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Different Factors Predicting Diabetic Foot Ulcer Development

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Abstract:

Background: Diabetic foot ulcer (DFU) is a common complication of diabetes mellitus (DM) that has spread over recent decades. DFU is considered as a major source of morbidity and a leading cause of hospitalization in diabetic patients, so identifying the contributing factors in DFU development is crucial. **Objective:** we aim to identify the factors predicting the risk of DFU occurrence and its risk stratification in patients with type 2 diabetes mellitus in Minia university hospital. **Methods:** 200 patients with type 2 diabetes mellites were assigned to a questionnaire of sociodemographic characteristics, diabetes treatment and smoking, and a foot risk classification system after a foot examination. **Results:** The highest proportion of patients, (35%) were categorized as having a high risk. Results showed a statistically significant association between the IWGDF score and age ($p = 0.001$), income ($p = 0.006$), education ($p < 0.001$), smoking ($p < 0.001$), and DM duration ($p < 0.001$). A higher proportion of patients aged 60 years or above, illiterate, current smokers, having low income, and having DM for $\geq$10 years are being classified as having a high risk. **Conclusion:** DFU development is associated with old age, low income, low education, smoking, and long duration of DM.

Keywords: Diabetic foot, ulcer, prevention.

Introduction:

The latest estimates show that there was a global prevalence of 425 million people with diabetes in 2017, which is expected to rise to 629 million by 2045 [(1)]. The complications associated with diabetes are commonly grouped into two categories: microvascular and macrovascular complications. Macrovascular complications of diabetes, including coronary heart disease, stroke and peripheral vascular disease, and microvascular complications, such as end-stage renal disease (ESRD), retinopathy and neuropathy, along with lower-extremity amputations (LEA), are responsible for much of the burden associated with diabetes [(2)]. Diabetic foot ulcer (DFU) is a common complication of DM that has shown an increasing trend over previous decades [(3)]. In total, it is estimated that 15% of patients with diabetes will suffer from DFU during their lifetime, and about 50%-70% of all lower limb amputations are due to DFU, and the rate of lower limb amputation in patients with DM is 15 times higher than patients without diabetes [(4)]. DFU is considered as a major source of morbidity and a leading cause of hospitalization in patients with diabetes [(5)]. Five-year survival in persons who present with diabetic foot ulceration has

previously been shown to be as low as 50% [6]. For this major burden of DFU, prevention is very important and the first step to achieve it is the appropriate foot screening, risk stratification and identifying the related factors given that it allows a more effective allocation of the limited resources available for prevention and treatment of this complication. The duration of diabetes mellitus (DM) was significantly associated with the IWGDF score ($p < 0.001$).

Methods:

This cross-sectional study was conducted on 200 type 2 diabetic patients and been diagnosed for more than 6 months of both sexes, collected from Endocrinology and Vascular surgery units of Minia University Hospital in the period from March to December 2023. Patients known to have type 1 diabetes mellitus or gestational diabetes and patients know to have severe psychiatric disorder or mental retardation were excluded. All included patients were subjected to a questionnaire that included questions about sociodemographic data (Age, sex, Marital status, Occupation, Education and income), diabetes duration and treatment, smoking, history of foot ulcer, lower extremity amputation and end-stage renal disease. Patients then had a comprehensive foot examination including: Assessment of dermatological status and presence of callus, assessment of musculoskeletal status for foot deformities, assessment of vascular status: by palpating peripheral pulsations (dorsalis pedis or posterior tibial), and assessment of neurological status:

1. Pressure sensation: using Semmes-Weinstein 10 gm monofilament applied at 3 sites: the plantar aspects of the distal part and the base of the first toe, and the planter aspect of the base of the fifth toe in both feet in supine position. This application is repeated twice at the same site, alternating with at least one 'mock' application in which no filament is applied (a total of three questions per site). Pressure sensation is present at each site if the patient correctly answers on two out of three applications; absent with two out of three incorrect answers.

2. Vibration sensation: using a 128 Hz tuning fork applied on a bony part on the dorsal side of the distal phalanx of the first toe (or another toe if the hallux is absent). This application is repeated twice, alternating with at least one 'mock' application in which the tuning fork is not vibrating. The test is positive if the patient correctly answers at least two out of three applications, and negative if two out of three answers are incorrect.

