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Prevalence And Risk Factors For Foot Ulcer In Patients Of Type 2 Diabetes Mellitus: A Hospital-Based Cross-Sectional Study

Author

Abstract:

Background: The prevalence of foot ulcers in T2DM patients varies geographically and across different populations. Several studies have reported prevalence rates ranging from 4% to 10% globally, with higher rates in older adults and those with longer diabetes duration. The implications of foot ulcers are physical discomfort, hospitalization, prolonged treatment, and increased economic burden on both patients and healthcare systems. **Objective:** The aim of this study was to study the prevalence and risk factors for foot ulcers in subjects with Type 2 Diabetes Mellitus.

Methods: A prospective cross-sectional study was conducted among T2DM patients attending diabetes clinics at the Diabetes Specialty Clinic of the Department of Medicine and & Surgical wards at a tertiary care teaching hospital in Navi Mumbai. The study was conducted over a period of 2 years (March 2021 to December 2023). Subjects aged 35 to 75 years with a confirmed diagnosis of Type 2 Diabetes Mellitus based on medical records or clinical assessments.

Results: The results of the study indicate that the prevalence of DFU was 11.54% and the independent risk factors of DFU development were a history of previous DFU or amputation, insulin usage, and foot deformity. This finding provides support for a multifactorial etiology of DFU.

Conclusion: In order to reduce the prevalence of DFU, all diabetes patients need to undergo a foot examination every year to identify risk factors for foot ulceration. It is also needed to have a cost-effective way of annual screening of diabetic patients.

Keywords: Diabetic foot ulcer, Prevalence, risk factors

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I. Introduction:

Type 2 Diabetes Mellitus (T2DM) is a chronic metabolic disorder characterized by elevated blood sugar levels resulting from insulin resistance and inadequate insulin production. One of the significant complications that arise from poorly managed T2DM is the development of foot ulcers. Foot ulcers are open sores or wounds that commonly occur on the feet of individuals with diabetes and can lead to severe complications, including infection and lower limb amputation. This study aims to delve into the prevalence of foot ulcers among patients with T2DM and to identify the associated risk factors that contribute to their occurrence.(1,2)

Foot ulcers in T2DM patients are a critical concern due to their substantial impact on quality of life, healthcare resources, and mortality rates. These ulcers often stem from a combination of factors, including peripheral neuropathy, impaired blood circulation, and compromised wound healing ability. The sensory neuropathy in diabetes can lead to reduced pain perception, making patients less aware of the presence of ulcers until they have progressed to an advanced stage. Additionally, poor blood circulation hampers the delivery of essential nutrients and immune cells to the affected area, further impeding the healing process. (1,3)

The prevalence of foot ulcers in T2DM patients varies geographically and across different populations. Several studies have reported prevalence rates ranging from 4% to 10% globally, with higher rates in older adults and those with longer diabetes duration. The implications of foot ulcers extend beyond the physical discomfort they cause; they often lead to hospitalizations, prolonged treatments, and increased economic burden on both patients and healthcare systems.(4)

Understanding the risk factors that contribute to foot ulcer development in T2DM patients is paramount for preventing these complications and improving patient outcomes. Common risk factors include poor glycemic control, duration of diabetes, peripheral neuropathy, vascular disease, smoking, improper foot care, and inappropriate footwear. Identifying these risk factors can aid healthcare practitioners in implementing targeted interventions and personalized care plans to mitigate the risk of foot ulcers.(5)

The aim of this study was to study the prevalence and risk factors for foot ulcers in patients of Type 2 Diabetes Mellitus. In light of the significant impact that foot ulcers have on the lives of T2DM patients and the

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healthcare system, this study seeks to comprehensively investigate the prevalence and risk factors associated with foot ulcers in this population. By enhancing our understanding of these factors, we can pave the way for better prevention strategies, early detection, and personalized interventions that address the unique needs of individuals with T2DM, ultimately improving their overall quality of life and well-being.

II. Methods And Materials:

Study Design: A prospective cross-sectional study design.

Study population: This study was conducted among T2DM patients attending diabetes clinics at the Diabetes Specialty Clinic of the Department of Medicine and & Surgical wards at a tertiary care teaching hospital in Navi Mumbai.

Study Duration: The study was conducted over a period of 2 years (March 2021 to December 2023).

Inclusion Criteria: Subjects aged 35 to 75 years with a confirmed diagnosis of Type 2 Diabetes Mellitus based on medical records or clinical assessments.

Exclusion Criteria:

- Subjects with a diagnosis of Type 1 Diabetes Mellitus, Genetic causes of Diabetes mellitus, and steroid-induced Diabetes mellitus
- Subjects with a documented history of foot ulcers or lower limb amputations, unrelated to diabetes, were excluded.
- Subjects with severe cognitive impairment or inability to provide informed consent or answer interview questions accurately were excluded.
- Pregnant individuals were excluded due to potential confounding factors related to pregnancy-induced changes.
- Subjects with terminal illnesses or conditions that significantly limit their life expectancy were excluded.
- Subjects with severe, uncontrolled comorbidities were excluded.
- Subjects who decline to participate or withdraw consent during the course of the study were not included in the analysis.

