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Risk Factors Associated with Adverse Outcomes in Patients with Diabetic Foot Infection in a Tertiary Hospital in Chattogram

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Abstract

Background: Diabetic Foot Infection (DFI) can result in lower extremity amputation and death in patients with diabetes and is an important cause of morbidity and mortality. The purpose of this study was to identify predictive factors for adverse outcomes consisting of major lower extremity amputation and mortality in patients with DFI.

Materials and methods: One hundred two patients diagnosed with DFI and followed-up in a tertiary hospital between November 2022 and April 2023 were included in this prospective study. All patients' demographic and diabetic foot characteristics at the time of presentation, degrees of DFI and clinical and laboratory findings were recorded. Major amputation and/or mortality were regarded as adverse outcomes. Patients were followed-up throughout hospitalization to discharge or mortality. Risk factors for adverse outcomes were identified using univariate and multivariate logistic regression analysis.

Results: The patients' median age was 60.0 years and the majority (72.5%) were men. Adverse outcomes developed in 11 patients during follow-up. The following factors were linked to adverse outcomes: presence of fever, presence of wound necrosis, isolation of Enterobacteriaceae species in wound culture, PEDIS grade 4, and Blood Urea Nitrogen (BUN) elevation. At multivariate logistic regression analysis only BUN higher than 31 mg/dL and presence of necrosis in the wound emerged as significant independent predictive factors for adverse outcome development.

Conclusions: The study findings show that the above factors may be useful in predicting adverse outcome development in patients with DFI. Early detection of these factors may be useful in preventing morbidity and mortality in these patients.

Key words: Adverse outcome; Diabetic foot infection; Major amputation; Mortality.

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Introduction

Diabetes Mellitus (DM) is a chronic public health problem capable of progressing with various micro- and macrovascular complications. Approximately 537 million adults worldwide are affected by DM, and this figure is expected to reach 783 million by 2045. The number of patients affected by chronic complications of diabetes such as Diabetic Foot Ulcer (DFU) is therefore expected to rise in line with the prevalence of DM and longevity.[1] Many DFUs become complicated by infection. Diabetic Foot Infection (DFI) resulting from the addition of infection to a background of ischemia, ulcer, and neuropathy, leads to increased lengths of hospital stay, increased health service costs, lower extremity amputation and even mortality.[2]

It is estimated that at least one extremity is lost due to DFU every 30 seconds among diabetic patients. In addition, DFU represents approximately half of all non-traumatic amputations.[3] These amputations are important surgical procedures performed for the purpose of preventing severe complications, such as widespread infection or sepsis, in patients with DFU. Amputation above the ankle, known as major lower extremity amputation, is a feared consequence of DFU. Major amputation associated with DFU results in severe physical impairment.[4] As a life-saving procedure, these amputations are the last resort in the treatment of diabetic foot and can cause severe economic, social and psychological effects through their immobilization of the patient.[5]

In addition, major amputation in patients with DFU increases the risk of mortality compared to minor amputation, has been linked to a decrease in survival rates, and has been identified as an independent risk factor for mortality.[6,7] This may be associated with the increased cardiovascular risk in a patient subgroup with an already high prevalence of cardiovascular disease.[8] The most important risk factors for mortality in patients with DFU are age, wound ischemia, impaired

renal function and male gender.[9] Previous studies have focused on diabetic foot independently of infection. However, infection is the most widespread cause of amputation.[10] In contrast to DFU, long-term survival rates in DFI are unknown. Moreover, very few studies have focused on patients with DFI. A knowledge of potential risk factors capable of predicting adverse outcomes consisting of major amputation and mortality in patients with DFI will therefore be useful in their prevention. The purpose of this study was to investigate risk factors associated with major amputation and mortality, regarded as adverse outcomes, in patients with DFI requiring hospitalization for treatment.

