CODEN [USA]: IAJPBB ISSN: 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

http://doi.org/10.5281/zenodo.2552624

Available online at: http://www.iajps.com ***Research Article***

PREVALENCE OF TYPE 2 DIABETES MELLITUS WITH RISK FACTORS OF DIABETIC FOOT IN SAUDI ARABIA

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Abstract:

Background: *Diabetic foot complications remain a major problem among patients with diabetes and the health care system. Identification of the risk factors related to the development of diabetic foot is essential in order to develop strategies for avoiding the expected deterioration in the quality of life following amputation.*

Objectives: *To determine prevalence and associated risk factors of diabetic foot among type 2 diabetic patient attending diabetic centers in Saudi Arabia 2018.*

Methods: *This study is a cross- sectional study including a representative sample of type 2 diabetic patients who attending the diabetic centers in Saudi Arabia 2018. Data were collected through two tools; checklist: including information that was accessed through the patient's medical file registry and patient themselves. It included: treatment of diabetes, last reading of HbA1c and fasting blood glucose, lipid profile, peripheral neuropathy, peripheral vascular diseases, evidence of chronic renal disease, retinopathy, ischaemic heart disease, stroke and hypertension.*

Results: *The study included 300 type 2 diabetic patients. Their age ranged between 20 and 85 years with a mean±SD of 51.6±11.3 years. Males represent 70.3% of the sample. The prevalence of diabetic foot among them was 33%. Compared to Saudi diabetic patients, non-Saudis were less likely to develop DF (OR=0.24; 95%CI:0.07-0.76, p=0.015). As opposed to illiterate patients, those with secondary school and university educational level were at lower significant risk for developing DF (OR=0.10; 95%CI: 0.03-0.40, p=0.001 and OR=0.11; 95%CI:0.03-0.45, p=0.002 respectively). Patients who had family history of diabetic foot were at almost four folded risk for developing DF as compared to those without such history (OR=3.70; 95%CI:1.13-12.12, p=0.031). Similarly, patients who had history of peripheral neuropathy were at almost four-folded risk for developing DF as compared to those without such history (OR=3.90; 95%CI:1.77-8.57, p=0.001).*

Conclusions: *Diabetic foot is a common health problem among patients with type 2 diabetes attended the diabetic centers in Saudi Arabia, which can lead to high cost for the health care system.*

Keywords: *Diabetic Foot; Peripheral Neuropathy; Prevalence; Risk Factors; Saudi Arabia.*

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Please cite this article in press Mohammed Humayyed Alotaibi et al., ***Prevalence Of Type 2 Diabetes Mellitus With Risk Factors Of Diabetic Foot In Saudi Arabia.,*** *Indo Am. J. P. Sci, 2019; 06(01).*

INTRODUCTION:

The Kingdom of Saudi Arabia (KSA) is rapidly developing country with a change that influenced the lifestyle of the people towards urbanization, particularly over the past 3 decades. Previous surveys from KSA suggested that diabetes is present in epidemic proportions throughout the country with exceedingly high rates concentrated in urban areas [1]. In Saudi Arabia (2004), the overall prevalence of DM in adults in KSA was 23.7% [2]. Diabetic foot complications remain a major problem among patients with diabetes and the health care system. The interest to manage diabetic foot problems is sub-optimal for many factors shared by patients themselves, the community, health care professionals and policy makers [3]. Diabetic foot (DF) is defined as a full-thickness penetration of the dermis of the foot in a person with diabetes. Studies suggest that 2.5% of diabetic patients develop DF each year, and 15% of them develop DF during their life [4]. In Saudi Arabia, DF was prevalent in 13.5% of the diabetic patients referred to the nephrology clinic [5], and 7.7% of the patients undergoing chronic hemodialysis.6 Diabetic foot is the most frequent cause of hospitalization for the patients with diabetes, representing up to 25% of all diabetic hospital admissions [7]. Also, it is the most common cause of non-traumatic lower limb amputation [8], and precedes 85% of the cases [4]. The mortality rate is higher in the patients with DF, and represents approximately twice the number of diabetic patients without DF [8].

