

Factors associated with severity and outcomes of diabetic foot ulcers: A single center hospital-based cross-sectional observational study in Eastern India

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ABSTRACT

Background: Diabetes mellitus (DM) affects millions globally and is associated with high morbidity, risk of infection, and potential for severe outcomes. In India, where the prevalence of diabetic foot complications is notably high, data on factors influencing the severity and outcomes of diabetic foot ulcers (DFUs) in specific regions, particularly Eastern India, remain sparse. **Methods:** This hospital-based cross-sectional study included Type 2 DM patients aged over 18 years, excluding those unwilling to participate and those with ulcers classified as Wagner grade less than 2. The study involved the complete enumeration of eligible patients presenting with DFUs. Clinical and demographic data were collected, including glycemic control, physical activity levels, and microbial cultures from ulcer specimens. **Results:** The study included 90 patients with a mean age of 56.1 years. Most participants were male (76.7%), with 47.8% receiving regular diabetes treatment and only 10% achieving good glycemic control. Positive swab cultures were found in 68.9% of patients, predominantly mono-microbial. Higher grade ulcers were associated with male gender (AOR 5.715), and positive swab cultures (AOR 17.470). Moderate-to-severe physical activity (AOR 9.683) and paresthesia (AOR 0.101) were significant predictors of gangrene, with absent distal pulses (COR 13.818) also indicating a higher risk for gangrene. Good glycemic control was associated with a reduced risk of gangrene (COR 0.125). **Conclusions:** Maintaining good glycemic control is crucial in preventing complications such as gangrene. Physical activity is generally beneficial in DM; however, excessive or high-impact activities may exacerbate existing foot ulcers and increase the risk of gangrene.

Keywords: Diabetes mellitus, diabetic foot, gangrene, India, risk factors, skin ulcer, type 2

Introduction

Diabetes mellitus (DM) is a chronic metabolic disorder marked by persistent hyperglycemia and is linked to numerous

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complications, including neuropathy, peripheral arterial disease, and impaired immune function.^[1] Among these, diabetic foot ulcers (DFUs) are particularly problematic due to their significant impact on morbidity, infection risk, and severe outcomes like lower extremity amputations. DFUs not only increase the risk of infections but also result in extended hospital stays, heightened healthcare expenses, and a reduced quality of life for affected individuals.^[2]

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DFUs are a major contributor to hospitalizations among diabetic patients, accounting for approximately 20% of such admissions. Infections associated with DFUs are especially critical, often leading to a substantial increase in the likelihood of amputation.^[3] This necessitates early and proactive management to prevent complications, underscoring the essential role of primary care and family medicine in diabetic care. Early detection and intervention by primary care physicians can significantly reduce the progression of DFUs from minor wounds to severe infections requiring hospitalization or amputation.^[4]

Research in India indicates that 30.4% of individuals with diabetes experience infections, predominantly involving diabetic foot. The global rise in diabetes prevalence is alarming, with a particularly severe impact in low- and middle-income countries. India, identified as having a disproportionately high diabetes burden, faces significant challenges due to socioeconomic factors, healthcare infrastructure, and patient awareness.^[5] Despite the high prevalence of diabetic foot complications in the Indian subcontinent, there is a lack of detailed data on the factors affecting the severity and outcomes of DFUs, particularly in Eastern India. This study aims to fill this gap by analyzing the clinical, demographic, and socioeconomic determinants of DFU severity and outcomes in a hospital-based cross-sectional study in Eastern India, to inform targeted interventions and enhance patient management strategies.

Materials and Methods

Study design and duration

This hospital-based cross-sectional study was carried out over a period of 6 months, from October 2022 to March 2023.

Inclusion criteria

This study included all type 2 diabetic patients, both newly diagnosed and those already on medication, who met the American Diabetes Association (ADA) definition of diabetes. Additionally, participants were required to have a foot ulcer classified as Wagner grade 2 or higher. Only individuals aged over 18 years were considered for inclusion in the study.

