

Evaluation of Therapeutic Methods used for the Treatment of Diabetic Foot Syndrome

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Abstract

Objective: Recent studies have shown a rampant increase in the number of patients with diabetes around the world. This constitutes an economic burden on the resources of states and hence has prompted many international organizations to devise awareness and educational programs about the dangers of this the disease and ways to deal with it. There are serious complications to diabetes which may include; high blood pressure, heart and kidney diseases, eye problems, neuropathy, and diabetic foot. The most feared development of this disease is the diabetic foot as it may lead to amputation. This study examines the prevalence of diabetes and complementary alternative medicine in the treatment of this disease and the attitudes toward managing diabetic foot in Makkah and Taif area in Saudi Arabia. **Methods:** Questionnaires were distributed in the Western region of Saudi Arabia. The sample size was 750. Responses were collected and proper descriptive statistical analysis was applied. **Results:** An alarming 34% of respondents have diabetes, 74% of surveyed population has diabetes within family members, and 40% of respondents have had a form of foot problem with the highest incident of leg pain and numbness. The majority of examined population has chosen traditional medical intervention rather than herbal medicine in dealing with foot problems. **Conclusions:** The culture of interfamily marriages has to be overlooked to curb rampant increase of diabetes incidents among family members. There is lack of statistical data related to the incident rate of lower-extremity amputations LEA among patients with diabetes in Saudi Arabia. Moreover, the role of diabetic centers has to be invigorated in spreading knowledge with regards to diabetes, and in devising proper follow-up procedures to patients with diabetes after referral to other departments in hospitals.

Key words: Amputation, complementary alternative medicine, diabetic foot, products for foot care, self-foot care

INTRODUCTION

There is a rampant increase in the number of patients with diabetes worldwide. According to the World Health Organization (WHO) 2015 statistic, the number of people with diabetes has risen from 108 to 422 million from the year 1980 to 2014.^[1] According to 2012 statistic, 29.1 million Americans or 9.3% of the population have diabetes, 86 million Americans at the age of 20, and older have pre-diabetes.^[2] There are 4.5 million people in the UK diagnosed with diabetes,^[3] and this number will rise to 5 million people by 2025 if trends continue.^[4] The prevalence of diabetes in Saudi Arabia reveals that about 25% of Saudis over 40 years of age have diabetes;^[5] more than 3 million individuals in Saudi Arabia are diagnosed with

diabetes.^[6] These alarming figures should put an immense pressure on governments to devise and implement national plans for diabetes, to increase levels of risk assessment and earlier identification of diabetes, to increase awareness of the signs and symptoms of diabetes, to organize public awareness campaigns to convey risk factors of diabetes and its complications, to provide access to education for all people diagnosed with diabetes, to deliver high caliber of

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nationally agreed standards of care, and to monitor diabetes care and outcomes.

There are two types of diabetes: Type 1 diabetes develops when the body cannot produce any insulin. It usually appears before the age of 40, especially in childhood. It is the less common of the two types of diabetes. Type 2 diabetes develops if the body can still make some insulin, but not enough, or when the body's cells have a diminished ability to respond to the action of produced insulin which is known as insulin resistance syndrome. Both types of diabetes can be treated and managed by healthful eating, regular physical activity, losing excess weight, and medications to lower blood glucose levels. Type 1 diabetes is treated by daily insulin doses by injections or through an insulin pump, whereas in Type 2 diabetes tablets and/or insulin can be required. Different methods are used to treat diabetes which can be broadly classified into: Use of medication, surgical intervention, physical exercises, diet control, homeopathic remedies, and pharmaceutical food supplements. Nonetheless, there is a growing interest among patients with diabetes to use oral natural products and herbs as part of complementary and alternative medicine (CAM).^[7-9] Traditional medicines derived from the botanical source are used by about 60% of the world's population as it is believed to be safe, cheap, and effective.^[9] The use of herbal plants for the treatment of diabetes mellitus (DM) is reviewed by Mohana *et al.*^[10] In a study carried out in Mecca by Al-saeedi *et al.*^[11] has shown that 30% of patients with diabetes are reported to have used herbal medicine to treat diabetes. The most commonly used herbs by patients were Fenugreek (6.1%), Chinaberry leaves (5.1%), and Harmal (Rhazya Stricta, 4.9%). A similar study conducted in Turkey^[12] has shown that 25% of patients with diabetes reported herb use. The herbs mostly used by patients were nettle (28%), thyme (27%), parsley (12%), and jujuba (12%). Therefore, there are wide varieties of herb species used for diabetes which are known demographically in each part of the world. In China, 200 special herbs were used to treat diabetes such as pumpkin, wheat, lotus root, and bitter melon.^[13] In India, herbs such as *Momardica charantia* Linn and *Trigonellafoenumgraecum* were accepted scientifically to exert antidiabetic effects.^[14] On the other hand, magnesium deficiency has been linked with chronic diseases, among them, diabetes mellitus.^[15] The average ingestion of magnesium worldwide is frequently below the recommended dietary allowances, which induces the development of magnesium deficiency.^[16] Studies had shown relation between the ingestion of food rich in magnesium and the reduction of risk of diabetes and its complications.^[17] Hypomagnesemia is usually observed in patients with diabetes with deficient metabolic control or associated with the DM chronic complications.^[18] Therefore, metabolic studies have suggested that magnesium supplementation has a beneficial effect on insulin action and glucose metabolism.^[19,20] It is thought that magnesium supplementation can correct the deficit in intracellular free magnesium levels, decrease platelet reactivity,

improve insulin sensitivity, protect against diabetes and its complications, and reduce blood pressure.

