

DOI: <https://dx.doi.org/10.18203/2319-2003.ijbcp20262778>

Original Research Article

A prospective study to assess the pharmacotherapeutic management of chronic diabetic foot ulcers in a tertiary care hospital

Jyothi Dammur Basavaraj*, Ajaykumar Rathod

Department of Pharmacology, Ballari Medical College & Research Centre, Ballari, Karnataka, India

Received: 07 June 2026

Revised: 24 July 2026

Accepted: 27 July 2026

*Correspondence:

Dr. Jyothi Dammur Basavaraj,
Email: drjyo6@gmail.com

Copyright: © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ABSTRACT

Background: Chronic diabetic foot ulcers (DFUs) are a major cause of morbidity, prolonged hospitalization, and non-traumatic lower-limb amputations in patients with diabetes mellitus. Effective management requires rational pharmacotherapy, appropriate antimicrobial use, and objective wound assessment. This study evaluated pharmacotherapeutic management, drug utilization using World Health Organization (WHO) prescribing indicators, microbiological profile, and clinical outcomes in patients with chronic DFUs admitted to a tertiary care teaching hospital.

Methods: A 12-month prospective observational study was conducted in collaboration with the Departments of Pharmacology and General Surgery. Forty-two patients aged ≥ 30 years with chronic DFUs were enrolled after Institutional Ethics Committee approval and informed consent. Drug utilization was assessed using WHO/INRUD prescribing indicators. Wound healing was evaluated using the leg ulcer measurement tool (LUMT) at baseline, 1 week, and 4 weeks. Wound swabs were subjected to microbiological analysis, and data were analyzed using descriptive statistics.

Results: Most patients were males aged 41–60 years. Wound cultures were positive in 57.1% of cases, with *Escherichia coli* and *Staphylococcus aureus* being the predominant isolates. Polypharmacy was common (mean 6.8 drugs/prescription), although most medications were prescribed from the Essential Medicines List. β -lactams and nitroimidazoles were the most frequently prescribed antimicrobials. Mean LUMT scores decreased significantly over four weeks, indicating improved wound healing, and clinical cure was achieved in 78.6% of patients.

Conclusion: Rational pharmacotherapy guided by WHO prescribing indicators, culture-directed antimicrobial therapy, and standardized wound assessment using LUMT were associated with significant clinical improvement in patients with chronic diabetic foot ulcers.

Keywords: Diabetic foot ulcer, Drug utilization, Prescriptions predictors, Prospective studies

INTRODUCTION

Diabetes mellitus is a major global health challenge associated with chronic hyperglycaemia and debilitating microvascular and macrovascular complications. Among these, DFU are one of the most serious and costly complications, contributing substantially to morbidity, mortality, impaired quality of life, and healthcare expenditure. Approximately 18.6 million people

worldwide develop DFUs annually, and nearly 80% of diabetes-related lower-limb amputations are preceded by a foot ulcer. In 2021, an estimated 536.6 million adults were living with diabetes, a figure projected to increase to 783.2 million by 2045.¹ The development of DFUs is multifactorial, involving peripheral neuropathy, peripheral arterial disease, repetitive trauma, poor glycaemic control, persistent inflammation, tissue ischemia, and secondary infection, all of which impair wound healing.¹ Despite standard management strategies—including debridement,

infection control, off-loading, vascular optimization, and glycaemic management—many chronic ulcers fail to heal adequately. Approximately 15–25% of DFUs result in lower-limb amputation, while recurrence rates remain as high as 40–70% following healing, emphasizing the need for improved therapeutic approaches.³

In India, the lifetime prevalence of DFUs among patients with diabetes is reported to be as high as 19.6%, with a considerable burden of high-risk feet and amputations.⁴ Management of chronic DFUs often requires hospitalization, prolonged antibiotic therapy, and multiple medications, increasing the risk of polypharmacy, irrational prescribing, and antimicrobial resistance.

However, prospective data on drug utilization patterns in Indian tertiary care hospitals remain limited. Therefore, this study aimed to evaluate pharmacotherapy and drug utilization practices using World Health Organization prescribing indicators in hospitalized patients with chronic diabetic foot ulcers to promote rational prescribing, antimicrobial stewardship, and improved patient outcomes.

The present study has been undertaken in the Department of Pharmacology in collaboration with the Department of General Surgery of Ballari Medical College & Research Centre, a tertiary care hospital, Ballari, with the following

Objectives

To assess the pattern of drugs in the treatment of chronic diabetic foot ulcers in patients admitted in general surgery wards. To evaluate the drug use in chronic diabetic foot ulcer patients using WHO prescribing indicators.

