Evaluation of Efficacy of Sinbad Scoring System in Predicting the Risk of Amputation in Diabetic Foot Ulcer Patients: A Retrospective Study

Lakeen Puthupattan[1], Vinayagam Ganesan[2]

[1]Post Graduate, Department of General Surgery, Sri Venkateshwaraa Medical College Hospital and Research Centre, Puducherry, India
[2]Associate Professor, Department of General Surgery, Sri Venkateswaraa Medical College Hospital and Research Centre, Puducherry, India

Abstract:

Background: This study focuses on diabetic foot ulcers (DFUs), a grave complication of diabetes leading to amputations and mortality. It aims to evaluate the SINBAD scoring system's effectiveness in predicting amputation risk among DFU patients, with potential implications for improved patient care.

Objective: The primary objectives of this study are to assess the long-term prognosis and outcomes of diabetic foot ulcer (DFU) patients, with a specific focus on the risk of amputation and mortality over an extended period. Additionally, the study aims to evaluate the efficacy of the SINBAD scoring system as a predictive tool for amputation risk in DFU patients, providing valuable insights for clinical decision-making and patient management.

Material and Method: This retrospective cohort study analyzed 58 DFU patients admitted to Sri Venkateshwaraa Medical College Hospital and Research Centre, Puducherry from January to June 2023. It utilized the SINBAD scoring system to categorize patients based on critical parameters. Statistical analysis with IBM SPSS Statistics 24 assessed the system's efficacy in predicting amputation risk, and ethical standards were maintained with institutional approval.

Result: In this study of 58 diabetic foot ulcer (DFU) patients, 81% had low SINBAD scores (<3), signifying a lower amputation risk, while 19% had higher scores (≥3), indicating a greater risk. Those with scores of 3 or higher had a significantly higher amputation rate (10 patients) compared to lower-scoring patients (no amputations) (p = 0.001). The SINBAD system demonstrated a sensitivity of 100% and specificity of 95%, highlighting its effectiveness in predicting amputation risk. Additionally, BK amputations showed the most significant association with SINBAD scores (p = 0.003), followed by Barefoot amputations (p = 0.025), with AK amputations showing a less significant association (p = 0.120).

Conclusion: The study underscores the utility of the SINBAD scoring system as an effective predictor of amputation risk in diabetic foot ulcer patients, with high sensitivity and specificity, offering valuable guidance for clinical decision-making and patient management.

Keywords: Diabetic foot ulcers, SINBAD scoring system, Amputation risk, Retrospective cohort study, Diabetes complications.

Introduction

Diabetes is a severe chronic disease that develops when the body cannot utilise the insulin that is produced, or when there is inadequate insulin production. It is a chronic metabolic condition. Between the ages of 20 and 79, diabetes is predicted to affect 537 million persons globally (10.5% of all adults in this age group). Globally, 643 million individuals will have diabetes by 2030, and 783 million will by 2045. The prevalence of diabetes has been increasing in South-East Asian (SEA) countries for at least 20 years, according to the IDF 10th edition, and current estimates have surpassed all prior projections [1,2]. Diabetes foot ulcers (DFUs) are a serious and disabling consequence of diabetes mellitus that place a heavy strain on global healthcare systems. One of the most prevalent consequences for those with poorly managed diabetes mellitus is diabetic foot ulcers. Poor foot care, peripheral vascular disease, underlying neuropathy, and poor glycemic management are the typical causes. It is also a frequent cause of foot osteomyelitis and lower extremity amputation. These ulcers typically develop in regions of the foot that experience pressure and recurrent stress [2,3]. Staphylococcus is a widespread infectious agent. The best results

will come from an interdisciplinary approach because the condition is frequently persistent. It is highly advantageous to have the combined expertise of a podiatrist, endocrinologist, primary care physician, vascular surgeon, and infectious disease specialist. It is a circumstance that is frequently seen in both inpatient and outpatient settings. More hospitalisations result from diabetic foot ulcers than any other diabetes complication [3-5]

These ulcers have serious side effects that might result in tissue necrosis, infection, and, in the end, lower extremity amputation6. For clinical management, treatment strategy optimisation, and patient outcomes improvement, early and accurate prediction of amputation risk in DFU patients is essential [7,8].

Due to the complex character of the illness, evaluating the risk variables connected to DFU-related amputation has proven difficult. To assist in risk stratification and decision-making, a number of scoring systems and clinical recommendations have been created, but the SINBAD (Site, Ischemia, Neuropathy, Bacterial Infection, Area, and Depth) scoring system has become well-known [8-10]. Including ulcer location, ischemia, neuropathy, bacterial infection, ulcer size, and depth, the SINBAD scoring system offers a thorough framework for assessing crucial DFU-related factors. This approach grades each characteristic, enabling a more complex evaluation of amputation risk [11,12,13].

However, more research and validation are need to determine the SINBAD grading system's effectiveness in predicting amputation risk among DFU patients. It is crucial to comprehend the system's performance characteristics in order to integrate it into clinical practise and make sure it can consistently inform treatment choices [14,15]. As a result, the objective of this retrospective cohort research is to thoroughly evaluate the SINBAD scoring system's ability to predict the probability of amputation in a cohort of DFU patients who were admitted to [Hospital Name] during the first half of 2023.