Exclusion criteria

Patients were excluded from the study if they were unwilling to participate, as informed consent is a critical component of ethical research. Additionally, patients with foot ulcers classified as Wagner grade less than 2 were not included in the study.

Study population

Patients with diabetic foot ulcers who presented to the institute during the study period were enrolled in the study. Patients who were unwilling to participate were not included in the study. DFU attending Outpatient and Inpatient department of General Medicine and Surgery were recruited.

Sampling technique

Complete enumeration; all patient records meeting the inclusion criteria were included in the study.

Ethical considerations

The study was undertaken according to the Declaration of Helsinki and after obtaining approval from the Institute Ethics Committee (IEC) with reference number AIIMS/Pat/IEC/2022/967. Informed consent was taken from all the recruited patients.

Study procedure

All Type 2 diabetic patients presenting with diabetic foot ulcers (Meggitt Wagner classification with ulcer grade ≥ 2) and meeting our inclusion criteria coming to clinical OPD of medicine and surgery department were recruited in the study. After physical examination, grading of ulcers was done by Wagner classification.^[6] A specimen sample (both a swab as well as a tissue sample) from the ulcer under proper asepsis and debridement was sent for culture in suitable culture media (Blood agar or Mc-Conkey agar), and growth was identified by gram stain.

Definitions

Type 2 DM: The American Diabetes Association (ADA) defines type 2 diabetes based on one of the following criteria:

- Fasting plasma glucose (FPG) ≥ 126 mg/dL (7.0 mmol/L) after no caloric intake for at least 8 hours.
- 2-Hour plasma glucose ≥ 200 mg/dL (11.1 mmol/L) during an Oral Glucose Tolerance Test (OGTT) with a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.
- HbA1C $\geq 6.5\%$ (48 mmol/mol), which reflects average blood glucose levels over approximately three months.
- Random plasma glucose ≥ 200 mg/dL (11.1 mmol/L) in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis.^[7]

Meggitt-Wagner foot ulcer classification

The classification is divided into six grades as follows:

Grade 0: high risk foot, no ulcer.

Grade 1: localized superficial ulcer, not clinically infected.

Grade 2: deep ulcer often with cellulites and infected.

Grade 3: deep ulcer/abscess with osteomyelitis.

Grade 4: localized forefoot gangrene.

Grade 5: full-foot gangrene.^[6]

Data collection

The records of patients who were admitted to the healthcare facility during the study period with a diagnosis of diabetic

foot ulcers were screened for potential inclusion in the study. The demographic details of the patients, including age, gender, and duration since diabetes diagnosis, were collected. Clinical parameters such as the number of foot ulcers, the presence of distal pulses, and signs of gangrene or infection were noted. Swab cultures were performed to identify the type of microbial infection (mono-microbial or poly-microbial). Additional data on patients' glycemic control, history of smoking and alcohol use, use of Ayurvedic medications, physical activity levels, and body mass index (BMI) were also gathered. The grading of foot ulcers was performed using the Meggitt–Wagner classification system.

Statistical analysis

The collected data were cleaned and coded in Microsoft Excel. Statistical analysis was conducted using IBM SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean and standard deviation (SD) or median and interquartile range (IQR) after normality checks. Categorical variables were presented as frequencies and proportions. Ordinal logistic regression analysis was used to identify predictors of higher-grade foot ulcers, with results reported as crude odds ratios (COR) and adjusted odds ratios (AOR) along with their 95% confidence intervals (CI). A *P* value of less than 0.05 was considered significant.

Results

A total of 90 patients were included in the study. The mean age of the participants was 56.1 years (SD = 9.7). The mean duration since diabetes diagnosis was 7.5 years (SD = 4.5). A majority of the participants, 69 (76.7%), were male. Less than half of the participants, 43 (47.8%), reported receiving regular diabetes treatment. Only 9 (10%) of the participants had good glycemic control. A history of smoking was reported by 22 (24.4%) participants and 12 (13.3%) had a history of alcohol use. The use of Ayurvedic medications was reported by 10 (11.1%) participants. Moderate-to-severe physical activity was reported by 41 (45.6%) participants. Regarding body mass index (BMI), 26 (28.9%) participants were classified as overweight or obese [Table 1].

