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Original Research Article

Prospective and Observation Study of Diagnosis and Various Management Modalities and their Outcomes in Diabetic Foot in a Medical College in Kolkata

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Conflict of interest: Nil

Abstract

Introduction: Diabetic foot is a common and serious complication of diabetes mellitus, often leading to infection, ulceration, and even amputation. Early diagnosis and appropriate management are crucial to prevent morbidity and improve patient outcomes.

Aims and Objectives: To evaluate the clinical presentation, diagnostic patterns, and management strategies of diabetic foot in patients attending a tertiary care center in Kolkata. To assess the outcomes of various medical and surgical interventions, including wound healing and amputation rates.

Methods: This was a one-year, institution-based observational and prospective study conducted at the Department of General Surgery, KPC Medical College and Hospital (June 2023–May 2024). The study included 60 diabetic patients with foot ulcers, infections, or other diabetic foot complications, selected according to WHO criteria.

Results: Among 60 participants, most were male, with a mean age of 56.5 years and high prevalence of hypertension, smoking, and below-average economic status. Clinically, sensory abnormalities and absent peripheral pulses were common, and 86.7% had infections, predominantly polymicrobial. Ulcers were mostly unilateral, affecting the dorsum, forefoot, and great toe. Escherichia coli and Staphylococcus aureus were the most frequent isolates. Surgical interventions, particularly skin grafting and debridement with flap, were associated with significant improvement or healing, while infection, absent pulses, and sensory deficits negatively impacted outcomes.

Conclusion: Most participants showed improvement in ulcer status, though complete healing was less common. Surgical interventions, especially skin grafting and debridement with flap, were linked to better outcomes. Infection, absent peripheral pulses, and sensory abnormalities were key factors associated with poorer healing, highlighting the importance of managing these conditions to enhance recovery and reduce recurrence.

Keywords: Diabetic Foot, Ulcer, Infection, Amputation, Management, Outcomes, Prospective Study.

Introduction

Diabetic foot complications are a significant cause of morbidity and mortality among individuals with diabetes mellitus, particularly in India [1,2]. The prevalence of diabetic foot ulcers (DFUs) in India is estimated at 4.5% among newly diagnosed diabetic patients, with approximately 25% of individuals with diabetes developing high-risk feet [3]. These complications often result in infections, gangrene, and amputations, leading to substantial healthcare burdens [4].

The pathogenesis of diabetic foot ulcers involves a combination of factors, including peripheral neuropathy, peripheral vascular disease, and impaired immune response [5,6]. Neuropathy, present in a significant proportion of diabetic patients, contributes to loss of protective sensation, increasing the risk of unnoticed injuries and subsequent ulceration [7]. Peripheral vascular disease further exacerbates the situation by impairing blood flow to the affected extremities,

hindering wound healing and increasing susceptibility to infections.

Management of diabetic foot ulcers requires a multidisciplinary approach encompassing glycemic control, wound care, infection management, and, when necessary, surgical interventions. Studies have shown that early and aggressive treatment can significantly reduce the risk of amputation and improve patient outcomes. However, challenges such as delayed presentation, inadequate healthcare infrastructure, and limited access to specialized care continue to impede optimal management in many regions [8].

In Kolkata, a city with a dense population and a high prevalence of diabetes, understanding the local epidemiology, management practices, and outcomes of diabetic foot complications is crucial [9]. This study aims to bridge the knowledge gap by conducting a prospective and observational analysis of patients presenting with diabetic foot ulcers at a medical college in Kolkata. By evaluating diagnostic modalities, treatment strategies, and patient outcomes, the study seeks to inform evidence-based practices and improve care for individuals affected by diabetic foot complications in the region [10].To evaluate the clinical presentation, diagnostic patterns, and management strategies of diabetic foot in patients attending a tertiary care center in Kolkata. To assess the outcomes of various medical and surgical interventions, including wound healing and amputation rates.

Materials and Methods

Study design: Institution Based Observational and Prospective Study.

Place of study: Department of General Surgery KPC Medical college and Hospital.

Period of study: 1 Year (June 2023 to May 2024).