The objectives of the study to categorize all Diabetic foot ulcers patients according to the SINBAD scoring system and to evaluate the risk of amputation as per the SINBAD scoring system in all Diabetic foot ulcer patients.

Methodology

Overview

Amputation risk was predicted for 58 DFU patients using the SINBAD score method in this study. For the sake of data accuracy and ethical compliance, strict inclusion and exclusion criteria were used. Calculations for sensitivity, specificity, PPV, and NPV were included of the statistical analysis. While admitting possible limitations, the study's objective was to evaluate the therapeutic utility and statistical significance of the SINBAD system in DFU patient care.

Participants

This retrospective cohort analysis included 58 patients with diabetic foot ulcers who were all admitted to the surgical ward of Sri Venkateshwaraa Medical College Hospital and Research Centre, Puducherry between the months of January 2023 and June 2023. The Medical Records Department was painstakingly queried for patient data, including demographic data, primary complaints, results of systemic and local examinations, operation information, and postoperative follow-up records.

The participants in this study were chosen using a stringent set of inclusion and exclusion criteria. The inclusion criteria made sure that everybody with a diagnosis of diabetic foot ulcers (DFUs) who was hospitalised to [Hospital Name]'s surgical unit between January 2023 and June 2023 was taken into account. Additionally, each participant required access to complete patient data, which included demographic data, clinical results, operation specifics, and postoperative records. To participate in the study, individuals also had to give their informed consent.

In contrast, the exclusion criteria were created to weed out those whose health or circumstances would interfere with the study's objectives or introduce confounding variables. Patients having illnesses other than DFUs that would significantly affect the study's goals were not allowed to participate. To enable a thorough assessment of the SINBAD score system's effectiveness, patients with limited or incomplete medical records were also removed. Additionally, anyone who declined to take part in the study were excluded. Finally, to ensure a clearly defined research period, subjects admitted beyond the designated term were eliminated.

Intervention

Utilising the SINBAD scoring system as a diagnostic tool to determine the amputation risk of individuals with diabetic foot ulcers (DFU) was the main intervention in this study. This approach carefully assesses crucial DFU-related factors, such as the ulcer's location, ischemia, neuropathy, bacterial infection, depth, and area. Each participant in the research was assigned a category based on these factors, and their cumulative SINBAD scores were computed to offer an overall evaluation of their risk for amputation.

This categorising method involved establishing the ulcer's extent and depth as well as analysing the

ulcer's location, ischemia, neuropathy, and bacterial infection. For example, "SITE" was rated as either "Forefoot" (0 points) or "Midfoot and Hindfoot" (1 points), while "ISCHEMIA" was rated according to the presence of clinical evidence of reduced pedal blood flow, with "Pedal blood flow intact, one pulse palpable" scoring 0 points and "Clinical evidence of reduced pedal blood flow" scoring 1. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the SINBAD scoring system were obtained after categorization statistical analysis was carried out using IBM SPSS Statistics version 24. The main goal of the statistical study was to demonstrate how well the SINBAD score system predicted individuals with diabetic foot ulcers who were at risk for amputation. This was accomplished by carefully correlating SINBAD scores with the frequency of amputations within the patient sample. To give a more detailed analysis of the results, the study divided the amputations into "Forefoot," "Below Knee," and "Above Knee" categories[13,16].

Assessment

The effectiveness of the SINBAD Scoring System in predicting amputation risk among diabetic foot ulcer (DFU) patients is one of the study's assessment criteria. Sensitivity, specificity, positive predictive value, and negative predictive value are important indicators that show how accurate the system is. Additionally, taking into account elements like patient demographics and ethical issues, the study looks at the connection between SINBAD scores and amputation results. The evaluation's goal is to ascertain the score system's

clinical usefulness and statistical significance, giving clinicians important information for managing DFU patients and making therapeutic decisions.

The Institutional Review Board or Ethics Committee of [Hospital Name] approved the study's conduct in order to uphold ethical standards throughout. To preserve the subjects' privacy, patient data was treated with the utmost secrecy and protection. Additionally, this technique acknowledges possible drawbacks such its retroactive character and the potential for bias in selection.

Statistical Analysis

Descriptive statistics were largely used in this study's statistical analysis to summarise the demographic details and other pertinent information about the study participants. Additionally, assessments of sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were made to evaluate how well the SINBAD scoring system worked in identifying individuals at risk for diabetic foot ulcers (DFUs) and predicting their likelihood of needing an amputation. In order to conduct a thorough review of the scoring system, the analysis also included statistical tests to identify correlations and discrepancies across variables, particularly in relation to amputation kinds and SINBAD scores. In order to protect data privacy and the integrity of the research, ethical concerns were kept throughout the analysis. A p-value less than a preset alpha threshold, which is typically 0.05., indicates a statistically significant difference, Table 1.

