Prevalence of diabetic foot ulceration and associated risk factors: an old and still major public health problem in Khartoum, Sudan?

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Background: Diabetic foot ulceration (DFU) is a major health problem across the globe. The objective of this study is to determine the prevalence of DFU and its associated risk factors in Sudanese individuals with diabetes.

Methods: Three hundred and ten individuals with type 2 diabetes, who have been on treatment for DM for at least 1 year and volunteered to participate, were enrolled in this study. Participants were interviewed using standardized pretested questionnaire to record medical history, socio-demographic, life style characteristics and presence of DFU.

Results: The prevalence of DFU was found to be 18.1% in this cohort (95% CI: 13.78–22.34%). Among different metabolic variants like hypertension, albuminuria, retinopathy, neuropathy, HbA1c, cholesterol, high density lipoprotein (HDL), low density lipoprotein (LDL) and triglyceride, only duration of diabetes was significantly associated with DFU (P<0.0018) as shown by logistic regression statistical analysis. Even after adjusting for all other potential risk factors, living with diabetes for more than 10 years is associated with an increase in the diabetic foot probability by 3.16 folds (95% CI: 052–10.48 folds increase), P=0.006. The adjusted effect for living with diabetes for more than 20 years on the diabetic foot complication probability is an increase by 1.73 folds (95% CI: 0.39–4.37 folds increase), P=0.005. However, living with diabetes for more than 5 years had a non-significant adjusted effect on diabetic foot probability.

Conclusions: Prevalence of diabetic foot ulcer was 18.1 % and the risk of development of diabetic foot ulcer is increased with duration of diabetes more than 10 years.

Keywords: Type 2 diabetes mellitus (type 2 DM); diabetic food ulceration; duration of diabetes mellitus (duration of DM); Sudan

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Introduction

Diabetes is now common and major health problem in Sudan. The estimated prevalence of diabetes in urban areas in North Sudan was thought to be around 19% in comparison with 2.5% in rural regions (1,2). Like other developed and developing countries, high prevalence of uncontrolled diabetes (85%) is noted in Sudanese individuals with type 2 diabetes (3). Therefore, it is not surprising that the prevalence of fatty liver among Sudanese individuals with type 2 diabetes was found to be as high as 50.3% (4). Importantly, Increasing age, a family history of diabetes, central obesity, obesity, an increase in metabolic syndrome parameters, hypertension and high triglyceride level and low high-density lipoprotein cholesterol (HDL-c) level were significant risk factors for both diabetes and fatty liver in Sudanese individuals (1-4). Unfortunately, the prevalence of diabetes in Africa is expected to increase to 28 million cases by 2030 in comparison with 14 million in 2011 (5-7). In systematic review, the global diabetic foot ulcer prevalence was 6.3% (highest in North America about 13%, lowest in Europe about 3% and Africa about 7.2%). Diabetic foot ulceration (DFU) was noted more in males, type 2 diabetics, older individuals, low body mass index (BMI), longer diabetic duration, hypertension, diabetic retinopathy (DR), and smoking history than in patients without DFU (8). Increase in prevalence of diabetes complications in Africa was attributed to rise in financial health expenditure, poor medical facility and lack of adequate diabetes service in urban and rural areas (9,10). The prevalence of diabetic foot in Cameroon, Nigeria and Tanzania were estimated to be 13%, 9.5% and 15% respectively (11-13). The cost associated with diabetic foot is enormous. For instance, the costs of treatment for diabetic foot that resulted in complete healing ranged from \$102 to \$3959 in Tanzania and in the United States, respectively. Importantly, the cost of diabetic foot that treated with transtibial amputation ranged from \$3,060 to \$188,645 in Tanzania and in the United States, respectively. On the other hand, the cost burden to the patient varied from the equivalent of 6 days of average income in the United States for diabetic foot with complete recovery to 5.7 years of average annual income in case of transtibial amputation in India (14). In addition, 28% to 51% of amputated diabetics will have a second amputation of the lower limb within five years of the first amputation. This was thought to be due to neuropathy, peripheral vascular disease, poor diabetes control and longer duration of diabetes (8,15). Therefore, the aim of this study is to determine the prevalence of diabetic foot in Sudanese individuals with type 2 diabetes.

Methods

Study design

This was a descriptive, cross sectional, hospital-based study.