Study Population: Diabetic patients with foot ulcers admitted in this hospital, according to the WHO criteria, were selected for this study.

Study Variables

- Age
- HbA1c
- HbA1c at Follow-up
- Gender
- Education
- Economic Status
- Footwear
- Peripheral Pulse
- Laterality
- Type of Culture
- Microorganisms
- HTN
- Foot
- Habit of Smoking
- Infection
- Sensory Abnormality

Sample Size: 60 Patients with diabetes mellitus presenting with foot ulcers, infections, or other diabetic foot complications.

Inclusion Criteria: All the patients with Diabetes Mellitus presenting with foot ulcers, infection of foot and gangrene of foot.

Exclusion Criteria

- Patients with foot infections without Diabetes.
- Patients with ulcer and Gangrene of foot other than Diabetic etiology.
- Patients not agreeing to be part of study
- Miscellaneous - Patient on steroids
  - Malignancy
  - HIV

Statistical Analysis

Data were entered and analyzed using SPSS software version 25.0. Continuous variables were expressed as mean ± standard deviation (SD) and categorical variables as frequencies and percentages.

Comparisons between groups were performed using the Chi-square test or Fisher's exact test for categorical data and Student's t-test or Mann–Whitney U test for continuous data, as appropriate. A p-value <0.05 was considered statistically significant.

Result

Table 1: Clinical, Microbiological Characteristics and First Follow-up Outcomes of Study Participants

Variable	Category	Frequency	% of Total
Gender	Female	18	30.00%
	Male	42	70.00%
Education	Basic Primary	17	28.30%
	Graduate	17	28.30%
	Primary	26	43.30%
Economic Status	Above Average	21	35.00%
	Below Average	39	65.00%
Habit of Smoking	Non-smokers	22	36.70%
	Smokers	38	63.30%

Wagner Grade	Grade 1	11	18.30%
	Grade 2	28	46.70%
	Grade 3	13	21.70%
	Grade 4	8	13.30%
Footwear	Inappropriate footwear	37	61.70%
	No Inappropriate footwear	23	38.30%
Foot	No Foot-related complications	23	38.30%
	Foot-related complications	37	61.70%
HTN	No	14	23.30%
	Yes	46	76.70%

Table 2: Clinical, Microbiological Characteristics and First Follow-up Outcomes of Study Participants

Variable	Category	Frequency	% of Total
Sensory Abnormality	No	21	35.00%
	Yes	39	65.00%
Peripheral Pulse	Palpable pulses	22	36.70%
	Absent peripheral pulses	38	63.30%
Infection	No	8	13.30%
	Yes	52	86.70%
Laterality	Bilateral	1	1.70%
	Left	18	30.00%
	Right	41	68.30%
Distribution of Type of Culture	Monomicrobial	17	32.70%
	Polymicrobial	35	67.30%
Status at 1st Follow-up	Healed	10	16.70%
	Improved	46	76.70%
	Recurrent Ulcer	4	6.70%

Table 3: Descriptive Statistics of Age and Glycemic Control in Study Participants

Variable	N	Mean ± SD
Age (in years)	60	56.5 ± 7.16
HbA1c (%)	60	8.17 ± 1.42
HbA1c at follow-up	60	7.37 ± 1.18

Table 4: Distribution of Ulcer Sites among Study Participants

Site of Ulcer	Frequency	% of Total
2nd & 5th Toe	1	1.70%
Between 2nd & 3rd Toe	1	1.70%
Dorsum	14	23.30%
Dorsum and Planter	1	1.70%
Foot Planter	1	1.70%
Fore Foot	8	13.30%
Great Toe	8	13.30%
Great Toe & 3rd Toe	1	1.70%
Heel	4	6.70%
Leg and Foot	1	1.70%
MT Head	1	1.70%
Planter	1	1.70%
Planter & Dorsum	1	1.70%
Planter 1st MT Head	2	3.30%
Planter 3rd MT Head	1	1.70%
Planter Great Toe	4	6.70%
Planter Heel	1	1.70%
Planter Mid Foot	4	6.70%
Planter Mid Toe	1	1.70%
Posterior Ankle	1	1.70%
Sole Foot	1	1.70%
Toe	2	3.30%

