



## A PROSPECTIVE OBSERVATIONAL STUDY IN PREDICTING DIABETIC FOOT ULCERS BY USING SINBAD SCORING SYSTEM

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### ABSTRACT

**Background:** Diabetic foot ulcers remain one of the most serious complications of diabetes mellitus and are a major contributor to lower-limb amputations globally. Reliable and easily applicable classification systems are essential for early risk stratification and outcome prediction. The SINBAD Classification System is a practical scoring tool that evaluates ulcer site, ischemia, neuropathy, bacterial infection, ulcer area, and ulcer depth to determine ulcer severity.

**Aim and Objectives:** To analyze the clinical characteristics and outcomes of patients with diabetic foot ulcers and to determine the prognostic utility of the SINBAD Classification System in predicting ulcer healing and limb salvage.

**Methods:** A prospective observational study was conducted involving 150 patients with diabetic foot ulcers presenting to a tertiary care center. Clinical data including demographic variables, duration of diabetes, comorbidities, ulcer characteristics, and microbiological findings were recorded. Ulcer severity was assessed using the SINBAD Classification System. Patients were followed until resolution of the ulcer or occurrence of adverse outcomes, including disarticulation, major amputation, or persistent non-healing. Statistical analyses were performed to evaluate associations between clinical variables, SINBAD scores, and treatment outcomes.

**Results:** The majority of patients were aged 61–70 years (44.6%) with a predominance of males (70.0%). Forefoot ulcers were most common (71.3%). Neuropathy and ischemia were present in 41.3% and 61.3% of patients, respectively. Overall, complete ulcer healing was achieved in 52.7% of cases, while 19.3% required disarticulation and 17.3% underwent major amputation. Increasing SINBAD Classification System scores demonstrated a significant association with adverse outcomes ( $p=0.04$ ). Advanced age, longer duration of diabetes, presence of neuropathy, and ulcer location were also significantly associated with poorer clinical outcomes.

**Conclusion:** The SINBAD Classification System is a simple and clinically effective tool for prognostic assessment in diabetic foot ulcers. Higher SINBAD scores correlate with increased risk of amputation and reduced healing rates. Early implementation of this scoring system may facilitate timely intervention, optimize management strategies, and improve limb-salvage outcomes in patients with diabetic foot disease.

**KEYWORDS:** Diabetic foot ulcer, SINBAD Classification System, Diabetes mellitus, Ulcer severity, Prognostic assessment, Limb salvage, Amputation risk, Neuropathy, Ischemia, Wound healing, Clinical outcomes, Risk stratification, Foot infection, Ulcer classification Tertiary, care study.

# 1. INTRODUCTION

Diabetic foot disease is a multifactorial clinical condition primarily driven by peripheral neuropathy, ischemia, and infection, which collectively lead to progressive tissue damage ranging from pre-ulcerative lesions to full-thickness ulcers caused by repetitive microtrauma. Nevertheless, these pre-ulcerative lesions are clinically important because they significantly increase the risk of progression to full-thickness ulceration if not identified and treated promptly. [1]

As a consequence, diabetic foot disease is associated with substantial morbidity, deterioration in quality of life, and significant economic burden for patients and healthcare systems. [2]

In India, an estimated 100,000 lower limb amputations are performed annually, and this number continues to increase. Diabetic foot lesions primarily arise from three major pathological mechanisms: peripheral neuropathy, ischemia, and infection, although additional contributing factors may also influence disease progression. [3]

Multiple demographic and lifestyle factors contribute to the rising incidence of diabetes-related amputations in India. These include the increasing prevalence of diabetes, longer life expectancy, an aging population, persistent tobacco use, and common practices such as barefoot walking. In addition, delayed presentation to healthcare facilities, attempts at unsupervised home-based procedures, and inadequate hygiene further increase the risk of infection and disease progression, ultimately leading to higher rates of lower extremity amputation. [4][5]

Multiple classification systems have been proposed to evaluate diabetic foot ulcers, enabling clinicians to assess disease severity and guide management strategies. The Wagner–Meggitt Classification is one of the most widely used systems and primarily categorizes ulcers based on depth and the presence of gangrene. The University of Texas Diabetic Foot Classification offers a more comprehensive evaluation by incorporating ulcer depth along with the presence of infection and ischemia. Similarly, the PEDIS Classification assesses key parameters including perfusion, ulcer size, depth, infection, and sensory loss, and is frequently applied in clinical research. [6]

