

## RISK FACTORS AND OUTCOMES OF DIABETIC FOOT ULCER AMONG DIABETES MELLITUS PATIENTS ADMITTED TO GOVERNMENT MEDICAL COLLEGE, VIJAYAWADA: PROSPECTIVE OBSERVATIONAL STUDY

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### 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 2022 to October 2023, a prospective observational study was conducted among diabetic patients with diabetic foot ulcers at Siddhartha Medical College, Vijayawada (SMC). **Result:** 100 DFU patients were admitted to the SMC throughout the research period, with 59 (59%) of them being men. The age group between 18 to 76 years, with an average of 57.6± 8.52 years. The following groups had higher frequencies among participants: married 57 (57%), schooling up to primary school 37 (37%) Type 2 diabetes mellitus affected 62 of them (62%). Amputations were performed on 32 (32%) of the patients, whereas 68 (68%) had no amputation. The most generally recommended antibiotic for the treatment of DFU was cloxacillin + metronidazole 40 (40%), followed by ceftriaxone. Furthermore, diabetic foot ulcer patients with neuropathy were more likely to require amputation (AOR =1.9524; 95% CI 0.8554, 4.456) 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.

## INTRODUCTION

A persistently increased blood sugar level is the characteristic of a group of metabolic diseases commonly referred to as diabetes mellitus (DM) or diabetes.<sup>[1]</sup> Frequent urination, increased thirst, and increased appetite are common symptoms.<sup>[2]</sup> Diabetic foot ulcers (DFUs) are a serious global health issue that afflict individuals worldwide. Diabetic foot

ulcers are among the most prevalent and dangerous side effects of diabetes. Diabetic ulcer infections are difficult and expensive to treat. Long-acting drugs are frequently provided to patients, or they may be admitted to the hospital for a prolonged stay. Between 15 and 25% of diabetics are thought to have DFU at some point in their lives.<sup>[3]</sup> In addition to needing to stay in the hospital longer, patients with DFU foot ulcers need also have their feet amputated, which increases the mortality rate.<sup>[4]</sup> In addition to increasing morbidity, foot ulcers can cause lasting

disability and drastically lower a patient's quality of life (QOL). Compared to patients without ulcers, those with DFU in particular had worse self-perceptions of their health, poor psychosocial adjustment, and restricted mobility. Compared to diabetics without foot ulcers, patients with diabetic foot ulcers had a worse survival rate.<sup>[5, 6]</sup>

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.<sup>[7]</sup> Preoperative problems in DM patients undergoing degenerative cervical spine surgery are similarly elevated.<sup>[8]</sup> Foot issues are still highly frequent in diabetic patients all over the world, affecting up to 15% of diabetic patients during their lives.<sup>[9]</sup> 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% to 51% of amputated diabetics would have a second lower limb amputation.<sup>[10,11]</sup> Diabetic foot difficulties are still the most common medical, social, and economic concerns for people with diabetes.<sup>[12]</sup>

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 challenges, no study has been conducted on the risk factors and consequences of DFU. Determining the risk factors and results of DFU patients admitted to Siddhartha Medical College, Vijayawada was the aim of this study.

## MATERIALS AND METHODS

### Study Design

A hospital-based study, Prospective observational study

### Study Setting

Siddhartha Medical College (SMC), Vijayawada

**Study Period:** September 2022 to October 2023, after obtaining institutional ethical permission.

To calculate the sample size, a total population of 475 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<sup>[13]</sup>, and accuracy of 10%, and a confidence level of 95%. A sample of approximately 105 participants was estimated as follows:

$$n = \frac{[Np(1-p)]}{(((d^2/Z^2)(1-\alpha)/2) \quad X(N-1)+pX(1-p))} \quad (1)$$

Where N is the population size (in this example, 475), 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, 1.75), 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 literatures 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.<sup>[14]</sup> 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. 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).

## RESULTS

### Socio-Demographic Characteristics

100 DFU patients were admitted to the SMC throughout the research period, with 59 (59%) of them being men. The age ranged from 18 to 76 years, with an average of 57.6± 8.52 years. About 28 (28%) of DFU patients were overweight, with 16 (16%) being obese, and the mean body mass index (BMI) was 23.26 ± 4.40 kg/m<sup>2</sup>. In the following categories, higher frequencies were observed among participants: schooling up to primary school 37 (37%) married 57 (57%) (Table-1).

