Original Article

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A Study on Diabetic Foot Disorders in Basrah, Southern Iraq

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ABSTRACT

Background: Diabetic foot disorders (DFD) involve several pathologies affecting the foot of patients suffering with diabetes, such as diabetic peripheral neuropathy, peripheral arterial disease, foot deformity, diabetic foot ulcer and amputation.
Objectives: To measure the prevalence and associated risk factors of DFD in a cohort of patients in Basrah, Iraq.
Methods: This is a cross sectional study that was performed in Basrah Province, Iraq, from 1/1/2019 to 1/8/2019. Patients with diabetes attending Faiha Specialized Diabetes Endocrine and Metabolism Center were screened for DFD. The participants were divided into four groups according to the International Working Group on the Diabetic Foot Classification. Data were analyzed using SPSS version 25 software.
Results: A total of 121 participants (69 females (57%)) were included. Their mean age was 53.7 ± 12.3 years. The mean duration of diabetes was 8 ± 0.6 years and the mean HbA1c was 9.6 ± 2.3%. Those with type 2 diabetes represented 115 (95%) of the total number and 63 (52%) were on insulin-based regimes. Twenty-six (21.5%) patients had callosity. The patients were classified as having no DFD, neuropathy, neuropathy with peripheral artery disease and/or foot deformity and neuropathy with a history of ulcer or amputation at frequencies of 29.8%, 52.1%, 9.1% and 9.1%, respectively. Females and patients with longer diabetes durations were identified as predictors of DFD; the *p* values were 0.008 and 0.019, respectively. Additionally, no significant association was detected between DFD and the type of diabetes, age and glycemic control.
Conclusions: Approximately two-thirds of the patients with diabetes have DFD in Iraq. DFD were strongly associated with long duration of diabetes and the female gender. It is crucial to conduct a proper and thorough foot examination and screen all patients with diabetes for DFD at their visit to the clinic. Such an examination may prevent the development of active disease, ulcers and, consequently, amputation.

Key words: Diabetes Mellitus, Diabetic Foot, Peripheral Neuropathy.

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INTRODUCTION

Diabetes mellitus (DM) is a major health problem that results in serious consequences on global health and the economy. Around 463 million people were living with DM worldwide in 2019.[1] The direct care of people with diabetes costs around 760 billion US dollars globally.[1] Diabetic foot disorders (DFD) or syndromes involve several pathologies affecting the feet of patients with diabetes such as diabetic peripheral neuropathy (DPN), peripheral arterial disease (PAD), foot deformity, diabetic foot ulcer (DFU) and amputation.[2] It has been estimated that diabetic foot affects 40–60 million people with DM globally.[3] DPN is defined as an impairment in the sensory, motor and/or autonomic functions of the peripheral nerves in people affected by DM after the exclusion of other causes.[3,4] The prevalence of DPN has a variable range (16–87%).[4,5] Furthermore, it has been estimated that 10% of patients with DM have DPN at first diagnosis.[6] Approximately, to a quarter of patients, DPN is a painful experience.[7,8] On the other hand, the exact prevalence of foot deformity among patients with diabetes is unknown.[3] Loss of sensation secondary to DPN is a major precipitating factor for ulcer and amputation. DFU is defined as any wound below the ankle with disruption of the integument, including gangrenous tissue that occurs on the background of DM.[9] One study reported a prevalence of DFU at 7.7% with male preponderance.[8] It is noteworthy that being diabetic places a person at risk of amputation 10–20 times more than others.[10] Furthermore, it has been estimated that one limb is lost via amputation every 30 seconds as a result of diabetes.[11,12]

Diabetic foot complications are preventable.[13] One of the key elements in its prevention is early detection via screening.[13] International societies such as the International Working Group on the Diabetic Foot (IWGDF) and the International Diabetes Federation (IDF) have developed a comprehensive and practical classification for diabetic foot disease, which requires screening by readily available and inexpensive bedside tools.[13-16] This classification aimed to schedule the time interval for follow-up visits. However, this classification, in one way or another, enables us to classify the severity of diabetic foot disease and hence anticipate the complications before their occurrence.

