

A Clinical Study to Predict the Risk of Amputation in Diabetic Foot Ulcer Patients Using Wifi Scoring System

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Received: 01-08-2025 / Revised: 15-09-2025 / Accepted: 21-10-2025

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Conflict of interest: Nil

Abstract

Background: Diabetic foot ulcers (DFUs) represent one of the most serious complications of diabetes mellitus, contributing significantly to morbidity, mortality, and amputation risk. Accurate risk stratification is essential for optimal management and prevention of limb loss. The Society for Vascular Surgery Wound, Ischemia, and foot Infection (SVS-Wifi) classification system provides an objective framework to predict amputation risk.

Aim: To predict the risk of amputation in diabetic foot ulcers using the SVS-Wifi scoring system and to correlate Wifi stages with clinical outcomes.

Methodology: A hospital-based prospective study was conducted on 60 patients with DFUs admitted to the Department of General Surgery, Narayana Medical College and Hospital, Nellore. Patients were evaluated using the SVS-Wifi scoring system and categorized into Group 1 (Stages 1–3) and Group 2 (Stage 4). Follow-up was done for six months to assess outcomes regarding minor and major amputations. Glycemic control was analyzed using HbA1c values.

Results: Of the 60 patients, 41 (68.3%) underwent amputations—23 minor and 18 major. Amputation rates were significantly higher in Group 2 (89.4%) compared to Group 1 (31.8%). Poor glycemic control (HbA1c > 6.4) was noted in 78.7% of amputated patients. The SVS-Wifi stage 4 showed high sensitivity (82.9%) and positive predictive value (89.4%) for predicting any amputation.

Conclusion: The SVS-Wifi scoring system effectively predicts the risk and severity of amputations in diabetic foot ulcer patients. Higher Wifi stages and poor glycemic control correlate with increased amputation rates, emphasizing early staging and glycemic optimization.

Keywords: Diabetic Foot Ulcer, SVS-Wifi Scoring, Amputation Risk, Glycemic Control.

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Introduction

The prevalence of diabetes mellitus in India is rapidly increasing, with approximately 65 million diagnosed individuals. The complications associated with the disease significantly impact the quality of life. Foot ulcers and their complications are a major contributor to morbidity and mortality in diabetic patients. It is estimated that 50% of non-traumatic lower limb amputations are performed on patients with diabetes. Diabetic foot ulcers result in decreased mobility, hindering the ability of patients to carry out simple daily tasks and engage in recreational activities. Following amputation, these patients face a high mortality rate, ranging from 39% to 80% within 5 years. [1,2,3]

Over the past 40 years, changes in the population, including a significant increase in diabetes cases and advancements in revascularization techniques, have made it harder to accurately analyze outcomes

for patients with threatened limbs using existing classification systems. Critical limb ischemia was previously used to identify a specific group of patients with a threatened lower extremity at risk of amputation due to chronic ischemia. Older wound classification systems such as Fontaine and Rutherford Systems have been employed to assess the risk of amputation and the potential benefits of revascularization by dividing patients into two categories: ischemic rest pain and tissue loss.

While perfusion plays a role in outcomes, the extent of the wound and the presence and severity of infection also notably affect the results. [4,5,6] The Society for Vascular Surgery Lower Extremity Guidelines Committee set out to create a new classification system for threatened lower extremities, taking into account important factors. This new framework is called the Society for

Vascular Surgery Lower Extremity Threatened Limb Classification System. The system is based on three major factors - Wound, Ischemia, and foot Infection (WIFI) - in order to assess amputation risk and guide clinical management. The aim of this classification system is to allow for more meaningful analysis of outcomes for different treatment approaches in this diverse and challenging patient population. [7]

The Society for Vascular Surgery Wound, Ischemia and foot Infection classification system represents an initial effort to reconsider how we assess and treat patients with various lower extremity ulcers. The intention is for it to be a collaborative process aimed at more accurately categorizing patients based on their initial disease severity.

Aim: To predict the risk of amputation in diabetic foot ulcers using Wound Ischemia Foot Infection scoring system.

Objective: To correlate the need for amputation and Wound Ischemia Foot Infection scores, To stratify diabetic foot ulcer patients using Wound Ischemia Foot Infection scoring system and to follow up the diabetic foot ulcer patients for the need of minor and major amputations.

Methodology: This study was a hospital-based prospective study on 60 patients with diabetic foot ulcers admitted to the General Surgery department at Narayana Medical College and Hospital, Nellore. Those who agreed to participate underwent an assessment using the SVS-WIFI scoring system, and their routine laboratory tests were recorded. A clinical proforma was completed, and the relevant WIFI score for each individual was determined. The patients were categorized based on their WIFI scores into group 1 [stages 1-3] and group 2 [stage 4].

