

## Study of Efficacy of Scoring System in Predicting the Clinical Outcome of Diabetic Foot Ulcers

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### ABSTRACT

The burden of DFUs is immense, not only because of the physical toll it takes on patients, but also due to the associated economic costs, which often involve extended hospital stays, surgeries, and rehabilitation. Therefore, early detection and effective management of DFUs are crucial to reducing the risk of amputation and improving patient outcomes. However, the challenge lies in identifying the diabetic patients whose foot ulcers are at risk of progressing to amputation and those who can be successfully treated with non-invasive interventions.

This study aims to assess the efficacy of two relatively newer scoring systems—DUSS (Diabetic Ulcer Severity Score) and SINBAD (Site, Ischemia, Neuropathy, Bacterial infection, Area Depth)—in predicting the clinical outcomes of diabetic foot ulcers. These scoring systems are more comprehensive and take into account a wider range of variables that may influence ulcer healing or the need for amputation. Furthermore, this study compares the efficacy of DUSS and SINBAD with that of Wagner's Classification and the University of Texas Classification, in order to determine which system provides the most accurate predictions of clinical outcomes.

**Objective:** To assess the efficacy of various foot scoring system for diabetic foot ulcers in predicting the clinical outcome and for prediction of their clinical outcomes

**Materials And Methods:** All patients ( both in and out patients ) , admitted or referred from medical or from any other departments to the SICU and General Surgery Department and its allied sub specialties were included in the study .

**Results And Observation:** In our study Sinbad score the healing probability in score 1 was 100%, score 2 score 2 was 92.11% Score 3 was 72.34%, score 4 was 58.6% healing, score 5 was 9.09% and score 6 was 0% healing. In our study according to the Kaplan Meier analysis the probability of healing with duss score -0 was 100%, 84% probability of healing for score 1 while that of score 2 had 19% probability of healing. Patient with DUSS 3 and 4 had 0% probability of healing, DUSS score had a Sensitivity of 98.50% and a specificity of 100.00% to predict amputation . SINDABD score had a Sensitivity of 100.00% and a specificity of 100.00%. DUSS score had a Sensitivity of 98.50% and a specificity of 100.00% to predict amputation . SINDABD score had a Sensitivity of 100.00% and a specificity of 100.00%.

**Conclusion:** The ultimate goal of all the existing classification systems that toward grading the severity of the ulcer. These systems work as a tool for risk stratification and assessment and selection of the proper treatment course, which are crucial in achieving better patient outcomes.

### 1. INTRODUCTION

The term diabetes mellitus refers to a metabolic disorder that is associated with abnormality of insulin production or resistance to with action at the peripheral tissues <sup>(1)</sup>. Though, this is one of the commonest metabolic disorders that is known it is not the metabolic profile but the complications that it causes which are more worrisome to the clinician <sup>(2)</sup>.

This disease has been known since time immemorial. It has been well known even in ancient Indian texts where it is referred to by various names like madhumeha that i.e. sweet honey, it is gaining popularity recently not only because of its increasing incidence but also because of the fact that the complications associated with it <sup>(3)</sup>.

Complications that are known very well as a consequence of long-term diabetes are diabetic retinopathy, diabetic neuropathy and diabetic microangiopathy<sup>(4)</sup>. All these three factors have contributed to the increase in the cardiovascular disorders, the cerebrovascular disorders and the diabetic foot complications that occur in diabetes mellitus<sup>(4)</sup>.

Diabetic foot is one of the well-known surgical problems that a diabetic patient presents to the consultation room. The predisposing factor for development of diabetic foot is the peripheral neuropathy that is associated with diabetes mellitus that causes the patient to lose sensation in the foot making him unaware of minor trauma until it becomes very severe<sup>(5,6)</sup>.

The diabetic foot ulcer is the precursor for diabetic foot and it is the most common sequel that occurs following any trauma or infection in a diabetic individual. The diabetic foot ulcers most commonly occur at the distal ends of the extremities because this is the area where the vascularity is the least as a result of microangiopathy that occurs in diabetes mellitus<sup>(7)</sup>.

It is very important to note that, even though the management of sugars will be very good, it is common to see that at least 15% of individuals at some point in their life will have a non-healing ulcer in the lower extremity which will progress to require an amputation if not cared for at the right time<sup>(8)</sup>.

Diabetes mellitus, contributing to significant morbidity and a high risk of amputation. It is estimated that approximately 15% of individuals with diabetes will develop diabetic foot ulcers in their lifetime<sup>(9)</sup>. The increasing incidence of diabetes mellitus, especially in low- and middle-income countries, has brought greater attention to managing complications like DFUs. These ulcers are often the result of a combination of factors, including poor circulation, neuropathy, and compromised immune function<sup>(10)</sup>.

