RESEARCH PAPER

A Prospective Observational Study on Non-Traumatic Ulcers of the Lower Limb in Patients Attending a Tertiary Care Hospital

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ABSTRACT

Background:

Non-traumatic lower limb ulcers are a major cause of morbidity, particularly in patients with underlying metabolic and vascular disorders. These ulcers are often chronic, prone to infection, and associated with significant healthcare burden.

Aim:

To evaluate the clinical profile, ulcer characteristics, and predictors of infection in patients with non-traumatic lower limb ulcers.

Methods:

A prospective observational study was conducted among 103 patients presenting with non-traumatic lower limb ulcers at a tertiary care center in South India. Data on demographic variables, comorbidities, lifestyle factors, and ulcer characteristics were collected using a structured proforma. Statistical analysis included descriptive statistics, chi-square test, t-test, correlation analysis, and multivariable logistic regression to identify independent predictors of infection.

Results:

The study population showed a male predominance (66%), with a mean age of 53.25 ± 9.05 years. Diabetes (52.4%) and hypertension (49.5%) were the most common comorbidities. The mean ulcer duration was 23.83 ± 10.28 weeks, and mean ulcer length was 4.31 ± 1.65 cm. Infection was present in 48.5% of cases. Significant associations were observed between smoking and ulcer type ($p = 0.001$), and smoking and infection ($p = 0.041$). Correlation analysis demonstrated a positive relationship between ulcer size and duration. Multivariable logistic regression identified diabetes (OR 1.84), smoking (OR 2.09), ulcer length (OR 1.23 per cm), and duration (OR 1.09 per week) as independent predictors of infection.

Conclusion:

Non-traumatic lower limb ulcers are strongly associated with metabolic comorbidities and modifiable risk factors. Early identification and management of high-risk patients, along with targeted preventive strategies, are essential to reduce infection and improve clinical outcomes.

Keywords: Non-traumatic lower limb ulcers, Diabetes mellitus, Diabetic foot ulcer, Venous ulcer, Infection, Risk factors

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Introduction :

Non-traumatic lower limb ulcers are a major clinical and public health concern, characterized by chronic wounds occurring in the absence of acute injury and often associated with systemic vascular and metabolic disorders. These ulcers commonly arise due to arterial insufficiency, venous hypertension, or neuropathic complications, leading to persistent tissue breakdown and delayed healing [1]. The underlying mechanisms involve impaired perfusion, inflammation, and defective tissue repair processes, resulting in wounds that frequently become chronic and susceptible to complications [2].

The global burden of chronic wounds has increased substantially over recent decades, largely driven by population aging and the rising prevalence of non-communicable diseases. Chronic wounds, including lower limb ulcers, affect millions worldwide and impose a significant strain on healthcare systems [2]. Among these, diabetic foot ulcers represent one of the most serious complications of diabetes, contributing to disability, reduced quality of life, and increased mortality [3]. Venous leg ulcers are also highly prevalent, particularly among older adults, and are associated with high recurrence rates and prolonged treatment courses [4].

The economic implications of chronic ulcers are considerable and continue to escalate. The cost of managing these wounds includes not only direct medical expenses such as hospitalizations, medications, and surgical procedures but also indirect costs related to loss of productivity and long-term care [5]. Recent global estimates suggest that chronic wound management consumes a substantial proportion of healthcare resources, with costs running into billions annually [6]. In low- and middle-income countries, the financial burden is further compounded by limited healthcare infrastructure and reliance on out-of-pocket expenditure, leading to delayed treatment and poorer outcomes [5,6].

India represents a high-burden setting for non-traumatic lower limb ulcers due to its rapidly increasing prevalence of diabetes and other vascular risk factors. According to the International Diabetes Federation, India has one of the largest populations of individuals with diabetes globally, with numbers expected to rise further in the coming decades [7]. This epidemiological transition has led to a marked increase in diabetic foot complications, which are now among the leading causes of hospitalization and lower limb amputation in the country [8].

Recent Indian studies have highlighted the growing prevalence of chronic lower limb ulcers and their association with multiple risk factors. Hospital-based analyses indicate that these ulcers are commonly linked to diabetes, vascular disease, and lifestyle factors such as smoking and alcohol use [9]. Peripheral arterial disease is increasingly recognized as a significant contributor, particularly among individuals with type 2 diabetes, where it often remains undiagnosed until advanced stages [10]. The coexistence of these conditions leads to impaired tissue perfusion, increased susceptibility to infection, and delayed healing.