Diabetes can affect many parts of the body and is associated with serious complications such as heart disease and stroke, neuropathy, nephropathy, retinopathy, and diabetic foot syndrome (DFS). DFS, as defined by the WHO, is an "ulceration of the foot (distally from the ankle and including the ankle) associated with neuropathy and different grades of ischemia and infection." The primary cause of foot ulcers appears to result from minor trauma in the presence of sensory neuropathy.^[21] Successful treatment of diabetic foot ulcers comprises addressing these three basic issues: Debridement, off-loading, and infection control. Foot disorders are among the most feared complications of diabetes^[22] as it may lead to lower-limb amputation if not well treated. The most common cause of hospitalizations among patients with diabetes is DFS, including ulcerations, infections, and gangrene.^[23] The risk of such complications increases in the geriatric population as older adults with diabetes are more likely to have multiple chronic diseases and morbidities^[24] Diabetes is estimated to be the primary causative factor in 45% of all lower extremity amputations (LEA) and 60% of non-traumatic amputations due to long-term complications of diabetes.^[25] The incidence of open wounds in patients with diabetes is very high and affects 1 of every 6 patients.^[25] These non-healing "diabetic ulcers" are the major cause of leg, foot, and toe amputations. In the UK, more than 125 amputations are carried out weekly, up to 80% of these are potentially preventable if people receive the correct management.^[26] The cost and burden of care for diabetic foot problems are substantial. It is estimated that between £600 and £700 million are spent each year on foot ulcers and amputations in the UK. Diabetes mellitus is one of the most common chronic diseases in the UK and its prevalence is increasing. By 2025, it is estimated that more than 4 million people will have diabetes. In 2009, in the UK, the number of people estimated to have either Type 1 or Type 2 diabetes was 2.6 million, a prevalence of 4%, with 1.9 million actually being registered as having diabetes. Type 2 diabetes is up to six times more common in people of South Asian descent, and up to three times more common in people of African and African-Caribbean origin. The life expectancy of people with diabetes is shortened by up to 15 years, and 75% die of macrovascular complications. The annual incidence of diabetic foot ulceration in the UK varies from 1.0 to 3.6%, with a prevalence of 5%. After a first amputation, people with diabetes are twice as likely to have a subsequent amputation as people without diabetes. Mortality rates after diabetic foot ulceration and amputation are high, with up to 70% of people dying within 5 years of having an amputation.^[27] In 2012, in the USA, nearly \$245 billion was spent annually in direct and indirect medical costs related to diabetes care.^[28] A study by Al-Tawfiq and Johndrow^[29] in Saudi Arabia concluded that patients with diabetic foot ulcers require intensive care management to reduce morbidity and mortality associated with major amputations in patients with diabetes. In 2002, the diabetic foot care program was

implemented at King Abdulaziz Medical City in Riyadh as comprehensive approach for diabetes foot care to reduce the lower-limb amputation rate and hence reduce the cost to patients, society, and the health-care system. A study by Al-Wahbi^[30] evaluating the program has concluded that it has increased the awareness of both patients and health-care staff concerning the prevention and management of diabetic foot disease and decreased the rate of LEA. In this regard, it has been reported that being aware of patients' knowledge about this condition and its treatment process may act as an aid in the prevention and the treatment of this disease.^[31,32] Aliasgharpour and Nayer^[33] has concluded that self-management of DFS is influenced by patients' experience, awareness, and attitudes [Figure 1]. On the other hand, to attain wound healing and thus circumventing amputation, correct disease management, patient's knowledge, and continuity of care have to interplay [Figure 2].

In this study, knowledge about complications of diabetes and methods of preventing these risks are assessed. The prevalence of using herbal medicine as a part of CAM is also investigated to assess the perception around their claimed use in reducing glycemic index and mitigating diabetes complications. Furthermore, self-management of DFS among patients with diabetes in Taif area will be also evaluated while focusing on the role of foot diabetic centers in disseminating knowledge about the prognoses, follow-up, and preventive measures with regard to diabetic foot ulcers. Furthermore, the various methods and pharmaceutical product used for the treatment of diabetic's patient's foot is highlighted. The relationship between physicians, pharmacists, and other health-care professions is also investigated to better estimate the problematic of diabetic patient foot.

