

Assessment of Treatment And Surgical Intervention For Diabetic Foot Ulcer

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Abstract

Background:

Diabetic foot ulcer (DFU) is one of the most common and severe complications associated with diabetes mellitus, leading to significant morbidity, risk of limb amputation, and increased healthcare costs. The condition results from a complex interplay of peripheral neuropathy, peripheral vascular disease, infection, and poor glycemic control. In India and other developing countries, delayed diagnosis, inadequate wound care, and limited access to multidisciplinary interventions contribute to poor outcomes. Early diagnosis and appropriate treatment—including both surgical and pharmacological strategies—are essential to reduce complications and improve healing. Given the high burden of DFUs in tertiary care settings, there is a critical need to assess and compare treatment modalities, particularly the role of surgical interventions and antibiotic regimens.

Objectives:

This study aimed to evaluate the effectiveness of different surgical and pharmacological treatments in the management of diabetic foot ulcers. The specific objectives were to (1) analyze the outcome of various surgical interventions, (2) assess wound healing, infection rates, and patient recovery, and (3) examine the cost-effectiveness of conservative versus invasive approaches in a tertiary care hospital setting.

Methods:

A prospective observational study was conducted over a six-month period (November 2023 to April 2024) at the Department of Surgery, Government Cuddalore Medical College and Hospital, Tamil Nadu, India. A total of 150 patients aged ≥ 18 years with chronic diabetic foot ulcers (≥ 4 weeks duration) were enrolled after applying inclusion and exclusion criteria. Data were collected using a structured proforma covering patient demographics, ulcer classification (Wagner Grade), duration of diabetes, ulcer location and duration, type of surgical intervention (debridement, amputation, dressing, conservative), and antibiotic treatment. Statistical analysis, including binary logistic regression, was used to identify significant predictors of healing outcomes. A p-value of < 0.05 was considered statistically significant.

Results:

Among the 150 patients, 70.7% were male, with a mean age of 55.6 ± 10.2 years. Patients with unhealed ulcers were significantly older than those who healed (mean age 57.5 vs. 52.8 years, $p = 0.015$). Logistic regression analysis revealed that higher Wagner grades (OR = 5.58, $p = 0.025$) and surgical amputation (OR = 0.001, $p < 0.001$) were strong negative predictors of healing. Conversely, conservative interventions such as debridement and dressing, although not statistically significant, showed more favorable healing trends. The treatment model showed an overall accuracy of 84%, with high sensitivity (93.1%) for predicting non-healing outcomes. Antibiotic regimens, including cefotaxime, piperacillin-tazobactam, and linezolid, were commonly used, but their statistical influence on healing was limited.

Conclusion:

The study underscores that advanced age and higher Wagner grade are significant predictors of non-healing in DFUs. Conservative surgical approaches may lead to better healing outcomes compared to amputation. Multidisciplinary care, involving surgeons, pharmacists, and wound care specialists, is essential for effective DFU management. Early intervention, proper wound classification, and patient education are vital to improve outcomes and reduce recurrence.

Keywords:

Diabetic foot ulcer, Wagner classification, surgical debridement, amputation, conservative management, wound healing, pharmacy practice, logistic regression, antibiotic therapy, multidisciplinary care.

I. INTRODUCTION

Diabetes mellitus is a global health burden affecting over 537 million people worldwide, with a significant proportion residing in low- and middle-income countries like India. One of the most devastating complications of long-standing diabetes is the development of diabetic foot ulcers (DFUs), which are defined as full-thickness wounds located below the ankle, typically resulting from a combination of peripheral neuropathy, peripheral arterial disease (PAD), and immunological compromise. DFUs represent a major source of morbidity and are associated with prolonged hospital stays, reduced quality of life, and a high risk of lower extremity amputation and death.

The pathogenesis of DFUs is multifactorial. Peripheral neuropathy leads to the loss of protective sensations, making patients susceptible to repetitive trauma and unnoticed injuries. Autonomic dysfunction contributes to dry, cracked skin, predisposing patients to secondary infections. Concurrently, peripheral vascular disease impairs blood supply, limiting oxygen and nutrient delivery to the wound site, thereby slowing the healing process. Moreover, immune dysfunction—characterized by impaired leukocyte activity and chemotaxis—further increases the risk of infection, particularly from multidrug-resistant organisms.

The International Diabetes Federation estimates that up to 25% of diabetic patients will develop a foot ulcer during their lifetime, and 85% of diabetes-related amputations are preceded by a foot ulcer. In India, the burden is particularly severe due to late presentation, limited access to diabetic foot care clinics, and poor awareness about foot hygiene among patients. Delayed intervention increases the risk of complications such as osteomyelitis, gangrene, and systemic sepsis.