Setting and population

Individuals with diabetes who attended diabetes center in the capital of Sudan, Khartoum were included in this study.

Inclusion criteria

Included adults over 18 years who were diagnosed as type 2 diabetes, individuals with diabetes on diet control, individuals with macro-micro diabetes complications were included and being on anti-diabetes treatment for at least 1 year.

Exclusion criteria

Exclusion criteria included: individuals below 18 years, individuals admitted with diabetes emergencies like diabetic ketoacidosis and pregnant ladies.

Data collection tools

A validated, pre-tested, interviewer-administered questionnaire was used to obtain demographic data, diabetes related enquiries in addition to physical measurements including anthropometric measurements and biochemical tests. Questions related to diabetic peripheral neuropathy (DPN), DR, diabetic foot and cardiovascular complications were included. Lipid profile and glycosylated hemoglobin (HbA1c) were tested by calibrated laboratory methods. Blood pressure, BMI and waist circumference were measured as these are indirectly related to complications of diabetes mellitus.

Laboratory methods

Fasting levels of plasma glucose, cholesterol, triglycerides, high density lipoprotein (HDL), low density lipoprotein (LDL) and HbA1c were measured using standardized laboratory techniques.

Ethical clearance

A written consent was obtained from all participants prior to enrolment. The following information was given during data collection, to insure that participants had the information needed to make the informed consent. Furthermore, participation was optional and no penalty for refusal. A complete description of the aims of the study, potential benefits and risks, and assurance of confidentiality of any information given, any other additional information requested by participants was provided during data collection. A formal ethical approval was obtained from the ethical committee of the Faculty of Medicine, University of Science and Technology in Khartoum (IRB No. 00008867).

Statistical analysis

Data had been collected, organized, coded and entered in master sheet in a personal computer and analysed using R statistical software version 3.1.2 and the Statistical Package for Social Science SPSS software program [version 21.0 computer program (SPSS, Inc., Chicago, IL, USA)]. The main variables analyzed were age, sex, BMI, blood glucose level, retinopathy, neuropathy, albuminuria, blood pressure and a family history of diabetes mellitus, duration of diabetes, cholesterol, triglyceride and HbA1c. ANOVA test was used to test for significance between proportions. P value <0.05 was considered statistically significant. Logistic regression analysis was used to establish absolute risk factors and to adjust for demographic and clinical variables.

Results

In this study, 310 individuals with type 2 diabetes were included. Their mean age was 58.7 years old. Males were 182 (58.7%) and females were 128 (41.3%). The prevalence of diabetic foot was found to be 18.1% in this cohort (95% CI: 13.78–22.34%). The mean BMI was 26.2 m²/kg. The presence of hypertension, nephropathy, retinopathy and neuropathy were found not to be associated with diabetic foot with P value (0.62, 0.34, 0.48 and 0.14) respectively. HbA1c, cholesterol, HDL, LDL and Triglyceride were also not statistically associated with diabetic foot with P value of (0.39, 0.35, 0.59, 0.99 and 0.62) respectively. Duration of diabetes was significantly associated with DFU (P<0.0018) (*Table1*).

Logistic regression to identify absolute predictors of diabetic foot

We conducted stepwise logistic regression for all the variables that were deemed clinically significant (Table 1) in order to identify absolute predictors of DFU. Utilizing the full logistic regression model that adjusts for all risk factors for diabetic foot simultaneously, only the duration of DM was the statistically significant. Even after adjusting for all other potential risk factors, living with diabetes for more than 10 years is associated with an increase in the diabetic foot probability by 3.16 folds (95% CI: 0.52-10.86 folds increase), P=0.006. The adjusted effect for living with diabetes for more than 20 years on the diabetic foot complication probability is an increase by 1.73 folds (95% CI: 0.34-4.37 folds increase), P=0.0053. However, living with diabetes for more than 5 years had a non-significant adjusted effect on diabetic foot probability. The risk is increased by 13.19 folds but this not significant P>0.05 (95% CI: -0.003 to 0.008) (Table 2).