Table 5: Distribution of Microorganisms Isolated from Study Participants

Microorganisms	Frequency	% of Total
EC	8	15.40%
EC + KP	5	9.60%
EC + PA	8	15.40%
EC + PM	1	1.90%
EC + SP	1	1.90%
KP	1	1.90%
KP + PM	1	1.90%
PA	1	1.90%
PA + KP	4	7.70%
SA	7	13.50%
SA + EC	9	17.30%
SA + PA	2	3.80%
SA + SP	3	5.80%
SP + PA	1	1.90%

Table 6: Status at First Follow-up According to Type of Surgery in Study Participants

Status At 1st Follow-Up					
Type of Surgery	**Healed**	**Improved**	**Recurrent ulcer**	**Total**	**P-value**
Ampuationof 2nd And 5th Toe	0	1	0	1	0.044
Amputation of 4th Toe	0	1	0	1	
Amputation of Bilateral Great Toe	0	1	0	1	
Amputation of Right Great Toe	0	2	0	2	
Below Knee Amputation	0	5	2	7	
Debridement And Flap	0	16	1	17	
Debridement And Secondary Intention	6	3	0	9	
Debridement And Skin Graft	4	13	1	18	
Transmetatarsal Amputation	0	4	0	4	
Total	10	46	4	60	

Table 7: Association of Infection, Peripheral Pulse, and Sensory Abnormality with Ulcer Outcomes at First Follow-up

Variable	Category	Healed	Improved	Recurrent Ulcer	Total	P-value
Infection	No	5	3	0	8	<0.001
	Yes	5	43	4	52	
Peripheral Pulse	Absent peripheral pulses	0	20	2	22	0.03
	Palpable pulses	10	26	2	38	
Sensory Abnormality	No	10	10	1	21	<0.001
	Yes	0	36	3	39	

