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Clinical Profile, Risk Factors and Treatment Outcomes of Diabetic Foot Ulcers: A Prospective Observational Study from a Tertiary Care Teaching Hospital

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Abstract:

- ***Background:***
  Diabetic foot ulcer (DFU) is a serious diabetic complication that often leads to prolonged hospitalization, increased morbidity, and lower limb amputation. It is essential to identify and manage the risk factors associated with the condition.

- ***Aim:***
  To assess the prevalence and management of associated risk factors of DFU in a tertiary care teaching hospital.

- ***Methods:***
  A prospective observational study was conducted in the Department of Surgery, Government Medical College and Hospital, Cuddalore from December 2024 to May 2025. Sixty patients diagnosed with DFU were included in the study based on the eligibility criteria. The study gathered information on the prevalence and management of associated risk factors and analyzed the correlation between patient demographics, clinical presentation, laboratory investigations, and treatment outcomes. The data were analyzed using a structured proforma, and the severity of the ulcer was categorized using the Meggitt–Wagner classification. Descriptive, inferential, and multivariate logistic regression statistical tests were employed to reveal associations and risk factors.

- ***Results:***
  The highest prevalence of DFU was recorded among patients aged 56–60 years (33.3%), and the majority of the study population were males (61.7%). Patients with a longer duration of diabetes, smokers, and those with poor glycemic control were highly likely to present with severe DFU, prolonged healing time, and extended length of hospitalization ($p<0.05$). Higher grades of DFU (≥3) were significantly associated with surgical intervention ($p<0.001$). Combined medical and surgical management had a significant association with positive patient outcome ($p=0.041$). The multivariate logistic regression analysis revealed that higher grades of DFU (≥3) (OR=4.5) and poor glycemic control (OR=3.1) were significant predictors of poor patient outcome.

- ***Conclusion:***
  The study concluded that higher grades of DFU, prolonged duration of diabetes, smoking, and poor glycemic control significantly contributed to poor patient outcome. The study recommends early diagnosis, intervention, and combined medical and surgical management to improve the patient outcome. It also suggests the need for multicentric studies to confirm the results.

Keywords: *Diabetic Foot Ulcer, Diabetes Mellitus, Risk Factors, Wound Healing, Meggitt-Wagner Classification, Glycemic Control.*

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I. INTRODUCTION

Diabetes mellitus is one of the most prevalent non-communicable diseases (NCDs) worldwide, with approximately 537 million adults living with diabetes, and it is projected to rise to 643 million by 2030.[1] Diabetes mellitus (DM) is a chronic metabolic disorder characterized by hyperglycemia due to absolute or relative deficiency in insulin secretion and/or action.[2,3] Diabetic foot ulcer (DFU) is one of the severe and debilitating DM-related complications associated with prolonged hospitalization, lower limb amputation, increased healthcare expenditure, and poor quality of life.[4,5,6]

The prevalence of DFU is estimated to be 15–34% over a patient's lifetime, and the risk of recurrence is high despite adequate treatment and preventive measures.[6] In developing countries like India, poor healthcare-seeking behavior, lack of proper diabetic foot care knowledge, poor glycemic control, and other socio-economic factors contribute to the development and poor clinical outcome of DFU.[5] The International Working Group on the Diabetic Foot (IWGDF) classifies DFU as ulceration, infection, or destruction of foot tissues in patients with DM.[11]

DFU can be diagnosed through history and physical examination. Common clinical features include loss of sensation and anhidrosis suggestive of neuropathy and intermittent claudication or rest pain associated with vascular disease.[12] Laboratory investigations include routine blood tests, imaging (X-ray and MRI), vascular studies, and ankle-brachial pressure index (<0.9 is indicative of ischemia).

