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Evaluation of Clinical and Lifestyle Risk Factors Contributing to the Disease Burden of Diabetic Foot Ulcers: A Prospective Observational Study

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Abstract: Background: Among the complications of diabetes, foot ulcers are particularly concerning due to their association with disability, infection and increased mortality risk. This prospective observational study evaluated the clinical and lifestyle risk factors contributing to DFUs. Methods: The study was conducted at GCMCH over a six-month period and included 50 patients clinically diagnosed with diabetic foot ulcers. Demographic and clinical details, such as ulcer characteristics, glycemic control (HbA1c), foot deformities, and time of presentation, were analysed to assess their association with diabetic foot ulcers. Results: DFU were predominant among female and those above age seventy-one. We observed that both ulcer grade and HbA1c levels showed strong positive correlation with healing duration. Dietary patterns did not influence ulcer recurrence. Conclusion: Clinical and lifestyle risk factors significantly contribute to high rates of amputation, recurrence, and mortality. Targeted preventive and therapeutic strategies addressing these risk factors are imperative to reduce the overall disease burden of diabetic foot ulcers.

Keywords: *Diabetic Foot Ulcer, Risk Factors, Recurrence, Amputation.*

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I. INTRODUCTION

Diabetes mellitus is a long-term metabolic condition marked by persistent elevations in blood glucose. The rise in the prevalence of diabetes is also followed by a rise in its complications, such as foot ulcers and amputations of the lower limbs, which are typical outcomes of poorly managed diabetes (Das et al.,2023). It is estimated that up to one in four individuals with diabetes will develop a foot ulcer at some point in their lives and it is estimated that 40-60 million people worldwide are affected by DFU (Lusendi et al., 2024). Among 14%-24% of them will require amputation of the ulcerated foot due to bone infection or other ulcer-associated complications.

The Wagner grading system helps classify ulcer severity on a scale of 1 to 5. The main processes driving DFU development are neuropathy, impaired circulation and infections often triggered by minor injuries (Raja JM et al., 2023). Patients may initially present with swelling, redness, excess moisture or unpleasant odour while advanced ulcers often show blackened necrotic tissue. The most evident sign of severe DFU is black tissue, referred to as eschar, that covers the ulcer area (Das et al.,2023).

Diabetic foot ulcer management involves preventive interventions such as self/clinical screening, insoles, and podiatric treatment; non-invasive modalities such as advanced wound dressings, biologics, adjunctive treatment, and antibiotics and invasive methods such as debridement, revascularization, skin grafting, and, when unavoidable, amputation (Raja JM et al., 2023).

Factors such as uncontrolled blood sugar, foot abnormalities, late medical attention and unsafe footwear habits significantly contribute to ulcer formation and complications that leads to lower limb amputations in diabetic patients, excluding peripheral vascular disease and peripheral neuropathy (Bekele et al., 2019). Exploring these risk factors that can potentially predict the development of ulcers, with an emphasis on the interaction between the risk factors and the development of DFU, might help prevent amputation and manage them in a timely manner.

This study aimed to assess the contribution of lifestyle and clinical risk factors to the diabetic foot ulcer burden. By analysing the predictors of delayed healing, recurrence, and amputation, it helps to support early intervention, improve patient outcomes, and reduce long-term complications.

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II. MATERIALS AND METHODS

➢ *Study Site*

This study was conducted in the Department of Surgery of the Government Cuddalore Medical College Hospital (GCMCH), Chidambaram, Tamil Nadu.

➢ *Study Design*

A prospective observational study.

➢ *Study Period*

The study was conducted for a period of six months (November 2024 to April 2025).

➢ *Sample Size*

As it was Preliminary Research, there was no sample size calculation. The number of participants was decided based on how many patients were available and met the inclusion and exclusion criteria.

➢ *Study Recruitment:*

- *Target Population:*

Patients clinically diagnosed with diabetic foot ulcer, at Government Cuddalore Medical College and Hospital, Chidambaram.

- *Study Population:*

The patients enrolled for the study were selected based on inclusion and exclusion criteria.

➢ *Inclusion Criteria:*

- Patients with type 1 or 2 diabetes mellitus.
- Participants who have diabetic foot ulcers of any grade, as per the Wagner classification system.
- Patients more than 18 years of age.
- Patient who provides informed consent and willing to participate in the study.

➢ *Exclusion Criteria*

- Participants who have known case of non-diabetic diabetic foot ulcers (e.g., traumatic, ischemic, or venous ulcers).
- Pregnant and lactating women.

➢ *Data Collection*

The data was collected in a predesigned data collection form through direct interview with patients and from patient medical records. Details like patient demographics, clinical history such as diabetes duration, glycaemic control, History of Past Ulcers or Amputation, presence of comorbidities and characteristics of the foot ulcer (size, depth, and infections) were recorded.

➢ *Data Analysis:*

The data gathered were recorded using Microsoft Excel and statistical analysis was performed using JASP (Jeffreys's Amazing Statistics Program) software.

III. RESULTS AND DISCUSSIONS

➢ *Descriptive Statistics:*

- *Demographic Profile:*

Among the 50 patients with diabetic foot ulcers included in the study, 26(52%) were female and 24 (48%) were male, indicating a slight predominance of females over males. Diabetic foot ulcers affect both sexes almost equally, although patterns may vary across different settings. Most patients belonged to the age group of 71 years and above, reflecting that elderly individuals remain at high risk due to long-standing diabetes and multiple comorbidities, which is similar to the findings of Shah et al.,2024.

