

# Screening for identification of patients at high risk for diabetes-related foot ulcers: a cross-sectional study

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Mohammed Al-Mohaithef<sup>1</sup> ,  
Sahar A Abdelmohsen<sup>2,3</sup>, Magda Algameel<sup>3,4</sup>  
and Amal Y Abdelwahed<sup>5,6</sup>

## Abstract

**Objective:** Diabetes affected 463 million people globally in 2019, and this number is anticipated to reach 700 million by 2045. Diabetes results in lower limb amputation every 30 seconds. Egypt has a high prevalence of diabetic foot disease among patients with type 2 diabetes mellitus (T2DM). We aimed to identify high-risk patients for diabetic foot ulcers (DFUs) in Egypt.

**Methods:** We designed a cross-sectional study among adult patients with diabetes at Asyut University Hospital. Inlow's 60-second diabetic foot screening tool was used to assess the risk of DFU. Neuropathy was assessed using the 10g monofilament test, and laboratory testing was performed to assess glycosylated hemoglobin (HbA1c) and diabetes control levels.

**Results:** Participants were aged  $46.11 \pm 9.18$  years; 56% had T2DM and HbA1c levels  $>7\%$ . In total, 47.9% of participants were at risk for DFUs. This risk was higher in patients who were older, male, widowed, working, illiterate, living in rural areas, and patients with diabetes duration  $>10$  years, body mass index  $>32$  kg/m<sup>2</sup>, uncontrolled blood glucose levels, on an insulin regimen, and smokers.

**Conclusions:** Increasing health care providers' awareness and ability to identify high-risk patients is critical to prevent DFUs and reduce the risk of amputation.

<sup>1</sup>Department of Public Health, College of Health Sciences, Saudi Electronic University, Riyadh, Saudi Arabia

<sup>2</sup>Department of Medical–Surgical Nursing, Faculty of Nursing, Assiut University, Egypt

<sup>3</sup>Department of Nursing Science, Prince Sattam bin Abdulaziz University, Wadi Aldawaser, Saudi Arabia

<sup>4</sup>Department of Gerontological Nursing, Faculty of Nursing, Damanhour University, Egypt

<sup>5</sup>Department of Community Health Nursing, Faculty of Nursing, Damanhour University, Egypt

<sup>6</sup>Department of Public Health, College of Health Sciences, Saudi Electronic University, Dammam, Saudi Arabia

### Corresponding author:

Mohammed Al-Mohaithef, Department of Public Health, College of Health Sciences, Saudi Electronic University, Abu Bakr Street, PO Box 93499, Riyadh 11673, Saudi Arabia.

Email: m.almohaithef@seu.edu.sa



## Keywords

Diabetes, diabetic foot ulcer, Inlow's 60-second diabetic foot screening tool, Egypt, risk factor, prevention

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## Introduction

In the past 30 years, the global incidence of diabetes has nearly quadrupled, with 422 million adults diagnosed, bringing the global prevalence of diabetes from 4.7% to 8.5%.<sup>1</sup> In Egypt, type 2 diabetes mellitus affects approximately 15.6% of the population.<sup>2,3</sup> The annual incidence of diabetes-related foot disease has been estimated at 1% to 4% and as high as 25% in some studies.<sup>4,5</sup> Diabetic foot ulcers (DFUs) are a leading cause of morbidity and mortality among adults with diabetes.<sup>6</sup> Approximately 25% of adults with diabetes will be affected by a DFU during their lifetime,<sup>5</sup> 20% of whom will require either minor or major amputation.<sup>7</sup>

It is estimated that between 1 and 3.5 million adults have a history of DFUs in the United States alone.<sup>8</sup> In Egypt, diabetes-related foot ulcers are estimated to affect 4% to 19% of people with diabetes.<sup>9</sup>

According to the International Working Group on the Diabetic Foot, the annual incidence of DFUs is approximately 2%, with a lifetime incidence of 15% to 25%.<sup>10</sup> Because 85% of lower limb diabetes-related amputations are preceded by a DFU, early detection of DFUs is a crucial step in preventing lower limb amputation. Early identification of patients at high risk for DFUs is a top priority owing to the clinical and economic burden of diabetic foot complications.<sup>11</sup>

In the present study, we aimed to identify patients with diabetes in Egypt who are at

high risk for the development of diabetic foot ulceration using Inlow's 60-second diabetic foot screening tool.

