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CLINICAL PROFILE AND OUTCOME OF PATIENTS WITH DIABETIC FOOT INFECTION: A SINGLE CENTRE STUDY

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Introduction: Diabetes mellitus with its limb and life-threatening complication such as diabetic foot infection and amputation are increasing at epidemic rates all over the world.
Aim of the study: The study aims to find out the clinical profile and outcomes of patients with diabetic foot infections (DFI).
Methods: This was a prospective study conducted at a tertiary care institute. A total of 82 patients were included and analyzed in this study from January 2020 to December 2022. This study recruited patients >18 years of age, with DFI. All patients underwent a detailed history and clinical examination. Patients were classified as per the International Working Group on the Diabetic Foot -IDSA classification. The patients were followed up every month for 3 months. Clinical outcome was studied regarding the rate of amputations, readmissions, and mortality.
Result: A total of 82 patients were included and analyzed in this study. There are 36 (43.90%) patients from the age range 55-65 which is height and the lowest is 2(2.44%) patients from the age range 15-24. The ulcer healing during follow-up of the study, the mean±SD of the baseline is 14.85±23.12. After 1 month the percentage of wound healing is 20.88% and the mean±SD is 11.75±22.68, after 2 months the percentage of wound healing is 43.16% and the mean±SD is 8.44±22.05 and after 3 months the percentage of wound healing is 57.04% and the mean±SD is 6.38±21.19. The p-value of follow-up duration is equal to <0.001 which was shown as a significant change.

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Conclusion: This study shows the predominance of monomicrobial growth and Gram-negative organisms in diabetic foot patients. With the increase in the severity of DFI, there was an increased rate of hospital readmissions, amputations (major and minor), and mortality. Dimensions of the ulcer may have a bearing on the rate of minor amputations.

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INTRODUCTION

Diabetes is one of the most prevalent chronic diseases. Such a profound demographic shift is likely to yield a corresponding increase in the prevalence of diabetes chronic complications, including those in the lower extremity, the diabetic foot [1]. It is estimated that the annual population-based incidence of a diabetic foot ulcer (DFU) ranges from 1.0% to 4.1%. The lifetime incidence may be as high as 25% [2]. Despite the efforts of conservative therapy, there will always be a percentage of ulcers that necessitate hospitalization. These cases may require surgical debridement, resection of distal osseous and soft tissue structure, endovascular intervention, daily dressings, strict glycemic control, and intravenous antibiotic therapy for eradication of infection [3, 4]. Foot problems in diabetics can frequently be life or limb-threatening, yet have not received the same level of attention as other diabetes complications [5]. Until today, descriptive data regarding demographical and clinical factors in foot ulcers among diabetic patients in Bangladesh are relatively few though we are all aware of its clinical importance [6, 7]. Exactly estimating the total burden of all foot complications is not easy, because the associated problems are managed by various specialties of the health services. Therefore, amputation rates have been usually recommended as the indicator of the quality of foot care [8]. Foot problems can be life or limb treated frequently in diabetic individuals. As many as 50% to 83% of all non-traumatic lower-extremity amputations are performed on diabetic patients [9-11]. The most important intervention to prevent foot ulceration and its consequences is early detection and appropriate treatment of high-risk patients. Several large clinical centers have experienced a 44-85% reduction in the rate of amputations among individuals with diabetes after the implementation of improved foot-care programs [4, 7]. In our study, we attempt to record the clinical profile and outcome of diabetic foot hospitalization and to provide a report which may become a reference for further improvement in diabetic foot management in our center, in Khulna, Bangladesh.

METHODOLOGY & MATERIALS

This was a prospective study conducted at a tertiary care institute. A total of 82 patients were included and analyzed in this study from January 2020 to December 2022. Informed consent was taken from all the patients. The study followed the Declaration of Helsinki guidelines and was approved by the Institutional Ethics Committee. All the patients underwent detailed history including duration of diabetes, presenting features and clinical examination at baseline including details of ulcer, evaluation of palpable pulses (i.e., femoral, popliteal, anterior tibial, posterior tibial, and dorsalis pedis), and Ankle-brachial index (ABI). The discharge from the ulcer was sent for microbiological examination. Patients were classified as per the IWGDF-IDSA classification into mild, moderate, and severe diabetic foot infections (DFI). [12] Ulcer size was determined by tracing the outline of the wound on a graph paper divided into 1 cm squares. The wound area was calculated by manually counting the squares within the wound. The ulcers of the patient were debrided, antibiotic was given as

per culture sensitivity, and the daily aseptic dressing was done. The patients were followed up every month for 3 months. The outcome was assessed in terms of ulcer healing, readmission, minor/major amputation, and mortality during the 3 months.

