

Analysis of Risk Factors and Management Strategies in Patients with Diabetic Foot - A Prospective Observational StudyRaviraj Bharai¹, Sapna Desai^{2*}¹Assistant Professor, Department of General Surgery, IIMSAR & Dr. BCRH, Haldia, India²Assistant Professor, Department of Pathology, IIMSAR & Dr. BCRH Haldia, India

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Abstract

Introduction: Diabetes mellitus is a global health concern, with diabetic foot disease, marked by neuropathic ulcers and gangrene, requiring surgical interventions to address anatomical issues and aid wound healing. This study aims to evaluate the efficacy of surgical management strategies in addressing diabetic foot complications and minimizing associated risks, with a focus on improving patient care and reducing limb loss.

Material and Method: This prospective observational study, conducted between March 2022 and February 2023 at a tertiary care center in Gujarat, India, focused on 50 patients diagnosed with diabetes mellitus presenting with diabetic foot complications. Patients with diabetic foot ulcers or gangrene, whether treated at the outpatient department (OPD) or admitted to the surgical ward, were included. Data, encompassing demographic and clinical details, were gathered through structured checklists from hospital records and interviews. Patient characteristics and associations between risk factors and outcomes were analyzed using statistical tests, with significance at $p < 0.05$.

Results: Utilizing the DIAFORA Score, we categorized the risk of lower extremity amputation, revealing that 42% of patients had a low risk, 36% had a medium risk, and 22% had a high risk. Diabetic foot was most common in patients aged 61-70 years (32%) and males (78%), with obesity playing a significant role, as 58% of obese patients were affected, and 77.8% of those with medium risk were obese. High-risk patients mostly had gangrene (72.7%), while moderate-risk patients had cellulitis with ulcers (33.3%), and low-risk patients had ulcers (61.9%). Significant associations were found between clinical factors like granulation, margins, discharge, and bacterial cultures and the risk of lower extremity amputation. Management strategies varied by risk category, with high-risk patients more likely to have below-knee amputation (27.3%), while low-risk patients predominantly underwent debridement (85.7%). Follow-up revealed higher recovery rates among low and medium-risk patients compared to high-risk ones.

Conclusion: Our study highlights the burden of diabetic foot complications, with high rates of amputation and gangrene. Elevated blood sugar levels, family history, obesity, and wound characteristics were significant predictors of amputation risk, emphasizing the need for comprehensive strategies to improve outcomes through early intervention and multidisciplinary management.

Keywords: Diabetic Foot, Surgical Management, Risk Factors, Limb Loss.

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Introduction

Diabetes mellitus is a chronic metabolic disorder characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. [1] The incidence of complications associated with diabetes mellitus is on the rise, marking it as a significant health concern in modern times. [2] One of the most common and debilitating complications of diabetes is diabetic foot disease, which encompasses a spectrum of conditions ranging from neuropathic ulcers to deep-seated infections and gangrene. [3] The pathogenesis of diabetic foot complications is multifactorial, involving peripheral neuropathy, peripheral arterial disease,

foot deformities, impaired wound healing, and immune dysfunction. [4]

Surgical interventions are indispensable in managing diabetic foot complications, addressing underlying anatomical abnormalities, facilitating wound healing, and halting further tissue damage. [5] These interventions may encompass debridement, revascularization procedures, osteotomies, soft tissue reconstruction, and, in severe cases, major amputations. [6] While medical advancements have improved the management of diabetic foot complications, surgical interventions

remain pivotal, especially when conservative approaches prove ineffective. [7]

Long-term follow-up is essential for evaluating the efficacy and sustainability of surgical interventions in diabetic foot management. It enables clinicians to monitor wound healing, assess functional outcomes, identify complications, and implement preventive measures to mitigate the risk of recurrence and disease progression. [8] Additionally, long-term follow-up provides valuable insights into the natural history of diabetic foot disease, including rates of re-ulceration, revascularization, and amputation. [9] This study examines surgical management of diabetic foot complications, assessing various interventions' effectiveness and long-term outcomes. By understanding surgical intricacies and their impact, we aim to improve patient care, refine treatments, and reduce limb loss and complications.

Material and Methods

This prospective observational study was conducted between the March 2022 and Feb 2023 at a tertiary care centre in Gujarat, India. The study population comprised patients diagnosed with diabetes mellitus and presenting with diabetic foot complications, such as foot ulcers or gangrene, who sought treatment at the outpatient department (OPD) or were admitted to the surgical ward of the tertiary care centre. The study protocol was approved by the institutional ethics committee, and all procedures were conducted in accordance with ethical principles outlined in the Declaration of Helsinki. Informed consent was obtained from all participants before data collection.

Inclusion Criteria: The study included patients diagnosed with diabetes mellitus who presented with diabetic foot complications, such as foot ulcers or gangrene, and sought treatment at the outpatient department (OPD) or were admitted to the surgical ward of the tertiary care centre, Gujarat.

