of elevated CVD, which is associated with low cholesterol levels. Caution would seem suitable in considering therapy in fragile thin elderly patients (Abelhafiz et al., 2012).

(1) See the link: (http://hp2010.nhlbihin.net/aptiii/calculator.asp?usertype=prof)

Table 8: Statins benefits in middle age individuals as well as the elderly

Author/year	Sample size	RR	CI lower	CI upper
Mihaylova et al2012	174149	0.57	0.36	0.89
Sever et al 2003	19342	0.71	0.59	0.86
Colhum et al 2004	2838	0.37	0.55	0.90
Nakamura et al 2006	7832	0.67	0.49	0.91
Ridker et al 2008	17802	0.56	0.46	0.69
Roberts et al 2007	50000	0.77	0.71	0.85

Figure



Blood pressure control and primary prevention of cardiovascular disease:

The Systolic Blood Pressure Intervention Trial (SPRINT), (Ambrosius et al 2014) which was a multi-centre randomized control trial included 9361 participants with a systolic blood pressure of at least 130mm Hg. The primary target of the trial was to assess if lowering systolic blood pressure to less than 120mm Hg, than the currently recommended less than 140mm Hg, will decrease the appearance of cardiovascular disease. Enrolled patients were 50 years or older with systolic blood pressure of at least 130mm Hg, with one of the other risk factors (example older than 75 years, intermediate to high risk for CVD) but without diabetes. The duration of the study was 3.26 years. The study found that reduction in both primary combined cardiovascular outcome and mortality, 25%, 27% respectively in the group randomized SBP to less than 120mm Hg (Ambrosius et al., 2014). The baseline mean blood pressure is 139.7 mm Hg for systolic blood pressure and 78.1 mm Hg for diastolic blood pressure.

One year later, mean systolic blood pressure was 121.4 mmHg in the intensive therapy group while 136.2 mmHg in the standard treatment group with marked reduction in the rate of the primary complex outcome in the intensive-treatment group compared to standard-treatment group (1.65% per year vs. 2.19% annually, the risk ratio with intensive treatment, 0.75; 95% confidence interval [CI], 0.64 to 0.89; P <0.001). All-cause mortality was also significantly reduced in the intensive-treatment group (hazard ratio, 0.73; 95% CI, 0.60 to 0.90; P=0.003). So reductions in the combined cardiovascular outcome and all-cause mortality were clinically significant but statistically not significant. On the other hand, there is bias as the interviewers knew about study group assignment in addition to dangerous side effects in the intensive treatment group. But still, the study is strong high evidence on the pyramid of evidence, with randomization, multi-centre, and minimizing the ascertainment bias by using the same format for interviewers, and a powerful study 88.7%. In addition participants were divided into subgroups which reduced confounders.

2-1 SPRINNT study
ACCORD study

Table 9: SPRINT and ACCORD studies:

Study type	Sample size	Outcome	Patients type	Author/years
Multicentre randomized control trial (SPRINT)	9361	Reduced primary composite outcome HR0.75 (95% CI 0.64-0.89) p<0.001 Reduced all-cause mortality HR0.73(95% CI 0.60-0.90)p0.003	50 years or older patient with systolic130 Or more/and increased cardiovascular risk/but no diabetes	Wright et al., 2015
Randomized trial (ACCORD)	4733	The annual rate of primary outcome HR0.88 (95% CI 0.73-1.06), p0.2 The annual rate of death HR1.07 (95% CI0.85-1.35), p0.55 The annual rate of stroke HR0.59(95% CI0.39-0.89) p0.01 Serious side effects 3.3%	Type 2 diabetes patients with a high risk of CVD events	William et al., 2010

ASCOT-BPLA study.

Table 10: Sever et al 2005 study:

Study type	Sample size	Outcome	Patients type	Author/year
A multicentre prospective randomized controlled trial	19257	Reduced fatal/non-fatal stroke RR0.77 (95% CI 0.66-0.89) p0.0003 Reduced all cardiovascular events and procedures RR0.84 (95% CI 0.78-0.90) p<0.0001 Reduced incidence of developing diabetes RR0.70 (95% CI 0.63-0.78) p<0.0001	Hypertensive patients aged 40-79 years with at least 3 other CVD risk factors.	Sever et al., 2005.

William et al., (2010), randomized trial enrolled 4733 individuals with type 2 diabetes and randomly assigned them to intensive treatment, aiming at systolic blood pressure <120 mmHg and standard therapy, aiming at systolic blood pressure <140 mmHg. After one year the mean systolic blood pressure was 119.3 in the intensive treatment group, and 133.5mmHg in the standard therapy group. The annual rate of primary outcome and death were reduced, but was clinically and statistically insignificant. So intensive therapy to reduce systolic blood pressure <120mmHG in diabetics, compared to standard therapy aiming at systolic<140mmHG, did not reduce combined Cardiovascular events.

Sever et al., (2005), multicentre prospective randomized controlled trial, enrolled 19257 hypertensive patients aged 40-79 years with at least three other CVD risk factors, were randomly assigned either amlodipine5-10mg, adding perindopril 4-8mg as needed (amlodipine regimen .n=9639), or atenolol adding Bendroflumethiazide 1.25-2.5mg and potassium as needed (atenolol regimen ,n=9618), after 5.5years study found clinically and statistically significant reduction in fatal, non-fatal stroke and all cardiovascular events and procedures in amlodipine regimen Group compared to atenolol regimen group and induced less diabetes than atenolol regimen, so new drugs had greater benefit for lowering blood pressure and preventing CVD than older drugs.

2010 Canadian hypertension education program highly recommended (grade A) statins.
Treatment in hypertensive patients older than 40 years with three or more cardiovascular risk factors or already atherosclerotic disease had been established regardless of the age (grade A).

If hypertensive patients have three or more of the following risk factors, statins should be considered. Derived from reference (Sever et al., 2003).
1- sex: male.
2- Age ≥55 years
3-peripheral arterial disease. /
4- Microalbuminuria or proteinuria
5- Diabetes mellitus
6- Smoking
7- Family history of premature cardiovascular disease
8- Total cholesterol to high-density lipoprotein ratio ≥6.