METHODS

Sample

This study was performed at the Western region of Saudi Arabia. The sample size was 750. Questionnaires were distributed to the public, patients, physicians, and pharmacists at governmental hospitals, health-care centers under the Ministry of Health (MOH) Administration, in addition to private clinics and pharmacies.

Data collection methods

The questionnaire was prepared in Arabic language and then was translated into English language; a total number of 20 questions were prepared. The data which are used for fulfilling the purpose of this study is divided into two groups; primary data collected from researchers and expert interviews and questionnaires distributed to the general public. Secondary data is collected from journals, books, theses, dissertations, articles, and World Wide Web.

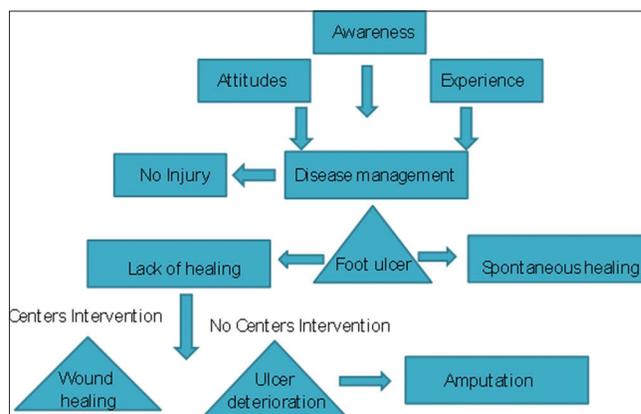


Figure 1: The relationship between experience, awareness, attitude, disease management, and ulcer modified from reference^[33]

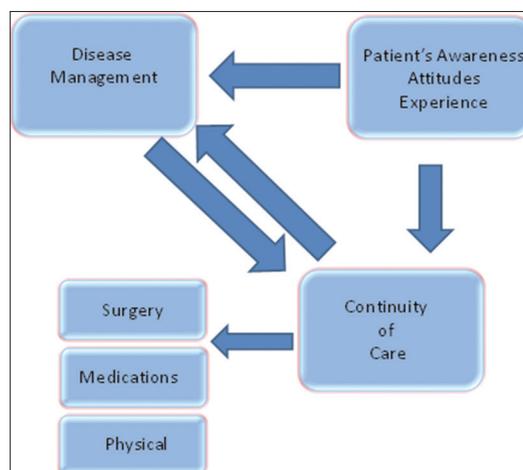


Figure 2: The relationship between continuity of care, disease management, and patient experiences

Study measures

The questionnaire includes three main sections; the first part highlights the prevalence of diabetes among respondents. The second part identifies the various foot care products and methods which are used for the treatment of diabetic foot. The third part highlights the role of diabetic foot centers in raising the awareness of DFS. Completed questionnaires are checked for completion. The responses were coded against google scholar website.^[34] Each variable is tested separately to explore its importance and proper descriptive statistical analysis was applied.

RESULTS AND DISCUSSION

Certainly, there is no profound statistics highlighting diabetes and its complications in the Arab world. This puts governments under immense pressure on the actual cost of care of diabetes and its complications. Diabetic foot ulcers, amputation, neuropathy, peripheral vasculopathy, and retinopathy are among serious complications of diabetes. Ahmed *et al.*^[35]

have summarized the prevalence of diabetic foot problems in Arab countries based on available statistics which need more updating. In this investigation, collected data which highlights the demographic prevalence of diabetes, diabetic foot problems, approaches of treatment, foot care products, and role of diabetic foot centers from a total of 750 questionnaires were received and analyzed. Data of respondents were tabulated and results were plotted as shown below.

Personal profile of respondents

As Figures 3-22 shows about 44% of respondents were in the age group of 18-25 years [Figure 3], 53% of the survey respondents were male [Figure 4], 9% of respondents work in the field of health, whereas the 29% works in private and public service sector [Figure 5], and large proportion of respondents hold university degree [Figure 6].

Prevalence of diabetes among respondents

An alarming 34% of respondents have diabetes [Figure 7], of which 58% have Type 2 and 36% with Type 1 [Figure 8]. Almost 30% of patients with diabetes in this survey have had the disease for almost 5 years [Figure 9]. Striking 74% of surveyed population has diabetes within family members