Materials and methods

This single-center study investigated risk factors associated with major amputation and mortality, regarded as adverse outcomes, in patients with DFI. Approval for the study was granted by the Ethical Review Committee of Chittagong Diabetic General Hospital. This prospective study was performed over a six-month period between November 2022 and April 2023 from patients at the Orthopedics and Footcare Department of Chittagong Diabetic General Hospital. The research was conducted in conformity with the Declaration of Helsinki.

One hundred and two patients diagnosed with DFI aged 34-87 were included in the study. Written informed consent was obtained from all participants. Major lower extremity amputation and/or death were regarded as adverse events.

Inclusion criteria

Only patients diagnosed with DFI and aged over 18 were included.

Exclusion criteria

Pregnant women and individuals aged under 18, and patients with type 1 DM, chronic liver disease, chronic kidney failure and receiving hemodialysis, cancer patients under treatment, patients with active infection other than DFI and those with acute or chronic inflammatory disease were excluded.

A detailed medical history was obtained from all participants. The patients' demographic characteristics (Age, gender, place of residence, education level and occupation) at the time of admission to the clinic, duration of DM, antidiabetic drugs used, comorbidities, vital findings, smoking status, diabetic foot characteristics and clinical and laboratory findings were recorded. Anthropometric data such as height, body weight, and body mass index were obtained using standard methods. Detailed descriptions regarding DFI were performed. Infection was defined as at least two consisting of local swelling, erythema, pain, local increased temperature, and purulent discharge. The wounds of the patients with DFI were recorded based on the Perfusion, Extent, Depth, Infection and Sensation (PEDIS) classification published by the International Diabetic Foot Working Group. Absence of signs and findings of infection was classified as PEDIS grade 1.

Patients with any two of such signs as local swelling or induration, erythema of 0.5-2 cm around the ulcer, local tenderness or pain, local increased temperature, or purulent discharge were classified as PEDIS grade 2. Patients with erythema exceeding 2 cm and any one of the grade 2 infection findings or infection involving structures deeper than the skin such as abscess, osteomyelitis, septic arthritis, or fasciitis without any signs of Systemic Inflammatory Response Syndrome (SIRS) were classified as PEDIS grade 3. Any foot infection with signs of SIRS was classified as PEDIS grade 4.[11]

Peripheral sensory neuropathy was diagnosed using electroneuromyography and Peripheral Artery Disease (PAD) or venous insufficiency using Doppler ultrasonography. Osteomyelitis was diagnosed either clinically or using methods such as magnetic resonance imaging or scintigraphy. Laboratory parameters including hemoglobin (g/dL) leukocyte, neutrophil, lymphocyte and platelet counts (10^9/L), Alanine Aminotransferase (ALT) (U/L) Aspartate Aminotransferase (AST) (U/L) creatinine (mg/dL) Blood Urea Nitrogen (BUN) (mg/dL) glucose (mg/dL) albumin (g/dL) C-Reactive Protein (CRP) (mg/L) Erythrocyte Sedimentation Rate (ESR) (mm/h) HbA1c (%) total cholesterol (mg/dL) and Low Density Lipoprotein Cholesterol (LDLC) (mg/dL) were recorded. Wound swab culture and sensitivity tests were also performed. Biochemical parameters were measured on a Beckman Coulter AU5821 (Japan) device. ESR values were measured using the Westergreen method on a StaRRsed device.

Complete blood count was studied using a Sysmex XN-9000 (Japan) device. HbA1c levels were calculated using the high-performance liquid chromatography method on a Premier Hb9210 device. Medical and surgical treatments administered were recorded.

The patients were followed-up until discharge or mortality during hospitalization. Patients with DFI remained enrolled in the study until one of three pre-determined outcomes was observed during the ward follow-up period–improvement of DFI, major amputation, or mortality. Lesions that healed with no signs or findings of clinical infection and without amputation were regarded as cured.

Amputations performed below the ankle were defined as minor, and those above the ankle as major.[4] Major amputation and mortality were regarded as adverse outcomes. The patients were divided into two groups based on the presence or absence of adverse outcomes.