## Methods

This was a cross-sectional study that included a convenience sample of adult patients with diabetes. The sample size was calculated using Epi Info, with a 10% margin of error and a 95% confidence interval, with the following inclusion criteria: diagnosis of diabetes mellitus and attending a diabetes follow-up clinic. We excluded any patients with an ulcer related to an accident or injury. The study was conducted at Asyut University Hospital, Egypt, from May 2018 to November 2018. Recorded study data included patient demographic characteristics such as age, sex, level of education, employment status, marital status, and residential area. We also collected diabetes-related patient medical profiles, including type and duration of diabetes, body mass index (BMI), smoking status assessed according to the World Health Organization Smoking and Tobacco Use Policy, treatment regimen, and level of glycemic control. Scores on Inlow's 60-second diabetic foot screening test<sup>12</sup> were obtained to assess patients' risk for DFUs. All patients underwent a complete foot examination; neuropathy was assessed using the 10g monofilament test, in which peripheral neuropathy was detected if sensation was lost at one or more locations. Laboratory testing was performed to assess glycosylated

hemoglobin (HbA1c) and diabetes control levels.

To interpret the results of Inlow's 60-second diabetic foot screening test, the highest score from the left or right foot was used, as follows: a score of 0 to 6 indicates no risk, a score of 7 to 12 mild risk, a score of 13 to 19 moderate risk, and a score of 20 to 25 indicates high risk.

### Ethical considerations

Before beginning the study, the hospital where the research was conducted provided written consent, and the study was approved by the Research Ethics Committee (Decision No: 43) of the Faculty of Nursing, Damanhour University. The reporting of this study conforms to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.<sup>13</sup> Each eligible patient with type 2 diabetes mellitus received an explanation of the study purpose. First, verbal consent for voluntary participation was obtained from each patient. The researchers then explained the aim and nature of the study; confidentiality of the collected data was guaranteed, as was the opportunity to withdraw from the study at any time. Patients who agreed to participate in the study provided their written informed consent.

### Statistical analysis

Data were entered and subsequently analyzed using IBM SPSS version 20 (IBM Corp., Armonk, NY, USA). Number, percentage, mean and standard deviation are used to describe quantitative data. We used the chi-square test to examine relationships between risk levels for categorical variables. Independent *t*-tests were used to examine connections between the amount of risk and quantitative factors for normally distributed data. Statistical significance was set at the 0.5% level.

### Results

The current study comprised 200 adult patients with diabetes. The mean participant age was  $46.11 \pm 9.18$  years; 53.5% of participants were male, 74% were married, 60% were illiterate, 14.5% had a university-level education, 59% were not working, and 80.5% of participants were living in rural areas. More than half of patients had type 2 diabetes and poor glycemic control (HbA1c levels  $>7\%$ ). Among the total, 47.9% of participants were at risk for the development of DFUs, according to the results of Inlow's 60 second diabetic foot screen test.

Table 1 revealed that the highest incidence of diabetes was in the age group 50 to 65 years (39%). Table 2 shows that 56% of participants had type 2 diabetes and 44% had type 1 diabetes. The mean duration of diabetes was  $13.14 \pm 7.36$  years, and mean BMI was  $26.95 \pm 6.75$  kg/m<sup>2</sup>.

Figure 1 shows that 52% of study participants were smokers. Fewer than half of participants were receiving insulin, 40% were receiving oral hypoglycemic agents, and 13.5% were receiving combined therapy (Figure 2). Figure 3 shows that 53% of the study population had poor glycemic control, 28% had fair control, and 19% had good glycemic control.

According to participants' results on Inlow's scale, the most notable findings were as follows: 22.6% of participants had dryness with fungus or light callus of the right foot. Nail assessment revealed that 40.5% of patients had unkempt and ragged toenails on the right foot. Sensation was lost in one or more sites of the left foot in 46.5% of participants. Pedal pulses were absent in the left foot among 19.4% of patients. The right foot was cool in 36.5% of patients; 7.5% of participants had amputation of the left foot and 5.5% had amputation of the right foot (Table 3).

