Assessment of Risk Factors Associated with Diabetic Foot Ulcers among Diabetic Patients Attending Suez Canal University Hospitals

Shorok Gamal[1], Abd-Raof El-Deib[1], Fawzi A. Khalil[1], Khalil A. Khalil[1], Seham A. Omar[1], Mohmed M. Abdou[1] and Hamdy Sliem[1*]

[1]*Internal Medicine Department, Faculty of Medicine, Suez Canal University, Ismailia, Egypt.*

Authors' contributions

This work was carried out in collaboration between all authors. All authors read and approved the final manuscript.

Original Research Article

ABSTRACT

Background: Diabetic patients are prone to multiple complications such as diabetic foot ulcers (DFUs). There are many risk factors associated with DFUs that could be simply prevented.
Aim: Assessment of risk factors associated with Diabetic Foot Ulcers and their prevalence among diabetic patients attending Suez Canal University Hospitals.
Patients and Methods: This was a descriptive cross-sectional study carried in Diabetic and Endocrinology clinic of Suez Canal University Hospital where 68 patients with diabetic foot ulcers were examined. Patients were interviewed using a structured questionnaire to document clinical history. Statistical analysis was performed using SPSS software Ver. 22.
Results: The mean age was 58.29± 10.86 years. The most prevalent and significant risk factors were: absence of foot self-care (95.6%), poor foot health education (92.6%), wearing inappropriate shoes (89.7%), insulin dependent therapy (83.8%), poor compliance on diet or treatment (73.5%),

_____

Corresponding author: E-mail: hamdy.sliem@yahoo.com;

poor glycemic control (72.1%), duration of diabetes more than 10 years (70.6%) and presence of peripheral neuropathy (67.6%) with *P* values <0.05%.
 Conclusion: The most prevalent risk factors among DFUs patients were: absence of foot self-care, insufficient receiving foot health education and wearing in-appropriate shoes.

1. INTRODUCTION AND RATIONALE

Diabetes mellitus (DM) is one of the main problems in health systems. Worldwide, the number of people with DM has more than doubled during the past 20 years. The latest global estimate from the International Diabetes Federation is that in 2015 there were 415 million people with DM and that by 2040 the number will be 642 million [1].

Patients with DM are prone to multiple complications such as diabetic foot ulcer (DFU), it occurs in both type 1 and type 2 diabetes and it has been estimated that the lifetime risk of a patient developing a foot ulcer is 25% [2,3].

The prevalence of diabetic foot ulceration is approximately 4%–10%, and the annual population-based incidence is approximately 1%–4% of diabetic patients worldwide. Patients aged more than 65 had 1.9 times more risk to undergo major amputation of the lower limb [4]. In most developed countries, the annual incidence of foot ulceration among diabetic patients is about 2%. In these countries, diabetes is the most common cause of non-traumatic amputation; approximately 1% of people with diabetes suffer a lower-limb amputation[5]. In the developing countries, foot ulcers and amputations are despondently very common. Often, poverty, a lack of sanitation and hygiene, and barefoot walking interact to compound the impact of diabetes foot damage [6]. Moreover, ischemia of lower limbs and infection are closely associated with amputation of diabetic foot patients [7].

Overall, the rate of lower limb amputation in patients with DM is 15 times higher than patients without diabetes. It is estimated that approximately 50%-70% of all lower limb amputations are due to DFU [6]. In addition, approximately 20% of hospital admissions among patients with DM are the result of DFU [8].

Therefore, the socio-economic burden incurred due to diabetes and related complications such as DFU and lower limb amputation are immense.

These include direct costs of medication, hospitalization, cost of treatment, and supplies. Patients and their relatives also incur indirect costs that may include time lost from work, loss of income from the patient and relatives, diversion of family resources from other basic needs, and premature death that has a great impact on the patient's dependents [9].

Is foot ulceration preventable? *Most likely YES if risk factors were considered.* Hence, the current study are designed to assess common risk factors associated with Diabetic Foot Ulcers and their prevalence among diabetic patients attending Suez Canal University Hospitals

2. SUBJECTS AND METHODS

The study was a descriptive cross-sectional study carried out in the Diabetic and Endocrinology clinic of Suez Canal university hospital, Ismailia since November 2013 to April 2016 . Following our faculty research and ethical committee approval and informed patient's consent, sixty-eight patients with current/or history diabetic foot ulcers, amputation of one limb (both gender, type 1 or type 2 DM) were included. Patients with foot ulcers due to trauma, vascular diseases or renal disease were excluded from the study.

