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Original Research Article

A prospective study to determine the application of site, ischemia, neuropathy, bacterial infection and depth scoring in the outcome and management of diabetic foot ulcers

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ABSTRACT

Background: The objective of the study was to classify diabetic ulcers based on the recently described SINBAD classification system and to determine the management based on SINBAD score.
Methods: Prospective study, conducted in Victoria Hospital from November 2017 to May 2019. 120 patients with diabetic ulcers were classified according to the SINBAD classification system, wherein a score of one is given for site beyond forefoot, presence of ischemia, presence of neuropathy, bacterial infection, area >1 cm^2 and depth beyond subcutaneous tissue. The wounds are scored at presentation and the outcome are evaluated according to respective score.
Results: In this study 120 patients with mean age of 50.12 years were included. Lower socio-economic groups correlated with higher incidence of diabetic foot. According to SINBAD classification 42.5% had forefoot, 57.5% had hind foot wounds, 56.3% were purely ischemic ulcers, 19.2% were neuropathic ulcers, 40.0% were neuro-ischemic ulcers 68.3% had bacterial infection, 70.8% had ulcer, size >1 cm^2, 55% had ulcer deeper than skin & sub cutaneous tissues. Healing probability in score 1 was 100%, score 2 was 87.5%, Score 3 was 70%, score 4 was 58.6% healing, score 5 was 7.1% and score 6 was 1.1% healing (p=0.004). Ischemia, neuropathy, bacterial infection, area >1 cm^2 and depth beyond subcutaneous tissue had significant effect on healing.
Conclusions: SINBAD classification system includes 6 parameters, describing the pathological evolution of diabetic ulcers. Treatment protocols can be determined based on the score. The system is easy to score and apply in routine practise.

Keywords: Classification, Diabetic foot, Diabetic foot scoring, Site, Ischemia, Neuropathy, Bacterial infection, Depth, Wound healing

INTRODUCTION

Foot ulcers are common complication of diabetes and represent a major source of morbidity. During the year 2014 the number of cases of diabetes worldwide was estimated to be 422 million with an estimated 1.5 million deaths due to high blood glucose.[1] The diabetic foot has increased from 0.7% in the 1980-88 period to more than 2.7% in the years 1998-2004. Lower limb amputations are at least 10 times more common in diabetics than non-diabetics.[2]

Although a multitude of factors are presumably implicated, foot lesion in diabetic patient can be

attributed to three factors - neuropathy, ischemia and infection.[3] Peripheral vascular disease (PVD) is on an increasing trend as an association with diabetic.[4] Neuropathic ulcers are two times more common than neuro ischemic ulcers (NIU). Hypertensive male patients with smoking habits and longer duration of type 2 diabetic mellitus are most prone to develop neuro-ischemic ulcers.[4]

Frequently, more than one element of this diabetic foot triad is present prior to ulceration and predispose the foot to ulceration when it is subjected to trauma. Once present, classification of the lesion facilitates a rational approach to treatment as well a prediction of its healing potential.[3]

A variety of wound classification systems have been used like Wagner's, University of Texas and PEDIS systems. The most widely used classification is one proposed by Wagner that is based on depth of penetration and extent of tissue necrosis.[5] However this system does not give an insight into the pathological processes occurring in the ulcer evolution and does not provide a management protocol.

The S(AD)SAD system was designed primarily for clinical audit and consists of just five features- size, (area, depth), infection (sepsis), ischaemia (arteriopathy) and neuropathy (denervation).[6] Each element is scored from 0-3. This system is effective and can be used for audits. However, it is very elaborate and its daily use in routine practise, especially in a high output centre is restricted.