Among the patients with diabetic foot ulcers, the majority, 81 (91%), had 2 foot ulcers, while 8 (9%) had a single foot ulcer. Positive swab cultures were found in 62 (68.9%) participants. Among the positive swab cultures, 51 (82.3%) were monomicrobial, and 11 (17.7%) were polymicrobial. An absent distal pulse was observed in 13 (14.4%) participants. Paresthesia was reported by 38 (42.2%) participants. Only 4 (4.4%) participants had foot deformities, and gangrenous changes were observed in 13 (14.4%) cases [Table 2].

The majority, i.e. 52 (58%) of the patients, had a grade 3 foot ulcer, followed by 27 (30%) having a grade 2 ulcer and 11 (12%) having a grade 4 ulcer [Figure 1].

On univariate analysis, it was observed that the duration since diabetes diagnosis [crude odds ratio (COR) 0.880, 95% CI:

0.793–0.977, *P* = 0.017], history of smoking (COR 5.814, 95% CI: 1.253–26.981, *P* = 0.025), and use of Ayurvedic medications (COR 0.237, 95% CI: 0.061–0.924, *P* = 0.038), and positive swab culture (COR 5.388, 95% CI: 1.759–16.498, *P* = 0.003) were significant predictors of developing higher grade foot ulcers.

On multivariate analysis, male gender [adjusted odds ratio (AOR) 5.715, 95% CI: 1.047–31.194, *P* = 0.044], duration since diabetes diagnosis (AOR 0.693, 95% CI: 0.559–0.859, *P* = 0.001), use of Ayurvedic medications (AOR 0.077, 95% CI: 0.008–0.735, *P* = 0.026), and positive swab culture (AOR 17.470, 95% CI: 3.101–98.429, *P* = 0.001) were significant independent predictors of developing higher grade foot ulcers [Table 3].

On univariate analysis, it was observed that age [crude odds ratio (COR) 0.916, 95% CI: 0.826–0.979], good glycemic control (COR 0.125, 95% CI: 0.027–0.589), moderate-to-severe physical activity (COR 5.645, 95% CI: 1.173–27.172), absent distal pulse (COR 13.818, 95% CI: 1.154–165.39), and paresthesia (COR 0.098, 95% CI: 0.020–0.476) were significant predictors of developing gangrene in patients with diabetic foot.

On multivariate analysis, it was seen that moderate-to-severe physical activity [adjusted odds ratio (AOR) 9.683, 95% CI: 1.507–62.214] and presence of paresthesia (AOR 0.101, 95% CI: 0.017–0.612) were significant independent predictors of developing gangrene [Table 4].

Discussion

This study examined the demographic and clinical characteristics of 90 patients with diabetic foot ulcers. The mean age of participants was 56.1 years, and the average duration since diabetes diagnosis was 7.5 years. The majority of participants were male (76.7%), and less than half (47.8%) received regular diabetes treatment. Only 10% had good glycemic control, while 42.2% experienced paresthesia, and 14.4% had gangrenous changes. Most patients (91%) had two-foot ulcers,

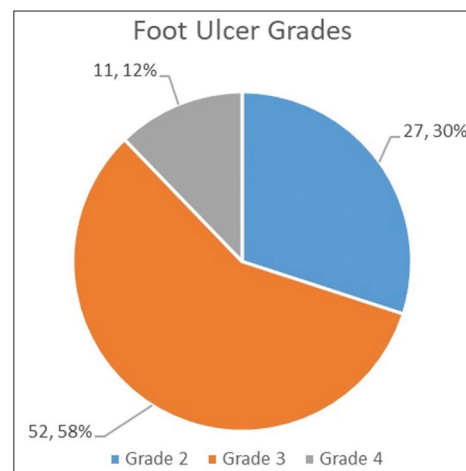


Figure 1: Grading of foot ulcers among the diabetic patients (*N* = 90)