Table 1: Summarizing the categories, definitions, and SINBAD scores:[16]

Category	Definition	Sinbad Score
Site	Forefoot	0
	Midfoot And Hindfoot	1
Ischemia	Pedal Blood Flow Intact, 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 Less Than 1 Cm	0
	Ulcer Greater Than Or Equal To 1 Cm	1
Depth	Ulcer Confined To Skin And Subcutaneous Tissue	0
	Ulcer Reaching Muscle, Tendon, Or Deeper	1

Results

Table 2: Demographic Characteristics

Demographic Factor	Number of Patients
Total Patients	58
Male Patients	40
Female Patients	18
Age Groups	

- Less than 50	8
- 50-60	35
- 60-70	11
- Over 70	4

Table 2 summarizes the demographic characteristics of 58 diabetic foot ulcer patients. It shows that the majority were male (69%), and the most common age group was 50-60 years (60% of patients), with smaller proportions in other age categories, Figure 1 and 2.
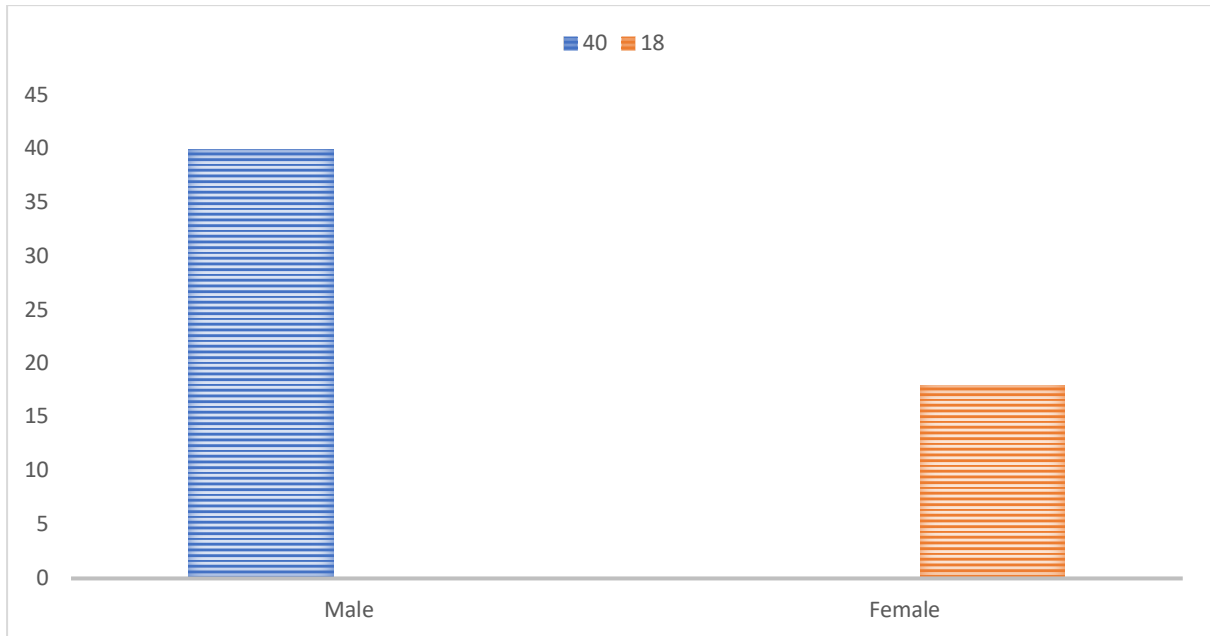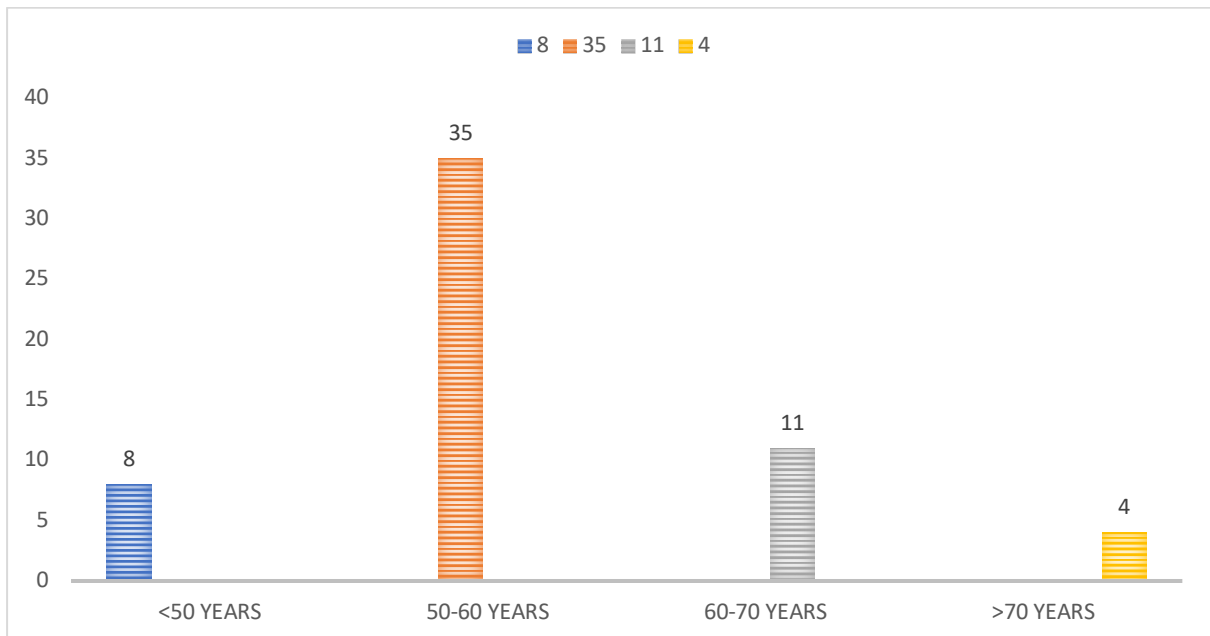