Ince et al validated a simplified variation of the S(AD)SAD score, SINBAD has been validated in three different continents, reliably predicting healing time.[7] It comprises of the same five clinical features as S(AD)SAD (ischaemia, neuropathy, bacterial infection, area and depth) but with the addition of site (forefoot vs. hindfoot). Each is graded as either present or absent (0 or 1), giving a maximum score of 6. Its simplicity in clinical practice has led it to being the system chosen for the UK national diabetic foot audit.[8]

The SINBAD classification also includes ulcer site because newer data suggest that ulcer site may also be an important determinant of outcome.[9] The components of the classification can be summed to produce a score between 0 and 6.

METHODS

It is a prospective comparative study with the study period from Nov 2017 to May 2019. The study is planned to be conducted on both outpatient and inpatient basis at Victoria Hospital and Hospitals attached to Bangalore Medical College and Research Institution, Bangalore.

Sample size required for the study is calculated using the formula; where n is the sample size, α the level of significance, 1-β, the power of the test and d, the effect size or Cohen's d.

The level of significance is chosen as 0.05 (i.e. p and lt;0.05), the power 1-β as 95% and Cohen's d or effect size as 0.35 The table values of =1.96 and =1.645 (obtained from standard normal table). The formula for minimum value of n resulted into 106. Considering 10% drop out rate,

N1=Total sample size including drop outs

N= Total sample size

Q= anticipated dropouts = 0.1 (10%)

$N1=\frac{106}{1-0.1}\approx 118$

A sample size of 120 was taken for better validation of results.

Inclusion criteria

Patients willing to give a written and informed consent, either sex of age group 40-70 years, wound or callus on only 1 foot and haemoglobin >9 gm % (if no- then optimised before the study) were included in the study.

Exclusion criteria

Patients suffering from malignancy, end stage renal disease, HIV, Hep B and Hep C positivity, previous lower extremity amputation, psychiatry disorders and patients not willing to give written informed consent were excluded.

After obtaining institutional ethics committee clearance and written informed consent, thorough history and examination findings are obtained. Cases are then classified according to the SINBAD classification system. If a subject had multiple ulcers at the same time, the most significant (generally the largest) was selected as the index ulcer for the purposes of the study. Follow up is done until amputation or death.

The presence of neuropathy was determined using vibration perception (128 Hz tuning fork) at two sites (hallux pulp and malleolus), point pressure (Semmes-Weinstein 10 g monofilament) at seven sites and ankle reflexes. The adequacy of arterial blood supply to the foot is determined by palpation of the dorsalis and posterior tibial foot pulses.

Ulcer characteristics are graded according to SINBAD classification system. Callus and necrotic tissue are removed by sharp debridement. Follow up done after every second week. Patient is followed up for at least 6 months. The primary outcome measure is incidence of ulcer healing, with disarticulations and debridement after at least 6-month follow-up. Secondary outcome measures included incidence of major amputation.

Table 1: SINBAD classification system.

Category	Definition	SINBAD score
Site	forefoot	0
	Mid foot and hindfoot	1
Ischemia	Pedal blood flow intact: at least one pulse palpable	0
	Clinical evidence of reduced pedal blood flow	1
Neuropathy	Protective sensation intact	0
	Protective sensation lost	1
Bacterial infection	none	0
	present	1
Area ulcer	<1cm^2	0
	>1cm^2	1
Depth	Ulcer confined to skin and subcutaneous tissue	0
	Ulcer reaching muscle, tendon or deeper	1
	Total possible score	6

Figure 1: Left diabetic foot; site- 1, ischemia-1, neuropathy-1, bacterial infection-1, area >1 cm^2-1, depth-1; total score=6.

Continuous descriptive variables to be presented as mean, SD, minimum, maximum and median values. The association between two categorical variables is to be analysed by Fisher's test. One-way ANOVA test is used for determining statistical significance between the healing percentage and stage and grade of the disease. Association of each parameters was tested for significance using Chi square test.

RESULTS

A total of 120 patients were included in the study. Mean age in my study population was 50.12±12.88 years. Among the total 120 cases, 10 (8.3%) were less than 40 years of age. 17 (14.2%) were 41-50 yrs. 27 (22.5%) were 51-60 years. 43 (35.8%) were 61-70 years and the remaining 23 (19.2%) were more than 70 years. 82 (68.3%) were males and remaining 38(31.7%) were females (Table 2).