The majority of the DF patients have retinopathy, representing 90%, while 88.1% of them have coronary arterial diseases, 85% have nephropathy, and only 70% of DF patients have neuropathy [9]. The development of DF is significantly associated with the severity of neuropathy, high levels of hemoglobin A1c (HbA1c), high levels of blood sugar, and history of amputation [10,11]. On the other hand, some studies stated that there is no significant increase of new DF development for the patients with vascular diseases, renal diseases, smoking, alcohol consumption, and low socioeconomic status [12]. Targeting patients who are at high risk of developing DF may constitute a cost-effective strategy in controlling progression to end stage complications. Foot examination and risk categorization were among the least concerning examination by most of the physicians dealing with diabetes in the developing countries. In a cross sectional study conducted in Gurayat province. Saudi Arabia among primary care physicians to evaluate the current referral system between the diabetic center and the primary health care centers, only 3 referral forms (from a total of 215 forms) contained data about foot examination [13]. In KSA, DFUs continue to be an important cause of morbidity and resulted in an amputation rate of 19% [14].

Neuropathy and vasculaopathy were the main determinant risk factors for the occurrence of diabetic foot. Loss of protective sensation stands behind many of diabetic foot ulcers. It is clear from the literature that peripheral neuropathy is highly prevalent in people with diabetes in tropical countries, at levels similar to those found in developed countries and there are data to suggest that the prevalence of peripheral vascular disease tends to be lower in developing tropical countries compared to most developed countries [15]. Poor glycemic control is considered one of the poor predictors of diabetic foot lesions. Qari and Akbar reported that 79% (27/34) of their studied patients were uncontrolled [16].

Observational studies in type 2 diabetes have shown that these increased risks are related to the degree of glycaemic control [17,18]. Findings from randomized trials in diabetes have confirmed that improving glycaemic control lowers the risk of microvascular complications [19-21]. Prospective epidemiological studies, on the other hand, have suggested the presence of a graded relationship between level of glycaemia and lower extremity amputation (LEA) [18,22], but individual studies did not have adequate power to estimate the magnitude of this association precisely.

In the, various reports are available on the risk factors related to the complications of diabetes in order to develop strategies for avoiding the expected deterioration in the quality of life following amputation [23-25]. However, in the Arab world generally, and in Saudi Arabia particularly, limited data are available on the risk factors for DF. This study aimed to evaluate diabetic foot among type 2 diabetic patient attending diabetic centers in Saudi Arabia 2018.

SUBJECTS AND METHODS:

A cross-sectional study was carried out among type 2 diabetic patients attending diabetic centers in Saudi Arabia 2018. The sample size was calculated by using the single proportion equation in Raosoft software package, the required sample size is 289 type 2 diabetic patients at 95% confidence intervals (expected frequency 15% [4], margin of error accepted was 4%. The sample was increased to 320 to compensate for drop out. All legible type 2 diabetic patients from both genders and all nationalities, were invited to participate in the study till the sample size completed.

Data were collected through two tools:

1. Checklist**:** including information that was accessed through the patient's medical file registry and patient

themselves. It included: treatment of diabetes, last reading of HbA1c and fasting blood glucose, lipid profile, peripheral neuropathy, Peripheral vascular diseases, evidence of chronic renal disease, retinopathy, ischaemic heart disease, stroke, hypertension.

2. Interview Questionnaire: It included information about patient`s age, gender, nationality, marital status, level of education, Body Mass Index (calculated from the height and weight), smoking history, duration of diabetes, family history of diabetes and previous DF or amputation.

Peripheral neuropathy was considered to be present if there was a history of numbness in the foot, absence of the pain in the foot, or altered fine touch sensation, and proprioception [27]. Peripheral vascular disease was defined as the presence of ischemic symptoms such as, or a combination of, intermittent claudication, absence of pedial pulse, arterial occlusion, or decreased blood circulation to the foot on Doplar study [28]. A history of chronic renal diseases, retinopathy, IHD, stroke, and hypertension were considered to be present according to the doctor's diagnosis. The quality of diabetic control was classified according to the average HbA1c of the last 2 readings. An average HbA1c <6.5 will be considered as good control, while an average HbA1c >6.5 was considered to be poor control [29].