The data were entered onto and analyzed using the same software. Demographic characteristics, underlying diseases, clinical findings, diabetic foot characteristics, laboratory parameters, and treatments were compared between the two groups in order to identify risk factors for adverse outcomes in patients with DFI. Categorical descriptive characteristics were expressed as frequency distributions and percentages, and continuous variables as median values (Interquartile range). Categorical variables were compared between the groups using the chi-square test and continuous variables using the non-parametric Mann-Whitney U test since parametric hypothesis test conditions were not met. Receiver Operating Characteristics (ROC) analysis was applied to estimate the ability to predict mortality of biomarkers and some continuous variables, cut-off points were determined, and the specificity and sensitivity of these were calculated. The Youden index (J = Sensitivity + Specificity-1) was used to determine cut-off values. Risk factors for adverse outcomes were determined using univariate and multivariate logistic regression analysis. The multivariate logistic regression model was created with body temperature elevation (≥38.3^0 C), presence of wound necrosis or *Enterobacteriaceae* in wound culture, PEDIS grade 4 and blood urea nitrogen >31 mg/dL, which emerged as significant in the univariate model (Model: Backward LR. Entry: 0.05 and Removal: 0.10). p values <0.05 were regarded as statistically significant.

Results

The median age of the patients in this study was 60.0 years (IQR; 53-67), and 74 (72.5%) were men. Amputation was performed on 32 patients (31.4%), eight (7.9%) of which represented major amputation. Mortality occurred in four (3.9%) cases during follow-up. Major amputation and/or mortality were regarded as adverse outcomes. Accordingly, 11 (10.8%) of cases resulted in adverse outcomes. The patients' demographic characteristics and underlying diseases according to adverse events are shown in Table I.

Table I The Distributions of the Patients' Demographic Characteristics and Underlying Diseases According to Adverse Events

	Adverse Outcomes			
	Total (n=102)	No (n=91)	Yes (n=11)	p
Gender (Male),n (%)	74 (72,5)	66 (72,5)	8 (72,7)	0,648
Age, median (IQR	60 (53 – 67)	60 (53 – 67)	61 (56 – 69)	0,447
Body mass index, (kg/m²)	27,4 (25,4 – 29,2)	27,4 (25,3 – 29,0)	27,7 (27,2 – 32,5)	0,268
Occupation, n (%)				**0,194**
Not working	31 (30,4)	29 (31,9)	2 (18,2)	
Self-employment	10 (9,8)	10 (11,0)	-	
Farmer	11 (10,8)	10 (11,0)	1 (9,1)	
Officer	5 (4,9)	4 (4,4)	1 (9,1)	
Retired	29 (28,4)	24 (26,4)	5 (45,5)	
Other	16 (15,7)	14 (15,4)	2 (18,2)	
Place of residence, n (%)				**0,071**
Village	29	28 (30,8)	1 (9,1)	
District	24	22 (24,2)	2 (18,2)	
Province	49	41 (45,1)	8 (72,7)	
Education level, n (%)				**0,892**
Not literate	23 (22,5)	21 (23,1)	2 (18,2)	
Literate	2 (2,0)	1 (1,1)	1 (9,1)	
Primary school graduate	58 (56,9)	52 (57,1)	6 (54,5)	
High school graduate	14 (13,7)	13 (14,3)	1 (9,1)	
Graduated from a Universty	5 (4,9)	4 (4,4)	1 (9,1)	
Underlying diseases, n (%)				
Coronary artery disease	42 (41,2)	36 (39,6)	6 (54,5)	0,340
Hypercholesterolemia	31 (30,4)	28 (30,8)	3 (27,3)	0,558
Hypertension	51 (50,0)	43 (47,3)	8 (72,7)	0,100
PAD	42 (41,2)	37 (40,7)	5 (45,59	0,501
Peripheral venous insufficiency	24 (23,5)	19 (20,9)	5 (45,5)	0,080
Peripheral neuropathy	44 (50,6)	38 (48,7)	6 (66,7)	0,254
Duration of Diabetes mellitus, (Years), median (IQR)	15 (10 – 20)	15 (10 – 20)	10 (5 – 15)	0,083
Drug used for diabetes mellitus, n (%)				**0,425**
OAD	13 (12,7)	13 (14,3)	-	
Insulin	58 (56,9)	50 (54,9)	8 (72,7)	
OAD + Insulin	28 (27,5)	26 (28,6)	2 (18,2)	
Not using	3 (2,9)	2 (2,2)	1 (9,1)	
Hospital admission due to the same DFI within the last three months	18 (17,6)	15 (16,5)	3 (27,3)	0,301
History of antibiotic use in the last three months	69 (67,6)	61 (67,0)	8 (72,7)	0,497
Smoking	32 (31,4)	28 (30,8)	4 (36,4)	0,473

