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Prognostic Utility of SINBAD and DUSS Scoring Systems in Predicting Outcomes of Diabetic Foot Ulcers: A Prospective Cohort Study

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ABSTRACT

Background and Objectives: Diabetic foot ulcers (DFUs) are one of the most serious complications of diabetes mellitus, leading to significant morbidity and risk of lower extremity amputations (LEAs). The SINBAD classification system and Diabetic Ulcer Severity Score (DUSS) have been proposed as predictive tools for ulcer outcomes, but no gold standard exists for prognostication. This study aims to evaluate the role of SINBAD and DUSS scores in predicting DFU outcomes, particularly healing and amputation rates.

Methods: A prospective cohort study was conducted at Tirunelveli Medical College from October 2022 to December 2023, involving 224 diabetic foot ulcer patients. Patients were assessed using SINBAD and DUSS scoring systems, and outcomes were monitored over six months. The primary outcome measures were ulcer healing and amputation. Statistical analyses included chi-square tests, independent t-tests, ROC curve analysis, and diagnostic accuracy tests to assess the predictive validity of SINBAD and DUSS scores.

Results: Among 224 patients, amputation was performed in 80 (35.7%) cases. The mean age of amputated patients was 59.99±11.12 years, compared to 57.10±11.55 years in non-amputated patients (p=0.07). Gender distribution showed a significant association, with males comprising 71% of the sample but having a lower amputation rate (p=0.007). The presence of infection, gangrene, and ascending cellulitis significantly correlated with amputation rates. ROC curve analysis indicated that SINBAD and DUSS scores had good predictive validity for amputation, with optimal cut-off values demonstrating high sensitivity and specificity.

Conclusion: The SINBAD and DUSS scoring systems are effective tools for predicting diabetic foot ulcer outcomes. A SINBAD score ≥3 was associated with a higher likelihood of delayed healing and amputation. Implementing these classification systems in routine clinical practice can aid in risk stratification and targeted management of DFUs.

Keywords: *Diabetic Foot Ulcers, Amputation, SINBAD Score, DUSS Score, Diabetic Neuropathy, Peripheral Arterial Disease, Prognostic Classification, Wound Healing, Predictive Modelling*

1. INTRODUCTION

One of the most prevalent metabolic diseases, diabetes mellitus affects 6·4% of people worldwide and is becoming more and more prevalent.[1] Diabetic neuropathy and peripheral vascular problems, which result in diabetic foot ulcers (DFUs), are the most significant consequences that patients with diabetes are at high risk of developing.[2] DFUs jeopardize the survival and well-being of diabetes patients and are among the most severe, costly, and concerning consequences.[3]

Diabetic neuropathy, macroangiopathy, and the combination of macroangiopathy and neuropathy are the key determinants in the aetiology of DFUs.[4] Diabetic foot can manifest as ischemic with infection, mixed ischemic and neuropathic, or neuropathic alone.[5] People with diabetes are increasingly experiencing lower extremity ulceration and amputations. DFUs affect 1–4% of diabetes patients each year, and 15–25% of them do so during the duration of their condition. 85% of people who have had lower limb amputations experience persistent DFUs, and over 50% of diabetes patients have lower extremity amputations (LEAs).[6,7]

Diabetes has reached pandemic proportions in India. According to estimates, the prevalence is 3% of the population in rural regions and 9% in metropolitan areas. This indicates that, of all the countries, India has the most number of diabetes. According to WHO forecasts, over 300 million people in India will have diabetes by 2025, making it the "diabetic capital of the world."[8]

DFU categorization systems are a crucial tool for evaluating and choosing treatments as well as for enhancing professional communication. They also help identify individuals who need specialized care and standardize prognostic estimate.[9] Therefore, it would be easier to make decisions if there was a single or simpler categorization system of DFUs that included the most reliable predicted indicators for LEA. However, no prognostic approach has been recognized as the gold standard as of yet.[10]

The Wagner-Meggitt classification, SINBAD, DUSS, IWGDF Guidelines, and PEDIS are clinical classification systems for diabetic foot.[11]