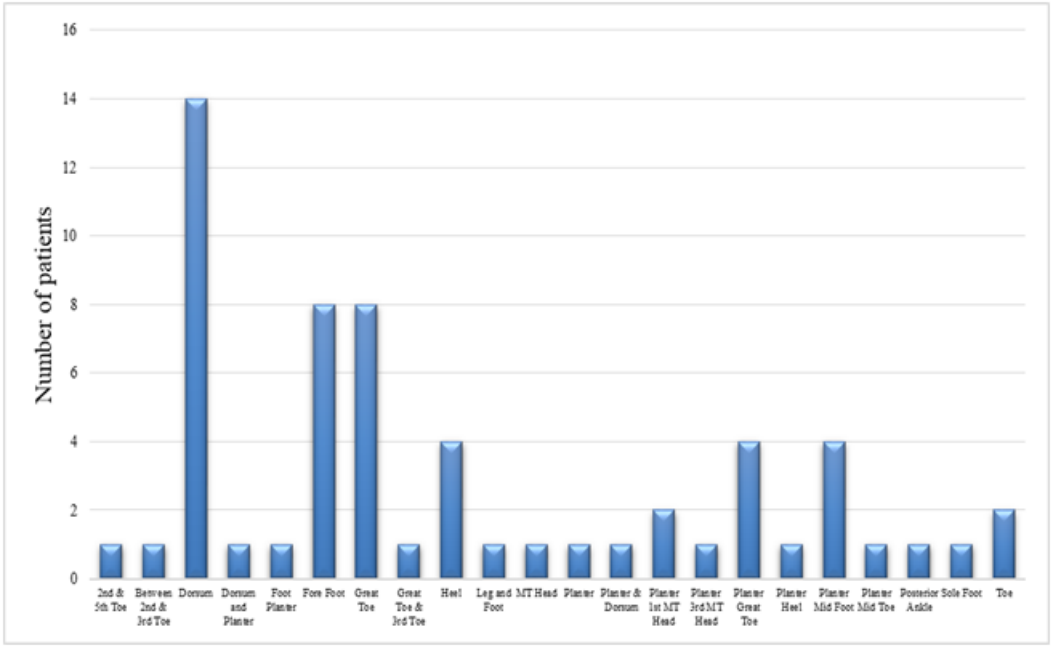

Figure 1: Distribution of Ulcer Sites among Study Participants

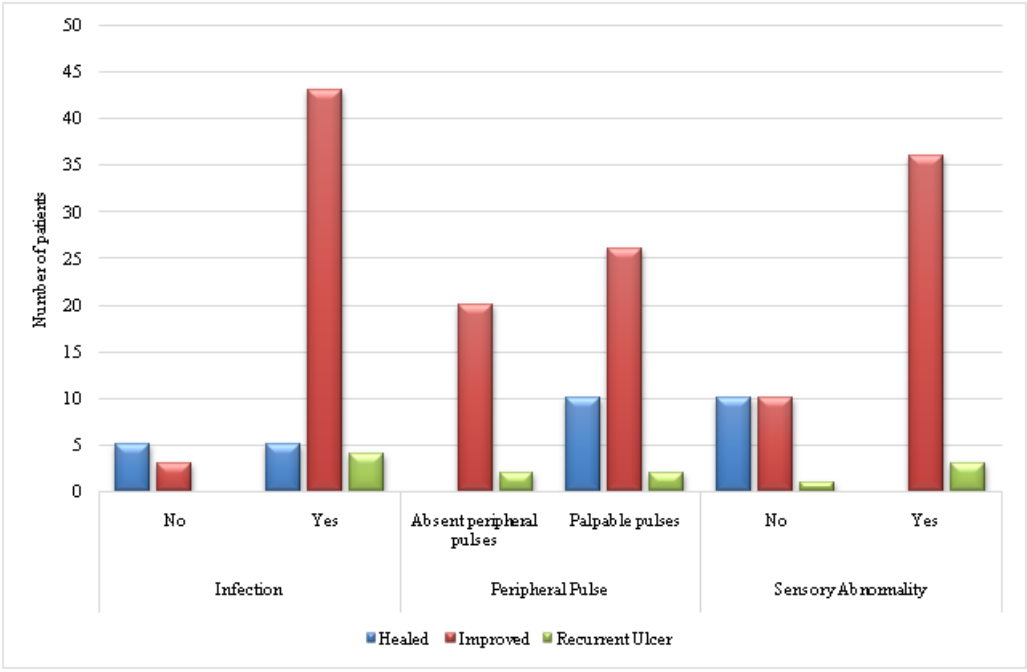

Figure 2: Association of Infection, Peripheral Pulse, and Sensory Abnormality with Ulcer Outcomes at First Follow-up

In this study, a total of 60 participants were evaluated for clinical, microbiological, and treatment-related outcomes. The majority were male (70%), with females representing 30% of the cohort. Regarding education, 43.3% had primary education, while 28.3% each were basic primary or graduate level. Most participants (65%) belonged to a below-average economic status, and 63.3% reported a history of smoking. Wagner grades 2 and 3 were predominant (46.7% and 21.7%, respectively), and inappropriate footwear and foot-related complications were present in 61.7% of participants. Hypertension was prevalent in 76.7% of the study population (Table 1). Clinically, 65% of participants exhibited sensory abnormalities, and 63.3% had absent peripheral pulses. Infection was observed in 86.7% of participants, and ulcer distribution was predominantly unilateral, with 68.3% affecting the right foot. Polymicrobial infections were more common (67.3%), and at the first follow-up, 16.7% of ulcers were healed, 76.7% showed improvement, and 6.7% were recurrent (Table 2). The mean age of participants was 56.5 ± 7.16 years, with baseline HbA1c levels averaging

8.17 ± 1.42%, which reduced to 7.37 ± 1.18% at follow-up (Table 3).

Ulcer sites were most frequently located on the dorsum (23.3%), forefoot (13.3%), and great toe (13.3%), with less common involvement of toes, heel, planter region, and mid-foot areas (Table 4). Microbiological analysis revealed that *Escherichia coli* (15.4%) and *Staphylococcus aureus* (13.5%) were predominant isolates, with mixed infections (e.g., SA + EC, 17.3%) being common (Table 5).