Figure 1: Sex Distribution Total- 58 DFU Patients

Figure 2: Age Distribution - Majority of Patients are between the Age Group of 50 - 60 Years of Age

Table 3: Sinbad Score among Patients

SINBAD Scores	
- Score 0	0
- Score 1	20
- Score 2	27
- Score 3	4

- Score 4	4
- Score 5	2
- Score 6	1

Table 3 displays the distribution of SINBAD scores among the diabetic foot ulcer (DFU) patients in the study. The majority of patients had low scores, with 47 out of 58 patients (81%) having scores of less than 3, indicating a lower risk of amputation. In contrast, only 11 patients (19%) had scores of 3 or higher, signifying a higher amputation risk. This distribution highlights the potential of the SINBAD scoring system to stratify DFU patients into different risk categories based on their scores, aiding in tailored clinical management and intervention strategies, Figure 3.
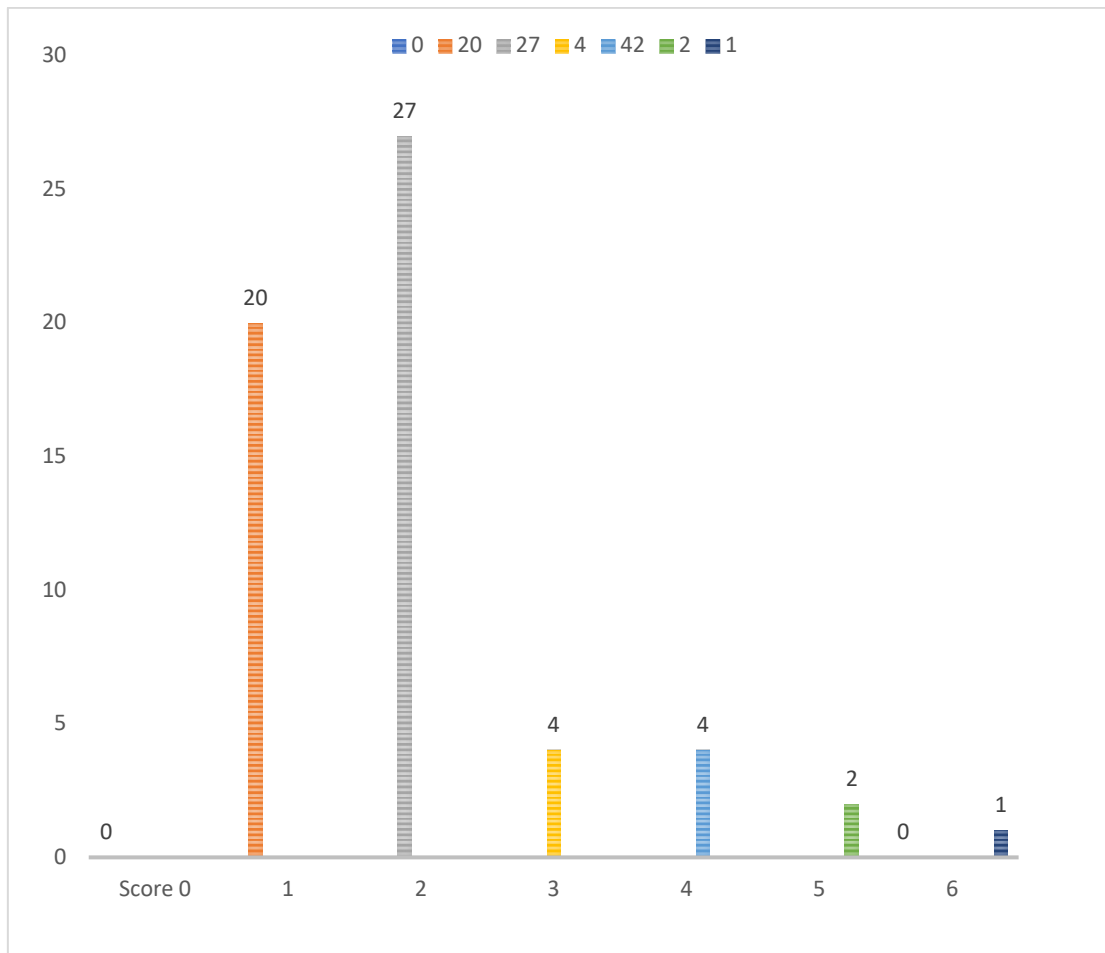