**Table 1.** Distribution of participants according to sociodemographic characteristics (N = 200).

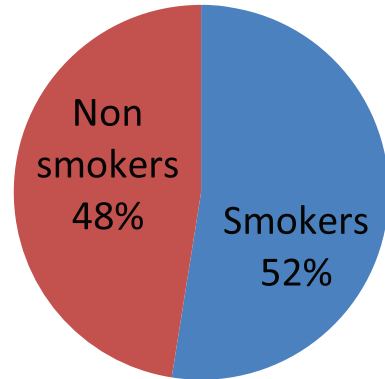
Characteristics	n	%
<b>Age group</b>		
18–28 years	9	4.5
29–39 years	40	20.0
40–49 years	72	36.0
50–65 years	79	39.5
Mean $\pm$ SD, years	46.11 $\pm$ 9.18	
<b>Sex</b>		
Male	107	53.5
Female	93	46.5
<b>Marital status</b>		
Single	27	13.5
Married	148	74.0
Divorced	21	10.5
Widowed	4	2.0
<b>Level of education</b>		
Illiterate	120	60.0
Basic education	46	23.0
Secondary school	5	2.5
University	29	14.5
<b>Employment status</b>		
Working	82	41.0
Not working	118	59.0
<b>Residence</b>		
Urban	39	19.5
Rural	161	80.5

**Table 2.** Distribution of participants according to medical profile (N = 200).

Medical data	n	%
<b>Diabetes type</b>		
Type 1	88	44
Type 2	112	56
<b>Duration of diabetes, years</b>		
Mean $\pm$ standard deviation	13.14 $\pm$ 7.36	
<b>Body mass index, kg/m<sup>2</sup></b>		
Mean $\pm$ standard deviation	26.95 $\pm$ 6.75	

To identify risk factors for the development of DFUs, the results for the identified parameters were categorized according to the International Working Group of the Diabetic Foot risk classification system.<sup>14</sup> Figure 4 illustrates that 47.9% of the study

# Smoking Status

**Figure 1.** Distribution of participants according to smoking status.

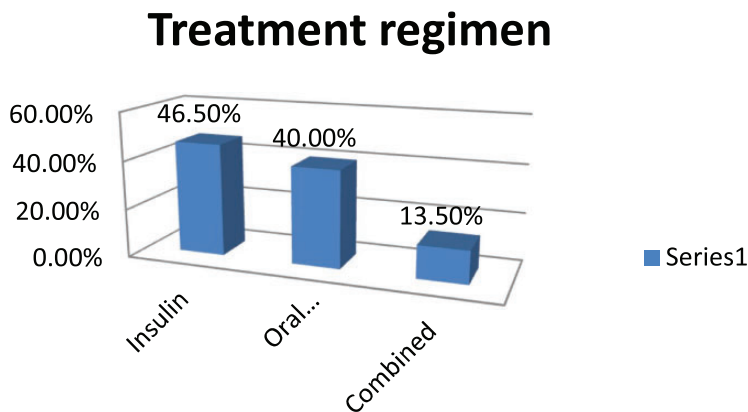
population was at risk for the development of DFUs, with 28.7% having mild risk, 14.5% moderate risk, and 4.7% high risk.

Table 4 illustrates a statistically significant difference between patients' sociodemographic characteristics and their level of risk for DFUs. Patients with diabetes who were male, married, aged 50–65 years, illiterate, working, and those living in rural areas had a high risk for DFUs (all  $P=0.001$ ).