Julius et al., (2004), (VALUE), randomized double-blind trial, enrolled 15245 hypertensive patients aged 50 years or older, treated or untreated/had high cardiovascular risk. Randomly assigned Valsartan or amlodipine, after 4.2 years, the study found no difference between the two groups in primary Combined endpoint (HR 1.04, CI 0.94-1.15, p0.49). Based on the study the important issue is immediate Blood pressure control in hypertensive patients with increased CVD risk.

VALUE study.
Canadian Hypertension Education Program subgroup members for 2010 collaborated with Canadian Diabetes Association Guidelines Committee, Canadian Stroke Network and Canadian Society of Nephrology for 2010 recommendation methods. Conducting Medline search for systematic review and clinical trials in addition to all relevant articles each subgroup had national and international expert opinion reviewer. Actually, the recommendations are highly evidenced, had 80% or more approval, were based on high-quality evidence studies, conducting high sensitive search, and divided into subgroups leading to minimize confounders. Furthermore they had many independent expert opinion interviewers. No conflict between voting members.

CHEP 2010 recommendation for hypertensive patients without indications:
1-First therapy is monotherapy thiazide diuretics (grade A). Long-acting CCB (grade B), beta-blocker in patients younger than 60 years (grade B), ACEI (non-black patients grade B) or ARB (grade B).
2-Another antihypertensive drug can be added if goal blood pressure not achieved with standard-dose mono therapy (grade B).
3-Initial combination therapy for the treatment of hypertension (grade C) if systolic blood pressure is 20 mmHg exceeds goal or if diastolic blood pressure is 10 mmHg above goal.
4-If blood pressure is uncontrolled despite combination treatment with two or more first-line anti-hypertension medications, or there are side effects, other antihypertensive medications may be added (grade D).
5-Possible causes for poor response to medications should be investigated (Grade D).
6-Alpha-blockers are not recommended as first-line therapy for uncomplicated hypertension (grade A); beta-blockers are not recommended as first-line treatment for uncomplicated hypertension in patients aged 60 years or older (grade A), and ACE inhibitors are not recommended in black patients as first-line therapy for uncomplicated hypertension (grade A) while these medications may be used in patients with specific co-morbidities or in combination therapy.

ESCAPE study.
A randomized clinical trial of effects of a multifaceted intervention on cardiovascular risk factors in high-risk hypertensive patients: the ESCAPE trial, aimed to assess if multifaceted intervention concentrated on general practitioners (GPS), could raise markedly the proportion of high-risk hypertension patients in primary prevention who attained all their recommended curative goals. The trial enrolled 1,832 high-risk hypertensive patients; and

Table 11: VALUE study:

Study type	Sample size	Outcome	Patients type	Author/year
Randomized double-blind trial	15245	No difference in combined end point HR1.04 (95% CI 0.94-1.15, P0.49)	Hypertensive patients aged 50 years or older Treated/or untreated/had high cardiovascular risk	Julius et al., 2004.

Table 12: ESCAPE study:

Study type	Sample size	Outcome	Patients type	Author/year
Randomized double-blind trial	15245	No difference in combined end point HR1.04 (95% CI 0.94-1.15, P0.49)	Hypertensive patients aged 50 years or older Treated/or untreated/had high cardiovascular risk	Julius et al., 2004.

included 257 GPs randomized by region; GPs given training session, electronic Blood pressure measurement device and recommendation leaflet. Along with regular follow up for 2 years, localize one consultation on hypertension, and other cardiovascular risk factors every 6 months. Study after two years found a proportion of patients achieving their curative goals was markedly increased in both groups, but more significantly in the intervention group, OR 1.89 (95% confidence interval (CI) 1.09 to 3.27, P=0.02), which is clinically significant but statistically insignificant. Blood pressure targets achievement are significantly more in the intervention group than regular care group OR2.03 (95% CI 1.44 to 2.88, P<0.0001), which is clinically and statistically significant. So trial summarized that multifaceted approach aimed at GP only, significantly increased proportion of high-risk hypertensive patients in primary prevention, attaining their recommended curative goals. The trial is a high rank of evidence, with randomization which increases the power of the study, in addition to a good sample size of participants (GPs and high-risk hypertensive patients); follow up period was sufficient. Furthermore, inclusion and exclusion criteria for patients were mentioned clearly, and ethical consent provided, statistical analysis was suitable for the study, with precise results clinically and statistically significant which made the study applicable to a practice.

Diabetes and primary prevention of cardiovascular disease:

Studies about the role of Aspirin in primary prevention of cardiovascular disease in diabetic patients was reviewed in nine trials which needed at least two years of follow up. Three of these trials exclusively studied patients with diabetes mellitus; the remaining trials enrolled general populations but included some patients with diabetes mellitus.

Aspirin for primary prevention of cardio-vascular disease in diabetic patients:

Randomized controlled studies (RCT):

Sacco et al., (2003), randomized trial, enrolled 1031 diabetics, aged 50 years or more/without CVD and 4495 individuals with one or more cardiovascular risk factors to compare effect of aspirin 100mg daily in two groups diabetics and non-diabetics in primary prevention of CVD versus Vit E 300mg daily. After 3.7 years, study found aspirin in diabetics patients non significantly reduced main endpoint and cardiovascular events, along with non-significant increase in cardiovascular death, while significantly reduced main endpoint, total cardiovascular events and cardiovascular death in non-diabetics. Vit E had no effect on any endpoints in both diabetics and non-diabetics. So based on study aspirin had low benefit in primary prevention of CVD in diabetics.

Ridker et al., (2005), randomized trial, involving 39876 initially healthy women aged 45 years and more, randomly assigned to 100mg daily aspirin each other day or placebo; followed them for 10 years, study found aspirin had significant reduction for ischemic stroke, but no significant reduction for major cardiovascular events, nor MI (fatal /non-fatal). For gastrointestinal bleeding, aspirin caused non clinically and statistically significant increase.

In 2008, Belch, et al, randomized, double-blind placebo-controlled trial, enrolled 1276 diabetics (type1 or2) aged 40years or >, had ABI=or<0.99, randomly assigned to aspirin 100mg daily, plus antioxidant capsule, aspirin plus placebo, placebo plus antioxidant or Placebo tablet plus placebo capsules, after 6, 7 years study demonstrated that aspirin caused non-significant reduction in primary event, non-clinically significant increase in death from CHD or stroke/same for antioxidant. Based on the study there are no recommendations for aspirin/or antioxidants for primary prevention of CVD. But the study had a bias due to the long duration of the study; some patients were lost to follow up or withdrew or died.