Exclusion Criteria: Patients were excluded if they did not have a confirmed diagnosis of diabetes mellitus, if they did not present with diabetic foot complications, or if they did not seek treatment at the study centre during the specified study period. Additionally, patients with incomplete medical records or who did not provide informed consent were excluded from the study.

Data were collected from hospital records and patient interviews, utilizing a structured checklist to gather information on patient demographics, including age, sex, duration of diabetes, comorbidities, and socioeconomic status. Clinical parameters such as the type of foot lesion, presence of infection, wound characteristics, previous

surgeries, and outcomes of hospital admissions were also recorded.

Descriptive statistics were used to summarize patient characteristics and clinical findings, with categorical variables presented as frequencies and percentages. Analysis was done with statistical software version SPSS 21 and Associations between risk factors and outcomes, such as lower extremity amputation, were assessed using appropriate statistical tests, with significance set at $p < 0.05$.

Results

The present prospective observational study was conducted at the General Surgery Department of a tertiary care centre in Gujarat focused on 50 patients with diabetic foot. Using the DIAFORA Score, the risk of lower extremity amputation was assessed and categorized as high, medium, or low risk. The findings revealed that 42% of patients had a low risk, 36% had a medium risk, and 22% had a high risk of lower extremity amputation. The incidence of diabetic foot was highest among patients aged 61-70 years (32%), followed by those aged 51-60 years (30%). The incidence of diabetic foot was more in male (78%) patients than females (22%). However, there was no significant difference in the distribution of age or sex groups concerning the risk of lower extremity amputation (p -value = 0.441).

Additionally, the incidence of diabetic foot was notably higher in obese patients (58%) compared to overweight (18%) or normal-weight diabetic patients (24%). Furthermore, a significant difference in the distribution of BMI with the risk of lower extremity amputation was observed (p -value = 0.017), indicating a higher risk among obese diabetic patients (63.6%). Additionally, the majority of patients with a medium risk of amputation were obese (77.8%). The study found that diabetic foot incidence was higher among the upper middle class (46%) and lower middle socioeconomic status (SES) patients, with 20% from the poor SES category. The study found significant differences in the risk of lower extremity amputation based on socioeconomic status (SES) and family history of diabetes ($p = 0.002$ and $p = 0.009$, respectively). Specifically, a majority of high-risk patients for amputation belonged to the upper middle-class SES and had a family history of diabetes, while moderate-risk patients were predominantly from the poor SES category and lacked a family history of diabetes.

Most common type of lesion among the patients with diabetic foot in present study was Ulcer (38%) followed by Cellulitis, Ulcer (22%) and Gangrene (22%). (Table 1) The study examined the relationship between diabetes duration and lower extremity amputation risk, revealing significant

differences ($p = 0.012$). High-risk patients had the longest mean duration (6.67 years), followed by medium-risk (4.28 years) and low-risk (2.52 years) patients. However, when comparing the extent of limb involvement with the risk of lower extremity

amputation, no significant difference was observed ($p = 0.442$). The majority of cases involved the forefoot (30.0%), followed by the ankle (16.0%) and calf (12.0%).

Table 1: Type of lesions with risk of lower extremity amputation

Risk of lower extremity amputation	High Risk	Low Risk	Medium Risk	Total	P value
Cellulitis	1 (9.1%)	3 (14.3%)	1 (5.6%)	5	<0.001
Cellulitis, Gangrene	1 (9.1%)	0 (0.0%)	1 (5.6%)	2	
Cellulitis, Ulcer	0 (0.0%)	5 (23.8%)	6 (33.3%)	11	
Gangrene	8(72.7%)	0 (0.0%)	3 (16.7%)	11	
Gangrene, Ulcer	1 (9.1%)	0 (0.0%)	1 (5.6%)	2	
Ulcer	0 (0.0%)	13(61.9%)	6 (33.3%)	19	

Comparing granulation, margins, and discharge with the risk of lower extremity amputation revealed significant associations ($p < 0.001$, $p < 0.001$, $p = 0.012$, respectively). The majority of medium-risk patients had unhealthy granulation (80.0%), ill-defined margins (90.0%), and purulent discharge (70.0%). Similarly, the majority of low-risk patients exhibited unhealthy granulation (90.0%) and ill-defined margins (90.0%), with purulent discharge in 50.0% of cases. Among high-risk patients, unhealthy granulation was reported in

20.0%, ill-defined margins in 20.0%, and all patients had purulent discharge. The pus culture findings revealed the presence of various bacteria, with Staph Aureus and Pseudomonas being the most prevalent at 30% each. E. Coli accounted for 22% of the cultures, while Klebsiella was found in 8% of cases. (Figure 1) High-risk diabetic foot patients mainly showed monophasic color Doppler findings, whereas medium-risk patients displayed biphasic patterns. This association was significant ($p < 0.001$).