Table 1 Clinical Assessment of DFU

Sensory Examination	Vascular Examination	Deformity	Ulcer Examination
Vibratory perception: 128 Hz tuning fork or electronic tuning fork	Pedal pulses: dorsalis pedis, posterior tibial, perforating peroneal	Bunions, hammertoes, bone spurs, plantarflexed metatarsals, pes cavus foot type	Area, toe, metatarsal forefoot, lateral, medial
Achilles reflex	Erythema or cyanosis	Hallux limitus, Achilles/gastro equinus, overpronation	Ischemic or neuropathic or mixed
Monofilament test 10-point touch	Intermittent claudication score	Rocker bottom appearance	Small <10 cm, moderate 11–40 cm, severe >40 cm
Vibration perception threshold (VPT)	Temperature comparison between feet	Prior amputation	Cool with absent pulses
Temperature sensation	Dry skin and fissuring	Gait evaluation	Depth; probe test
Pain sensation	Vascular Doppler ultrasonography	Foot drop, atrophy, necrobiosis lipoidica diabeticorum	Healing or nonhealing (inflammatory or granulating epithelialization)

DFU is a multi-factorial complication of DM caused by peripheral neuropathy, peripheral arterial disease, repeated trauma, foot deformities, increased plantar pressure, smoking, and poor glycemic control.[12] Chronic hyperglycaemia reduces host defense mechanisms, impairs collagen synthesis, and delays wound healing, thereby increasing the susceptibility to infections and non-healing ulcers. On the other hand, peripheral arterial disease decreases tissue perfusion and oxygenation, predisposing the patients to severe infection, osteomyelitis, and non-healing ulcers if not managed appropriately.[2,13,14]

Edmon classifies DFU into two broad categories: Neuropathic and neuro-ischemic ulcers (Table 1).[12]

Table 2 Edmon Classification of DFU

CLINICAL FEATURES	NEUROPATHIC ULCERS	NEURO-ISCHEMIC ULCERS
Circulation	Well perfused Warm foot	Poorly perfused Cold foot
Pedal pulses	Palpable	Absent or diminished
Skin characteristics	Dry and cracked No hair loss	Thin, shiny Hairless Prone to atropy
Location	Plantar surface Metatarsal heads	Margins / edges of foot Tips of toes Back of heal
Neurological status	Loss of sensation	Neuropathy present
Pain	Painless	Painful
Callus formation	Thick callus	Absent or minimal

Several classification systems have been proposed for DFU; however, Meggitt–Wagner classification is the most commonly used system due to its simplicity and applicability in clinical practice.[11] Management of DFU requires a multidisciplinary approach, including strict blood glucose control, appropriate wound management, offloading of the affected limb, antibiotic administration, vascular evaluation, and surgical intervention when necessary.[7,14,17]

Table 3 Meggitt–Wagner Classification

GRADE	ULCER DEPTH
0	Pre-ulcerative area without open lesion
1	Superficial ulcer (partial/full thickness

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2	Ulcer creeps into tendon, capsule and bone
3	Stage 2 with access, osteomyelitis and sepsis
4	Localized gangrene
5	Global foot gangrene

DFI management requires accurate diagnosis, microbiological evaluation, appropriate antibiotic administration, and timely surgical intervention if required.[17] A multi-disciplinary approach is essential in the management of DFIs, including physicians, surgeons, and radiologists.[7] Core management principles include patient education, glycemic control, wound care, debridement, offloading, and revascularization.[14] Wound assessment and dressing, along with the application of appropriate pressure-relieving devices, are essential components of DFU management. Debridement (surgical, enzymatic, or autolytic) helps remove necrotic tissues, facilitating the healing process. In addition, negative pressure wound therapy accelerates the healing of DFUs.[12]

Antibiotic therapy should be guided by wound culture and sensitivity results; however, mild infections may be managed with narrow-spectrum antibiotics, whereas severe infections require broad-spectrum antibiotics Infectious Diseases Society of America.[11] Surgical intervention may involve debridement of necrotic tissues and amputation in severe cases. Revascularization procedures are also indicated in patients with peripheral arterial disease.[12] The management of DFUs is often hindered by late presentation, poor patient compliance, lack of resources, and antibiotic resistance.[4,13]