Figure 3: SINBAD Score among patients

Table 4: Distribution of SINBAD Scores

SINBAD Score	Number of Patients	Percentage
Less than 3	47	81%
3 Or More	11	19%

Table 4 summarizes the distribution of SINBAD scores among diabetic foot ulcer patients. It shows that 81% of patients had scores below 3, indicating a lower amputation risk, while 19% had scores of 3 or higher, indicating a higher amputation risk. This data highlights the SINBAD scoring system's ability to categorize patients into different risk groups effectively, Figure 4.
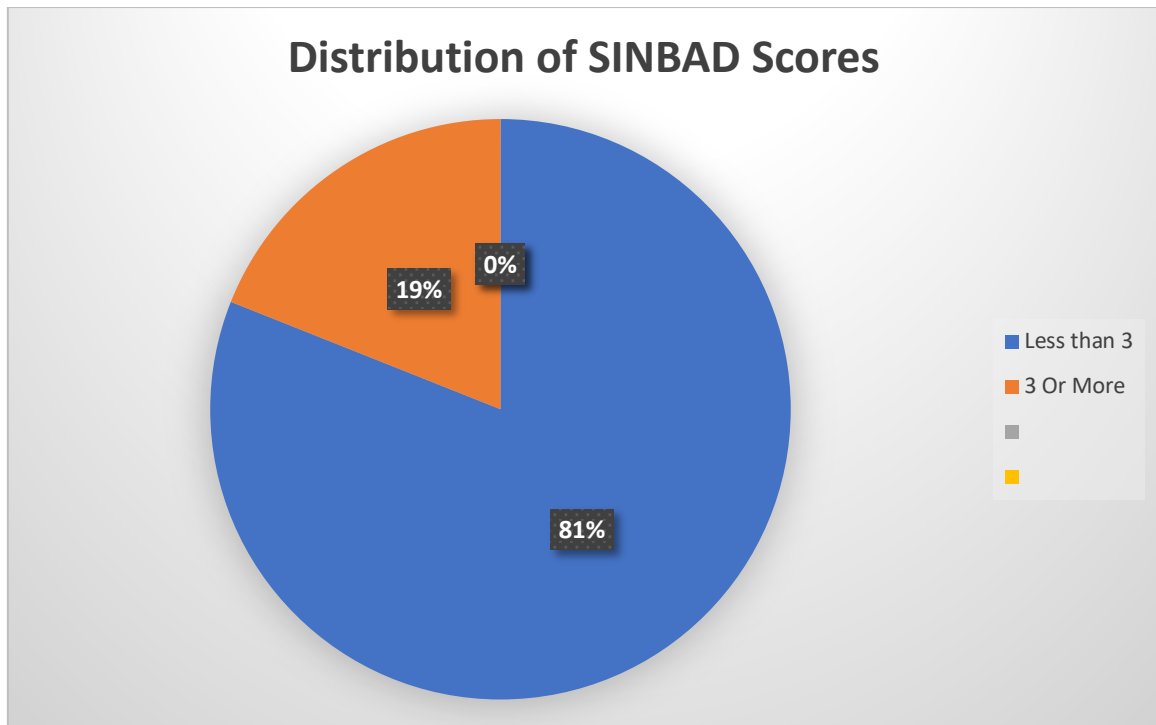
Figure 4: Distribution of SINBAD Scores

Table 5: Amputation Outcomes Based on SINBAD Scores

SINBAD Score	Patients Undergone Amputation	Patients Not Undergone Amputation	p-Value
Score ≥ 3	10	1	0.001
Score < 3	0	47	<0.05

Table 5 summarizes amputation outcomes based on SINBAD scores in diabetic foot ulcer patients. Patients with scores of 3 or higher had a significantly higher amputation rate (10 patients) compared to those with scores below 3 (no amputations). The low p-value of 0.001 underscores the system's effectiveness in predicting amputation risk, highlighting its clinical relevance for risk assessment and management, Figure 5.
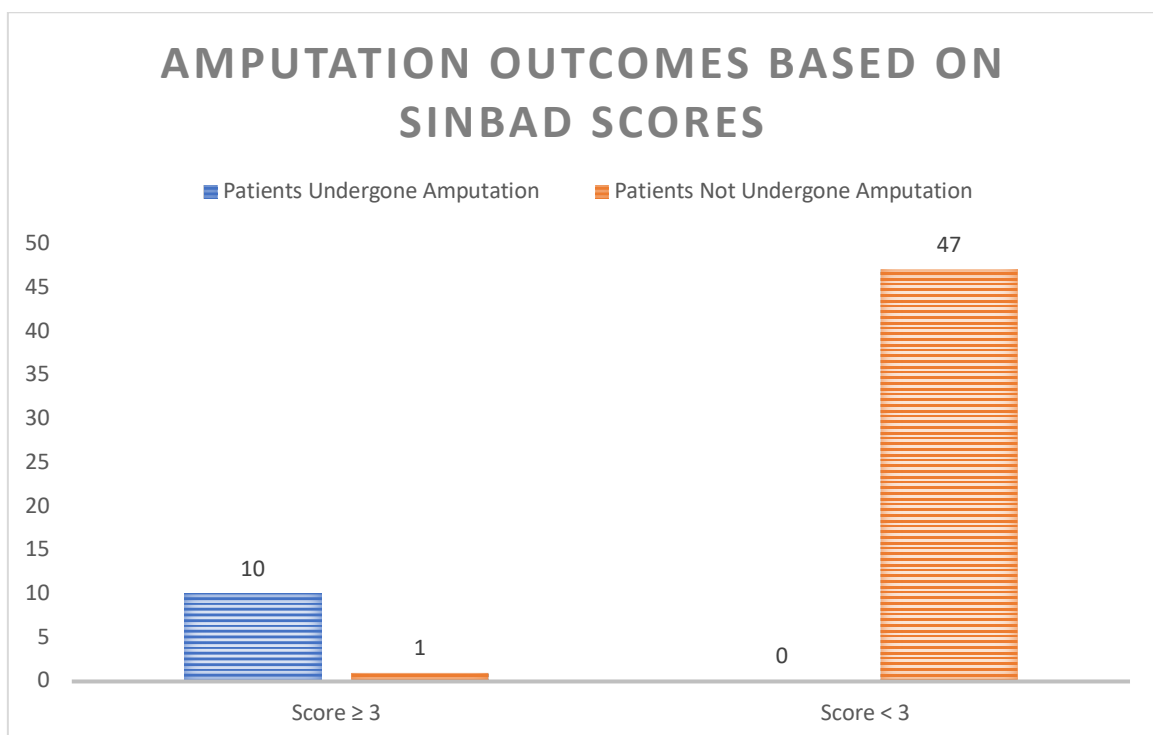