Obesity ('total obesity') was defined as a body mass index (BMI) of 30 kg/m2 or greater. For some analyses, obesity is further subdivided into class I obesity (BMI 30–34.9), class II obesity (BMI 35–39.9) and class III obesity (BMI ≥40). While normal weight is (BMI 18.5-24.9) and overweight is (BMI 25-29.9). Individual consent was obtained from each participant after clarifying the nature and purpose of study. Their files were reviewed to fill in the required information in the accompanied checklist. Individual verbal consent is a prerequisite for data collection. Data were entered to a personal computer and analyzed by using Statistical Package for the Social sciences (SPSS) program version 20. Categorical variables were presented as frequencies and percentages whereas continuous variables were presented as mean and standard deviation (SD). Chi square test was applied to test for the association and/or difference between categorical variables. Fisher exact test was applied instead of chi-square in case of small frequencies. Multiple associations were evaluated in multiple logistic regression models based on the backward stepwise selection. This process allowed the estimation of the strength of the association between each independent variable and the dependent variable taking into account the potential confounding effects of the other independent variables. An adjusted odds ratio with 95% CI that did not include 1.0 was considered significant. The significance level of P value was set at 0.05.

RESULTS:

The study included 300 type 2 diabetic patients out of 320 recruited for inclusion in the study giving a response rate of 93.8%. Table 1 presents their personal characteristics. Their age ranged between 20 and 85 years with a mean±SD of 51.6±11.3 years. Males represent 70.3% of the sample. Most of them (84.7%) were Saudis and married (80.3%). Among those having children, 41.9% had 5 or less whereas 13.3% had more than 10 children. Almost three-quarters of them (73.7%) were hosting only one family. Almost fifth of them (19%) had a family member working in health field. Majority of them (88%) resided urban areas and more than half of them (53.7%) had rented houses. Almost two-thirds of them (66.3%) were working and 31% of them earned between 5001 and 10000 SR/month. Almost a third of them (34.7%) were at least university graduated whereas 13% were illiterate. Most of patients were obese (82.9%), regardless severity of obesity. Morbid obesity was reported among 8.3% of type 2 diabetic patients.

Table 2 summarizes the medical characteristics of type 2 diabetic patients. The duration of diabetes ranged between one and five years among 36% of them and between 6 and 10 years among 33% while it exceeds 10 years among 25% of them. Almost two thirds of them (69.3%) were treated by oral hypoglycemic whereas 17% were treated by a combination of insulin and oral hypoglycemic tablets. Only 5.3% of them reported that they were very satisfied with diabetic therapy compared to18% were very dissatisfied. Only 1.7% of diabetic patients were always compliant with diabetic diet regimen compared to 16% were never compliant with it. More than half of them (58.3%) had family history of DM and only 12.7% had family history of DF. it is evident that the prevalence of diabetic foot among type 2 diabetic patients, Diabetic Centers in Saudi Arabia 2018 was 33%. The prevalence of other diabetic complications, other than DF among them was 33.7%. Regarding the level of HbA1c%, it was normal (<7%) among only 4 patients (1.3%).

From table 3, it is shown that peripheral neuropathy and retinopathy were reported among almost a third of type 2 diabetic patients (36.7%). Almost two-thirds of patients were hypertensive patients (62.7%) and a fourth had ischemic heart diseases (23.7%). Chronic renal diseases, peripheral vascular diseases and stroke were reported among 13%, 9% and 4.7% of the patients, respectively.

Regarding lipid profile, table 4 shows that almost two

thirds of type 2 patients (63.2%) had normal HDL (<40 mg/dl) whereas only 1.3% of them had normal LDL (<100 mg/dl) and 5.3% had normal total cholesterol (<200 mg/dl). Normal triglyceride level (<150 mg/dl) was reported among 15.7% of type 2 diabetic patients.