According to the 2019 Diabetic Foot (DFU) guidelines published by the International Working Group of the Diabetic Foot (IWGDF), there are three categories of important factors that can be used to score DFUs: ulcer-related (area, depth, site, single or multiple, and infection), limb-related (peripheral arterial disease (PAD) and loss of protective sensation), and patient-related (end-stage renal failure).[13] The IWGDF incorporates six of these eight factors and is simple to use, with a maximum score of six points.[13]

DUSS may be useful for research reasons including surgical audit and disease outcome prediction, as well as for stratifying the disease's severity for care.[14] Therefore, the purpose of this study was to evaluate the role of SINBAD Classification system and DUSS score as predictor of diabetic foot ulcers outcomes.

2. MATERIALS AND METHODS

It was a Prospective cohort study among all diabetic foot ulcers patients attending General Surgery department at Tirunelveli Medical College for a period between October 2022 to December 2023

Sample size- N=224 through Consecutive sampling

Inclusion criteria

All diabetic foot ulcer patients of either sex.

Exclusion criteria

Patients with ulcers pertaining to trauma and other vascular, neurological pathologies.

Methodology

Detailed assessment of the ulcer was done. The system incorporated consideration of location, presence of neuropathy and ischaemia, size of ulceration and whether infection was present. SINBAD score and DUSS score were used. A score ≥3 was considered a severe ulceration, which will lead to delayed healing. SINBAD score was also utilized in reviewing patients care. These patients were followed up in the surgical outpatient clinic once in fortnight for 1st month, then once in a month till the ulcer healed or for a minimum period of upto 6 months. Ulcer healing and amputations were assessed.

Statistical analysis

SPSS (Statistical Package For Social Sciences) version 21. (IBM SPASS statistics [IBM corporation: NY, USA]) was used to perform the statistical analysis

- Data was entered in the excel spread sheet.
- Descriptive statistics of the explanatory and outcome variables were calculated by mean, standard deviation for quantitative variables, frequency and proportions for qualitative variables.
- Inferential statistics like
    - Chi-square test was applied for qualitative variables to find the association.
    - Independent sample t test was applied to compare the quantitative parameters between the groups.
    - ROC curve was computed to find the cut-off values, sensitivity and specificity of SINBAD and DUSS

Score to predict amputation.

- Diagnostic accuracy tests were applied to calculate the sensitivity, specificity, positive predictive value, negative predictive value and accuracy of SINBAD and DUSS Score.

- The level of significance is set at 5%

3. RESULTS

Table 1: Comparison of the mean age based on amputation using independent sample t test

Amputation	N	Minimum	Maximum	Mean	S.D	Mean diff	p value
Not Done	144	31.0	94.0	57.10	11.55	-2.89	0.07
Done	80	28.0	88.0	59.99	11.12		

Amputation was not done in 144 patients with a mean age of 57.10 ± 11.55 years. Amputation was done in 80 patients, having a mean age of 59.99 ± 11.12 years.

Table 2: Distribution of the subjects based on age groups

Age Groups		Amputation		Total
		Not Done	Done	
28 to 40 yrs	Count	8	2	10
	%	5.6%	2.5%	4.5%
41 to 50 yrs	Count	37	14	51
	%	25.7%	17.5%	22.8%
51 to 60 yrs	Count	48	27	75
	%	33.3%	33.8%	33.5%
61 to 70 yrs	Count	37	24	61
	%	25.7%	30.0%	27.2%
71 to 80 yrs	Count	10	12	22
	%	6.9%	15.0%	9.8%
> 80 yrs	Count	4	1	5
	%	2.8%	1.3%	2.2%
Total	Count	144	80	224
	%	100.0%	100.0%	100.0%
Chi-square value-6.88				
p value-0.23				

10 patients (4.5%) belonged to the age group of 28 to 40 years, of which amputation was done in 2 patients (2.5%). 51 patients (22.8%) belonged to the age group of 41 to 50 years, of which amputation was done in 14 patients (17.5%). 75 patients (33.5%) belonged to the age group of 51 to 60 years, of which amputation was done in 27 patients (33.5%).61 patients (27.2%) belonged to the age group of 61 to 70 years, of which amputation was done in 24 patients (30%). 22 patients (9.8%) belonged to the age group of 71 to 80 years, of which amputation was done in 12 patients (22%). 5 patients (2.2%)

belonged to the age group of >80 years. The distribution of subjects based on age group was statistically not significant. (p=0.23)

