

ORIGINAL ARTICLE

Diabetic Foot Ulcer Risk in Adults with Type 2 Diabetes Mellitus: A Cross-Sectional Study

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ABSTRACT

Objective: To determine the prevalence and factors associated with diabetic foot ulcer (DFU) risk in adults with type 2 diabetes mellitus (T2DM) patients.

Methods: This cross-sectional study was conducted in the rural and urban areas of South Sulawesi Province, Indonesia, from April to December 2022. The study included people diagnosed with T2DM for at least one year, aged 18-60 years. The outcome of the study was DFU risk among people diagnosed with T2DM, which was measured using the screening for the High-Risk Diabetic Foot 60-Second Tool and Ipswich Touch Test.

Results: Of total 361 T2DM patients, the mean age was 53.8 ± 5.8 years. There were 118 (32.7%) males and 243 (67.3%) females. Overall risk of DFU was observed in 110 (30.5%) patients. A significant association of DFU risk found with gender (p-value 0.007), education (p-value < 0.001), occupation (p-value 0.033), ethnicity (p-value 0.039), and diabetes complications (p-value < 0.001). Females were 0.48 times less likely at risk of DFU as compared to males (cOR 0.52, 95% CI 0.33 to 0.84, p-value 0.007). There was 0.62 times less risk of DFU in patients who had no diabetes complications as compared to patients with diabetes complications (cOR 0.38, 95% CI 0.22 to 0.65, p-value < 0.001).

Conclusion: The study highlighted a notable prevalence of DFU in T2DM patients. Gender, education, occupation, ethnicity, and diabetes complications emerged as key factors influencing DFU risk. Moreover, females and patients without diabetes complications had significantly lower DFU risk.

Keywords: Diabetic Foot, Foot Ulcer, Type 2 Diabetes Mellitus, Noninsulin-Dependent Diabetes Mellitus

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INTRODUCTION

Diabetic foot ulcer (DFU) is one of the main complications of diabetes mellitus (DM) and is the most challenging complication of diabetes,¹ with the burden of expensive health financing. A meta-analysis study has found that DFU mortality within the last five years is high by nearly 50%.² In addition, one in three patients with diabetes mellitus may endure DFU at some point in their lifetime. DFU is one of the leading causes of morbidity in DM patients; it is estimated that the annual incidence of DFU is approximately 2%, and the lifetime incidence of DFU is 15%-25%.³

The treatment of foot ulcers is challenging due to their multifactorial etiology, a high burden on patients, the health care system, and society.³ Moreover, when the ulcer is successfully cured, the risk of its recurrence is high ranging from 30% to 40% within the first year.⁴ Although much progress has been made over the past two decades⁵ and several relevant national and international guidelines are available,^{3,6} diabetic ulcers

still become a major healthcare problem^{7,8} because it is not effectively cured.

The residence of patients with DFU shows an interesting phenomenon and highlights the comparison between urban and rural areas. Some previous studies revealed different findings on DFU risk and incidence. Some show that rural areas faced higher DFU challenges than urban areas.^{9,10} Meanwhile, another study demonstrates the opposite result with variations in risk factors.¹¹

The study aims to address the significant health burden posed by DFU among individuals with Type 2 Diabetes Mellitus (T2DM). DFU can lead to severe complications, including infections and lower limb amputations, imposing substantial physical, emotional, and financial costs on patients and healthcare systems. Understanding the prevalence and associated risk factors of DFU in T2DM patients is crucial for developing effective preventive strategies, improving patient care, and reducing the overall burden of diabetes-related complications. Thus, this study aims to investigate the

prevalence and risk factors of DFU among T2DM patients to inform targeted interventions and enhance clinical management practices.

METHODS

This cross-sectional study was conducted in the rural and urban areas of South Sulawesi Province, Indonesia, from April to December 2022. The rural and urban areas were determined using a cluster-randomized technique. This study selected three rural areas (Sibulue District, Selayar Islands, and Labakkang District) and three urban areas (Tamalanrea District, Pampang District, and Sudiang Raya District). Sampling in urban and rural areas was randomized. This study was approved by the Ethics Committee of Nani Hasanuddin Health Institute (Registration number: 033a/STIKES-NH/KEPK/III/2022) and was conducted by the Declaration of Helsinki. All participants submitted the consent, participated voluntarily, and signed the consent form.