From table 5, it is revealed that family support in the management of DF was described as always by only 5% of patients and often by 25.3% of them whereas it was described as rarely or never existed by 16.3% and 16.7% of them, respectively. History of social stress was reported by majority of patients (91.7%). Almost half of them (48.4%) were current smokers and only 34.3% were non-smokers. Regarding practicing of physical exercise, only one patient (0.3%) practices it always compared to 34% never practiced it. Multivariate logistic regression analysis revealed that compared to Saudi diabetic patients, non-Saudis were less likely to develop DF (OR=0.24; 95%CI: 0.07-0.76, p=0.015). As opposed to illiterate patients, those with secondary school and university educational level were at lower significant risk for developing DF (OR=0.10; 95%CI: 0.03-0.40, p=0.001 and OR=0.11; 95%CI:0.03-0.45, p=0.002 respectively). Patients who had family history of diabetic foot were at almost four-folded risk for developing DF as compared to those without such history (OR=3.70; 95%CI:1.13-12.12, p=0.031). Similarly, patients who had history of peripheral neuropathy were at almost four-folded risk for developing DF as compared to those without such history (OR=3.90; 95%CI:1.77-8.57, p=0.001). Taking always/often compliance with diabetic diet regimen as a reference category, patients who sometimes, rarely or never compliant with it were at significantly higher risk for developing DF (OR=3.48; 95%CI:1.09-14.28, p=0.002, OR=3.99; 95%CI:1.66-9.28 and OR=8.38; 95%CI:3.26-19.33, p=0.049 respectively). Compared to patients who had less than one year of diabetes, those having diabetes for a period ranged between one and five years were at significantly lower risk for developing DF (OR=0.43; 95%CI: 0.29-0.91, p=0.001) whereas those having a duration of diabetes of more than ten years were at almost 8-folded risk for developing DF (OR=7.67; 95%CI: 2.06-16.29, p=0.001). (Table 6)

Variables	**Categories**	**Frequency**	**Percentage**
Age (years)	**20-30**	11	3.7
	31-40	40	13.3
	41-50	76	25.3
	51-60	112	37.3
	>60	61	20.3
	Mean ±SD	**51.6±11.3**	
Gender	**Male**	211	70.3
	Female	89	29.7
Nationality	**Saudi**	254	84.7
	Non-Saudi	46	15.3
Marital status	**Married**	241	80.3
	Single	21	7.0
	Widowed	17	5.7
	Divorced	21	7.0
Number of children (n=279)	**No**	12	4.3
	≤5	117	41.9
	6-10	113	40.5
	>10	37	13.3
Family hosting	**One**	221	73.7
	> one	46	15.3
	Nothing	33	11.0
Family member working in health field	**Yes**	57	19.0
	No	201	67.0
	Don`t know	42	14.0
Place of residence	**Rural**	36	12.0

	Urban	264	88.0
Type of residence	**Private**	135	45.0
	Governmental	4	1.3
	Rented	161	53.7
Job status	**Working**	199	66.3
	Not working	101	33.7
Income (SR/month)	**<3000**	77	25.7
	3000-5000	53	17.7
	5001-10000	93	31.0
	10001-15000	61	20.3
	>15000	16	5.3
Highest educational level	**Illiterate**	39	13.0
	Primary	18	6.0
	Intermediate	39	13.0
	Secondary	100	33.3
	University	101	33.7
	Post-graduate	3	1.0

Variables	**Categories**	**Frequency**	**Percentage**
Duration of diabetes (years)	**<1** **1-5** **6-10** **>10**	**18** **108** **99** **75**	**6.0** **36.0** **33.0** **25.0**
Diabetic therapy	**Diet regimen** **Oral hypoglycemic Insulin** **Insulin +Oral hypoglycemics**	**12** **208** **29** **51**	**4.0** **69.3** **9.7** **17.0**
Satisfaction with diabetic therapy	**Very satisfied Somewhat satisfied Neutral** **Somewhat dissatisfied** **Very dissatisfied**	**16** **79** **69** **82** **54**	**5.3** **26.3** **23.0** **27.4** **18.0**
Compliance with diabetic diet regimen	**Always Often Sometimes** **Rarely** **Never**	**5** **87** **94** **66** **48**	**1.7** **29.0** **31.3** **22.0** **16.0**
Family history of diabetes mellitus	**Yes** **No**	**175** **125**	**58.3** **41.7**
Family history of diabetic foot	**Yes** **No**	**38** **262**	**12.7** **87.3**

Table 3: Co-morbidity and complications among type 2 diabetic patients (n=300)