Table 3: Distribution of the subjects based on gender

Gender		Amputation		Total
		Not Done	Done	
Females	Count	33	32	65
	%	22.9%	40.0%	29.0%
Males	Count	111	48	159
	%	77.1%	60.0%	71.0%
Total	Count	144	80	224
	%	100.0%	100.0%	100.0%
Chi-square value- 7.28				
p value-0.007*				

*significant

65 (29%) were females and 159 (71%) were males. Out of 65 females (22.9%), amputation was done in 32 patients (40%). Out of 159 females (71%), amputation was done in 48 patients (60%). The distribution of subjects based on gender was statistically significant. (p=0.007)

Table 4: Distribution of the subjects based on diagnosis

Diagnosis		Amputation		Total
		Not Done	Done	
Bilateral Diabetic Foot Ulcer	Count	10	0	10
	%	6.9%	0.0%	4.5%
Left Diabetic Foot Ulcer	Count	81	6	87
	%	56.3%	7.5%	38.8%
Left Diabetic Foot Ulcer with Ascending Cellulitis	Count	1	16	17
	%	0.7%	20.0%	7.6%
Left Diabetic Foot Ulcer with Necrotising Fasciitis	Count	2	1	3
	%	1.4%	1.3%	1.3%
Left Diabetic Foot Ulcer, Gangrene 1-5th toes	Count	0	3	3
	%	0.0%	3.8%	1.3%
Left Diabetic Foot Ulcer, Gangrene 1st toe	Count	0	4	4
	%	0.0%	5.0%	1.8%
Left Diabetic Foot Ulcer, Gangrene 2-4th toes	Count	0	2	2

	%	0.0%	2.5%	0.9%
Left Diabetic Foot Ulcer, Gangrene 2nd toe	Count	0	1	1
	%	0.0%	1.3%	0.4%
Left Diabetic Foot Ulcer, Gangrene 3-4th toes	Count	0	4	4
	%	0.0%	5.0%	1.8%
Left Diabetic Foot Ulcer, Gangrene 3-5th toes	Count	0	4	4
	%	0.0%	5.0%	1.8%
Left Diabetic Foot Ulcer, Gangrene 4th toe	Count	0	3	3
	%	0.0%	3.8%	1.3%
Right Diabetic Foot Ulcer	Count	50	1	51
	%	34.7%	1.3%	22.8%
Right Diabetic Foot Ulcer with Ascending Cellulitis	Count	0	16	16
	%	0.0%	20.0%	7.1%
Right Diabetic Foot Ulcer, Gangrene 1-5th toes	Count	0	2	2
	%	0.0%	2.5%	0.9%
Right Diabetic Foot Ulcer, Gangrene 1st toe	Count	0	6	6
	%	0.0%	7.5%	2.7%
Right Diabetic Foot Ulcer, Gangrene 2-4th toes	Count	0	2	2
	%	0.0%	2.5%	0.9%
Right Diabetic Foot Ulcer, Gangrene 2nd toe	Count	0	1	1
	%	0.0%	1.3%	0.4%
Right Diabetic Foot Ulcer, Gangrene 3-5th toes	Count	0	3	3
	%	0.0%	3.8%	1.3%
Right Diabetic Foot Ulcer, Gangrene 4th toe	Count	0	4	4
	%	0.0%	5.0%	1.8%
Right Diabetic Foot Ulcer, Gangrene 5th toe	Count	0	1	1
	%	0.0%	1.3%	0.4%
Total	Count	144	80	224
	%	100.0%	100.0%	100.0%
Chi-square value-188.39				
p value-0.001*				