Sample size was calculated by OpenEpi software taking prevalence of DFU risk 47.9%,⁹ confidence interval was taken as 95%, and margin of error 5%. The estimated sample size came out to be 384. However, to adjust for non-response and incomplete data, 390 T2DM patients were included. Later on 29 samples were removed due to a considerable amount of missing information. Therefore, 361 patients' data were finally included in the study.

This study recruited participants using the random sampling method. The inclusion criteria were people diagnosed with T2DM, aged 18-60 years (adults), lived in their residence for at least one year, willingly participated in the study, and completed the consent form. Meanwhile, the exclusion criteria were people newly diagnosed with T2DM (less than a year), pregnant women diagnosed with gestational diabetes, and patients with a history of mental and communication disorders.

Data were collected through home visits with the accompany of the community nurses in the region. The community nurses accompanied the researchers because the nurses significantly knew the house locations of research samples, namely the T2DM sufferers. Self-designed questionnaires were employed to obtain data on sociodemographic characteristics such as gender, education, occupation, ethnicity, smoking, length of suffering from DM, blood glucose level (controlled \leq 200 mg/dl, uncontrolled $>$ 200 mg/dl), diabetes complications (vision, nerve, kidney, and heart problems), and using insulin.

The outcome, i.e., Risk of DFU was determined using two tools. Firstly, the Screening for High-Risk Diabetic Foot 60-Second Tool was utilized to evaluate high-risk diabetic foot conditions. This tool assesses the presence of previous ulcers, amputation, foot deformity, no ankle pulse, active ulcer, ingrown toenails, calluses, blisters, and cracks.¹² Secondly, foot sensitivity was also assessed using the Ipswich Touch Test (IpTT).¹³ This test involves lightly touching the tips of the first, third, and fifth toes of each foot with a soft object, such as a cotton wisp or the examiner's finger, while the patient's eyes are closed. The patient is then asked to indicate whether they can feel the touch. Decreased foot sensitivity was indicated by the patient's inability to feel touch on two or more of the six toes. Conversely, if the patient can feel the touch on all or most of the toes, they are considered to be at lower risk. Thus, a diabetic patient was labeled as at-risk for DFU if one or more answers are "Yes," in 60 second tool or decreased sensitivity was found in IpTT. The outcome of the study was DFU risk among people diagnosed with T2DM and predictors of (DFU) risk.

Statistical Package for Social Sciences (SPSS) version 24 was used for the purpose of statistical analysis. Mean and standard deviation was calculated for quantitative variable such as age. Frequency and percentages were calculated for qualitative variables such as gender, education, occupation, ethnicity, smoking, length of suffering from DM, blood glucose level, diabetes complications, and using insulin. Inferential statistics were explored using Chi-square/Fisher Exact test to identify the association of T2DM patients' characteristics with DFU risk. The p-value of ≤ 0.05 was considered statistically significant. Moreover, binary logistic regression was also applied for identification of potential factors for DFU risk. Both univariable and multivariable logistic regression were applied.

RESULTS

Of total 361 T2DM patients, the mean age was 53.8 ± 5.8 years. There were 118 (32.7%) males and 243 (67.3%) females. The most prominent education was senior high school 87 (24.1%), majority of the patients were employed 186 (51.5%), Makassar 288 (79.8%), non-smoker 324 (89.7%), and their education was senior high school 87 (24.1%). In most of the patients duration of diabetes was less than 5 years 274 (75.9%), had uncontrolled blood glucose level 234 (64.8%), did not use insulin 313 (86.7%), and had no diabetes complications 290 (80.3%).

Overall risk of DFU was observed in 110 (30.5%) patients.