Effective management of DFUs requires a multidisciplinary approach, involving physicians, surgeons, podiatrists, wound care specialists, and pharmacists. The cornerstone of treatment includes glycemic control, infection management, pressure offloading, vascular assessment, and appropriate surgical intervention. Surgical approaches may include conservative wound debridement, incision and drainage, or more aggressive procedures like amputations in cases of extensive tissue necrosis or gangrene. Adjunct pharmacological therapy, particularly antibiotics, plays a crucial role in infection control and must be selected based on culture sensitivity data and local antibiogram trends.

The Wagner classification system is the most widely used method for grading diabetic foot ulcers. It categorizes ulcers from grade 0 (intact skin) to grade 5 (extensive gangrene of the foot), aiding clinicians in assessing the severity of ulcers and deciding on treatment modalities. However, despite the widespread use of this system, DFU outcomes are still highly variable and influenced by multiple patient-specific factors, including age, comorbidities, ulcer duration, and type of intervention.

Pharmacy practice is pivotal in DFU management, especially in the rational use of antibiotics, patient counseling on foot care, medication adherence, and glycemic control. Clinical pharmacists also contribute by monitoring drug interactions and adjusting therapies based on renal function or culture results.

Given this background, the present study was designed to assess the outcomes of different surgical and medical interventions for DFUs in a tertiary care hospital. Through this research, we aim to provide insights into the most effective treatment approaches and emphasize the role of early intervention and multidisciplinary management—including pharmacy services—in improving healing outcomes and reducing DFU-related complications.

II. MATERIALS AND METHODS

Study Design and Setting

This was a prospective, observational study conducted over a period of six months, from **November 2023 to April 2024**, in the Department of Surgery, Government Cuddalore Medical College and Hospital (GCMCH), Tamil Nadu, India. GCMCH is a 1200-bedded rural tertiary care teaching hospital providing multidisciplinary services, including specialized diabetic wound care. The study was carried out in collaboration with the Department of Pharmacy, Annamalai University, to integrate clinical and pharmaceutical perspectives.

Study Population

The study included diabetic patients presenting with foot ulcers of varying severity, admitted to the surgical ward during the study period.

Inclusion Criteria:

- Patients aged ≥ 18 years
- Diagnosed cases of **type 1 or type 2 diabetes mellitus.
- Presence of diabetic foot ulcer of minimum 4 weeks' duration.
- Willing to provide informed consent .

Exclusion Criteria:

- Patients with healed diabetic foot ulcers .
- Cases requiring major amputation above the ankle level.
- Patients with untreated osteitis or osteomyelitis .
- Individuals with other causes of foot ulceration (e.g., vasculitis, malignancy).

Data Collection Tool

A validated data collection proforma was developed in consultation with surgeons, clinical pharmacists, and epidemiologists. The proforma was designed to capture:

- Patient demographic details (age, gender)
- Diabetes duration and comorbidities
- Ulcer characteristics: location, duration, Wagner classification
- Type of surgical intervention (e.g., debridement, amputation, conservative)
- Antibiotic regimens administered
- Duration of hospital stay
- Treatment outcomes: healed vs unchanged
- Laboratory parameters: fasting blood sugar (FBS), HbA1c, ESR, CRP
- Imaging results: X-rays, Doppler studies (when applicable)

Patients were followed from admission until discharge or healing, and wound status was assessed regularly.

Treatment Protocols

Patients received treatment as per standard institutional guidelines. Surgical interventions included:

- Conservative dressing and wound care
- Surgical debridement
- Incision and drainage
- Minor or major amputation (when indicated)

Antibiotics such as ceftriaxone, piperacillin-tazobactam, linezolid, or cefotaxime were administered based on culture sensitivity or empirical evidence, in consultation with microbiology experts and clinical pharmacists.

Study Variables

Independent variables : Age, gender, diabetes duration, Wagner grade, ulcer location, ulcer duration, surgical method, antibiotic used.

Dependent variable : Treatment outcome (Healed vs. Unchanged).

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS (Statistical Package for Social Sciences) version 26.0. Descriptive statistics were used to summarize patient characteristics (mean, standard deviation, frequencies, percentages). Chi-square tests were performed to evaluate associations between categorical variables. Binary logistic regression was employed to identify predictors of healing outcomes. Model fitness was assessed using -2 log-likelihood, Nagelkerke R², and Cox & Snell R². Receiver Operating Characteristic (ROC) curves were used to evaluate sensitivity and specificity of the prediction model. A p-value <0.05 was considered statistically significant.