Table 2: Age distribution of the studies population.

Age in years	No. of cases
<40	10
41-50	17
51-60	27
61-70	43
>70	23
Total	120

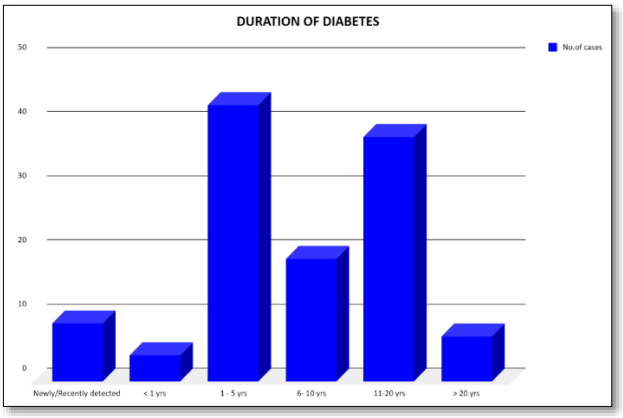

Figure 2: Duration of diabetes in the study population.

As far as occupation was concerned, daily wage laborers (coolies) consisted of the majority 57 (47.5%), followed by farmers 28 (23.3%). Majority of females were home makers. 10 cases were masons (8.3%). Remaining 5 were unemployed and 5 belonged to other occupation categories. There was statistical significance on the association of diabetic foot with low socioeconomic strata of the society (p<0.005).

Based on the duration of diabetes treatment 13 (10.8%) were detected less than 1 year, 43 (35.8%) were 1-5 years; 19 (15.8%) were 6-10 years, 38 (31.7%) were 11-20 years remaining 7*5.8%) had diabetes more than 20 years (Figure 2).

Majority of the cases had associated hypertension. 43 (35.8%) were normotensive 33 (27.5%) has <5 years of hypertension, 14 (11.7%) were 6-10 years. 21 (17.5%) 11-20 years and remaining 9 (7.5%) had hypertension for more than 20 years (Figure 3).

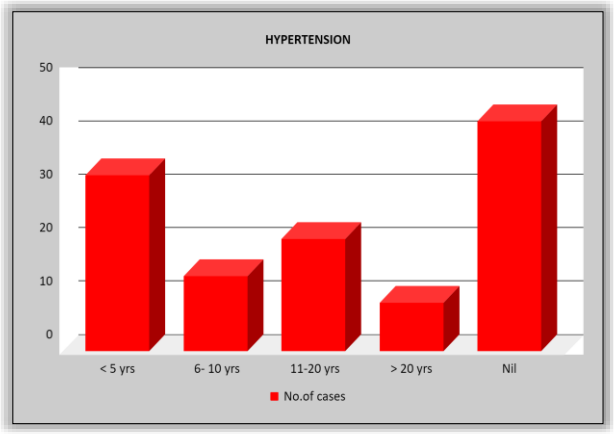

Figure 3: Age distribution of patients.

Associated comorbidities were present in some. 2 (1.6%) had renal failure, 7 (5.8%) had liver disease, 14 (11.6%) had cardiac disease. 2 (1.7%) had thyroid disorders, 2 (1.74%) had neurological disease, 16 (13.3%) had respiratory disease (Figure 4).

In our study population, 78 patients had a history of alcohol consumption. Majority had a duration of consumption for more than 20 years. 70 out of 120 patients had significant smoking history.

According to Sindbad's classification, in the study population 51 (42.5%) were the site was forefoot, 69 (57.5%) were the site was hind foot, 70 (56.3%) were purely ischemic ulcers, 22 (19.2%) were neuropathic ulcers, 48 (40.0%) were neuro-ischemic ulcers 82 (68.3%) had bacterial infection, 85 (70.8%) had ulcer, size >1 cm^2, 66 (55%) had ulcer deeper than skin and sub cutaneous tissues (Table 3).