After examination they were assigned to a foot risk classification system proposed by The International Working Group on the diabetic foot (IWGDF):

a. Someone without loss of protective sensation (LOPS) and without peripheral artery disease (PAD) is classified as IWGDF 0 (very low risk of ulceration).

b. A person with either LOPS or PAD but no additional risk factors is stratified as IWGDF 1 (low risk).

c. When a combination of risk factors (LOPS, PAD or foot deformity) is present a person is stratified as IWGDF 2 (moderate risk).

d. All persons with either LOPS or PAD and a history of foot ulcer, lower extremity amputation or with end-stage renal disease are stratified as IWGDF 3 (high risk).

Ethical approval was obtained from the ethical committee of Faculty of Medicine, Minia University.

Statistical analysis:
All data were collected tabulated and statistically analyzed using SPSS 26 for windows (SPSS Inc., Chicago, IL, USA). Data were tested for normal distribution using the Shapiro Walk test. Qualitative data were represented as frequencies and relative percentages. Quantitative data were expressed as Mean + standard deviation (SD) and range. Independent T test and Mann Whitney test were used to calculate difference between quantitative variables in two groups for parametric and nonparametric variables respectively.
All statistical comparisons were two tailed with significant level of P-value < 0.05 indicates significant, P<0.001 indicates highly significant reference while P> 0.05 indicates nonsignificant difference.

Results:
Table (1) shows the sociodemographic data, diabetes duration and treatment, and smoking history of the study participants. Among 200 diabetic patients, 114 were males (57%) and 86 females (43%). Participants were predominantly aged 60 years and older (61%). In terms of education, nearly half of the participants were illiterate (48%), and only 17% had higher education. Most participants were married (81%). Occupational status showed that over half of the participants were non-workers or retired (52%). Income levels indicated that 53% of the participants had a low income, 35% had a moderate income, and 12% had a high income.

Regarding the duration of diabetes, 17% had been diagnosed for less than 5 years, 34% had diabetes for 5-10 years, and 49% had been living with diabetes for over 10 years. The majority of the patients were managing their diabetes with oral agents (51%), while 43% were using insulin, 5% were on both oral agents and insulin, and 1% were managing with diet alone. Smoking habits revealed that 47% of the participants were non-smokers, 31% were current smokers, and 22% were ex-smokers **Table (1)**

The findings of foot examination of the studied diabetic patients are shown in ***Figure (1).*** In terms of sensory neuropathy, a considerable proportion of patients exhibited loss of pressure sensation (56.5%) and vibration sensation (62%). The presence of LOPS was observed in 62% of the patients. PAD was present in 15% of the participants. Regarding other foot complications, 34% of the patients had foot deformities, and 53% had calluses. Fungal infections were observed in 29% of the patients. Notably, 17% of the patients had undergone amputation ***Figure (1)***

Presence of ESRD and ulcer history are documented in ***Table (2).*** While the majority of patients did not have ESRD, a notable 12% (24 out of 200) were diagnosed with ESRD. Regarding ulcer history, the data showed that 20% (40 out of 200) of the participants reported having experienced ulcers in the past ***Table (2)***.

Risk assessment of diabetic patients for foot ulcers according to IWGDF is shown in ***Figure (2)***. The highest proportion of patients, constituting 35%, were categorized as having a high risk and 24% were found to be at moderate risk. Additionally, 25% of patients were classified as having a very low risk, while 16% were categorized as low risk ***Figure (2)***.

Table (3) shows the distribution of study patients across different categories of the IWGDF risk score based on various

demographic and clinical factors. The results showed a statistically significant association between the IWGDF score and age (p = 0.001), with a higher proportion of patients aged 60 years or above being classified as having a high risk (42.6%) compared to 23.1% among patients aged below 60 years. Similarly, the level of education demonstrated a significant association with the IWGDF score (p < 0.001), where a higher percentage of illiterate patients (47.9%) were categorized as having a high risk compared to 17.6% among highly educated patients.

The IWGDF score was found to be significantly associated with income level (p = 0.006), as a larger proportion of patients with low or moderate income were classified as having a moderate risk (40%) or high risk (35.8%) compared to those with high income where majority were classified as very low risk (58.3%). Smoking status also showed a significant relationship with the IWGDF score (p < 0.001), with current smokers had a higher proportion (51.6%) in the high-risk category, compared to 23.4% among non-smokers. However, the study did not find a statistically significant association between the IWGDF score and variables such as sex (p = 0.57), marital status (p = 0.11), and occupation (p = 0.19) ***Table (3)***.