Data Confidentiality and Storage

All patient data were stored securely in password-protected systems accessible only to study investigators. Hard copies of the data collection forms were archived in the Department of Pharmacy library for academic reference, and no identifying personal information was disclosed in the reporting.

III.RESULTS

This study enrolled a total of 150 patients diagnosed with diabetic foot ulcers, admitted to a tertiary care hospital over a six-month period. The study population was predominantly male, with 106 (70.7%) males and 44 (29.3%) females. The overall mean age of the patients was 55.6 ± 10.2 years. Patients were followed until either the wound healed or remained non-healed at discharge. Based on the final clinical outcome, 34 patients (22.7%) had healed ulcers, while 116 patients (77.3%) showed no significant improvement, classifying them under the non-healed category.

Patients in the non-healed group were older, with a mean age of 57.5 ± 10.98 years, compared to 52.8 ± 11.3 years in the healed group. This age difference was statistically significant ($p = 0.015$), suggesting that older age is a predictor of poor healing outcomes in diabetic foot ulcer patients.

The average duration of diabetes was slightly longer in the non-healed group (5.9 ± 4.8 years) than in the healed group (4.8 ± 5.9 years), though this difference was not statistically significant. Similarly, the average ulcer duration in the non-healed group was much longer (167.3 ± 382.1 days) than in the healed group (66.4 ± 120.8 days), indicating that chronic ulcers tend to have a worse prognosis. However, due to wide variability and standard deviation, this difference did not achieve statistical significance.

Regarding ulcer severity, most patients had ulcers classified as Wagner Grade II or III, reflecting moderate tissue involvement or deep infection. The average Wagner grade among the non-healed group was 2.75 ± 0.93 , compared to 2.61 ± 1.28 in the healed group. Though the difference appears modest, logistic regression later confirmed Wagner grade as a statistically significant predictor of non-healing ($p = 0.025$).

Surgical interventions were categorized into conservative (debridement, dressing, incision and drainage) and aggressive (amputation) treatments. Among the 150 patients, 31 underwent amputation, 38 received debridement only, 47 were managed with conservative dressing or drainage, and 34 underwent multiple or combined procedures.

Healing outcomes varied sharply by intervention type. Patients who underwent amputation had a disproportionately high rate of non-healing. Logistic regression analysis revealed amputation to be a statistically significant negative predictor of healing, with an odds ratio (OR) of 0.001 ($p < 0.001$). In contrast, conservative procedures were associated with better outcomes, although the differences in healing rates between dressing-only, incision and drainage, and debridement groups were not statistically significant on their own. However, these treatments consistently showed a more favorable trend toward healing when compared to amputation.

All patients received antibiotics based on culture sensitivity or empirical evidence. The most commonly administered antibiotics were: Cefotaxime (47 patients), Piperacillin + Tazobactam (39 patients), Linezolid (21 patients), Cefixime (17 patients), and other antibiotics or combinations (26 patients). When healing outcomes were compared across antibiotic regimens, there was no statistically significant association between antibiotic type and ulcer healing. This finding suggests that the choice of antibiotic, while essential for infection control, does not independently determine wound healing, especially in the presence of other dominating factors like ulcer severity and surgical management.

A binary logistic regression model was constructed to identify variables that significantly influenced healing outcomes. The model demonstrated strong predictive ability, with an overall accuracy of 84%. It was particularly sensitive in detecting non-healed ulcers (sensitivity = 93.1%) but had a lower specificity in identifying healed cases (specificity = 52.94%).

The following variables emerged as statistically significant predictors of healing: Age (each year increase raised odds of non-healing by 8%, OR = 1.08, $p = 0.015$), Wagner Grade (each increase in ulcer grade associated with a fivefold increase in likelihood of non-healing, OR = 5.58, $p = 0.025$), and Amputation (strong negative predictor, OR = 0.001, $p < 0.001$). Other variables such as gender, duration of diabetes, ulcer location, and type of antibiotic therapy were included in the model but did not demonstrate statistical significance.

The model's goodness-of-fit was assessed using multiple statistical tests: Chi-square = 46.98, $df = 21$, $p = 0.001$, -2 Log Likelihood = 113.59, Nagelkerke $R^2 = 0.41$, Cox & Snell $R^2 = 0.27$, and McFadden $R^2 = 0.29$. These values suggest that the model offers moderate predictive power and performs well in a clinical research setting.