DFI: Diabetic Foot Infection, OAD: Oral Antidiabetic, PAD: Peripheral Artery Disease

Distributions of clinical findings at time of presentation and foot characteristics in terms of adverse events are shown in Table II. The foot characteristic of necrosis in the wound site was present in all the cases with adverse outcomes and was detected statistically significantly more frequently (p=0.002). PEDIS grade 4 was also significantly more common in cases developing adverse outcomes, while PEDIS grade 2 was significantly less common in those cases (p=0.016 and p=0.012, respectively).

Table II Distributions of Clinical Findings at Time of Presentation and Foot Characteristics in Terms of Adverse Events

	Adverse Outcomes			
	Total (n=102)	No (n=91)	Yes (n=11)	p
Vital findings, n (%)				
Fever (≥38,3^{0}C)	7 (6,9)	4 (4,4)	3 (27,3)	0,026
Hypotension (<90/60 mm/Hg)	2 (2,0)	1 (1,1)	1 (9,1)	0,205
Tachycardia (>90 beats/min)	7 (6,9)	6 (6,6)	1 (9,1)	0,562
Wound formation time (Days), median (IQR)	30 (15 – 60)	30 (15 – 60)	45 (30 – 90)	0,229
Affected side, n (%)				0,270
Left	47 (46,1)	40 (44,0)	7 (63,6)	
Right	41 (40,2)	38 (41,8)	3 (27,3)	
Both	14 (13,7)	13 (14,3)	1 (9,1)	
Localization of DFI, n (%)				**0,158**
Sole of foot	11 (10,8)	11 (12,1)	-	
Thumb	29 (28,4)	28 (30,8)	1 (9,1)	
Other fingers	31 (30,4)	27 (29,7)	4 (36,4)	
Heel	10 (9,8)	9 (9,9)	1 (9,1)	
Metatarsal	5 (4,9)	2 (2,2)	3 (27,3)	
The back of foot	6 (5,9)	5 (5,5)	1 (9,1)	
Stump place	3 (2,9)	2 (2,2)	1 (9,1)	
Lateral foot	3 (2,9)	3 (3,3)	-	
Ankle	4 (3,9)	4 (4,4)	-	
Fluid in the wound	89 (87,3)	79 (86,8)	10 (90,9)	0,576
Edema in the wound	86 (84,3)	77 (84,6)	8 (81,8)	0,545
Necrosis in the wound	47 (46,1)	37 (40,7)	10 (90,9)	0,002
Osteomyelitis	43 (42,2)	38 (41,8)	5 (45,5)	0,530
DFI severity score (PEDIS)				
Grade 2	34 (33,4)	34 (37,4)	-	0,012
Grade 3	62 (60,8)	54 (59,3)	8 (72,7)	0,390
Grade 4	6 (5,9)	3 (3,3)	3 (27,3)	0,016

DFI: Diabetic Foot Infection¸ PEDIS: Perfusion, Extent, Depth, Infection and Sensation.

Distributions of patients' laboratory findings during presentation in terms of adverse events are shown in Table 3. Blood nitrogen urea levels were significantly higher in the cases concluding with adverse outcomes (p=0.001). Ninety-five species of microorganism were isolated in the wound cultures of 76 (74.5%) patients. Nineteen (18.6%) of these were polymicrobial. No agent was identified in 26 patients (25.5%). Isolation of *Enterobacteriaceae* (n=37, 36.3%) in wound culture was significantly more common in the cases resulting in adverse events (p=0.011).