The duration of diabetes mellitus (DM) was significantly associated with the IWGDF score (p < 0.001). Among patients with DM for less than 5 years, 64.7% were classified as very low risk, while only 11.8% were classified as high risk. In contrast, patients with DM for more than 10 years showed a different trend, with only 10.2% classified as very low risk and 44.9% as high risk. Regarding the association between the type of treatment and IWGDF risk category, the post-hoc analysis revealed that patients managed by oral agent and insulin have more proportion of high-risk category (40%) compared to patients on diet alone (0%). However, the differences in proportions across other risk categories were not statistically significant between the different treatment groups ***Table (4)***.

Table (1): distribution of studied cases according to Demographic data and special habits

Demographic data		**Frequency**	**Percentage (%)**
Sex	Male	114	57%
	Female	86	43%
Age	< 60 years	78	39%
	≥60 years	122	61%
Education	Illiterate	96	48%
	Read and write	20	10%
	Basic and secondary school	50	25%
	High education	34	17%
Marital status	Single	2	1%
	Married	162	81%
	Widowed	34	17%
	Divorced	2	1%

Occupation	Non worker/Retired	104	52%
	Farmer	50	25%
	Semiprofessional/ Professional	22	11%
	Free business	24	12%
Income	Low	106	53%
	Moderate	70	35%
	High	24	12%
Duration of DM	<5 years	34	17%
	5-10 years	68	34%
	>10 years	98	49%
DM TTT	Diet alone	2	1%
	Oral agents	102	51%
	Insulin	86	43%
	Oral and insulin	10	5%
Smoking	Non-smokers	94	47%
	Current smokers	62	31%
	Ex-smoker	44	22%

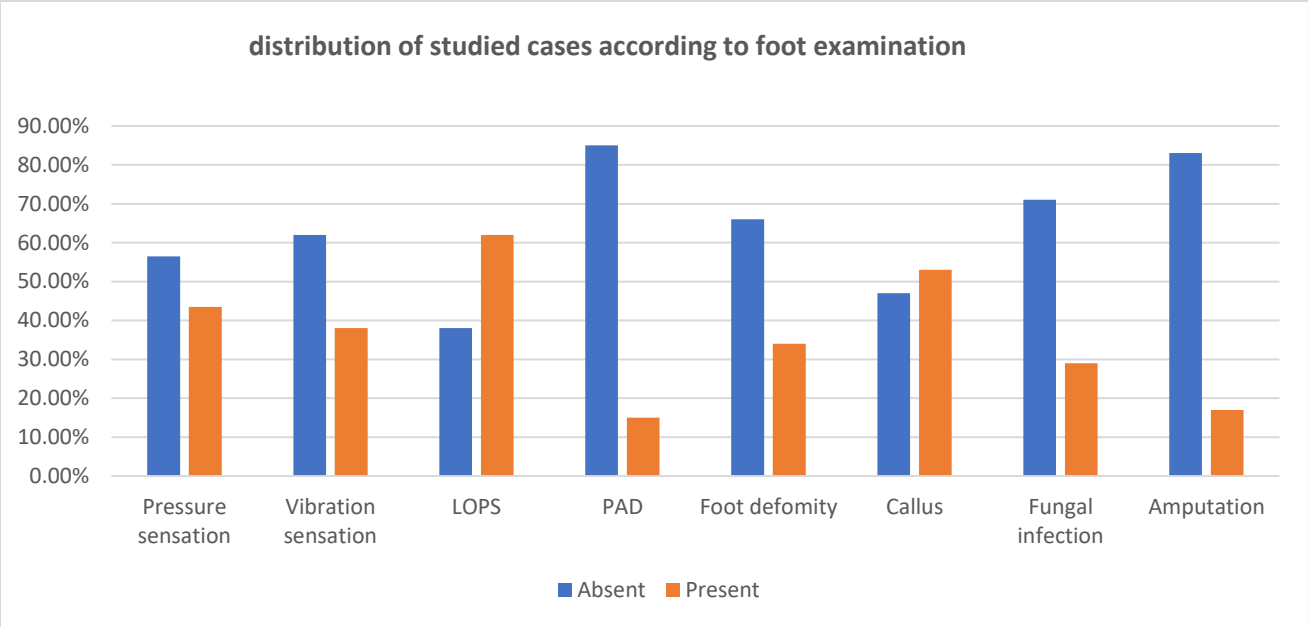

Figure (1): distribution of studied cases according to foot examination

Table (2): distribution of studied cases according to presence of ESRD and ulcer history

Associated condition		Frequency	Percentage
End stage renal disease	No	176	88%
	Yes	24	12%
Ulcer history	Absent	160	80%
	Present	40	20%