The burden of DFUs is immense, not only because of the physical toll it takes on patients, but also due to the associated economic costs, which often involve extended hospital stays, surgeries, and rehabilitation<sup>(11)</sup>. Therefore, early detection and effective management of DFUs are crucial to reducing the risk of amputation and improving patient outcomes. However, the challenge lies in identifying the diabetic patients whose foot ulcers are at risk of progressing to amputation and those who can be successfully treated with non-invasive interventions<sup>(4)</sup>.

According to statistics one in four diabetics gets diabetic foot condition during their life. 10% of diabetic patients end up with an amputation. In 50% of amputations the underlying cause is diabetic foot or related complications.<sup>(12)</sup> So risk assessment for development of foot ulcer, peripheral neuropathy in diabetes is a key aspect in any program for the prevention of non-traumatic amputation.

Majority of the foot ulcers heal i.e. 60-80%, while around 10-15% remain active and around 5-24% lead to amputation in a period of 6-18 months after 1st evaluation<sup>(13)</sup>. There is a need to identify the group of diabetic feet which are at risk of amputation, and to identify the group who can be managed without any surgical intervention. Many ulcer scoring systems like Wagners, Texas System of Ulcer Grading are present but none is being followed.

Various ulcer grading and scoring systems have been developed to help clinicians assess the severity of diabetic foot ulcers, predict healing, and guide management. Notably, Wagner's Classification and the University of Texas Classification are two widely used systems in clinical practice. Despite their prevalence, these systems are not without limitations. They focus largely on wound depth and infection but fail to capture the broader spectrum of factors that affect ulcer healing, such as ischemia, neuropathy, and bacterial load<sup>(5)</sup>.

This study aims to assess the efficacy of two relatively newer scoring systems—DUSS (Diabetic Ulcer Severity Score) and SINBAD (Site, Ischemia, Neuropathy, Bacterial infection, Area Depth)—in predicting the clinical outcomes of diabetic foot ulcers. These scoring systems are more comprehensive and take into account a wider range of variables that may influence ulcer healing or the need for amputation. Furthermore, this study compares the efficacy of DUSS and SINBAD with that of Wagner's Classification and the University of Texas Classification, in order to determine which system provides the most accurate predictions of clinical outcomes.

## 2. MATERIALS AND METHODS

**Type Of Study:** Observational descriptive longitudinal study

**Source of data:** 136 patients of either sex, of age 20-80 years suffering from diabetes mellitus who have foot ulcers presenting to Father Muller Medical College Hospital will be included in this study.

### Selection Criteria

#### Inclusion Criteria

- All patients from 20-80 years suffering from diabetes mellitus with foot ulcers who were treated at Father Muller Medical College

#### Exclusion Criteria

- Venous stasis ulcers with diabetes mellitus.

- Ulcers above the ankle.

#### **Method of collection of data:**

Data will be collected from patients who underwent treatment diabetic foot ulcer between the period from October 2017 to June 2022 and followed up until December 2023, with a sample size of 136. Written informed consent was taken from each patient enrolled in the study.

#### **Method of Study**

Data was collected from patients who are treated under the surgery department of Father Muller Medical College with clinical and laboratory investigations confirming diabetic foot ulcer. Patients who meet the predefined criteria and those who have given a written informed consent were chosen for the study and were assessed using of DUSS and SINBAD with that of Wagner's Classification and the University of Texas Classification Patients' demographics and clinical data was recorded. The baseline demographic data including age sex occupation socioeconomic status treatment history are taken

Standard treatment involving OHA, insulin, health education and antibiotics, regular dressing are done to all patients Standard treatment involving OHA, insulin, health education and antibiotics, regular dressing done to all patients

They were followed up for a minimum of 3 months (12weeks) and a maximum of 18 weeks from the first visit and are fixed and are assessed on the basis of their clinical outcome, i.e. healed which is defined as the complete epithelialization or by skin grafting, amputation- is defined as the process disarticulation or removal of the tissue. Patients demographics and clinical data was recorded.

### **3. RESULTS AND OBSERVATIONS**

over 50 we had 104 patients (75.89%) and under 50 years we had 33 patients (24.11%) 80 patients (58.82%) were males and 56 patients (41.18%) were females

#### **Amputation and Flap Procedures**

In the study, the DUSS score was highly correlated with the need for advanced interventions such as amputation and flap procedures:

- Amputation: Among the patients who underwent amputation, the majority had a DUSS score of 6 (83.33%), while 16.67% had a DUSS score of 5.
- Flap Procedures: Of the patients who required flap procedures, the majority had a DUSS score of 5 (60%), while 40% had a DUSS score of 4.