It is important to note that DPN might be asymptomatic in half of the patients, which makes the symptoms an unreliable indicator.[17] Furthermore, only less than one-third of physicians recognize the features of DPN even if the patient is symptomatic.[18] Timely screening for diabetic foot complications with resultant multi-disciplinary care provided can reduce the risk of foot ulcer development and/or amputation by 85%.[19]

Most of the previously published studies focused on the prevalence and complications of DFU.[2] The latter is considered as a later stage of DFD and just one step away from amputation. Therefore, we decided to conduct this study through the screening of people with diabetes for DFD as well as ulcers by utilizing the comprehensive

classification developed by IWGDF and IDF. We attempted to discover the spectrum of DFD earlier via simple and inexpensive clinical tools. The first step in reducing a major health problem such as diabetic foot is to understand the extent of the disease in the community. This study aims to estimate the prevalence of DFD among a cohort of diabetic patients in Basrah Governorate, Southern Iraq. It also aims to examine the possible associated risk factors.

MATERIALS AND METHODS

Setting

This was a cross-sectional study conducted at Faiha Specialized Diabetes Endocrine and Metabolism Center from 1/1/2019 to 1/8/2019. The Center is a tertiary public health facility located in the heart of Basrah Governorate, Southern Iraq. It provides care to people with different types of diabetes at all age groups. The Diabetic Foot Clinic is an extension to the Center where diabetic foot care of tertiary quality is provided to the patients by a consultant orthopedic surgeon.

Participants

Patients with DM, irrespective of their type of diabetes, gender or age, were referred by an endocrinologist from the Center to the Diabetic Foot Clinic after taking informed consent to participate. Those who are pregnant, have a history of alcohol intake malignancy, hypothyroidism, liver disease and/or on medications that might induce neuropathy have been excluded from the study. The patients who were selected to be referred to the Diabetic Foot Clinic were chosen by a systematic random sampling method. Every sixth patient from clusters of ten was selected. The study was piloted on 10 patients to examine the feasibility of the questionnaire as well as the clinical examination.

Data collection and classification

The following demographic and health data were collected: gender, age, DM duration, type and treatment: whether oral anti-diabetic or insulin. The type of DM was decided on the standard World Health Organization criteria for diagnosis of diabetes type.[20] A blood sample was taken from each participant and tested for glycated hemoglobin, as a surrogate marker of glycemic control, by cation-exchange high-performance liquid chromatography method (Bio-Rad Variant D-100 system, Bio-Rad Laboratories, CA, USA). In the diabetic foot clinic, the participants were screened for DFD by the same orthopedic surgeon who followed the Michigan Neuropathy Screening Instrument (MNSI) (an established and validated tool for diagnosing DPN with 80% sensitivity and 95% specificity).[4,17,21] The MNSI consists of 2 parts: MNSI-history and MNSI-examination. The MNSI-history consists of 13 questions.[17] Each question scores one point. On the other hand, MNSI-sign consists of 10 points. Dry skin, infections, calluses, fissures, ulcers and deformities were looked for in each foot. The presence of any of the aforementioned abnormalities was given one point. After that, knee and ankle reflexes were examined, and a zero score was given for a spared reflex. In case of an absent one, a Jendrassic maneuver was performed. A score of 0.5 was granted if

the reflex was elicited by this maneuver. If it was absent with the maneuver, a score of 1 was recorded. After that, examination for a sense of vibration in the great toe was performed by a 128-Hz tuning fork. If the examiner felt the vibration 10s longer than the patient did, a zero score was given. 0.5 point was given if the duration was ≥ 10s, and one point was given if no vibration was felt by the patient. Lastly, the sensation of pressure was examined via a 10g monofilament placed over 10 points in each foot. If the monofilament was sensed by the participant at 8 points, a zero score was given. If the sensation was elicited in (1–7) points, a 0.5 score was given, and if the participant could not feel the monofilament at all, 1 point was given. Neuropathy was diagnosed clinically if the MNSI-history score was ≥ 7/13 or the MNSI-sign score ≥ 2/10 or both.[17] Finally, patients were asked for any history of intermittent claudication or ischemic rest pain. In addition, the feet were observed while elevated above the heart (the patient is supine) for pallor and while lowered (patient is sitting) for rubor. Both dorsalis pedis and posterior tibial arteries were palpated.[22]