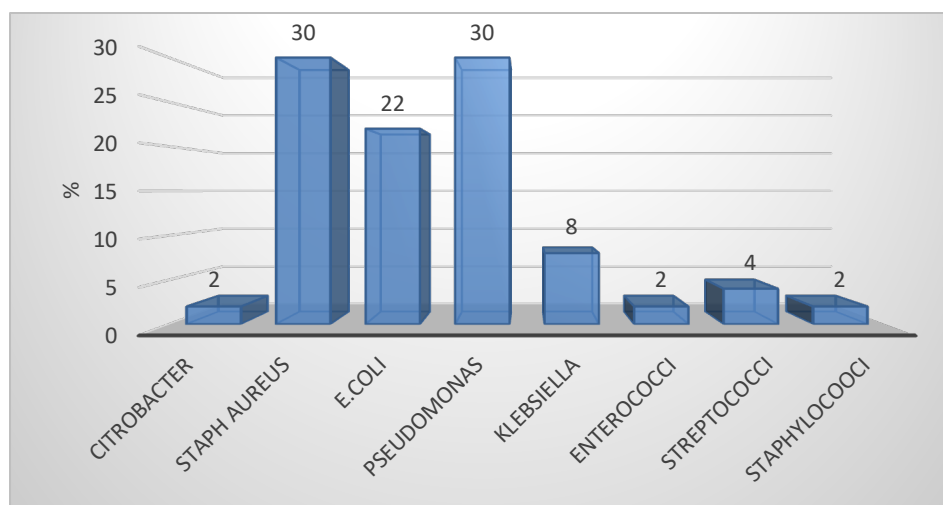


Figure 1: Culture finding among study patients

The table displays management strategies employed across different risk categories for lower extremity amputation. Notably, below knee amputation was more common among high-risk patients (27.3%), while low-risk patients predominantly underwent debridement (85.7%). The association between management strategies and risk level was significant ($p = 0.001$). (Table 2)

Table 2: Management strategies among diabetic foot patients

Management Strategies	High Risk	Low Risk	Medium Risk	Total	P value
Below Knee Amputation	3 (27.3%)	0 (0.0%)	0 (0.0%)	3	0.001
Debridement	2 (18.2%)	18 (85.7%)	11 (61.1%)	31	
Debridement & Amputation	2 (18.2%)	0 (0.0%)	2 (11.1%)	4	
Debridement with Fasciotomy	0 (0.0%)	1 (4.8%)	0 (0.0%)	1	
Debridement with SSG	0 (0.0%)	2 (9.5%)	2 (11.1%)	4	
Toe Amputation	4 (36.4%)	0 (0.0%)	3 (16.7%)	7	

During follow-up, the majority of high-risk patients experienced complete recovery (45.5%), while 27.3% were lost to follow-up. Similarly, 95.2% and 72.2% of low and medium-risk patients achieved complete recovery, respectively. These findings demonstrated a significant association with a p-value of 0.019.

Discussion

Diabetic foot ulcers present a substantial global health challenge, often leading to severe complications such as infections and lower extremity amputations, significantly impacting individuals' quality of life. [10] Preventive measures, including regular foot inspections, proper footwear, glycemic control, and patient education, are crucial in reducing ulcer incidence. [11] Early detection of pre-ulcerative lesions and prompt intervention are essential to prevent progression to full-thickness ulcers. [12] However, despite treatment advancements, managing diabetic foot ulcers remains challenging, especially in cases of chronic wounds or vascular complications, emphasizing the importance of addressing underlying vascular disease for successful wound healing.

In our investigation involving 50 diabetic foot patients, we observed that 42% were categorized as having a low risk of lower extremity amputation, 36% had medium risk, and 22% exhibited a high risk of amputation. Interestingly, our study revealed a uniform distribution of amputation risk across all age groups. The incidence of diabetic foot was notably higher in individuals aged 61-70 years (32%), followed closely by those aged 51-60 years (30%). We also noted 22% of patients were older than 70 years, while 16% were younger than 50 years. These findings align with previous research by Khataniar et al., indicating a higher prevalence of diabetic foot ulcers in the 51-60 age group, although age did not emerge as a significant risk factor for amputation in our study (p-value: 0.491). [13] Additionally, Johannesson et al. found a higher incidence of amputation in the 65-74 age group compared to individuals above 75 years old. [14] This disparity in amputation rates among older diabetic patients could be attributed to either the relatively better health of the older population in that region or potential reluctance to operate on older diabetic patients.

