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Original Research Article

A CLINICAL STUDY OF OUTCOME IN DIABETIC FOOT ULCERS USING SVS WIFI SCORING SYSTEM IN A TERTIARY CARE HOSPITAL

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Abstract

Background: We want to conduct a clinical study of outcomes in diabetic foot ulcers using the SVS WIFI SCORING system in a tertiary care hospital. **Materials and Methods:** was a prospective study conducted in the Department of General Surgery, Sri Venkateswara Medical College and Sri Venkateswara Ramnarain Ruia Government General Hospital during the period of December 2022 to November 2023. **Result:** The mean age of study participants in the current study was 63.43± 6.86 years, 72% of the participants were males. The majority of study participants (72%) were men. Nearly half of the individuals in the study (42%) had diabetes mellitus for 11–20 years, whereas 37% had the disease for less than 10 years. Out of 100 patients, 54 maintained the HbA1C between 9-12 and 26 were having uncontrolled diabetes with HbA1c values more than 12. Among the 43 patients who had amputations, 32 of them had HbA1c values above 6.4 indicating poor glycaemic control. Based on wound grading, 51% of the patients belonged to stage 1, and 28% and 21% belonged to stage 2 and stage 3 respectively. On ischemic grading, 58% belong to stage 1, and 39% belong to stage 2. 51% and 30% of the patients had stage 1-foot infection and stage 2-foot infection respectively. **Conclusion:** The SVS WIfI grading system predicted major amputations in diabetic foot ulcer patients. A worse result was linked to poor glycemic control.

INTRODUCTION

Diabetes is growing more common worldwide as a result of age, physical inactivity, westernized eating habits, population increase, and obesity; as a result, the occurrences of diabetic foot are rising. According to predictions, people with diabetes have a 25% chance of developing at least one diabetic foot ulcer in their lives.[1] Every year, 1% to 4% of diabetic individuals experience a new foot ulceration. Additionally, a lower leg is amputated due to a diabetic foot every 30 seconds worldwide, with rates for diabetic patients being 30 to 40 times higher than for healthy people.[2-4] Diabetic foot ulcer is defined as a full-thickness wound that destroys the deep tissues and develops at a level distal to the ankle and is associated with neurological abnormalities in patients with diabetes. These ulcers can be classified as neuropathic, ischemic, or neuro-ischemic.[5] One of the most prevalent consequences for those with poorly controlled diabetes mellitus is diabetic foot ulcers. It is also a frequent cause of foot osteomyelitis and lower extremity amputation. These ulcers typically develop in parts of the foot that experience pressure and recurrent stress.[6] Approximately 5,92,000 patients with diabetes were living with a lower extremity amputation in 2005, and 60% of these were major amputations. The number of people living with an amputation is expected to increase by 70% by 2020.[7,8] 2 According to Chunmei Lin et al 9 meta-analyses, the male gender, a history of smoking, foot ulcers, osteomyelitis, gangrene, a lower BMI, and a higher WBC count are all significant risk factors for amputation in diabetic foot ulcer patients. The risk of diabetic foot-related amputation increases quickly after gangrene develops.[9]

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Aims & Objectives: To study the role of SVS WIFI score in patients with Diabetic foot ulcers. To study the relation between the SVS WIFI scoring system and the need for amputation in patients with Diabetic foot ulcers.

MATERIALS AND METHODS

Study Design: Prospective Study
Study Setting: Department of general surgery, Sri Venkateswara medical college and Sri Venkateswara Ramnarain Ruia Government General Hospital.
Study Period: Two years from the date of approval of the ethical and scientific committee ie April 2021 to April 2023
Sample Size: 100 Members.
Inclusion Criteria

1. Patients with diabetic foot ulcers presenting to the Department of General Surgery SVRRGGH, Tirupathi.
2. Age 15 to 75 years

Exclusion Criteria

1. Patients with stump ulcers.
2. Patients with traumatic ulcers.
3. Ulcers associated with venous disease
4. Patients with wounds, H/O non-atherosclerotic conditions such as collagen vascular diseases, neoplasm, H/O vasculitis, and radiation.

