FORMULATING A RISK FOR AMPUTATION IN PATIENTS PRESENTING WITH DIABETIC FOOT

Abstract

Background: Diabetic foot infections (DFIs) are a major cause of morbidity and lower-limb amputations. This study analyzes clinical risk factors and predictors of amputation.

This study aims to formulate evidence-based guidelines for effective diabetic foot management by applying risk-score stratification to predict amputation risk and optimize limb-salvage outcomes.

Methods: A prospective observational study on 50 diabetic patients with foot infections. Data included neuropathy, vascular status, ulcer grade, infection severity, comorbidities, HbA1c, and outcomes.

Results: Majority were aged 51–60 years (82%). Sensory neuropathy was present in 90%, motor neuropathy in 12%. Wagner Grade 4 (44%) and Grade 3 (38%) strongly predicted amputation. HbA1c >7% was seen in 82% of amputees. Deep bone ulcers were present in 46%. PAD with 30–80% vessel block was significant. Comorbidities were present in 68%.

Conclusion: Poor glycemic control, neuropathy, advanced Wagner grade, PAD, deep ulcers, and comorbidities were major predictors of amputation. Early risk stratification and intervention may reduce limb loss.

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Introduction

Diabetic foot infections (DFIs) remain one of the most severe and costly complications of diabetes mellitus worldwide. They represent a complex interplay between neuropathy, peripheral arterial disease (PAD), immunological dysfunction, and chronic hyperglycemia. The lifetime risk of a person with diabetes developing a foot ulcer is estimated to be 19–34%, and nearly 50–70% of all non-traumatic lower-limb amputations are attributed to diabetic foot complications. The global incidence of DFIs ranges between 2% and 20%, influenced by socioeconomic factors, access to care, footwear habits, glycemic control, and comorbidities.

Neuropathy contributes to unrecognized trauma, while vasculopathy limits tissue perfusion and delays healing. Superimposed infection rapidly progresses to deep-tissue involvement, osteomyelitis, sepsis, and ultimately amputation if not treated aggressively. Identifying early predictors of limb loss—such as ulcer depth, infection grade, HbA1c levels, and severity of PAD—is crucial to preventing progression to major amputation.

With India being home to nearly 77 million people with diabetes and a rising burden of rural and urban DFIs, there is a critical need to identify clinical predictors of limb loss in our population. This study was undertaken to analyze patient demographics, comorbidities, ulcer characteristics, neuropathy, vascular status, and biochemical markers as predictors of amputation in diabetic foot infections.

AIM:
To formulate guidelines for effective management of diabetic foot by applying risk score stratification to prevent inadvertent amputations.

Objectives:
To understand the risk stratification which can predict amputation of the limb among patients with diabetic foot.
To formulate guidelines for effective management to ensure limb salvage among patients with Diabetic foot based on risk stratification.

Materials and Methods

This prospective observational study was conducted in the Department of Surgery over an 18-month period and included **50 consecutive patients** diagnosed with diabetic foot infections.

Study Design

- Prospective observational cohort.
- Sample size: 50 patients meeting inclusion criteria.
- Ethical approval obtained prior to study commencement.

Inclusion Criteria

- Patients >18 years with Type 1 or Type 2 diabetes mellitus.
- Presence of a clinically infected foot ulcer.
- Willingness to participate and provide informed consent.

Exclusion Criteria

- Non-diabetic foot ulcers.
- Charcot neuroarthropathy without ulceration.
- Traumatic amputations.
- Immunosuppressive therapy or malignancy.

Data Collected

1. **Demographic Variables**
   - Age, sex, occupation, socioeconomic status.
2. **History**
   - Duration of diabetes
   - Glycemic control (HbA1c)
   - Barefoot walking habits
   - Smoking/alcohol consumption
3. **Clinical Examination**
   - Sensory neuropathy: 10g monofilament, vibration, temperature
   - Motor neuropathy: intrinsic muscle weakness, clawing, deformity
   - Vascular assessment: dorsalis pedis/posterior tibial pulses, ankle-brachial index
4. **Ulcer Evaluation**
   - Duration, location
   - Wagner grading
   - Ulcer depth
5. **Vascular Imaging**
   - Doppler ultrasound
   - Percentage of vessel block
   - Rutherford classification
6. **Laboratory Investigations**
   - CBC, ESR, CRP,RFT
   - HbA1c
7. **Comorbidities**
   - Hypertension, CKD, CAD, stroke
8. **Outcome**
   - Limb salvage vs. minor amputation vs. major amputation.