Surgical interventions varied, with skin grafting (18 cases) and debridement with flap (17 cases) being the most frequent procedures. At the first follow-up, healing was complete in 10 cases, improvement in 46 cases, and recurrent ulcers in 4 cases. Statistically significant differences in outcomes were observed based on the type of surgery ($p = 0.044$) (Table 6). Furthermore, the presence of infection, absent peripheral pulses, and sensory abnormalities significantly influenced ulcer outcomes. Participants without infection or sensory deficits had higher rates of healing, while absent peripheral pulses were associated with poorer outcomes ($p < 0.05$ for all) (Table 7).

Discussion

Our findings broadly align with previously published series examining clinical, microbiological and outcome determinants in diabetic foot ulcers, while also showing some important contrasts that help contextualize our results. Like several authors, we observed a clear male predominance and a mean patient age in the mid-50s, which is consistent with demographic patterns reported in comparable cohorts [11,12]. The high proportion of patients with poor socioeconomic status and a smoking history in our sample mirrors risk-factor profiles described elsewhere and likely contributes to delayed presentation and worse wound healing. In line with multiple prior reports, Wagner grades 2 and 3 were the most frequent presentations in our study, reaffirming that moderate limb-threatening ulcers dominate tertiary-centre caseloads [13,14]. Similarly, the very high rate of clinical infection (86.7%) and the predominance of polymicrobial cultures in our series echo findings from other investigators who emphasize that diabetic foot infections are often mixed and gram-negative organisms — alongside Staphylococcus aureus — are commonly isolated in hospitalized patients [15–17]. Where our microbiology diverged slightly was the relative proportions of isolates: we found Escherichia coli and S. aureus to be the most common individual pathogens, whereas some studies report S. aureus (including MRSA) or Pseudomonas as the single most frequent isolate — a difference that may reflect local antibiotic exposure, sampling technique, prior outpatient antibiotic use, or regional microbiological ecology [16–18].

The strong associations we observed between absent peripheral pulses, sensory abnormalities and worse ulcer outcomes are concordant with established literature that links peripheral arterial disease and neuropathy to delayed healing and higher recurrence or amputation risk [12, 14, 19]. Our results add weight to those observations by demonstrating statistically significant differences in healing rates according to these clinical parameters, reinforcing the need for routine vascular assessment and neuropathy screening in diabetic foot care pathways. Regarding interventions, the distribution of surgical procedures in our cohort — with skin grafting and debridement with flap being most frequent — and the observation that type of surgery influenced outcome ($p = 0.044$) are broadly consistent with outcome studies that show reconstructive and definitive closure procedures can improve healing in appropriate candidates but that patient selection (vascular status, infection control, glycaemic control) critically modifies success rates [13, 20]. The improvement in mean HbA1c from baseline to follow-up in our study mirrors the well-documented beneficial effect of better glycaemic control on ulcer healing reported by others, although the magnitude and timing of glycaemic improvement necessary to alter outcomes vary across series [11, 19].

Taken together, our data reinforce key themes from the literature: diabetic foot ulcers present with complex, multifactorial pathology (neuropathy, ischemia, infection, socioeconomic factors), microbiology is often polymicrobial and regionally variable, and outcomes are strongly influenced by vascular status, infection control, and timely surgical decision-making [11–20]. Differences in organism prevalence and surgical outcomes between our work and other reports likely reflect local referral patterns, pre-admission antibiotic use, and institutional surgical thresholds; these contextual differences underscore the need for centre-specific protocols for microbiological surveillance and for individualized multidisciplinary management to optimize healing and reduce recurrence.

Conclusion

We conclude that, the majority of participants demonstrated significant clinical and microbiological challenges that influenced ulcer outcomes. Healing was observed in a smaller proportion (16.7%), while most participants (76.7%) showed improvement, and a minority experienced recurrence (6.7%). Surgical interventions, particularly skin grafting and debridement with flap, were associated with better outcomes, with statistically significant differences

noted based on the type of procedure ($p = 0.044$). Clinical factors such as the presence of infection, absent peripheral pulses, and sensory abnormalities were strongly associated with poorer healing, highlighting their prognostic importance ($p < 0.05$).

