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A Prospective Study to Determine the Effects of Ulcer Size, Ulcer Age, Duration of Diabetes, Glycaemic Control, Infection, Lower Limb Ischemia and Neuropathy on Outcome of Diabetic Foot Ulcer

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Abstract: ***Background**: India is projected to become the diabetic capital of the world, placing a heavy burden on healthcare resources. A majority of diabetic patients develop foot ulcers during their course of illness. The foot is highly vulnerable to injury and infection, and is the primary site for neuropathy and ischaemia. Ulcers increase the risk of progression, often leading to amputation—85% of amputations are preceded by ulcers. However, up to 40% of amputations are preventable with proper wound care. **Methodology**: This prospective observational study was conducted at Hi-Tech Medical College & Hospital, Bhubaneswar from March 2023 to January 2025. It included diabetic foot ulcer patients from the Departments of General Surgery and Plastic Surgery. Patients were enrolled through random sampling, and clinical, demographic, and laboratory data were collected. Diagnosis was based on clinical signs and elevated blood sugar levels. **Result & Conclusion**: The study included 75 patients (52 males, 23 females), mostly in their 40s to 60s. Ulcers were most commonly found on the plantar aspect (66.7%), followed by the dorsum (30.7%). Most ulcers were Grade II (56%) and Grade III (34.7%), with fewer cases in Grades I, IV, and V. Statistical analysis showed significance (Z=3.02; p=0.0025).*

Keywords: Diabetes, Diabetic foot ulcer, ulcer, amputation, neuropathy, vasculopathy

1. Introduction

India has the dubious distinction of becoming the diabetic capital of the world within the next few years; with its attendant complications it is going to burden the resources of the country. A significant number of such patients will require long-term hospital treatment and amputations. The etiopathogenesis of diabetic foot lesions are multifactorial. Diabetic neuropathies, vasculopathy, poor control of diabetes and bacterial infection are some of them. According to Modi et al., overall incidence of diabetics in India is 1.2%. The death in each year is due to its complications (2.1% in urban, 1.5% in rural), which are usually common in age group of 40 – 60 years affecting both sexes equally. The complications are more prevalent among the people of lower economic status due to negligence, illiteracy and poverty. The number of people with diabetes mellitus was estimated to be 131 million in the year 2000, it is projected to increase to 366 million till 2030. Previous studies have shown that diabetic patients have 25% lifetime risk of development of ulcer. The annual incidence of diabetic foot ulcer in India is approximately 3% and reported incidence in US and UK studies ranges as high as 10%. A possible reason is younger age of onset and shorter duration of diabetes. Frequent complication of diabetes mellitus is foot infection. This affects 12% of patients with diabetes mellitus and remains one of the leading reason for the patient's morbidity. If neglected, patient may lose his foot and also his life. Treatment includes thorough wound management, good microbiological control using appropriate antibiotics and strict glycaemic control. Many recent approaches like vacuum dressing, platelet derived growth factors, larval therapy have revolutionized the management of diabetic foot. Hence the present study has been undertaken to evaluate the predisposing factors, modes of presentation and management protocols in diabetic foot**.**

2. Materials and Methods

1) **Study Area**: Hi- Tech Medical College & Hospital, Bhubaneswar
2) **Study Duration**: March 2023 to January 2025
3) **Study Population**: Study population was divided based on patients managed conservatively and those requiring major and minor amputations.
4) **Study Setting**: This study was conducted in the Department of Surgery, Hi-Tech Medical College and Hospital, BBSR in collaboration with the Department of Plastic Surgery. Patients attending the General Surgery OPD who met the inclusion criteria were included in the study.
5) **Inclusion Criteria:** A) Age- 18 - 65 years patients B) Non pregnant C) Type 2 diabetes mellitus patients attending Surgery outdoor or admitted in gangrene ward of department of General Surgery.
6) **Exclusion Criteria:** A) Type 1 diabetes mellitus B) Secondary diabetes C) Gestational diabetes mellitus D) Patients not agreeing to be part of study

Parameters Studied:

- Fasting blood sugar (FBS)
- Post-prandial blood sugar (PPBS)
- Glycosylated haemoglobin (HbA1c)
- Lipid Profile
- Culture from wound bed
- Ankle-brachial pressure index for ischaemia.
- Colour Doppler study of lower limb (selected cases).
- NCV assessment for neuropathy (selected cases).