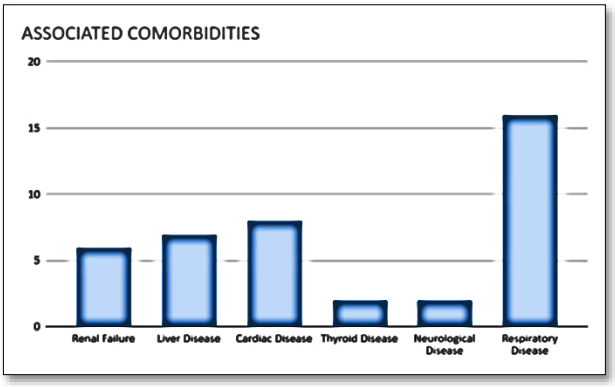

Figure 4: Associated co morbidities in the study population.

Table 3: Classification of cases according to SINBAD system of classification.

SINDBAD scaling of wound - category	No. of cases
Grade 1	9
Grade 2	16
Grade 3	30
Grade 4	29
Grade 5	14
Grade 6	22
Total	120

Table 4: Outcome of wounds classified according to SINBAD system of classification.

SINBAD Scaling of wound - Category	Amputation	Disarticulation	Non Healing	Healing / Healed
Grade 1	0	0	0	9
Grade 2	0	0	2	14
Grade 3	0	6	3	21
Grade 4	7	3	2	17
Grade 5	4	3	6	1
Grade 6	13	1	6	2
Total	24	13	19	64
P value	0.004 significant			

As per the Sindbad scaling of wound score 1 had 100% healing score 2 had 87.5% healing. Score 3 had 70% healing score 4 had 58.6% healing, score 5 had 7.1% healing and score 6 had 9.1% healing had a p value 0.004 which is significant as the scores are higher the healing probability is lessened. This suggests that early amputation can be provided to patients with lesions belonging to grade 4 and 5.

Significance of site of the wound on healing

On performing Chi- square test, among the cases around 29(%) had healing ulcer in site 0 and 22(%) had non healing ulcers. In site 1 the healed cases were 32(%) and non-healed were 38(%). But the difference was not statistically significant (χ^2 = 1.67, p-value=0.196).

Table 5: Healing probability based on the SINBAD classification.

Grade	Healing probability (%)
1	100
2	87.5
3	70
4	58.6
5	7.1
6	1.1

Significance of ischemia on wound healing

In grade 0 where no ischemia was present, 40% cases had healing ulcer and 10% cases had non healing ulcer. In grade 1, with ischemia, 20% cases had healing ulcer and 50% cases had non healing ulcer. The difference was statistically significant (test statistic= 30.85, p-value= 0.000).

Significance of neuropathy on wound healing

In grade 0, without neuropathy, 36% cases had healing ulcer and 12% cases had non healing ulcers. In grade 1, with neuropathy, 24% cases had healing ulcer and 48% cases had non healing ulcer. The difference was statistically significant (test statistic χ^2= 20.00, p-value= 0.000)

Significance of bacterial infection on wound healing

In grade 0, without bacterial infection, 28% cases had healing ulcer and 10% cases had non healing ulcer. In grade 1, with bacterial infection, 32% cases had healing ulcer and 50% cases had non healing ulcer. The difference was statistically significant (test statistic χ^2= 12.47, p-value= 0.000)

Significance of area on wound healing

In grade 0, area <1 cm^2 27% cases had healing ulcer and 8% cases had non healing ulcer.

In grade 1, area >1 cm^2 33% cases had healing ulcer and 52% cases had non healing ulcer.

The difference was statistically significant (test statistic χ^2= 14.56, p-value= 0.000).

Significance of depth on wound healing

In grade 0, 37% cases had healing ulcer and 17% cases had non healing ulcer.