More recently, the SINBAD Classification System has gained wider acceptance due to its simplicity and practical applicability. This system evaluates ulcer site, ischemia, neuropathy, bacterial infection, area, and depth using a binary scoring method, enabling rapid and standardized assessment. In countries such as India, where diabetic foot disease poses a substantial healthcare burden, the use of standardized classification systems facilitates improved clinical documentation, supports treatment planning, and enhances the comparability of outcomes across different healthcare settings. [7]

## 1.1 SINBAD CLASSIFICATION

**Table 1:** SINBAD Scoring Six elements were graded as follows [7]

Category	Definition	SINBAD score
Site	Forefoot	0
	Midfoot and hindfoot	1
Ischemia	Pedal blood flow intact: at least one pulse palpable	0
	Clinical evidence of reduced pedal blood flow	1
Neuropathy	Protective sensation intact	0
	Protective sensation lost	1
Bacterial infection	None	0
	Present	1
Area	Ulcer < 1cm	0
	Ulcer ≥ 1cm	1
Depth	Ulcer confined to skin and subcutaneous tissue	0
	Ulcer reaching muscle, tendon or deeper	1

## 1.2 Aim and Objectives

This study aims to evaluate the prognostic value of the SINBAD Classification System in predicting clinical outcomes among patients with diabetic foot ulcers. Specifically, the study assesses the ability of the SINBAD score to identify patients at increased risk of adverse outcomes, including lower limb amputation. Additionally, it seeks to determine factors that may assist in improving early risk stratification and reducing morbidity and mortality associated with diabetic foot disease. **Materials and Methods** Study Design and Setting This prospective observational study was conducted at the Sri Venkateswara Institute of Medical Sciences, Tirupati, India, a tertiary care teaching hospital. The study was carried out over a one-year period from December 2023 to November 2024 in both outpatient and inpatient settings after obtaining institutional

ethical approval.

### **1.3 Study Population**

Patients aged 40–70 years with diabetic foot ulcers involving a single foot and a hemoglobin level  $\geq 9$  g/dL who provided written informed consent were included in the study; patients with lower hemoglobin levels were optimized prior to enrolment. Exclusion criteria comprised individuals unwilling to provide consent, patients younger than 40 years, those with malignancy, end-stage renal disease, HIV infection, hepatitis B or C infection, psychiatric illness, or a history of prior lower limb amputation, and patients with foot ulcers secondary to non-diabetic venous or arterial disorders

### **1.4 Clinical Assessment**

A detailed clinical history and physical examination were performed for all enrolled patients. Diabetic foot ulcers were evaluated using the SINBAD Classification System, which assesses ulcer site, ischemia, neuropathy, bacterial infection, area, and depth. Each parameter was assigned a binary score, yielding a total score ranging from 0 to 6.

In patients presenting with multiple ulcers, the largest or most clinically significant ulcer was considered the index ulcer for analysis.

Peripheral neuropathy was assessed using vibration perception with a 128-Hz tuning fork applied to the great toe and ankle, pressure sensation using a 10-g Semmes–Weinstein monofilament at three plantar sites, and evaluation of ankle reflexes. Peripheral arterial perfusion was assessed by palpation of dorsalis pedis and posterior tibial pulses.

### **1.5 Management and Follow-up**

Initial wound management included manual debridement to remove necrotic tissue and callus when required. Appropriate antibiotic therapy and wound care were provided according to standard clinical protocols. Patients were followed up every two weeks and monitored for a minimum duration of three months or until a definitive clinical outcome was achieved.

### **1.6 Outcome Measures**

The primary outcome measure was ulcer healing or the requirement for lower limb amputation. Minor amputation was defined as the removal of a digit or part of the foot distal to the ankle joint, whereas major amputation referred to amputations performed above the ankle joint. Secondary outcomes included the occurrence of major amputations and the identification of clinical factors associated with poor healing outcomes.

