

# **Prospective observational study: Risk factors and outcomes of diabetic foot ulcer among diabetes mellitus patients admitted to Government Medical College, Nizamabad**

## **ABSTRACT**

**Background:** Diabetes mellitus (DM), sometimes known as diabetes, is a collection of metabolic illnesses defined by a persistently high blood sugar level. Frequent urination, increased thirst, and increased appetite are common symptoms. In all nations, DM complications have become a serious public health issue.

**Objectives:** One of the consequences of diabetes mellitus is a diabetic foot ulcer. Diabetic patients with foot infections, particularly gangrene, require long-term hospitalization and are in danger of having their limbs amputated.

**Materials and Methods:** From September 2020 to October 2021, a prospective observational study was conducted among diabetic patients with diabetic foot ulcers at Government Medical College (GMC).

**Results:** 100 DFU patients were admitted to the GMC throughout the research period, with 61 (61.00%) of them being men. The age group between 18 to 78 years, with an average of 58.9 9.56 years. The following groups had higher frequencies among participants: married 56 (56.00 percent), schooling up to primary school 36 (36.00 percent). Type 2 diabetes mellitus affected 59 of them (59.00%). Amputations were performed on 35 (35.00%) of the patients, whereas 65 (65%) had no amputation. The most generally recommended antibiotic for the treatment of DFU was cloxacillin + metronidazole 39 (39.00 Percent), followed by ceftriaxone. Furthermore, diabetic foot ulcer patients with neuropathy were more likely to require amputation (AOR = 1.6250; 95 Percent CI: 0.6479, 4.0756) than diabetic foot ulcer patients without neuropathy.

**Conclusion:** Blood glucose level, higher body mass index, inappropriate antibiotics use, neuropathy and advanced grade of diabetic foot ulcer were independent predictors of amputation. Thus, a focus on weight loss, treating hyperglycemia, and prescribing suitable antibiotics for patients with neuropathy and advanced diabetic foot ulcers might reduce the unfavorable consequences of diabetic foot ulcers.

**Keywords:** Diabetic foot ulcer, diabetes mellitus, amputations, cloxacillin, metronidazole.

## 1. Background

Diabetes mellitus (DM), sometimes known as diabetes, is a collection of metabolic illnesses defined by a persistently high blood sugar level [1]. Frequent urination, increased thirst, and increased appetite are common symptoms [2]. In all nations, DM complications have become a serious public health issue [3]. Multiple long-term problems impact practically every system in the body, and it frequently results in blindness, heart, and blood vessel disease, stroke, renal failure, amputations, and nerve damage [4].

Diabetic foot ulcers (DFU) are a severe health problem that affects people all over the world. A diabetic foot ulcer is one of the most common and serious complications of diabetes. Treatment of an infection in a diabetic ulcer is tough and costly. Patients are commonly prescribed long-acting medications or brought to the hospital for an extended stay. It is estimated that 15 to 25% of diabetics may develop DFU over their lifetime [5]. Patients with a DFU foot ulcer not only have to stay in the hospital longer, but they should also have their feet amputated, which raises death rates [6]. Foot ulcers can cause permanent impairment and significantly reduce the quality of life (QOL) of patients, in addition to increased morbidity. Individuals with DFU, in particular, have limited mobility, poor psychosocial adjustment, and worse self-perception of health than patients without ulcers. Patients with diabetic foot ulcers had a worse survival rate than diabetics who did not have a foot ulcer [7, 8].

DM has been identified as one of the most frequent and serious diseases, linked to a higher risk of postoperative infections and poor outcomes following lumbar spine surgery [9]. Preoperative problems in DM patients undergoing degenerative cervical spine surgery are similarly elevated [10]. Foot issues are still highly frequent in diabetic patients all over the world, affecting up to 15% of diabetic patients during their lives [11]. The most prevalent cause of extended hospitalization and amputation of their limbs is DFU owing to gangrene. Furthermore, after five years of the initial amputation, 28 Percent to 51 Percent of amputated diabetics would have a second lower limb amputation [12, 13]. Diabetic foot difficulties are still the most common medical, social, and economic concerns for people with diabetes [14]. The focus of this research is to see whether participant-driven group education affected ulceration in a group of diabetic patients with a previously healed index ulcer (high risk of ulceration, according to the International Consensus on the Diabetic Foot) over 20 months. Despite these obstacles, no research on DFU risk factors and outcomes has been done. The purpose of this study was to determine the risk factors and outcomes of DFU patients admitted to Nizamabad Government General Hospital.