Scoring System for Diabetic Neuropathy:

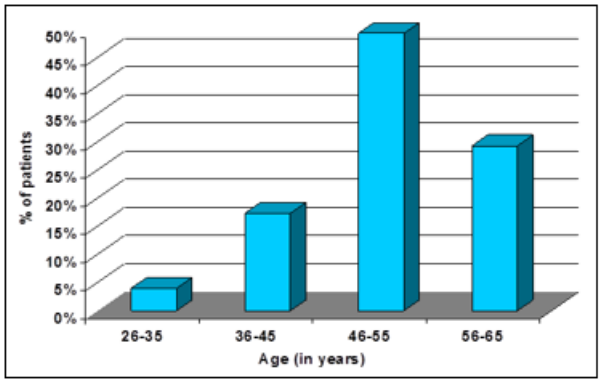
- **Stage 0**: (No neuropathy) No symptoms and fewer than 2 abnormalities on testing
- **Stage I:** No symptoms, but 2 or more abnormalities of functional testing.
- **Stage II:** Symptoms of lesser degree than state III along with 2 or more functional abnormalities
- **Stage III:** (Disabling neuropathy) Disabling symptoms and 2 or more functional abnormalities.

The functional tests done are:

- Nerve conduction
- Neurologic examination
- Quantitative nerve testing of muscle strength
- Threshold of vibratory, cooling or warming sensation
- Autonomic function

3. Results & Analysis

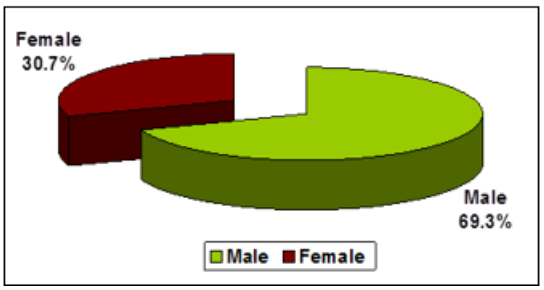
Sample size has been calculated with help of Epi Info (TM) 3.5.3. EPI
INFO which is a trademark of the Centres for Disease Control and Prevention (CDC).



Graph 1: Age Distribution

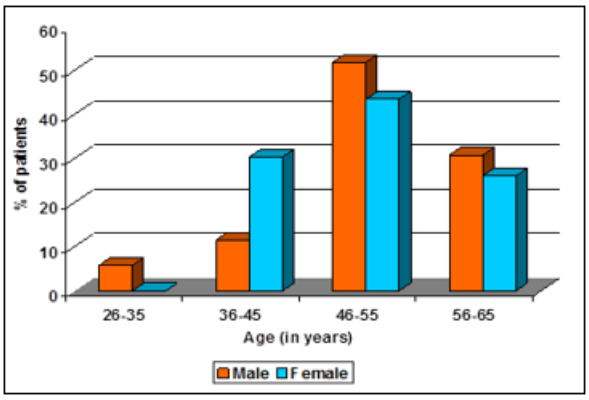
The mean (mean ± s.d.) age of the patients was 51.42±8.49 years with range 28-65 years and the median age was 50.0 years.

Test of proportion showed that the proportion of the patients with age between 46-55 years (39.0%) was significantly higher (Z=2.89; p=0.0039). Only 4.0% of the patients were with age<35 years.