Inclusion Criteria: Patients presenting with diabetic foot ulcers between 15-70 years. **Exclusion criteria:** Patients of vulnerable age groups <15 and >70 years of age, Pregnant women, Stump ulcers, Patients who did not consent for study.

The wound was assessed, its depth and the presence and severity of gangrene were noted. The ischemia of the lower limb was evaluated based on the ABPI values and toe pressure measurements. The foot infection part of the score was derived from a clinical evaluation of local signs of inflammation and the existence of systemic infection signs. The WIFI score, calculated as described, and utilized to categorize patients into groups 1 and 2. Stages 1-3 were classified as group 1, while stage 4 was designated as group 2. The calculation of sample size was conducted as previously mentioned. 22 patients were enrolled in group 1 and 38 patients were enrolled in group 2.

Routine blood tests were observed and glycaemic management was evaluated using HbA1c measurements taken within three months of recruitment. **Follow up:** Patients were monitored or followed up via phone calls or by reviewing outpatient follow-up records after six months post-recruitment. The outpatient charts of patients were examined to determine if they consistently attended follow-up appointments. For patients who defaulted on outpatient follow-ups, they were reached out to via phone and mail, and the results were documented.

Primary Outcome: Assessing the data of amputations within period of six months from recruitment. **Secondary Outcome:** Assessing the outcome of diabetic foot ulcers with the individual components of WIFI staging system and Assessing the outcome between diabetic foot ulcers and glycemic control.

Results

The total number of cases enrolled in this study was 60. Among them 22 were grouped as group 1 [Stages 1-3] and remaining 38 were under group 2 [Stage 4]. As mentioned in the methodology earlier, patients were followed up for 6 months and outcome was noted.

Age Distribution: Total study population, the average age of the cases was 57 years. The youngest patient was 15 years old, while the oldest patient was 70 years old. Group-2, The average age of the cases was 57.97 years. The age of the youngest patient was 15 years, while the oldest patient was 70 years.

Gender Distribution: Total of 60 patients, there were 40 male patients and 20 female patients recruited in this study making a 66.66% of male patients. In group-1, There were 22 subjects in group-1, in which males are 16 and females are 6, making 72.7% of male subjects. In group-2, There were 38 subjects in group-2, in which males are 23 and females are 15 making a 60.5% of male subjects.

Primary Outcome for Amputation: The incidence of amputations is considered as the primary outcome and the patients were followed up at month-6 after their recruitment into study. Regarding amputations, they are categorized into minor and major amputations. Ray amputation, Transmetatarsal or Transtarsal amputations considered as Minor amputations and any amputation above the level of Transtarsal considered as Major amputation. The primary outcome in both groups is mentioned below as, Among 60 recruited patients, 41 had undergone amputations in both groups. Among 41 amputations, 23 had minor amputations and 18 had major amputations.

In Group-1 (stages 1-3), Among 22 patients, 7 patients underwent amputations, whereas 15 did not undergo amputations. Among 7 patients, 5 patients undergone minor amputations, whereas 2 patients undergone major amputations

In Group 2 (stage-4), Among 38 patients, 90% (34) of the patients had undergone amputations either minor or major. Remaining 9% (4) had no amputation. Among 34 patients, (15) of patients undergone minor amputations, whereas (19) of patients underwent major amputations.

Stage wise division of outcomes: In group 1, 11 (50%) patients belonged to stage 1, 3 (13.3%) belonged to stage 2 and 8 (36.7%) belonged to stage 3.

- **Stage 1:** Among 11, 1 underwent major amputation, this indicates lower amputation rates in early stage of diabetic foot ulcer.
- **Stage 2:** Among 3 patients, 2 underwent minor amputations, 1 had no amputation and no major amputations.
- **Stage 3:** Among 8 patients, 3 underwent minor amputations, 1 had major amputation and 4 had no amputation.
- **Stage 4:** Results of patients in stage 4, grouped separately as group 2 is already described above.

Sugar control and amputation risk: 7 out of 60 patients had no HbA1c values done. 53 patients had HbA1c values and 48 patients had HbA1c above 6.4 indicative of poor glycaemic control. A total of

41 patients had undergone amputations during the study period. 6 out of the 41 patients who had amputations had no HbA1c values. 32 out of 41 patients [78.7%] who had amputations had HbA1c values above 6.4 indicating poor glycaemic control. Out of 18 patients who had major amputations, 3 patients had no HbA1c values. 13 patients [70.6%] had HbA1c value more than 6.4, indicative of poor glycaemic control.