Table III Distributions of Patients' Laboratory Findings During Presentation in Terms of Adverse Events

	Adverse Outcomes			
	Total (n=102)	No (n=91)	Yes (n=11)	p
Microorganism isolation n(%)				
Polymicrobial	19 (18,6)	17 (18,7)	2 (18,2)	0,666
*Enterobacteriaceae**	37 (36,3)	29 (31,9)	8 (72,7)	0,011
Staphylococcus aureus	14 (13,7)	14 (15,4)	-	0,180
Non-fermenter gram negative**	9 (8,8)	8 (8,8)	1 (9,1)	0,658
Other gram positive***	35 (34,3)	32 (35,2)	3 (27,3)	0,438
No agent	26 (25,5)	25 (27,5)	1 (9,1)	0,171
Biomarker at the time of hospital admission				
Leukocyte (10^9/L)	10.18 (8.03 – 12.72)	10.37 (7.95 – 13.00)	9.72 (8.25 – 12.62)	0,978
Neutrophil lymphocyte ratio	4,33 (2,73 – 7,42)	4,29 (2,75 – 7,18)	6,15 (2,53 – 11,71)	0,242
Hemoglobin (g/dL)	12,0 (10,9 – 13,8)	12,2 (10,9 – 13,8)	10,7 (8,8 – 13,6)	0,213
Platelet (10^9/L)	312 (247 – 374)	312 (247 – 375)	284 (247 – 367)	0,670
CRP (g/dL)	66 (20 – 138)	54 (15 – 138)	110 (50 – 171)	0,116
ESH (mm/sa)	61 (35 – 85)	61 (35 – 81)	64 (27 – 101)	0,340
BUN (mg/dL)	24 (17 – 39)	23 (17 – 34)	40 (25 – 58)	0,005
Creatinine (mg/dL)	1,1 (0,8 – 1,4)	1,0 (0,8 – 1,3)	1,1 (0,9 – 4,2)	0,084
Glucose (mg/dL)	235 (161 – 314)	234 (156 – 318)	250 (183 – 263)	0,842
AST (U/L)	18 (14 – 26)	18 (14 – 26)	20 (14 – 26)	0,812
ALT (U/L)	17 (12 – 25)	17 (12 – 25)	19 (11 – 25)	0,957
HbA1c (%)	9,4 (8,2 – 11,0)	9,4 (8,2 – 11,1)	8,9 (7,5 – 10,9)	0,323
Total cholesterol (mg/dL)	159 (133 – 190)	159 (136 – 186)	156 (118 – 225)	0,840
LDLc (mg/dL)	102 (87 – 123)	102 (87 – 123)	89 (78,5 – 144)	0,655
Albumin (g/dL)	2,9 (2,7 – 3,5)	2,9 (2,6 – 3,5)	2,8 (2,7 – 3,5)	0,530

**Escherichia coli, Klebsiella pneumoniae, Enterobacter spp., Proteus spp., Citrobacter spp., Morganella morganii, Serratia marcescens.*

***Pseudomonas aeruginosa, Acinetobacter baumannii.*

****Staphylococcus epidermidis, Enterococcus spp., Streptococcus spp.*

ALT: Alanine Aminotransferase, AST: Aspartate Aminotransferase, BUN: Blood Urea Nitrogen, CRP: C-Reactive Protein, DFI: Diabetic Foot Infection, ESR: Erythrocyte Sedimentation Rate, LDLc: Low Density Lipoprotein Cholesterol.