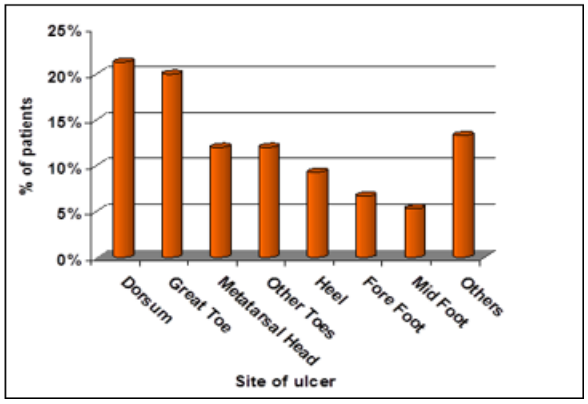


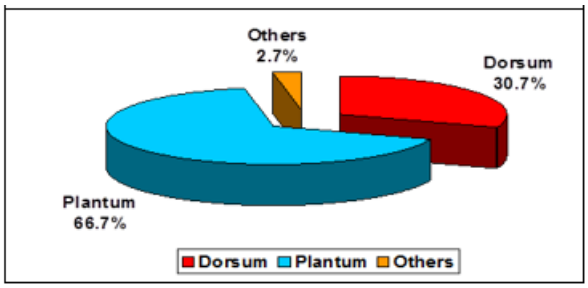
Graph 2: Gender Distribution

Test of proportion showed that proportion of males 52(69.30%) was significantly higher than that of females 23(30.7%) (Z=5.45; p=0.0001).

