



CLINICAL STUDY OF PROGNOSTIC FACTORS INFLUENCING OUTCOMES IN PATIENTS WITH DIABETIC FOOT DISEASE: A PROSPECTIVE OBSERVATIONAL STUDY

General Surgery

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ABSTRACT

Background: Diabetic foot disease (DFD) is among the most devastating complications of diabetes mellitus and remains a major cause of prolonged hospitalization, lower limb amputation, disability, and mortality worldwide. The outcome of diabetic foot disease is influenced by multiple interacting prognostic factors including peripheral neuropathy, peripheral arterial disease, infection, ulcer severity, osteomyelitis, glycaemic control, and associated comorbidities. Early identification of these factors is essential for appropriate risk stratification and timely intervention. The present study was undertaken to evaluate the clinical and laboratory prognostic factors influencing healing, limb salvage, and amputation in patients presenting with diabetic foot disease. **Methods:** A prospective observational study was conducted in the Department of General Surgery, Index Medical College Hospital and Research Centre, Indore. Fifty consecutive patients with diabetic foot disease fulfilling the inclusion criteria were enrolled. Demographic characteristics, duration of diabetes, ulcer characteristics, Wagner grade, type of diabetic foot lesion, infection, osteomyelitis, vascular status, laboratory investigations, operative procedures, healing duration, complications, length of hospital stay, recurrence, and amputation rates were recorded. Statistical analysis included descriptive statistics, chi-square test, Spearman correlation, logistic regression, and linear regression to identify independent prognostic factors associated with poor clinical outcomes. **Results:** The mean age of patients was approximately 58 years, with male predominance. Neuro-ischaemic and infected diabetic foot lesions constituted the majority of presentations. Higher Wagner grade, presence of osteomyelitis, larger wound size, peripheral vascular disease, and poor glycaemic control were significantly associated with delayed wound healing and increased risk of amputation. Seventeen patients required lower limb amputation. Osteomyelitis demonstrated a strong association with postoperative complications. Logistic regression identified advanced Wagner grade, neuro-ischaemic disease, and osteomyelitis as independent predictors of amputation. Increased wound size correlated significantly with prolonged healing duration. **Conclusion:** Clinical outcome in diabetic foot disease is determined by multiple interrelated prognostic factors rather than ulcer severity alone. Comprehensive assessment of infection, vascular insufficiency, neuropathy, osteomyelitis, and glycaemic status enables early risk stratification and facilitates limb salvage. Multidisciplinary management, prompt surgical intervention when indicated, aggressive infection control, optimisation of metabolic status, and structured follow-up remain essential to reduce amputation rates and improve functional outcomes.

KEYWORDS

Diabetic Foot Disease; Diabetic Foot Ulcer; Wagner Classification; Osteomyelitis; Prognostic Factors; Limb Salvage; Amputation; Peripheral Arterial Disease; Neuropathy

INTRODUCTION

Diabetes mellitus has emerged as one of the most important non-communicable diseases worldwide, affecting more than 537 million adults, with the burden expected to rise substantially over the coming decades. The increasing prevalence of diabetes, particularly in developing countries such as India, has resulted in a parallel increase in chronic complications, among which diabetic foot disease (DFD) is one of the most disabling and economically burdensome. DFD encompasses a spectrum of pathological conditions involving infection, ulceration, gangrene, neuropathy, peripheral arterial disease (PAD), and Charcot neuroarthropathy occurring in patients with diabetes mellitus. It is estimated that nearly one in five individuals with diabetes will develop a foot ulcer during their lifetime, and diabetic foot complications account for the majority of diabetes-related hospital admissions and non-traumatic lower-limb amputations worldwide.

