Diabetic foot predictors for amputation

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Abstract
Background: Diabetic foot ulcers are the main cause of non-traumatic lower extremity amputation. The objective of this study was to evaluate the risk factors for major amputation in diabetic foot patients.
Materials & Methods: This open, single Centre, prospective and observational study conducted in Triveni Hospital, Nanded for a period from Nov. 2018 to dec. 2020 The patients admitted in Triveni Hospital with diabetic foot problems were selected for the study with proper consent of patients and his/her attendants.
Results: In this study Fifty patients were admitted to the diabetic wound in Triveni Hospital for foot ulcers between nov.2018 to dec 2020 Among the 50 patients, Male: Female ratio was 4.6:1. out of which 41 (82.0%) were male, 18 (36.0%) belonged to the 50 to 59 years age group, 15 (30.0%) were having complaints for Ulcer, 15 (30.0%) were smoker. The Amputation rate was 42.0%.
Conclusion: In the results of analysis, poor glycemic control, peripheral arterial disease, peripheral neuropathy and higher Wanger grade are significant risk factors for amputation in diabetic foot infection.

Keywords: Diabetic foot, Wagner grading, HbA1c, TLC, Albumin Introduction

INTRODUCTION

According to the World Health Organisation and to the International Working group on the Diabetic foot, diabetic foot is defined as infection, ulceration or destruction of tissues of the foot associated with neuropathy and/or peripheral artery disease in the lower extremity of the people with diabetes (1).

The prevalence of diabetes is rapidly rising all over the globe at an alarming rate (2). As per WHO, 422 million adults aged over 18 years were living with diabetes in 2014 (3). As per International Diabetes Federation (IDF) Diabetes Atlas, 424.9 million people worldwide, or 8.8% of adults 20-79 years, are estimated ton have diabetes by the end of 2017 and 629 million people between 20-79 years will have diabetes by the end of 2045 (4).

As per IDF Diabetes Atlas, India is home to the second largest number of adults living with diabetes worldwide after China with 72.9 million people between 20-79 years by 2017 and if the same trend continues India will become Diabetic capital of the world with 134.3 million people with diabetes by 2045 (4).

The reported prevalence of diabetic peripheral neuropathy ranges from 16% to as high as 66%. Amputation in diabetics is10-20 times more common as compared to those of non-diabetics. Every 30 seconds a lower limb or part of a lower limb is lost to amputation somewhere in the world as a consequence of diabetes (4). The aim of this study is to identify the predictive factors for major lower limb amputations among patients with diabetes mellitus who get admitted to our hospital for diabetic foot problems.

Objectives:

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The effects of Duration of Diabetes mellitus, low serum albumin levels and a positive bacterial culture on being predictors of patients undergoing major lower limb amputation.

Materials and Methods

This open, single Centre, prospective and observational study to be conducted in Triveni Hospital Hospital, Nanded for a period from Nov 2018 to Dec 2020 The patients admitted in Triveni Hospital with diabetic foot problems will be selected for the study with proper consent of patients and his/her attendants.

The inclusion criteria were patients who are diagnosed cases of diabetes for more than 10 years, above 30 years of age and of either gender. patients were excuded with the history of limb trauma. Formal written informed consent was obtained from all the patients. The study was approved by the institutional ethical committee.

Data of patients was collected in the form of presenting complaints, history of present condition, clinical history, general physical, systematic and local examination, relevant risk factor identification and laboratory evaluation. Data was collected in a per test pro forma which includes the details like: age, sex, occupation, subjective complaints(S), objective findings(O), assessment of clinical condition (A) and plan of management. The analysis of collected data will be made with appropriate statistical parameters.

Statistical Analysis:

Continuous data will be summarised as Mean + SD (standard deviation) while discrete (categorical) in number and percentage. Quantitative data will be analysed by, ,mean, SD, T TEST. Quantitative data will be analysed by percentage, Chi square test, fisher exact test.

Results:

A total 50 patients were included in this study, male : female ratio was 4.6:1. Among the 50 patients, out of which 41 (82.0%) were male, 18 (36.0%) belonged to the 50 to 59 years age group, 15 (30.0%) were having complaints for Ulcer, 15 (30.0%) were smoker. The Amputation rate was 42.0% (Table 1)

Table No. 1: Socio demographic frequency classification of the patients with Diabetic foot Amputation or without Diabetic foot Amputation.