Table 1: Demographic details of the study participants (n=90)

Variable	Categories	Count (n)	Percentage (%)
Gender	Male	69	76.7%
	Female	21	23.3%
Age (Mean±SD)		56.1 (9.7)	
Duration since diabetes diagnosis (Mean±SD)		7.5 (4.5)	
Regular Treatment	Yes	43	47.8%
	No	47	52.2%
Glycemic Control	Good	9	10%
	Poor	81	90%
History of Smoking	Yes	22	24.4%
	No	68	75.6%
History of Alcohol Use	Yes	12	13.3%
	No	78	86.7%
Use of Ayurvedic Medications	Yes	10	11.1%
	No	80	88.9%
Physical Activity	Moderate to Severe	41	45.6%
	Mild	49	54.4%
Body Mass Index	Overweight or Obese	26	28.9%
	Normal	64	71.1%

Table 2: Clinical characteristics of the diabetic foot ulcers (n=90)

Variable	Categories	Count (n)	Percentage (%)
Number of Foot Ulcers	1	8	9%
	2	81	91%
	>2	0	0%
Swab Culture	Positive	62	68.9%
	Sterile	18	20%
	Contaminated	10	11.1%
Infection type [for positive swab culture (n=62)]	Mono-microbial	51	82.3%
	Poly-microbial	11	17.7%
Distal Pulse	Absent	13	14.4%
	Present	77	85.6%
Paresthesia	Yes	38	42.2%
	No	52	57.8%
Foot Deformity	Yes	4	4.4%
	No	86	95.6%
Gangrenous Change	Yes	13	14.4%
	No	77	85.6%

with 68.9% showing positive swab cultures, predominantly mono-microbial.

The ordinal logistic regression analysis revealed several significant associations with higher grades of foot ulcers. Male patients had significantly higher odds of developing more severe foot ulcers compared to females (AOR 5.715, $P = 0.044$). This disparity could be attributed to differences in health-seeking behavior, with men potentially being less likely to seek early medical intervention, thus allowing ulcers to progress to more severe stages.^[8] This finding is also consistent with various other studies reported. One possible hypothesis for this difference is the greater burden of financial support typically shouldered by men, who are often

the primary earners working outside the home.^[9] Additionally, it has been reported that the probability of healing is higher in females compared to males as a first event.^[10] Another significant contributing factor is the increased incidence of smoking among males compared to females,^[11] as smoking is known to exacerbate higher grades of DFUs^[12] and is concurrent with the findings of our study (COR 5.814, $P = 0.025$). Smoking increases pulse wave velocity, contributing to peripheral artery disease. Additionally, smoking causes vasoconstriction, significantly reducing blood flow to the foot and contributing to delays in the healing of foot ulcers.^[13]

Another significant independent predictor for DFU is positive swab culture (AOR: 17.470, $P = 0.001$). A positive swab culture in foot ulcers is often linked to higher grades of ulcers due to several interrelated factors. One primary reason is that a positive culture typically indicates the presence of pathogenic microorganisms, such as bacteria or fungi. The severity of these infections often correlates with the extent of tissue damage, leading to more advanced ulcer grades. As infections become more severe, they can exacerbate the deterioration of the ulcer, resulting in larger and more complex wounds.^[14] In addition, infected ulcers generally experience delayed healing. The presence of pathogens interferes with the normal wound-healing process, causing ulcers to remain open longer and potentially worsen. Increased inflammation, a common consequence of infection, further contributes to the progression of ulcers. Chronic inflammation can aggravate the condition, causing more severe ulceration.^[15]

The duration of diabetes and the use of Ayurvedic medications were associated with lower odds of developing higher-grade ulcers (AOR 0.693, $P = 0.001$ and AOR 0.077, $P = 0.026$, respectively). This may indicate that patients with longer diabetes histories have better self-management skills or that they have adapted to manage their condition more effectively over time. Complementary treatments may have a protective effect, possibly by enhancing overall health and immune function.^[16] However, more research is needed to understand the mechanisms behind this association and to validate these findings in larger populations.