## 2. Materials and Methods

A prospective observational study was carried out in the Department of general surgery Government general hospital and Government Medical College, Nizamabad for 12 months (September 2020 to October 2021), after obtaining institutional ethical permission.

### Study Design

A hospital-based study, Prospective observational study

### Study Setting

Government Medical College (GMC), Nizamabad

### Study Period

September 2020 to October 2021

To calculate the sample size, a total population of 450 patients with type 2 DM diagnosed during the 6-month study period was considered, with a prevalence of 50% of at least 1 risk for ulceration [15], and accuracy of 10%, and a confidence level of 95%. A sample of approximately 105 participants was estimated as follows:

$$n = \frac{[Np(1 - p)]}{\left[\left(\frac{dZ}{2}\right)^2(1 - \alpha) + pX(1 - p)\right]} \quad (1)$$

where N is the population size (in this example, 450), p denotes the expected percentage of the event (in this case, 50%), d denotes accuracy (in this case, 10%), Z denotes the normal distribution's standard score (in this case, 1.87), and is 5%. The sample size was extended to 105 individuals diagnosed with type 2 diabetes who were receiving treatment at that health facility during the research period. All of the patients were at least 18 years old, were of both genders, required medication, and were under the care of endocrinologists. Five people were dropped from the research because they had associated communicative or neurological issues that made it hard for them to engage in the questionnaire or hindered their responsiveness to sensory stimulation in their feet during clinical assessments. MD 100 patients were the final sample size. Conveniently, all patients that met the eligibility criteria during the trial period were included in the final analysis.

Data was gathered utilizing a questionnaire that was created by studying various literature and adapting it to the data provided. Data was collected by a medical doctor, a nurse, and a pharmacist, and the data was overseen by another medical practitioner. To avoid contamination, a pus sample was taken from the ulcers before any ulcer cleaning, antibiotics, or debridement. The samples were promptly transferred to the lab, where a thin smear was formed on grease-free or oil-free slides. The most likely coverage of antibiotics for treatments

of diabetic foot infection for identified gram stain and appropriateness of dosage regimens were determined using standard guidelines from the Infectious Diseases Society of America (IDSA) for diagnosis and treatment of diabetic foot infection [16]. Two weeks before the actual data collection, 5% of the sample was pretested to ensure the acceptability and consistency of the data collecting instrument. After patients were discharged from the hospital, they were followed for three months using telephone interviews.

A diabetic patient's foot with the potential for pathologic outcomes such as infection, ulceration, and/or deep tissue damage. DFU healing was defined as the full closure of the ulcer with intact skin (complete epithelialization) and no drainage or sinus development. Amputations below the ankle are minor, whereas amputations above the ankle are significant.

According to the International Working Group on the Diabetic Foot (IWGDF) Risk Classification System, category 0 included people with DM but no loss of protective sensation (LOPS) or peripheral arterial disease (PAD); category 1 included people with LOPS but no deformities on their feet, as determined by physical examination; category 2 included people with PAD but no LOPS, and category 3 included people with LOPS but no PAD. Individuals with any form of unhealed ulcers or soft tissue deterioration on their foot were identified with the DFU disease.

It was diagnosed if the patient had at least one of the following symptoms: scorching pain, skin vibrations, gradual numbness, freezing, high sensitivity to touch, muscular weakness, and lack of coordination. It is a peripheral artery and vein disease that frequently affects diabetic people. 70–130 mg/dl fasting blood glucose (Good glycemic control). Fasting blood glucose levels of 70 mg/dl and greater than 130 mg/dl (Poor glycemic control) Antibiotics are provided following the guidelines of the Infectious Diseases Society of America (IDSA) for the treatment of diabetic foot infections based on gram stains and dosing regimens. Antibiotics were prescribed based on gram stains and dosage regimens, but the IDSA guideline for the treatment of diabetic foot infection was inconsistent.

### **Data processing and analysis**

The tools Epi Info®, version 7, and IBM SPSS Statistics®, version 22, were used to tabulate and further analyze the data. Categorical variables were described using absolute (n) and percentage (percent) frequencies, whereas continuous variables were described using standard deviation (SD) averages, minimum and maximum values. The proportions were compared using the chi-square trend test. When the anticipated frequency was 5 in more than 20% of the table cells and/or table cells with values of 1, Fisher's exact test was used instead of the chi-squared test. Adjusted odds ratio (AOR) was used to define the strength of the link,

and factors with a p-value of 0.05 had a statistically significant association with amputation. The significance level for all statistical tests was set at 5% (p 0.05).