Statistical Analysis

- Descriptive statistics expressed as mean ± SD and percentages.
- Chi-square test for categorical variables.
- Logistic regression for predictors of amputation.
- p-value <0.05 considered statistically significant.
- Analysis performed using SPSS 25.0.

Results

A total of **50 patients** with diabetic foot infections were included. The majority were middle-aged to elderly males with long-standing, poorly controlled diabetes. The following sections detail the demographic, clinical, biochemical, vascular, and outcome characteristics.

1. **Age and Sex Distribution**

The study cohort predominantly consisted of patients aged **51–60 years (82%)**, followed by **61–70 years (12%)**. Only a small proportion were younger than 50. The **mean age was 55 ± 5 years**, indicating that DFIs are most frequent in the sixth decade of life. Males constituted **90%** of cases, likely reflecting outdoor activity, barefoot walking, and occupational exposure.

Table 1. Age Distribution

Age Group (years)	Frequency	Percentage
41–50	3	6%
51–60	41	82%
61–70	6	12%
Total	**50**	**100%**

2. **Duration of Diabetes**

Most patients had diabetes for more than five years, with **68%** reporting a duration ≥5 years. Long-standing hyperglycemia contributed heavily to neuropathy, PAD, and infection.

Table 2. Duration of Diabetes

Duration	Frequency	Percentage
<5 years	16	32%
≥5 years	34	68%

3. **Glycemic Control (HbA1c)**

Poor glycemic control was striking: **82% of patients had HbA1c >7%**, reflecting chronic uncontrolled diabetes. Higher HbA1c strongly correlated with ulcer depth, infection severity, and amputation rate.

Table 3. HbA1c Distribution

HbA1c Level	Frequency	Percentage
≤7%	9	18%
>7%	41	82%

4. **Neuropathy Profile**

4.1 Sensory Neuropathy

Sensory neuropathy was present in **90%** of cases. Loss of protective sensation predisposed to unrecognized trauma and plantar ulcers.

4.2 Motor Neuropathy

Motor neuropathy was seen in **12%**, associated with muscle wasting, imbalance, and foot deformities.

Table 4. Neuropathy Distribution

Parameter	Present	Percentage
Sensory Neuropathy	45	90%
Motor Neuropathy	6	12%

5. **Footwear & Barefoot Walking Habits**

Nearly **76%** of patients frequently walked barefoot, especially in rural settings. This was strongly associated with traumatic ulcers, foreign body penetration, and subsequent infection.

Table 5. Barefoot Walking

Habit	Frequency	Percentage
Yes	38	76%
No	12	24%

6. **Comorbidities**

A total of **68%** of patients had at least one comorbidity. Hypertension and chronic kidney disease (CKD) were the most common. CKD significantly increased the risk of major amputation.

Table 6. Comorbidity Distribution

Comorbidity	Frequency	Percentage
Hypertension	24	48%
CKD	16	32%
CAD	8	16%
Stroke	4	8%
None	16	32%

7. **Wagner Ulcer Grading:** The majority of patients presented with advanced ulcer grades, indicating late presentation.

- **Wagner Grade 4:** 44%
- **Wagner Grade 3:** 38%
- **Wagner Grade 2 or lower:** 18%

Higher Wagner grades were strongly predictive of amputation.

Table 7. Wagner Grade

Grade	Frequency	Percentage
1	3	6%
2	6	12%
3	19	38%
4	22	44%

8. Ulcer Depth & Bone Involvement

Deep ulcers involving bone (osteomyelitis) were present in **46%** of patients. These cases had the highest amputation rates.

Table 8. Ulcer Depth

Depth	Frequency	Percentage
Soft tissue only	27	54%
Bone involvement	23	46%

9. Vascular Assessment

Vessel Block Percentage

Peripheral arterial disease was highly prevalent:

- 30–60% stenosis in **52%**
- 61–80% stenosis in **36%**
- 80% stenosis in **6%**

Rutherford Classification

Most patients fell between **Rutherford Grade 3–4**, representing moderate to severe ischemia.

Table 9. Vessel Block

Vessel Block (%)	Frequency	Percentage
<30%	3	6%
30–60%	26	52%
61–80%	18	36%
>80%	3	6%

10. Amputation Outcomes

Of the 50 patients:

- **20 (40%)** underwent **major amputation**
- **14 (28%)** underwent **minor amputation**
- **16 (32%)** achieved limb salvage

Major amputation strongly correlated with:

- HbA1c >7%
- Wagner grade 3/4
- Bone involvement
- Vessel block >60%
- Comorbidities (CKD, hypertension)
- Sensory neuropathy

Table 10. Outcomes

Outcome	Frequency	Percentage
Limb Salvage	16	32%
Minor Amputation	14	28%
Major Amputation	20	40%

Diabetic foot infections represent a complex interplay between neuropathy, vasculopathy, impaired immunity, and chronic hyperglycemia. The present study evaluated key clinical predictors of limb loss among 50 diabetic patients and identified several significant risk factors including poor glycemic control, sensory neuropathy, higher Wagner grade, PAD, and presence of comorbidities.

