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Original Article

Study of the clinical aspect of diabetic foot ulcers and its surgical management

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Abstract

Objective: Diabetes is a global epidemic and a leading cause of death by disease. It is the common underlying cause of foot ulcers, infection, and ischemia, which are among the most serious complications of diabetes. This work aimed to study the clinical profile, surgical management, and outcome of patients with diabetic foot infections.

Methods: Prospective study recruiting patients >18 years of age with diabetic foot infections. All patients underwent a detailed history and clinical examination, being distributed as per their different sociodemographic, clinical, and foot ulcer site characteristics, with further management and evaluation.

Results: One hundred patients were recruited, with a mean age of 51.32±11.45 years. Majority of patients (73%) had a lower socioeconomic status. All patients had type 2 diabetes, with male predominance (78%). Mean diabetes mellitus duration was 9.68±5.03 years. Ulcer (92.31%) and discharge (72.31%) were the commonest complaints. During correlation analysis, a strong statistically significant ($p<0.001$) correlation was observed between amputation and HBA1c level (0.747) and SINBAD score (0.871), while correlation with RBS level was weak (0.532). Commonest presenting site was forefoot, followed by hindfoot.

Conclusion: The SINBAD score is simple to use in daily practice, being more effective in describing diabetic foot. Primary and secondary healthcare systems in developing countries have limited resources, using different approaches to manage diabetic foot care. The SINBAD system can be used as a primary screening tool. Provision of correct and convenient footwear and efficient treatment of minor injuries are recommended to downturn ulcer occurrence.

Level of Evidence II; Prospective Study; Lesser Quality (eg, patients enrolled at different points in their disease or <80% follow-up).

Keywords: Diabetic foot; Infections; Ulcer.

Introduction

Diabetes is the biggest cause of disease-related mortality on a global scale. The International Diabetes Federation estimates that 8.8% of adults globally, or 425 million individuals, have diabetes. It has been estimated that 72.9 million people in India have diabetes, and this number is expected to increase to 134.3 million by the year 2045[1].

The three most serious consequences of diabetes-foot ulcers, infection, and ischemia-are significantly attributed to the disease. The most frequent diabetes mellitus consequence requiring hospitalization is diabetic foot infection (DFI), which is a soft tissue or bone infection just under the malleoli and the most frequent cause of non-traumatic lower extremity amputation[2].

Decreased blood supply and lack of sensation because of neuropathy leads to foot infections in diabetic individuals, which makes DFIs a common and serious problem. Such infections can emerge in a wound from trauma or from skin ulcers brought on by peripheral neuropathy. Osteomyelitis can result from an infection that often involves more than one type of germ and can spread to other surrounding tissues, including bone[3].

Study performed at the Department of General Surgery, Gandhi Medical Collage and Associated Hamidia Hospital, Bhopal (M.P.), India.

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Those with diabetes mellitus have a 15% risk of developing foot ulcer. Over two thirds of the affected population undergo lower limb amputations, with ulceration being the most frequent precursor to this[4]. When diabetes is in its advanced stages and management fails, lower extremity amputation is a disease consequence. Diabetes patients have a 15–30-fold increased risk of amputation compared to non-diabetic people. Every 30 seconds a lower limb or a portion of a lower limb is amputated as a result of diabetes somewhere around the globe[5].

Due to the high incidence of diabetes, diabetic foot occurrence is also increasing because of the increased life expectancy among affected patients. The patient or primary care physician ignorance continues to be a hurdle in improving the outcome of diabetic foot lesions. In India, situation has worsened due to habits like walking barefoot, poor awareness, hygiene issues etc.[6].

In this context, the present prospective, observational study was conducted to evaluate the various presentations of diabetic foot ulcer (DFU). We also studied different aspects of DFU management by dressing/debridement/amputation.