### 3. Results

#### Socio-demographic characteristics

100 DFU patients were admitted to the GMC throughout the research period, with 61 (61.00%) of them being men. The age ranged from 18 to 78 years, with an average of 58.9 9.56 years. About 27 (27.00%) of DFU patients were overweight, with 15 (15.00%) being obese, and the mean body mass index (BMI) was 23.89 4.42 kg/m<sup>2</sup>. In the following categories, higher frequencies were observed among participants: schooling up to primary school 36 (36.00 percent) married 56 (56.00 percent) (Table-1).

**Table 1: Sociodemographic characteristics of respondents in GMC, Nizamabad**

Socioeconomic characteristics		
Age (years)	Average (standard deviation)	58.9 ± 9.56
		n (%)
Gender	Male	61 (61.00 %)
	Female	39 (39.00 %)
Marital status	Married/consensual union	56 (56.00 %)
	Single	28 (28.00 %)
	Widowed	12 (12.00 %)
	Divorced/separated	04 (04.00 %)
Educational level	Illiterate	25 (25.00 %)
	Primary school	36 (36.00 %)
	Secondary school	25 (25.00 %)
	Above Secondary school	11 (11.00 %)
BMI (kg/m <sup>2</sup> )	<24.5	58 (58.00 %)
	24.5–29.5	27 (27.00 %)
	>29.5	15 (15.00 %)

*BMI: Body mass index*

#### Medical conditions and behavioral characteristics

A total of 35 (35.00%) of the participants had foot ulcers and chronic health problems or co-morbidity with other diseases. Among these, 52 (52.00 %) participants had hypertension as a comorbidity. 40 (40.00 %) of the study participants were current smokers and 42 (42.00 %) were current alcohol drinkers (Table 2).

**Table 2: Co-morbidities, complications and behavioral characteristics among diabetic foot ulcer patients attending the GMC, Nizamabad**

Variables		n (%)
Behavioral characteristics	Previous alcohol drinker	36 (38.00 %)
	Current alcohol drinker	42 (42.00 %)
	Previous smoker	32(32.00 %)
	Current smoker	40 (40.00 %)
<b>Clinical characteristics</b>		
Co-morbidities and complications	Retinopathy	52 (52.00 %)
	Neuropathy	51 (51.00 %)
	Nephropathy	42 (42.00 %)
	Hypertension	52(52.00 %)
	Peripheral vascular disease	39 (39.00 %)
	Coronary heart disease/ischemic heart disease	38 (38.00 %)
	Dyslipidaemia	35 (35.00 %)

Among 100 study participants, 59 (59.00%) of them had type 2 diabetes mellitus. 20 (20.00%) were diabetic for more than 10 years and 53 (53.00%) participants had poorly controlled blood glucose levels. DFU size greater than 5 cm<sup>2</sup> was identified among 11 (11.00%) patients (Table 3).

**Table 3: Clinical characteristics of diabetic foot ulcer patients among diabetes mellitus patients admitted to GMC, Nizamabad**

Variables		n (%)
Types of DM	Type 1 DM	41 (41.00%)
	Type 2 DM	59 (59.00%)
Duration of DM	<5years	38 (38.00%)
	5–10years	42 (42.00%)
	>10 years	20 (20.00%)
Glycaemic control	Poor control	53 (53.00%)
	Good control	47 (47.00%)
Size of Ulcer	<1 cm <sup>2</sup>	62 (62.00%)
	1–5 cm <sup>2</sup>	27 (27.00%)
	>5 cm <sup>2</sup>	11 (11.00%)

About 35 (35.00%) of the patients were amputated and 65 (65%) patients had no amputation.

#### **Antibiotics prescribed to treat DFU**

Empiric antibiotic regimens were prescribed for DFU patients after gram stain results were obtained and given based on the severity of the infection as well as the likely etiologic agent. Accordingly, an initial antibiotic course for a soft tissue infection of about 7 days for mild infections and 10–21 days for moderate to severe infections were given. Cloxacillin +

Metronidazole 39 (39.00 %) was the most commonly prescribed antibiotic for the treatment of DFU followed by ceftriaxone (Table 4).