Table 1 Distribution of Study Participants Based on Age and Gender

Variable	Category	No. of patients(n=50)	Percentage (%)
Age	18-50	4	8.0
	51-60	16	32.0
	61-70	12	24.0
	71 and above	18	36.0
Gender	Male	24	48.0
	Female	26	52.0

- *History of Diabetes:*

Table 2 Distribution of Patients Based on History of Diabetes

Variable	Category	No. of patients(n=50)	Percentage (%)
Type of diabetes	Type 1	21	42.0
	Type 2	29	58.0
Duration of diabetes	< 5 years	4	8.0
	5-10 years	14	28.0
	>10 years	32	64.0

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Type 2 was predominant over Type 1, and diabetes was present for more than 10 years in most patients. A high-risk status for complications is indicated by such a long duration, consistent with emerging accounts of the increasing diabetes burden worldwide Bell & Lain, 2025.

- *Ulcer Characteristics:*

Table 3 Distribution of Patients Based on Ulcer Characteristics

Variable	Category	No. of patients(n=50)	Percentage (%)
Wagner ulcer classification	Grade 1	9	18.0
	Grade 2	10	20.0
	Grade 3	10	20.0
	Grade 4	15	30.0
	Grade 5	6	12.0
Duration of ulcer	< 4 weeks	14	28.0
	4-12 weeks	18	36.0
	>12 weeks	18	36.0

Unlike findings from a central Indian cohort, were Grade 2 ulcers are predominant, but in this study severe ulcer stages were common in subjects (Shah et al., 2024). Of the ulcers, 36% persisted for ≥12 weeks, highlighting the delayed presentation and its association with severe grades of disease.

- *Antibiotic Usage and Resistance Patterns:*

Table 4 Distribution of Patients Based on Antibiotic Usage and Resistance Patterns

Variable	Category	No. of patients(n=50)	Percentage (%)
Antibiotics used	Yes	18	36.0
	No	32	64.0
Antibiotic resistance	Yes	29	58.0
	No	21	42.0

In our study, 64% of the patients were treated with antibiotics, and 42% of them were resistant. Consistent with AI-Mansour et al., (2024), high prevalence of antibiotic resistance was observed among DFU cases.

- *Type of Surgical Intervention:*

Table 5 Distribution of Patients Based on Surgical Intervention

Surgical procedures	No. of patients(n=50)	Percentage (%)
Debridement	9	18.0
Major amputation	14	28.0
Minor amputation	21	42.0
None	6	12.0

New evidence indicates that multidisciplinary pathways can reduce major amputations to a minimum of 4.1%, which coincides with the findings of Valabhji et al. (JBJI, 2025), and early limb salvage procedures should be considered.

➢ *Inferential Statistics:*

- *Pearson's Correlation:*

Table 6 Correlation Between Clinical Parameters and Ulcer Healing

Correlation pair	Pearson's (r)	p value
Ulcer grade with Healing time (weeks)	0.924	< 0.001
HbA1c (%) with Healing time (weeks)	0.900	< 0.001
HbA1c (%) with Ulcer grade	0.811	< 0.001
Duration of diabetes (years) with Healing time (weeks)	0.226	0.114

Correlation analysis of clinical factors affecting ulcer healing revealed that ulcer grade and were very strongly correlated with healing time, indicating that ulcer severity and poor glycemic control significantly delayed recovery. HbA1c also showed a strong correlation with ulcer grade, whereas the duration of diabetes was weakly associated with healing time. This suggests that current metabolic control and ulcer characteristics are more important than disease duration in predicting the healing outcomes.

- *Association Between Footcare Practices and Amputation:*

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Table 7 Association Between Footcare Practices and Amputation:

Footcare practice	Amputation			Total
	Major	Minor	None	
Good	2	13	12	27
Poor	12	8	3	23
Total	14	21	15	50

Table 8 Chi-Square Test for Association Between Footcare Practices and Amputation:

Chi-square	Value	DF	p
$\chi 2$	22.22	2	< 0.001

Chi-square test results as shown in the Table 8 reveals a statistically significant association between foot care practice and amputation. Patients with poor foot care practice more likely to undergo major or minor amputations, whereas those with good foot care had lower amputation rates, highlighting the protective role of proper foot care.

- *Association Between Treatment Compliance and Ulcer Recurrence:*

Table 9 Association Between Treatment Compliance and Ulcer Recurrence:

Treatment compliance	Ulcer recurrence		Total
	No	Yes	
Good	4	32	36
Poor	9	5	14
Total	13	37	50

Table 10 Chi-Square Test for Association Between Treatment Compliance and Ulcer Recurrence:

Chi-square	Value	df	p
$\chi 2$	14.814	1	< 0.001

The chi-square test showed a significant association between treatment compliance and ulcer recurrence. Patients with poor compliance had a much higher recurrence rate than those with good compliance, indicating that non-adherence to treatment is a risk factor for ulcer recurrence.

- *Association Between Dietary Pattern and Ulcer Recurrence:*

Table 11 Association Between Dietary Pattern and Ulcer Recurrence:

Dietary pattern	Ulcer recurrence		Total
	No	Yes	
Healthy	5	16	21
Unhealthy	8	21	29
Total	13	37	50

Table 12 Chi-Square Test for Association Between Dietary Pattern and Ulcer Recurrence:

Chi-square	Value	DF	p
$\chi 2$	0.090	1	0.764

The Chi-square test showed no significant association between dietary patterns and ulcer recurrence. Therefore, dietary patterns did not appear to influence ulcer recurrence in the present study sample.

IV. CONCLUSION

Our findings suggest that more severe ulcers and poor blood sugar regulation significantly prolong healing. Additionally, inadequate foot care and lack of treatment adherence were linked to higher recurrence and amputation risks. Conversely, diabetes duration had a minimal influence. Targeted preventive and therapeutic strategies addressing these risk factors are imperative to reduce the overall disease burden of diabetic foot ulcers.

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The authors declare that there are no conflicts of interest associated with this study.

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