Methods

A cross-sectional study with an 18-month duration was carried out among 100 patients having history of diabetes, aged above 18 years, of both genders, and diagnosed with diabetic foot. The study was conducted in the surgical department of a tertiary care center from January 2020 to June 2021. Prior to the study, approval from the ethical committee and an informed written consent from patients were obtained. Random blood sugar (RBS) and glycated hemoglobin (HbA1c) levels were checked from collected blood samples. The Site, Ischemia, Neuropathy, Bacterial Infection, and Depth (SINBAD) score classification was performed after examining the DFUs. Demographics, such as age, gender, diabetes mellitus duration, and other risk factors of foot ulcers were also noted. The mean and standard deviation for continuous variables, i.e., age, RBS level, and HbA1c level, and the frequency and percentage for categorical variables, such as distribution of age, HbA1c, gender, diabetes mellitus duration, SINBAD scores, and other risk factors of foot ulcers, were calculated. The correlation among amputation, SINBAD score, HbA1c level, and RBS level was assessed taking $p \leq 0.05$ as statistically significant.

Result

A total of 100 patients were included in the study. All patients were aged between 18 years and >65 years. Mean age of patients was 51.32±11.45 years and the male:female ratio was 3.54:1. Maximum incidence of diabetic foot lesions was seen in the age group range of 51 to 60 years. Nearly 70% of patients belonged to the lower socioeconomic class (Table 1). Maximum duration of diabetes among the study population was 11–15 years, with a mean duration of 12.03±6.96 years. Ninety eight percent of patients had an RBS level higher than 200 mg/dL, with a mean level of 276.68 mg/dL. An HbA1C level higher than 10 mmols/mol was observed only in 8% of patients, with majority of patients presenting an HbA1C level between 8 and 9 mmols/mol (98%), while mean HbA1C level among studied population was 7.648 mmols/mol. Sixty percent of the study population had a family history of diabetes, and hypertension was a chief comorbidity reported in 32% of patients. Smoking and alcohol use history were reported in 60% and 32% of patients, respectively, while previous surgery and DFU history were reported by 12% and 14% of patients, respectively (Table 2). Out of the total 100 patients included in the study, forefoot was found to be the major ulcer site (35%). When it comes to grading, Grade 2 DFUs (28%) were predominant, followed by Grade 3 (24%), Grade 6 (20%), Grade 1 (16%), Grade 4 (6%), and Grade 5 (6%) according to the SINBAD score (Table 3). Foot ulcers were pure neuropathic in 32 cases and ischemic in 30 cases. Infection was found in approximately 75% of cases. About 94% of cases presented with ulcers with an area larger than 2 cm^2. Concerning depth, ulcer restricted to skin and surrounding subcutaneous tissue was observed in 74% of cases; ulcer reaching muscle and tendon, in 10% of cases; and ulcer reaching muscle and tendon and exposed bone, in 16% of cases. Table 3 shows the different management options for therapeutic treatment of patients classified according to the SINBAD score. Among surgical procedures, serial debridement and amputation was done in 32% of patients, as majority of ulcers were Grade 4 according to the SINBAD score. Below-knee amputation was performed in the majority

Table 1. Sociodemographic profile of study subjects

Sociodemographic variables patients (n=100) (%)		
Age group (years)		
18–25	2	
26–30	6	
31–35	2	
36–40	12	51.32±11.45 years
41–45	8	
46–50	12	
51–55	20	
56–60	14	
61–65	14	
>65	10	
Sex		
Male	78	
Female	22	
Socioeconomic class		
Lower class	33	
Upper-lower class	40	
Lower-middle class	23	
Upper-middle class	3	
Upper class	1	

Table 2. Characteristics of diabetic foot ulcer patients

Characteristics of diabetic foot ulcer Patients (n=100) (%)		
Diabetes duration		
<5 years	22	
5–10 years	34	9.68±5.03 years
11–15 years	28	
16–20 years	16	
>20 years	0	
<5 years	22	
Smoking history	60	
Alcohol use history	68	
Previous surgery history	12	
Diabetic foot ulcer history	14	
Family history of diabetes	54	
RBS level (mg/dL)		
<200	2	
≥200	98	
HbA1C level (mmols/mol)		
6–8	77	
8–10	15	
>10	8	

RBS: Random blood sugar; HbA1C: Glycated hemoglobin.