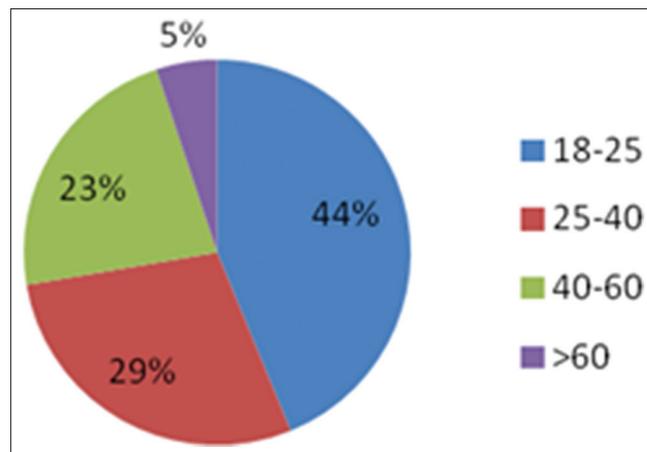


Figure 3: Age range of respondents

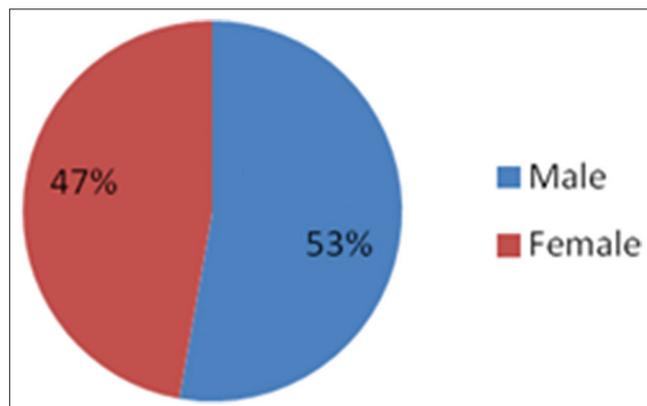


Figure 4: Gender of respondents

[Figure 10]. This reflects the high and alarming prevalence rate of diabetes and its hereditary predisposition in Saudi Arabia. It is confirmed from accumulated data over the past three decades that Type 2 diabetes in KSA is epidemic.^[35] According to the report in 2014 by Centers for Disease Control and Prevention, the total diagnosed and undiagnosed diabetes in the United States are 29.1 million, 9.3% of the population.^[2] Furthermore, according to the International Diabetes Federation (IDF),^[36] KSA is number 6 of the top ten countries for the prevalence of diabetes and is expected to continue in the coming two decades with the prevalence rate of 20.0% in the age group 20-79 years. This percentage is almost similar to the Saudi MOH report. Other countries in the “top-ten” include Kuwait 21.1%, Lebanon 20.2%, Bahrain 19.9%, and United Arab of Emirates 19.2%.^[36] Nonetheless, as our data suggests, we think that the proposed prevalence rate of 20% in Saudi Arabia is a low estimate of the real accumulated number of patients with diabetes in the age group 20-79 years. In a study by Alqurashi *et al.*, in 2011,^[37] of 6024 participants, diabetes mellitus was present in 1792 patients, i.e., 30% which highly conforms well with our results 34%.

Foot condition among surveyed population and applied method of treatment

Diabetic foot problems, such as ulcerations, infections, and gangrene, are the most common cause of hospitalization