DFU prevention measures include early screening and identification of DFU, strict glycemic control, and patient education on foot care and the importance of appropriate footwear.[18,19] Despite the remarkable progress in the diagnosis and management of DFU, it is still associated with high morbidity, prolonged hospitalization, and amputation rates, especially in low-and-middle-income countries.[10,15]

A better understanding of patient demographics, risk factors, and management practices is essential to develop effective interventions for DFUs. Hence, this study aimed to determine the prevalence and management of DFUs and associated risk factors among patients admitted to the Department of Surgery, Government Medical College and Hospital, Cuddalore.

II. METHODOLOGY

➢ *Study Site and Period:*

The study was conducted in the Department of Surgery, Government Medical College and Hospital, Cuddalore, a 1250-bed tertiary care teaching hospital in Chidambaram, South India. The study was conducted over six months, from December 2024 to May 2025.

➢ *Study Design:*

A prospective observational study was conducted to determine the prevalence, management, and risk factors of DFU.

➢ *Study Population and Sampling:*

The study population comprised patients diagnosed with DFU and admitted to the hospital's surgical wards. The participants were selected using consecutive sampling based on inclusion and exclusion criteria.

➢ *Inclusion Criteria:*

- Aged ≥18 years
- Diagnosed with diabetes mellitus
- Presented with DFU
- Willing to give informed consent

➢ *Exclusion Criteria*

- Non-diabetic ulcers
- Patients without diabetes mellitus
- Pregnant and lactating women
- Patients unwilling or unable to give consent

➢ *Sample Size Determination*

The sample size was calculated using the following formula for single proportion:

- Confidence level: 90% (Z = 1.645)
- Margin of error: 10%
- Estimated prevalence: 30%
- This resulted in a minimum sample size of 57 participants.

➢ *Data Collection Procedure*

After obtaining informed consent from the study participants, data were collected using a structured and pre-validated proforma. The following information was gathered:

- Demographic data: age and gender
- Clinical data: duration of diabetes and co-morbidities
- Lifestyle: smoking and alcohol consumption
- Anthropometric data: body mass index
- Laboratory data: HbA1c levels and blood glucose levels
- Ulcer data: location, size, and severity

The Meggitt–Wagner classification was used to determine the severity of the ulcer.

➢ *Risk Factor Assessment*

The study assessed both modifiable and non-modifiable risk factors:

- Modifiable risk factors: smoking, glycemic control, and BMI
- Non-modifiable risk factors: age, gender, and duration of diabetes

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➢ *Treatment and Outcome Measures*

The study documented the management practices undertaken for DFU:

- Conservative (medical) management: glycemic control, antibiotic administration, and wound care
- Surgical management: debridement and amputation
- Combined management: medical and surgical management

The study also assessed the patient outcome measures, including:

- Wound healing
- Length of hospital stay
- Need for surgical intervention

➢ *Statistical Analysis:*

Data were analyzed using statistical software after entering them into excel sheets.

- *Descriptive Analysis*

The analysis involved calculating the means and standard deviations for continuous variables and frequencies and percentages for categorical variables.

- *Inferential Analysis*

The association between categorical variables was evaluated using the Chi-square test:

✓ Duration of diabetes and ulcer severity
✓ Smoking and wound healing
✓ Glycemic control and healing duration
✓ Wagner grade and surgical intervention

A p-value of <0.05 was considered statistically significant.

- *Multivariate Analysis*

The study used multivariate logistic regression analysis to determine the independent predictors of poor patient outcome. The following variables were included:

✓ Duration of diabetes (>10 years)
✓ Smoking
✓ Glycemic control (HbA1c >8%)
✓ Wagner grade (≥3)

The results were reported as Odds Ratios (OR) with confidence intervals to interpret the magnitude of the association between the independent variables and the outcome.

➢ *Ethical Considerations*

The study obtained informed consent from all the participants. In addition, the study maintained patient confidentiality throughout the research process.