Data Collection: Data was collected through medical record reviews, clinical examinations, and patient interviews. The information on diabetes duration, HTN, Dyslipidemia, BMI, glycemic control, medication history, and comorbidities was collected from medical records and Clinical examinations. The Detailed sociodemographic, behavioral history, and history of foot disease were collected and the foot deformity assessment was done. Patient interviews were conducted to capture lifestyle factors, self-care practices, and footwear habits. Laboratory investigations like Fasting blood sugar, post-prandial blood sugar, HbA1c, and Lipid profile were done.

Sample Size: The sample size was calculated by considering a 95% confidence level, a prevalence rate of 8%, and a 5% margin of error. The sample size was calculated using the formula z^2pq/d^2 . The minimum required sample size was 113. Adding a 15% non-response rate, the required sample size was 130.

Statistical Analysis: Descriptive statistics was used to summarize the demographic and clinical characteristics of the study sample. The prevalence of foot ulcers was calculated. The independent sample t-test and chi-square test were used. Logistic regression analysis was performed to identify significant risk factors for foot ulcer development.

III. Results:

The study aims to determine the prevalence of foot ulcers among T2DM patients and highlight the significant risk factors associated with diabetic foot ulcers. For this purpose, a hospital-based prospective, cross-sectional study was conducted among 130 study subjects in order to study the prevalence and risk factors for diabetic foot ulcers among patients with Type 2 diabetes mellitus.

In the current study, out of 130 study subjects, the majority of the study subjects (36.1%) were in the age group of 56-65 years followed by 27.7% in the age group of 46-55 years, 20.8% in the age group of 35-45 years and 15.4% in the age group of 66-75 years. The mean age of the patients was 54.78 ± 10.32 years. The proportion of male subjects was higher (n=73,56.2%) as compared to the female subjects (n=57,43.8%). According to the BMI, 44 (33.8%) subjects had normal BMI, 77 (59.3%) subjects were overweight and 9 (6.9%) were obese. The mean BMI of study subjects was 25.76 ± 4.38 kg/m2. The majority of patients were from the lower middle class (44.7%) followed by upper middle class (17.7%), upper class (16.1%), upper lower (13.8%), and lower class

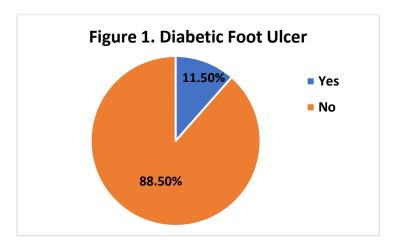
(7.7%). Out of 130 subjects, 24 (18.5%) subjects were educated up to the primary level while 27 (20.7%) and 39 (30.1%) subjects studied till SSC and HSC respectively, 34 (26.1%) subjects were graduates and 6 (4.6%) patients had no formal education.109 (83.9%) subjects were urban residents while 21 (16.1%) were rural residents. The majority of the subjects (51.6%) had diabetes for 5-10 years while 33 (25.4%) and 18 (13.8%) patients had diabetes for <5 years and 11-15 years respectively. 12 (9.2%) patients had diabetes for >15 years. The mean duration of diabetes was 8.26 ± 5.22 years. (Table 1)

Table 1. Distribution of	study subjects according t	to Sociodemographic ch	aracteristics
Variable		Frequency	Percentage
	35-45	27	20.80%
	46-55	36	27.70%
Age (years)	56-65	47	36.10%
	66-75	20	15.40%
	Mean ±SD	54.78	± 10.32
Gender	Male	73	56.15%
Gender	Female	57	43.85%
	Normal	44	33.80%
BMI	Overweight	77	59.30%
BMI	Obese	9	6.90%
	Mean ±SD	25.76	± 4.38
	Lower	10	7.70%
	Lower Middle	58	44.70%
Socio-economic Status	Upper Lower	18	13.80%
	Upper Middle	23	17.70%
	Upper	21	16.10%
	Primary	24	18.50%
	SSC	27	20.70%
Education	HSC	39	30.10%
	Graduation	34	26.10%
	Uneducated	6	4.60%
Residence	Urban	109	83.90%
Residence	Rural	21	16.10%
	<5 years	33	25.40%
	5-10 years	67	51.60%
Duration of Diabetes	11-15 years	18	13.80%
	>15 years	12	9.20%
	Mean ±SD	8.26	± 5.22