### **1.7 Statistical Analysis**

Data were entered into Microsoft Excel and analysed using Epi Info software (version 7.2.0). Continuous variables were summarized as mean  $\pm$  standard deviation, while categorical variables were expressed as frequencies and percentages. The Student's t-test was used for comparison of continuous variables, and the chi-square test was applied for categorical variables. A p-value  $<0.05$  was considered statistically significant.

## **2. Results**

### **2.1 Baseline Characteristics of the Study Population**

A total of 150 patients with diabetic foot ulcers were included in the study. The study population predominantly comprised older individuals, with the largest proportion in the 61–70-year age group (44.6%), followed by those aged 51–60 years (32.7%) and 41–50 years (20.7%). A marked male predominance was observed, with males accounting for 70.0% of cases and females for 30.0%.

The duration of diabetes varied among participants. The majority of patients (60.0%) had a disease duration between 6 and 10 years. A further 20% had diabetes for more than 10 years, whereas 20% had a disease duration of less than 5 years. Nearly half of the study population (48.0%) had no associated comorbid conditions. Among those with comorbidities, hypertension was the most frequently identified disorder (34.0%), followed by combinations of hypertension with other metabolic or cardiovascular conditions.

### **2.2 Ulcer Characteristics**

The ulcer distribution revealed that the forefoot was the most commonly affected anatomical site, accounting for 71.3% of cases. Ulcers involving the hindfoot and midfoot were less frequent, representing 14.7% and 14.0% of cases, respectively. This distribution suggests that areas subjected to repetitive mechanical stress and pressure during ambulation are particularly susceptible to ulcer formation in patients with diabetes.

With respect to ulcer size, the majority of lesions (93.3%) had a surface area  $\geq 1$  cm<sup>2</sup>, while only 6.7% were smaller than this threshold. Assessment of ulcer depth demonstrated that superficial ulcers were more common, occurring in 68.0% of patients, whereas deeper ulcers involving underlying tissue structures accounted for 32.0% of cases.

Peripheral neuropathy, defined by the loss of protective sensation, was identified in 41.3% of patients. Clinical evidence of peripheral ischemia was present in 61.3% of cases. In addition, signs of bacterial infection were observed in a substantial proportion of ulcers (88.0%), indicating a high burden of infected diabetic foot lesions within the study population.

### 2.3 Distribution of SINBAD Scores

Higher scores were more frequently observed. A score of 4 was the most common (36.7%), followed by scores of 6 (29.3%) and 5 (11.3%). In contrast, lower scores ( $\leq 3$ ) were comparatively less frequent. This distribution indicates that a substantial proportion of patients presented with relatively advanced ulcer severity at the time of clinical evaluation.

### 2.4 Clinical Outcomes

Clinical outcomes were categorized as ulcer healing, disarticulation procedures, major amputation, or persistent non-healing ulcers. Complete ulcer healing was achieved in 52.7% of patients during the study period. However, a notable proportion required surgical intervention. Disarticulation procedures were performed in 19.3% of patients, while 17.3% underwent major amputations. Persistent non-healing ulcers were observed in 10.7% of cases.

These findings suggest that although more than half of the patients experienced successful ulcer resolution, a considerable proportion developed complications necessitating limb-sacrificing procedures.