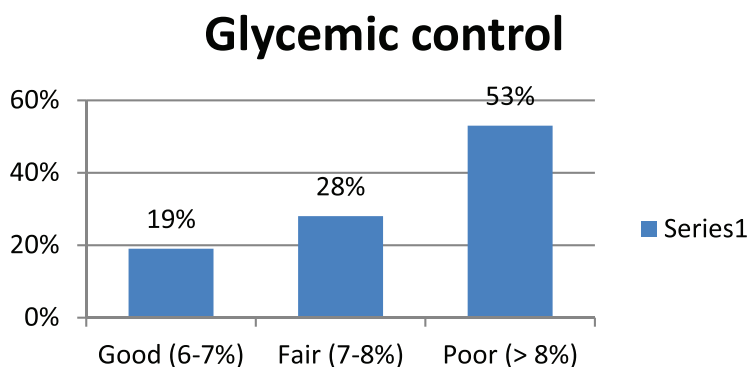
The risk of DFUs was increased in patients with the following characteristics; type 2 diabetes, longer duration of diabetes, mean BMI  $28.02 \pm 4.39$ , smokers, receiving insulin therapy, and patients with uncontrolled blood glucose levels (all  $P=0.001$ ), as shown in Table 5.

## Discussion

We conducted the present study to assess the risk of DFUs among patients with diabetes (N = 200). DFUs are a common but avoidable condition in individuals with diabetes. Loss of sensation owing to somatic



**Figure 2.** Distribution of participants according to treatment regimen.



**Figure 3.** Distribution of participants according to glycemic control.

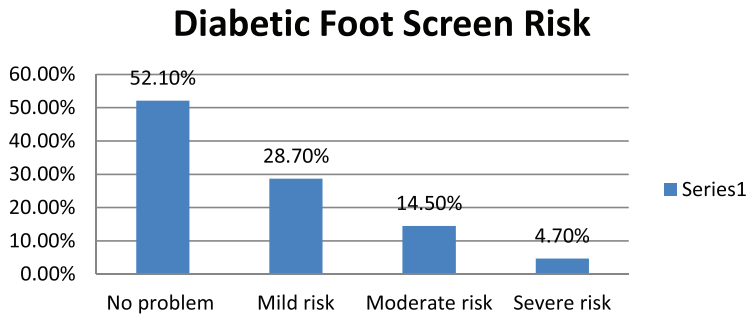
neuropathy, vascular impairment, structural foot deformity, and poor glycemic management are all risk factors for DFUs,<sup>15,16</sup> as is a history of ulceration.<sup>15,17</sup> In this study, 47.9% of the study population was at risk for the development of DFUs, with 28.7% having mild risk, 14.5% moderate risk, and 4.7% high risk. This result was consistent with that of Jbour et al.<sup>18</sup> There was a significant difference between patients' sociodemographic characteristics and the risk for DFUs. Male patients with diabetes, those aged from 50 to 65 years, smokers, and patients living in rural areas had a high risk for DFUs. This result is in accordance with the findings of Assaad-

Khalila et al.,<sup>19</sup> who reported a significantly higher prevalence of foot ulceration among men than women (14.1% and 9.7%, respectively;  $P = 0.002$ ).

The risk for DFU development was higher among patients living in rural areas, which might be attributable to the dry climate in Upper Egypt where the study was conducted, as well as the tradition of walking barefoot. This result was in concordance with the findings of another study.<sup>20</sup> Patients' smoking habits are another important risk factor for DFU development. According to Xia et al.,<sup>21</sup> smoking is an important risk factor for peripheral vascular disease, which is linked to DFUs.