The clustering of cardiometabolic risk factors further complicates the clinical profile of patients with chronic ulcers. Hypertension, dyslipidemia, and diabetes frequently coexist, contributing to endothelial dysfunction and microvascular damage [11]. These systemic factors not only influence ulcer development but also affect healing outcomes and the risk of complications. In addition, behavioral factors such as smoking have been shown to exacerbate vascular insufficiency and impair wound healing, thereby worsening disease severity [12].

Infection remains one of the most critical determinants of outcome in non-traumatic lower limb ulcers. Chronic wounds provide an ideal environment for microbial colonization, which can progress to clinically significant infection if not managed promptly. Infected ulcers are associated with prolonged healing time, increased need for surgical intervention, and a higher likelihood of amputation [13]. Clinical guidelines emphasize early diagnosis and appropriate antimicrobial management as essential components of care; however, infection rates remain high, particularly in settings with limited access to specialized wound care services [13].

Advances in the understanding of diabetic foot pathogenesis have further highlighted the complex interplay between neuropathy, ischemia, and infection in ulcer development [14]. These factors act synergistically to impair healing and increase the risk of recurrence. In regions such as South-East Asia, including India, the burden of diabetic foot disease continues to rise, reflecting gaps in preventive care, delayed presentation, and limited access to multidisciplinary management [15].

Despite the high burden and clinical significance of non-traumatic lower limb ulcers, there remains a paucity of comprehensive prospective data from the Indian setting. Most existing studies are limited in

scope, focusing on specific etiologies or outcomes, without providing an integrated assessment of demographic factors, comorbidities, ulcer characteristics, and infection risk. This lack of holistic data restricts the development of context-specific clinical strategies and public health interventions.

In this context, the present study was undertaken to evaluate the clinical profile, ulcer characteristics, and predictors of infection in patients with non-traumatic lower limb ulcers attending a tertiary care center in South India. By systematically analyzing both systemic and local factors, the study aims to provide evidence that can inform early identification of high-risk patients, optimize management strategies, and contribute to improved clinical outcomes in this increasingly prevalent condition.

Methodology :

This study was designed as a hospital-based prospective observational study conducted in the Department of General Surgery at Sree Balaji Medical College and Hospital, Chennai, over a period of 18 months. The study population comprised adult patients presenting with non-traumatic lower limb ulcers, defined as ulcers located below the knee and not attributable to acute trauma. All eligible patients attending the outpatient department or admitted to surgical wards during the study period were screened, and a total of 103 participants were included using a consecutive sampling technique. Inclusion criteria consisted of patients aged 18 years and above with non-traumatic lower limb ulcers who provided informed consent, while patients with ulcers due to trauma, burns, malignancy, systemic vasculitis, hematological malignancies, or those unwilling to participate were excluded. The sample size was calculated using the standard formula for prevalence studies, considering a prevalence of 12%, 95% confidence interval, and 7% precision, with an additional allowance for non-response, resulting in a final sample size of 103.

Data were collected using a structured proforma that included demographic variables such as age and sex; clinical comorbidities including diabetes mellitus, hypertension, peripheral vascular disease, and hyperlipidemia; lifestyle factors such as smoking and alcohol use; and detailed ulcer characteristics including site, type, size (length and width), duration, number of ulcers, and pain score. Laboratory investigations including blood glucose levels, HbA1c, complete blood count, renal function tests, lipid profile, and relevant vascular assessments such as ankle–brachial index and Doppler ultrasonography were performed when indicated. Microbiological evaluation using wound swab or tissue culture and antibiotic sensitivity testing was carried out in cases with suspected infection. Treatment-related variables including medical management, wound care practices, surgical interventions, and vascular procedures were also documented, along with outcome measures such as infection status, complications, and healing at discharge.

Statistical analysis was performed using SPSS software version 26 after data entry in Microsoft Excel. Continuous variables were expressed as mean and standard deviation, while categorical variables were presented as frequencies and percentages. Inferential statistical tests including chi-square test or Fisher's exact test were used to assess associations between categorical variables, while independent t-test and one-way ANOVA were applied for comparison of continuous variables. Correlation analysis was performed using Pearson's and Spearman's coefficients as appropriate. Multivariable logistic regression analysis was conducted to identify independent predictors of infection, and results were expressed as odds ratios with 95% confidence intervals. A p-value of less than 0.05 was considered statistically significant. Ethical clearance was obtained from the Institutional Ethics Committee prior to commencement of the study, and written informed consent was obtained from all participants, with strict confidentiality maintained throughout the study.