Ogawa, et al 2008, in a multicentre randomized blind trial involving 2539 type 2 diabetics without a history of CVD, were randomly assigned to aspirin versus non-aspirin, after 4.3 years, the study found aspirin caused no (clinically and statistically) significant reduction in atherosclerotic events, combined endpoint and cause mortality. So the study showed that low dose aspirin in type 2 diabetic patients did not reduce CVD events.

The trials that exclusively studied patients with diabetes mellitus were the Early Treatment of Diabetic Retinopathy (ETDRS), (ETDRS Investigators 1992), the Prevention of Progression of Arterial Disease and Diabetes (POPADAD), (Belch J, et al 2008) and the Japanese Prevention of Atherosclerosis with Aspirin in Diabetes (JPAD). These trials included a total of 7,526 patients with 38,275 patients–years of follow-up between them (Ogawa et al., 2008).

Aspirin therapy resulted in a 15% relative risk (RR) reduction in fatal plus nonfatal myocardial infarction in patients in the ETDRS (RR 0.85, 95% CI 0.73–1.00) which is clinically insignificant. In the JPAD study, (Ogawa, 2008) a similar reduction was observed for fatal plus nonfatal coronary heart disease events (RR 0.81, 95% CI 0.49–1.33) but the number of events was small (28 in the treatment group versus 35 in the control group) and the findings were statistically and clinically insignificant. Neither trial reduced the risk of stroke, although not many strokes occurred.

In January 2009, the American Diabetes Association (ADA) revised the strength of its recommendation for the use of aspirin for primary prevention of cardiovascular events in patients with diabetes mellitus, going from evidence level A (clear evidence from well-conducted, randomized trials) to level C (conflicting evidence with weight supporting recommendation) (ADA 2009). Canadian guidelines were similarly revised. (Canadian Diabetes Association, 2008). Others have suggested that aspirin should not be used for primary prevention in patients with diabetes mellitus because they consider the benefits to be unproven in the face of known deleterious effects (Barnett et al., 2010).

Ongoing trials such as ASCEND (British Heart Foundation 2010) and ACCEPT-D (De Berardis et al 2007) should help clarify the aspirin effect in primary prevention of

Table 13: Aspirin studies for primary prevention of Cardiovascular disease in diabetic patients:

Study type	Sample size	Outcome	Patients type	Author/ year
A randomized trial(PPP)	1031 diabetics 4495 with one or more major cardiovascular risk factors.	In diabetic patient aspirin non significantly reduced main endpoint (RR 0.90, 95% CI 0.50-1.62) Reduced (non significantly) total cardiovascular events (RR 0.89, 95% CI 0.62-1.26) Increased (non significantly) in cardiovascular death RR 1.23 (95% CI 0.69-2.19) In non-diabetics, aspirin reduced main endpoint, cardiovascular events, and death RRs 0.59 (0.37-0.94), 0.69(0.53-0.90), 0.32 (0.14-0.72)	1031 diabetics Aged 50 years or older. 4495 with one or more major cardiovascular Risk factors.	Sacco et al., 2003
A randomized trial (WHS)	39876 (total) 1027(diabetics)	Aspirin reduced (non significantly) major cardiovascular events RR 0.91 (95% CI 0.80-1.03, p0.13) Reduced ischemic stroke RR 0.76 (95% CI 0.63-0.93, p0.009. No effect on fatal/non-fatal MI (RR 1.02, 95% CI 0.84-1.25, p0.83) Non significantly increased Gastrointestinal bleeding Requiring transfusion RR1.40 (95% CI 1.07-1.83, p0.02)	Initially, healthy women aged 45 years or more	Ridker et al., 2005
Multicentre randomized double-blind placebo-controlled trial (POPADAD)	1276	Aspirin reduced (non significantly) primary event/HR 0.98 (95% CI 0.76-1.26) Increased (non significantly) death from coronary heart disease or stroke HR 1.23 (95% CI 0.79-1.93). Anti-oxidants no effect on Primary event HR 1.03 (95% CI 0.79-1.33). Non-significantly increased death from CHD and stroke HR 1.21(95% CI 0.78-1.89).	Diabetics (type 1 or 2) aged 40 years or more With ABI = or<0.99/no evidence of CVD.	Belch et al., 2008
Multi-centre prospective randomized blind trial (JPAD)	2539	Aspirin non significantly reduced atherosclerotic events HR 0.80 (95% CI 0.58-1.10), p0.16 Non significantly reduced combined end point HR 0.10 (95% CI 0.01-0.79, p0.0037. Non significantly reduced total cause mortality HR 0.90(95% CI 0.57-1.14, p0.67.	Patients with type2 diabetes without a history of CVD.	Ogawa et al., 2008

cardiovascular disease in diabetic patients, in the future. The study considered aspirin as a suitable potential treatment at the current time for primary prevention of cardiovascular disease in diabetic patients and patient with high cardiovascular disease risk. But there was no definitive current evidence because we depend on very few events in trials to accurately assess their effects, and our results depend on analysis of subcategories of large trials which have a large possibility for bias.

Meta-analysis studies:

Xie et al., (2014) meta-analysis, showed a low dose of aspirin is beneficial for primary prevention of CVD. The effect differs by sex and diabetic status. The therapy should be individualized and more research is needed regarding primary prevention in diabetics. The study had also bias and confounders.

De Berardis et al., (2009) meta-analysis found that aspirin reduced cardiovascular events and mortality, beside all-cause mortality but it was non clinically significant while aspirin reduced MI in men significantly. So gender had an effect but there is still no evidence for benefit of aspirin for CVD primary prevention in diabetics.

Baigent et al., (2009), meta-analysis found aspirin reduced serious vascular events and non-fatal MI and was found to be statistically significant but it caused gastrointestinal and extra-cranial bleeding, so before aspirin is used for primary prevention, the risk benefit ratio needs to be weighed up.