*significant

Left Diabetic Foot Ulcer was noted in 87 patients (38.8%) of which amputation was done in 6 patients (7.5%), Left Diabetic Foot Ulcer with Ascending Cellulitis was noted in 17 patients (7.6%) of which amputation was done in 16 patients (20%), Left Diabetic Foot Ulcer with Necrotising Fasciitis was noted in 3 patients (1.3%) of which amputation was done in 1 patient (1.3%), Left Diabetic Foot Ulcer, Gangrene 1-5th toes of which amputation was done in all 3 patients (3.8%), Left Diabetic Foot Ulcer, Gangrene 1st toe was noted in 4 patients of which amputation was done in all 4 patients (5%), Left Diabetic Foot Ulcer, Gangrene 2-4th toes was noted in 2 patients of which amputation was done in all 2 patients (0.9%). The distribution based on diagnosis was statistically significant. (p=0.001)

Table 5: Comparison of the mean sinbad score based on amputation using independent sample t test

Amputation	N	Minimum	Maximum	Mean	S.D	Mean diff	p value
Not Done	144	2.0	5.0	2.500	.7755	-2.26	0.001*
Done	80	3.0	6.0	4.762	.7994		

*Significant

Mean SINBAD score in which amputation was not done was 2.5 ± 0.77. Mean SINBAD score in which amputation was done was 4.7 ± 0.79. The comparison of mean SINBAD score based on amputation was statistically significant. (p=0.001)

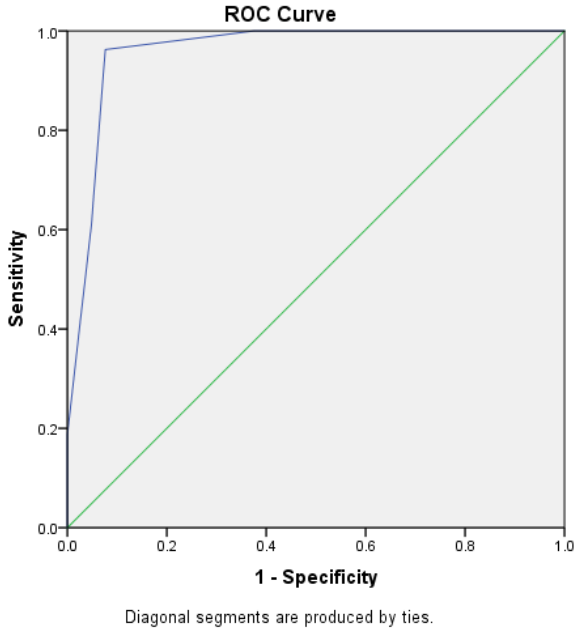
Table 6: Comparison of the mean duss score based on amputation using independent sample t test

Amputation	N	Minimum	Maximum	Mean	S.D	Mean diff	p value
Not Done	144	1.0	4.0	1.549	.6239	-1.41	0.001*
Done	80	2.0	4.0	2.962	.7538		

*Significant

Mean DUSS score in which amputation was not done was 1.5 ± 0.62. Mean DUSS score in which amputation was done was 2.96 ± 0.75. The comparison of mean DUSS score based on amputation was statistically significant. (p=0.001)

Table 7: ROC curve to predict amputation based on SINBAD score

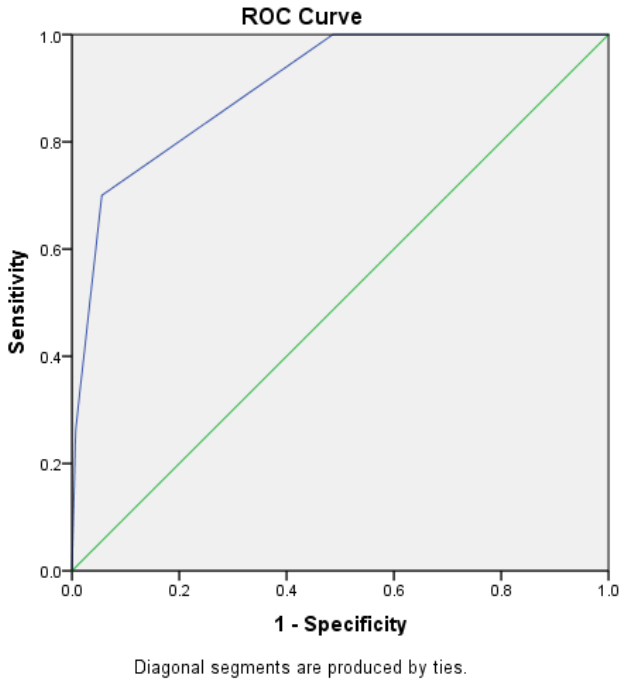


Area Under the Curve					
Test Result Variable	Area	Std. Error	p value	Asymptotic 95% Confidence Interval	
				Lower Bound	Upper Bound
SINBAD Score	.959	.013	.001*	.935	.984