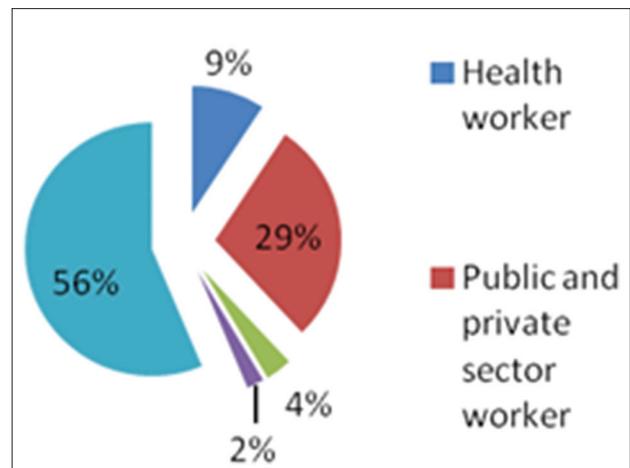


Figure 5: Occupation of respondents

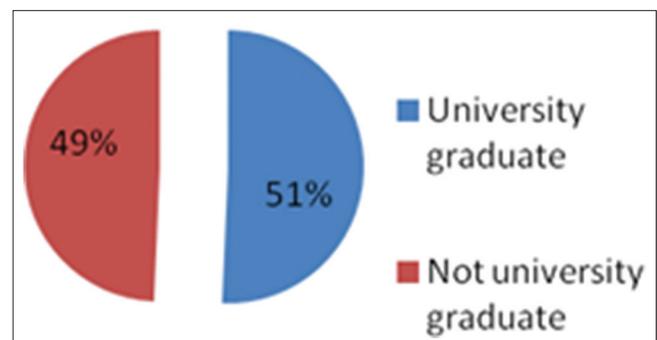


Figure 6: Education level of respondents

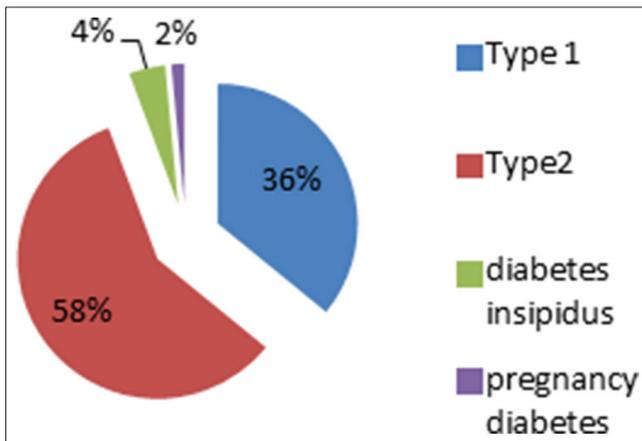


Figure 7: Diabetes prevalence of respondents

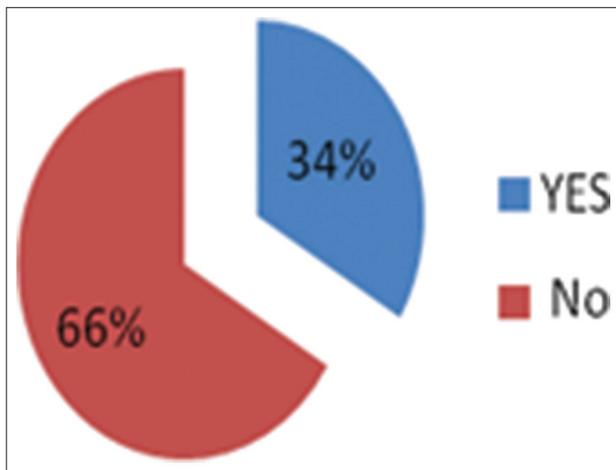


Figure 8: Type of diabetes

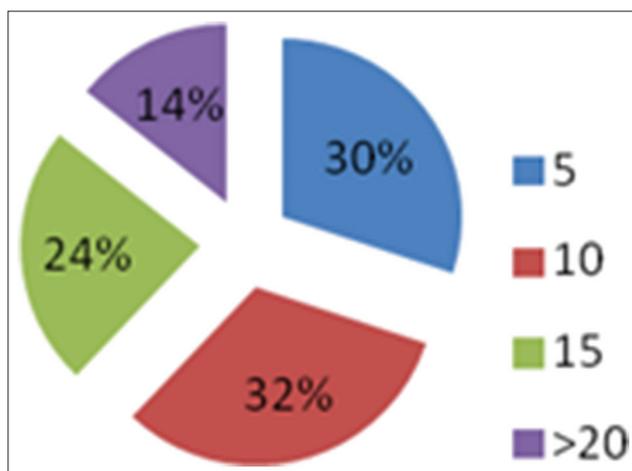


Figure 9: Number of years with diabetes

among patients with diabetes which may lead to amputation. The risk of ulceration and amputation among patients with diabetes regardless of the type of diabetes increases by 2-4 folds with the progression of age and duration of diabetes.^[38] Foot ulceration can be prevented by almost up to 70% through programs that could reduce its risk factors, where simple interventions can reduce amputations.^[39] As

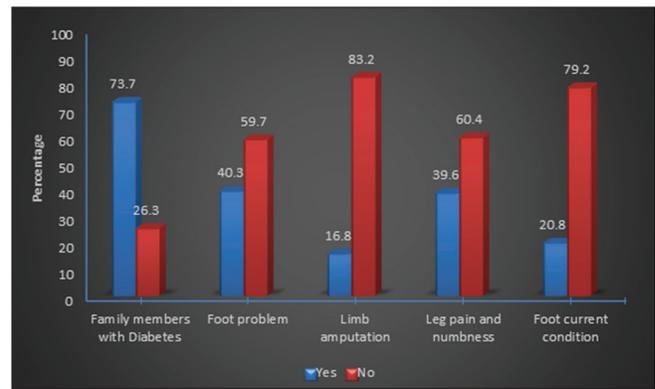


Figure 10: Current condition of patients with diabetes among surveyed population

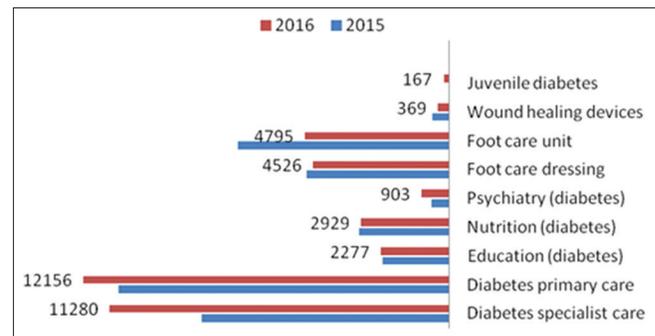


Figure 11: Comparison of the number of visits of patients with diabetes to the various units in Al Noor diabetic center between 2015 and 2016