In grade 1, 23% cases had healing ulcer and 43% cases had non healing ulcer.

The difference was statistically significant (test statistic χ^2= 13.46, p-value= 0.000).

Table 6: Table describing the significance of site, ischemia, neuropathy, bacterial infection, area and depth on healing.

Variable	χ^2	p
Site	1.67	0.196
Ischemia	30.85	0.000
Neuropathy	20.00	0.000
Bacterial infection	12.47	0.000
Area	14.56	0.000
Depth	13.46	0,000

DISCUSSION

Data on the burden of diabetes-related complications from developing countries are not accurately maintained. Therefore, comparisons between them are made difficult by the use of different clinical methods. This necessitates the need for a robust system of classification. A number of classification groups have been used to seek associations between baseline variables and clinical outcome, with inconsistent results. Here we have described the utility of SINBAD classification, which is a simplified version of the S(AD)SAD classification for predicting the outcome of diabetic ulcers.

Majority of the patients in our study population were elderly. Male gender constituted higher proportions. Most of the patients belonged to the lower socioeconomic strata. There was a statistical significance between diabetic foot affecting lower economic strata. These finding are similar the findings reported by Yazdanpanah et al, on their population-based study on diabetic foot.[9] History of Smoking and alcohol consumption was present in a substantial number of patients. In one of the multivariate analysis, the significant independent potential risk factors for recurrence of foot ulcers were smoking, poor glycemic control (HbA1c cutoff of 10 %), peripheral neuropathy with lost ankle reflex, peripheral arterial disease and previous ulcer location.[10]

The most widely accepted classification system for diabetic foot ulcers and lesions is the Wagner ulcer classification system, which is based on the depth of penetration, presence of osteomyelitis or gangrene, and the extent of tissue necrosis. The drawback of the Wagner classification system is that it does not adequately address all diabetic foot ulcerations and infections and only Grade 3 (of the 6 grades) infers infection.[11,12] Further, the system is limited in its ability to identify and describe vascular disease as an independent risk factor.[13,14] In addition, superficial wounds that are infected or dysvascular are not able to be classified by this system. These factors are overcome to an extent in the SINBAD classification.

SINBAD scoring system consists of 6 parameters. Out of the 6 parameters, site of the lesion had no statistical significance on healing. Presence of ischemia,

neuropathy, bacterial infection, area >1 cm^2 and depth beyond the subcutaneous tissue had an impact on healing, which was proved with statistical significance. The results are comparable with the results of the study by Ince et al, Beckert et al reported that site of the wound had significant effects on healing, however our data suggests the contrary.[7,15]

According to our study in SINBAD scoring, healing probability decreased proportionally with the increase in the score. A wound of score 1 and 2 can conserved and treated with debridement and antibiotics and rarely requires minor amputations. Score 5 and 6 have very low healing probability and most of the patients classified with score 5 and 6 ended up with amputation. Whereas score 3, majority could be conserved with dressing while equal numbers required minor amputations. Majority of Patients with score 4 required minor amputations while substantial numbers also had to be treated with major amputations.

CONCLUSION

To conclude, diabetic foot constitutes a great burden of cases, especially in the developing countries. Effective classification systems are the need of the hour to offer quick and cost-effective treatments, which are patient compliant. The present classification systems used each have their own advantages and disadvantages. The SINBAD classification is a recently described classification system and is a simplified version of the S(AD)SAD System and consist of size, ischemia, neuropathy, bacterial infection, area and depth. Presence of each feature is given a score of 1 and the total score is calculated. SINBAD is more effective in describing the disease processes and is also simple to use in daily practice and for auditing purposes.

It is also seen that five out of six parameter of SINBAD classification are statically significant in relationship to healing. These parameters are ischemia, neuropathy, bacterial infection, area and depth. Higher scores or the grades of all three systems go towards non healing and advocate the need for early amputations.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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