III. RESULTS

➢ *Demographic Characteristics of Study Population*

A total of 60 patients with DFU were included in the study.

- *Age Distribution*

The highest prevalence of DFU was recorded among patients aged 56–60 years (33.33%).`

Table 4 Age-wise Distribution of Patients (N = 60)

Age Group (years)	Frequency	Percentage (%)
18–35	2	3.33
36–40	4	6.67
41–45	2	3.33
46–50	4	6.67
51–55	10	16.67
56–60	20	33.33
61–65	2	3.33
66–70	9	15.00
>70	7	11.67

- *Gender Distribution*

The majority of the study population were male (61.7%), while 38.3% were female.

Table 5 Gender Distribution

Gender	Frequency	Percentage (%)
Male	37	61.7
Female	23	38.3

- *BMI Distribution*

The majority of the patients (76.7%) had normal BMI (18.6–24.9 kg/m²).

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Table 6 BMI Distribution

BMI (kg/m²)	Frequency	Percentage (%)
<18.5	0	0
18.6–24.9	46	76.7
25–29.9	14	23.3
>30	0	0

➢ *Lifestyle Factors*

The majority of the patients followed a mixed diet (80%), and most were non-smokers (68.33%) and non-alcoholic (63.33%).

Table 7 Lifestyle Characteristics

Factor	Category	Frequency	Percentage (%)
Diet	Mixed	48	80
	Diabetic diet	12	20
Alcohol	Yes	22	36.67
	No	38	63.33
Smoking	Yes	19	31.67
	No	41	68.33

➢ *Prevalence of Risk Factors*

Elevated blood sugar levels (FBS, RBS, PPBS, HbA1c) have the highest prevalence, more than 75%. Male gender has higher prevalence (62%) than female gender (39%). Neuropathy (63%), Arteriopathy (45%), and Hypertension (47%) also have significant prevalence. Nephropathy has the lowest prevalence at approximately 10%.

Table 8 Distribution of Patients Based on Prevalence of Risk Factors

RISK FACTOR		NO. OF PATIENTS	PREVALENCE
Age (56-60)		20	33.33%
Gender	Male	37	61.67%
	Female	23	38.33%
Duration (>10 Yrs)		22	36.67%
Alcohol Consumption		22	36.67%
Smoking		19	31.67%
FBS (>=126 mg/dl)		46	76.67%
RBS (>=200 mg/dl)		51	85%
PPBS (>=200 mg/dl)		48	80%
HbA1C (>=7%)		49	81.67%
BMI (>=25 Kg/m$^{2)}$		14	23.33%
Neuropathy		38	63.33%
Arteriopathy		27	45%
Retinopathy		12	20%
Nephropathy		6	10%
Hyperlipidemia		18	30%
Hypertension		25	46.67%
Foot Deformity		20	33.33%

➢ *Management Strategies*

Both the management strategies: Antibiotics + Insulin therapy and OHA + Antibiotics + Insulin therapy are employed equally with a percentage of 45% and OHA + Antibiotics is least employed with only 10%.

Table 9 Distribution of Patients Based on Management Strategies Performed

STRATEGIES	NO. OF PATIENTS	PERCENTAGE
OHA + Antibiotics	6	10%
Antibiotics + Insulin therapy	27	45%
OHA + Antibiotics + Insulin Therapy	27	45%

➢ *Inferential Analysis*

Statistical analysis was performed to evaluate associations between risk factors and clinical outcomes.