Table 1: Association of T2DM patients’ characteristics with diabetic foot ulcer risk (n= 361)

Variables	Total	Risk of Diabetic Foot Ulcer		p-value
		At Risk (n= 110)	Not at Risk (n= 251)	
Age (years)				
≤ 50	86	22 (25.6)	64 (74.4)	0.259
> 50	275	88 (32.0)	187 (68.0)	
Gender				
Males	118	47 (39.8)	71 (60.2)	0.007*
Females	243	63 (25.9)	180 (74.1)	
Education				
Not Attending Schools	77	20 (26.0)	57 (74.0)	<0.001*
Elementary Schools	75	14 (18.7)	61 (81.3)	
Junior High Schools	59	16 (27.1)	43 (72.9)	
Senior High Schools	87	28 (32.2)	59 (67.8)	
Higher Education	63	32 (50.8)	31 (49.2)	
Occupation				
Unemployed	175	44 (25.1)	131 (74.9)	0.033*
Employed	186	66 (35.5)	120 (64.5)	
Ethnicity				
Bugis	73	15 (20.5)	58 (79.5)	0.039*
Makassar	288	95 (33.0)	193 (67.0)	
Smoking				
Yes	37	16 (43.2)	21 (56.8)	0.075
No	324	94 (29.0)	230 (71.0)	
Duration of Diabetes				
≤ 5 Years	274	78 (28.5)	196 (71.5)	0.142
> 5 Years	87	32 (36.8)	55 (63.2)	
Blood Glucose Level				
Controlled	127	37 (29.1)	90 (70.9)	0.684
Uncontrolled	234	73 (31.2)	161 (68.8)	
Diabetes Complications				
Yes	71	34 (47.9)	37 (52.1)	<0.001*
No	290	76 (26.2)	214 (73.8)	
Using Insulin				
Yes	48	18 (37.5)	30 (62.5)	0.256
No	313	92 (29.4)	221 (70.6)	
Residence				
Urban	209	66 (31.6)	143 (68.4)	0.644
Rural	152	44 (28.9)	108 (71.1)	

- T2DM : Type 2 diabetes mellitus

* p-value ≤ 0.05 (Chi-Square test)

Table 2: Association of T2DM patients' characteristics with diabetic foot ulcer risk in rural and urban areas (n= 361)

Variables	Risk of Diabetic Foot Ulcer					
	Urban		p-value	Rural		p-value
	At Risk (n= 66)	Not at Risk (n= 143)		At Risk (n= 44)	Not at Risk (n= 108)	
Age (years)						
≤ 50	8 (23.5)	26 (76.5)	0.203 [^]	14 (26.9)	38 (73.1)	0.196 [^]
> 50	58 (33.1)	117 (66.9)		30 (30.0)	70 (70.0)	
Gender						
Males	33 (45.2)	40 (54.8)	0.002 ^{^*}	14 (31.1)	31 (68.9)	0.703 [^]
Females	33 (24.3)	103 (75.7)		30 (28.0)	77 (72.0)	
Education						
Not Attending Schools	11 (28.2)	28 (71.8)	0.025 ^{^*}	9 (23.7)	29 (76.3)	0.095 [^]
Elementary Schools	8 (18.2)	36 (81.8)		6 (19.4)	25 (80.6)	
Junior High Schools	11 (30.6)	25 (69.4)		5 (21.7)	18 (78.3)	
Senior High Schools	18 (32.1)	38 (67.9)		10 (32.3)	21 (67.7)	
Higher Education	18 (52.9)	16 (47.1)		14 (48.3)	15 (51.7)	
Occupation						
Unemployed	22 (21.8)	79 (78.2)	0.003 ^{^*}	22 (29.7)	52 (70.3)	0.860 [^]
Employed	44 (40.7)	64 (59.3)		22 (28.2)	56 (71.8)	
Ethnicity						
Bugis	65 (31.6)	141 (68.4)	0.948 [~]	30 (36.6)	52 (63.4)	0.025 ^{^*}
Makassar	1 (33.3)	2 (66.7)		14 (20.0)	56 (80.0)	
Smoking						
Yes	9 (50.0)	9 (50.0)	0.079 [^]	7 (36.8)	12 (63.2)	0.417 [^]
No	57 (29.8)	134 (70.2)		37 (27.8)	96 (72.2)	
Duration of Diabetes						
≤ 5 Years	48 (29.8)	113 (70.2)	0.377 [^]	30 (26.5)	83 (73.5)	0.308 [^]
> 5 Years	18 (37.5)	30 (62.5)		14 (35.9)	25 (64.1)	
Blood Glucose Level						
Controlled	27 (27.3)	72 (72.7)	0.204	10 (35.7)	18 (64.3)	0.382 [^]
Uncontrolled	39 (35.5)	71 (64.5)		34 (27.4)	90 (72.6)	
Diabetes Complications						
Yes	24 (61.5)	15 (38.5)	<0.001 ^{^*}	10 (31.3)	22 (68.8)	0.747 [^]
No	42 (24.7)	128 (75.3)		34 (28.3)	86 (71.7)	
Using Insulin						
Yes	5 (26.3)	14 (73.7)	0.605 [^]	13 (44.8)	16 (55.2)	0.036 ^{^*}
No	61 (32.1)	129 (67.9)		31 (25.2)	92 (74.8)	