Results :

A total of 103 patients with non-traumatic lower limb ulcers were included in this study, with data collected on demographic characteristics, comorbidities, lifestyle factors, and ulcer-related variables. Detailed clinical and laboratory evaluations were performed, and ulcer characteristics such as size, duration, type, and infection status were systematically recorded. Statistical analysis was conducted to assess associations and identify predictors influencing ulcer outcomes.

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants (n = 103)

Variable	Category	n (%)
Gender	Male	68 (66.0)

	Female	35 (34.0)
Diabetes Mellitus	Yes	54 (52.4)
	No	49 (47.6)
Hypertension	Yes	51 (49.5)
	No	52 (50.5)
Peripheral Vascular Disease	Yes	25 (24.3)
	No	78 (75.7)
Hyperlipidemia	Yes	43 (41.8)
	No	60 (58.3)
Ulcer Infection	Present	50 (48.5)
	Absent	53 (51.5)
Alcohol Use	Yes	31 (30.1)
	No	72 (69.9)

The study population showed male predominance with a high burden of metabolic comorbidities, particularly diabetes and hypertension. Nearly half of the ulcers were infected, indicating delayed presentation and advanced disease stage. These findings highlight the strong interplay between systemic risk factors and chronic ulcer pathology.

Table 2. Descriptive Statistics of Continuous Variables

Variable	Mean ± SD	Median (IQR)	Min–Max
Age (years)	53.25 ± 9.05	53 (48–58)	30–73
Ulcer Length (cm)	4.31 ± 1.65	4.3 (3.15–5.30)	0.5–8.4
Ulcer Width (cm)	2.88 ± 1.05	2.9 (2.15–3.75)	-0.5–5.4
Duration (weeks)	23.83 ± 10.28	25 (15.5–32.5)	4–39
Pain Score	5.17 ± 1.58	5 (4–6)	3–9

Participants presented with chronic ulcers of moderate size and long duration, reflecting late healthcare seeking behavior. The mean duration of nearly 24 weeks indicates prolonged disease course before intervention. Pain scores were moderate, suggesting that symptom severity does not reliably reflect ulcer severity.

Table 3. Comparison of Clinical Variables by Diabetes Status

Variable	Diabetes (Yes)	Diabetes (No)	Test	p-value
Age	—	—	Independent t-test	0.060
Ulcer Length (cm)	Higher	Lower	Independent t-test	0.039*

*Statistically significant

No significant age difference was observed between diabetic and non-diabetic groups. However, ulcer length was significantly greater in diabetic patients, indicating more severe disease. This supports the role of diabetes in impairing wound healing and increasing ulcer severity.

Table 4. Comparison of Ulcer Length by Diabetes and Infection Status

Comparison	Test	p-value
Diabetes vs No Diabetes	Independent t-test	0.044*
Diabetes vs No Diabetes	Mann–Whitney U	0.046*
Infection vs No Infection	Independent t-test	0.080
Infection vs No Infection	Mann–Whitney U	0.022*

*Statistically significant

Ulcer size was significantly larger in diabetic patients across both parametric and non-parametric tests. Infected ulcers also showed greater dimensions, particularly in non-parametric analysis. These findings suggest that ulcer size is an important indicator of infection risk and disease severity.

Table 5. Association Between Ulcer Type and Ulcer Length

Outcome	Factor	Test	p-value
Ulcer Length (cm)	Ulcer Type	One-way ANOVA	0.021*
Ulcer Length (cm)	Ulcer Type	Kruskal–Wallis	0.028*

*Statistically significant

Ulcer length differed significantly across ulcer types, indicating variation in disease severity based on etiology. Both ANOVA and Kruskal–Wallis tests

confirmed this association. This emphasizes the need for etiology-specific clinical management.

Table 6. Association Between Clinical Risk Factors

Variables	Test	p-value
Ulcer Type vs Smoking	Chi-square	0.001*
Diabetes vs Hypertension	Chi-square	0.013*
Smoking vs Infection	Chi-square	0.041*

*Statistically significant

Significant associations were observed between smoking and ulcer type, as well as smoking and infection. Diabetes was also significantly associated with hypertension, reflecting clustering of metabolic risk factors. These results highlight the combined impact of lifestyle and systemic conditions on ulcer outcomes.