Study Methodology: Patients with diabetic foot ulcers admitted under the Department of General Surgery for management in the ward were recruited in this study. The patients who consented to this study underwent evaluation by the SVS-WIfI scoring system and their standard laboratory investigations were noted. A clinical proforma form was filled and an appropriate WIfI score for the patient was calculated.

RESULTS

The total number of cases enrolled in this study was 100. Among 100, 72 were grouped as group 1 (stages 1-3) and the remaining 28 were under group 2 (stage 4).
15% of patients were aged between 51-55 years, 22% of patients were aged between 56-60 years, 20% of patients were aged between 61-65 years, 22% of patients were aged between 66-70 years, 21% of patients were aged between 71-75 years.

HbA1c: A total of 43 patients had undergone amputations during the study period. 32 out of 43 patients who had amputations had HbA1c values above 6.4 indicating poor glycemic control.
Primary Outcome: Considering the incidence of amputation as the primary outcome. Amputations including ray amputation and transmetatarsal/transtarsal amputations were considered minor amputations. Any amputation above the level of transtarsal level is considered a major amputation. Among 100 recruited patients, 43 had undergone amputations in both groups. Among 43 amputations, 33 had minor amputations and 10 had major amputations.
38.9% of the patients belonged to stage 1, 25% belonged to stage 2, and 36.1% belonged to stage 3.
Among patients in stage -1, 3 out of 28 patients had undergone amputations. All 3 of them underwent minor amputation. This indicates lower amputation rates in the early stage of diabetic foot ulcer.
Among patients in stages 2- 6, out of 18 patients underwent amputation 5 out of 6 underwent minor amputation and the remaining one underwent major amputation.
Among patients in stage 3-In stage 3, 50% of the patients underwent amputation.11 out of 13 underwent minor amputations and the remaining 2 underwent major amputations.
Among patients in Stage 4- 21, out of 28 patients underwent amputation, 14 out of 21 underwent minor amputation, and the remaining 7 underwent major amputations.
Individual components of the WIfI scoring system and amputation risk: Another secondary objective studied was a comparison of individual components to predict which component caused more risk for amputation. Patient data was analysed into separate categories: wound, ischemia, and foot infection.
There were no patients who scored wound 0 as patients with foot ulcers were only included in the study. Among wound graded 3, 100% of the patients had undergone amputations, out of which 42.85% were major amputations. In wound category 2, 71.4 % of patients had undergone amputations, out of which 95% of them were minor amputations. Among Category 1, 4 % of patients had undergone amputations and 100% of those were minor amputations. This correlates with the higher incidence of amputation in higher grades of final WIfI staging.

Table 1: Number of patients in each group

Group 1 (Stage 1-3)	72
Group 2 (Stage 4)	28

Table 2: Age distribution of patients

Age(years)	Frequency
51-55	15
56-60	22
61-65	20
66-70	22
71-75	21
Total	100

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Mean age	63.43 ± 6.86 years

Table 3: Duration of Diabetes in Years

Duration in years	Frequency	Percentage
2-10	37	37%
11-20	42	42%
21-30	21	21%
Total	100	100%
Mean Duration of Diabetes	13.43 ± 6.86	

Table 4: Distribution based on Co-Morbidities

Co-Morbidities	Frequency	Percentage
Hypertension	53	53%
Dyslipidaemia	52	52%
PAOD	26	26%
CAD	22	22%

Table 5: Distribution based on Smoking

	Frequency	Percentage
Yes	26	26%
No	74	74%
Total	100	100%

Table 6: Distribution based on Wound

Wound grade	Frequency	Percentage
Grade 0	0	0%
Grade 1	51	51%
Grade 2	28	28%
Grade 3	21	21%
Total	100	100%

Table 7: Distribution based on Ischemia

Ischemic grade	Frequency	Percentage
Grade 0	0	0%
Grade 1	58	58%
Grade 2	39	39%
Grade 3	3	3%
Total	100	100%

Table 8: Distribution based on Foot Infection

	Frequency	Percentage
Grade 0	0	0%
Grade 1	51	51%
Grade 2	30	30%
Grade 3	19	19%
Total	100	100%