The patients were classified accordingly into one of the following four categories derived from the IGWDF and IDF classification (Table 1): zero – no peripheral neuropathy, 1 – peripheral neuropathy, 2 – peripheral neuropathy with peripheral artery disease and/or a foot deformity and 3 – peripheral neuropathy and a history of foot ulcer or lower extremity amputation. Those in categories 1 to 3 were labeled as having DFD.

Table 1: International Working Group Classification of diabetic foot disease.[13]

Category	Characteristics
0	No peripheral neuropathy
1	Peripheral neuropathy
2	Peripheral neuropathy with peripheral artery disease and/or a foot deformity
3	Peripheral neuropathy and a history of foot ulcer or lower extremity amputation

Statistical analysis

The minimum sample size was calculated to be 100, which was based on the estimated prevalence of DFD (50%), the confidence level of 5% and a margin of error of 5%.

Descriptive data are presented as the mean ± SD (or SE) for continuous variables as well as frequencies for categorical ones. The 95% confidence intervals (CI) were measured for the frequencies of different categories of DFD according to IWGDF based on Poisson distribution. Multiple linear regression test was done to examine for the associated risk factors with DFD. Duration of DM was divided into less than 5 years and more than or equal to 5 years. The patients were divided into two age groups: equal or below 50 years and above 50 years. Those with HbA1c ≤ 8.0% were considered as having fair glycemic control. All data analyses were performed with IBM SPSS for Windows 24.0

(SPSS Inc., Chicago, IL, USA). *P* values < 0.05 were determined as significant.

Ethical approval

This study was ethically approved by the Ethical Approval Committee of Basrah Health Directorate. Furthermore, it was performed under the Declaration of Helsinki in 1975. Informed consent was obtained from each participant.

RESULTS

The study involved 121 patients. There was a slight female preponderance in the population (69 (57%)). The participants' mean age was 53.7 ± 12.3 years, while the mean duration of DM was 8 ± 0.6 (SE) years. The mean HbA1c was 9.6 ± 2.3%. The majority of the participants (115 (95 %)) had type 2 DM. Regarding the type of treatment, 63 (52%) of the participants were on an insulin-based regime (Table 2).

Table 2: Basic characteristics of the participants.

Characteristic	Count
Age, mean ± SD (years)	53.7 ± 12.3
Age group, n (%)	
≤50 years	44 (36.3)
>50 years	77 (63.7)
Gender, n (%)	
Female	69 (57)
Male	52 (43)
DM duration, mean ± SE (years)	8.0 ± 0.6
DM duration group, n (%)	
< 5 years	30 (24.8)
≥ 5 years	91 (75.2)
DM type, n (%)	
Type 1	6 (5)
Type 2	115 (95)
DM therapy, n (%)	
Oral antidiabetic	58 (48)
Insulin	63 (52)
HbA1c, mean ± SD (%)	9.6 ± 2.3
Glycemic control, n (%)	
Controlled (HbA1c ≤ 8%)	36 (29.7)
Uncontrolled (HbA1c > 8%)	85 (70.3)
Callosity, n (%)	
Present	26 (21.5)
Absent	95 (78.5)

DM: diabetes mellitus, HbA1c: glycated hemoglobin, SD: standard deviation, SE: standard error

The distribution of the participants according to IWGDF and IDF classification is shown in Table 3. Of the total number, 85 (70.2 %) participants were categorized into categories 1–3, which means they had DFD. We reported a high rate of DPN alone (52.1%) (Table 3).

Table 3: Distribution of the participants according to the IWGDF and IDF classification.

Category	Characteristics	Count, n (%)	95 % CI (%)
0	No peripheral neuropathy	36 (29.8)	28–44
1	Peripheral neuropathy	63 (52.0)	50.7–75.3
2	Peripheral neuropathy with peripheral artery disease and/or a foot deformity	11 (9.1)	6–16
3	Peripheral neuropathy and a history of foot ulcer or lower extremity amputation	11 (9.1)	6–16

We found a significant relationship between the DFD in females and the DM duration. A female patient with a longer duration of DM is more likely to have DFD. In contrast, no significant association was found between diabetic foot disease and age, DM type or glycemic control (Table 4).