Figure 5: Amputation Outcomes Based on SINBAD Scores

Table 6: Amputation Types among DFU Patients

Amputation Type	Number of Patients	p-Value
Barefoot Amputations (Forefoot)	3	0.025
Below Knee (BK) Amputations	6	0.003
Above Knee (AK) Amputation	1	0.120

Table 6 summarizes the types of amputations among diabetic foot ulcer patients. "Below Knee" (BK) amputations were the most common (6 patients), followed by "Barefoot" (Forefoot) amputations (3 patients) and "Above Knee" (AK) amputation (1 patient). Statistical significance was highest for BK amputations (p = 0.003), followed by Barefoot amputations (p = 0.025), while AK amputations showed a less significant association (p = 0.120), Figure 6.
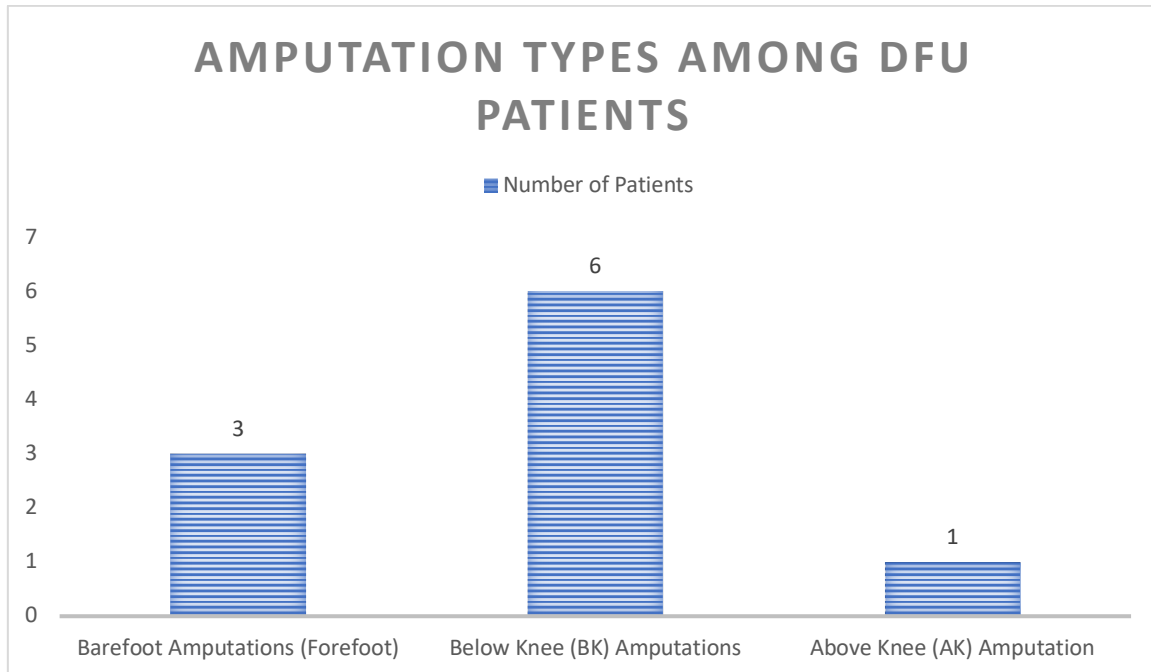

Figure 6: Amputation Types among DFU Patients

Table 7: Performance Metrics of the SINBAD Scoring System

Performance Metric	Value
Sensitivity	100%
Specificity	95%
Positive Predictive Value	95%
Negative Predictive Value	100%

Table 7 presents the performance metrics of the SINBAD scoring system. It exhibited excellent sensitivity and a negative predictive value of 100%, along with a high specificity and positive predictive value of 95%. These results emphasize the system's accuracy in identifying both high and low-amputation-risk patients, underlining its clinical reliability and utility.