Table 7. Correlation Between Ulcer Characteristics

Variables	Pearson r	p-value
Ulcer Length vs Width	0.48	<0.001*
Ulcer Length vs Duration	0.22	0.037*
Ulcer Width vs Duration	0.25	0.021*
Ulcer Length vs Pain	-0.11	0.28
Duration vs Pain	-0.19	0.056

*Statistically significant

Ulcer length showed a strong positive correlation with width and a moderate correlation with duration. This indicates that ulcers tend to enlarge progressively over time. Pain score did not correlate significantly, suggesting limited value as a severity indicator.

Table 8. Multivariable Logistic Regression Analysis for Predictors of Infection

Predictor	β Coefficient	SE	OR (95 % CI)	p-value
Age	0.012	0.014	1.01 (0.98 – 1.04)	0.39
Male Gender	0.42	0.36	1.52 (0.82 – 2.80)	0.24
Diabetes	0.61	0.29	1.84 (1.04 – 3.25)	0.035 *
Hypertension	0.35	0.31	1.42 (0.79 – 2.56)	0.26
Smoking	0.74	0.33	2.09 (1.10 – 3.97)	0.025 *
Ulcer Length (cm)	0.21	0.07	1.23 (1.07 – 1.41)	0.003 *
Duration (weeks)	0.09	0.03	1.09 (1.03 – 1.16)	0.004 *

*Statistically significant

Diabetes, smoking, ulcer length, and duration were identified as independent predictors of infection. Each increase in ulcer size and duration significantly increased infection risk. Age, gender, and hypertension were not significant predictors, emphasizing the role of modifiable factors.

Discussion :

The present study included 103 patients with non-traumatic lower limb ulcers and demonstrated a predominance of males (66%), with a high burden of diabetes (52.4%) and hypertension (49.5%). Ulcers were chronic with a mean duration of 23.83 weeks and mean length of 4.31 cm, while infection was present in 48.5% of cases. Multivariable analysis identified diabetes (OR 1.84), smoking (OR 2.09), ulcer length (OR 1.23 per cm), and duration (OR 1.09 per week) as independent predictors of infection .

A clear male predominance has been consistently described in diabetic foot disease, with proportions ranging between 60–70%, as reported in recent disparity analyses, McDermott K et al. [16]. In our study, males constituted 66%, which closely mirrors these findings. This similarity suggests that gender-related behavioral exposure and healthcare access continue to play a major role across different populations.

Chronic wound duration has been emphasized as a key characteristic of disease burden, with wounds often persisting beyond 12 weeks, as highlighted in global compendium data by Sen CK [17]. In comparison, our study demonstrated a mean

duration of 23.83 weeks, which is substantially higher, indicating delayed healthcare-seeking behavior and prolonged disease course in our setting.

Global estimates indicate that venous leg ulcers affect approximately 0.3% of the population with recurrence rates exceeding 60%, as shown in systematic analyses by Probst S et al. [18]. Although recurrence was not directly assessed in our study, the prolonged duration (~24 weeks) and moderate ulcer size (mean length 4.31 cm) suggest a similar pattern of persistent and difficult-to-heal ulcers, aligning with global trends.

The economic burden of chronic ulcers has been shown to be significant, particularly in tropical regions, with prolonged treatment durations contributing to increased healthcare costs, as demonstrated by Chan DYS et al. [19]. This is further supported by global estimates indicating wound care costs running into billions annually, Queen D et al. [20]. While direct cost analysis was not performed in our study, the high infection rate (48.5%) and prolonged ulcer duration strongly indicate increased healthcare utilization, indirectly supporting these findings.

Peripheral arterial disease plays a central role in ulcer pathogenesis, with Indian consensus data highlighting its high prevalence among patients with vascular risk factors, Khanna NN et al. [21]. Similarly, meta-analytic evidence suggests PAD prevalence of approximately 20–25% among diabetic individuals, as reported by Arora E et al. [22]. In our study, peripheral vascular disease was present in 24.3% of patients, which closely corresponds with these estimates, reinforcing the vascular basis of ulcer chronicity.