The pathogenesis of diabetic foot disease is multifactorial. Chronic hyperglycaemia results in peripheral sensory, motor, and autonomic neuropathy, which predisposes the foot to repetitive unnoticed trauma, abnormal plantar pressure distribution, and skin breakdown. Sensory neuropathy leads to loss of protective sensation, allowing minor injuries to progress unnoticed, whereas motor neuropathy causes intrinsic muscle wasting and foot deformities such as claw toes, hammer toes, and prominent metatarsal heads that further increase focal pressure points. Autonomic neuropathy reduces sweating, producing dry, fissured skin that facilitates bacterial invasion. In addition, peripheral arterial disease compromises tissue perfusion and oxygen delivery, resulting in delayed wound healing and increased susceptibility to gangrene. Superimposed bacterial infection frequently converts a chronic ulcer into a limb-threatening condition requiring urgent surgical intervention.

Diabetic foot disease represents a major public health challenge because of its high morbidity, prolonged hospitalization, repeated

surgical procedures, and significant healthcare expenditure. Lower-limb amputation remains one of the most devastating consequences of diabetic foot disease and is associated with impaired mobility, psychological distress, reduced quality of life, and increased long-term mortality. Even after successful wound healing or amputation, recurrence rates remain high owing to persistent neuropathy and biomechanical abnormalities. Therefore, identifying patients at increased risk of poor outcomes before irreversible tissue loss occurs has become an essential component of diabetic foot management.

Several clinical, laboratory, and radiological parameters have been proposed as predictors of prognosis in diabetic foot disease. These include advanced age, duration of diabetes, poor glycaemic control, smoking, chronic kidney disease, peripheral arterial disease, ulcer size and duration, Wagner grade, osteomyelitis, systemic infection, nutritional status, and inflammatory markers. Among these, ulcer severity grading systems such as the Wagner classification remain widely used because they provide a simple and reproducible assessment of wound depth, infection, and gangrene, thereby facilitating treatment planning and prognostication. However, no single parameter accurately predicts outcome, and prognosis is usually determined by the interaction of multiple patient-related and disease-related factors.

Recent international guidelines advocate a multidisciplinary approach involving surgeons, endocrinologists, vascular specialists, infectious disease physicians, podiatrists, wound-care nurses, and rehabilitation teams. Early diagnosis, meticulous glycaemic control, aggressive infection management, prompt surgical debridement, vascular assessment with timely revascularization, pressure off-loading, and appropriate wound care have substantially improved limb salvage rates in specialized diabetic foot centres. Nevertheless, outcomes remain suboptimal in many low- and middle-income countries where delayed presentation, barefoot walking, limited access to specialist care, and socioeconomic constraints contribute to advanced disease at initial presentation.

In India, diabetic foot disease continues to be a common indication for admission to surgical wards. Most patients present with infected ulcers, extensive tissue necrosis, or gangrene requiring repeated debridement or amputation. Despite advances in wound care, antibiotics, and vascular interventions, the rate of major amputations remains considerable. Understanding the prognostic factors associated with limb loss and delayed healing in the Indian population is therefore essential for improving clinical decision-making and optimizing resource utilization.

The present prospective observational study was undertaken to evaluate the various clinical and laboratory prognostic factors influencing the management and outcome of diabetic foot disease in patients admitted to a tertiary care teaching hospital. Particular emphasis was placed on assessing the relationship between ulcer severity, diabetic foot type, osteomyelitis, wound characteristics, surgical procedures, healing duration, postoperative complications, and amputation. Identification of these predictors may facilitate early risk stratification, guide individualized treatment strategies, improve limb salvage rates, and ultimately reduce the burden of diabetic foot disease on patients and healthcare systems.

MATERIALS AND METHODS

Study Design and Setting

This prospective observational study was conducted in the Department of General Surgery, Index Medical College Hospital and Research Centre, Indore, Madhya Pradesh, India, after obtaining approval from the Institutional Ethics Committee. The study was carried out over the study period specified in the approved research protocol. Written informed consent was obtained from all participants before enrolment.

Study Population

The study included consecutive adult patients with diabetic foot disease admitted to the Department of General Surgery during the study period. A total of 50 patients were enrolled using consecutive sampling. Patients were evaluated clinically and managed according to institutional protocols, with treatment individualized based on ulcer severity, vascular status, infection, and general medical condition.