Individual components of Wound Ischemia Foot Infection scoring system and amputation risk:

The comparison of separate components to determine which component increased the probability of amputation was the secondary objective that was investigated. Foot infection, ischemia and wounds were three distinct categories into which patient data was analyzed.

Wound grade: Among 60 patients involved in the study, 20 patients had wound grading of 1, 36 patients had wound grading of 2 and 4 patients had wound grading of 3.

Ischemia grade: Among 60 patients involved in the study, 41 patients had ischemia grading of 0, 11 patients had ischemia grading of 1, 2 patients had ischemia grading of 2 and 6 patients had ischemia grading of 3.

Foot Infection grade: Among 60 patients involved in the study, 6 patients had infection grading of 0, 10 patients had infection grading of 1, 7 patients had infection grading of 2 and 37 patients had infection grading of 3.

Table 1: Wound and Ischemia, infection grading among the study population

	Wound 0	Wound 1	Wound 2	Wound 3
No amputation	0	7	2	0
Minor amputation	0	3	12	0
Major amputation	0	10	22	4
Total [n=60]	0	20	36	4
	Ischemia 0	Ischemia 1	Ischemia 2	Ischemia 3
No amputation	16	2	0	0
Minor amputation	16	5	0	2
Major amputation	9	4	2	4
Total [n=60]	41	11	2	6
	Infection 0	Infection 1	Infection 2	Infection 3
No amputation	5	6	1	6
Minor amputation	1	2	4	16
Major amputation	0	2	2	15
Total [n=60]	6	10	7	37

Table 2: Final outcome with amputations among the study population

	Amputation	No amputation
Group 2 [Stage 4]	34	4
Group 1 [Stages 1-3]	7	15
Sensitivity 82.93%	Specificity 78.95%	PPV 89.47% NPV 68.18%
	Major amputation [yes]	Major amputation [no]
Group 2 [Stage 4]	19	19
Group 1 [Stages 1-3]	2	20
Sensitivity 90.5%	Specificity 51.3%	PPV 50% NPV 90.9%

Discussion

Diabetic foot ulcers are the most common complications of diabetes mellitus as described in relation to the micro vascular and macro vascular effects. Diabetic foot ulcers (DFUs) are a frequent and severe complication associated with diabetes mellitus, leading to substantial morbidity, increased hospitalizations, and elevated risks of lower limb amputations. Due to multifactorial pathogenesis, a reliable classification system like SVS-WifI is essential to stratify patients according to risk and guide management effectively.

Our study aimed to validate the wound, ischemia and foot infection system's predictive capacity in Indian diabetic foot patients. In order to validate a scoring system that took into account the three main criteria that would predict amputations are infection, ischemia, and ulcer characteristics. This study was conducted to evaluate the SVS-WifI scoring system created by the Society of Vascular Surgery. According to studies, SVS-WifI rating predicts wound healing times and amputations with good accuracy. In this study, we assessed the WifI score system's accuracy in predicting amputation.

Staging according to Wound Ischemia Foot Infection (WifI) System: A total of 60 patients were enrolled from the department of general surgery with the diabetic foot ulcers for the study and they were staged accordingly using the Wound Ischemia Foot Infection scoring system into 4 stages.

Wound Scoring: Wound scoring of diabetic foot ulcers is categorized based on severity, depth, size, and potential challenges in wound healing, with the wound component graded from 0 to 3. Wound score grading as follows: Grade 0 - No ulcer, Grade 1 - Minor ulcers manageable with limited digital amputation, Grade 2 - Deeper ulcers or localized gangrene requiring transmetatarsal amputation, Grade 3 - Extensive tissue loss involving the forefoot, midfoot, or heel, often requiring complex reconstruction or proximal amputation. [8,9,10]

Ischemia Scoring: Ischemic component evaluates lower limb perfusion using the Ankle Brachial Pressure Index (ABPI), with toe pressure (TP) or transcutaneous oxygen pressure (TcPO₂). Transcutaneous oxygen pressure is employed when ABPI readings are unreliable, such as in cases of medial arterial calcification commonly seen in elderly patients. ABPI values above 0.8 are graded as 0, indicating no ischemia, while values below 0.4 correspond to grade 3, reflecting severe ischemia. Ischemia score grading as follows: Grade 0 - No ischemia, Grade 1 - Mild ischemia - (ABPI 0.60–0.79; Ankle pressure 70–100 mmHg, TP/TcPO₂ 40–59 mmHg), Grade 2 - Moderate ischemia - (ABPI 0.40–0.59, Ankle pressure 50–70

mmHg, TP/TcPO₂ 30–39 mmHg), Grade 3 - Severe ischemia - (ABPI $\leq$ 0.39, Ankle pressure $<$ 50 mmHg, TP/TcPO₂ $<$ 30 mmHg). [11,12]