Sixty eight patients fulfilled the above criteria were assessed through a structure interview questionnaire including; Name, Age, Sex, Occupations, Educational status, and marital status, Duration of the disease and Type of diabetes, Body weight, Cigarette smoking, Type of treatment, Co-Morbidities, symptoms of Peripheral neuropathy (Positive symptoms as; burning or shooting pain, electrical or sharp sensations, etc. and Negative symptoms as; numbness, feel feet dead, etc.), receiving health education, Diabetic self care practice and wearing of fitting foot wear (with fitting size, wide toe box, adequately padded heel, flexible outsole and not with high heel) and Previous history of diabetic foot ulcers or amputation. Examination of both feet included, Inspection (Skin, Nail, Deformity and Footwear), Palpation (Temperature, Range of Motion), Neurological examination including (pressure sensation using

a 10 g Semmes-Weinstein mono-filament at ten sites: Digits (1st, 3rd, 5th.), Metatarsal heads (1st, 3rd, 5th.), Midfoot (Medial and Lateral), heel, Top (dorsum) of foot and Vibratory sensation using a 128Hz tuning fork), peripheral pulsation was assessed by evaluating the dorsalis pedis (DP) and posterior tibial (PT) pulses on the same limb with a hand held vascular Doppler [10]. For all the patients, Laboratory investigations were done including: Fasting blood glucose level, 2-hours Postprandial blood glucose level, HbA1c and Lipid profile.

2.1 Statistical Analysis

The data were coded and organised. The final study results were stated using the SPSS program version 22. Results were presented through tables. Categorical data are summarised as a percentage of the group total with corresponding 95% Confidence intervals and were expressed either as frequency or mean±SD. The Chi - square test was used for qualitative variables while the independent *t* test was used for quantitative variables. All socio-demographic risk factors linked with diabetic foot, as well as clinical and laboratory status, which were bring into being to be significant on univariate analysis, were integrated in a logistic regression analysis model to appraise the relations between the diabetic foot ulcer and different risk factors after adjustment for potential confounders, including age, gender and smoking habits. All variables in this model were categorised, and the co-efficient, odds ratio and 95% confidence interval [OR (95% CI)], and *P*-value, for each category as compared to the baseline category are adjusted for other variables. *P*-value of <0.05 was considered as statistically significant.

3. RESULTS

Table 1 shows socio-demographic characteristics of the studied population, mean age was 58.3 years, 54.4% were males, 55.9% from urban areas. Non significant *P* value.

Table (2). Shows the Frequency of co-morbidities among studied population, with 42(61.8%) patients had hypertension, 23 (33.8%) patients had ischemic heart disease and 22 (32.4%) were smokers with significant *P* values.

As shown in **Table (3).** Only 6 (8.8%) patients had average weight, 20 (29.4%) were overweight, 32 (47.1%) had obesity class 1 and 9 (13.4%) had obesity class2. With significant *P* value.

Table 4. illustrates risk Factors Related to Diabetic History and Treatment Among studied population, the majority of patients had type 2 diabetes 64 (94.1%) patients, 48 (70.6%) patients gave history of diabetes for more than 10 years, 57(83.8%) patients were on insulin therapy, 50 (73.5%) patients reported no compliance on diet or treatment, 35(51.5%) patients checked glucose monthly and only 6(8.8%) checked glucose daily. *P* values were significant.

Table 5 shows frequency of self-care related risk factors among studied population; Diabetic foot self-care was deficient in 65 (95.6%) patients, 63(92.6%) patients denied receiving health education regarding diabetic foot self-care and 61(89.7%) patient had inappropriate foot wear. Significant *P* values.

Table 1. Demographic data

Demographic data		Frequency %	*P* value
Gender	Male	37 (54.4%)	0.422
	Female	31 (45.6%)	
Age	Range	20-85 years	--
	Mean±SD	58.29±10.86	
Residence	Rural	30 (44.1%)	0.385
	Urban	38 (55.9%)	

Table 2. Frequency of co-morbidities among studied population

Risk Factor	Frequency	Percent%	P value
Hypertension	42	61.8%	0.012
Ischemic heart disease	23	33.8%	0.032
Smoking	22	32.4%	0.046

Table 3. Distribution of BMI among patients with DFUs

BMI	Frequency	Percent %	P value
Normal	6	8.8 %	0.001
Overweight	20	29.4 %	
Obesity 1	32	47.1 %	
Obesity 2	9	13.2 %	
Obesity 3	1	1.5 %	

Table 6 shows distribution of significant risk factors found during foot examination among patient with DFUs, it was noticed that ; peripheral neuropathy was the most prevalent risk factor which was found in 46 (67.6%) patients followed by callus in 23(33.8%) patients, foot deformities in 20 (29.4%), Tinea Pedis in 18(26.5%) and only 6 (8.8%) patient had absent peripheral pulsation.