**Table 4: Commonly prescribed individual antibiotics for treating diabetic foot ulcers in GMC, Nizamabad**

Antibiotics	n (%)
Ampicillin	5 (5.00 %)
Amoxicillin	2 (2.00 %)
Ceftriaxone	15 (15.00 %)
Ceftazidime	3 (3.00 %)
Chrompenicol	4 (4.00 %)
Ciprofloxacin	3 (3.00 %)
Cloxacillin + Metronidazole	39 (39.00 %)
Metronidazole	24 (24.00 %)
Gentamycin	4 (4.00 %)
Vancomycin	1 (1.00 %)
Total	100 (100.00 %)

#### Risk factors and outcomes of diabetic foot ulcer

65 (65%) of the patients with DFU were healed, whereas 35 (35%) had to have their limbs amputated. On multivariate logistic regression analysis, foot ulcer grade 4, improper antibiotic usage, overweight, obesity, poor blood glucose management, and neuropathy were revealed to be predictors of amputation. Diabetic patients with Grade 4 diabetic foot ulcers were 1.7 times more likely to have their feet amputated (AOR = 0.5629; 95 percent CI:0.2222,1.4265) than diabetic patients with Grade 3 diabetic foot ulcers. Furthermore, diabetic foot ulcer patients with poor blood glucose control were more likely to require amputation than diabetic foot ulcer patients with adequate blood glucose control (AOR=1.8258; 95 percent CI: 0.7177, 4.6449). Furthermore, those DFU patients who had neuropathy were more likely to undergo amputation as compared to those diabetic foot ulcer patients without neuropathy (AOR = 1.6250; 95% CI: 0.6479,4.0756) (Table-5).

**Table 5: Multivariate logistic regression analysis result of factors associated with amputation among diabetic foot ulcer patients admitted to GMC, Nizamabad**

Variables		Amputation	No Amputation	AOR(95%CI)	P-value
Gender	Male	17 (27.9 %)	44 (72.1 %)	1.4972 [0.5745, 3.902]	0.4089
	Female	8 (20.5%)	31 (79.5 %)		
Drinking Alcohol Currently	Yes	9 (21.4 %)	33 (78.6 %)	0.7159 [0.2810,1.8242]	0.4837
	No	16 (27.6 %)	42 (72.4 %)		
Smoking cigarette currently	Yes	9 (22.5 %)	31 (77.5 %)	0.7984 [0.3128,2.0380]	0.6377
	No	16 (26.7 %)	44 (73.3 %)		
Types of DM	Yes	8 (19.5 %)	33 (80.5 %)	0.5989	0.2933

	No	17 (28.8 %)	42 (71.2 %)	[0.2302,1.5581]	
Retinopathy	Yes	12(23.1 %)	40 (76.9 %)	0.8077	0.6442
	No	13 (27.1%)	35 (72.9 %)	[0.3263,1.9992]	
Neuropathy	Yes	15 (29.4 %)	36 (70.6%)	1.6250	0.3007
	No	10 (20.4 %)	39(79.6 %)	[0.6479,4.0756]	
Nephropathy	Yes	14(33.3 %)	28 (66.7 %)	2.1364	0.1050*
	No	11 (19 %)	47 (81 %)	[0.8532,5.3496]	
Hypertension	Yes	14(33.3%)	28(66.7 %)	2.1364	0.1050*
	No	11(19%)	47(81 %)	[0.8532,5.3496]	
Peripheral Vascular Disease	Yes	9(23.1 %)	30(76.9%)	0.8438	0.7227
	No	16(26.2 %)	45(73.8 %)	[0.3302,2.1563]	
Coronary Heart Disease	Yes	6(15.8%)	32(84.2 %)	0.4243	0.1014*
	No	19(30.6 %)	43(69.4 %)	[0.1522,1.1834]	
Dyslipidaemia	Yes	8(22.9 %)	27(77.1 %)	0.8366	0.7167
	No	17(26.2 %)	48(73.8 %)	[0.3192,2.1928]	
Glycaemic Control	Yes	16(30.2 %)	37(69.8 %)	1.8258	0.2063
	No	9(19.1 %)	38(80.9 %)	[0.7177,4.6449]	
Grade of Ulcer	≤4	14(33.3 %)	28(66.7 %)	0.5629	0.2258
	≥4	11(19 %)	47(81 %)	[0.2222,1.4265]	

\*Shows statistically significant  $p$ -value  $\leq 0.25$  at 95% CI. \*\*Shows statistically significant  $p$ -value  $\leq 0.05$  at 95% CI.

#### 4. Discussion

The focus of this research was to determine the risk factors and outcomes of DFU patients who were admitted to GMC, Nizamabad. This study discovered that nearly half of the patients had poor glycaemic control and that patients with poor blood glucose control were more likely to have their limbs amputated than those with good blood glucose control. This was supported by research undertaken in India, Sudan, the United States, and Germany [18-21]. This suggests that the relevance of glycemic control as a fundamental intervention in DFU management and the avoidance of needless limb wasting should be inferred and highlighted by these findings. As a result, maintaining adequate plasma glucose management lowers the risk of amputation in diabetic foot ulcer patients. The possible reason could be due to the decreased blood flow circulations to the lower limb as a result of fat accumulations among higher BMI patients.