The role of aspirin in ETDRS (TYPE1 or type 2 DM), JPAD (TYPE 2DM) and POPADAD (TYPE 1 and type 2 DM), studies which were exclusively for diabetic patients showed a reduction in CHD risk in both ETDRS and JPAD

Table 14: Meta-Analysis studies for the effect of aspirin in CVD risk in diabetics:

Study type	Sample size	Outcome	Patient type	Author/year
Meta-analysis	107686	Aspirin reduced: Major cardiovascular events RR 0.90 (95% CI 0.85-0.95), MI RR0.86 (95% CI 0.75-0.93), ischemic stroke RR0.86(0.75-0.98), all-cause mortality RR 0.94 (0.98-0.99) In subgroups, reduced MI among men RR 0.71(0.59-0.85) Reduced ischemic stroke among women RR 0.77(0.63-0.93) Reduced MI among diabetic men RR 0.65 (0.51-0.82)	Mixed men and women without CVD, some diabetics	Xie et al., 2014
Meta-analysis	10117	Aspirin non statistically significant reduction on major cardiovascular events RR 0.90 (95% CI 0.81 -1.00), cardiovascular mortality RR 0.94 (95% CI 0.72-1.23, all-cause mortality 0.93 (0.82-1.05), significantly reduced the risk of MI in men RR0.57(0.34-0.94)	Diabetic patients with no pre-existing CVD event	De Berardis et al., 2009
Meta-analysis	95000 (low average risk) 660000 person-years 3554 serious vascular events	Reduced serious vascular events p0.0001, 0.51 Reduced non-fatal MI 0.18, p0.0001 Effect on stroke insignificant 0.20%, p0.4 Increased major gastrointestinal and extracranial bleeding 0.10% per year, p<0.0001	95000 (low average risk) 660000 person-years 3554 serious vascular events	Baigent et al., 2009

studies, but POPADAD had no effect on CHD risk. The overall effect of aspirin on CHD in 3 studies is clinically insignificant.

Primary prevention Trials found that low dose Aspirin in patients with/without diabetes is associated with an absolute risk of hemorrhagic stroke in around 1 in 10,000 people yearly (Blackwell et al., 2009).

A meta-analysis of six primary prevention trials found that aspirin is associated with a 54% increase in gastrointestinal risk bleeding (RR 1.54, 95% CI 1.30 to 1.82), which is clinically significant. Diabetics who used aspirin have 55% more risk for aspirin side effects (RR 1.55, 95%CI 1.13 to 2.14) than non–diabetics. So the risk for aspirin-related adverse effects is clinically significant in diabetics. Two trials mentioned the use of statins or other lipid-lowering medications; statin use in JPAD was 26%, while another lipid-lowering therapy in PPP was 13%.

Recommendations based on trials data:
1-Aspirin low dose (75-162 mg/day) in diabetics with high CVD risk (10-years CV risk is over 10%) and not at increased risk for bleeding. Diabetics at increased CVD risk include men over 50 years/women over 60 years, who had one or more of the following risk factors: dyslipidemia/ hypertension/smoking/albumin urea, family history of premature CVD (ACCF/AHA class IIa, level of evidence: B) (ADA Level of evidence: C).

2-Aspirin should not be recommended for CVD primary prevention in diabetics with low CVD risk (men under 50/ women under 60/no additional major CVD risk factor-10-years CVD risk under 5%) As the risk overweight benefit (ACCF/AHA CLASS III, LEVEL of evidence: C), (ADA Level of evidence: C).

3-Aspirin low dose (75-162mg/day) might be deemed effective in diabetic with intermediate CVD risk (younger patients with one or more risk factors, or older patients with no risk factors or patients with a 10-year CVD risk of 5%-10%) till advanced research is obtainable (ACCF/AHA Class IIb, Level of Evidence: C), (ADA Level of Evidence: E).

Examples for sources for CVD risk assessment in diabetics:
American Diabetes Association Risk Assessment Tool, Diabetes PHD: http://www.diabetes.org/phd
UKPDS Risk Engine: http://www.dtu.ox.ac.uk/riskengine/index.php

Limitation of Current study:
No two independent investigators, publication bias, confounders; in addition to language restriction furthermore it is difficult and time consuming.

Advantages of current study:
High level of evidence in hierarchy of evidence, rank one with meta-analysis study. The study design is suitable for aim of the study. Time of systematic review is sufficient. The sources of reviewed studies were comprehensive. Statistical analysis is precise and suitable. Inclusion and exclusion criteria for recruited studies were clear.

Conclusion

Statin is beneficial for primary prevention of cardiovascular disease in middle age individuals as well as the elderly, who have dyslipidemia or diabetics aged 40-75 years, or 10-years CVD risk =>7.5%. According to AHA/ACC or =>10% or according to NICE or USPSTF. Statin is effective for primary prevention of CVD in moderate and high risk individuals but no evidence for its benefit in low risk individuals. Caution would seem suitable in considering therapy in fragile thin elderly patients, who have substantial determinants of elevated CVD. No definite evidence for non-statin therapy benefit for primary prevention of CVD, but can be used in hypercholesterolemia patients or high CVD risk patients who did not tolerate statins or who had not responded to the maximum dose of statins. PCSK-9 inhibitors need more search about their safety, effectiveness and cost-effectiveness before they are recommended for primary prevention of cardiovascular disease. No evidence for aspirin benefit in primary prevention of CVD in diabetic patients; ongoing trials should help clarify their effect in primary prevention of CVD in the future. Immediate blood pressure control is important in the primary prevention of CVD in hypertensive patients with high cardiovascular risk.

