Original Article

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Assessment of predictors of diabetic foot ulcers in a tertiary care hospital of Maharashtra, India: A cross-sectional comparative study

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Abstract:

BACKGROUND: The chances of nonhealing foot ulcer among the diabetic is 10-20 times more than people without diabetes. Foot ulcer among diabetes population affects more than 40-60 million globally. There is a dearth of quality data on the factor among the diabetes patients, which hastens the progression of diabetic foot. The study aims to assess the risk factors associated with foot ulcer among the diabetics.

MATERIALS AND METHODS: The study was a cross-sectional comparative study in tertiary care hospital in Maharashtra, India. The study population included 200 diabetic foot ulcer patients and 200 of their age and gender matched comparator were patients with diabetes without foot ulcers. The sampling method was stratified random sampling.

RESULTS: The mean age of both the groups of patients was around 54 years. Alcohol consumption, physical activity outside home, low foot care practices, irregularity of diabetic medication, and family history of diabetes among mothers were found to be factors associated with diabetes foot ulcer.

CONCLUSION: There is a need to stratify the diabetes patients in regular care as per risk categories depending on the presence of above risk factors. This will not only prioritization of diabetes care in terms of future risk but also reduce the progression of complications like diabetes foot and resulting amputation through an active preventive intervention.

Keywords:

Diabetic foot, foot ulcer, India.

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Introduction

The number of people living with diabetes all over the world is more than 537 million, which is expected to rise to 640 million by the year 2030.^[1] In India, the prevalence of diabetes ranges from 14%-20%, with more than 60 million people living with diabetes.^[2] The prevalence varies greatly depending on their area, rural or urban. The complications in diabetes, which are mostly insidious in onset, ranges from nephropathy, neuropathy, and retinopathy. The diabetic

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foot ulcer (DFU) is a result of peripheral neuropathy. The chance of amputation among the patients with DFU is 10-20 times higher as compared to people without diabetes.^[3] There is one preventable lower limb amputation occurring among the DFU patients every 30 seconds all over the world. There have been several studies done over the years showing the risk factors for development of DFU. The risk factors include elderly age more than 50 years, longer duration of diabetes, history of smoking, male gender, rural area of residence, insulin use, and early onset of other microvascular complication such

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as diabetic neuropathy and nephropathy etc.^[4–7] Most of the studies have assessed the diabetic risk through application of validated scales like INLOW'S 60-s diabetic foot screening tool.^[8] Most of the researches focus on immediate inherent risk factors like peripheral arterial disease or loss of protective sensation. In spite of all the research done, there is a dearth of data on socioenvironmental risk factors associated with foot ulcer among diabetic patients in developing economies including India. The study aims to assess the risk factors associated with DFU patients.

Materials and Methods

Study design and setting

This was a cross-sectional comparative study. Study setting: A multidisciplinary tertiary care hospital in a Metropolitan city in India.

Study participant and sampling

The study population included patients coming to the hospital with a diagnosis of diabetes type II with foot ulcer and their comparator group of diabetes without foot ulcer (DWFU). The sample size of DFU group was calculated to be 196 (anticipated proportion of foot ulcer among the diabetics as 15% and absolute precision of 5%). Systematic random sampling was applied in selecting every even number of DFU patients coming to the diabetes OPD from the day of starting of data collection till 200 of DFU group was selected. An equal number (N = 200) of comparator group was selected among DWFU patients, after group matching for age and gender. All the adult diabetic type II patients presenting with ulcer in one or both of their lower limbs were included as DFU group and without foot ulcer as DWFU group. All patients who were severely ill or having diabetes type I were excluded from the study.

Data collection tool and technique

The data collection was done using a semi-structured prevalidated questionnaire. The information obtained were related to demographic information, disease-related information, treatment history, addiction history, and foot care practices etc.

Ethical consideration

The ethical clearance was approved by the Institutional Ethics Committee of Grant Government Medical college, Mumbai, India. SPSS version 16 was used to enter, code, and analyse the data. The qualitative data were presented as frequency and percentage. Chi-squared test was applied for finding the association among the qualitative variables. Multivariate logistic regression was applied to assess the factors contributing to DFU. Among all the patients participated in the study (N = 400), 200 were DFUs and rest 200 were DWFUs. Both the group of patients were comparable in terms of gender distribution, mean age, area of residence, marital status, living arrangement, housing condition, and socioeconomic status (P value >.5 for each variable). However, both the groups are significantly different in terms of types of family, housing condition, and the types of toilets (P value. 009 and <.001, respectively) [Table 1].

The pattern of personal habit revealed that there was no difference of chewing tobacco consumption (*P* value. 7) and smoking (*P* value. 3). The consumption of alcohol was significantly higher among the DFU patients (54% of current or ex-alcoholics vs. 26%) as compared to DWFU patients (*P* value <.05).

The activity profile among both the groups of the patients revealed that the DFU group had significantly higher mean hours of active activity like physical exercise, household work, work outside home, or commute to work as compared to the DWFU group (6.9 hrs vs.