Table 3. Characteristics of foot ulcer site among the study population

Characteristics of foot ulcer site Patients (n=100) (%)	
Foot ulcer site	
Forefoot	36
Forefoot and great toe	8
Hindfoot	22
Hindfoot and midfoot	10
Hindfoot, midfoot, and forefoot	18
Distal one-third of the leg and foot	2
Midfoot	4
Ischemia	30
Neuropathy	32
Bacterial infection	74
Ulcer area	
<1 cm	0
1–2 cm	6
>2 cm	94
Ulcer depth	
Limited to skin and subcutaneous tissue	74
Limited to involvement of muscle and tendon	10
Involvement of muscle and tendon and exposed bone	16
SINBAD score	
Grade 1	16
Grade 2	28
Grade 3	24
Grade 4	6
Grade 5	6
Grade 6	20

SINBAD score: Site, Ischemia, Neuropathy, Bacterial Infection, and Depth score.

of cases (24%), while ankle amputation was necessary in 6% of patients. Partial foot/transmetatarsal amputation was performed in only 2% of cases. Correlation analysis was used to determine which factors can most accurately predict the risk of outcome measures (Table 4). Strong statistically significant ($p<0.001$) correlation coefficients were observed between amputation and HBA1c level (0.747) and SINBAD score (0.871), while there was a weak correlation between amputation and RBS level (0.532). The SINBAD score showed a weak correlation with RBS level (0.578) and HbA1C level (0.571).

Discussion

Diabetic foot ulcer is a prevalent cause of hospitalization in patients with diabetes, and is the result of several sociocultural habits in India, such as barefoot walking, insufficient diabetic treatment facilities, low education level, and poor socioeconomic status. This condition is the most common consequence of diabetes mellitus, usually not healing and resulting in lower limb amputation. However, it can be effectively managed with awareness, blood sugar management, wound debridement, advanced dressing, and treatments. In certain circumstances, surgery can diminish the severity of problems, which can enhance patients' health and quality of life, notably when a multi-disciplinary team effort is used.

Concerning age distribution in our study, among the 100 cases involved, the age of the youngest patient was 24 years and the age of the eldest patient was 71 years. The highest number of cases was found in the age group 51–55 years (20.0%). These findings were concordant with the study reported by Seth et al.[7], where majority of cases were reported in the age group 55–64 years, while being partially concordant with observations reported by Madan et al.[8] (33%), Rooh-Ul-Muqim et al.[9] (32%), and Kumar and Gupta[10] (30.9%) with the age group 51–60 years. The mean age of disease presentation in our study was 51.32±11.45 years, being comparable to that found in the study conducted by Madan et al.[8]. This age aspect might be associated with type 2 diabetes mellitus, which is often prevalent in older patients, although new findings reveal that it also affects

Table 4. Correlation analysis between amputation and SINBAD score and other variables (n=100)

		HbA1C Level	Amputation	RBS Level	SINBAD score
Amputation	Correlation coef. Significance level (p)	0.747 <0.0001	----	0.532 <0.0001	0.871 <0.0001
SINBAD score	Correlation coef.* Significance level (p)	0.571 <0.0001	0.871 <0.0001	0.578 <0.0001	----

*Pearson correlation coefficient.
SINBAD score: Site, Ischemia, Neuropathy, Bacterial Infection, and Depth score; HbA1C: Glycated hemoglobin; RBS: Random blood sugar.

adolescents[11,12]. Among the 100 cases evaluated, 78 patients were male, while 22 patients were female (M:F 3.54:1), which was consistent with previous studies reported by Madan et al.[8], Mote et al.[13], and Gohel et al.[14], who reported that more male patients were affected by the condition when compared to female patients. Male patients may have a higher prevalence of diabetic foot due to injuries acquired at their workplaces and during outdoor activities. In our study, upper-lower class population was predominant, with about 40% of cases, while the population belonging to the upper class constituted only about 1% of patients. Gohel et al.[14] also reported a majority of lower class patients (57%) in their study. Duration of diabetes was 5–10 years in most patients, with a mean duration of 9.68±5.03 years; in contrast to our study, Kumar and Gupta[10] reported a duration of 1–5 years in majority. This variation may be due to a late detection of diabetes in our selected population. Alcohol use and cigarette smoking were reported by 32% and 60% of patients, respectively, which was quite comparable to the findings reported by Chalya et al.[15], where smoking habits and alcohol use were reported by 35.3% and 49.3% of patients, respectively. In our study, 54 patients (54%) had a family history of diabetes mellitus, a percentage higher than that found in the study by Kumar and Gupta (38.2%)[10]. Forefoot was found to be the major ulcer site (36%) in our studied population. Ulcer at distal one-third of the leg and foot (2%) was the least common site. Yosuf et al.[16] also found forefoot as the most common site of DFU.