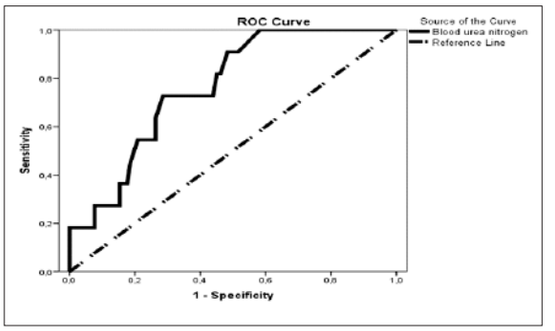

Figure 1 ROC Curve of Blood Nitrogen Urea Levels at Hospitalization for Adverse Outcomes

The ROC curve of BUN levels for adverse outcomes during hospitalization is shown in Figure 1. The area under the curve was 0.762 (95% Confidence Interval [CI] 0.641 – 0.884), and the cut-off for predicting adverse outcomes was >31 mg/dL (p=0.005). Sensitivity in predicting adverse outcome at this cut-off value was 72.7%, with specificity of 71.4%.

Logistic regression analysis for adverse outcomes is shown in Table IV. At multivariate logistic regression analysis of initial temperature elevation, presence of necrosis in the wound site, detection of *Enterobacteriaceaein* wound culture, PEDIS grade 4, and BUN 31 mg/dL, which were found to be significant at univariate logistic regression analysis, the presence of necrosis in the wound site increased the risk of adverse outcomes 20.125-fold and BUN exceeding 31 mg/dL increased the risk 9.454-fold, and these were identified as independent risk factors.

Table IV Logistic Regression Analysis for Adverse Outcomes

	Univariate OR (95% CI)	p	Multivariate OR (95% CI)	p
Fever (≥38,3°C)	8,156 (1,546 – 43,020)	0,013		
Necrosis in the wound	14,595 (1,791-118,914)	0,012	20,125 (2,293 – 176,611)	0,007
Enterobacteriaceae in the wound	5,701 (1,408 – 23,079)	0,015		
PEDIS grade 4	11,000 (1,899 – 63,705)	0,007		
BUN> 31 mg/dL	6,667 (1,640 – 27,107)	0,008	9,454 (2,072 – 43,132)	0,004

BUN: Blood Urea Nitrogen, PEDIS: Perfusion, Extent, Depth, Infection and Sensation.

Discussion

Patients with DFI are at an increased risk of major amputation or mortality with the presence of chronic ischemia threatening the lower extremities.[10] Previous studies have described various risk factors for major amputation of mortality in patients with DM. In the present study, fever, the presence of necrosis in the wound site, isolation of *Enterobacteriaceae* species in wound culture, PEDIS grade 4 and BUN > 31 mg/dL emerged as predictive factors for adverse outcome in patients with DFI. In the model constructed with these risk factors, BUN exceeding 31 mg/dL and the presence of necrosis in the wound site were identified as independent predictive factors for adverse outcome development.

Nephropathy is one of the microvascular complications of DM.[12] However, studies examining the relationship between renal function and major amputation have reported inconsistent results. While some research has described impaired renal function as a predictive factor for major amputation, other studies have found no association between kidney function, urea levels and amputation or major amputation in patients with DM.[5,12-14] Our own findings indicate that increased BUN in patients with DFI is associated with adverse outcomes. A BUN value exceeding 31 mg/dL predicted adverse outcomes with 72.7% sensitivity and 71.4% specificity. Adeleye et al. reported that kidney failure was an independent predictor or mortality in patients with DFU.[15] Diabetic nephropathy is associated with an increased risk of neuropathy and PAD.[16] Studies have reported that, high levels of BUN in severe infections other than DFI occur as a result of tissue damage and increased protein breakdown and renal urea reabsorption due to dehydration.[17,18] In addition, kidney failure can lead to mortality in patients with DFI by triggering such cardiovascular risk factors as oxidative stress and inflammation.[15] The BUN elevation in cases concluding with mortality and major amputation in the present study was associated with their involving more than one of the risk factors described above.