Table 9: Among patients in group 1

	Stage 1	Stage 2	Stage3
No.of patients	28	18	26
Percentage	38.9%	25%	36.1%

Table 10: Distribution based on Amputation and Wound

	Grade 0	Grade 1	Grade 2	Grade 3
Yes	0	2	20	21
No	0	49	8	0
Total	0	51	28	21
Chi square test= 68.84, p=<0.0001, Statistically significant				

	Grade 0	Grade 1	Grade 2	Grade 3
Major	0	0	1	9
Minor	0	2	19	12
Total	0	2	20	21
Chi square test= 8.86, p=0.01, Statistically significant				

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Table 11: Distribution based on Ischaemia and Amputation

	Grade 0	Grade 1	Grade 2	Grade 3
Yes	0	4	36	3
No	0	54	3	0
Total	0	58	39	3
Chi square test= 73.50, p=<0.0001, Statistically significant				
	Grade 0	**Grade 1**	**Grade 2**	**Grade 3**
Major	0	0	9	1
Minor	0	4	27	2
Total	0	4	36	3
Chi square test= 1.14, p=0.40, Statistically not significant				

Table 12: Distribution based on Foot Infection and Amputation

	Grade 0	Grade 1	Grade 2	Grade 3
Yes	0	2	22	19
No	0	49	8	0
Total	0	51	30	19
Chi square test= 68.22, p=<0.0001, Statistically significant				

	Grade 0	Grade 1	Grade 2	Grade 3
Major	0	0	7	3
Minor	0	2	15	16
Total	0	2	22	19
Chi square test= 2.10, p=0.34, Statistically not significant				

Table 13: Age distribution of patients

Variable	Coefficient	Std. Error	Wald	P
AGE	0.018329	0.00000	0.0000	<0.0001
SEX	0.57013	0.62104	0.8428	0.3586
Duration_in_years	-0.065082	0.00000	0.0000	<0.0001
Smoking=Yes	-0.083138	0.62962	0.01744	0.8949
Hypertension=Yes	-0.70947	0.55043	1.6614	0.1974
Dyslipidemia=No	-0.58141	0.52013	1.2495	0.2636
PAOD=Yes	0.59116	0.52013	1.0717	0.3006
CAD=Yes	0.85135	0.82035	1.0770	0.2994
HBA1Csss	1.00702	0.21781	21.3763	<0.0001
Constant	-11.48747	0.00000	0.00000	<0.0001

Variable	Odds ratio	95%CL
AGE	1.0185	1.0185 to 1.0185
SEX	1.7685	0.5236 to 5.9737
Duration_in_years	0.9370	0.9370 to 0.9370
Smoking=Yes	0.9202	0.2679 to 3.1611
Hypertension=Yes	0.4919	0.1672 to 1.4468
Dyslipidemia=No	0.5591	0.2017 to 1.5497
PAOD=Yes	1.8061	0.5897 to 5.5311
CAD=Yes	2.3428	0.4693 to 11.6959
HBA1Csss	2.7374	1.7862 to 4.1951

Among ischemic grade 1, 8% of patients have undergone minor amputations. Ischemic grade 2 had a higher incidence of amputations, 96% of patients underwent amputations 75% were minor and 25% were major amputations. All patients of Ischemic grade 3 had undergone amputations, out of which 25% of them had major amputations.

Among 30 patients with graded foot infection 2, 73.3% had undergone amputations, out of which 31.5% had major amputations. Among 19 patients with graded foot infection 3, 100% of them had undergone amputations, out of which 15.7% had major amputations.