Amputation was a substantial risk factor for advanced Wagner stage ulcers. Wagner Grade 4 DFU patients were four times more likely to have their limbs amputated than Wagner Grade 4 diabetic foot ulcer patients. This outcome was in line with research undertaken in Tanzania and the United States [22, 23]. The majority of patients in the advanced Wagner stage developed gangrene, which might be the explanation. Another factor

that predicts amputation in diabetic foot ulcer patients is peripheral neuropathy. Diabetic patients with neuropathy were more likely to have limbs amputated than diabetics without neuropathy. This finding was in line with research done in Germany and Gondar [24, 25]. As a result of the increased length of pressure on the diabetic foot, this might be attributed to peripheral neuropathy, which exposes the patient to a foot infection. Furthermore, elevated blood glucose levels might damage peripheral nerves, increasing the risk of amputation.

Cloxacillin + metronidazole was the most commonly prescribed individual antibiotic in GMC during the study period, accounting for 39 (39.00 percent), followed by ceftriaxone (15). (15.00 percent ). Bekele et al. [26] published similar research. Cefradine, clindamycin, and ciprofloxacin were the most regularly recommended antibiotics in a UK study by Wong and Coppini [27]. However, according to research conducted in Sweden, metronidazole (56%) and ciprofloxacin (54%) were the most regularly used antibiotics, followed by flucloxacillin (40%) and cefadroxil (31%). Semi-synthetic penicillin, second and third-generation cephalosporins, and fluoroquinolones were also found to be the most commonly used antibiotics in a study conducted in Switzerland by Pittet et al [29]. The variety of individual antibiotic use in a variety of settings was mostly due to the etiologic agent identified, patient condition, availability of the drugs, and preference of the physicians.

Amputations were performed on 35 (35.00%) of the patients, whereas 65 (65%) had no amputation. The outcome of DFU was strongly linked to the use of ineffective antibiotics to treat diabetic foot infections. Diabetes foot ulcers treated with unsuitable antibiotics were 2.5 times more likely to require amputation than those treated with appropriate antibiotics. This was corroborated by research done in the United Kingdom, which found that with effective antibiotic medication, the amputation incidence reduced from over 70% to around 30% [30]. Antibiotics were given incorrectly in nearly half of the cases in our study region. Therefore, because of excessive and inappropriate use of antibiotics for treating diabetic foot infections, treatment failure and the risk of amputation increased.

Antibiotics prescribed incorrectly can lead to the development of resistant bacteria. 65 (65%) of the patients with DFU were healed, whereas 35 (35%) had to have their limbs amputated. On multivariate logistic regression analysis, foot ulcer grade 4, improper antibiotic usage, overweight, obesity, poor blood glucose management, and neuropathy were revealed to be predictors of amputation. Diabetes duration previous to presentation has no bearing on the outcome of diabetic foot ulcers. The inhibitory effects of diabetes on wound healing were proven by Saleem et al [31], however, the duration of diabetes may not be as significant as total blood glucose management. Diabetic patients in rural settings frequently

go barefoot [32]. This may expose their feet to being injured and may result in infections. Despite this, most of the patients in our study area were come from urban and the place of residence had no significant associations with the outcomes of DFU.

This was due to the differences in the quality of diabetic foot care and the difficulty of obtaining consent for major or even minor surgery that required amputation of an affected limb. The reason for this reluctance lies in part in cultural factors where the loss of a limb may be considered worse than a loss of life.

### **Conclusion**

Blood glucose level, higher BMI (overweight and obesity), inappropriate antibiotics are given; neuropathy and advanced grade of diabetic foot ulcer were factors that predicted the amputation among DFU patients. The rate of DFU amputation was found to be significant, with the majority of patients having their legs amputated below the ankle. Cloxacillin + metronidazole was the most generally recommended antibiotic for treating diabetic foot ulcers, and almost half of the medications were given incorrectly.

Patients with neuropathy and advanced-stage diabetic foot ulcers should be given additional attention to reducing the unwanted effects of DFU. To reduce the risk of DFU, health educators should highlight the need of losing weight and controlling hyperglycemia. In addition, laboratory services such as culture and sensitivity testing should be increased to determine the pathogen's particular strain for final therapy. These prescribers should be required to prescribe empiric antibiotics as little as feasible. Even though death was not recorded in our investigation, earlier studies have identified DFU as a key outcome. As a result, we recommend that more studies be conducted to determine death rates and related variables.

### **COMPETING INTERESTS DISCLAIMER:**

**Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.**

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