**Table 2: Variables and Clinical Outcomes**

Variables	n	Healed (%)	n Non-healing (%)	Amputation n (%)	Disarticulation n (%)	p-value
Age groups in years	41-50	31	25(80.6)	3(9.7)	0(0.0)	< 0.001
	51-60	49	30(61.2)	2(4.1)	6(12.2)	
	61-70	70	24(37.9)	11(17.2)	20(20.7)	
Comorbidities	Yes	78	22(28.2)	12(15.4)	22(28.2)	< 0.001
	No	72	57(79.2)	4(5.6)	4(5.6)	
Duration of diabetes in years	<5	30	28(93.3)	2(6.7)	0(0.0)	< 0.001
	6-10	90	50(55.6)	8(8.9)	11(12.2)	
	11-18	30	1(3.3)	6(20.0)	15(50.0)	
Site of ulcer	Forefoot	107	68(63.6)	8(7.5)	12(11.2)	< 0.001
	Midfoot	22	6(27.3)	5(22.7)	5(22.7)	
	Hindfoot	21	5(23.8)	3(14.3)	9(42.9)	
Ischemia status	Present	92	46(50.0)	10(10.9)	18(19.6)	0.79
	Absent	58	33(56.9)	6(10.3)	8(13.8)	
Peripheral sensation	Intact	88	54(61.4)	8(9.1)	9(10.2)	0.02
	Lost	62	25(40.3)	8(12.9)	17(27.4)	
Bacterial infections	Present	132	69(52.3)	16(12.1)	22(16.7)	0.46
	Absent	18	10(55.6)	0(0.0)	4(22.2)	
Area of ulcer	< 1 cm <sup>2</sup>	10	8(80.0)	0(0.0)	1(10.0)	0.32
	$\geq 1$ cm <sup>2</sup>	140	71(50.7)	16(11.4)	25(17.9)	
Depth of ulcer	Superficial	108	62(57.4)	8(7.4)	19(17.6)	0.10
	Deep	42	17(40.5)	8(19.0)	7(16.7)	
SINBAD score	0-2	17	13(76.5)	0(0.0)	1(5.9)	0.04
	3-4	72	41(56.9)	8(11.1)	8(11.1)	
	5-6	61	25(41.0)	8(13.1)	17(27.9)	

## 3. DISCUSSION

Diabetic foot ulcers represent one of the most severe complications of diabetes mellitus, frequently leading to prolonged hospitalization, infection, and limb amputation. Effective clinical classification systems are therefore essential for stratifying ulcer severity, guiding management decisions, and predicting outcomes. The

present study evaluated the clinical characteristics and outcomes of patients with diabetic foot ulcers and examined the prognostic value of the SINBAD Classification System in predicting healing and limb salvage

### **3.1 Association Between Demographic Factors and Outcomes**

Statistical analysis demonstrated a significant association between patient age and clinical outcomes ( $p < 0.001$ ). Older patients exhibited lower healing rates and a greater likelihood of requiring surgical intervention compared with younger individuals. In particular, patients older than 60 years were more frequently subjected to disarticulation or major amputation procedures. Similar findings were reported by Prarthana D et.al. [8] and Jayalal JA et.al. [9], who also observed a progressive decline in healing with increasing age. This trend likely reflects the cumulative effects of long-standing diabetes, vascular insufficiency, and the higher prevalence of systemic comorbidities among elderly patients.

In contrast, gender did not show a statistically significant association with treatment outcomes, despite the higher prevalence of diabetic foot ulcers among male patients. Comparable gender distributions have been reported by Venkata Ramana et. al.[10], where males constituted approximately 70–80% of patients with DFUs. This disparity may be attributed to greater occupational exposure to trauma, higher prevalence of tobacco and alcohol use, and relatively lower adherence to preventive foot-care practices among men

### **3.2 Ulcer Characteristics and Clinical Outcomes**

Ulcer location was significantly associated with clinical outcomes ( $p < 0.001$ ). Forefoot ulcers demonstrated comparatively higher healing rates, whereas ulcers involving the midfoot and hindfoot were associated with poorer outcomes and an increased need for surgical management. These findings are consistent with reports by Prarthana D et. al. and Venkata Ramana et. al., who similarly observed reduced healing in ulcers involving the midfoot and hindfoot. The unfavorable outcomes in these regions may be explained by complex anatomy, limited soft tissue coverage, and delayed detection of deep infections.

Peripheral neuropathy also showed a significant relationship with adverse outcomes ( $p = 0.02$ ). Patients with loss of protective sensation had lower healing rates and were more likely to undergo amputation procedures. This observation highlights the critical role of sensory neuropathy in delayed ulcer detection and the progression of tissue damage. These findings are in agreement with previous studies by Jayalal JA et. al. and Venkata Ramana et. al., which highlighted neuropathy as a major risk factor for ulcer progression and limb loss. Early identification of neuropathy and routine foot examination therefore, remain critical components of diabetic foot care.

In contrast, ulcer size and depth did not demonstrate statistically significant associations with treatment outcomes. Similarly, although ischemia and bacterial infection were frequently observed, they did not independently correlate with outcome. Nevertheless, a clinically meaningful trend toward poorer healing in ischemic ulcers was observed, similar to the findings reported by Prarthana D et. al. These observations reinforce the importance of vascular assessment and timely management of infection to improve ulcer healing.