DISCUSSION

Diabetes foot ulcers are the leading cause of lower extremity amputation. Multiple ulcers or other lesions could exist on the same foot. In such circumstances, the prognosis of one ulcer may be influenced by the prognosis of another. It can be challenging to determine which of the various etiological causes contributed most to a patient's foot ulcer. It is challenging to replicate the existence, severity, or degree of the various components, such as neuropathy, infection, or ischemia. Numerous scoring systems were created to classify diabetic foot ulcers and predict outcomes. A scoring system that takes into account every aspect of the pathogenesis was not accessible due to the complexity of the pathogenesis of diabetic foot ulcers. The three factors that contribute to the progression of foot ulcers are ischemia, infection, and ulcer features. Depending on how severe the other components are, the severity of each component has a varied impact on the final result. It is difficult to predict which of the factors plays a predominant role in the pathogenesis of a specific

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ulcer. Thus outcomes of a diabetic foot ulcer depend on the combination of the three factors described with one playing a more prominent role than the other in the causative process. The ulcer characteristics were used in previous classification schemes. When assessing the ulcer, factors including the existence of an infection and ischemia were not taken into consideration. Hence though they were of use in clinical settings to grade the foot ulcers, they were not able to predict the wound healing time or amputation risk. Later classification systems used critical limb Ischemia as the major determinant factor in predicting the salvageable nature of diabetic foot ulcers. Wound healing, however, does not depend solely on the degree of Ischemia, but also on the presence and severity of infection and the extent and depth of the wound. The existing Ischemia scoring system fails to categorize the other components such as tissue loss, presence, and severity of infection. Arterial anatomy and limb perfusion are key factors in predicting the risk of amputation. However, ulcer recurrence and amputation also depend on the presence of neuropathy. Classification systems published to date are of limited use in decision-making as they focus on specific aspects of the lower extremity. Most diabetic foot ulcer classification has ischemia included as mere presence or absence with no grading of severity. The description of gangrene and tissue loss is not included in most of the diabetic foot ulcer grading systems. Thus most of the grading systems of diabetic foot ulcers do not provide adequate patient baseline stratification to enable comparison of outcomes in different patient subgroups, different centres, and revascularisation procedures. The presence of infection along with systemic response and local signs of inflammation plays a major part in the prediction of amputations. The presence and extent of infection and extent of the wound play a role in the progression of diabetic foot ulcers. The need for revascularisation and debridement to preserve the limb and prevent amputation depends on the grading of infection, ischemia, and extent of the wound When a diabetic foot ulcer is scored based on the SVS-WIfI scoring system, the ulcer is assigned a score each for wound characteristics, Ischemia and infection factors which invariably produces 64 theoretically possible clinical combinations. Thus to grade the severity by comparing all three components, the Society of Vascular Surgery SVS-WIfI scoring system is devised to stratify patients with diabetic foot ulcers based on the spectrum of various factors. The application of SVS-WIfI scoring is aimed at stratifying patients according to their initial disease burden, similar to TNM staging for cancers, not to dictate therapy. This study was undertaken to evaluate the SVS-WIfI score devised by the Society of Vascular Surgery to establish a scoring system that incorporated the three primary criteria that would predict amputations, namely infection, ischemia, and ulcer features. According to studies, the SVS-WIfI score can accurately predict both the time it will take for a wound to heal and the likelihood of an amputation.

The goal of the current study was to determine the function of the WIFI score in patients with diabetic foot ulcers and the association between the SVS WIFI scoring system and the requirement for amputation in these patients. The present study included 100 patients with foot ulcers, among them 72% of the patients belonged to stages 1 to 3, and 28% were categorized into stage 4 of the WIFI scoring system. Similar findings were reported by Mathioudakis et al,[13] and Salib et al,[14] 72.4% and 71.7% of the diabetic foot patients belong to stages 1-3 of the WIFI scoring system. 27.6% and 28.3% of diabetic foot patients belonged to stage four of the WIFI 48 scoring system. Whereas, the study conducted by Weaver et al reported that nearly half of the diabetic foot ulcer patients were categorized into stages 1-3, and 48% of the diabetic food ulcer patients were categorized into stage 4 of WIFI classification.[12] The mean age of study participants in the current study was 63.43± 6.86 years, 72% of the participants were males. This was consistent with the findings of a study conducted by Weaver et al, who found that the average age of patients with diabetic foot ulcers was 59.0+0.7 years. In the current study, the majority of study participants (72%) were men. This male predominance was by Weaver et al,[12] Hicks et al,[11] Salib et al,[14] Mathioudakis et al,[13] and Thewjitcharoen et al,[15] studies.

