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Predictive Factors for Lower Extremity Amputation in Diabetic Foot Patients: A Prospective Observational Study

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Abstract: ***Background**: Diabetic foot ulcers (DFUs) are a frequent and severe complication of diabetes mellitus, often resulting in lower extremity amputation (LEA). Early identification of risk factors can mitigate this outcome. **Objectives**: To evaluate the predictive significance of clinical, laboratory, and microbial factors associated with LEA in patients with DFUs. **Methods**: A prospective observational study was conducted at ASRAM Medical College, Eluru, over 24 months (July 2022–June 2024). A total of 150 diabetic foot patients were enrolled and analyzed based on clinical history, examination, ABI, lab values (Hb, WBC, CRP, LDL), and microbiological culture. **Results**: Out of 150 patients, 64 (42.6%) underwent amputation. Factors significantly associated with LEA included presence of gangrene (100%), absent distal pulses (100%), ABI <0.3 (96.8%), osteomyelitis (100%), Hb <10 g/dL (62.5%), elevated WBC (>10,000/mm³), CRP >10 mg/L (93.7%), LDL >100 mg/dL (68.7%), and antibiotic-resistant infections (28%). **Conclusion**: LEA in diabetic foot is strongly associated with vascular insufficiency, infection, anemia, and inflammatory markers. Early identification of these risk factors is crucial in preventing progression to amputation.*

Keywords: Gangrene, vascular insufficiency, osteomyelitis, inflammatory markers, antibiotic resistance.

1. Introduction

The prevalence of diabetes mellitus continues to rise globally, with India alone accounting for over 65 million cases . Diabetic foot ulcers are a leading cause of non-traumatic lower extremity amputations, with up to 24% of ulcers requiring surgical intervention. The prognosis post-amputation remains poor, with a 5-year survival rate of only 59% . Therefore, understanding and mitigating the risk factors associated with LEA is critical.

2. Review of Literature

Several studies have explored predictors of amputation in diabetic foot. Aziz et al. (2011) found polymicrobial infections and osteomyelitis to be significant. Kristy Pickwell et al. (2015) identified elevated CRP, deep ulcer, and periwound edema as independent risk factors. Lin et al. (2020), in a meta-analysis, reported male sex, smoking, low BMI, and gangrene as major predictors.

3. Materials and Methods

Study Design: Prospective observational study
Study Period: July 2022 to June 2024

Study area: Department of General Surgery, ASRAM Medical College and General Hospital, Eluru

Sample Size: 150 patients

Inclusion Criteria: Diabetic foot patients ≥18 years with confirmed infection or ulcer

Exclusion Criteria: Non-diabetic ulcers, immunocompromised patients

Investigations included:
- Blood tests: Hb, WBC, CRP, LDL, HbA1c
- Imaging: X-ray, MRI, Doppler
- ABI measurement
- Tissue cultures for microbiology and sensitivity testing

Statistical Tools: Epi Info v26; Chi-square and t-test; $p<0.05$ was significant.

4. Results

Age and Gender Distribution
Majority of patients were aged 56–65. Males were more commonly affected, but gender was not statistically significant.

Table 1: Age Distribution

Age Group	Conservative	Amputation
35–45	16	10
46–55	29	21
56–65	36	25
>65	5	8

Duration of Diabetes and Amputation: Longer diabetes duration (>5 years) was significantly associated with amputation ($p<0.05$).

Table 2: Duration vs. Amputation

Duration	Amputation (%)
<3 yrs	3
3–5 yrs	21
>5 yrs	40

Risk Factor

Risk Factor	Amputation Rate	Statistical Significance
Gangrene	100%	$p < 0.05$
Absent distal pulses	100%	$p < 0.05$
ABI < 0.3	96.8%	$p < 0.05$
Osteomyelitis	100%	$p < 0.05$
Hb <10 g/dL	62.5%	$p < 0.05$
WBC >10,000	71.8%	$p < 0.05$
CRP >10 mg/L	93.7%	$p < 0.05$
LDL >100 mg/dL	68.7%	$p < 0.05$
Antibiotic resistance	28.1%	$p < 0.05$

Microbiological Findings

- Most common organisms: *Staphylococcus aureus*, *Klebsiella*, *E. coli*, *Pseudomonas*, *Proteus*
- Antibiotic-resistant strains were more likely to lead to amputation ($p<0.05$)

Ulcer Grading and ABI

Using the Wagner classification:

- All Grade 4 and Grade 5 ulcers led to LEA.
- Grade 2 ulcers were mostly managed conservatively.

ABI Findings:

a) ABI <0.3 = 100% amputation
b) ABI 0.3-0. U = mixed outcome
c) ABI >0. U = all conservtively managed
d) Laboratory Markers
   - Hemoglobin: Amputation in 62.5% of patients with Hb <10 g/dL
   - CRP >10 mg/L: Strong predictor of poor healing and progression
   - WBC >10,000/mm³: Correlated with infection and amputation
   - LDL >100 mg/dL: Contributed to atherosclerosis and ischemia

5. Discussion

Highest number of cases were found in the age group of 56-65 years. Of the 99 males 45 underwent amputation and 54 were managed conservatively. Among the 51 females 19 underwent amputation where as the rest of 32 were treated conservatively. Majority of the patients who underwent minor or major amputations had been suffering from diabetes since 3-5 years,100% of patients with presence of gangrene ended up in minor or major amputation. 100 % of patients with absent pulse went for amputation. All patients with confirmed osteomyelitis underwent amputation. Common organisms obtained from ulcer samples are Staphylococcus aureus, Klebsiella, Pseudomonas, E.coli and Proteus.18 cases which reported antibiotic resistant organisms ended up in amputation, very strong correlation between grade 4 and 5 ulcers and amputation. patients who had an ABPI recording below 0.3 undewent amputations. Amputation chances increases with fall in haemoglobin < 10gm%. Total WBC count reflects the rate of wound infection, and hence amputation rate tends to increases with increase in total WBC. Inflammatory markers like CRP are a reliable indicator of amputation chances.

> High levels of LDL have been shown to be independent risk factors for foot ulcers, which can delay wound healing and result in amputation. The study reinforces previous findings highlighting gangrene, ischemia, infection, and inflammation as leading predictors for amputation. Peripheral arterial disease, often diagnosed via ABI, was a major contributor. ABI <0.3 had the highest amputation rate. This is in line with Gong et al. (2023), who emphasized the prognostic value of ABI.

Microbial infections with resistant strains resulted in worse outcomes, highlighting the importance of early and appropriate antibiotic therapy. Elevated CRP and WBC supported the role of systemic inflammation. These biomarkers, as shown by Lin et al. (2020) and Premalatha et al. (2023), can help stratify patients by risk.

Nutritional markers like hemoglobin and LDL also played crucial roles. Anemia reduces oxygen delivery, impairing healing; high LDL contributes to atherosclerosis, worsening ischemia.

6. Conclusion

Key Predictors of Amputation:

1) Presence of gangrene
2) Absent distal pulses
3) ABI <0.3
4) Osteomyelitis
5) Hb <10 g/dL
6) Elevated WBC, CRP
7) LDL >100 mg/dL
8) Antibiotic resistance

Clinical Implication:

Routine use of ABI, CRP, and basic lab tests, combined with early detection of infections, drastically reduce LEA incidence in diabetic foot patients.

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