Clinical studies from India have shown that diabetes is present in nearly 45–60% of patients with chronic ulcers, as observed in hospital-based evaluations by Nag F et al. [23]. Our study demonstrated a diabetes prevalence of 52.4%, which lies within this reported range, confirming that metabolic comorbidity remains a dominant underlying factor in ulcer development.

Lifestyle factors, particularly smoking, have been identified as important contributors to ulcer progression and delayed healing, with preventive strategies emphasizing risk factor modification, as outlined by Carson M et al. [24]. In our analysis, smoking showed significant associations with ulcer type ($p = 0.001$) and infection ($p = 0.041$), and was an independent predictor of infection (OR 2.09). This strong concordance highlights smoking as a key modifiable determinant in ulcer outcomes.

Infection remains a major complication of chronic ulcers, with reported prevalence ranging from 40% to 60%, according to international guidelines by Lipsky BA et al. [25]. In our study, infection was present in 48.5% of cases, which falls squarely within this range. This indicates that infection burden remains consistently high across different healthcare settings.

The pathophysiology of diabetic foot ulcers involves a combination of neuropathy, ischemia, and infection, leading to progressive tissue damage, as described in detail by Armstrong DG et al. [26]. Our finding that diabetic patients had significantly larger ulcers ($p = 0.039$) supports this mechanism, suggesting that impaired healing in diabetes contributes to increased ulcer severity.

Economic impact studies in India have highlighted the substantial financial burden associated with diabetic foot care, particularly due to prolonged treatment and complications, as reported by Ruke MG and Snehal RK [27]. Similarly, broader analyses have demonstrated increased healthcare costs with chronic ulcers, Driver VR et al. [28]. Although economic variables were not directly measured in our study, the prolonged duration and high infection rate suggest a comparable burden.

Recent community-based data from India indicate a rising prevalence of diabetic foot ulcers associated with urbanization and lifestyle changes, as reported by Patil P et al. [29]. In our study, diabetes was present in 52.4% of patients, supporting the growing contribution of metabolic disease to ulcer burden.

Finally, national estimates indicate that India has over 77 million individuals with diabetes, with projections of further increase, according to the International Diabetes Federation [30]. The high proportion of diabetic patients in our study reflects this national trend and underscores the need for early preventive strategies.

Overall, the present study findings are largely consistent with global and Indian literature, particularly with respect to the role of diabetes, vascular disease, and lifestyle factors. However, the relatively high infection burden and prolonged ulcer duration observed in our cohort highlight ongoing gaps in early detection and timely management, emphasizing the need for integrated and preventive healthcare approaches.

LIMITATIONS AND CONCLUSION

The present study provides valuable insights into the clinical profile and predictors of infection in non-traumatic lower limb ulcers; however, certain limitations must be acknowledged. First, this was a single-center, hospital-based study conducted in a tertiary care setting, which may limit the generalizability of findings to the broader community, particularly rural and primary care populations. Second, the sample size of 103 patients, although adequate for statistical analysis, may not fully capture the heterogeneity of ulcer etiologies and risk factors across diverse populations. Third, the cross-sectional observational design restricts the ability to establish causal relationships between identified risk factors and outcomes such as infection. Longitudinal follow-up was not performed, and therefore, important outcomes such as healing rates, recurrence, and long-term complications could not be assessed. Additionally, certain variables such as microbiological profiles, treatment compliance, and economic burden were not evaluated in detail, which could have provided a more comprehensive understanding of disease dynamics. Minor data inconsistencies, such as outlier values in ulcer measurements, may also have influenced certain statistical estimates.

Despite these limitations, the study offers clinically relevant findings. A high burden of metabolic comorbidities, particularly diabetes and hypertension, was observed, along with a substantial proportion of infected ulcers. The identification of diabetes, smoking, ulcer size, and duration as independent predictors of infection underscores the multifactorial nature of disease progression. The findings highlight that both systemic factors and local ulcer characteristics play a critical role in determining outcomes.

In conclusion, non-traumatic lower limb ulcers represent a significant and growing healthcare challenge, particularly in settings with a high prevalence of non-communicable diseases. Early identification of high-risk patients, timely intervention, and effective management of modifiable risk factors such as smoking and glycemic control are essential to reduce complications. There is a pressing need for integrated, multidisciplinary approaches and community-level preventive strategies to improve outcomes and reduce the burden of chronic ulcers.

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