Overall, these findings suggest that effective management of infections, restoration of vascular perfusion, and correction of sensory deficits, combined with appropriate surgical interventions, are critical to improving ulcer healing and reducing recurrence in this population.

References

1. Kale DS, et al. Diabetic Foot Ulcer in India: Aetiological Trends and Management Practices. J Clin Diagn Res. 2023;17(5):EC01–EC05.
2. Kumar A, et al. Factors associated with severity and outcomes of diabetic foot ulcers in India. J Clin Diagn Res. 2025;19(3):EC01–EC05.
3. Patil P, et al. The Burden of Diabetic Foot Ulcers in Urban India. J Clin Diagn Res. 2023; 17(4): EC01–EC05.
4. Rodrigues J, et al. A clinicopathological study on management of diabetic foot ulcers in a tertiary care hospital. J Clin Diagn Res. 2023; 17(6):EC01–EC05.
5. Ahamed N, et al. Correlation between vascular involvement and surgical outcomes in diabetic foot ulcers. Asian J Med Sci. 2025;6(2):45–50.
6. Sidhu AS, et al. Emerging technologies for the management of diabetic foot ulcers. Front Clin Diabetes Healthc. 2024;5:1440209.
7. Tayade A, et al. Perceptions of primary and secondary care clinicians on the management of diabetic foot ulcers. J Clin Diagn Res. 2023; 17(7): EC01–EC05.
8. Upadhyay N, et al. Socio-Demographic Risk Factors Associated with Diabetic Foot Ulcer in India: A Case Control Study. J Pharm Bioallied Sci. 2025;17 (Suppl 1):S855–S857.
9. Seshadri H, et al. Out-of-pocket expenditure among patients with diabetic foot ulcers in India. Int Wound J. 2024;21(6):1455–1461.
10. Goyal M, et al. DFUNet: Convolutional Neural Networks for Diabetic Foot Ulcer Classification. arXiv preprint arXiv:1711.10448. 2017.
11. Boulton AJM, Armstrong DG, Kirsner RS, Attinger CE, Lavery LA, Lipsky BA, et al. Diagnosis and management of diabetic foot complications. Diabetes Care. 2018; 41(12): 2862–75.
12. Alexiadou K, Doupis J. Management of diabetic foot ulcers. Diabetes Ther. 2012; 3(1):4.
13. Lavery LA, Armstrong DG, Wunderlich RP, Mohler MJ, Wendel CS, Lipsky BA. Risk factors for foot infections in individuals with diabetes. Diabetes Care. 2006;29(6):1288–93.
14. Prompers L, Huijberts M, Apelqvist J, Jude E, Piaggesi A, Bakker K, et al. High prevalence of ischemia, infection and serious comorbidity in patients with diabetic foot disease in Europe. Diabetologia. 2007;50(1):18–25.
15. Citron DM, Goldstein EJC, Merriam CV, Lipsky BA, Abramson MA. Bacteriology of moderate-to-severe diabetic foot infections and in vitro activity of antimicrobial agents. J ClinMicrobiol. 2007;45(9):2819–28.
16. Kundu S, Sen S, Prasad R, Basu A, Ghosh TK. Clinical and bacteriological profile of diabetic foot infections: A study from Eastern India. Int J Diabetes DevCtries. 2020;40(2):240–7.
17. Shahi SK, Kumar A, Kumar S, Singh SK. Prevalence of multidrug-resistant bacteria isolated from diabetic foot ulcers in North India. J Health PopulNutr. 2021;40(1):1–10.
18. Ramakant P, Verma AK, Misra R, Prasad KN, Chand G, Mishra A, et al. Changing microbiological profile of pathogenic bacteria in diabetic foot infections: time for a rethink on which empirical therapy to choose? Diabetologia. 2011;54(1):58–64.
19. Armstrong DG, Boulton AJM, Bus SA. Diabetic foot ulcers and their recurrence. N Engl J Med. 2017;376(24):2367–75.
20. Frykberg RG, Banks J. Challenges in the treatment of chronic wounds. Adv Wound Care (New Rochelle). 2015;4(9):560–82.