Table 1: Demographic Characteristics of all the diabetes patients

	DFU	DWFU	Р
Gender			
Male	175 (87.9%)	170 (85.8%)	0.552
Female	25 (12.1%)	230 (14.2%)	
Mean age	55.34+1.3	53.08+1.4	>0.05
Residential area			
Rural	29 (15%)	17 (10%)	>0.05
Urban	171 (85%)	183 (90%)	
Marital status			
Not married	25 (12%)	12 (6%)	0.01
Married living without spouse	3 (2%)	0	
Widowed or separated	15 (8%)	29 (14%)	
Married	157 (78%)	159 (80%)	
Socioeconomic Class			
Class 2	24 (12.0%)	16 (8%)	0.11
Class 3	100 (50.0%)	108 (54%)	
Class 4	72 (36.0%)	76 (38%)	
Class 5	4 (2.0%)	0	
Living arrangement of patients of diabetes Mellitus			
Alone	7 (4%)	6 (4%)	>0.05
With Family	193 (96%)	194 (96%)	
Types of Family			
Nuclear	135 (67.5%)	104 (52%)	<0.05
Joint Family	64 (32%)	84 (42%)	
Three generation	1 (0.5%)	12 (3%)	
Type of toilet			
Open air defecation	20 (10%)	24 (12%)	<0.001
Public toilet	68 (34%)	104 (52%)	
Private toilet	112 (56%)	72 (36%)	

	DFU (%) (<i>n</i> =200)	DWFU (%) (<i>n</i> =200)	Odd's ratio	Р
Type of treatment				
Insulin	107 (54%)	56 (28%)	1.9-4.5	<0.0001
Metformin	85 (42%)	136 (68%)	0.2-0.5	<0.0001
Sulfonylurea	36 (18%)	44 (22%)	0.4-1.2	0.3
Others	4 (2%)	12 (6%)	0.1-1	0.04
Taking treatment				
Irregularly	97 (48.5%)	40 (20.4%)	2.2-5.3	<0.0001 (VHS)
Regularly	103 (51.5%)	156 (79.6%)		
Cause of change of medicine				
Not applicable	44 (22%)	88 (44%)		<0.001 (VHS)
Changed himself	37 (18%)	23 (11.9%)		
Changed after advice of doctor	119 (60%)	89 (44.1%)		
Change of dose of medicine (number of times)				
DFU	200	1	0-2	<0.001
DWFU	200	2	1-3	

Table 3: Foot care practices among all the diabetes patients (*n*=400)

	DFU	DWFU	Р
Do you inspect Foot			
No	185 (92%)	192 (96%)	0.09 (NS)
Yes	15 (8%)	8 (4%)	
Do you walk barefoot			
No	12 (6%)	8 (4%)	<0.01 (VHS)
Bare foot inside house	80 (40%)	139 (69.5%)	
Barefoot inside & outside house	108 (54%)	53 (26.5%)	
Do you use footwear			
No	8 (4.1%)	0 (0%)	0.02 (S)
Chappal	144 (73.5%)	157 (78.5%)	
Shoe	44 (22.4%)	43 (22.5%)	
Do you use socks			
No	177 (88%)	172 (86%)	0.4 (NS)
Nylon	13 (6%)	8 (4%)	
Cotton	12 (6%)	20 (10%)	
Do you wash foot daily			
No	23 (11.5%)	4 (2%)	<0.05 (HS)
Yes	177 (88.5%)	196 (98%)	
How do you take care of callus			
Self-care	143 (71.5%)	85 (41.5%)	<0.001 (VHS)
Visits physician regularly	40 (20%)	11 (5.5%)	
Not applicable	17 (8.5%)	106 (53%)	

6.08 hrs; *P* value. 03). The sleep hours did not differ significantly among them (*P* value. 9)

The history of having diabetic mother was significantly higher among DFUs group as compared to DWFU group (68% vs. 53%, *P* value. 03). There was no significant difference of history of diabetes among any other relatives (first/second or third-degree relatives) among both the groups of patients.

Disease progression and treatment

The median duration of disease among the DFU group was 10 years as compared to 5 years among DWFU group (*P* value <.001). The recent change of dose or the

pattern of medication was significantly higher among the DWFU group (*P* value <.001).

Majority of the patients from both the groups were taking treatment for diabetes and had similar nontreatment rates of around 4%. The use of insulin was significantly higher among the DFU group, whereas use of metformin was significantly higher among the DWFU group (each *P* value <.01). The irregularity of the treatment was significantly higher among the DFU group.

Significantly a higher number of the patients among the DFU group reported recent change in dose or pattern

of medicine consumption as compared to the DWFU group (78% vs. 56%, *P* value <.01) [Table 2].

Foot care pattern among the patients revealed, majority of the patients, that is, more than 90% of them in both the groups had no habit of inspecting foot after coming back to home any times during the day. Bare foot walking inside the house was significantly higher among DWFU group, whereas bare foot walking outside the home was significantly higher among the DFU group (*P* value. 02). Foot washing apart from bathing was significantly more common among the DWFU group (*P* value <.05) [Table 3].