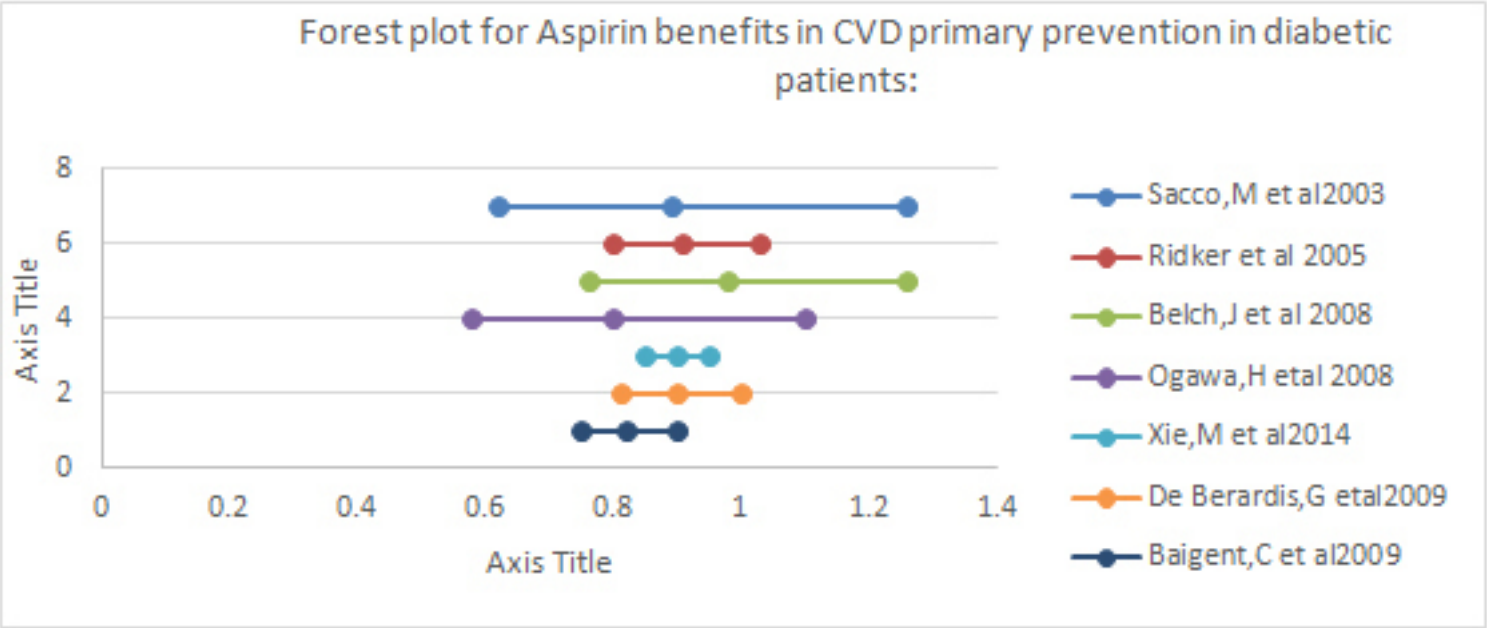
Recommendations

1-To control risk factors for CVD, mainly hyperlipidemia, hypertension and diabetes through pharmacological and non-pharmacological measurements.
2-To follow best practice guidelines recommendations for primary prevention of cardiovascular disease in hypercholesterolemia patients/hypertensive and diabetic patients, mainly AHA, ACC, NICE, USPSTF, adult treatment panel III (ATPIII) of national cholesterol education program national collaborated centre for primary care, European society of cardiology and European atherosclerosis society, American Diabetes Association (ADA), Canadian diabetes association and 2010 Canadian hypertension education program.
3-To lower systolic blood pressure to less than 120 than the currently recommended less than 140, will significantly reduce appearance of cardiovascular disease in hypertensive patients with other risk factors but without diabetes.
4-No need for intensive therapy to reduce systolic blood pressure less than 120 in diabetic patients because such will not reduce combined cardiovascular events.
5-To use new antihypertensive medications like amlodipine adding perindopril rather than to use old medications like atenolol adding flumethiazide and potassium, because the new medications had greater benefit for lowering blood pressure and preventing CVD than old medications.
6-To follow 2010 Canadian hypertension education program recommendation for statin therapy in

Table 15: Aspirin benefits in CVD primary prevention in diabetic patients:

Author/year	Sample size	RR	CI lower	CI upper
Sacco et al2003	5526	0.89	0.62	1.26
Ridker et al 2005	39876	0.91	0.80	1.03
Belch et al 2008	1276	0.98	0.76	1.26
Ogawa etal 2008	2539	0.80	0.58	1.10
Xie et al2014	107686	0.90	0.85	0.95
De Berardis etal2009	10117	0.90	0.81	1.00
Baigent et al2009	758554	0.82	0.75	0.90

Figure



hypertensive patients older than 40 years with 3 or more cardiovascular risk factors (grade A).

7-Immediate blood pressure control is important in hypertensive patients with increased CVD risk.

8-To follow Canadian hypertension education program 2010 recommendations of high grade evidence level A and B for hypertensive patients without indications.

9-Training sessions for general practitioners where required, with electronic blood pressure measurement device and recommendation leaflet are recommended .

10-No need for aspirin for primary prevention of CVD in diabetic patients.

11-To use statins for primary prevention of CVD in moderate and high risk individuals. No indication for its use in low risk individuals.

12-ADA recommendation for aspirin for primary prevention of CVD in diabetic patients is grade C (conflicting evidence).

13-Canadian diabetes association 2008, suggested that aspirin should not be used for primary prevention of CVD in diabetic patients as the benefit is unproven in the face of known deleterious effects.

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Management of depression in primary care - A cross-sectional study in the North-East of England, UK

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Abstract

Background: Depression is a common and serious disorder that impairs quality of life. Since general practitioners (GP) are considered gatekeepers to secondary care, the choice of interventions offered in primary care can have a significant impact not only on patients' quality of life, but also on health service demands.

Objective: To evaluate the confidence of GPs in diagnosing and managing depression; and, to assess the factors influencing their strategy in treating depression.

Methods: A cross-sectional study was carried out among GPs working in the North-East of England, UK. The survey questionnaire consisted of mostly close-ended questions with some allowing for free-text comments (see Appendix 1). The responses obtained were analysed using Microsoft Excel.

Results: Among the total of 63 respondents, most GPs were comfortable diagnosing depression. Most would consider combining talking therapies with antidepressants (68.3%) at presentation, followed by referral to talking therapies alone (41.2%). In only 14.3% of cases would antidepressant therapy alone be considered. For those patients non-responsive to initial treatment, 25.4% considered offering a different antidepressant or adjunct medication (such as a sedative, anxiolytic, or beta-blocker), and another 25.4% of GPs considered a combination with another antidepressant. 46.0% of participants were not comfortable prescribing dual antidepressants due to concerns about side effects, lack of experience, paucity of guidelines, and lack of timely access and guidance from the local mental team. Nearly all (98.4%) GP participants would agree to prescribe dual antidepressants on advice of the mental health team with telephone advice being the preferred means of communication in 65.1% of cases.

Conclusion: The results of this study can help to develop closer co-operation between primary and secondary care by not only upskilling GPs through various means (educational events, training posts, etc.), but by also creating better communication channels at the interface between those two services.