Variables	Amputation				P
Age Group	Yes	No	Total	Value	
30-39	1(25.0%)	3(75.0%)	4(100.0%)		
40-49	3(25.0%)	9(75.0%)	12(100.0%)		
50-59	9(50.0%)	9(50.0%)	18(100.0%)		
60-69	5(50.0%)	5(50.0%)	10(100.0%)		
70-79	2(50.0%)	2(50.0%)	2(100.0%)	NS	0.73

>=80	1(50.0%)	1(50.0%)	2(100.0%)	
Gender				
Male	20(48.78%)	21(51.22%)	41(100.0%)	
Female	1(11.11%)	8(88.89%)	9(100.0%)	0.038 Significant
Presenting complaints				
Abscess	2(25.0%)	6(75.0%)	8(100.0%)	
Cellulities	3(30.0%)	7(70.0%)	10(100.0%)	
Gangrene	10(83.33%)	2(16.67%)	12(100.0%)	
Ulcer	2(13.33%)	13(86.67%)	15(100.0%)	
Necrotizing fasciitis	2(66.67%)	1(33.33%)	3(100.0%)	HS 0.005
Charcot's foot	1(100.0%)	0 (00.0%)	1(100.0%)	
Osteomyelities	1(100.0%)	0 (00.0%)	1(100.0%)	
Smoking				
Yes	7(46.67%)	8(53.33%)	15(100.0%)	
No	14(40.0%)	21(60.0%)	35(100.0%)	NS 0.66
Total	21 (42.0%)	29 (58.0%)	50 (100.0%)	

Table No. 2: Clinical Examination in the study subjects

Variables	Amputation		Total	P Value
	Yes	No		
PDA				
Present	4(44.44%)	5(55.56%)	9(100.0%)	
Absent	17(41.46%)	24(58.54%)	41(100.0%)	NS 0.87

Wagner grading				
Grade 0	0 (00.0%)	0 (00.0%)	0 (00.0%)	
Grade 1	0 (00.0%)	0 (00.0%)	0 (00.0%)	
Grade 2	0(00.0%)	12(100.0%)	12(100.0%)	
Grade 3	3(23.08%)	10(76.92%)	13(100.0%)	
Grade 4	14(70.0%)	6(30.0%)	20(100.0%)	0.0017 HS
Grade 5	4(80.0%)	1(20.0%)	5(100.0%)	
Total	21 (42.0%)	29 (58.0%)	50 (100.0%)	

In the above table no. 2 shows that the clinical examination about study subjects, among 50 patients, out of which 9 (18.0%) were suffering from Peripheral artery disease & 14 (66.7%) were having grade 4 patients as per Wagner grading

In the below table no. 3 shows that the laboratory parameters according to the Diabetic foot amputation, among the 50 patients, 43 (86.0%), 36 (72.0%), 46 (92.0%) & 17 (34.0%) were found abnormal in TLC count, Albumin, HbA1C & Bacteria culture respectively.

Table No. 3: Findings of the Laboratory parameters in with Diabetic foot Amputation & without Diabetic foot Amputation patients.

Variables	Amputation		Total	P Value
	Yes	No		
TLC				
Normal	1(14.29%)	6(85.71%)	7(100%)	
Above Normal	20(46.51%)	23(53.49%)	43(100%)	0.11 NS
Albumin				
Normal	1(7.14%)	13(92.86%)	14(100%)	
Below Normal	20(55.56%)	16(44.44%)	36(100%)	0.0018 HS
HbA1C				

Normal(4.6 - 6.4)	0(0%)	4(100%)	4(100%)	
Above Normal (>6.4)	21(45.65%)	25(54.35%)	46(100%)	
Bacteria culture				
Positive	20(60.61%)	13(39.39%)	33(100%)	
Negative	1(5.88%)	16(94.12%)	17(100%)	0.0002 HS

Table No. 4: Univariate analysis of Laboratory parameters with Diabetic foot Amputation & without Amputation patients.

Parameters	Amputation		P Value
	Yes	No	
TLC	22525.24$\pm$8195.28	18091.03$\pm$7782.46	0.058 NS
HbA1C	8.47$\pm$1.41	7.43$\pm$1.5	0.0165 S
Albumin	2.24$\pm$0.58	3.62$\pm$0.97	0.123 NS

In the above table no. 4 shows that amongst various laboratory investigations only HbA1C were statistically significant.