- T2DM : Type 2 diabetes mellitus

* p-value ≤ 0.05 (^Chi-Square/~Fisher Exact test)

Table 3: Binary logistic regression analysis for variables predicting diabetic foot ulcer risk in T2DM patients (n = 361)

	Univariable analysis		Multivariable analysis	
	COR (95% CI)	p-value	aOR (95% CI)	p-value
Gender				
Males	1		1	
Females	0.52 (0.33 to 0.84)	0.007*	0.60 (0.35 to 1.02)	0.062
Education				
Not Attending Schools	1			
Elementary Schools	0.65 (0.30 to 1.41)	0.282		
Junior High Schools	1.06 (0.49 to 2.28)	0.881		
Senior High Schools	1.35 (0.69 to 2.66)	0.384		
Higher Education	2.94 (1.44 to 5.98)	0.003*		
Occupation				
Unemployed	1		1	
Employed	1.63 (1.03 to 2.58)	0.034*	1.15 (0.68 to 1.94)	0.596
Ethnicity				
Bugis	1		1	
Makassar	0.52 (0.28 to 0.97)	0.041*	0.66 (0.34 to 1.24)	0.201
Diabetes Complications				
Yes	1		1	
No	0.38 (0.22 to 0.65)	<0.001*	0.42 (0.24 to 0.73)	0.002*

COR: Crude odds ratio, aOR: Adjustedodds ratio, CI: confidence interval, *p-value ≤ 0.05

Table 4: Sign and Symptoms of risk of diabetic foot ulcer risk in rural and urban areas among T2DM patients (n= 110)

Sign and Symptoms	Total	Urban Areas (n= 66)	Rural Areas (n= 44)
Previous Ulcer	15	5 (2.4)	10 (6.6)
Foot Deformity	13	0 (0.0)	13 (8.6)
No Ankle Pulse	3	0 (0.0)	3 (2.0)
Active Ulcer	10	4 (1.9)	6 (3.9)
Ingrown Toenails	12	4 (1.9)	8 (5.3)
Calluses	6	0 (0.0)	6 (3.9)
Blisters	31	25 (12.0)	6 (3.9)
Cracks	35	24 (11.5)	11 (7.2)
Decrease in Foot Sensitivity	41	17 (8.1)	24 (15.8)

- T2DM : Type 2 diabetes mellitus

All data presented as number (%)

A significant association of DFU risk found with gender (p-value 0.007), education (p-value <0.001), occupation (p-value 0.033), ethnicity (p-value 0.039), and diabetes complications (p-value <0.001). There were 209 (57.9%) patients from urban areas and 152 (42.1%) patients from rural areas. The risk of DFU was insignificantly higher in

urban areas as compared to rural areas i.e., 66 (31.6%) vs. 44 (28.9%) respectively (p-value 0.644) (Table 1). A significant association of DFU risk in urban areas was found with gender (p-value 0.002), education (p-value 0.025), occupation (p-value 0.003), and complications (p-value <0.001). While a significant association of DFU

risk in rural areas was found with ethnicity (p-value 0.025) and using insulin (p-value 0.036) (Table 2).