Key words: antidepressants, combination therapy, depression, primary care, primary-secondary care interface

Introduction

Mental disorders are a growing public health problem with a considerable burden world-wide (1). Depression causes significant morbidity, increased mortality, reduced functioning, and loss of quality of life with resulting social and economic impact (2). In the UK in 2014, it was estimated that 19.7% of people aged 16 and above had symptoms of anxiety or depression – a 1.5% rise from the year before (3).

Although antidepressants are well-established in the treatment of depression, only 50–60% of patients respond to first-line treatment and experience complete remission of symptoms (4). For non-responders who are compliant with an adequate dose of medication, current guidelines recommend either switching (either within or between classes), augmentation with a non-antidepressant medication, or combination therapy (5). However, evidence on effectiveness of combination antidepressant therapy is limited (4). Psychotherapy can also be considered at any point alongside pharmacological treatment. In addition, in those where there is limited response to treatment, secondary care services can be involved (5,6).

There has been some work done in primary care to understand how GPs approach the treatment of depression (7,8). Several factors may impact on a treatment strategy including clinician factors such as knowledge, skills, and time-pressure; patient factors such comorbidities, socio-cultural background, and choice; availability and access to talking therapies; prescribing costs, etc. to name just a few.

This study aimed to explore the ease and confidence with which primary care colleagues identify and treat depression, and to look at some of the factors that may have a bearing on the management of this condition. It is hoped that this will help to inform any changes that may be needed in the way local secondary mental health services co-operate with primary care. Assessing the experience of GPs will also help to identify ways of better supporting and empowering them in managing depression within primary care.

Methods

A cross-sectional study was carried out among GPs working in the North-East of England, UK. GPs of more than 4 years' experience were surveyed. They were invited to reflect on their experiences and a questionnaire (see Appendix 1) was used to capture their responses. The opinion and help of a consultant psychiatrist working for the local metal health trust (Tees, Esk and Wear Valley Foundation NHS Trust) was sought in designing both this study and the questionnaire.

Between March 2020 and May 2020,80 GPs were contacted by email with an outline of what the research entailed. The email also included a link to an online questionnaire on surveysparrow.com – which allowed responses to be captured anonymously. Around 8-10 weeks were allowed for responses and a reminder was sent half-way through for those who had yet to complete the survey.

The survey questionnaire was divided into three parts. The first part consisted of questions to assess the ability of GPs and their confidence in diagnosing depression. The second part looked at the management options for depression and factors influencing prescribing. The third part focused on how comfortable they felt in using combination therapy including dual antidepressants in those patients who do not demonstrate any improvement initially.

The responses were analysed using Microsoft excel.

Results

A total of 63 (78.8%) GPs responded.

Diagnosis of depression

The confidence levels of GPs in diagnosing depression were generally high with a score ranging from 8 to 10 (mean of 8.6) for the majority (80.9% of respondents). The details are given in Table 1.

Table 1: Confidence of GPs in diagnosing depression

Question	Response	Number	%
How comfortable are you in making a diagnosis of depression?	Score of 5	1	1.6
	Score of 6	0	0
	Score of 7	11	17.5
	Score of 8	22	34.9
	Score of 9	16	25.4
	Score of 10	13	20.6
Do you categorise depression as Mild/Moderate/Severe in routine appointments?	Yes	36	57.1
	No	27	42.9
Are there any circumstances where you might question your diagnosis of depression?	No improvement with antidepressants and/or CBT	31	49.2
	Multiple consultations on the part of the patient despite objective improvement	27	42.9
	Other features making the diagnosis less clear-cut e.g mania, hypomania, anxiety, personality traits etc	52	82.5
	Patient rejecting diagnosis	6	9.5
	Lack of confidence in making the diagnosis	2	3.2
	Other	5	7.9

36 out of 63 GPs (57.1%) would normally categorise depression in terms of severity. The main reason for not able to do so was due to other co-existing features making the diagnosis less obvious. This was followed closely by a lack of improvement to initial treatment.

Management of depression

The details of the various management options are given in Table 2.

Table 2: Management options for depression

Question	Response	Number	%
What is your preferred initial management plan in mild to moderate cases of depression when someone is at low risk?	Refer to IAPT services/talking therapy	26	41.2
	Start on antidepressants	9	14.3
	Both IAPT services/talking therapy and antidepressants are suggested and the patient decides after discussing the options	43	68.3
What influences your management plan?	Level of confidence with the prescription of and overseeing the management with antidepressants	21	33.3
	CBT is more likely to be useful and is not associated with side-effects	17	27.0
	IAPT services/talking therapy are not easily accessible where I work	15	23.8
	Shared-management is something I strive for in my practice	39	61.9
	Time constraints – I chose what I think is more likely to suit the patient's needs	8	12.7
	Other	1	1.6
What are the factors that make you more likely to choose a particular antidepressant?	Safety profile of medication/side-effect	49*	N/A
	Patient co-morbidities	41*	N/A
	Previous use of a specific antidepressant	46*	N/A
	Use of other medications which might interact with an antidepressant	34*	N/A
	Local/national guidelines	36*	N/A
	Other reasons	12*	N/A
	* Average score assigned based on order in which option was ranked against others		
If choosing antidepressants or other medication, what is your preferred first line?	SSRI	63	100

A significant proportion (68.3%) favoured a combination of both antidepressants and talking therapies and would share the options with patients followed by 41.2% who would consider just talking therapies initially. Antidepressants alone would only be used by about 14.3% of GPs. If prescribing, 100% of GPs would prescribe an SSRI as their first-line drug and the reason for this choice is due to its safety profile. Other factors influencing prescribing include – in that order – previous response to treatment, patient comorbidities, the existence of guidelines which clinicians could refer to and drug interactions.

When asked what influences their management plan, 61.9% of GP respondents aimed for a shared management plan which took into account patient preferences, while in 12.7% of cases, time pressure meant that a clinician would decide for the patient. Talking therapies was not seen as being an easily accessible option by 23.8% of GPs.

Combination therapy including dual antidepressant use

In cases where an SSRI did not benefit a patient (assuming compliance and optimal dosing), a further consultation to agree on a better option would be carried out in most instances (88.9%). An equal number (25.4%) stated that they would consider either adding in an alternative antidepressant or offering an alternative medication (such as a different antidepressant or non-antidepressant medication such as beta-blockers, anxiolytics, or sedatives). In those combining treatment, the most favoured medication to be considered as an add-on was Mirtazapine (41.5%) as an antidepressant, and a beta-blocker as a non-antidepressant (41.5%).