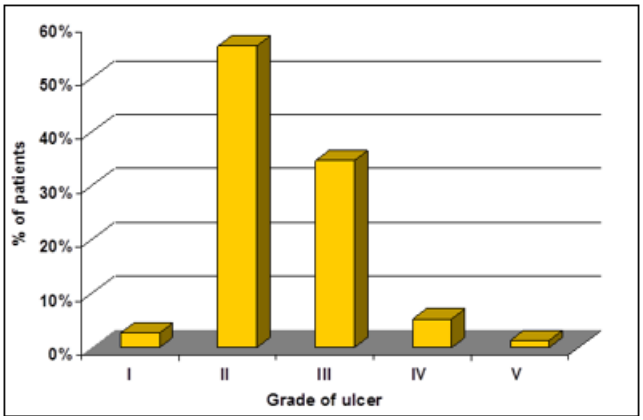


Graph 3: Age and Gender Distribution

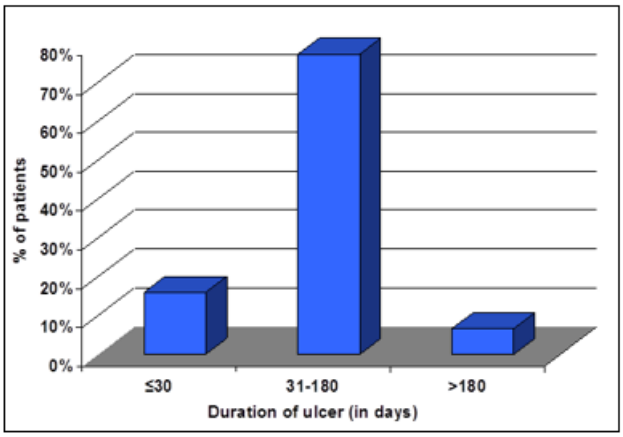




Graph 4, 5: Distribution of site of ulcer

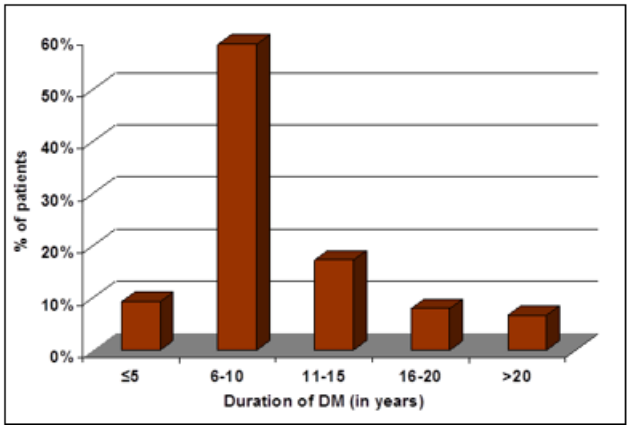


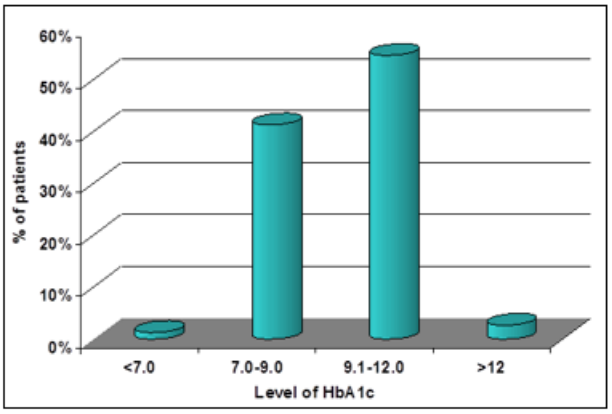
Graph 6: Distribution of grade of ulcer



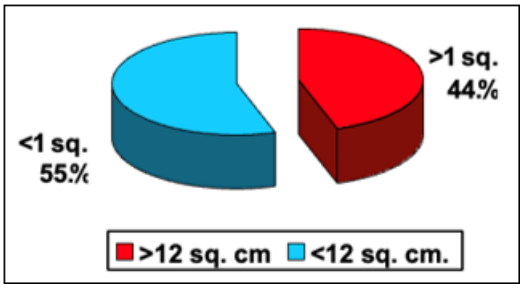
Graph 7: Distribution of duration of ulcer