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Table 10 Association Between Risk Factors and Clinical Outcomes

Variable	Outcome Assessed	p-value	Significance
Duration of diabetes (>10 years)	Higher Wagner grade	0.021	Significant
Smoking	Poor wound healing	0.034	Significant
HbA1c >8%	Delayed healing & prolonged hospital stay	0.018	Significant
Wagner grade ≥3	Need for surgical intervention	<0.001	Highly Significant
Combined medical + surgical management	Better outcomes	0.041	Significant

- *Key Findings from Inferential Analysis:*

✓ Patients with a longer duration of diabetes (>10 years) were likely to present with severe DFU.
✓ Smoking was significantly associated with delayed and poor wound healing.
✓ Poor glycemic control (HbA1c >8%) was significantly associated with delayed healing and prolonged length of hospitalization.
✓ Higher grades of DFU (≥3) were significantly associated with surgical intervention.
✓ Patients who received combined medical and surgical management had significantly better patient outcome compared to those who received conservative management.

➢ *Multivariate Logistic Regression Analysis*

To identify independent predictors of poor outcomes, multivariate logistic regression was performed.

Table 11 Logistic Regression Analysis of Risk Factors

Variable	Odds Ratio (OR)
Duration of diabetes >10 years	2.8
Smoking	2.3
Poor glycemic control (HbA1c >8%)	3.1
Wagner grade ≥3	4.5

➢ *Interpretation of Regression Analysis:*

- *Multivariate Analysis Showed that:*

✓ Wagner grade ≥3 (OR = 4.5) was the strongest predictor of poor patient outcome
✓ Poor glycemic control (HbA1c >8%) (OR = 3.1) significantly predicted poor patient outcome
✓ Long duration of diabetes and smoking also predicted poor patient outcome

- *Overall Interpretation:*

Higher grades of DFU and poor glycemic control significantly predicted poor patient outcome. Summary of Key Results.

✓ Majority of patients were middle-aged males
✓ Chronic diabetes (>10 years) strongly influenced ulcer severity
✓ Lifestyle factors (smoking) worsened healing outcome
✓ Poor glycemic control significantly delayed recovery
✓ Advanced ulcer grade predicted need for surgery
✓ Combined management approach resulted in better patient outcome

IV. DISCUSSIONS

The present prospective observational study aimed to determine the prevalence, risk factors, and management of DFU. The study revealed that DFU is a complex clinical entity with multiple risk factors that influence patient outcome.

➢ *Demographic Characteristics*

The study found that the majority of patients with DFU were aged 56–60 years. This suggests that DFU predominantly affects middle-aged and elderly populations. This is consistent with previous studies showing that the incidence of DFU increases with age due to the cumulative effects of hyperglycemia on peripheral nerves and blood vessels.[17,15]

In addition, the study revealed that male patients were more likely to develop DFU than their female counterparts (61.7% vs. 38.3%). This finding aligns with previous research indicating that males are more likely to engage in outdoor activities, putting them at higher risk of foot injuries and subsequent DFU development.[7,20]

Most patients (76.7%) had a normal BMI, suggesting that BMI may not be a significant predictor of DFU in this population. However, other studies have shown that obesity contributes to increased plantar pressure, which can lead to DFU development.[21]

➢ *Lifestyle Factors*

The study found that a significant proportion of patients followed a mixed diet (80%). This indicates that patients did not adhere to a diabetic diet, which may contribute to poor glycemic control and, consequently, DFU development.

The study also found that smoking was significantly associated with poor wound healing outcome ($p = 0.034$). This is consistent with previous research showing that smoking impairs microvascular function and reduces tissue oxygenation, thereby delaying the DFU healing process.[11,12]

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Although alcohol consumption was not significantly associated with DFU outcome, it can contribute to poor glycemic control and hinder the healing process.

➢ *Clinical Characteristics and Risk Factors*

The study found that patients with a longer duration of diabetes (>10 years) were more likely to develop severe DFU ($p<0.0010$). This is consistent with previous studies showing that chronic hyperglycemia damages peripheral nerves and blood vessels, increasing the susceptibility to DFU.[22,23]

The study also revealed that poor glycemic control (HbA1c >8%) was significantly associated with delayed healing and prolonged length of hospitalization ($p<0.0011$). Chronic hyperglycemia reduces the immune response, impairs collagen synthesis, and decreases angiogenesis, thereby delaying the DFU healing process.[2,14]

The study highlights the importance of maintaining optimal glycemic control to prevent DFU and promote healing in patients with DFU.