Table 7 displays the relation between HbA1c, FBS, PPBS and Lipid profile and gender: The most significant relation was between gender and HDL level (*P*-value <0.05).

4. DISCUSSION

The current study was a cross-sectional descriptive study aimed to assess the most common and important risk factors associated with diabetic foot ulcers and their prevalence among diabetic patients attending Suez Canal university hospitals. In this study 68 diabetic patients with age over 18, presented with diabetic foot ulcers were included. Our data were obtained by history taking, examination and investigations. The range of age of our patients was between 20 and 85 years, with mean age of 58.29± 10.86 years, 37 patients of them were Males (54.4%), that was not significant.

Another study by Dinh and Veves [11] which included 248 patients with diabetes were enrolled in a 30-month with equal frequency of males and females, its results showed that women have a lower risk than men for foot ulceration, which was consistent with our results.

Table 4. Risk factors related to diabetic history and treatment

Diabetic History		Frequency	Percent (%)	P value
Type of DM	1	4	5.9%	0.001
	2	64	94.1%	
Duration (Years)	<10	20	29.4%	0.001
	>10	48	70.6%	
Treatment	Oral	11	16.2%	0.001
	Insulin	57	83.8%	
RBS Checking	No	18	26.5%	0.019
	Monthly	35	51.5%	
	Weekly	9	13.2%	
	Daily	6	8.8%	

Table 5. Frequency of self-care related risk factors among studied population

	Frequency	Percent%	P value
No foot care	65	95.6%	0.001
Inappropriate foot wear	57	83.8%	0.001
No health education	63	92.6%	0.001

Table 6. Distribution of Podological risk Factors among studied population

Risk factors	Frequency	Percent%	P value
Callus	23	33.8%	0.001
Tinea Pedis	18	26.5%	0.001
Deformities	20	29.4%	0.002
Peripheral Neuropathy	46	67.6%	0.003
Absent Peripheral dorsalis Pulsation	6	8.8%	0.042

Table 7. Relation between HbaA1c, FBS, PPBS, lipid profile and gender

Lab.	Gender	Mean	Std. deviation	*P*-Value
HbA1c	male	8.3108	2.31346	0.142
	female	7.5968	1.63003	
FBS	male	229.108	86.4245	0.474
	female	215.645	67.7621	
PPBS	male	287.162	91.8705	0.416
	female	270.129	79.5586	
LDL	male	141.891	52.5678	0.715
	female	137.193	52.5353	
HDL	male	43.4054	6.85752	0.044
	female	47.5484	9.27304	
Cholesterol	male	241.675	59.0329	0.485
	female	234.129	66.8180	
Triglycerides	male	180.270	85.3332	0.892
	female	192.935	107.726	

Current data had revealed that, DFU had more distribution in urban areas (55.9%) than rural areas (44.1%), but it wasn't significant difference. That could be explained by more awareness of patients in urban areas regarding seeking medical advice earlier than patients in rural areas. On the other hand, a study done by Deribe et al. [12] in which 216 diabetic patients were involved , 53.1% of diabetic patients with foot ulcer were from rural and the remaining 42.1% were from urban area . That difference may be due to difference in race, Environment and traditional habits.

Whereas 32.4% of the patients were smoker and the vast majority of them were males, smoking may be an important significant risk factor for males in developing DFU more than female. This is explained by strong relation between smoking and peripheral vascular disease which is associated with DFU. In more, Ding et al meta-analysis indicated that smoking had an overall negative effect on the wound healing of diabetic foot individuals [13].

In addition, 29.4% of our patients with DFU were overweight, 47.1% of them had obesity class1, 13.2% had obesity class2, 1.5% had obesity class 3 and only 8.8% of them had normal BMI**.** This significant association could be due to higher foot pressure in those with greater weight and higher BMI [14].

The majority of our patients had type 2 diabetes 94.1% and 70.6 % had diabetes for a long duration more than 10 years. That may be due to increased incidence of diabetic complications as peripheral neuropathy and PVD with long duration of the disease.

In agreement with current results, Reiber[15] noticed in his study a six-fold increase in the risk of DFU in patients with 20 years or more of DM compared with patients with a shorter duration of DM. In this study, 61.8% of patients had hypertension and it was more among females, while 33.8% of them had ischemic heart disease with similar frequencies among males and females. In Ahmed et al. [14] study 56% of patients had hypertension, with no significant difference with our study.