The rationale for using combined pharmacotherapy was to help further with symptom management including insomnia and anxiety when the patient was already established on an adequate dose of a first-line antidepressant. The responses are summarised in Table 3.

Table 3: Use of combination therapy including dual antidepressants

Question	Response	Number	%
Do you feel comfortable combining additional antidepressants/other medication?	Yes	34	54.0
	No	29	46.0
If yes, what would be your choice of add-on medication – assuming there is no contraindication? (N=34)	Mirtazapine	22	41.5
	Anxiolytics	3	5.7
	Venlafaxine	4	7.5
	Sedative	2	3.8
	Beta Blocker	22	41.5
If you were choosing to add in a second antidepressant what would be the rationale? (N=33)	Symptom management e.g. insomnia, anxiety	23	35.9
	Patient already on a decent dose of first antidepressant	22	34.4
	CBT not working	8	12.5
	On (and only on) advice of mental health team	8	12.5
	Not applicable – I do not feel comfortable prescribing combination medication	3	4.7
What makes you comfortable using a combination of antidepressants? (N=31)	Experience in dealing with similar patients over many years as a GP	21	28.0
	Previous training in psychiatry	13	17.3
	Attending online lectures/online courses/local mental health updates	10	13.3
	Advice from mental health team colleagues	18	24.0
	Local guidelines	11	14.7
	Not applicable as I am not comfortable using a combination	2	2.7
If you are not comfortable prescribing a second antidepressant, is it because of: (N=29)	Lack of experience in this area of mental health	12**	N/A
	Lack of access to timely advice/guidance from the local mental health team	8**	N/A
	Local guidelines advise not to use combination of antidepressants in primary care	11**	N/A
	Concerns about side-effects, interactions, etc	15**	N/A
	Not applicable as I am not comfortable doing this	6**	N/A
	** Average score assigned based on order in which option was ranked against others		

Owing to their previous experience, a fair proportion of GPs (at least 33.3%) surveyed were comfortable with a combination of antidepressant drugs. The most common reasons that would deter from combination therapy with 2

antidepressants are – in that order – concern about side-effects/interactions, lack of experience, paucity of guidelines, and lack of timely access and guidance from the local mental team.

A large proportion of GPs (74.6%) would be open to the idea of initiating a second antidepressant if appropriate education/resources were provided by secondary care. Nearly all (98.4%) GP participants would agree to prescribe dual antidepressants on advice of the mental health team – the medium of telephone (65.1%) seemed to be preferred followed by written advice (33.3%) either in the form of a letter or by email.

Discussion

Our study aimed to evaluate the confidence of GPs in diagnosing and managing depression, and to assess the factors influencing their strategy in treating depression. The use of an online survey which was distributed electronically allowed us to capture the views of a cross-section of practising GPs in a relatively wide geographical area of Teesside in the North-East of England, UK. Our primary care colleagues surveyed tend to rely on similar drug formularies, local guidelines and have access to the same mental health services (overseen by the Tees, Esk and Wear Valley Foundation NHS Trust).

Comparison of findings with existing literature/guidance
Most people with depression are managed in primary care in the UK (9). In our survey, most doctors (80.9%) felt confident in diagnosing depression but the wide heterogenous nature of this condition and associated presentation of patients made it less easy to always to certain about and label the condition.

Antidepressants are generally more effective for moderate or severe depression and less so for mild depression, for which active monitoring, physical activity, psychological therapies and/or social prescribing are preferred (6,7). Many patients with depression are likely to benefit from talking therapies but this is not always available. In the North-East of England, the Improving Access to Psychological Therapies (IAPT) programme has expanded in the last decade or so of its existence and psychological interventions can now benefit more people who can self-refer.10 In spite of this, talking therapies was not seen as being easily accessible by 23.8% of GPs in the study, although it is unclear whether this is to do with the way services are organised or patient and clinician expectations, which may both be influenced by waiting times. As a consequence, antidepressants are still widely prescribed.

NICE guidance (5) recommends that several factors are considered when prescribing antidepressants – these include age, side-effects, potential interactions, comorbidities, previous response to medication and potential harm from overdose or discontinuation symptoms. An SSRI is generally advised first-line. This was evident in the response of all 63 GPs surveyed who would prescribe an SSRI in the absence of any obvious contraindication. Only about 50-60% of people who are treated with an adequate dose of an antidepressant for long enough show a demonstrable response (11,12). NICE further recommend that for people who do not respond, a dose increase or a switch (within the same class or to a different one) can be considered, especially if there are any side-effects (5). Vortioxetine is also a possible option for those who have not responded adequately to 2 different antidepressants (13).

Another possible strategy is that of antidepressant augmentation with lithium, an antipsychotic or another antidepressant such as Mirtazapine (14). NICE advise against the combination of antidepressants without first seeking advice from a psychiatrist (5). The use of benzodiazepines for more than 2 weeks alongside an antidepressant is generally not advised due to the risk of dependency, but benzodiazepines can be a useful adjunct in certain cases such as insomnia or increased anxiety either during initiation of or withdrawal from/switch of an antidepressant (5).

In our study both adding in another antidepressant and the switch to a different antidepressant or non-antidepressant medication such as a beta-blocker were equally favoured (41.5% in both instances). Mirtazapine was commonly cited as the second antidepressant of choice if a combination strategy with 2 antidepressants was adopted. There is some evidence on the efficacy of combining two antidepressants (15-18). However, it is interesting to note that a more recent trial in UK primary care failed to show any clinically important benefit of adding Mirtazapine to existing antidepressant treatment (9).

Contrary to NICE guidance which advises against the combination of antidepressants in primary care without liaising with specialist mental health services, it was interesting to note that at least 33.3% of total GPs surveyed felt comfortable initiating this strategy unsupervised based on their previous experience (either within primary care or previous training in psychiatry). With help from secondary care (telephone or written correspondence such as letters or email), almost every single GP surveyed would be happy doing so.

Combination therapy is not without its own risks though (19). There is the risk of serotonergic toxicity depending on combination used as well as less serious side-effects such as weight gain, sedation, dizziness, hypotension to name just a few.