Varying degrees of necrosis may be seen due to peripheral circulation impairment deriving from micro- or macrovascular complications may be seen in patients with DFI. Previous studies have shown that the presence of necrosis in the wound is associated with an increased risk of major amputation.[15,19] Consistent with previous research, the presence of necrosis in the wound site

increased the risk of adverse outcome development 20 times in the present study.[15,19] A recent study from Nigeria reported similar findings, to the effect that mortality rates were eight times higher in patients with DFU with gangrene than in those without gangrene.[15] Shatnawi et al. also reported that gangrene increased the risk of major amputation 4.2 times, while kidney failure raised it 3.5 times.[19] Impaired arterial perfusion can also represent a cause of amputation in diabetics. The presence of necrosis in the wound, together with the presence of PAD and atherosclerosis in other vessels can also cause an increased risk of cardiac death.

Body temperature elevation, one of the criteria for SIRS, also emerged as a potential risk factor for the development of adverse outcomes in this study. This finding is consistent with other studies of major amputation.[5, 13-14]

Various results have been reported in previous studies examining the relationship between the microorganism agent in diabetic foot and the development of major amputation or mortality. The limited available data concerning pathogens associated with mortality suggest that polymicrobial infection with *Pseudomonas spp.* and the monomicrobial isolation of other Gram-negative microorganisms may be associated with poorer outcomes in soft tissue infections in hospitalized diabetic patients.[20] According to a report by Cardosa et al. *Acinetobacter spp.* and Klebsiella spp. isolated in the wound cultures of patients with DFI are associated with a greater risk of major amputation.[21] Fejfarova et al. reported that a statistically significantly greater presence of resistant *Staphylococcus spp.* in patients with DM with lower extremity amputation compared to non-amputated patients.[22] In contrast to previous studies, no significant effect of *Staphylococcus aureus* isolation of adverse outcome development was observed in the present study. This may be attributable to the limited number of patients with S. aureus as a causative agent and the fact that these were all included in the group without adverse outcome development. *Enterobacteriaceae spp.* (n=37, 36.3%) were most frequently isolated in our patients' wound culture specimens. *Enterobacteriaceae spp.* were more frequently detected in patients with adverse outcomes, even though this did not represent an independent risk factor. The fimbriae and capsule with colonizing ability, toxin production and tissue invasion all play a role among the factors determining the virulence of *Enterobacteriaceae spp.*[23]

The PEDIS classification, widely employed in clinical practice, exhibited a significant effect on the development of adverse outcomes in this study. PEDIS grade 4 severity was detectedsignificantly more frequently in patients developing adverse outcomes. Similarly to our findings, Chaudhary et al. also reported that PEDIS grades in patients with DFI had a significant impact on major amputation and mortality rates.[24] Since PEDIS grade 4 severity indicates the presence of diffuse cellulitis or deep infection SIRS, a relationship between higher PEDIS grades and major amputation or mortality is an expected finding.

Limitations

There are a number of limitations to this study. The first is that all the patients were enrolled from a single center. Various risk factors for major amputation and mortality have been reported in the literature, such as age, male gender, smoking, type 2 DM, high BMI, hypertension, dyslipidemia, weak glycemic control, peripheral neuropathy, and PAD. The patient profiles, ethnic origins and cultural characteristics in these studies may have given rise to this variation. The number of patients, also a limitation of the present study, might therefore be usefully increased in future multi-center research. Another limitation is the use of swab cultures in this study, since we were unable to obtain intraoperative cultures. However, a particular strength of this study lies in its prospective nature.

Conclusion

Among the factors analyzed in this study, BUN exceeding 31 mg/dL and the presence of necrosis in the wound emerged as independent risk factors for adverse events in patients with DFI. Understanding the risk factors for adverse outcomes in patients with DFI, an entity associated with high morbidity and mortality, and developing strategies to control these will help ensure that patients with DFI receive appropriate medical care and prevent major amputation or mortality.

Recommendation

Large sample size study to be performed to find the actual scenario of the community of Bangladesh.

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Contribution of authors

SSA-Conception, design, acquisition of data, data analysis, manuscript writing & final approval.

AD-Design, critical revision & final approval.

MSK-Data analysis, interpretation of data, critical revision & final approval.

Disclosure

All the authors declared no competing interest.

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