In the study done by Al Kafrawy et al. [16] results showed that 74% of the patients with DFU had previous history of DFU and amputation with significant difference compared to those without DFU.

Likewise, in the present study we found that 60.3% of the patients had history of DFU and 35.3% had history of lower limb amputation as a result of diabetic foot. This may be attributed to previous foot ulcer and amputation leading to loss of protective sensation and peripheral neuropathy [17].

One of the most common significant risk factors among our patients was absence of foot self-care as reported by 95.6% of them, also in-appropriate foot wear found in 83.8% of our

patient and 92.6% of them even denied receiving health education regarding diabetic foot self-care. That may be due to repetitive trauma induced by inappropriate foot wear that couldn't be detected by patients with peripheral neuropathy.

Our results were similar to a wide study that done in Mansoura by El-Nahas et al. [18] which enrolled 1220 diabetic patients over 12 months, it showed that 61.6% of the patients used inappropriate footwear and 93.8% received no prior foot education.

During foot Examination, we found that 67.6% of the patients had peripheral neuropathy so, it was an important significant risk factor of DFUs. This may be attributed to the fact that sensory neuropathy leads to loss of protective function and loss of recognition of the consequence of repetitive trauma. Similar results were documented by Al Kafrawy et al. [16]. They showed in their study that peripheral neuropathy was the main risk factor for DFU which was analogous to our results.

Current results revealed that, the most widespread significant risk factors were; absence of foot self-care (95.6%), non attendance a prior foot health education (92.6%), wearing in-appropriate shoes (89.7%), insulin dependent therapy (83.8%), no compliance on diet or treatment (73.5%), poor glycemic control (72.1%), Duration of diabetes more than 10 years (70.6%), peripheral neuropathy (67.6%), over weight (61.8%) and history of pervious DFU (60.3%).

When we clustered the most common risk factors together, we found that all of our patients had more than one significant risk factor and 38.2% of them had more than 10 risk factors. This in agreement with studies of Martin et al. [19], and Rogers et al. [20] which reported that most of the patients had 4 or more risk factors. Adding together, these results are in agreement with previous study conducted in surgery department, Suez Canal University where the author documented that "Peripheral vascular disease and peripheral neuropathy, poor glycemic control and anaemia together with lack of foot self-examination, are main significant risk factors for diabetic foot ulceration" [21]. On the subject of diabetes control, Xiang et al reported that a reasonable HbA1c target, a range between 7.0% and 8.0% during treatment, could facilitate ulcer

healing without increase of mortality in patients with DFU [22].

Coming to the end, certainly DFUs are a serious complication of diabetes and are associated with disability, and poor quality of life. Fortunately, Ku and Liang recently reviewed that Incretin-based therapy may have a position in the treatment of DFUs. Aside from glucose control, the benefits of such treatment take place from attenuation of inflammatory response, bringing on angiogenesis, improvement of keratinocyte migration and the enhancement of tissue remodeling. They suggested that prospect research on the topical application of incretin-based therapy is necessary and such therapeutic approaches may offer new hope in improving the treatment of impaired DFUs [23].

The main limitation of the current study is the sample size. Further wide prospective studies are required.

5. CONCLUSION

The most prevalent risk factors in a descending order were: absence of foot self-care, non attendance a prior foot health education and wearing in-appropriate shoes. Health education for improving the patients knowledge regarding foot care and diabetes control, improving compliance, civilizing family supportive role, and appropriate regular follow-up diabetic care are recommended.

CONSENT AND ETHICAL APPROVAL

Following our faculty research and ethical committee approval and informed patient's consent, sixty-eight patients with current/or history diabetic foot ulcers, amputation of one limb (both gender, type 1 or type 2 DM) were included.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. International Diabetes Federation. IDF Diabetes Atlas 7th ed.
Available:http://www.diabetesatlas.org (2016).

2. Shahbazian H, Yazdanpanah L and Latifi SM. Risk assessment of patients with diabetes for foot ulcers according to risk classification consensus of International Working Group on Diabetic Foot (IWGDF). Pak J Med Sci. 2013;29:730-34.

3. Bazian H, Yazdanpanah L, Latifi SM. Risk assessment of patients with diabetes for foot ulcers according to risk classification consensus of International Working Group on Diabetic Foot (IWGDF). Pak J Med Sci. 2013;29:730-34.