**Table 1: Sociodemographic characteristics of respondents in SMC, Vijayawada.**

Socioeconomic Characteristics		
Age (years)	Average (standard deviation)	57.6± 8.52
		n (%)
Gender	Male	59 (59 %)
	Female	41 (41 %)
Marital status	Married/consensual union	57 (57 %)
	Single	26 (26 %)
	Widowed	14 (14 %)
	Divorced/separated	3 (3 %)
Educational level	Illiterate	27 (27 %)
	Primary school	37(37 %)
	Secondary school	22 (22 %)
	Above Secondary school	14 (14 %)
BMI (kg/m <sup>2</sup> )	<24.5	56 (56 %)
	24.5–29.5	28 (28 %)
	>29.5	16 (16 %)

BMI: Body mass index

### Medical conditions and behavioural characteristics

The table-2 shows that co-morbidities, complications and behavioural characteristics among diabetic foot ulcer patients attending the SMC. A total of 38 (38%) of the participants had foot ulcers and chronic health problems or co-morbidity with other diseases. Among these, 53 (53%) participants had hypertension as a comorbidity. 38 (38 %) of the study participants were current smokers and 45(45%) were current alcohol drinkers.

**Table 2: Co-morbidities, complications and behavioural characteristics among diabetic foot ulcer patients attending the SMC, Vijayawada**

Variables		n (%)
Behavioral characteristics	Previous alcohol drinker	33 (33 %)
	Current alcohol drinker	45 (45 %)
	Previous smoker	31 (31 %)
	Current smoker	38 (38 %)
<b>Clinical characteristics</b>		
Co-morbidities and complications	Retinopathy	53 (53 %)
	Neuropathy	49 (49 %)
	Nephropathy	40 (40 %)
	Hypertension	53 (53 %)
	Peripheral vascular disease	37 (37 %)
	Coronary heart disease/ischemic heart disease	35 (35 %)
	Dyslipidaemia	32 (32 %)

Among 100 study participants, 62 (62%) of them had type 2 diabetes mellitus. 22 (22%) were diabetic for more than 10 years and 56 (56%) participants had poorly controlled blood glucose levels. DFU size greater than 5 cm<sup>2</sup> was identified among 9 (9%) patients (Table 3). About 38 (38%) of the patients were amputated and 62 (62%) patients had no amputation.

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

Variables		n (%)
Types of DM	Type 1 DM	39 (39%)
	Type 2 DM	62 (62%)
Duration of DM	<5years	32 (32%)
	5–10years	46 (46%)
	>10 years	22 (22%)
Glycaemic control	Poor control	56 (56%)
	Good control	44 (44%)
Size of Ulcer	<1 cm <sup>2</sup>	63 (63%)
	1–5 cm <sup>2</sup>	28 (28%)
	>5 cm <sup>2</sup>	9 (9%)

**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 40 (40 %) 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 SMC, Vijayawada**

Antibiotics	n (%)
Ampicillin	6 (6 %)
Amoxicillin	3 (3 %)
Ceftriaxone	12 (12 %)
Ceftazidime	3 (3%)
Chrompenicol	4 (4%)
Ciprofloxacin	3 (3%)
Cloxacillin + Metronidazole	40 (40 %)
Metronidazole	22 (22 %)
Gentamycin	5 (5 %)
Vancomycin	2 (2%)
Total	100 (100.00 %)

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

Table-5 shows that multivariate logistic regression analysis result of factors associated with amputation among diabetic foot ulcer patients admitted to SMC. 62 (62%) of the patients with DFU were healed, whereas 38 (38%) 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 more likely to have their feet amputated (AOR = 0.3684; 95% CI: 0.1600, 0.8483) 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. Furthermore, those DFU patients who had neuropathy were more likely to undergo amputation as compared to those diabetic foot ulcer patients without neuropathy (AOR =1.9524; 95% CI 0.8554, 4.456).

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

Variables		Amputation (N=38)	No Amputation (N=62)	AOR (95%CI)	P-value
Gender	Male	23 (38.98%)	36 (61.02%)	1.1074 [0.4862, 2.522]	0.808
	Female	15 (36.59%)	26 (63.41%)		
Drinking Alcohol Currently	Yes	19 (42.22 %)	26 (57.78 %)	1.38 [0.6149, 3.1178]	0.431
	No	19 (34.55 %)	36 (65.45 %)		
Smoking cigarette currently	Yes	18 (47.37 %)	31 (52.63 %)	1.89 [0.8241,4.334]	0.130
	No	20 (32.26 %)	44 (67.74 %)		
Retinopathy	Yes	23 (43.40 %)	30 (56.60 %)	1.635 [0.3263,1.9992]	0.2377
	No	15 (31.91%)	32 (68.09 %)		
Neuropathy	Yes	22 (44.90 %)	27 (55.10%)	1.7824 [0.7877,4.033]	0.163
	No	16 (31.37 %)	35 (68.63 %)		
Nephropathy	Yes	19 (47.50 %)	21 (52.50 %)	1.9524 [0.8554,4.456]	0.110
	No	19 (31.67 %)	41 (68.33 %)		
Hypertension	Yes	23 (43.40 %)	30 (56.60 %)	1.635 [0.3263,1.9992]	0.2377
	No	15 (31.91%)	32 (68.09 %)		
Peripheral Vascular Disease	Yes	11 (29.73 %)	26 (70.27%)	0.5641 [0.2378, 1.338]	0.191
	No	27 (42.86 %)	36 (57.14 %)		
Coronary Heart Disease	Yes	8 (22.86%)	27 (77.14 %)	0.3457	0.022**