Table 3 reveals binary logistic regression analysis for predicting DFU risk in T2DM patients. It was found that females were 0.48 times less likely risk of DFU as compared to males (cOR 0.52, 95% CI 0.33 to 0.84, p-value 0.007). There was 0.62 times less risk of DFU in patients who had no diabetes complications as compared to patients with diabetes complications (cOR 0.38, 95% CI 0.22 to 0.65, p-value <0.001). At the univariate level, gender (p-value 0.007), occupation (p-value 0.034), ethnicity (p-value 0.041) and diabetes complications (p-value <0.001) showed significant odds ratios. Furthermore, the findings of the multivariable analysis were also presented after adjusting the variables found significant in the univariable analysis. At this stage only diabetes complications variable showed significant odds ratios.

Decrease in foot sensitivity was the most common sign and symptoms observed in rural and urban areas i.e., 24 (15.8%) and 17 (8.1%) (Table 4).

DISCUSSION

Overall, one-third of the study's respondents were at risk of developing DFU. Not all patients with T2DM are at risk of ulceration. Most retrospective and prospective studies had revealed that ulceration risk factors are defined in various risk classification systems.^{3,14} These key factors include peripheral neuropathy, foot deformity, peripheral vascular disease, ulceration of the foot, and previous foot or leg amputation. The classification systems showed similar diagnostic/prognostic outcomes, such as sensitivity, specificity, predictive values, and likelihood ratio to with the predict ulceration.¹⁵ The severity of the ulcer is related with the timing of the initial expert assesment: the longer the time before getting an expert assessment, the more severe the ulcer and the worse the clinical outcome.¹⁶

According to this study, females were less likely than males to develop DFU. This is inconsistent with the study's findings, which showed that male sex increases the likelihood of developing DFU.¹⁷ Males had a higher prevalence of previous lower limb revascularization, and their ulcers were deeper, more frequently probed to bone, and deeply infected. Males presented with twice as many systemic infections as females.¹⁸ In addition, female sex was substantially related with an increased likelihood of ulcer healing as a first occurrence.¹⁸ Furthermore, education, occupation, and diabetes complications were found to be related with

DFU risk. This is consistent with prior research, which found that these factors contribute to the onset of DFU.¹⁹ A study reported that employees such as daily laborers, retirees, and farmers were more likely to develop foot ulcers than students, self-employed, government employees, non-employees, and housewives.¹⁹

Furthermore, this study also found that T2DM patients in urban areas had a higher prevalence of ulcer risk than those in rural areas. This condition was triggered by several factors, but the most significant factor such as the poor diabetes control, poor patient awareness, late diagnosis, and poor foot self-care practice.^{20,21} This contradicts previous studies which found that diabetics living in rural areas are more likely to develop foot ulcers than diabetics living in urban areas.²² This could be due to a lack of access to health information and services, or walking barefoot, which can lead to injuries and poor wound healing.²²

The significant discrepancy in findings is because the majority of research conducted in rural areas included older samples, who are of course at greater risk of having DFU than the adult population. Moreover, this study only focuses on the adult population; study on other populations, such as the elderly, is critical because older patients are more likely to have type 2 diabetes, macrovascular complications, and severe gangrene. This patient group has severe comorbidities and illnesses that make self-care difficult, which could delay healing and increase the risk of developing new foot ulcers.²³ The study included a small proportion of the sample. It is recommended that further research employ a larger population in a more significant number of areas. Moreover, the number of both samples in the population (urban and rural areas) is not equal, so the assessment results are not balanced, and the calculation of the proportion of respondents at risk of developing DFU is deemed weak. Further studies should improve the ulcer risk classifications by considering analyses of the foot strength levels and foot function of T2DM sufferers.

CONCLUSION

The study highlighted a notable prevalence of DFU in T2DM patients. Gender, education, occupation, ethnicity, and diabetes complications emerged as key factors influencing DFU risk. Females and patients without diabetes complications displayed lower DFU odds. Urban residency showed heightened DFU risk, particularly among females and those with lower education levels. Conversely, in rural areas, ethnicity

and insulin use were notable predictors of DFU risk. These aspects may be helpful in identifying and lowering the risk of DFU. Early screening of all T2DM patients in the health service significantly prevents DFU risk opportunities.

ETHICAL APPROVAL: This study was approved by the Ethics Committee of Nani Hasanuddin Health Institute (Registration number: 033a/STIKES-NH/KEPK/III/2022, dated: 14.03.2022).

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