**Table 3.** Distribution of participants according to Inlow's 60-second diabetic foot screening tool (N = 200).

Parameters of Inlow's 60-second diabetic foot screening tool	Left foot		Right foot	
	n	%	n	%
<b>1. Assessment for skin and nail changes</b>				
Skin				
Intact and healthy	113	56.5	118	59.2
Dry with fungus or light callus	42	21.0	45	22.6
Heavy callus buildup	22	10.8	20	9.8
Open ulceration or history of previous ulcer	23	11.7	17	8.4
Nails				
Well-groomed and appropriate length	98	49.0	92	45.8
Unkempt and ragged	68	34.0	81	40.5
Thick, damaged, or infected	34	17.0	27	13.7
<b>2. Assessment for peripheral neuropathy/loss of protective sensation</b>				
Sensation – Monofilament testing				
No: peripheral neuropathy was not discovered (there was sensation at all locations)	107	53.5	108	54.1
Yes: peripheral neuropathy discovered (sensation was lost at one or more sites)	93	46.5	92	45.9
Sensation – Four questions (Are the feet ever numb? Do they ever tingle? Do they ever burn? Do they ever feel like insects are crawling on them?)				
No to all questions	114	57.1	110	54.8
Yes to any of the questions	86	42.9	90	45.2
<b>3. Assessment for peripheral arterial disease</b>				
Pedal pulses				
Present	161	80.6	164	81.9
Absent	39	19.4	36	18.1
Dependent rubor				
No	175	87.6	175	87.3
Yes	25	12.4	25	12.7
Cool foot				
No	130	64.9	127	63.5
Yes	70	35.1	73	36.5
<b>4. Assessment for bony deformity and footwear</b>				
Deformity				
No deformity	160	80	169	84.5
Deformity	20	10	15	7.5
Amputation	15	7.5	11	5.5
Acute Charcot (+ warmth and erythema)	5	2.5	5	2.5
Range of motion				
Full range to hallux	105	52.5	118	59.0
Hallux limitus	46	23	38	19
Hallux rigidus	34	17	33	16.5
Hallux amputation	15	7.5	11	5.5
Footwear				
Appropriate	100	50.0	96	48.0
Inappropriate	65	32.5	69	34.5
Causing trauma	35	17.5	35	17.5



**Figure 4.** Distribution of participants according to risk of diabetic foot ulcer.

**Table 4.** Relationship between risk of DFUs and patient sociodemographic characteristics.

Variables	Level of risk								P value
	No risk (n = 104)		Mild risk (n = 57)		Moderate risk (n = 29)		High risk (n = 10)		
	N	%	N	%	N	%	N	%	
Age (years)									
18–28	18	17.5	4	6.3	2	8.3	1	10.6	0.001*
29–39	22	21.3	8	13.6	3	11.0	3	27.7	
40–49	23	21.9	15	26.8	7	23.4	2	17.0	
50–65	41	39.3	30	53.3	17	57.2	4	44.7	
Sex									
Male	46	43.8	33	57.8	13	43.4	7	72.3	0.001*
Female	58	56.2	24	42.2	16	56.6	3	27.7	
Marital status									
Single	13	12.7	7	12.9	1	3.4	1	10.0	0.001*
Married	44	42.4	38	65.2	17	60.0	1	10.0	
Divorced	18	17.7	5	9	4	13.8	1	10.0	
Widowed	28	27.3	7	12.9	7	22.8	7	70.0	
Education level									
Illiterate	42	40.5	30	52.3	15	51.7	5	50.0	0.001*
Basic education	38	37.1	19	33.1	11	37.9	2	20.0	
Secondary school	12	11.2	5	9.4	2	6.9	2	20.0	
University	12	11.2	3	5.2	1	3.5	1	10.0	
Employment status									
Not working	42	39.4	25	43.8	13	44.8	2	20.0	0.001*
Working	58	60.6	32	56.2	16	55.2	8	80.0	
Area of residence									
Rural	47	45.1	31	54.3	20	68.9	6	60.0	0.001*
Urban	53	54.9	26	45.7	9	31.1	4	40.0	

**Table 5.** Relationship between risk of DFUs and patient's medical profile.

Variables	Level of risk								P value
	No risk (n = 104)		Mild risk (n = 57)		Moderate risk (n = 29)		High risk (n = 10)		
	N	%	N	%	N	%	N	%	
Type of diabetes									
Type 1	39	37.5	28	49.5	15	51.7	3	30.0	0.001
Type 2	65	62.5	29	50.5	14	48.3	10	70.0	
Duration of diabetes									
Mean $\pm$ standard deviation	9.85 $\pm$ 5.87		12.80 $\pm$ 6.93		12.48 $\pm$ 6.27		11.15 $\pm$ 4.87		0.001
Body mass index									
Mean $\pm$ standard deviation	29.39 $\pm$ 7.06		28.57 $\pm$ 3.93		28.44 $\pm$ 3.32		28.02 $\pm$ 4.39		0.001
Smoking									
Smoker	39	37.5	23	40.3	10	34.4	7	70.0	0.001
Nonsmoker	65	62.5	34	59.7	19	65.6	3	30.0	
Treatment									
Oral hypoglycemic agent	32	30.7	15	26.3	4	13.7	1	10.0	0.001
Insulin	64	61.5	38	66.6	20	68.9	6	60.0	
Combined	8	7.8	4	7.1	5	17.4	3	30.0	
Blood glucose level									
Controlled	67	64.5	19	33.4	4	13.8	10	10.0	0.001
Uncontrolled	33	35.5	38	66.7	25	86.2	9	90.0	