Implications for practice
In order to allow patients – especially those who are more resistant to initial treatment – to be managed appropriately and for GPs to continue to practice within an acceptable regulatory framework, it is important for proper channels to exist at the primary and secondary care interface. In our survey, 15.4% of the GPs did not think that help/advice could be obtained in a timely manner. There was a two-fold preference for telephone advice compared to written advice, and this is something that can be used by health

commissioners in either shaping existing or implementing triage and guidance services at secondary care level. With the changes brought about by the creation of primary care networks (PCNs) and the expansion of its workforce by the creation of additional roles, it will now also be possible to employ mental health practitioners who may act as a liaison between primary care and secondary mental health services (20). Social prescribers are already operating as part of PCNs and there is emerging evidence that social prescribing can help to improve mental well-being and lead to a reduction in depression and anxiety (21).

Empowering GPs by providing access to suitable training and resources will also allow healthcare professionals in primary care to be become more confident in independently overseeing the management of depression (e.g. specialist interest in mental health training posts, regular educational events aimed at GPs led by secondary care colleagues, producing new or revamping existing local primary care guidelines on the management of depression, etc.)

Limitations and potential areas for future research

This study relied on GP colleagues reporting what their preferred strategy would be based on their experience. What was not looked at in any detail are factors such as existing specialist interest in mental health problems, length of experience as a practising GP, where the practice is situated and associated patient demographics such as level of deprivation (which can influence severity of depression and availability/choice of treatment), and details regarding the ease of access to mental health services which may vary across the North-East. These factors can all influence the way mental health issues are managed in primary care.

The survey also did not allow respondents to offer any detailed written views on how they think they can best be supported in their role. Other areas that were not looked but which could be explored in future include which second-line antidepressants are used, the length of time spent in consultations (seeing more than a third of GPs wanted a shared management plan), and the experience and role of GPs in prescribing other augmentation strategies such as antipsychotics and lithium (which we suspect will be largely directed by secondary care).

This piece of research has also focussed on patients who newly present with depression. General practice is more complex than this and there is often a large group of patients with treatment-resistant depression – this is another area that could be looked at and the findings compared to existing research (22).

Conclusion

This study adds to the existing literature on what influences the management of depression in primary care. The GPs who participated felt reasonably confident in diagnosing and initiating the management of depression with most normally sharing the decision with patients. NICE guidelines are followed when it comes to initial prescribing as the safety profile of medication and patient comorbidities – amongst various factors – are kept in mind, but it was surprising to note that a fair proportion of GPs felt comfortable combining two antidepressants without involving the mental health team which is at variance with NICE guidance. The skills mix and experience of practising GPs surveyed may partly explain this. It is clear that despite this, more support – either in the form of educational or training opportunities, or by easier access to advice, especially by phone – would make a difference to the confidence and ability of GPs in managing depression in primary care. The results of this study can help to inform any restructuring of local health services to allow closer co-operation between primary care and secondary mental health services.

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Appendix 1 - Questionnaire

Questions:

Choose the most appropriate answers (you may choose more than one response)

1. How comfortable are you making a diagnosis of depression?
a. Very
b. In most instances
c. Only in some instances
d. Not at all

Supplementary Q – Do you categorise depression as Mild/Moderate/Severe in routine appointments? Y/N

2. Are there any circumstances where you might question your diagnosis of depression?
a. No improvement with antidepressants and/or CBT
b. Multiple consultations on the part of the patient despite objective improvement
c. Other features making the diagnosis less clear-cut e.g. mania, hypomania, anxiety, personality traits, etc.
d. Patient rejecting the diagnosis
e. Lack of confidence in making the diagnosis
f. Other? ……

3. What is your preferred initial management plan in mild-moderate cases of depression when someone is at low risk?
a. Refer to IAPT services/talking therapy
b. Start on antidepressants
c. Start other medication e.g. hypnotic
d. Start Antidepressant and hypnotic/other meds
e. Both IAPT services/talking therapy and antidepressants are suggested and the patient decides after discussing the options
f. Refer to secondary care services

4. What influences your management plan?
a. Level of confidence with the prescription of and overseeing the management with antidepressants
b. CBT is more likely to be useful and is not associated with side-effects
c. IAPT services/talking therapy are not easily accessible where I work
d. Shared-management is something I strive for in my practice
e. Time constraints – I choose what I think is more likely to suit the patient's needs

5. If choosing antidepressants or other medication, what is your preferred first-line?
a. SSRI
b. SNRI
c. TCA
d. Sedatives
e. Anxiolytics
f. Beta-blocker

6. What are the factors that make you more likely to choose a particular antidepressant?
Please rank your choices from a to f
a. Safety profile of medication/side-effects
b. Patient co-morbidities
c. Previous use of a specific antidepressant
d. Use of other medications which might interact with an antidepressant
e. Local/national guidelines
f. Other reasons

7. If someone does not show any real improvement with a particular medication, what is your preferred next step?
a. Detailed chat with patient covering expectations, efficacy of medication, dose change, compliance, possible use of counselling (if not already having)
b. Offer alternative medication e.g. different antidepressant, sedative, anxiolyics, beta-blocker
c. Add in another antidepressant
d. Refer to secondary care for the patient to be seen
e. Seek advice/guidance from secondary services through other channels e.g. telephone discussion, email correspondence, etc.

8. Do you feel comfortable combining additional antidepressants/other medication?
a. Yes
b. No

9. If yes, what would be your choice of add-on medication (assuming there is no contraindication)?
a. Mirtazapine
b. Anxiolytics
c. Venlafaxine
d. Sedative
e. Beta-blockers

10. If you were choosing to add in a second antidepressant what would be the rationale?
a. Symptom management e.g. insomnia, anxiety
b. Patient already on a decent dose of first antidepressant
c. CBT not helping
d. On (and only on) advice of mental health team
e. Not applicable (I do not feel comfortable prescribing combination medication)

11. What makes you comfortable using a combination of antidepressants?
a. Experience in dealing with similar patients over many years as a GP
b. Previous training in psychiatry
c. Attending online lectures/online courses/local mental health updates
d. Advice from mental health team colleagues
e. Local guidelines
f. Not applicable as I am not comfortable using a combination

12. If you are not comfortable prescribing a second antidepressant, is it because of:
a. Lack of experience in this area of mental health
b. Lack of access to timely advice/guidance from the local mental health team
c. Local guidelines advise not to use combination of antidepressants in primary care