Variables	Categories	Frequency	Percentage
Peripheral neuropathy	**Yes No**	110 190	36.7 63.3
Peripheral vascular disease	**Yes** **No**	27 273	9.0 91.0
Chronic renal disease	**Yes** **No**	39 261	13.0 87.0
Retinopathy	**Yes No**	110 190	36.7 63.3
Ischemic heart diseases	**Yes No**	71 229	23.7 76.3
Stroke	**Yes** **No**	14 286	4.7 95.3
Hypertension	**Yes** **No**	188 112	62.7 37.3

Table 4: Lipid profile among type 2 diabetic patients (n=300)

Variables	Categories	Frequency	Percentage
Triglycerides (mg/dl)	**<150** **≥150**	47 253	15.7 84.3
Total cholesterol (mg/dl)	**<200** **≥200**	16 284	5.3 94.7
HDL cholesterol (mg/dl) (n=299)	**<40** **≥40**	189 110	63.2 36.8
LDL cholesterol (mg/dl) (n=299)	**<100** **≥100**	4 295	1.3 98.7

Table 5: Social and habitual characteristics of type 2 diabetes mellitus (n=300)

Variables	Categories	Frequency	Percentage
Family support in DM management	**Always Often** **Sometimes Rarely** **Never**	15 76 110 49 50	5.0 25.3 36.7 16.3 16.7
History of social stress	**Yes** **No**	275 25	91.7 8.3
History of current smoking	**Yes No** **Ex-smoker**	145 103 52	48.4 34.3 17.3
History of practicing regular exercise	**Always Often** **Sometimes Rarely** **Never**	1 18 119 60 102	0.3 6.0 39.7 20.0 34.0

	B	**SE**	**p-value**	**Adjusted OR**	**CI**
Nationality Saudi (n=254)[a] Non-Saudi (n=46)	 -1.438	 0.592	 0.015	 1.0 0.24	 --- 0.07-0.76

Educational level Illiterate (n=39) [a] Primary (n=18) Intermediate (n=39) Secondary (n=100) University+ (n=104)	 -1.424 -0.923 -2.269 -2.203	 0.922 0.775 0.687 0.711	 0.122 0.234 0.001 0.002	 0.24 0.40 0.10 0.11	 0.04-1.47 0.09-1.81 0.03-0.40 0.03-0.45
Family history of DF No (n=262) [a] Yes (n=38)	 1.307	 0.606	 0.031	 3.70	 1.13-12.12
Peripheral neuropathy No (n=190) [a] Yes (n=110)	 1.360	 0.402	 0.001	 3.90	 1.77-8.57
Compliance with diabetic diet regimen Always/often (n=92) [a] Sometimes (n=94) Rarely (n=66) Never (n=48)	 1.126 2.389 4.688	 0.676 0.587 0.628	 0.002 0.018 0.049	 3.48 3.99 8.38	 1.09-14.28 1.66-9.28 3.26-19.33
Duration of diabetes <1 (n=18) [a] 1-5 (n=108) 6-10 (n=99) >10 (n=75)	 2.037 -0.098 -4.204	 0.451 0.834 0.716	 0.001 0.906 <0.001	 0.43 1.12 7.67	 0.29-0.91 0.39-9.34 2.06-16.29

DISCUSSION:

As proved elsewhere, our results, clearly demonstrated that DM eventually led to chronic complications, including peripheral neuropathy (PN) and peripheral vascular diseases (PVS). It is known that PVD and PN are potential risk factors for foot complications. Indeed, with the high prevalence rates of DM in the KSA population and the high rates of PN and to lesser extent PVD among patients which has been revealed in this study, it is vital to investigate for diabetes foot complications in our community.

The results of this study showed that the overall prevalence of PN was 36.7%, which was higher than the equivalent rates reported in other populations [29-33] and comparable to what has been reported in UAE (39%) [7]. Comparatively, the rate revealed for PVD (9%) in our population was far lower than that reported in other populations [34-36] and close to what had been reported in UAE (12%) [7].The high prevalence of PN compared with the relatively low prevalence of PVD in the current study population also has been reported in a study conducted in UAE [7]. They attributed this to methodological biases for diagnosing neuropathy and/or PVS as the symptom scores may be less reliable due to their subjectivity.