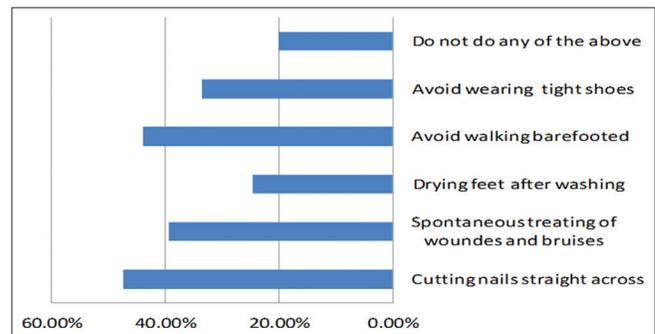


Figure 12: Type of foot health care

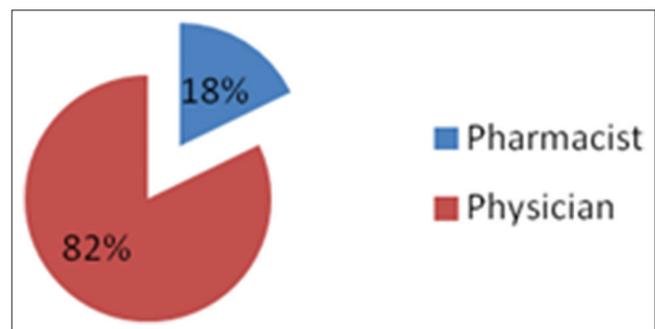


Figure 13: Type of consultant profession

Figure 10 suggests, 40% of respondents have had a form of foot problem with highest incident of leg pain and numbness.

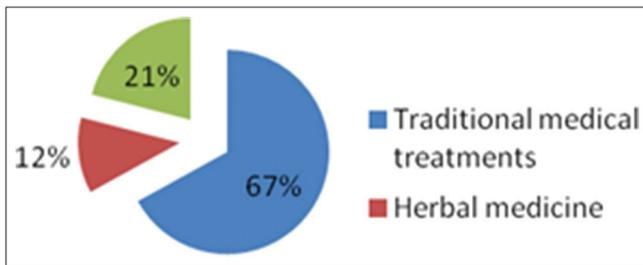


Figure 14: Preferred treatment method

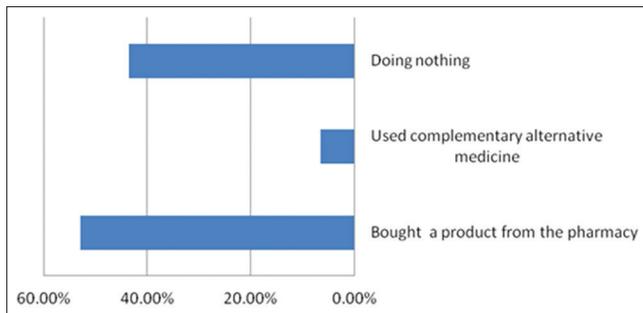


Figure 15: Applied treatment for foot problems

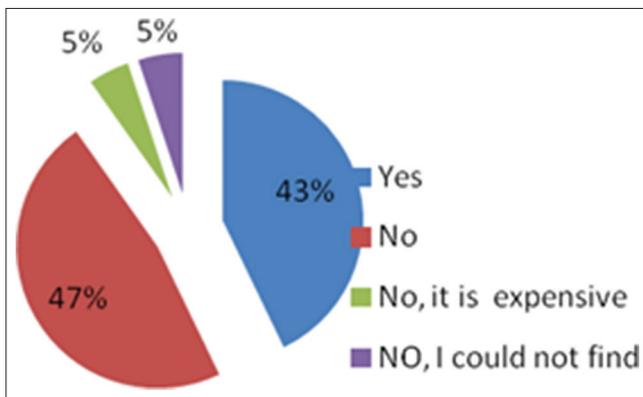


Figure 16: Products used for foot care

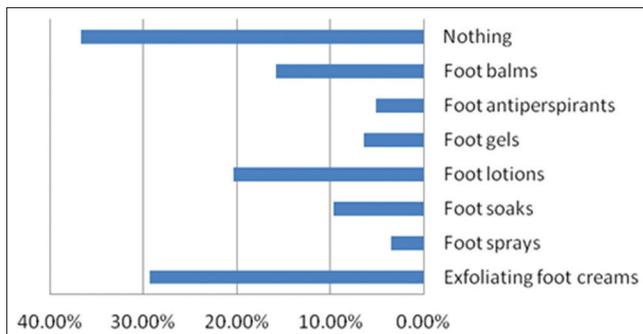


Figure 17: Preferred foot care products

17% of the surveyed population has stated that they know someone who has had limb amputation as a result of diabetes complication. This reflects the severity and the complicated dimension of the diabetic foot problem in Saudi Arabia. It seems to be that the majority of surveyed population has dry feet with no ulceration.