- **Inclusion criteria:**
- The patients >18 years of age with diabetic foot
- **Exclusion criteria:**
- The patients who had deranged renal function tests
- Previously undergone revascularization surgery or Burger's disease

The statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS Version 20, IBM, NY, USA). The normality of the data was checked by the Kolmogorov Smirnov test. The quantitative data were presented as mean ± SD for normally distributed data, means were compared using an independent *t*-test, and for skewed data/scores Mann–Whitney U-test was applied. The Chi-square test was applied for qualitative data. A value of $P < 0.05$ was considered statistically significant. The association of clinical outcome (ulcer healing, readmission, minor/major amputations, and mortality) with various parameters were computed using the Cross Tabs-Chi-square test or ANOVA. A baseline logistic regression analysis was carried out with all the parameters.

RESULT

This is a prospective study, a total of 82 patients were included and analyzed in this study. The age distribution is shown in table-1. There are 36 (43.90%) patients from the age range 55-65 which is height and the lowest is 2(2.44%) patients from the age range 15-24. Figure-1 shows the gender distribution, 49(59.76%) patients were male and 33(40.24%) patients were female. Table-3 shows the complication of patients in the study, 74(90.24%) patients had ulcers, 57(69.51%) patients were discharged, 46(56.10%) patients had trauma, 31(37.80%) patients had swelling, 17(20.73%) patients had pain, 16(19.51%) patients had gangrene, and only 5(6.10%) patients had a fever. The microbiological distribution of the study is shown in table-4 with Gram-negativity and positivity. Table-5 shows the ulcer healing during follow-up of the study, the mean±SD of the baseline is 14.85±23.12. After 1 month the percentage of wound healing is 20.88% and the mean±SD is 11.75±22.68, after 2 months the percentage of wound healing is 43.16% and the mean±SD is 8.44±22.05 and after 3 months the percentage of wound healing is 57.04% and the mean±SD is 6.38±21.19. The p-value of follow-up duration is equal to <0.001 which was shown as a significant change (Table-5). The association of the severity of diabetic foot infection with clinical outcome is shown in table-6. The severity of DFI is analyzed into 3 groups; 33 patients with mild, 39 patients with moderate and only 10 patients with severe infection. The total mortality rate of the study is 3(3.366%) which is poor (Table-6).

Table-1: Age distribution of the study population (N=82).

Age (Years)	Frequency	Percentage
15-24	2	2.44
25-34	3	3.66
35-44	2	2.44
45-54	17	20.73
55-64	36	43.90
65-74	17	20.73
≥75	5	6.10

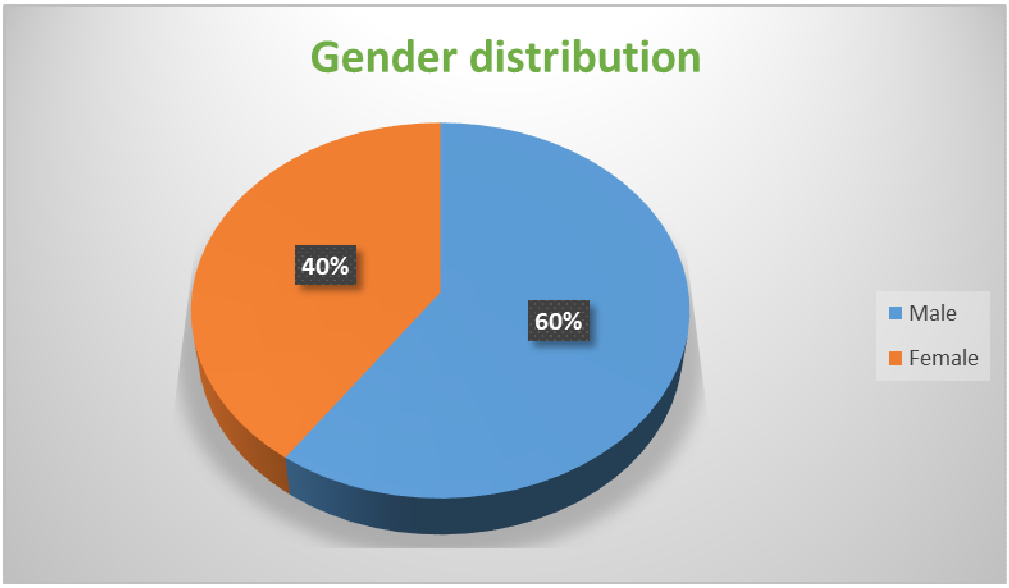

Figure-1: Gender distribution of the study.

Table-3: Complication of patients in the study.