Table 8: Distribution of duration of DM

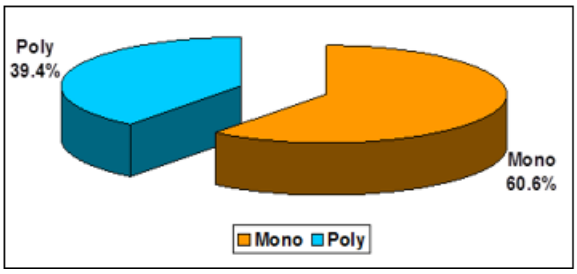




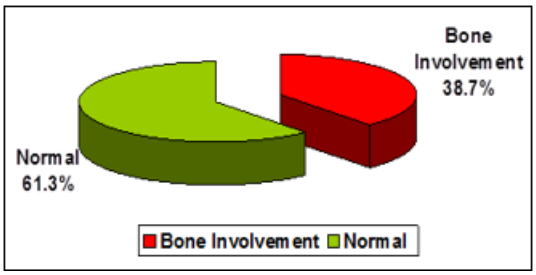
Graph 9: Distribution of level of HbA1c



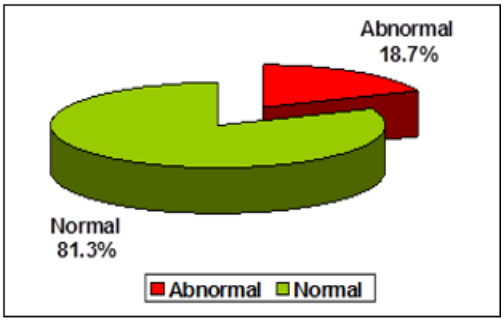
Graph 10: Distribution of size of ulcer



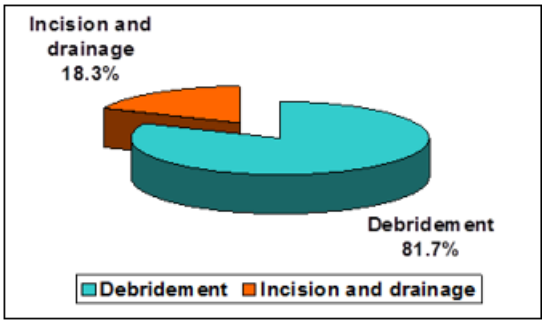
Graph 11: Distribution of type of CS



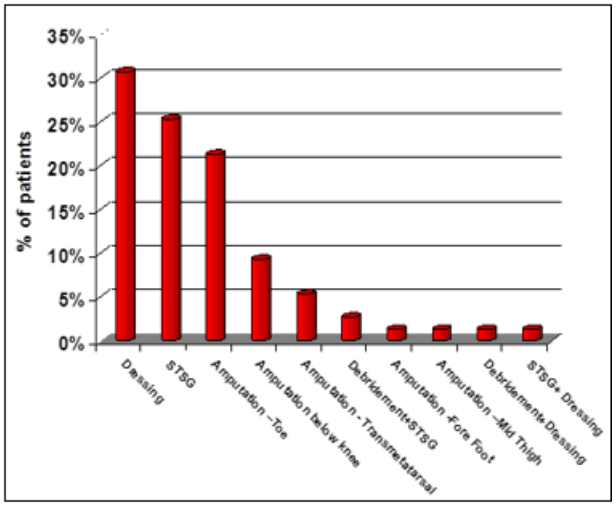
Graph 12: Distribution of findings of X-ray