In our study, we observed a higher incidence of diabetic foot among male patients (82%) compared to females (18%). However, upon comparing sex distribution with the risk of lower extremity amputation, no significant difference was found. This finding aligns with previous studies, such as Khataniar et al. [15], Rehman et al. [16], and Chen et al. [17]. Similarly, Singh et al. [18] observed a mean patient age of 57.56 years, with the majority

falling within the 45–64 age group, and a male-to-female ratio of 2.28, consistent with the findings of Yerat and Rangasamy. [19] The higher incidence of diabetic foot ulcers among males may be attributed to their increased exposure to injury, often due to spending more time barefoot in farm areas and engaging in risky activities. Conversely, females commonly use skin softeners, potentially reducing their risk of developing ulcers. In this study, a significant proportion of males (70.5%) did not use skin softeners, compared to females (29.5%). The progression of diabetes can lead to skin dryness, prompting individuals to rub their skin, which may result in skin breaks and ultimately, the formation of diabetic foot ulcers. [20]

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Our study revealed a higher incidence of diabetic foot among obese patients (58%) compared to overweight (18%) or normal-weight diabetic individuals (24%). Additionally, obese diabetic patients had a higher risk of lower extremity amputation (63.6%), with the majority of those at medium risk also being obese (77.8%). These findings are consistent with prior research indicating a link between obesity and diabetic foot complications. [21,22] Additionally, lower socioeconomic status emerged as a significant risk factor, with patients from disadvantaged backgrounds facing a higher risk of diabetic foot complications. Moreover, a family history of diabetes was associated with an increased risk of diabetic foot complications. These findings emphasize the importance of addressing obesity, socioeconomic disparities, and family history in diabetic foot management strategies. [23–26]

In our study, ulcers were the most prevalent lesion in our study (38%), followed by cellulitis with ulcers (22%) and gangrene (22%). High-risk patients mostly had gangrene (72.7%), moderate-risk patients had cellulitis with ulcers (33.3%), and low-risk patients primarily had ulcers (61.9%). This aligns with findings from Monteiro-Soares et al. [27], where multiple diabetic foot ulcers, gangrene, and bone involvement were prevalent. Conversely, our study highlighted gangrene as the most frequent presentation among amputated patients, consistent with prior research indicating infection and ischemia as common causes of amputation. [28,29] Furthermore, a significant association was found between the duration of diabetes and the risk of lower extremity amputation, echoing previous studies that linked longer diabetes duration with a higher risk of diabetic foot ulcers. [24,30]

Our study found a significant correlation between the risk of amputation and unhealthy granulation, with 77.8% of medium-risk and 18.2% of high-risk patients displaying this characteristic. This association has not been previously explored, but granulation tissue development has been noted in DFU trials. [31,32] Additionally, purulent discharge was significantly associated with the risk of amputation, observed in all high-risk patients and a majority of medium- and low-risk patients. Purulent discharge serves as an early sign of DFUs, indicating microbial activity and potential infection. Moreover, glycemic parameters, including fasting blood sugar ($p=0.008$) and HbA1c ($p=0.002$), showed a significant association with the risk of amputation. While previous meta-analyses have shown conflicting results regarding glycemic control and DFU outcomes, our findings emphasize the importance of glycemic management in preventing severe complications like amputation in diabetic patients. [33–35]

In our study, the most common microorganisms isolated from pus culture were *Pseudomonas* (48%), *Staph Aureus* (40%), and *E.Coli* (36%), consistent with findings by Noor et al. [36] and other studies. [37] High-risk patients predominantly exhibited monophasic Doppler findings, whereas medium-risk patients displayed biphasic patterns, aligning with previous studies. [38,39] Management strategies varied, with toe amputation more prevalent among high-risk patients (36.4%), contrasting with findings by Almohammadi et al. [40]. Follow-up revealed a significant association between amputation risk and complete recovery rates, with high-risk patients showing the lowest recovery rate (45.5%) and notable loss to follow-up (27.3%), consistent with prior studies. [41–44]

Our study has limitations, including incomplete secondary data and reliance on fasting blood sugar for glycemic control assessment due to cost constraints. Lack of follow-up for discharged

patients and potential bias in reporting behaviors were also limitations. Additionally, the cross-sectional design hinders establishing causality. Larger, prospective studies with better glucose control measures are needed for conclusive evaluation.

Conclusion

In conclusion, our study underscores the significant burden of diabetic foot complications, particularly in our population, as evidenced by the high incidence of amputations and gangrene. Factors such as elevated fasting blood sugar levels, positive family history, obesity, prolonged disease duration, along with specific wound characteristics like ill-defined margins, unhealthy granulations, and purulent discharge, emerged as significant predictors of amputation risk. The findings emphasize the urgent need for comprehensive strategies to mitigate these risks and improve outcomes. Despite the challenges posed by diabetic foot complications, the relatively favorable recovery rates observed in our study underscore the importance of early intervention and multidisciplinary management approaches

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