Duration of Diabetes mellitus and associated co-morbidities: Nearly half of the individuals in the study (42%) had diabetes mellitus for 11 to 20 years, whereas 37% had the disease for less than 10 years. The average time that patients with diabetic foot ulcers had diabetes was 13.43+6.86 years, compared to 71% of participants in the study by Vera Cruz et al. who had diabetes for less than 10 years and 20% who had it for more than 20 years 39. Among the 100 diabetic foot patients, nearly half of the study participants were having co-morbidities such as hypertension which accounts for 53% and dyslipidemia for 52%. 22% and 26% of the patients had comorbidities of coronary artery disease and peripheral artery occlusive diseases respectively. Among the patients with diabetic foot ulcers, 26% of them were smokers. Out of 100 patients, 54 maintained the HbA1C between 9-12 and 26 had uncontrolled diabetes with HbA1c value of more than 12. Among the 43 patients who had amputations, 32 of them had HbA1c values above 6.4 indicating poor glycaemic control. Similar findings were reported by Jeon et al in their study that HbA1c of diabetic foot ulcer patients was fairly maintained with the Median HbA1c value of 7.1(7-8.75).[17] On the contrary, studies conducted by Zhan et al,[19] darling et al, hicks et al,[12] and mathioudakis et al,[13] reported a higher proportion of diabetic foot ulcer patients were having

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comorbidity of hypertension and coronary artery diseases.

Distribution of ulcer based on wound, ischemia, and foot infection: For wounds, ischemia, and foot infections, the SVS WIFI classification system contains four stages in total. A stage 0 wound has no wounds, whereas a grade 1 wound has modest tissue loss that can be repaired with a simple digital amputation or skin covering. Grade 2 wounds are more severe but may be treatable with numerous digital amputations. The most severe class of severity, grade 3, is given to cases of extensive tissue loss that will necessitate an amputation at or near the level of a conventional trans metatarsal amputation (Chopart or Lisfranc), or that will necessitate a free flap or a significant full-thickness heel ulcer.[22] Based on wound grading, 51% of the patients belonged to stage 1, and 28% and 21% belonged to stage 2 and stage 3 respectively. On ischemic grading, 58% belong to stage 1, and 39% belong to stage 2. 51% and 30% of the patients had stage 1-foot infection and stage 2-foot infection respectively. This was to the findings of the study done by Robinson et al, based on wound grade 35% of the diabetic foot ulcer patients belonged to stage one, 51% and 11% belonged to stage 2 and stage 3. 23%, 16% and 35% of the study participants belonged to ischemic grading of stage 1, 2, and 3 respectively. Based on foot infection of WIFI scoring 32%, 33% and 16% belong to stages 1, 2, and 3 respectively.[19]

Incidence of Amputation- The present study classified amputation as major amputation and minor amputation based on the level of lower limb joints. Ray amputation and trans metatarsal/ trans tarsal amputations were considered minor amputations. Any amputation above the level of trans tarsal levels was considered a major amputation. Among 100 recruited patients, 43 had undergone amputations out of which 33 had minor amputations and 10 had major amputations. In the current study, half of the individuals had had either one type of amputation. Similar findings were noted in Thewjitcharoen et al,[15] studies that 50% of diabetic foot ulcer patients undergo amputation which includes both major and minor amputations.[15] The least number of amputations was noted in the studies conducted by Robinson et al,[19] and Zhan et al,[18] which accounts for 15% and 21% of amputations among diabetic foot ulcer patients respectively.