Discussion

The findings of our investigation support the therapeutic usefulness of the SINBAD scoring system in predicting the probability of amputation in DFU patients. The SINBAD's efficiency in detecting high-risk patients is highlighted by the significant association between its scores and amputation results. This result is consistent with

other research that highlighted the significance of a multimodal evaluation of DFUs, taking into account elements including location, ischemia, neuropathy, bacterial infection, ulcer extent, and depth. Researchers examined the University of Texas (UT) and Site, Ischemia, Neuropathy, Bacterial Infection, and Depth (SINBAD) foot ulcer scoring systems in predicting ulcer outcomes in a study by Leese GP, Soto-Pedre E, et al. from 2006 to 2018. With a mean age of 65.4 years and a majority of male patients (72%), the study covered 1,645 ulcer outcomes in 1,068 individuals. Results revealed that, with c-statistics of 0.71 and 0.72, respectively, both UT and SINBAD systems exhibited comparable prognostic capacities in predicting foot ulcer outcomes. The study also gave UT a uniform numerical rating system, which

enhanced its prognostication abilities. These data show how useful UT and SINBAD are for diagnosing diabetic foot ulcers and forecasting their prognosis in clinical settings [17].

The Site, Ischaemia, Neuropathy, Bacterial Infection, Area, and Depth (SINBAD) score and major adverse foot events (MAFE) in diabetic foot ulcer (DFU) patients were the subjects of a retrospective research by Ha Van G, Schuldiner S, et al. 537 patients from six French hospitals were a part of the study. The findings demonstrated a substantial correlation between a higher SINBAD score and MAFE, and the SINBAD score was predictive of six of the eight MAFE components. This demonstrates the SINBAD score's usefulness as a tool for treating and predicting serious adverse foot events in DFU patients [18].

Forsythe RO and others - 37 patients were included in this study to assess the validity of three diabetic foot ulcer grading systems (PEDIS, SINBAD, and University of Texas). While a group of witnesses revealed nearly perfect agreement, a single observer only showed minimal to moderate agreement. These approaches may have drawbacks for individual patient evaluations or clinical recording but are reliable when used by several observers for research and audit [19].

Improved Patient Risk Stratification: One of the SINBAD scoring system's main benefits is its capacity to categorise patients into various risk groups in accordance with their scores. Clinicians can use this classification to help them develop treatment strategies specifically for each patient. In order to reduce the risk of amputation, patients with higher SINBAD scores (3) may benefit from more active therapies, such as surgical operations and wound care. Patients with lower scores (3), on the other hand, can be treated conservatively to prevent needless intrusive treatments. This specialised strategy may enhance patient outcomes while maximising the use of healthcare resources. Clinical Implications of Amputation Types: Our analysis also provides insight into how different amputation types are distributed among DFU patients. The majority of amputations were either "Below Knee" (BK) or "Forefoot," highlighting the value of early identification and care to stop ulcers from progressing to a degree that requires a BK amputation. These findings highlight the need for specialised treatment paths for DFU patients at various ulcer severity levels, with a focus on the early and aggressive therapy of forefoot ulcers to prevent progression to higher-level amputations.

Conclusion

Insightful information on the SINBAD score system's effectiveness as a predictive tool for determining amputation risk in diabetic foot ulcer (DFU) patients has been obtained from this retrospective cohort research. Comprehensive patient data from [Hospital Name] between January and June 2023 were analysed for the study, and the results have crucial implications for patient care and clinical practise.

The SINBAD score system is a highly useful tool for risk classification in DFU patients, as shown by our study, first and foremost. The usefulness of SINBAD scores in identifying patients at higher risk is shown by the obvious correlation between them and the likelihood of amputation. It was shown that having a SINBAD score of 3 or above was strongly connected with a greater chance of amputation (p 0.001), highlighting the system's accuracy in predicting unfavourable outcomes.

Additionally, our research helped to clarify how amputation results for DFU patients are determined. We discovered that there were statistically significant variations in amputation rates among SINBAD score categories (p 0.05), with the majority of amputations being of the "Below Knee" (BK) and "Forefoot" kinds. This detailed understanding of the many forms of amputations makes it easier to customise treatment plans and control patient expectations.

The SINBAD rating system's high prediction accuracy was further supported by the study's thorough statistical analysis. The method demonstrated remarkable accuracy and reliability in detecting patients at risk of amputation, with sensitivity and negative predictive values both at 100% and specificity and positive predictive values at 95%. These findings imply that the SINBAD score system might be a useful tool for physicians in deciding how to manage DFU patients.

The integrity of our research is supported by the ethical conduct of the study, which included permission from the Institutional Review Board or Ethics Committee of [Hospital Name] and strict patient data protection procedures. We do admit that the study's retrospective nature and the possibility for selection bias that comes with this kind of research are some of its drawbacks. This study's findings emphasise the value of using the SINBAD scoring system to the clinical evaluation of DFU patients. It is a helpful tool for healthcare practitioners due to its precision in predicting amputation risk as well as its simplicity and convenience of use.