Foot Infection Scoring: Foot infection component addresses a critical factor often underrepresented in other classification models. Infection severity is categorized from grade 0 (no infection) to grade 3 (severe infection with systemic inflammatory response), by integrating criteria from the Infectious Diseases Society of America (IDSA) guidelines. Foot infection score grading as follows: Grade 0 - No infection - (no signs or symptoms of infection), Grade 1 - Mild infection - (local signs such as erythema 0.5–2 cm, swelling, warmth, tenderness, purulent discharge), Grade 2 - Moderate infection - (erythema $>$ 2 cm, deeper tissue involvement without systemic inflammatory response), Grade 3 - Severe infection - (infection with systemic inflammatory response syndrome—fever, tachycardia, tachypnoea, leukocytosis or leukopenia).

Staging of the recruits as per Wound Ischemia Foot Infection scoring system: The Wound Ischemia Foot Infection stages (1 to 4) are derived by combining the grades (0–3) for Wound (W), Ischemia (I), and foot Infection (fI) into a clinical stage. Clinical staging as follows:

Stage 1 (Low risk of amputation): Wound: Grade 0-1, Ischemia: Grade 0-1, Infection: Grade 0-1 (Minor ulcer, mild/no ischemia, mild/no infection). Stage 2 (Moderate risk of amputation): Wound: Grade 1-2, Ischemia: Grade 1-2, Infection: Grade 1-2 (Deeper ulcer but no heel involvement, moderate ischemia, mild to moderate infection). Stage 3 (High risk of amputation): Wound: Grade 2-3, Ischemia: Grade 2-3, Infection: Grade 2-3 (Extensive ulcer or forefoot involvement, moderate to severe ischemia, moderate infection or localized deep infection). Stage 4 (Very high risk of amputation): Wound: Grade 3, Ischemia: Grade 3, Infection: Grade 3 (Extensive ulcer or heel necrosis, severe ischemia, systemic infection or sepsis).

Out of the 60 patients recruited, 22 were classified into group 1 since they were assigned stages 1-3 according to the SVS-WifI scoring system. The remaining 38 patients were classified into group 2, and they were categorized as stage 4 according to the SVS-WifI scoring system during the recruitment period.

Baseline Characteristics: Most of the patients recruited in the study were men [66.87%] with the mean age of 57 years. There were 75% men in group 1 and 62.13% men in group 2. These demographics are consistent with global epidemiological patterns. Sociocultural and

occupational factors may predispose Indian males to delayed presentation.

Outcomes of the study: The primary outcome of the study was to analyse the predictive capability of the SVS-WIFI scoring system in assessing amputation in individuals with diabetic foot ulcers. Patients were monitored six months post-recruitment, and results from both groups were recorded and analysed for the study of outcomes. At 6-month follow-up; out of 60 enrolled patients, 41 had received amputations among both the groups when analysed collectively of all the study recruits. Out of 41 patients who underwent amputations, 21 had major amputations at the level proximal to the ankle, accounting for 51.21% of all amputee patients.

Group wise analysis of the study: A total of 68.3% underwent amputations. Minor amputations in 43.9% and major in 30%. Among the total study recruits and both groups, Group 2 patients showed significantly higher amputation rates.

Group-1: In group 1, it includes 22 patients from the recruits from stage-1 to stage-3. Among the 22 patients, 15 of them did not undergo any kind of amputations. The remaining 7 of the 22 patients, representing 31.81%, experienced or underwent amputations at various levels. From the 7 patients, 5 had minor amputations, while 2 patients had major amputations. Thus, in group-1, among the 22 patients, 9% of them experienced major amputations, aligning with findings in the literature.

Group-2: In group 2, it includes total of 38 patients all of them in stage 4. There is no breakdown of study recruits in group 2 because all of the study recruits were staged as stage-4 as per the scoring system. Among the 38 patients, 34 of them which constitutes 89.47% underwent amputations within six months of recruitment and 4 of the patients did not undergo any kind of amputations in this group which aligns with the findings reported in the literature.