In summary, this study indicates that increasing age, higher Wagner classification, and undergoing amputation are significantly associated with poor healing outcomes in diabetic foot ulcer patients. Conservative treatment strategies offer better results, particularly when implemented early. Although the use of specific antibiotics did not significantly affect healing, their role remains essential for infection management. The study supports a holistic, multidisciplinary approach for DFU management with strong emphasis on early intervention and conservative care strategies wherever possible.

IV.DISCUSSION

This study evaluated the clinical outcomes of surgical and pharmacological interventions for diabetic foot ulcers in a tertiary care setting, focusing on predictors of ulcer healing. The findings highlight the importance of patient age, ulcer severity as measured by the Wagner classification, and the type of surgical approach used.

Age was found to be a significant factor, with older patients experiencing a higher likelihood of non-healing ulcers. This result aligns with existing literature, as aging is associated with impaired immune response, reduced vascular perfusion, and delayed tissue regeneration, all of which contribute to poor wound healing. Comorbidities often seen in elderly diabetic patients, such as cardiovascular or renal disease, further compound this issue.

The Wagner classification system proved to be a strong predictor of healing outcomes. Patients with higher Wagner grades, which indicate deeper ulceration and more severe infection or gangrene, showed significantly lower healing rates. This supports the use of the Wagner scale as a practical tool for clinical decision-making and outcome prediction.

Amputation was strongly associated with non-healing outcomes in this study. While amputation may be necessary to manage severe or life-threatening infections, it is generally considered a last resort due to the physical, emotional, and economic consequences

for patients. In contrast, conservative surgical procedures such as debridement and proper dressing were associated with more favorable healing trends, especially when implemented early. These findings emphasize the importance of timely, less invasive interventions wherever possible.

Antibiotic therapy is central to DFU management. Although this study found no statistically significant difference in healing outcomes based on the specific antibiotic used, this does not diminish their clinical value. The choice of antibiotic must still be guided by microbial culture and sensitivity patterns. The role of pharmacists in ensuring rational antibiotic use, adjusting for renal function, and preventing antimicrobial resistance is crucial.

Pharmacists also play a key role in patient education, especially regarding medication adherence, blood glucose monitoring, and foot care practices. Their involvement enhances the effectiveness of multidisciplinary care and supports long-term ulcer prevention strategies.

This study aligns with existing evidence that multidisciplinary management leads to better outcomes in DFU cases. The integration of surgical, medical, and pharmacy services is essential to achieve holistic care, reduce hospital stay durations, and prevent recurrence or complications.

CONCLUSION

Diabetic foot ulcer (DFU) is a complex and serious complication of diabetes mellitus that continues to pose a major health challenge, particularly in developing countries. This study highlights several key findings that contribute to our understanding of DFU management and outcomes. Age and ulcer severity emerged as the most significant predictors of healing. Older patients, especially those above 55 years, were more likely to experience poor outcomes, reflecting the cumulative impact of vascular compromise, delayed tissue regeneration, and multiple comorbidities. Similarly, patients with higher Wagner grades—particularly grades III and above—had significantly lower rates of healing due to deeper tissue involvement, infection, and potential for gangrene.

One of the most important observations from this study is the strong negative association between amputation and ulcer healing. While amputation is often necessary in cases of extensive infection or necrosis, it should be viewed as a last resort. The high rate of non-healing among amputees underlines the importance of early detection and less aggressive management options when feasible. Conservative surgical approaches such as debridement and regular wound dressing, when initiated early, offer better chances for recovery and limb preservation.

Antibiotic therapy remains essential in the treatment of DFUs, primarily to control and prevent the spread of infection. However, this study found no significant difference in healing outcomes based on the type of antibiotic used, suggesting that effective DFU management depends more on the appropriateness and timing of treatment than on the specific drug selected. Clinical pharmacists have an important role in this regard, ensuring rational antibiotic use, adjusting doses based on renal function, preventing drug resistance, and educating patients on adherence.

The findings of this research reaffirm the importance of a multidisciplinary approach to diabetic foot care. Effective collaboration between surgeons, endocrinologists, microbiologists, and pharmacists is necessary for individualized treatment planning, infection control, glycemic management, and follow-up. Moreover, patient education on foot hygiene, self-examination, footwear, and lifestyle modifications is critical to prevent recurrence.

In conclusion, diabetic foot ulcers can be effectively managed and many amputations can be prevented through timely diagnosis, careful ulcer classification, appropriate conservative treatment, and integrated care. The role of clinical pharmacists extends beyond drug dispensing—they contribute actively to the therapeutic decision-making process and long-term patient outcomes. Strengthening multidisciplinary foot care teams and promoting early, evidence-based interventions are essential strategies for improving the prognosis of DFU patients and reducing the associated burden on healthcare systems.

Disclosure of conflict of interest: None

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