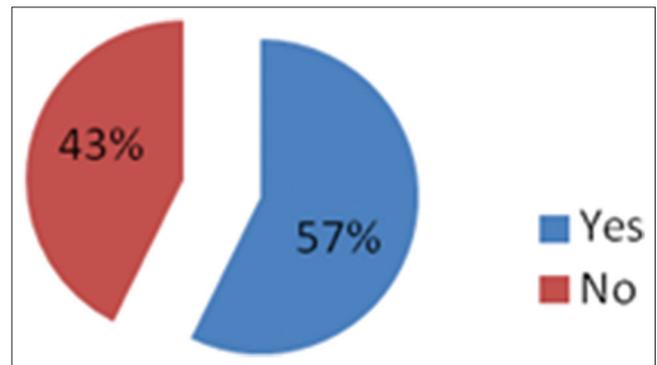


Figure 18: Patients' satisfaction of foot care products

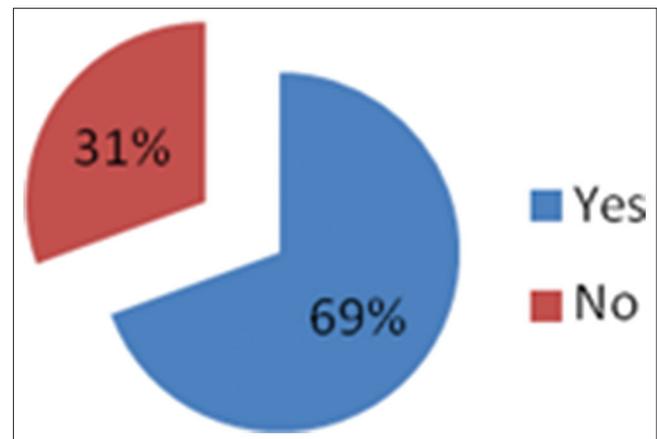


Figure 19: Effectiveness of treatment

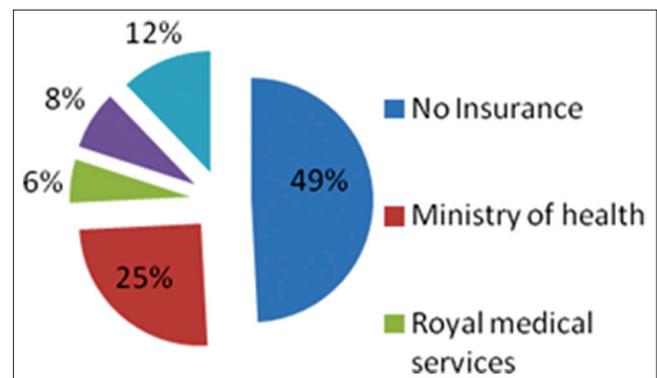


Figure 20: Type of insurance

Four diabetic centers were contacted in four tertiary hospitals in the Western region of Saudi Arabia. Diabetic centers in Al Noor Specialist Hospital in Makkah the Holy city, King Abdulaziz Specialist Hospital in Taif, Prince Mansour Military Hospital in Taif, and in King Faisal Specialist Hospital in Jeddah. At the end, we were able to obtain statistical data with regards to patients with diabetes from diabetic centers in Al Noor and King Abdulaziz Specialist Hospitals. Figure 11 shows number of visits of patients with diabetes to the various units in Al Noor diabetic center between 2015 and 2016. There are more than 7000 visits by patients to the foot care unit in 2015 in comparison to 4800