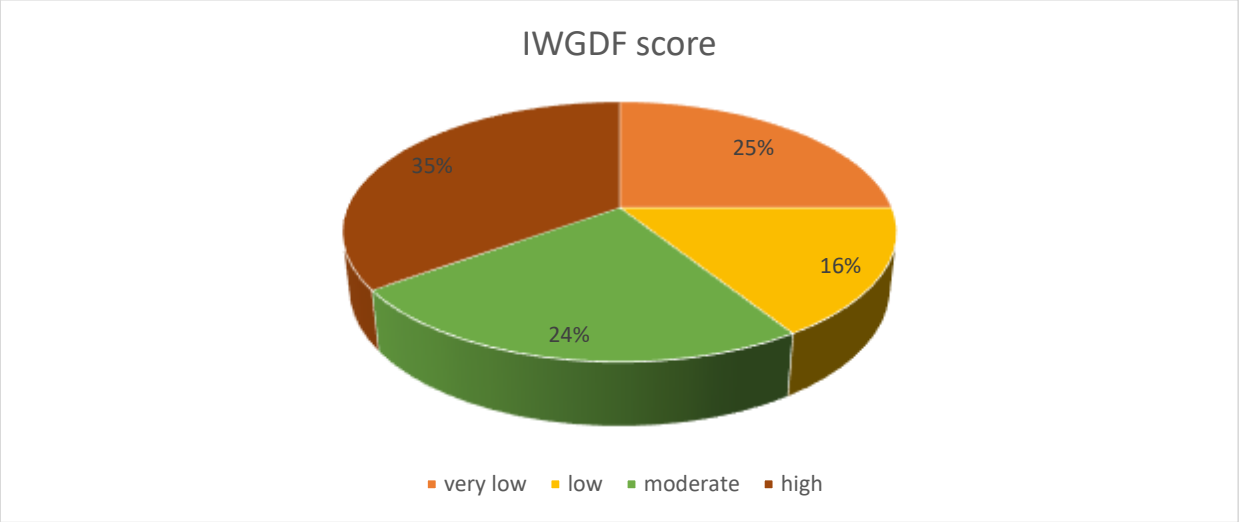

Figure (2): distribution of studied cases according to IWGDF score

Table (3): relation between demographic data of studied patients and their risk strata

	IWGDF Score				x2	P value
	Very Low	Low	Moderate	High		
	(n=50)	(n=32)	(n=48)	(n=70)		
Sex						
Male	26 (22.8%)	16 (14.0%)	30 (26.3%)	42 (36.8%)	1.9	0.57
Female	24 (27.9%)	16 (18.6%)	18 (20.9%)	28 (32.6%)		
Age						
< 60 years	30 (38.5%)	14 (17.9%)	16 (20.5%)	18 (23.1%)	15.4	0.001*
≥60 years	20 (16.4%)	18 (14.8%)	32 (26.2%)	52 (42.6%)		
Education						
Illiterate	18 (18.8%)	14 (14.6%)	18 (18.8%)	46 (47.9%)	46	<0.001*
Read and write	4 (20.0%)	0 (0.0%)	6 (30.0%)	10 (50.0%)		
Basic and secondary school	10 (20.0%)	10 (20.0%)	22 (44.0%)	8 (16.0%)		
High education	18 (52.9%)	8 (23.5%)	2 (5.9%)	6 (17.6%)		

Marital status						
Single	0 (0.0%)	0 (0.0%)	2 (100.0%)	0 (0.0%)	13.7	0.11
Married	40 (24.7%)	26 (16.0%)	36 (22.2%)	60 (37.0%)		
Widowed	10 (29.4%)	6 (17.6%)	8 (23.5%)	10 (29.4%)		
Divorced	0 (0.0%)	0 (0.0%)	2 (100.0%)	0 (0.0%)		
Occupation						
Nonworker/Retired	30 (28.8%)	14 (13.5%)	26 (25.0%)	34 (32.7%)	12.4	0.19
Farmer	6 (12.0%)	14 (28.0%)	12 (24.0%)	18 (36.0%)		
Semiprofessional/Professional	8 (36.4%)	2 (9.1%)	4 (18.2%)	8 (36.4%)		
Free business	6 (25.0%)	2 (8.3%)	6 (25.0%)	10 (41.7%)		
Income						
Low	24 (22.6%)	16 (15.1%)	28 (26.4%)	38 (35.8%)	17.9	0.006*
Moderate	12 (17.1%)	14 (20.0%)	16 (22.9%)	28 (40.0%)		
High	14 (58.3%)	2 (8.3%)	4 (16.7%)	4 (16.7%)		
Smoking						
Non-smoker	30 (31.9%)	22 (23.4%)	20 (21.3%)	22 (23.4%)	23	<0.001*
Current smoker	10 (16.1%)	2 (3.2%)	18 (29.0%)	32 (51.6%)		
Ex-smoker	10 (22.7%)	8 (18.2%)	10 (22.7%)	16 (36.4%)		