Discussion

The global prevalence was estimated to be 6.3% and in Africa it was estimated to be around 7.2% (8). In this study we have shown that the prevalence of diabetic foot is around 18.1% which is higher than the estimated prevalence regionally and internationally. For example the prevalence of diabetic foot in Cameroon, Nigeria and Tanzania were estimated to be 13%, 9.5% and 15% respectively (11-13). There is very limited research about prevalence of DFU in Sudan and to our knowledge this represents the first study about prevalence of diabetic foot. The DFU is characterized by infection, ulceration, peripheral neuropathy and peripheral vascular disease (16). The prevalence of neuropathy and peripheral vascular disease in Sudan was well documented in the literature. For instance, the prevalence of peripheral neuropathy in Sudan in association with diabetes showed progressive increase over the last 2 decades, as the prevalence in 1989 was 28.1%, in 1991 was 31.5%, 1995 it was 37% and in 2000 it was 66% (17-20). Importantly, this was attributed to prolonged duration of diabetes and poor glycemic control (17). In Tanzania it was noted that 100% of patients who presented with foot ulcers to a large diabetes outpatient clinic, had varying degrees of severity of peripheral neuropathy (13). In this study the prevalence of neuropathy in association with diabetic foot was 82.1%, this was not statistically significant as the

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Table 1 Anthropometric measurement for individuals with diabetes Khartoum (N=310)

Factor/covariate	DFU (%)	No DFU (%)	Total (%)	P value
Gender				0.608
Men	35 (62.5)	147 (57.7)	182 (58.7)	
Women	21 (37.5)	107 (42.3)	128 (41.3)	
Age, mean ± SD, (years)	57.7	59	58.7	0.401
BMI, mean ± SD	25.7	26.3	26.2	0.303
Family history				0.608
Negative	18 (32.1)	87 (34.4)	105 (34.0)	
Positive	38 (67.9)	167 (65.6)	205 (66.0)	
Duration of diabetes				0.0018
Up to 5 years	0 (0)	34 (13.5)	34 (11.0)	
6 to 10 years	5 (8.9)	47 (18.5)	52 (16.8)	
11 to 20 years	23 (41.1)	94 (36.9)	117 (37.7)	
More than 20 years	28 (50.0)	79 (31.2)	107 (34.5)	
Hypertension				0.672
Negative	31 (55.4)	130 (51.2)	161 (51.9)	
Positive	25 (44.6)	124 (48.8)	149 (48.1)	
Cholesterol (mean)	171.5	157.6	162.9	0.359
HbA1c (mean)	9.84	10.15	10.09	0.396
Triglycerides (mean)	149.9	142.5	143.9	0.627
HDL (mean)	38.21	37.06	37.26	0.599
LDL (mean)	122.35	113.69	115.2	0.998
Retinopathy				0.342
Both eyes	41 (73.2)	162 (63.9)	203 (65.6)	
Left eye	6 (10.7)	28 (11.0)	34 (10.9)	
Right eye	1 (1.8)	20 (7.8)	21 (6.8)	
Negative	8 (14.3)	44 (17.3)	52 (16.7)	
Albuminuria				0.480
Negative	35 (62.5)	174 (68.5)	209 (67.4)	
Positive	21 (37.5)	80 (31.5)	101 (32.6)	
Neuropathy				0.140
Negative	10 (17.9)	73 (28.6)	83 (26.8)	
Positive	46 (82.1)	181 (71.4)	229 (73.2)	

No significant association was found between DFU group and other metabolic factors like hypertension, albuminuria, retinopathy, neuropathy, HbA1c, cholesterol, HDL, LDL and triglyceride when using ANOVA testing. Only duration of diabetes was statistically significant.

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Table	2	Logistic	regression	anal	VS1S

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Factor/acuariata	OR —	95% con	95% confidence	
Factor/covariate		Lower	Upper	r value
Male gender	1.234	0.521	2.920	0.633
Age	0.992	0.959	1.026	0.642
BMI	0.968	0.891	1.053	0.448
FH	0.878	0.423	1.819	0.726
Duration over 10	4.158	1.507	11.476	0.006
Duration over 20	2.733	1.39	5.37	0.005
Hypertension	0.812	0.406	1.624	0.555
Cholesterol	1.002	0.995	1.009	0.560
HbA1c	0.943	0.750	1.185	0.613
Triglycerides	1.000	0.995	1.004	0.859
HDL	1.005	0.979	1.032	0.725
LDL	1.004	0.997	1.011	0.274
Retinopathy	0.894	0.421	1.898	0.770
Albuminuria	1.413	0.711	2.809	0.324
Neuropathy	1.858	0.767	4.502	0.170