In the present study, the mean age was 55 ± 5 years, consistent with global trends showing that diabetic foot complications peak in the fifth and sixth decades of life. This age group also tends to have longer duration of diabetes and cumulative end-organ damage. The study sample was predominantly male (90%), similar to findings by Shatnawi et al. and Boulton et al., who reported male predominance due to increased outdoor work, barefoot walking, and higher exposure to foot trauma.

Neuropathy was highly prevalent: 90% had sensory neuropathy, which aligns with the literature showing neuropathy as the strongest initiating factor in ulcer formation. Sensory loss leads to unrecognized trauma, while motor neuropathy contributes to muscle imbalance and foot deformities, increasing focal pressure points. These findings mirror those of Tesfaye et al. (NEJM), who emphasized neuropathy as an independent risk factor for ulcer progression.

Ulcer severity was an important determinant of outcome. In this cohort, 82% of patients had Wagner Grade 3 or 4 ulcers, indicating deep tissue or gangrenous involvement. Higher Wagner grades were strongly associated with amputation. Similar observations were made in studies by Lavery et al. and Shettigar et al., who noted that Grade ≥3 ulcers have significantly poor healing potential without aggressive surgical intervention.

Ulcer depth and bone involvement were critical predictors of amputation. Nearly 46% of patients had deep ulcers with osteomyelitis. This parallels findings by Mutihir et al. and Jeffcoate et al., who reported that bone involvement increases amputation risk by 3–5 times due to chronic infection, biofilm formation, and poor antibiotic penetration.

Glycemic control, assessed by HbA1c, emerged as a major predictor. In this study, 82% of patients had HbA1c >7%, and most major amputations occurred in this group. Poor glycemic control impairs neutrophil activity, angiogenesis, collagen deposition, and macrophage function. Shatnawi et al. found that HbA1c >7.5% significantly increases the risk of both minor and major amputation.

Peripheral arterial disease (PAD) was prevalent, with over half of the patients showing 30–60% stenosis, and 36% showing 61–80% stenosis. PAD contributes to tissue ischemia, delayed healing, and gangrene. Studies by Prompers et al. and Hinchliffe et al. have identified PAD as the strongest predictor of non-healing ulcers and major limb loss. The Rutherford grading in this study also showed that patients with Grade 3 or 4 ischemia were more likely to undergo amputation.

Comorbidities, including hypertension (48%), CKD (32%), and CAD (16%), significantly influenced outcomes. CKD, in particular, is known to exacerbate vascular calcification, impair immunity, and reduce tissue perfusion, all of which contribute to higher amputation rates. These findings align with Lavery et al., who identified CKD as an independent risk factor for major limb loss.

Barefoot walking, seen in 76% of cases, remains a major cultural and socioeconomic risk factor in India. Walking without protective footwear leads to repeated trauma, foreign body injuries, and late presentation—consistent with Indian studies by Bansal et al. and Ramachandran et al.

Overall, the present study findings are highly consistent with global evidence. The combination of neuropathy, ischemia, infection, and metabolic dysfunction forms a "pathogenic triad" that accelerates progression to major amputation. Early detection, aggressive wound care, vascular assessment, infection control, and optimized glycemic management remain essential to preventing limb loss.

CONCLUSION

Diabetic foot infections continue to be a major cause of morbidity and lower-limb amputations. This study highlights the most significant predictors of amputation:

- Sensory neuropathy (90%) predisposed to trauma and ulceration.
- High HbA1c (>7%) was strongly correlated with amputation risk.
- Advanced Wagner grades (≥3) were powerful predictors of limb loss.
- Deep ulceration with bone involvement significantly increased the likelihood of amputation.
- Peripheral arterial disease, particularly stenosis >60%, was associated with poor wound healing and higher amputation rates.
- Comorbidities such as hypertension and CKD compounded the severity and contributed to poor outcomes.

These findings underscore the need for early risk stratification and multidisciplinary diabetic foot care. Improving glycemic control, screening for neuropathy and PAD, education regarding protective footwear, and timely surgical intervention can significantly reduce the incidence of amputations. Strengthening diabetic foot clinics, particularly in rural regions, is essential to improving limb salvage outcomes and reducing healthcare burden.

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