Complication	Frequency	Percentage
Pain	17	20.73
Swelling	31	37.80
Ulcer	74	90.24
Gangrene	16	19.51
Discharge	57	69.51
Fever	5	6.10
Trauma	46	56.10

Table-4: Microbiological distribution of the study.

Spectrum	Frequency	Percentage
Microbiological distribution		
Gram-negative	44	53.66
Gram-positive	18	21.95
Mono-microbial	45	54.88
Polymicrobial	8	9.76
Sterile	29	35.37
Candida	0	0.00
Gram-negative		
Escherichia coli	18	21.95
Klebsiella pneumoniae	7	8.54
Proteus mirabilis	2	2.44
Acinetobacter	16	19.51
Gram-positive		
Staphylococcus aureus	18	21.95
MRSA	2	2.44

Table-5: Ulcer healing during follow-up of the study.

Ulcer area (cm2)	Baseline	1 month	2 month	3 month
Mean±SD	14.85±23.12	11.75±22.68	8.44±22.05	6.38±21.19
Percentage of wound healing		20.88	43.16	57.04
P-value		<0.001	<0.001	<0.001

Table-6: Association of the severity of diabetic foot infection with clinical outcome.

Outcome	Severity of DFI								P-value
	Total		Mild (N=33)		Moderate (N=39)		Severe (N=10)		
	N	%	N	%	N	%	N	%	
Ulcer healing in 1st month			41	50.00	23	28.05	23	28.05	0.03
Ulcer healing 2nd month			65	79.27	56	68.29	46	56.10	0.03
Ulcer healing 3rd month			76	92.68	68	82.93	59	71.95	0.02
Minor amputation	32	39.02	5	15.63	16	50.00	11	34.38	0.003
Major amputation	6	7.32	0	0	4	66.67	2	33.33	0.001
Readmission at 1st month	8	9.76	0	0	6	75	2	25	0.002
Readmission 2nd month	5	6.10	0	0	2	40	3	60	0.01
Readmission in 3rd month	3	3.66	0	0	2	66.67	1	33.33	0.04
Mortality	3	3.66	0	0	2	66.67	1	33.33	0.04

DISCUSSION

Diabetic foot lesions are one of the most common causes of hospitalizations and are caused by several socio-cultural practices in India like barefoot walking, inadequate facilities for diabetic care, low level of education, and poor socioeconomic conditions. The mean age in our patients was 58.49 ± 11.04 years which was similar to that previously reported in the literature. [13, 14] The Maximum number of patients was found in the 55–64 age group (n = 29, 44.62%). It may be because that Diabetes Mellitus type II is classically seen in elderly patients, though recent reports have shown it to affect the adolescent population too.[15, 16] A large number of Type II patients remain asymptomatic and develop complications due to prolonged hyperglycemia, whereas Diabetes Mellitus type 1 is detected early and the affected patients do not have any complications at presentation.[17] The male preponderance for DFU reported by other studies,[18, 19, 20] was also seen in our study, with the disease being 5 times more common in males than females. The males high risk of developing diabetic foot complications because of the increased prevalence of neuropathy, less joint mobility, and higher foot pressure. [21] The mean duration of diabetes mellitus in our patients was 12.03 ± 6.96 years. The mean value of HbA1c observed in our study was 7.23 ± 1.57. Christman et al. observed that for each 1.0%-point increase in HbA1c, the daily wound-area healing rate decreased by 0.028 cm^2/day. [22] IWGDF-