Inclusion Criteria

Patients fulfilling the following criteria were included:

- * Age ≥ 18 years.
- * Previously diagnosed or newly diagnosed diabetes mellitus.
- * Presence of diabetic foot ulcer, cellulitis, gangrene, abscess, osteomyelitis, or other diabetic foot lesions requiring surgical evaluation.
- * Patients willing to provide written informed consent.

Exclusion Criteria

Patients with the following conditions were excluded:

- * Foot ulcers unrelated to diabetes mellitus.
- * Acute traumatic wounds.
- * Malignant ulcers of the foot.
- * Patients with severe systemic illness precluding surgical management.
- * Patients unwilling to participate or lost before completion of evaluation.

Clinical Evaluation

A detailed history was obtained regarding age, sex, duration of diabetes, treatment received for diabetes, smoking status, hypertension, chronic kidney disease, previous foot ulcer, previous amputation, and other associated comorbidities.

General physical examination and local examination of the affected limb were performed. Particular attention was paid to:

- * Site of ulcer
- * Number of ulcers
- * Ulcer size
- * Depth of ulcer
- * Presence of callus
- * Presence of exposed tendon or bone
- * Purulent discharge
- * Cellulitis
- * Gangrene
- * Peripheral pulses
- * Foot deformity
- * Neurological status

Patients were classified according to the Wagner grading system,

which remains one of the most widely accepted methods for assessing ulcer severity.

Laboratory Investigations

The following investigations were performed in all patients:

- * Complete blood count
- * Random blood sugar
- * Fasting blood sugar
- * HbA1c
- * Renal function tests
- * Serum electrolytes
- * Serum albumin
- * Erythrocyte sedimentation rate
- * C-reactive protein
- * Wound swab culture and antibiotic sensitivity
- * Blood culture whenever clinically indicated

Radiological Investigations Included:

- * Plain X-ray of the foot
- * Doppler arterial study
- * Magnetic resonance imaging (MRI) whenever osteomyelitis or deep soft tissue infection was suspected.

Management Protocol

All patients underwent multidisciplinary management comprising:

- * Optimization of blood glucose levels using insulin therapy whenever indicated.
- * Broad-spectrum empirical antibiotics followed by culture-directed antimicrobial therapy.
- * Daily sterile wound dressing.
- * Surgical debridement whenever required.
- * Drainage of abscesses.
- * Minor amputations (toe or ray amputation) when indicated.
- * Major amputations (below-knee or above-knee amputation) in patients with non-salvageable limbs.
- * Skin grafting or secondary wound closure after adequate granulation tissue formation.
- * Patient education regarding foot care and glycaemic control before discharge.

The choice of surgical intervention depended upon vascular status, extent of infection, tissue viability, and overall clinical condition.

Outcome Measures

Primary Outcome

The primary outcome was the clinical outcome of diabetic foot disease at completion of treatment, categorized as:

- * Complete healing without amputation
- * Healing after minor amputation
- * Persistent non-healing ulcer
- * Recurrence
- * Major amputation

Secondary Outcomes

Secondary outcome measures included:

- * Duration of wound healing
- * Length of hospital stay
- * Postoperative complications
- * Osteomyelitis
- * Requirement of surgical intervention
- * Limb salvage
- * Mortality (if any)

Statistical Analysis

Data were entered into Microsoft Excel and analysed using appropriate statistical software.

Continuous variables were expressed as mean $\pm$ standard deviation (SD) or median with interquartile range (IQR) depending upon data distribution.

Categorical variables were presented as frequency and percentage.

The following statistical tests were used:

- * Shapiro-Wilk test for normality.
- * Chi-square test or Fisher's exact test for categorical variables.
- * Student's t-test or Mann-Whitney U test where appropriate.
- * Spearman's rank correlation for non-parametric variables.
- * Multivariable logistic regression to identify independent predictors of amputation.

- * Multiple linear regression for factors affecting wound-healing duration.

Ap-value <0.05 was considered statistically significant.

Ethical Considerations

The study was approved by the Institutional Ethics Committee of Index Medical College Hospital and Research Centre, Indore. All participants provided written informed consent before enrolment. Patient confidentiality was maintained throughout the study, and all procedures were conducted in accordance with the ethical principles of the Declaration of Helsinki.

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