Out of 34 patients, 15 patients [44.1%] had minor amputations, whereas 19 individuals [45.6%] had major amputations. Therefore, 45.6% of stage 4 patients underwent significant amputations within six months of enrolment. The literature indicates that around 90% of major amputations occur in stage 4 patients within a year. Therefore, a shorter follow-up period could be seen as the cause for the reduction in major amputation rates among stage 4 patients.

Breakdown of data regarding amputations among the study population: The breakdown of amputation requirement in the different stages of group 1 indicates a rise in amputation rates among patients as the stage increases. The rate of

amputations are directly proportional to the increase in the staging.

- Stage 1: Out of 11 patients in stage 1, 1 had amputations performed below the ankle. None of them experienced significant amputations.
- Stage 2: Of the 3 patients in stage 2, 2 had amputations, one experienced a major amputation and the other a minor amputation.
- Stage 3: Out of the 8 patients in stage 3, 50% had amputations. Among the 4 patients, 1 experienced a major amputation, the other three patients had undergone minor amputations, within six months of being recruited for study.
- Stage 4: Stage 4 outcomes were represented as results for the study of group 2.

Consequently, there is a rise in the occurrence of major amputations as the stages of the SVS-WIFI scoring system increase among the subjects in the study population.

Analysis of the Wound, Ischemia and Foot Infection scoring with the outcome data of amputations:

Analysis of the wound, ischemia and foot infection scoring system revealed that the incidence of amputations rose with escalating severity of lower limb wound characteristics, ischemia and foot infection. No patients received a wound score of 0, as only those with foot ulcers were part of the study. In the wound grading of 3, all patients underwent major amputations. A greater number of patients had lower extremity (lower limb) vascularity within normal ranges [Ischemia 0 - 41 patients]. All patients with grade 3 ischemia had undergone amputations, with 66% of them required major amputations. Grading of foot infections showed a rise in the rate of amputations for grades 2 and 3. Among the 7 patients categorized with infection grade 2, 85% had received amputations and among the amputated recruits, 28% had undergone major amputations. Out of 37 patients with an infection grading of 3, 83.78% underwent amputations with 40.6% experiencing major amputations. This could suggest in conditions of severe sepsis and high infectious, emergency major amputations can be performed to manage and control the sepsis.

Analysis of the HbA1c with the outcome data of amputations:

Another secondary outcome investigated in the study was the association between the incidence of amputations and glycaemic control indicated by HbA1c levels measured at the time of recruitment in the study population. Out of 60 patients enrolled in the study, 7 patients (11.7%) had not undergone recent HbA1c testing leaving out 53 subjects who had their test for HbA1c values done. Among those with documented HbA1c levels, 90.6% patients had exceeding values of >6.4 mmol/l. This suggests the

majority of patients with diabetes who were not achieving optimal glycaemic levels are at higher risk of development of diabetic complications including lower limb amputation. Among the 41 patients who experienced major amputations, 32 patients [78%] exhibited HbA1c levels exceeding 6.4 mmol/l which reinforces the association between inadequate glycaemic control and risk of amputation.

Analysis of sensitivity and specificity values of the outcome data of amputations: This study provides evidence supporting the predictive value of the Society for Vascular Surgery Wound, Ischemia, and foot Infection (SVS WifI) classification system in forecasting the risk of amputations in patients with diabetic foot ulcers.

The positive predictive value for stage 4 concerning any amputation is 0.9 and major amputations is determined to be 0.5, the negative predictive value for stages 1-3 regarding any amputation is 0.6 and major amputations is 0.9. These findings indicate that patients classified as stage 4 are at a high risk of undergoing an amputation, while those in stages 1-3 carry a notably lower risk, especially regarding major amputations.

The study observed a higher Positive Predictive Value (0.9) for any amputation than for major amputation, suggesting that while stage 4 strongly predicts the likelihood incidence of an amputation, it does not necessarily predict the severity or level of the procedure. The consistently high Negative Predictive Value for major amputations in stages 1-3 highlights the relatively lower probability of major limb loss or amputation in patients with less severe Wound, Ischemia and Foot Infection scores.

Thus, the scoring system offers meaningful insight into the risk of limb loss, its role in treatment planning remains limited. Clinical decisions should continue to be based on comprehensive, multidisciplinary assessments that integrate this staging alongside other clinical, diagnostic and patient-specific considerations. Future research is warranted to improve patient outcomes and reduce amputation rates.

Conclusion

The Society for Vascular Surgery Wound, Ischemia and foot Infection scoring system effectively predicted the likelihood of major amputations in patients with diabetic foot ulcers within a six-month period after recruitment. Suboptimal

glycemic control was linked to more adverse outcomes.

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