The impact of sex on lower extremity morbidity could be influenced by a variety of circumstances. These may include activity levels, smoking habits, hormonal variation, degree of treatment compliance, level of denial regarding a diabetes diagnosis, social support mechanisms, and educational level.<sup>22</sup> In this study, age was a significant risk factor, with higher risk for DFUs among patients aged 50–65 years. This could be because older people often live alone and have impaired vision, other health issues, and a reduced ability to care for their feet. A significant difference was found between the risk for DFUs and patients' medical profile ( $P = 0.001$ ), with a high risk for DFUs among patients with type 2 diabetes, those with increased duration of diabetes, patients with a mean BMI  $28.02 \pm 4.39 \text{ kg/m}^2$ , smokers, patients receiving insulin therapy, and those with uncontrolled blood glucose levels.

We found a statistically significant association between having diabetes for a longer period and the risk of developing DFUs (mean diabetes duration  $13.14 \pm 7.36$  years). This is most likely owing to additional risk factors that develop over time, such as peripheral neuropathy and peripheral artery disease.

In agreement with the current study results, elevated blood glucose levels are linked to the development of diabetic foot ulceration, as reported previously.<sup>23</sup> The Diabetes Control and Complications Trial of type 1 diabetes mellitus and the UK Prospective Diabetes Study of type 2 diabetes mellitus demonstrated that intensive diabetes management minimizes the risk of neuropathy and other problems associated with DFUs.<sup>24,25</sup> Additionally, the administration of insulin therapy for the treatment of diabetes was identified as a high-risk factor for DFUs in the Seattle Diabetic



Foot Study. It is possible that this factor reflects diabetes severity. Moreover, studies have shown an association between elevated BMI and a higher risk of foot ulceration.<sup>26</sup>

Peripheral sensory neuropathy was found in the left foot among 46.5% of participants and in the right foot among 45.9%. This is comparable to other studies reporting that patients with DFUs have a prevalence of peripheral sensory neuropathy of 70% to 100%.<sup>5</sup> In agreement with the current results, several studies have found that patients with a history of ulceration or amputation are more likely to develop DFUs. Apelqvist and colleagues<sup>27</sup> found ulceration recurrence rates of 34% and 70% after 1 year and 5 years, respectively. Murray et al.<sup>28</sup> reported a 56.8% relative risk of developing an ulcer on the site of a previous ulcer. Furthermore, the factor most closely connected with the development of new ulceration is a history of ulceration or amputation; after a successful major amputation, the likelihood of limb amputation on the opposite side is 12% in the first year and more than 50% after 3 years.<sup>29</sup>

## Limitations of the study

In this study, we assessed both types of diabetes. Therefore, some factors such as insulin use and distal neuropathy, which are related to the future development of DFU, might be different between patients with type 1 and type 2 diabetes mellitus. Another limitation of this study is its cross-sectional nature, making it impossible to prove cause and effect.

## Conclusion

In this study, we found that 47.9% of patients with diabetes were at risk for the development DFUs. Older age, male sex, being illiterate, having type 2 diabetes and

longer diabetes duration, being on an insulin regimen, uncontrolled glucose level, and smoking were the most common risk factors detected in our study.

## Availability of data and materials

On reasonable request, the corresponding author will provide the datasets used/or analyzed in the current work.

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## Declaration of conflicting interest

The author declares that there is no conflict of interest.

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## ORCID iD

Mohammed Al-Mohaithef  <https://orcid.org/0000-0002-8312-1005>

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