Ten percent of the DFU group and 52% of the DWFU group did not develop callus anytime in their life after diagnosis of diabetes. Among those who developed calluses, a significantly higher number of patients among the DWFU group were self-treating the calluses (*P* value. 04).

Pattern of laboratory diagnosis among the patients revealed regular blood sugar estimation was significantly more common among the DWFU group as compared to DFU group (66% vs. 90%) (*P* value <.01).

A multivariate analysis showed alcohol abstinence, daily foot washing, and inspecting the foot after coming back at home and taking diabetes treatment regularly has a significant protective effect in development of foot ulcer among the diabetic patients. A history of family history of diabetes among the mothers of the patients increases the chances of foot ulcer by 3 to 26 times [Table 4].

Discussion

This study included 400 diabetic patients with or without foot ulcer. In our study, most of the participants were males (86%) and other 14% were females. The mean age of our participants was 55.34 years. Dr Jayalakshmi *et al.*^[9] did a study to assess the quality of life of DFU patients and concluded, of 118 DFU patients, 81.4%

Table 4: Multivariate Analysis assessing factors associated with diabetic foot ulcer

	Adjusted odds ratio	95% Cl	Р
Current Alcoholic	(Reference)		
Non alcoholic	0.21	0.079-0.55	0.004
Ex alcoholics	0.477	0.24-0.936	0.002
No history of diabetes in mother	(Reference)		
History of diabetic mother	10.31	3.9-26 0.9	< 0.0010
Never washes foot	1 (reference)		
Daily foot washing	0.91	0.875-0.954	0.01
Never checks foot	(reference)		
Inspects foot daily	0.17	0.037-0.74	0.019
Taking treatment irregularly	(Reference)		
Taking treatment regularly	0.409	0.227-0.73	0.003

were male and 18.6% were female. Majority of the participants were in 41-60 years of age group (64.4%). Dr Muduli *et al.*^[10] in 2012 assessed the complications and its prevalent management among DFU patients in India. Mean age of the patients was 54.7 years. Dr Akila *et al.*^[4] in 2020 assessed the diabetic foot risk among 196 diabetes patients. Fifty seven percent of the patients were in the age group 40-60 years. Fifty seven percent were females. 57.1% of the patients had diabetes since more than 10 years of age and concluded the diabetic foot risk is the highest among 20-40 years aged diagnosed patients (about 90%). The DFU was more commonly found among the males. The occurrence of foot ulcer increases significantly after 10 years of disease diagnosis.

Dr. Jalilian et al.^[11] in 2020 did a systematic review on the factors responsible for severity of DFU and concluded high body mass index, smoking, lack of diabetis control, type of diabetic medication, and old age were factors significantly associated with foot ulcer. Dr. Saleem *et al.*^[12] did a study to assess the risk factors associated with DFU patients and concluded age more than 50 years, residence in rural area, and diabetes more than 10 years were significantly associated with amputation among the DFU patients (P value <.001). Dr. Saurabh et al.^[13] in 2014 found old age and illiteracy were found to be significantly associated with poor diabetes foot care practice. In this present study, there was a difference of tobacco chewing or smoking among DFUs and DWFUs. But alcohol consumption was significantly more among the DFUs (P value <.05). Median duration of disease since diagnosis was also significantly higher among DFUs (P value. 001). Foot care practices are better among DWFUs. Foot care practices have been proven to be very effective in preventing the occurrence of ulcer. Among all the addictions and habits, alcohol consumption was found to be the worst type of addiction contributing to foot ulcer. This might be due to high risk unsteady gait and higher chances of injury.

Studies have shown a significant difference existing among the DFU patients.^[11] Our study results showed a significant higher insulin use as therapy among the DFUs. Studies found in the study among DFUs majority of the participants were unaware regarding the foot care practice.^[4,13] This study also confirmed better foot care practices among DWFUs.

Our study is a cross-sectional comparative study with age and gender-matched controls among the diabetics with or without foot ulcer and found that nonconsumption of alcohol, washing of foot, checking of foot, and taking regular diabetic treatment have a statistically significant protective effect among the diabetic patients. The study adds to the knowledge of DFU in developing countries, where the government health program for noncommunicable diseases still lack the emphasis on life-saving intervention in the form of health education in the community.

Limitations and recommendations

The limitation of the study lies in its unmatched confounders, which could be minimized in other study designs such as a cohort study or case-control study. There is a need to stratify diabetic patients during follow-up visits on the basis of risk factors of alcohol consumption, foot care practices, adherence to regular medication for diabetes, and maternal history of diabetes, as they have higher chances of development of foot ulcer. Health education regarding foot care among diabetic patients should be introduced by the peripheral healthcare providers during household visits.

Conclusion

Although there has been much research on the etiology of DFU, the use of predictive factors and risk factors in risk stratification of the diabetes patients in the outpatient basis in primary healthcare level in developing countries is still rare. There is a need to incorporate identified risk factors associated with DFU as red flag signs to assess the diabetes patients. This can help in segregating the patients as per risk categories, and personalized preventive measures can be applied to slow the progress of the disease.

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Conflicts of interest

There are no conflicts of interest.

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