	No	30 (46.15 %)	35 (53.85 %)	[0.136,0.874]	
Dyslipidaemia	Yes	7 (21.88 %)	25 (78.13 %)	0.3342	0.023**
	No	31 (45.59 %)	37 (54.41 %)	[0.1274,0.8767]	
Grade of Ulcer	≤4	14 (26.92 %)	38(73.08%)	0.3684 [0.1600,0.8483]	0.01**
	≥4	24 (50 %)	24 (50 %)		

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

## DISCUSSION

Finding the risk factors and outcomes of DFU patients who were admitted to SMC, Vijayawada, was the main goal of this study. According to this study, over half of the patients had poor glycaemic control, and those who had poor blood glucose control had a higher risk of limb amputation than those who had good blood glucose control. Research conducted in Germany, the US, India, and Sudan<sup>[16-19]</sup> provided evidence for this. This implies that these results should be used to deduce and emphasise the importance of glycemic control as a key intervention in DFU therapy and the prevention of unnecessary limb waste. Therefore, in patients with diabetic foot ulcers, maintaining appropriate plasma glucose control reduces the risk of amputation. 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.

An important risk factor for advanced Wagner stage ulcers was amputation. Wagner Grade 4 diabetic foot ulcer patients had a fourfold higher risk of amputation than Wagner Grade 4 DFU patients. This result was consistent with studies conducted in Tanzania and the United States.<sup>[20, 21]</sup> Perhaps this explains why most patients in the advanced Wagner stage got gangrene. Peripheral neuropathy is another characteristic that predicts amputation in people with diabetic foot ulcers. Compared to diabetics without neuropathy, those with neuropathy have a greater probability of having limbs amputated. This finding was in line with research done in Germany and Gondar<sup>[22, 23]</sup> 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 SMC during the study period, accounting for 40 (40%), followed by ceftriaxone 12 (12%). Bekele et al.<sup>[24]</sup> published similar research. Cefradine, clindamycin, and ciprofloxacin were the most regularly recommended antibiotics in a UK study by Wong et al.<sup>[25]</sup> However, a study done in Sweden found that the most often used antibiotics were cefadroxil (31%), flucloxacillin (40%), and metronidazole (56%) followed by ciprofloxacin (54%). In a research done in Switzerland by Pittet et al., semi-synthetic penicillin, second and third-generation cephalosporins, and fluoroquinolones were also discovered to be the most often used antibiotics.<sup>[26]</sup> 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.

Of the patients, 32 (32%) underwent amputations, whereas 68 (68%) did not have one. The use of inadequate antibiotics to treat diabetic foot infections was substantially correlated with the outcome of DFU. An amputation was 2.5 times more likely to be necessary for diabetic foot ulcers treated with inappropriate antibiotics than those treated with the right ones. Research conducted in the UK supported this, showing that the incidence of amputations decreased from over 70% to about 30% when given efficient antibiotics.<sup>[27]</sup> In our research location, antibiotics were administered inappropriately in almost half of the instances. Therefore, treatment failure and the risk of amputation increased due to the overuse and improper use of antibiotics for diabetic foot infections.

Antibiotics prescribed incorrectly can lead to the development of resistant bacteria. 68 (68%) of the patients with DFU were healed, whereas 32 (32%) 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<sup>[28]</sup>, however, the duration of diabetes may not be as significant as total blood glucose management. Diabetic patients in rural settings frequently go barefoot.<sup>[29]</sup> 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. This hesitation may be partially attributed to cultural issues, such as the belief that losing a limb is worse than losing one's life.

## CONCLUSION

Amputation among DFU patients was predicted by blood glucose level, higher BMI (overweight and obesity), improper antibiotic use, neuropathy, and advanced diabetic foot ulcer grade. It was discovered that DFU amputation rates were high, with most



patients having their legs amputated below the ankle. For the treatment of diabetic foot ulcers, cloxacillin with metronidazole was the most commonly prescribed antibiotic combination; however, over 50% of the prescriptions were administered improperly.

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. Although our analysis did not record any deaths, previous research has shown DFU as a significant effect. Therefore, we advise conducting more research to ascertain fatality rates and associated factors.

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