Logistic regression analysis showed that there was high risk after 10 years of duration of diabetes [increase risk by 3.16 folds (95% CI: 0.52–10.86 folds increase), P=0.006]. After 20 years there was significant association but not similar as after 10 years duration of diabetes [increase by 1.73 folds (95% CI: 0.34–4.37 folds increase), P=0.0053] .However, living with diabetes for more than 5 years had a non-significant adjusted effect on diabetic foot probability. The risk for all those with diabetes for more 5 is increased by 13.19 folds but this not significant P>0.05 (95% CI: -0.003 to 0.008).

prevalence of neuropathy in non DFU group was 71.4%. This could be alarming, as this may suggest that there is high potential risk of developing DFU in the non DFU group. This may also explain why no significant association was found between DFU group and other metabolic factors like hypertension, nephropathy, retinopathy, neuropathy, HbA1c, cholesterol, HDL, LDL and triglyceride. This due to the fact, that these variables are present in high levels in non-diabetic ulcer foot group. Several studies have shown association between diabetic foot and hypertension, albuminuria, retinopathy, neuropathy, HbA1c, cholesterol, HDL, LDL and triglyceride (8,11-16). Peripheral vascular disease is another important contributor in pathogenesis of diabetic foot, and prevalence of peripheral vascular disease in Sudan in 1989 was estimated to be 6.2% and

this increased to 10% in 1995 (18,20). Due to increase in urbanization across Africa there is an increase in prevalence of peripheral vascular disease. For instance, the prevalence of peripheral vascular disease in Nigeria was estimated to be 54% and in Tanzania was estimated to be 21% (13,21).

Importantly, only the duration of DM was the statistically significant risk factor. There was high risk after 10 years of duration of diabetes [increase risk by 3.16 folds (95% CI: 0.52-10.86 folds increase), P=0.006]. After 20 years there was significant association but not similar as after 10 years duration of diabetes [increase by 1.73 folds (95% CI: 0.34-4.37 folds increase), P=0.0053] .However, living with diabetes for more than 5 years had a non-significant adjusted effect on diabetic foot probability. The risk for all those with diabetes for more than 5 is increased by 13.19 folds but this not significant P>0.05 (95% CI: -0.003 to 0.008). Gumaa et al. showed that having diabetes for longer than 10 years was significant risk factors for development of diabetic foot in Sudanese individuals with diabetes (22). Malik et al. mentioned that ulceration, previous amputation, prolonged diabetes duration and poor long-term control of glycaemia and lipids are important risk factors for amputation in populations with diabetes (23).

In systemic review by international research collaboration for the prediction of diabetic foot ulcerations (PODUS), they showed that inability to feel a 10 g monofilament (OR =3.184; 95% CI: 2.654-3.82), at least one absent pedal pulse (OR =1.968; 95% CI: 1.624-2.386), a longer duration of a diagnosis of diabetes (OR =1.024; 95% CI: 1.011-1.036) and a previous history of ulceration (OR =6.589; 95% CI: 2.488–17.45) were all predictive of risk of diabetic foot. Interestingly, the authors of this report commented that the results in the validation data set for duration of diabetes were unexpected, where a longer duration of diabetes was protective against ulceration (24). This may explain the decrease in odd ratio in our study when the duration of diabetes was 20 years or more in comparison with odd ratio for 10 years. In another meta-analysis it was shown that age, gender, diabetes duration, BMI, HbA1c and neuropathy are associated with DFU. Diabetic neuropathy, peripheral vascular disease, foot deformity and previous DFU or lower extremity amputation were consistently associated with DFU development (25). Further research is needed to assess whether tropical disease like mycetoma and leishmaniasis may have impact in development of DFU in Sudan.

This study is not without limitations. The study design was a cross-sectional study, so we could not take account of the temporal relationship between potential risk factors

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and outcomes. Another limitation is the short duration of the study and we are not able to assess for late diagnosis of diabetes. Despite these factors, we believe that this study is novel and its findings reflect the trend of rising frequency of DFU in developing countries.

Conclusions

Prevalence of diabetic foot ulcer among individuals with type 2 DM was 18.1 %, which is higher when compared with regional and global figures, as well the DFU was significantly associated with duration of diabetes for at least 10 years.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The study was approved by the ethnical committee in University Medical and Science and Technology (UMST), Khartoum, Sudan (IRB No. 00008867). Written informed consent was obtained from the patient.

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