METHODS

The present prospective observational study was conducted in the Department of Pharmacology in collaboration with the Department of General Surgery, Ballari Medical College & Research Centre, a tertiary care hospital, Ballari, Karnataka from January 2025–December 2025

Inclusion criteria

Patients diagnosed with chronic diabetic foot ulcers, admitted in the General Surgery wards. Patients of either sex. Age 30 years and above. Patients willing to give written informed consent.

Exclusion criteria

Non-diabetic ulcer, pregnant women, mentally retarded patients, patients with HIV, TB, or undergoing cancer chemotherapy. Patients on long-term steroids or other immunosuppressive agents. Chronic liver disease, chronic renal failure, chronic heart failure with IHD, associated

varicose veins or DVT. Peripheral vascular disease (TAO), hypoproteinaemia or anaemia.

An open-labelled prospective observational study was designed for a duration of 12 months, consisting of patient registration, treatment, and follow-up visits. A total of 42 patients suffering from chronic diabetic foot ulcers were registered by applying the inclusion and exclusion criteria mentioned above.

The study was conducted after obtaining written informed consent from all patients and approval from the VIMS Institutional Ethics Committee. All procedures were performed according to the Declaration of Helsinki.

A detailed history and clinical examination of all patients were recorded. Patients were monitored closely for any undesirable symptoms during the study. They were advised to discontinue the treatment and report immediately if any adverse events occurred.

Patients were followed up at 1 week and 4 weeks after the baseline visit. Data collected included demographic details, past medical history, investigations, list of prescribed drugs, and treatment details.

Assessment tools

LUMT, to detect changes in the appearance of leg ulcers. Wound assessment in patients with diabetic foot ulcer was carried out using the LUMT, a validated and standardized instrument for evaluating chronic lower-limb ulcers. The tool includes clinician-rated (A1–A14) and patient-rated (B1–B3) domains, enabling comprehensive assessment of wound severity and healing. The clinician-rated domains assess exudate characteristics, ulcer size, depth, undermining, necrotic tissue type and amount, granulation tissue type and amount, wound edges, peri wound skin condition, leg edema, and bioburden. Each domain is scored from 0 to 4, with higher scores indicating greater severity.

The patient-rated domains evaluate pain severity, pain frequency, and ulcer-related quality of life. The total LUMT score is obtained by summing all domain scores; a decrease in score over time indicates wound improvement. LUMT assessment was performed at baseline and during follow-up visits by the same investigator to minimize observer variability. Changes in total LUMT score were used to evaluate treatment response. Drug use assessment: WHO/INRUD prescribing indicators.

Statistical analysis

All collected data were entered into a master chart in Excel and analysed using SPSS version 21.0. Data was analysed using descriptive statistics viz. mean, standard deviation and percentages wherever applicable.

RESULTS

Diabetic ulcers were the most common type, observed in 17 patients (40%), followed by traumatic and mixed etiology ulcers in 12 patients (29%). Arterial ulcers accounted for 7 patients (17%), while venous ulcers were observed in 6 patients (14%).

Table 1: Age distribution of patients (n=42).

Age group (in years)	Number of patients (N)	%
41–60	30	71.4
>60	12	28.6
Total	42	100.0

Table 2: Gender distribution.

Gender	Number of patients (N)	%
Male	29	69.0
Female	13	31.0
Total	42	100.0

Table 3: Distribution of types of chronic leg ulcers.

Type of ulcer	Number of patients	%
Diabetic ulcer	17	40
Venous ulcer	6	14
Arterial ulcer	7	17
Traumatic/mixed	12	29

Table 4: Organisms isolated from wound culture.

Organism isolated	Number	%
<i>Escherichia coli</i>	6	25.08
<i>Klebsiella species</i>	5	20.08
<i>Pseudomonas aeruginosa</i>	4	16.7
<i>Staphylococcus aureus</i>	6	25.0
MRSA	1	4.2
Others	2	8.3

Table 5: Class of antimicrobials prescribed.

Antimicrobial class	Number	%
β -lactams	37	52
Nitroimidazoles	28	39
Oxazolidinones	4	6
Fluoroquinolones	2	3

Table 6: LUMT score changes during treatment.

Time point	Clinician-rated domain (Mean $\pm$ SD)	Patient-rated domain (Mean $\pm$ SD)
Baseline	23.1 $\pm$ 6.2	10.2 $\pm$ 1.3
End of 1st week	13.4 $\pm$ 2.1	6.9 $\pm$ 1.2
End of 4th week	5.6 $\pm$ 4.8	4.3 $\pm$ 1.6

Table 7: Final clinical outcome.