### **3.4 Impact of Duration of Diabetes**

The duration of diabetes showed a strong association with clinical outcomes ( $p < 0.001$ ). Patients with a longer duration of disease were significantly more likely to experience adverse outcomes. Individuals with diabetes for more than 10 years demonstrated substantially lower healing rates and higher incidences of both disarticulation and major amputation compared with those with shorter disease duration. These findings emphasize the cumulative impact of long-standing diabetes on vascular integrity, neuropathy, and impaired wound healing.

### **3.5 Relationship Between SINBAD Score and Outcomes**

A statistically significant association was observed between increasing scores on the SINBAD Classification System and worsening clinical outcomes ( $p = 0.04$ ). Patients with lower scores ( $\leq 3$ ) had a significantly higher probability of ulcer healing. In contrast, individuals with higher scores ( $\geq 5$ ) demonstrated increased rates of disarticulation and major amputation. These observations are consistent with Prarthana D et.al. study.

This relationship highlights the prognostic value of the SINBAD scoring system in predicting the clinical course of diabetic foot ulcers and underscores its usefulness as a practical tool for risk stratification in routine clinical practice.

Significantly poorer outcomes among patients with multiple comorbidities, particularly those with renal impairment and peripheral vascular disease. Similarly, Jayalal JA et. al. emphasized the role of systemic comorbid conditions as important predictors of diabetic foot ulcer outcomes, demonstrating higher amputation rates in patients with co-existing chronic illnesses.

### **3.6 Preventive Measures and Patient Education**

Comprehensive preventive strategies were recommended for all patients as part of diabetic foot management. These included strict glycemic control (70.7%), increased physical activity (72.0%), weight reduction (60.7%), smoking cessation (39.3%), and alcohol cessation (39.3%). Off-loading footwear was advised for 25.3% of patients, and all participants were counseled regarding daily foot inspection and regular clinical follow-up.

## **4. CONCLUSION**

The findings confirm the prognostic value of the SINBAD Classification System as a simple and effective tool for predicting outcomes in patients with diabetic foot ulcers. Lower scores (0–2) were associated with favorable healing outcomes (76.5%), whereas higher scores (5–6) were strongly associated with poor prognosis and increased amputation risk. Among the six SINBAD parameters, ulcer location, neuropathy, and ulcer depth demonstrated significant correlations with healing outcomes.

The study also highlighted the substantial impact of systemic factors on ulcer prognosis. Patients with comorbid conditions exhibited markedly reduced healing rates and higher amputation rates compared with those without comorbidities. Similarly, the duration of diabetes showed a strong influence on outcomes, with patients having a shorter disease duration (<5 years) demonstrating excellent healing rates, while those with long-standing diabetes (11–18 years) experienced significantly poorer outcomes.

Importantly, the SINBAD Classification System proved to be a practical and reliable prognostic tool that can be readily applied even in resource-limited healthcare settings. Its simplicity facilitates early risk stratification, clinical decision-making, and outcome monitoring in patients with diabetic foot ulcers.

### **4.1 Limitations**

This study has several limitations. The relatively short follow-up period limited the ability to evaluate long-term outcomes, particularly mortality. Increased mortality in patients with diabetic foot ulcers is often observed during extended follow-up and is frequently related to associated systemic comorbidities rather than the ulcer itself. Therefore, longer follow-up durations may provide better insight into long-term clinical outcomes and survival.

Additionally, although the SINBAD Classification System is a simple and widely used tool—especially in primary care and resource-limited settings—its limitations should be recognized when managing complex, chronic, or limb-threatening diabetic foot ulcers.

This study implements a multi-stage computational pipeline designed to distill raw transcriptomic data into a validated predictive model. The workflow follows a logical progression: Data Acquisition - Preprocessing - Functional Enrichment - Network Construction - Hub Gene Selection - Machine Learning Classification. This "funnel" approach progressively discards noise and retains high-value biological signals, ensuring that the final predictive model is based on biologically plausible mechanisms rather than statistical artifacts. (Libbrecht & Noble, 2015).



**Figure 1:** Image showing a: Fore foot ulcer; b: Healing wound after negative pressure wound therapy; c: Pre-debridement wound; d: Post Surgical debridement wound; e: Healing ulcer.

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