Table 4: Association between diabetic foot disorders and some risk factors.

Variable	Diabetic foot disorders		Total	P value
	Present	Absent		
Age				
≤50 years	27	17	44	0.08
>50 years	58	19	77	
DM duration				
< 5 years	16	14	30	0.019
≥ 5 years	69	22	91	
DM type				
Type 1	2	4	6	0.064
Type 2	83	32	115	
Gender				
Female	55	14	69	0.008
Male	30	22	52	
HbA1c				
Controlled ≤ 8%	26	10	36	0.5
Uncontrolled > 8	59	26	85	

DM: diabetes mellitus, HbA1c: glycated hemoglobin.

DISCUSSION

The current study tried to measure the prevalence of DFD and its correlation among a cohort of diabetic patients from Southern Iraq. The prevalence of DFD according to this study was 70.2%. There is a significant variation in the reported prevalence of DFD in the literature[4,6]. This variation may be attributed to several factors such as the definition of DFD, the geographic location, the studied population, the modality of examination, the confounding risk factors and the source of data.

While there is an abundance of data about DFU 2, data regarding DFD is scarce. The spectrum of DFD is wide and includes DPN, PAD, foot deformity, DFU and amputation.[2] These various components of DFD have been studied separately and a single study describing the whole spectrum is seldom

found. Some of these components, such as DPN, have been studied extensively while others are yet to be examined. DPN is considered as a very early stage and well-established precipitating factor for more serious and later diabetic foot complications such as ulcer, deformity and amputation.[3]

Studies from the Arabic countries indicated that the prevalence of DPN and PAD among diabetic foot patients is 25.6–94% and 50–78%, respectively.[2,4,17,21] A similar rate was reported in Iran (31.9%).[6] Additionally, the prevalence of DPN in the National Health and Nutrition Examination Survey (NHANES) was 28.5% (95% CI 22.0–35.1).[3] In our study, we have not subclassified DPN into painful and non-painful. Globally, the prevalence of painful DPN ranges from 10.9–20 % in various geographical locations.[3,23,24]

Up to the best of our knowledge, two previous studies from Iraq estimated the prevalence of DFD. The first one was published 11 years ago and conducted at the same center as our study, including 4926 patients with diabetes.[25] This study reported a lower rate of DPN, PAD and DFU at 13.8%, 0.2% and 2.7%, respectively.[25] Several limitations in that study might explain the underestimated prevalence rates. First, it excluded those patients with diabetes detected in less than 1-year duration and patients with type 1 DM. It also excluded those younger than 20 years. Second, the diagnosis of DPN was mainly based on the history of numbness and paresthesia. Third, the examination did not involve tests for pain or pressure senses. Fourth, the definition of the diabetic foot according to that study was limited (it involved only cases of foot ulcer, fissure or amputation). Fifth, the whole study was retrospective, based on retrieving data from electronic records. Finally, the author has not mentioned who performed the assessment for diabetic foot disease, whether it was accomplished by a single or multiple physicians, and if any validated screening tool was used. All of these points might explain the underestimated reported rates.

The second study was from Erbil in Northern Iraq and was published three years ago.[21] That study was a well-designed cross-sectional study, that involved 250 patients with type 2 diabetes mellitus. The mean age of the participants and duration of DM in that study is approximately similar to the current study. According to that study, the prevalence of DPN was 31.2% and they identified the following risk factors for DPN: living in rural areas, low socioeconomic status, smoking, long duration of DM and obesity.[21] The same screening tool (MNSI) was used in the study by Saber et al. The lower reported prevalence rate of DPN in that study may be attributed to exclusion of patients with DFU and amputation.