4. Khalfallah M, Gouta EL, Dougaz W, Jerraya H, Samaali I, et al. Predictive factors for major amputation of lower limb in diabetic foot: about 430 patients. Tunis Med. 2018;96(5):298-301.

5. Bowering CK. Diabetic foot ulcers: pathophysiology, assessment, and therapy. Can Fam Phys. 2011;47:1007–16.

6. Leone S, Pascale R, Vitale M, et al. Epidemiology of diabetic foot. Infez Med 2012;20(S1):8-13.

7. Xu B, Yang CZ, Wu SB, Zhang D, Wang LN, Xiao L, Chen Y, et al. Risk factors for lower extremity amputation in patients with diabetic foot. Zhonghua Nei Ke Za Zhi. 2017;56(1):24-28.
DOI:10.3760/cma.j.issn.0578-1426.2017.01.007.

8. Kibachio JM, Muriuki Z, Juma R, et al. Risk factors for diabetic foot ulcers in type 2 diabetes, a case control study, Nyeri, Kenya. African Journal of Diabetes Medicine. 2013;21:20-22.

9. Snyder RJ, Hanft JR. Diabetic foot ulcers--effects on QOL, costs, and mortality and the role of standard wound care and advanced-care therapies. Ostomy Wound Manage. 2009;55:28-38.

10. Höliner I, Haslinger V, Lütschg J, Müller G, Barbarini D, Saely CH et al. Validity of the neurological examination in diagnosing diabetic peripheral neuropathy. Pediatr Neurol. 2013;49(3):171-7.
DOI:10.1016/j.pediatrneurol. 2013.03.014. Epub 2013 Jul 4.

11. Dinh T, Veves A. The Influence of Gender as a Risk Factor in Diabetic Foot Ulceration. Wounds. 2008;20(6):1-4.

12. Deribe B, Woldemichael K, Nemera G. Prevalence and factors influencing diabetic foot ulcer among diabetic patients attending Arbaminch Hospital, South Ethiopia. J Diabetes Metab. 2014;5(1): 1-7.

13. Ding H, Fu XLMiao WW, Chen HL. Association between cigarette smoking and diabetic foot healing: A systematic review and meta-analysis. Int J Low Extrem Wounds. 2018;21.
DOI:10.1177/1534734618809583. [Epub ahead of print]

14. Ahmed AA, Algamdi SA, Algurashi A, et al. Risk factors for diabetic foot ulceration among patients attending primary health care services .The Journal of Diabetic Foot Complications. 2014;6(2):40-7.

15. Reiber GE. Epidemiology of foot ulcers and amputations in the diabetic foot. In: Bowker JH, Pfeifer MA (eds.). The diabetic foot. 6th ed. 2011;13–32.

16. Al Kafrawy NA, Mustafa EA, Dawood A, et al. Study of risk factors of diabetic foot ulcers. Menoufia Medical Journal. 2014;27:28–34.

17. Unachukwu C, Babatunde S, Ihekwaba AE. Hand and/or foot ulcers: A cross-sectional hospital-based study in Port Harcourt, Nigeria. Diabetes Res Clin Pract. Diabetes. 2007;75:148-52.

18. El-Nahas MR, Gawish HMS, Tarshoby MM. The prevalence of risk factors for foot ulceration in Egyptian diabetic patients. Practical Diabetes International. 2008; 25(9):362–6.

19. Martín BV, Herranz de la Morena L, Castro DI, et al. Diabetic foot and risk factors [in Spanish]. An Med Interna. 2007;24:263–6.

20. Rogers LC, Driver VR, Armstrong DG. Assessment of the diabetic foot.In: Krasner D, Rodeheaver GT, Sibbald RG, eds. Chronic wound care: a clinical source book for healthcare professionals. 4th ed.; 2007; 549–55.

21. Hokkam EN. Assessment of risk factors in diabetic foot ulceration and their impact on the outcome of the disease. Prim Care Diabetes. 2009;3(4):219-24. DOI:10.1016/j.pcd.2009.08.009. Epub 2009 Sep 23

22. Xiang J, Wang S, He Y, Xu L, Zhang S, Tang Z. Reasonable glycemic control would help wound healing during the treatment of diabetic foot ulcers. Diabetes Ther. 2018 Nov 21. DOI:10.1007/s13300-018-0536-8. [Epub ahead of print]

23. Ku HC, Liang YJ. Incretin-based therapy for diabetic ulcers: from bench to bedside. Expert Opin Investig Drugs. 2018;19:1-8. DOI:10.1080/13543784.2018.1548607. [Epub ahead of print]