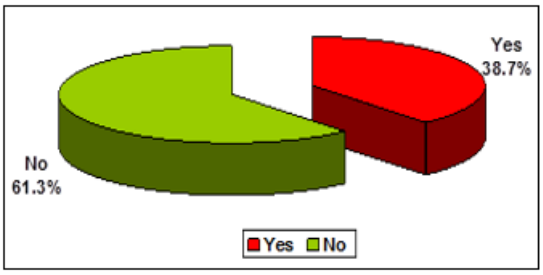
Graph 13: Distribution of ABPI



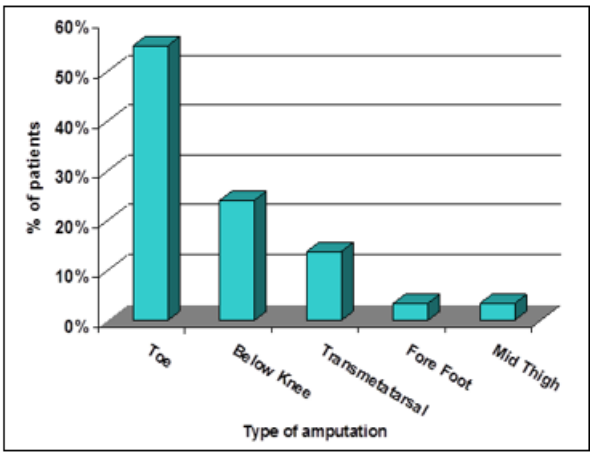
Graph 14: Distribution of Treatment



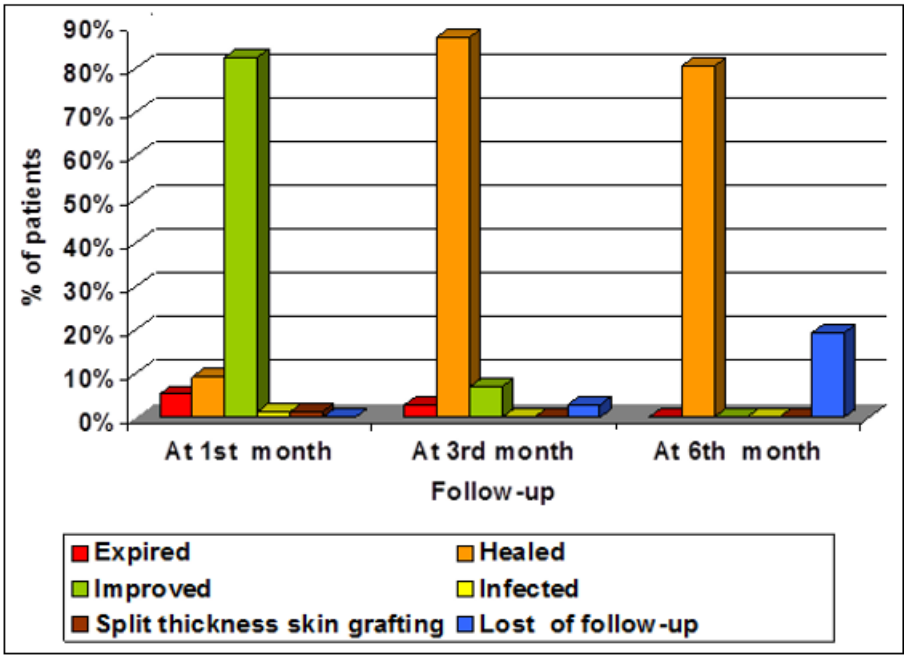
Graph 15: Distribution of Outcome



Graph 16: Distribution of Outcome (Amputation)



Graph 17: Distribution of type of amputation



Graph 18: Distribution of status at different follow-up

4. Discussion

Foot infections are a common and serious complication of diabetes mellitus, a condition involving metabolic, vascular, and neuropathic factors. Diabetic patients have a 25% lifetime risk of developing ulcers, and up to 50% of amputations can be prevented through patient education.

In this study, 75 patients were evaluated between September 1, 2022, and June 30, 2024. The mean age was 51.42±8.49 years (range: 28–65), with no significant association between age and amputation, though those >50 had a 1.3 times higher risk. Males (69.3%) outnumbered females (30.7%), likely due to greater exposure to trauma; however, gender was not significantly associated with amputation.

Right-sided ulcers were more common (60%), with only 4% having bilateral ulcers. Ulcers were most frequent on the dorsum (21.3%) and great toe (20.0%), more often on the plantar aspect.

The mean ulcer size was 21.60±24.19 sq. cm (range: 1–130), median 12.0 sq. cm. Size was not significantly linked to amputation, though larger ulcers (>12 sq. cm) had a 1.19 times higher risk. The mean ulcer duration was 100.53±71.34 days (median: 90), with most lasting 1–6 months—duration showed no association with amputation.

The mean diabetes duration was 11.04±5.34 years (90.7% had >5 years), and mean HbA1c was 9.37±1.23 (range: 6.5–12.8), with no significant link to amputation (p=0.86), though poor glycaemic control was common in amputees.

Ischemic ulcers (10.7%) and abnormal Doppler findings (18.7%) were significantly associated with amputation. Ischemic ulcers increased amputation risk 14.31 times, and abnormal Doppler findings increased it 15.52 times.

Infection was present in 66/75 cases; 60.6% were monomicrobial, 39.4% polymicrobial. *Staphylococcus aureus* was the most common pathogen. Microbial type had no significant association with amputation.

Of the 75 patients, 29 underwent amputation (21 minor, 8 major). All patients who died had undergone amputation, mostly below-knee. Patients were followed for up to 6

months. Four died in the first month (remaining: 71), two died and two were lost to follow-up by the third month (final: 67). Those lost to follow-up had healed ulcers at previous visits.

5. Conclusion

Most patients were aged 46–55 years. Male cases outnumbered females, likely due to greater exposure to trauma from outdoor activities. Ulcers were more common on the plantar aspect, particularly the great toe. The most frequent ulcer type by Texas classification was 2B, though detailed subclassification wasn't done. Most ulcers were Wagner grade II, with amputation risk increasing with ulcer grade.

Amputation risk was higher in patients with diabetes duration >10 years and poor glycemic control. Neuropathy was the most common risk factor for diabetic foot ulcers. Although fewer patients had ischemia, it showed a strong association with amputation. Osteomyelitis also increased amputation risk.

Staphylococcus aureus was the most common pathogen, and polymicrobial infections further increased amputation risk. Ulcer size >12 sq. cm and duration of 1–6 months were common but not independent risk factors for amputation.

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