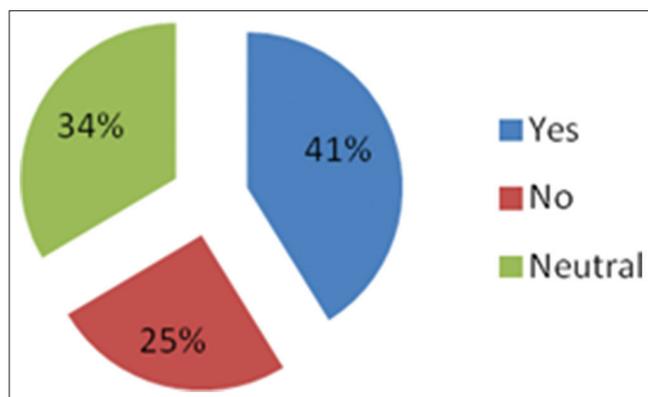


Figure 21: Performance of diabetic foot centers

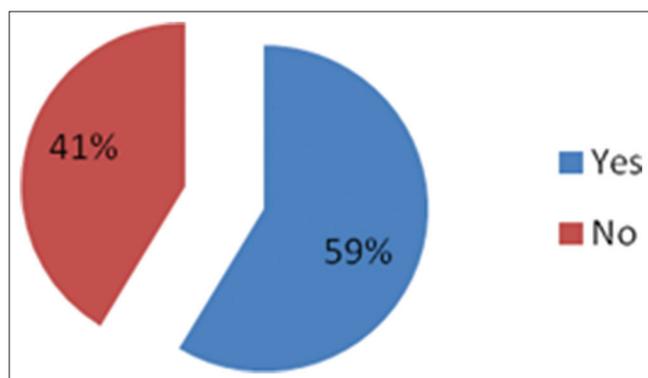


Figure 22: Availability of educational and counseling programs

visits in 2016. This reduction in the patient's number of visits to the foot care unit in 2016 might be due to the increase in awareness among patients with diabetes with regards to the complications to the DFS. Nonetheless, there are more than 4500 visits to the foot care unit for dressing due to inflamed foot ulcers. Yet, there are no records of the number of patients who have been referred to the surgery department for further actions. This suggests the lack of following up procedures in the case of patients whom have been referred to other departments in the hospital. Moreover, data obtained from the registry at the diabetic center in King Abdulaziz Specialist Hospital in Taif showed that, in the year 2016, they had 4300 visits by 175 patients registered with diabetic foot ulcers. Their records had shown that four patients had LEA in 2016. King Abdulaziz University Hospital (KAUH) is a tertiary care general hospital in Jeddah city with a bed capacity of 650. A retrospective study over a 5-year-period (January 2004-December 2008) by Alzahran^[40] reported 222 diabetes-related lower-limb amputations performed in KAUH. This means that approximately 45 amputations were performed on patients with diabetes per year. In this study, nonetheless, it was difficult to predict the incidence of LEA rate for patients with diabetes who live in the Western part of Saudi Arabia due to the absence of national registry or official data for diabetes-related amputations in KSA. There is, however, confusion about LEA rate related to diabetes in Saudi Arabia, yet a prevalence rate value of 1.06

is being reported,^[41] however, there is no studies showing LEA incidence rate. LEAs are a crucial indicator for the quality of care of diabetes in a population.^[42] There is a large variation in LEA incident rates in different communities, ranging from 0.461 to 96/1000 people with diabetes.^[43] The incidence of LEA is 4 in the USA,^[44] 2.5 in the UK,^[45,46] 1.75 in the Republic of Ireland,^[47] and 3.2 in the Canary Islands in Spain^[48] per 1,000 person-years in people with diabetes.

The majority of the respondents choose the option of cutting nails across or avoid wearing tight shoes or avoid walking bare footed as measures for foot care [Figure 12]. This shows the awareness among patients with diabetes about preventive measures related to complications of diabetic foot. This awareness is also manifested in the type of consultant the surveyed population has chosen for foot-related problem as the majority of respondents opt for a physician for consultation [Figure 13]. This, however, reflects the education level of the tested sample as 50% hold university degree. This level of education is also reflected in the preferred applied treatment method as the majority of examined population has chosen traditional medical intervention rather than herbal medicine or random use of pharmaceutical foot care products in dealing with foot problems [Figure 14].

More than 40% of respondents have stated not to do anything or not to use any form of foot care products in dealing with foot problems related to diabetes. This, however, reflects the fact that there is still yet some ambiguity and compromised understanding with regards to the seriousness of diabetic foot complications [Figure 15]. Moreover, it appears that types, proper use, and benefits of foot care products in the treatment of foot-related problems are not clear enough among surveyed population as, more than 47% of respondents stated not to have used foot care products [Figure 16]. Figure 17 presents the preferred foot care products of respondents, most of patients preferred doing nothing and <30% preferred the exfoliating foot creams. This obviously stems from the fact that there is no education or awareness available for patients with diabetes with regards to the various types of available foot care products which highlights their importance as preventive or curative treatment for foot ulcers. Nonetheless, there is a large segment of the surveyed population which has stated improvement in their foot-related problem due to direct medical intervention [Figures 18 and 19]. Large segment of the surveyed population almost 50% has no insurance which will have serious impact on the prognosis and complication of patients with diabetes [Figure 20].

Although there are positive feelings and contentment toward the role of diabetic centers in serving diabetic population as it is evident from Figures 21 and 22, the role of diabetic foot centers has to be invigorated and focused in disseminating knowledge among patients with diabetes and health workers to avoid serious complication of the disease. This is achieved by increasing number of educational and counseling programs to reach out and get the message across to the

diabetic community. Yet, the role of diabetic foot centers needs to be more effective in spreading the knowledge to patients with diabetes with regards to the implementation of best practices to prevent the deterioration of foot-related problems associated with the disease. Studies have shown that by providing continuous health education by the health workers, gap between knowledge and practice regarding self-care among diabetic patients can be bridged.^[49]

CONCLUSIONS AND RECOMMENDATIONS

An alarming 34% of respondents have diabetes, which is 1.5 fold higher than the projected rate by IDF, 74% of surveyed population has diabetes within family members and 40% of respondents have had a form of foot problem with highest incident of leg pain and numbness. The majority of examined population has chosen traditional medical intervention rather than herbal medicine in dealing with foot problems. The culture of interfamily marriages has to be overlooked to curb the rampant increase of diabetes incidents among family members. There is lack of statistical data related to the incident rate of LEA among patients with diabetes in Saudi Arabia. Moreover, the role of diabetic centers has to be invigorated in spreading knowledge and counseling programs with regards to diabetes to prevent complications, and in devising proper follow-up procedures to diabetic patients after referral to other departments in hospitals. Therefore, suitable regulations have to be enforced for better coordination between diabetic centers and the other departments in hospitals.

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