Discussion:

Diabetic mellitus is a major cause of non-traumatic lower limb amputation. Various factors are responsible for amputations in patients of diabetic foot. This study was done in 50 patients who were admitted in Triveni hospital,nanded with different presentations of diabetic foot. They were followed during stay in the hospital.

In this study, majority of the patients were in 5th & 6th decades of life, 56.0% number of patients of age group between 50 - 59 years were 18 (36.0%) patients & between 60 - 69 years were 10 (20.0%) which is comparable with previous study of Imad R Musa et.al. (5) in which the maximum number of patients were of age group between 50 - 59 years. Zameer Aziz et. al. (6) in a study of

100 patients with diabetic foot infection found majority to be amongst 5th and 6th decades of life was 59.0%.

In this study gender classification, males were 82.0% & females were 18.0%, which is comparable with the previous study by Yufeng Jiang et. al. (7) which reveals 65.0% were males & 30.04% were females and also with the study by S Morbach et.al. (8) In which 58.7% of the patients were male, suggesting male preponderance.

In our study total number of patients presenting with ulceration were 15 (30.0%) out of which 13.33% underwent amputation. In the study done by Aziz Nather et.al. (6) presentation of ulcer were 27.7%. Followed by the study total number of patients presenting with gangrene were 24.0% out of which 83.33% underwent amputation. The rates of amputation was maximum among the patients presenting with features of gangrene. This was similar to the findings by Nawaf J. Shatnawi et. al. (9) which had 31.0% patents with gangrene and also in the study by Aziz Nather et. al. (6) where gangrene was found in 31.7%.

In this study total of 15 (30.0%) had history of smoking out of which 46.67% underwent amputation. There were 70.0% patient without history of smoking out of which 40.0% underwent lower limb amputation.

Also, the relationship of smoking with lower limb amputation was found to be not a statistically significant, similar to the finding by Aziz Nather et. al. (6) where smoking was not found to be predictive factor for lower limb amputation.

Total of 9 (18.0%) patients were found to be having suffering from peripheral arterial disease as compared to 41 (82%) of those without having features of PAD. Among all of having features of PAD, 4 (44.44%) underwent amputation as compared to 17(41.46%) who underwent amputation without having features of amputation. This was not comparable with the previous study by Andrej Brechow et al. (10)

Out of 50 patients, none of patients were grade 0 and 1, 12 (24%) were of grade 2, 13 (26%) were

of grade 3, 20 (40%) were of grade 4 and 5 (10%) were of grade 5. Majority of the patients 33 (66%) were of grade 3 and grade 4, this is in comparison with findings by Tjokorda Dde Dalem Pemayun et al. (11) where majority of patients, 75.5% were in grade 3 and grade 4.

In my study 14 (28%) patients had normal range of serum albumin out of which 1 (7.1%) underwent amputation, 36(72%) patients had below normal level of serum albumin out of which 20 (55.56%) underwent amputation. This is in concordance with the study of Nazri Mohd Yusof et al.

(12) and H.B Leung et al. (13) who concluded low serum albumin to be an independent factor responsible for amputation.

Culture positivity was found in 33 (66%) of samples out of which 20 (60.61%) underwent amputation. Culture negative samples were 17 (34%) out of which 1 (5.88%) underwent amputation. This is in comparison with the previous study of Zameer Aziz et al. (6) who proposed bacterial culture positivity to be responsible factor for lower extremity amputation.

In my study 7 (14%) patients had normal range of TLC out of which 1 (14.29%) underwent amputation and 43 (86%) patients had raised TLC out fo which 20 (26.51%) underwent lower extremity amputation. This above finding was consistent with the findings of N. Saltoglu et al. (14)

In my study 4 (8%) patients had normal range of HbA1C and none of them underwent lower limb amputation and 46 (92%) had raised level of HbA1C

out of which 21 (45.65%) patients underwent lower line amputation. This is in concordance with the previous study Wenhui Zhao et al. (15)

Conclusion:

In the results of analysis, poor glycemic control, peripheral arterial disease, peripheral neuropathy and higher Wanger grade are significant risk factors for amputation in diabetic foot infection. Strict control diabetes, which is the primary disease, is first of all required for the risk reduction.

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