IDSA classification classifies the severity of DFI according to the extent of involvement and the presence of systemic inflammatory response. [12] In our study, there was a preponderance of patients with moderate DFI (49.23%) whereas severe DFI was present in 12.3% of patients. The proximal bigger arteries were more palpable than distal smaller vessels because diabetes is microangiopathy. Moreover, they are prone to tissue edema due to microvascular disease, making palpation of pulses more difficult. [23] The mean ABI in this study was 0.58 ± 0.11. Williams et al. observed that ABI values <0.9 indicate significant arterial disease and values >1.15 shall be regarded as unreliable due to the presence of arterial calcification. [23] In our study, monomicrobial growth was present in 55.38%, and polymicrobial growth was seen in 9.23% of patients. The cultures were sterile in 35.39% of patients. The reported proportion of monomicrobial growth in the literature varies from 63.5% to 83.5% while that of polymicrobial growth varies from 14.3% to 35%.[19, 20, 24, 25] According to Jasmine et al., 20.4% had sterile cultures, whereas they were seen only in 9.8% according to a study by Bansal et al.[19, 24] 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. This necessity has lately been demonstrated by many studies, including the present one, and other studies from Eastern countries, which reported a significant shift toward more Gram-negative organisms isolated from DFIs. [25] In our study, predominantly Gram-negative organisms were isolated in 35 (71.43%) patients while Gram-positive organisms were isolated in 14 (28.57%) patients. Ramakant et al. similarly observed that Gram-negative organisms (n = 932, 51.7%) were more common than Gram-positive organisms (n = 511, 31.3%) in DFI. [18] Gadepalli et al. in their study on 80 ulcer specimens observed that 23 patients (28.7%) had Gram-negative and only 11 patients (13.8%) had Gram-positive infections. [13] Some studies from the west reported Gram-positive organisms to be the predominant organisms in DFI. [16-18] The difference observed in the prevalence of Gram-negative bacilli in DFI between diabetic patients from eastern and western countries remains largely unknown. However, environmental factors such as sanitary habits, for example, the use of water for perianal wash (ablution) after defecation leading to contamination of hands with faecal flora, could be responsible for increased Gram-negative infections in the developing world compared with the West. [25] Our culture revealed that the most common isolates were E. coli (21.54%), Acinetobacter (20%), Klebsiella pneumonia (9.23%), and Proteus Mirabilis (3.08%) among the Gram-negative organisms. A similar finding was reported by Jog et al. which showed 37.7% of E. coli, 12.6% of K. pneumonia and 7.93% of Proteus species among Gram-negative isolates. [19] Another study from North India reported pseudomonas to be the most common isolate from bone and soft tissue (26.9 and 23.2%, respectively) followed by Acinetobacter in DFUs. They hypothesized that infection in DFU is usually polymicrobial due to its chronic nature but when inadequately treated with antimicrobials, the sensitive organisms such as E. coli, and Proteus is killed, leading to a preponderance of monomicrobial growth and multidrug-resistant organisms like Pseudomonas. [26] In our study, among Gram-positive organisms, S. aureus was the most common isolate which was present in 14 (21.54%) of the patients. Gadepalli et al. also observed that S. aureus was the most frequent organism isolated in DFI, being present in 13.7% of patients. [13] Though detection of foot pulses is more difficult in patients with diabetes, in our study, we found a significant association

of palpable infrapopliteal arteries with total number of readmissions, minor/major amputations and ulcer healing at 1st, 2nd and 3rd months. This suggests that the presence of palpable infrapopliteal arteries (anterior tibial, posterior tibial and dorsalis pedis artery) was clinically associated with favourable outcomes regarding ulcer healing and a lesser number of readmissions and amputations. ABI did not show any association with outcome, i.e., minor and major amputations, ulcer healing or mortality in our study, but it showed a borderline significance with a total number of readmissions (P = 0.05). Although ABI is highly predictor of arterial occlusive disease, long-standing diabetes mellitus causes calcification of media of the vessels resulting in high systolic pressure in the ankle making it less reliable in diabetic foot patients. [27] Nearly 39% of our patients underwent minor amputations, and 7.69% of patients underwent major amputations while two patients died during the follow-up. The mortality rate and rate of major and minor amputation increased with the increase in the severity of DFI. Though there was significant ulcer healing at all follow-up visits with appropriate antibiotic therapy, poor ulcer healing was seen with increasing severity of DFI. Therefore, the Infectious Diseases Society of America-(IDSA-IWGDF) system is clinically helpful in predicting outcomes in patients with DFI. Lavery et al. conducted a prospective study to validate the IDSA-IWGDF system to predict outcomes in DFI. They observed that there was a trend toward an increased risk of amputation, higher-level amputation, and lower extremity-related hospitalization with increasing infection severity. It supports the clinical value of the IDSA-IWGDF diabetic foot classification in predicting clinical outcomes. [28] According to Wukich et al., 55% of patients with a severe DFI required some amputation as compared to 42% of patients with a moderate DFI. [29] Patients undergoing minor amputations had a significant association with the dimensions of the ulcer. On ROC plots, the ulcer area of 2.13 cm^2 had a sensitivity of 88%. This might suggest that the dimensions of ulcers can be a good screening tool to predict the unfavorable outcome regarding minor amputations.

Limitations of the study:

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION AND RECOMMENDATIONS

The small sample size is the limitation of this study. To conclude, the risk of DFU occurs during the late 5th and early 6th decades of life and is common in male patients. There was a predominance of monomicrobial growth and Gram-negative organisms. Delayed ulcer healing, amputations (major and minor), hospital readmissions and mortality increased with the increasing severity of DFI. Minor amputation was seen in more than one-third of patients with DFU. The higher number of minor and major amputations poses a burden on the existing healthcare and human resources of the country. An increase in dimensions of ulcer has a bearing on the rate of minor amputations. Hence, healthcare education and screening programs should be strengthened especially in developing nations, to prevent DFI. Healthcare should be made more accessible, to facilitate early diagnosis of DFI and its complications, and to minimize the rate of amputations.

Conflict of interest: None declared

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