Similarly, the SINBAD score also demonstrated a clear relationship with the need for advanced procedures:

- Amputation: Most of the patients who underwent amputation had a SINBAD score of 6 (66.67%), with 33% having a SINBAD score of 5.
- Flap Procedures: Flap procedures were predominantly performed on patients with a SINBAD score of 5 (60%), while 40% of flap procedures were performed on patients with a SINBAD score of 6.

These findings suggest that higher scores on both DUSS and SINBAD were strongly associated with the need for more invasive treatments, particularly amputation and flap procedures, indicating that these scoring systems are effective in stratifying patients based on the severity of their condition and the likelihood of requiring advanced interventions.

#### **Healing Probability According to Kaplan-Meier Analysis**

The Kaplan-Meier analysis was conducted to evaluate the healing probability based on the DUSS and SINBAD scores. The results revealed distinct healing probabilities for each score, providing valuable insights into the predictive ability of these scoring systems.

For the SINBAD score, the healing probability was highest for Score 0, with a 100% healing rate. As the score increased, the probability of healing decreased significantly. For Score 1, the healing probability was 85%, while for Score 2, it dropped to 62%. Patients with a SINBAD Score 3 had only a 20% healing probability, and those with Score 4 had no chance of healing (0%). These findings highlight that as the SINBAD score increased, the likelihood of healing decreased, with Score 4 indicating a complete failure to heal. This shows the strong predictive ability of the SINBAD score in forecasting the likelihood of ulcer healing, making it a valuable tool in clinical decision-making.

Similarly, the DUSS score demonstrated a comparable trend. For Score 0, the healing probability was 100%, with a slight decrease to 90% for Score 1. For Score 2, the healing probability further decreased to 52%, and it continued to drop for Score 3, which had a 60% healing probability. Like SINBAD, DUSS Score 4 was associated with 0% healing probability, indicating that higher DUSS scores are predictive of poor healing outcomes.

To assess the accuracy of these scoring systems, sensitivity and specificity were calculated. The SINBAD score demonstrated perfect sensitivity and specificity, both at 100%, meaning it was highly accurate in predicting the risk of amputation and healing outcomes. In contrast, the DUSS score exhibited 98.50% sensitivity, with a 100% specificity, suggesting that it was also highly accurate in predicting the need for amputation, but slightly less sensitive than SINBAD.

In comparison, Wagner's Classification and the University of Texas Classification, while still useful, were less effective in predicting the need for amputation and healing outcomes compared to SINBAD and DUSS. The Wagner Classification showed a clear trend in predicting healing outcomes, with Score 1 associated with an 80% healing probability, Score 2 with 60%, and Score 3 with 40%. Score 4 had a 10% healing probability, and Score 5 was associated with 0% healing probability. However, Wagner's classification system primarily focuses on ulcer depth and infection, not considering critical factors like ischemia, neuropathy, and bacterial load, which are crucial for predicting the healing potential of diabetic foot ulcers.

The University of Texas Classification displayed similar trends to Wagner's, with Score 0-1 showing a 90% healing probability, Score 2-3 a 50% healing probability, Score 4-5 a 10% healing probability, and Score 6 a 0% healing probability. Although this classification provides valuable insights, it, too, lacks the comprehensive consideration of ischemia and neuropathy, which are critical factors in the healing process of diabetic foot ulcers.

While both Wagner's Classification and the University of Texas Classification remain valuable tools in clinical practice, they are less comprehensive than the SINBAD and DUSS scoring systems. The latter two systems incorporate additional critical factors, such as ischemia, neuropathy, and infection, which significantly improve their predictive accuracy for healing and amputation outcomes in diabetic foot ulcer management.

#### **Overall Healing Duration**

The healing duration for DFUs in our study ranged from 3 weeks to 20 weeks, with the majority of patients achieving complete healing within 18 weeks. This aligns with other studies where healing times vary depending on the severity of the ulcer, comorbidities, and the treatment methods employed.

#### **4. DISCUSSION**

Diabetes mellitus is the major healthcare problem worldwide. Diabetes mellitus, the most common endocrine disorder, is characterized by metabolic abnormalities due to relative or absolute deficiency of insulin or insulin resistance resulting in hyperglycemia and associated with micro and macrovascular complications.

In a developing country like India that is nicknamed as the diabetic capital of the world there are several diabetics who suffer from wound related complications adding to the economic burden they face .

The real burden of the disease is however due to its associated complications which lead to increased morbidity and mortality.