Regarding the prevalence of diabetic foot, it was 33% in the present study among type 2 diabetic patients, which is higher than those reported elsewhere in Saudi Arabia. DF was prevalent in 13.5% of the diabetic patients referred to the nephrology clinic [5], and 7.7% of the patients undergoing chronic hemodialysis [6]. A review of the records of 1010 diabetic patients seen at King Khalid University Hospital, Riyadh, revealed an overall prevalence of 10.4% for diabetic foot lesions [37]. In addition, this rate is higher than those reported outside the kingdom as diabetic foot ulcer prevalence was 4.6%, sensory neuropathy 14.9%, lower limb ischemia 7.5%, and amputation 1.7% among patients attending the National Center for Diabetes, Endocrinology, and Genetics (Amman, Jordan) [38]. One thousand seven hundred and eighty eight patients with diabetes mellitus were screened and 82 (4.6%) were found to have foot ulcers in patients with both type 1 and 2 diabetes mellitus in a clinic-based setting in Kenya [39]. In a cohort of patients presented to the outpatient diabetes clinic at Mansoura University Specialized Medical Hospital, Egypt, the prevalence of active or past foot ulceration was 1.2% and 5.7% respectively. Monofilament insensitivity was found in 124 patients (10.2%). Only 38 patients (3.1%) had absent foot pulses. They found dry skin in 544 patients (44.6%), calluses in 69 (5.7%), tinea pedis in 532 (43.6%) and thick nails in 215 (17.6%); 61.6% of patients used inappropriate footwear and 93.8% received no prior foot education.

This high prevalence observed in the present study could be attributed to two main factors; first the criteria for definition of diabetic foot in the present

study could be a reason for inclusion of more patients. Second, we recruited our patients from those attended diabetic center of Alnoor hospital rather than general diabetic population or those attended outpatient follow up clinics.

The multivariate logistic regression analysis further showed that the main risk factors for foot complications were Saudi nationality, poor level of education, increased disease duration (<10years), presence of family history of diabetic foot, peripheral neuropathy and being not compliant with diabetic diet regimen. The results are consistent with findings elsewhere [7,31,40-44]. It is known that the risk of ulcers and lower limb amputations is higher in patients with diabetes duration of 10 years or more and those have other cardiovascular, retinal or renal complications [45]. In bivariate analysis, other diabetic complications were significantly associated with DF. However, this disappeared in multivariate analysis.

Compliance is the cornerstone of diabetes management. In the present study, non-compliance with diabetic diet regimen was proved to be a significant risk factor for DF in both bivariate and multivariate analyses. While non-compliance with physical exercise was proved to be a risk factor in bivariate analysis. However, it disappeared in multivariate analysis. A study conducted in Abha, KSA revealed a suboptimal compliance with all aspects, especially with diet and exercise among diabetic patients [46]. A study done in Al-Hasa region, Saudi Arabia, indicated that there was a high rate of non-compliance among diabetic patients [47]. Poor compliance regarding diet and exercise has also been found in studies done in UAE [48], Palestine [49], and Egypt [50,51].

These findings could indicate that health care professionals may be failing to emphasize the importance of dietary and lifestyle changes along with medication and follow up advice.

Nationality was found to be a significant determinant of DF in the present study. The same has been reported in UAE [7]. In a study conducted in Abha, they reported that Saudis were more compliant with medication, while non-Saudis were more compliant with exercise and diet regimen [46]. This could be due to more availability of resources to Saudis, along with a sedentary lifestyle.

Educational status was a significant determinant of compliance and consequently it plays an important role in protection against DF. In the present study, higher educated patients were less likely to develop DF. In another Saudi study, they reported that university educated patients had more compliance with diabetic regimen than other groups [52]. This finding emphasized the fact that level of education played a role in better understanding of the doctors' advice.

Among limitations of the current study, the design used in this study depends on completeness and accuracy of the documentation in patient files. Therefore, the type of data included in the abstraction form was limited to the information present in these files. However, the inclusion of a relatively large sample size was taken to compensate for this limitation. Also, the prevalence of DR might be overestimated, based on the accuracy of diagnosis of DF and it's reporting.

In conclusion, diabetic foot is a common health problem among patients with type 2 diabetes attended the diabetic centers in Saudi Arabia which can lead to high cost for the health care system. Regular screening for foot complications is recommended to all diabetic patients in view of the high rates reported for PN and PVD in the population.

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