➢ *Ulcer Severity and Clinical Outcomes*

The study found that higher grades of DFU (≥3) were significantly associated with surgical intervention ($p<0.0012$). This is because higher grades indicate severe ulcerations that often require surgical debridement and amputation to manage complications such as osteomyelitis and gangrene.[5,24]

➢ *Management Outcomes*

The study found that combined medical and surgical management was significantly associated with better patient outcome than conservative management ($p<0.0013$). This suggests that a multidisciplinary approach, including glycemic control, antibiotic therapy, wound care, and surgical intervention when necessary, is essential in the management of DFU.[11,17]

➢ *Multivariate Logistic Regression Analysis*

The study used multivariate logistic regression analysis to determine the independent predictors of poor patient outcome. The following variables were included:

- Wagner grade ≥3 ($p<0.0014$)
- Poor glycemic control (HbA1c >8%) ($p<0.0015$)
- Duration of diabetes >10 years ($p<0.0016$)
- Smoking ($p<0.0017$)

The analysis revealed that higher grades of DFU (≥3) and poor glycemic control (HbA1c >8%) were the most significant predictors of poor patient outcome. This is consistent with previous studies showing that higher grades of DFU and poor glycemic control are strongly associated with adverse clinical outcomes such as prolonged hospitalization and amputation.[5,25]

➢ *Clinical Implications*

The study's findings have several clinical implications, including the need for early screening and intervention, strict glycemic control, smoking cessation, and combined medical and surgical management of DFU. In addition, the use of the Meggitt–Wagner classification system can help guide DFU management based on the severity of the ulcer.

➢ *Overall Interpretation*

The study provides valuable insights into the management of DFU by highlighting the importance of assessing ulcer severity using the Meggitt–Wagner classification system and implementing a combined medical and surgical management approach. The study also emphasizes the need for strict glycemic control to prevent DFU and promote healing in patients with DFU.

V. CONCLUSIONS

The discussed sample represents diabetic foot ulcers (DFU) among middle-aged and older people, being primarily male. Thus, the prevalence of DFU is considerable among men for various reasons. In this study, the development of DFU was associated with the number of years diabetes has been present, meaning the longer the disease has been present, the higher the likelihood of developing DFU occurs. Additionally, it has been suggested that multiple negative outcomes and developments emerge when patients do not adequately monitor their blood sugar levels. In particular, the study revealed that poor control of blood sugar, expressed as higher than normal HbA1c levels (>8%), significantly increases the chances of delayed healing processes and hospitalization time.

Moreover, there is a significant association between tobacco smoking and poor healing outcomes, making it necessary to ensure patients know how detrimental it is to their health. Besides, the findings suggest that the association between poor DFU outcomes and higher Wagner grades is present.

Accordingly, higher grades result in surgical interventions. Multivariable logistic regression analysis identified higher grades, poor control of blood sugar levels, longer disease duration, and tobacco smoking were the most common predictors of negative DFU outcomes. Overall, the study suggests that a combined approach to DFU treatment is beneficial for patients in terms of recovery outcomes and managing the development of additional severe conditions.

Therefore, it is essential to ensure proper treatment and control of diabetes to prevent DFUs from occurring. Early intervention and appropriate interventions to manage DFUs are critical to avoid costly and difficult surgeries, prolonged hospitalization, and additional severe health problems for the patient. In addition, it is essential to note that the combined therapy approach is better than the traditional conservative approach to managing DFUs.

In order to ensure positive DFU treatment outcomes for the majority of patients, healthcare providers should consider early intervention, strict control of blood sugar to prevent additional DFU complications, and encourage patients to undergo appropriate DFU treatment. Overall, the study

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identified several DFU predictors and provided evidence on the benefits of a combined treatment approach of DFUs. However, more multicenter studies should be conducted to confirm the validity of the obtained results.

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