*significant

The area under the curve for SINBAD score is 0.959 and is statistically significant (p=0.001). The best cut off to predict amputation would be 3.5 with 96.3% sensitivity and 92.4 % specificity.

Table 8: ROC curve to predict amputation based on duss score



Area Under the Curve					
Test Result Variable	Area	Std. Error	p value	Asymptotic 95% Confidence Interval	
				Lower Bound	Upper Bound
DUSS Score	.904	.020	.001*	.866	.943

*significant

The area under the curve for DUSS score is 0.904 and is statistically significant (p=0.001). The best cut off to predict amputation would be 2.5 with 70% sensitivity and 94.4 % specificity.

Table 9: Association of SINBAD score and amputation

SINBAD Score		Amputation		Total
		Not Done	Done	
< 3.5	Count	133	3	136
	%	92.4%	3.8%	60.7%
>3.5	Count	11	77	88
	%	7.6%	96.3%	39.3%
Total	Count	144	80	224
	%	100.0%	100.0%	100.0%
Chi-square value-169.29				
p value- 0.001*				

*significant

136 patients (60.7%) had a SINBAD Score of <3.5, of which, amputation was done in 3 patients (3.8%). 88 patients (39.3%) had a SINBAD Score of >3.5, of which, amputation was done in 77 patients (96.3%). The association of SINBAD score and amputation was statistically significant. (p=0.001)

Statistic	Value	95% CI
Sensitivity	96.25%	89.43% to 99.22%
Specificity	92.36%	86.74% to 96.13%
Positive Likelihood Ratio	12.60	7.13 to 22.27
Negative Likelihood Ratio	0.04	0.01 to 0.12
Positive Predictive Value	87.50%	79.84% to 92.52%
Negative Predictive Value	97.79%	93.59% to 99.26%
Accuracy	93.75%	89.74% to 96.54%

Sensitivity was 96.25%, specificity was 92.36%, PLR was 12.60, NLR was 0.04, Positive Predictive Value was 87.50%, Negative Predictive Value was 97.79% and accuracy was 97.79%.

Table 10: Association of DUSS score and amputation

DUSS Score		Amputation		Total
		Not Done	Done	
<2.5	Count	136	24	160
	%	94.4%	30.0%	71.4%
>2.5	Count	8	56	64
	%	5.6%	70.0%	28.6%
Total	Count	144	80	224
	%	100.0%	100.0%	100.0%
Chi-square value-104.65				
p value- 0.001*				

*significant

160 patients (71.4%) had a DUSS score of <2.5, of which, amputation was done in 24 patients (30%). 64 patients (28.6%) had a DUSS score of >2.5, of which, amputation was done in 56 patients (70%). The association of DUSS score and amputation was statistically significant. (p=0.001)

Statistic	Value	95% CI
Sensitivity	70.00%	58.72% to 79.74%
Specificity	94.44%	89.35% to 97.57%
Positive Likelihood Ratio	12.60	6.33 to 25.08
Negative Likelihood Ratio	0.32	0.23 to 0.44
Positive Predictive Value	87.50%	77.86% to 93.30%
Negative Predictive Value	85.00%	80.18% to 88.81%
Accuracy	85.71%	80.44% to 90.02%

Sensitivity was 70%, specificity was 94.44%, PLR was 12.60, NLR was 0.32, Positive Predictive Value was 87.50%, Negative Predictive Value was 85.00% and accuracy was 85.71%.