Final clinical outcome	Number	%
Clinical cure	33	78.6
Surgery (debridement)	4	9.5
Minor amputation	3	7.1
Major amputation	2	4.8

Escherichia coli and *Staphylococcus aureus* were the most frequently isolated organisms (25% each), followed by *Klebsiella species* (20.8%) and *Pseudomonas aeruginosa* (16.7%). Methicillin-resistant *Staphylococcus aureus* (MRSA) was isolated in one patient (4.2%).

β -lactam antibiotics were the most commonly prescribed class (52%), followed by nitroimidazoles (39%). Other antimicrobials included oxazolidinones (6%) and fluoroquinolones (2%). The mean clinician-rated LUMT score decreased from 23.1 $\pm$ 6.2 at baseline to 5.6 $\pm$ 4.8 at the end of 4 weeks, while the patient-rated score decreased from 10.2 $\pm$ 1.3 to 4.3 $\pm$ 1.6, indicating significant improvement in ulcer healing during the treatment period.

Clinical cure was achieved in 33 patients (78.6%). Surgical intervention in the form of debridement was required in 4 patients (9.5%). Minor amputation was performed in 3 patients (7.1%), and major amputation was required in 2 patients (4.8%).

DISCUSSION

Chronic leg ulcers, particularly diabetic foot ulcers, constitute a major cause of morbidity, prolonged hospitalization, and non-traumatic lower-limb amputations worldwide. The problem is especially pronounced in developing countries such as India due to the rising prevalence of diabetes mellitus, delayed presentation, poor glycaemic control, and limited access to multidisciplinary wound care services. Effective management requires a comprehensive approach involving rational pharmacotherapy, appropriate antimicrobial selection, meticulous wound care, and objective monitoring of healing outcomes.

The present prospective observational study was undertaken to evaluate the pharmacotherapeutic management, drug utilization pattern, microbiological profile, and clinical outcomes of patients with chronic leg ulcers using WHO prescribing indicators and the LUMT. The findings were systematically compared with published Indian and international studies to assess concordance with existing evidence.

Demographic characteristics

Age distribution

In the present study, the majority of patients belonged to the 41–60 years age group, followed by patients aged more than 60 years, indicating that chronic leg ulcers

predominantly affect middle-aged and elderly individuals. Similar age distributions were reported by Khan et al and Ullah et al (>45 years in nearly 70% of patients) who noted that most diabetic foot ulcer patients were above 45 years of age, highlighting age as a major non-modifiable risk factor.⁶

Gender distribution

A clear male predominance was observed in the present study. This finding is consistent with reports by Paramasivamsasanger et al (male patients 65–72%) (male predominance~68%), who documented male predominance in diabetic foot ulcer cases, attributing it to occupational exposure, increased outdoor activity, and delayed healthcare-seeking behavior among males.⁷

Distribution of ulcer types

Diabetic ulcers constituted the most common type of chronic leg ulcer in the present study, followed by traumatic or mixed-etiology ulcers. This predominance of diabetic ulcers is consistent with observations by Baig et al (diabetic ulcers accounting for >70% of chronic leg ulcers) who emphasized that neuropathy, ischemia, and infection are the principal contributors to ulcer formation and chronicity in diabetic patients.⁸ The presence of mixed-etiology ulcers highlights the multifactorial nature of chronic leg ulcers, particularly in patients with multiple comorbidities.

Microbiological profile

Wound culture positivity was observed in more than half of the patients, with monomicrobial infections being more common than polymicrobial infections. However, a considerable proportion of cases demonstrated polymicrobial growth, suggesting advanced disease and increased severity of infection.

In the present study, *Escherichia coli* and *Staphylococcus aureus* were the most frequently isolated organisms, followed by *Klebsiella* species and *Pseudomonas aeruginosa*. This mixed predominance of Gram-negative bacilli and Gram-positive cocci is comparable with findings reported by Varun et al.⁹

Drug utilization pattern and WHO prescribing indicators

Analysis of WHO prescribing indicators revealed an average of 6.8 drugs per prescription, indicating polypharmacy. This observation is comparable with findings reported by Ashok et al (mean drugs per prescription 6.4) (range 5–7 drugs per encounter), who documented higher drug counts among hospitalized diabetic patients due to the need for antimicrobials, analgesics, antidiabetic agents, and supportive therapy.¹⁰ Although the number of drugs per prescription exceeded WHO optimal values, it is justified in the context of infected chronic ulcers with associated comorbidities.