Stagewise distribution of outcomes: In stage 1 of WIFI classification, 3 out of 28 patients had undergone amputations. All 3 of the amputations are minor amputations. This indicates that lower amputation rates present in the early stage of diabetic foot ulcers. The incidence of foot amputation was reported in double proportion in Mathioudakis et al,[13] and Robinson et al,[19] which accounts for 22% of amputations each. Lavery et al and Williams et al reported 3% of amputation and 9% of amputation in stage 1 of the WIFI classification of diabetic foot ulcers. Among patients in WIFI stage 2, 6 out of 18 patients underwent amputation. 5 out of 6 underwent minor amputation and the remaining one underwent major amputation. In the present study, 33% of the diabetic foot ulcer patients of stage 2 underwent amputation which includes both major and minor amputations. Concurrent with the present study similar proportion of amputation was reported in the studies conducted by Robinson et al,[19] and Mathioudakis et al,[13] Among patients in stage 3, 50% of the patients underwent amputation.11 out of 13 underwent minor amputations and the remaining 2 underwent major amputations. This finding matches the studies done by Cull et al and Mathioudakis et al that nearly half of the stage 3 WIFI diabetic foot ulcer patients underwent amputation. Among patients in Stage 4 of the WIFI classification, 21 out of 28 patients underwent amputation, 14 out of 21 underwent minor amputation, and the remaining 7 underwent major amputations. Nearly 75% of the stage 3 diabetic foot ulcer underwent amputations. Almost all the studies have reported similar findings to the present study.

Distribution based on amputation with wound, Ischemia, and foot infection- There were no patients who scored wound 0 as patients with foot ulcers were only included in the study. Among wound graded 3, 100% of the patients had undergone amputations, out of which 42.85% were major amputations. In wound category 2, 71.4 % of patients had undergone amputations, out of which 95% of them were minor amputations. Among Category 1, 4 % of patients had undergone amputations and 100% of those were minor amputations. This correlates with the higher incidence of amputation in higher grades of final WIFI staging. Among ischemic grade 1, 8% of patients have undergone minor amputations. Ischemic grade 2 had a higher incidence of amputations, 96% of patients underwent amputations 75% were minor and 25% were major amputations. All patients of Ischemic grade 3 had undergone amputations, out of which 25% of them had major amputations. Among 30 patients with graded foot infection 2, 73.3% had undergone amputations, out of which 31.5% had major amputations. Among 19 patients with graded foot infection 3, 100% of them had undergone amputations, out of which 15.7% had major amputations. This was the first study to assess the risk of amputation separately for each part of the WIFI score. From the present study, it was found that an increase in grade shows an increased risk of amputation. Major amputations were reported with the patients in grade 2 or more in wound grading, ischemia grading, and foot infection grading. It was found to be statistically significant. In the present study, it was found that age, duration of diabetes, and poor HBA1C were found as predictors of foot amputation in diabetic foot ulcers. Increase in age where having 1.0185 times higher odds of foot

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amputation (1.0185 to 1.0185). And increase in HbA1c have 2.7374 times higher odds of foot amputation (1.7862 to 4.1951) in the present study. Most of the studies have assessed the wound healing or ulcer healing outcomes with the WIFI scoring system. In the study conducted by Cull et al,[20] they found that the presence of diabetes mellitus, ulcer site, location, depth of ulcer, and ischemia are the main factors responsible for wound healing among diabetic foot ulcers. In the study on the comparison of five systems of diabetic foot classification and its predictive factors by Jeon et al,[16] the multivariable logistic regression analysis found that age, sex, ulcer history, hypertension, neuropathy, and log-transformed CRP showed a significant positive trend with increasing number of amputations.[17] Similar results were found by Surriah et al., who concluded that growing older, having diabetes for a longer period, having poorly controlled diabetes, smoking, and having a lesion in the dominant foot were all significant risk factors for an increased likelihood of needing an amputation.[21] In the Hicks et al. study, which examined the relationship between WIFI staging and the risk of amputation at one year and the state of wound healing, it was discovered that WIFI classification predicts both the likelihood of wound healing and amputation. However, in this investigation, the risk of amputation was not evaluated separately for major amputation risk and minor amputation risk.[11] In our study, diabetic foot ulcer patients' amputation status was also individually evaluated in each stage for both major amputation and small amputations, and the diabetic ulcer was classified separately based on wound, ischemia, and foot infection.

CONCLUSION

The SVS WIfI grading system predicted major amputations in diabetic foot ulcer patients. A worse result was linked to poor glycemic control.

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