In terms of predictors of gangrene development, the multivariate analysis identified moderate to severe physical activity (AOR 9.683, $P = 0.017$) and the presence of paresthesia (AOR 0.101, $P = 0.013$) as significant independent predictors. While moderate-to-severe physical activity is generally beneficial for health, it may pose a risk for developing gangrene in diabetic patients with foot ulcers. This counterintuitive finding suggests that the type and intensity of physical activity need to be carefully managed in diabetic patients. Activities that exert excessive pressure on the feet, such as prolonged walking or high-impact exercises, can exacerbate existing ulcers and increase the risk of gangrene due to compromised blood flow and tissue damage in insensate feet.^[17] This highlights the importance of tailored exercise therapy that considers the specific needs and limitations of diabetic patients with foot ulcers. On the other hand, the presence of paresthesia, a condition characterized by

Table 3: Predictors of developing higher grade ulcers in diabetic foot patients (n=90)

Variable	Crude odds ratio	95% CI of Crude OR		P	Adjusted odds ratio	95% CI of Adjusted OR		P
		Lower bound	Upper bound			Lower bound	Upper bound	
Age (in years)	0.995	0.949	1.042	0.824		-		
Male Gender	2.125	0.768	5.879	0.147	5.715	1.047	31.194	0.044
Duration since Diabetes Diagnosis (in years)	0.880	0.793	0.977	0.017	0.693	0.559	0.859	0.001
Regular Treatment	1.870	0.742	4.713	0.184	2.690	0.543	13.328	0.226
Good Glycemic Control	0.224	0.049	1.016	0.052	0.237	0.026	2.153	0.201
History of Smoking	5.814	1.253	26.981	0.025	3.841	0.336	43.876	0.279
History of Alcohol Use	1.333	0.331	5.365	0.685		-		
Use of Ayurvedic Medications	0.237	0.061	0.924	0.038	0.077	0.008	0.735	0.026
History of Walking Bare Foot	1.150	0.445	2.975	0.773		-		
Moderate to Severe Physical Activity	1.647	0.654	4.150	0.290		-		
Overweight or Obese	2.200	0.730	6.631	0.161	3.606	0.632	20.564	0.149
Positive Swab Culture	5.388	1.759	16.498	0.003	17.470	3.101	98.429	0.001
Mono-microbial infection	1.466	0.333	6.459	0.613		-		

Nagelkerke Pseudo $R^2=0.578$ **Table 4: Predictors of developing gangrene in diabetic foot patients (n=90)**

Variable	Crude odds ratio	95% CI of Crude OR		P	Adjusted odds ratio	95% CI of Adjusted OR		P
		Lower Bound	Upper Bound			Lower Bound	Upper Bound	
Age (in years)	0.916	0.826	0.979	0.010	0.938	0.865	1.017	0.121
Male Gender	0.983	0.244	3.964	0.981		-		
Duration since Diabetes Diagnosis (in years)	0.950	0.844	1.071	0.404		-		
Regular Treatment	0.753	0.232	2.446	0.637		-		
Good Glycemic Control	0.125	0.027	0.589	0.009	0.323	0.040	2.585	0.287
History of Smoking	1.930	0.393	9.467	0.418		-		
History of Alcohol Use	0.821	0.158	4.260	0.814		-		
Use of Ayurvedic Medications	1.588	0.184	13.706	0.674		-		
History of Walking Bare Foot	0.864	0.257	2.902	0.813		-		
Moderate to Severe Physical Activity	5.645	1.173	27.172	0.031	9.683	1.507	62.214	0.017
Overweight or Obese	0.600	0.176	2.042	0.414		-		
Positive Swab Culture	0.736	0.144	3.761	0.713		-		
Mono-microbial infection	1.492	0.266	8.380	0.649		-		
Absent Distal Pulse	13.818	1.154	165.39	0.038	1.079	0.056	20.771	0.960
Paresthesia	0.098	0.020	0.476	0.004	0.101	0.017	0.612	0.013