4. DISCUSSION

Globally, DFU is a leading indication for non-traumatic amputation of the lower extremities.[15] According to estimates from the Global Lower Extremity Amputation Study Group, diabetes was linked to between 25% and 90% of all amputations.[15] Four clinically specified parameters—palpable pedal pulses, bone probing, ulcer location, and the presence of numerous ulcerations—were used to construct the DUSS. The purpose of this study was to evaluate the contribution of the DUSS score and SINBAD Classification to the comparison of foot ulcer treatment outcomes. With a mean age of 59.99 ± 11.12 years, 71% of the participants in this research were male. The majority of patients (33.5%) were between the ages of 51 and 60. These findings were consistent with a research by Jeon BJ et al. that included 57·7% men and a mean age of 61·1 years.[16]

Left diabetic foot ulcer was the most prevalent diagnosis in this study, occurring in 38.8% of patients, with 6 patients (7.5%) having an amputation. This was followed by left diabetic foot ulcer with ascending cellulitis, occurring in 17 patients (7.6%), with 16 patients (20%) having an amputation. In a similar vein, Menezes et al. observed that 42% of the research participants had an acute presentation, such as cellulitis or an abscess, as their first symptom after trauma.[17]

The mean SINBAD score in the current investigation, when no amputation was performed, was 2.5 ± 0.77. The average SINBAD score at the time of amputation was 4.7 ± 0.79. Amputation-based mean SINBAD score comparisons were statistically significant. (p=0.001) In a similar vein, 61% of patients in a research by Ha Van G et al. had a low SINBAD score (between 0 and 3) and 39% had a high score (between 4 and 6).[18]

According to a different research, a SINBAD score of less than three is linked to a 60% healing rate at twelve weeks, compared to 35% if the score is greater than three, and a 2.7% vs 0.7% probability of MajA after six months.[19]

Amputation was performed on 3 patients (3.8%) out of 136 patients (60.7%) with a SINBAD Score of less than 3.5. Of the 88 patients (39.3%) with a SINBAD Score greater than 3.5, 77 patients (96.3%) underwent amputation. Amputation and SINBAD score were statistically significantly correlated. (p=0.001) The study's positive predictive value was 87.50%, negative predictive value was 97.79%, accuracy was 97.79%, sensitivity was 96.25%, specificity was 92.36%, PLR was 12.60, and NLR was 0.04.

Amputation-free, the mean DUSS score was 1.5 ± 0.62. The average DUSS score at the time of the amputation was 2.96 ± 0.75. Amputation-based mean DUSS score comparisons were statistically significant. (p=0.001) According to Menezes et al., the majority of the study group's patients got scores of 1 (42.5%), 2 (26.5%), and 3 (22%). Scores of 0 (4.5%) and 4 (4.5%) were the lowest.[17]

Wounds with a high DUSS indicated a significant likelihood of severe amputation in the original Beckert et al. investigation.[14] Individuals with a score of 0 were at no risk of major amputation, but those with a score of 1 were at 2.4%, those with a score of 2 were at 7.7%, those with a score of 3 were at 11.2%, and those with a score of 4 were at 3.8%.14 Menezes et al. also observed that there were no significant amputations among individuals with scores of 0–2.87 On the other hand, all nine patients (100%) who received a score of four had significant amputations. The outcome of the illness was positively correlated with the severity of DUSS.[17] The study's sensitivity was 70%, specificity was 94.44%, accuracy was 85.71%, PLR was 12.60, NLR was 0.32, and the positive predictive value was 87.50% and the negative predictive value was 85.00%. In this investigation, the SINBAD score outperformed the DUSS score in terms of specificity and sensitivity.

Limitations

They were as follows:

1. short follow-up period
2. absence of information on ulcer healing.

5. CONCLUSION

For the purpose of evaluating the healing process and selecting the best course of therapy, diabetic foot ulcers must be accurately classified. By integrating clinically assessable wounds based on many factors, the scoring system and clinician communications offer a simple diagnostic tool for forecasting the likelihood of healing or amputation. Although it doesn't change the wound treatment process, study groups can be categorized based on the severity of ulcers, which can assist give a straightforward, efficient method in a clinical context without the need for any sophisticated investigative tools. The two grading systems in this investigation had about identical wound predictability, however SINBAD was more precise.

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