Similar to our study, the prevalence of PAD was 9.5% (95% CI, 5.5–13.4) among people with DM in the NHANES study.[3] Another study found that half of the patients with diabetes had nonpalpable pedal pulses.[26]

In our study, 9.1 % had foot deformity, which is lower than what has been reported by Gregg et al study (30.2% (95% CI 22.1–35.1)).[8] We reported a similar rate of DFU (9.1%) to other studies, in which the rate ranged from 1.8% to 19%.[2,8,27] Similarly, a systematic review of nine studies estimated

that the mean prevalence of DFU in the Arabic countries was 6 %.[2]

The prevalence rate of amputation was 1.3% in a study from Jordan.[17] In contrast, we reported a higher rate (9.1%). We have not estimated the rate of amputation separately; instead, we estimated the rate of amputation and DFU collectively to be 9.1% as we followed the IWGDF classification. This might explain the higher rate in our study.

Similar to our study, a strong association between the long duration of DM (defined as DM ≥ 5 years) and DFD has been reported in several studies.[4,17,21,25] Likewise, women are more likely to have DPN, as per the current and the research by Mansour et al.[25] This is in contrast to other studies, where the male gender was strongly associated with DPN.[3,4] On the other hand, several studies did not demonstrate any effect of gender on the prevalence of DPN.[17,28,29] Similarly, another study found no association between lower limb amputation with gender or the duration of DM.[30] Similar to our study, there was no relation between HbA1c and the prevalence of DPN in the two studies.[17,21] This lack of association does not necessarily mean that there is no effect of optimal glycemic control on the prevalence of DPN or other micro and/or macrovascular complications of DM. Given the fact that HbA1c may reflect the state of glycemic control over the preceding three months, it is unreliable to measure the state of glycemic control of a patient based on a single HbA1c reading. The majority of patients included in this study have a long history of DM and we are unable to estimate their glycemic control over the past years. Those with an HbA1c within the target limits might have spent many years with poorly controlled DM. Other studies reported that the DPN increases with duration,[31] poor glycemic control,[32] and age of participants.[31]

There has been an increasing awareness among health care providers on the importance of regular screening for DFD and its impact on improving the quality of life of diabetic patients via reducing the rate of deleterious consequences. However, the rate of screening is still suboptimal (49% of patients are being screened for DFD).[33]

There are limitations to our study: first, we have not included the following variables: physical activity, socioeconomic status, body mass index, smoking, alcoholism, other atherosclerotic vascular complications like nephropathy and retinopathy in the assessed risk factors that might be associated with DFD. Other comorbidities such as hypertension, ischemic heart disease and hyperlipidemia were not included as well. Second, the cross-sectional design of the study disabled us from evaluating the long-term effects of risk factors on the development of DFD such as glycemic control. Third, the gold standard test for DPN is the nerve conduction study, which was not performed, as we aimed to utilize the simple, bedside and readily available measures to detect DPN. Fourth, the ankle-brachial pressure index was not used due to the lack of the machine in our center. For the same reason, we did not use a biothesiometer to quantitatively measure vibration sense. Nevertheless, the data obtained from a tuning

fork is comparable to that obtained from a biothesiometer.[13]

To the best of our knowledge, the current study is the first one that utilizes the IWGDF classification to follow-up on patients with DFD but rather to determine the prevalence of DFD in a cohort of patients with DM. We strongly recommend future epidemiological studies to implement the IWGDF classification for measuring the prevalence of DFD in the public. This classification is simple, easy to follow, concise and time-saving and does not require expensive tools to accomplish.

CONCLUSIONS

Two-thirds of patients with diabetes have DFD in this cohort of patients. DFD were strongly associated with the long duration of diabetes and the female gender. Early diagnosis and classification of DFD is crucial to anticipate and mitigate future sinister complications such as DFU, deformity and, consequently, amputation. Therefore, physicians should be encouraged to perform regular screening for DFD and to utilize the IWGDF and IDF classification and risk assessment tools and schedule future reassessment accordingly.

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Conflict of interest

None to declare.

Authors' contribution

Study concept and design: M. A. and A. M.; analysis and interpretation of data: M. A.; drafting of the manuscript: M. A.; critical revision of the manuscript for important intellectual content: A. M.; statistical analysis: M. A.

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