Table (4): relation between demographic data of studied patients and their risk strata

	IWGDF Score				x2	P value
	Very Low	Low	Moderate	High		
	(n=50)	(n=32)	(n=48)	(n=70)		
Duration of DM						
<5 years	22 (64.7%)	6 (17.6%)	2 (5.9%)	4 (11.8%)	48	<0.001*
5-10 years	18 (26.5%)	14 (20.6%)	14 (20.6%)	22 (32.4%)		
>10 years	10 (10.2%)	12 (12.2%)	32 (32.7%)	44 (44.9%)		
DM TTT						
Diet alone	2 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	17.7	0.04*
Oral agents	28 (27.5%)	22 (21.6%)	18 (17.6%)	34 (33.3%)		
Insulin	20 (23.3%)	8 (9.3%)	26 (30.2%)	32 (37.2%)		
Oral and insulin	0 (0.0%)	2 (20.0%)	4 (40.0%)	4 (40.0%)		

Discussion:

Diabetic foot ulcer (DFU) is a common complication of DM that has shown an increasing trend over previous decades [3]. In our study the highest proportion of patients, constituting 35%, were categorized as having a high risk for DFU development and 24% were at moderate risk. In a previous study, high risk patients constituted 29.1% of the collected sample, while 23.9 % had moderate risk for DFU occurrence[7]. While in another study patients were categorized into 'low' (64%), 'moderate' (23%) or 'high' (13%) risk of developing foot ulcers [8]. This difference between studies can be partly due differences in the scoring systems used to classify patients. There are several studies that suggest that the sociodemographic variables play an important role in diabetic foot ulceration and not just the clinical factors[9-11]. Our study results showed a

statistically significant association between the risk score and age (p = 0.001), with a

higher proportion of patients aged 60 years or above being classified as having a high risk (42.6%) compared to 23.1% among patients aged below 60 years. High risk patients had a mean age of 53.4 ± 10.2 in another study [7], and the prevalence of diabetic foot complications was higher in older patients in the study by DeBerardis et al [12].

Regarding other sociodemographic data like the level of income and education, our study showed a statistically significant association between the risk score and levels of education ($p < 0.001$), and income level ($p = 0.006$) with a higher risk score being associated with low levels of education and income. These results are consistent with results from the study by DeBerardis et al, where the prevalence of diabetic foot complications was higher in older patients, those with limited formal education and a low sociodemographic status, divorced or widowed with greater duration of diabetes, high HbA1c, treated with insulin, and with micro and macrovascular complications [12]. However, our study did not find a statistically significant association between the score and variables such as sex ($p = 0.57$), marital status ($p = 0.11$), and occupation ($p = 0.19$). Smoking as a factor showed significant statistical association with diabetic foot ulcer and the odds of having diabetic foot ulcer in smokers were 4.11 times more than non-smokers (95% CI: 2.00, 8.43) [13]. Consistent results in our study showed that current smokers had a higher proportion (51.6%) in the high-risk category, compared to 23.4% among non-smokers. Patients with DM for more than 10 years showed a trend where only 10.2% classified as very low risk and 44.9% as high risk indicating a significant association with the risk score ($p < 0.001$). Similar results in another study showed that longer mean durations of DM of 13.2 ± 12.7 and 13.5 ± 8.0 years were associated with moderate and high risks of DFU development respectively [7]. the prevalence of diabetic foot complications was higher in those with greater duration of diabetes in the study by DeBerardis et al [12]. So, we can say that first step to achieve the goal of DFU prevention should be the appropriate foot screening and risk stratification along with addressing the associated risk factors.

Conclusion: DFU development is associated with various risk factors including old age, low income, low education, smoking, and long duration of DM.

Recommendations: Risk stratification of all diabetic patients for DFU and frequent examination according to their risk along with addressing the different modifiable risk factors.

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analysis, interpretation, and revision of this manuscript. Dr. Abdelrahman Abdelaziz Ali contributed through Data collection, analysis, interpretation, and statistical analysis of this manuscript.

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