Fourteen percent of patients had a past history of foot ulcers, and 12% of patients had a history of previous amputations in our study. This was partially comparable to a previous study[15] in which 10.3% of patients had a previous history of foot ulcers and 4.4% of patients had previous amputations.

Considering the distribution of ischemia, clinical evidence of reduced blood flow was observed in 30% of patients, while loss of protective sensation was found in 32% of patients during assessment of neuropathy. Ischemia and neuropathy were observed by Chalya et al.[15] in 57.4% and 30.8% of patients, respectively, which was partially comparable with results found in our study. Typically polymicrobial in nature, DFIs include anaerobes and gramme-positive and gramme-negative aerobes. Bacterial infection was noted in 74% of the population with DFU. In the study by Jasmine et al.[17], 20.4% of patients had sterile cultures, whereas they were seen only in 9.8% of patients in Bansal et al.[18]. The traditional recognition that DFI is mostly caused by *S. aureus* or gram-positive species may not reflect a universal clinical feature, and geographic variance emphasizes the need for local treatment guidelines[19]. Most of the ulcers in our study were larger than 2 cm^2 (94%), none of them was found smaller than 1 cm^2, and the mean ulcer size was 32.87 cm^2, while the study reported by Seth et al.[7] found a mean ulcer size of 14.85 cm^2. Ulcer confined to skin and subcutaneous tissue was observed in 74% of cases. About 10% of cases observed involved ulcers reaching muscle and tendon, while ulcer reaching muscle and tendon and exposed bone was observed in 16% of cases. Considering the SINBAD score, Grade 2 DFUs were predominant and Grade 5 DFUs were the least common. In the study by Venkataramana et al.[20], the majority of DFU cases reported were Grade 3, followed by grades 4, 6, 2, 5, and 1. The difference may be attributed to the variation of locality of participant settings.

Regarding the RBS level, only 2% of patients had a blood sugar level of less than 200 mg/dL, while majority (98%) of patients had a blood sugar level higher than 200 mg/dL, with a mean level of 276.68 mg/dL. With regards to diabetes control, in our study, the majority of patients had an HbA1C level of 8–9 mmols/mol (98%), which was comparable to previous findings[21] of HbA1c levels >7 (mmols/mol) in more than 82% of patients. Conservative management of ulcer was predominant (68%), and other surgical procedures were also seen, such as serial debridement and amputation (32%), with below-knee amputation (24%) being the most common and ankle amputation (6%), the least common procedure. Partial foot amputation/transmetatarsal amputation was performed in only 2% of cases. In their study, Karbhari et al.[21] performed a conservative management in two patients and below-knee amputation, in 2% of patients. Our study has higher figures due to late presentation, unawareness, and to the low socioeconomic status of participants. During correlation analysis, strong statistically significant ($p<0.001$) correlation coefficients were observed between amputation and HBA1c level (0.747) and between amputation and SINBAD score (0.871), while there was a weak correlation between amputation and RBS level (0.532). The SINBAD score showed a weak correlation with RBS level (0.578) and HbA1C level (0.571). The limitation of this study is its small sample size.

Conclusion

Diabetic foot is a widespread condition, especially in developing countries. Effectiveness in classification systems demands quick and cost-effective treatments, which require patient compliance. The classification system used has advantages and disadvantages. Recently described, the SINBAD score is a simplified version of the S(AD)SAD system and considers size, ischemia, neuropathy, bacterial infection, area, and depth. One point is attributed to the presence of each feature, and the total score is then calculated. The SINBAD score is simple to use in daily practice and more effective in describing the disease processes for auditing purposes. Primary and secondary healthcare systems have different approaches to manage diabetic foot care. Moreover, the effective use of diagnostic tools by physicians to assess the nature and severity of diabetic foot is crucial. Simple hygienic practices, regular or at least annual foot examination, and patient education are recommended. Provision of correct and convenient footwear and efficient treatment of minor injuries can downturn ulcer occurrence.

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