Antimicrobial utilization pattern

β -lactam antibiotics were the most commonly prescribed antimicrobial class, followed by nitroimidazoles. This prescribing pattern is consistent with studies by Paramasivamsasanger et al (β -lactams ~ 60%) (β -lactams as first-line in >65%), where β -lactams formed the cornerstone of empirical therapy due to their broad-spectrum coverage.¹¹ The frequent use of nitroimidazoles reflects the need for anaerobic coverage in chronic and deep ulcers. The average duration of antimicrobial therapy was approximately seven days, (mean duration 7–10 days). The average duration of antimicrobial therapy was approximately seven days for diabetic foot management.

Overall interpretation

Overall, the present study demonstrates that chronic leg ulcers predominantly affect middle-aged and elderly males, with diabetic ulcers being the most common etiology. The microbial profile, antimicrobial utilization pattern, and clinical outcomes observed are largely consistent with previously published studies. Rational pharmacotherapy, adherence to essential medicines, and regular wound assessment using standardized tools such as LUMT contribute significantly to favourable clinical outcomes.

CONCLUSION

This prospective observational study evaluated pharmacotherapy, drug utilization, microbiological profile, and clinical outcomes in patients with chronic diabetic foot ulcers. Diabetic ulcers predominantly affected middle-aged males, with *Escherichia coli* and *Staphylococcus aureus* as the common pathogens. Rational prescribing, culture-guided antimicrobial therapy, and standardized wound assessment using LUMT significantly improved healing outcomes with minimal adverse drug reactions, supporting effective management and adherence to standard treatment guidelines.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Armstrong DG, Tan TW, Boulton AJ, Bus SA. Diabetic foot ulcers: a review. JAMA. 2023;330(1):62-75.
2. Parveen K, Hussain MA, Anwar S, Elagib HM, Kausar MA. Comprehensive review on diabetic foot ulcers and neuropathy: Treatment, prevention and management. World J Diabetes. 2025;16(3):100329.
3. Rastogi A, Kulkarni SA, Agarwal S, Akhtar M, Arsule S, Bhamre S, et al. Topical esmolol hydrochloride as a novel treatment modality for diabetic foot ulcers: a

- phase 3 randomized clinical trial. *JAMA Network Open.* 2023;6(5):2311509.
4. Ruke MG, Elavarasan SS, Devarajan A, Viswanathan V. Progress and challenges in diabetic foot care in South-East Asia and India-Current scenario. *Diab Res Clin Pract.* 2025;2:26.
 5. Woodbury MG, Houghton PE, Campbell KE, Keast DH. Development, validity, reliability, responsiveness of the LUMT. *Adv Skin Wound Care.* 2004;17(4):190–8.
 6. Khan F, Ullah A. Pharmacotherapy patterns of diabetic foot ulcer patients at a tertiary care hospital: a prospective study. *Healthcraft Front.* 2024;2(3):118-29.
 7. Paramasivamsasanger K, Mariappan P, Govindasamy D, Karunakaran P, Ramesh R. A prospective observational study of drug prescription pattern of antibiotics in diabetic foot ulcer. *Int J Basic Clin Pharmacol.* 2020;9:1020-5.
 8. Bhamre SD, Dikle AM. A study of microbial profile and drug resistance pattern in patients with diabetic foot at a tertiary health care center. *MVP J Med Sci.* 2020;7(1):9-15.
 9. Varun S, Nair A, Moonnumacke D. Medication utilization practices in patients with diabetic foot ulcers in a tertiary care hospital. *World J Pharm Res.* 2022;11(11):1224-35.
 10. Ashok P, Subrahmanian VT, Raj R, Babu RR, Ramshad TP, Kevin L. Prescription pattern analysis of type II diabetes mellitus inpatients and associated comorbidities. *J Drug Deliv Ther.* 2020;10(3):1-6.
 11. Paramasivamsasanger K, Mariappan P, Govindasamy D, Karunakaran P, Ramesh R. A prospective observational study of drug prescription pattern of antibiotics in diabetic foot ulcer. *Int J Basic Clin Pharmacol.* 2020;9:1020-5.

Cite this article as: Basavaraj JD, Rathod A. A prospective study to assess the pharmacotherapeutic management of chronic diabetic foot ulcers in a tertiary care hospital. *Int J Basic Clin Pharmacol* 2026;15:927-31.