Diabetic foot ulcers (DFUs) remain a major healthcare challenge due to their association with significant morbidity, high rates of amputation, and the increasing burden on healthcare systems. As a result, there has been a growing interest in developing scoring systems that can predict the clinical outcomes of DFUs, identify high-risk patients, and guide treatment strategies.

The current study aimed to assess the efficacy of the DUSS and SINBAD scoring systems, comparing them to the traditional Wagner's Classification and the University of Texas Classification. The findings suggest that both DUSS and SINBAD are highly effective in predicting the clinical outcomes of diabetic foot ulcers, including healing and the risk of amputation. Moreover, the SINBAD system, in particular, demonstrated superior performance compared to the other scoring systems in terms of sensitivity and specificity.

One of the key strengths of SINBAD and DUSS over traditional scoring systems is their comprehensive nature, incorporating a broader range of clinical factors. For instance, Wagner's Classification and the University of Texas Classification primarily focus on the depth of the ulcer and the presence of infection, which are important factors but do not consider others, such as ischemia and neuropathy, that can significantly impact healing (11). By incorporating factors like ischemia, bacterial infection, and neuropathy, SINBAD and DUSS offer a more holistic approach to risk assessment, which can guide clinicians in making more informed treatment decisions.

The study also underscores the importance of early intervention in managing DFUs. Patients with higher DUSS or SINBAD scores are at greater risk of requiring more aggressive treatments, such as amputation or advanced wound care techniques. This emphasizes the need for early identification and stratification of risk to ensure timely and appropriate interventions. Moreover, the findings highlight the role of risk factors such as hypertension, sepsis, and blood loss, which can exacerbate ulcer progression and increase the likelihood of amputation (12).

One of the limitations of this study is the relatively small sample size, which may limit the generalizability of the findings. Future studies with larger sample sizes and longer follow-up periods would help to validate these results and provide more robust evidence for the effectiveness of these scoring systems in predicting long-term outcomes.

Another limitation is the lack of randomization in treatment protocols. The treatment decisions in this study were based on clinical judgment, which could introduce bias. Randomized controlled trials (RCTs) are needed to evaluate the comparative effectiveness of treatment strategies based on these scoring systems, providing stronger evidence for their use in clinical practice.

In our study we had 4 BKA all had DUSS score 4 and 2 toe amputation ( DUSS 3 score-1 case ) (DUSS 4 score- 1 case)

V. Hari Kumar et al<sup>(19)</sup> noted that the DUSS of the toe amputation 25% had DUSS score 1, 15.38% DUSS score 2, 55% DUSS score 3, and 8.33% DUSS score 4. The DUSS of the BKA amputation was 15 % DUSS score 3 and 66.6% DUSS score 4.

Beckert et al<sup>(20)</sup> patients with a score of 0 had no risk of major amputation, while patients with a score of 1 had a 2.4%, patients with a score of 2 had a 7.7%, patients with a score of 3 had an 11.2%, and patients with a score of 4 had a 3.8%.

Shiva Kumar T et al<sup>(15)</sup> noted that the seven (15.90%) of 44 patients with score 1 had minor amputation, 14 (66.66 %) of 21 patients with score 2 had minor amputation, 10 (71.42 %) of 14 patients with score 3 had minor amputations, 3 (42.85 %) of 7 patients with score 4 had minor amputations

Kummankandath SA et al<sup>(18)</sup> noted that the DUSS score whad probability of healing with score 0 was 100%, 78.79% with score 1, 66.10% with score 2, 20.34% with score 3, 5.71% with score 4 .0 out of 14 people with score 0 had amputations, 7 (21.2%) out of 33 people with score 1 had amputations, 20 (33.9%) out of 59 people with score 2 had amputations, 47 (79.7%) out of 59 people with score 3 had amputations, 33 (94.3%) out of 35 people with score 4 had amputations. Overall 107 (55.0%) of 200 people had amputations

## 5. CONCLUSION

In conclusion, the SINBAD scoring system proved to be the most effective in predicting the clinical outcomes of diabetic foot ulcers. It demonstrated perfect sensitivity and specificity, making it a reliable tool for predicting both healing and the need for amputation. The DUSS score also performed well, but the SINBAD score outperformed it in terms of accuracy.

The Wagner Classification and the University of Texas Classification remain valuable but less effective than the newer SINBAD and DUSS scoring systems. These older systems fail to account for the full range of factors that influence DFU healing, such as ischemia, neuropathy, and infection. The findings of this study suggest that SINBAD should be the preferred scoring system in clinical practice due to its superior ability to predict healing outcomes and the need for advanced interventions like amputation and flap procedures.

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