Nagelkerke Pseudo $R^2=0.442$

tingling or numbness due to nerve damage, was associated with a lower risk of gangrene, which may initially seem surprising, as nerve damage is typically considered a risk factor for severe foot complications.^[18] However, it is possible that patients experiencing paresthesia are more vigilant in their foot care, recognizing the increased risk of injury and infection due to reduced sensation. Consequently, these patients may adopt more protective measures, such as regularly inspecting their feet, wearing appropriate footwear, and seeking prompt medical attention for any signs of ulceration or infection, thereby reducing the likelihood of gangrene.

The univariate analysis showed that patients with an absent distal pulse had a much higher crude odds ratio (COR 13.818, $P = 0.038$) for developing gangrene. An absent distal pulse is a clear indicator of peripheral artery disease, which impairs blood supply to the extremities and hinders the healing process. This lack of circulation can lead to tissue necrosis and increase the risk of infections, culminating in gangrene.^[19] This finding

underscores the importance of vascular assessment in diabetic foot care and the need for interventions that improve blood flow to the extremities. Good glycemic control was another significant factor in the univariate analysis (COR 0.125, $P = 0.009$), indicating a protective effect against gangrene. Effective glycemic control, by minimizing damage to blood vessels and nerves, helps prevent the complications associated with diabetes, including poor wound healing and increased susceptibility to infections, which are key contributors to gangrene development.^[20] This finding highlights the critical role of maintaining stable blood glucose levels in reducing the risk of gangrene in diabetic patients.

Understanding the predictors of diabetic foot ulcer (DFU) severity, such as gender disparities, poor glycemic control, smoking habits, and infection status, allows primary care physicians to identify high-risk individuals early and implement targeted management strategies. Early detection of these factors allows primary care providers to implement preventive measures like routine foot screenings, smoking cessation programs,

and individualized patient education. Moreover, addressing modifiable risk factors at the primary care level can help delay disease progression, reduce the burden of hospitalizations, and prevent severe outcomes such as gangrene or amputations. The findings of this study underscore the importance of equipping primary care teams with the knowledge and tools to proactively manage diabetic complications, ultimately improving patient outcomes and reducing healthcare costs.

Despite being carried out in a regional referral hospital with a diverse population, this study carries limitations of the single-center approach and a relatively small sample size, which may limit the broader applicability of the findings to the entire region. Additionally, the cross-sectional design of the study restricts the ability to determine causality or track changes over time. Moreover, the dependence on self-reported data, especially concerning addiction and treatment history, may introduce recall bias or lead to socially desirable responses.

Conclusion

This study identifies key factors influencing the severity and outcomes of diabetic foot ulcers in type 2 diabetic patients. Healthcare providers should emphasize the importance of regular diabetes management, including glycemic control and routine foot care, to prevent the progression of foot ulcers. Additionally, educating patients on the appropriate types and intensities of physical activity is essential in minimizing the risk of complications. Complementary treatments, such as Ayurvedic medications, may offer additional benefits and should be explored further in future research. Overall, a comprehensive approach that addresses the multifaceted needs of diabetic patients is essential for effectively managing and preventing diabetic foot complications.

Author contributions

Concept and design: AK, BNN, MK, PK; literature search: AK, BNN, VSO, RB; data acquisition: AK, KJ, RP; data analysis: BNN, VSO, RB; statistical analysis: BNN, VSO, RB; manuscript preparation: VSO, RB, KJ, RP; manuscript editing: AK, BNN, MK, PK; manuscript review: AK, BNN, VSO, RB, MK, PK, KJ, RP. All authors take responsibility for the integrity of the work.

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Conflicts of interest

There are no conflicts of interest.

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