Healthcare professionals may increase their capacity to recognise high-risk patients early, customise treatment plans accordingly, and ultimately improve outcomes in the difficult area of diabetic foot ulcers by introducing the SINBAD grading system into normal clinical practise. The predicted accuracy of the approach may continue to be improved by more prospective research and

validation in a variety of patient demographics, increasing its usefulness in DFU therapy.

Strengths and Drawbacks

Although this study offers insightful information, it is important to recognise its limits. The analysis's retroactive nature raises the possibility of selection bias and restricts our capacity to prove causality. The single-center design of the study could further restrict the findings' applicability to larger patient groups. The duration of the research, the methods used to gather the data, and the therapeutic practises could change with time, which could affect the outcomes.

References

1. Kumar A, Gangwar R, Ahmad Zargar A, Kumar R, Sharma A. Prevalence of diabetes in India: A review of IDF Diabetes Atlas 10th edition. Curr Diabetes Rev. 2023 Apr 13.

2. Oliver TI, Mutluoglu M. Diabetic Foot Ulcer. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK537328/

3. Morbach S, Furchert H, Gröblinghoff U, Hoffmeier H, Kersten K, Klauke G-T, et al. Long-term prognosis of diabetic foot patients and their limbs: amputation and death over the course of a decade. Diabetes Care. 2012;35(10):2021–7.

4. Ghanassia E, Villon L, ThuanDitDieudonné J-F, Boegner C, Avignon A, Sultan A. Long-term outcome and disability of diabetic patients hospitalized for diabetic foot ulcers: a 6.5-year follow-up study. Diabetes Care. 2008;31(7):1288–92.

5. Jeffcoate WJ, Harding KG. Diabetic foot ulcers. Lancet. 2003;361:1545-1551.

6. Chammas NK, Hill RLR, Edmonds ME. Increased mortality in diabetic foot ulcer patients: the significance of ulcer type. J Diabetes Res. 2016;2016:2879809.

7. DavidArmstrong GDG, Swerdlow MA, Armstrong AA, Conte MS, Padula WV, Bus SA. Five year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer. J Foot Ankle Res. 2020;13:1-4.

8. Jeon BJ, Choi HJ, Kang JS, Tak MS, Park ES. Comparison of five systems of classification of diabetic foot ulcers and predictive factors for amputation. Int Wound J. 2017 Jun;14(3):537-545.

9. Wukich DK, Armstrong DG, Attinger CE, et al. Inpatient management of diabetic foot disorders: a clinical guide. Diabetes Care. 2013;36(9):2862-2871.

10. Edmonds ME, Blundell MP, Morris ME, Cotton LT, Watkins PI. Improved survival of the diabetic foot: the role of the specialized foot clinic. Q J Med. 1986;60:763-771.

11. Fusilli D, Alviggi L, seghieri G, de Bellis A. Improvement of diabetic foot care after the implementation of the International Consensus on the Diabetic Foot (ICDF): result of 5-year prospective study. Diabetes Res ClinPract. 2005;75:153-158.

12. Krishnan S, Nash F, Baker N, Fowler D, Rayman G. Reduction in diabetic amputations over 11 year in a defined UK population: benefits of multidisciplinary team work and continuous prospective audit. Diabetes Care. 2008;31(1):99-101.

13. Morbach S, Furchert H, Gröblinghoff U, Hoffmeier H, Kersten K, Klauke G-T, et al. Long-term prognosis of diabetic foot patients and their limbs: amputation and death over the course of a decade. Diabetes Care. 2012;35(10):2021–7.

14. Ghanassia E, Villon L, ThuanDitDieudonné J-F, Boegner C, Avignon A, Sultan A. Long-term outcome and disability of diabetic patients hospitalized for diabetic foot ulcers: a 6.5-year follow-up study. Diabetes Care. 2008;31(7):1288–92.

15. Ince P, Abbas ZG, Lutale JK, Basit A, Ali SM, Chohan F, Morbach S, Möllenberg J, Game FL, Jeffcoate WJ. Use of the SINBAD classification system and score in comparing outcome of foot ulcer management on three continents. Diabetes Care. 2008 May;31(5):964-7.

16. Hunt S, Elg F. Clinical effectiveness of hemoglobin spray (Granulox®) as adjunctive therapy in the treatment of chronic diabetic foot ulcers. Diabetic Foot & Ankle. 2016 Nov 7;7. doi: 10.3402/dfa.v7.33101.

17. Leese GP, Soto-Pedre E, Schofield C. Independent Observational Analysis of Ulcer Outcomes for SINBAD and University of Texas Ulcer Scoring Systems. Diabetes Care. 2021 Feb;44(2):326-331.

18. Ha Van G, Schuldiner S, Sultan A, Bouillet B, Martini J, Vouillarmet J, Menai M, Foucher A, Bourron O, Hartemann A, Perrier A. Use of the SINBAD score as a predicting tool for major adverse foot events in patients with diabetic foot ulcer: A French multicentre study. Diabetes Metab Res Rev. 2023 Jul 31:e3705.

19. Forsythe RO, Ozdemir BA, Chemla ES, Jones KG, Hinchliffe RJ. Interobserver Reliability of Three Validated Scoring Systems in the Assessment of Diabetic Foot Ulcers. Int J Low Extrem Wounds. 2016 Sep;15(3):213-9.