Of the 130 study subjects, 28 (21.5%) were smokers, 51 (39.2%) consumed alcohol regularly, 16 (12.3%) were tobacco chewers, 9 (6.9%) were both smokers and chewing tobacco, and 27 (20.8%) were smokers as well as consuming alcohol. The majority of the subjects (83.1%) were using oral hypoglycaemic agents while 18 (13.8%) subjects were using insulin and 4 (3.1%) patients had not treated their diabetes. A family history of diabetes was present among 55 (42.3%) subjects. The prevalence of diabetic foot ulcers (DFU) among study subjects was found to be 11.5%. (Table 2)(figure 1)

Table 2. Distribution of study subjects according to study parameters							
	Habits Frequency Percentage						
	Smoking	28	21.50%				
	Alcohol	51	39.20%				
Habits	Tobacco chewing	16	12.30%				
	Smoking + Tobacco chewing	9	6.90%				
	Smoking + Alcohol	27	20.80%				
	OHA	108	83.10%				
DM Therapy	Insulin	18	13.80%				
	Untreated	4	3.10%				
Family History of	Yes	55	42.3%				
Diabetes	No	75	57.7%				

DFU	Yes	15	11.50%	
DFU	No	115	88.50%	



No significant difference in the mean age, mean BMI and Mean duration of diabetes was observed among the study subjects with and without diabetic foot ulcer (p>.05) (Table 3)

Table 3. Comparison of study parameters among subjects with and without DFU						
		Diabetic Foot Ulcer				
Parameters	Yes		No		p Value	
	Mean	SD	Mean	SD		
Age	55.47	10.43	54.69	10.35	>0.05	
BMI	25.85	4.12	25.75	4.42	>0.05	
Duration of Diabetes	9.27	6.63	8.13	5.03	>0.05	

The association of various study parameters was tested with the diabetic foot ulcer using the chi-square test for association. The results indicated that the study parameters like Sex, Smoking, Alcohol, Tobacco chewing, Smoking + Tobacco chewing, Smoking + Alcohol, Diabetes Mellitus Therapy, Family History of Diabetes, Dyslipidemia, Knowledge of foot care practices, Pre-existing foot deformities, and H/o past foot ulcer found to be significantly associated with the Diabetic Foot Ulcer (p<.05) (Table 4)

Table 4. Association between study parameters and DFU status						
		Diabetic Foot Ulcer				p Value
Parameters		Yes		No		
		n	%	n	%	Value
Sex	Male	12	16.40%	61	83.60%	<0.05
Sex	Female	3	5.30%	54	94.70%	<0.03
C1-:	Yes	9	32.10%	19	67.90%	-0.05
Smoking	No	6	5.90%	96	94.10%	<0.05
A1 1 1	Yes	11	21.50%	40	78.50%	-0.05
Alcohol	No	4	5.10%	75	94.90%	<0.05
T. 1	Yes	8	50%	8	50%	<0.05
Tobacco chewing	No	7	6.10%	107	93.90%	
Constitute a Tabana abanda	Yes	5	55.50%	4	44.50%	<0.05
Smoking + Tobacco chewing	No	10	8.30%	111	91.70%	<0.05
G 11 . A1 1 1	Yes	9	33.30%	18	66.70%	-0.05
Smoking + Alcohol	No	6	5.80%	97	94.20%	<0.05
	OHA	7	6.50%	101	93.50%	
Diabetes Mellitus Therapy	Insulin	7	38.90%	11	61.10%	< 0.05
	Untreated	1	25%	3	75%	
Eil- Hi-t	Yes	10	18.20%	45	81.80%	<0.05
Family History of Diabetes	No	5	6.70%	70	93.30%	
Dyslipidemia	Yes	12	80.00%	77	66.96%	< 0.05

	No	3	20.00%	38	33.04%	
	Self-examination of foot					
	Yes	4	26.67%	84	73.04%	<0.05
	No	11	73.33%	31	26.96%	<0.03
			Type of footwear:	chappals, shoe		
Knowledge of foot care practices	Yes	6	40.00%	81	70.43%	<0.05
practices	No	9	60.00%	34	29.57%	
	Barefoot walking					
	Yes	10	66.67%	62	53.91%	<0.05
	No	5	33.33%	28	24.35%	
Due existing fact deformities	Yes	13	86.67%	35	30.43%	<0.05
Pre-existing foot deformities	No	2	13.33%	80	69.57%	
H/o past foot ulcer	Yes	14	93.33%	27	23.48%	<0.05
	No	1	6.67%	88	76.52%	<0.03

Logistic regression analysis was performed in order to identify the significant risk factors for foot ulcer development. The results indicated that dyslipidemia (OR = 1.974; 95% CI = 1.0525–7.4155; p<0.05), Self-examination of the foot (OR = 0.1342, 95% CI = 0.098-0.453, Type of footwear: chappals, shoe (OR = 0.2798, 95% CI = 0.092 – 0.847);p<0.05), Barefoot walking (OR = 11.43, 95% CI = 2.379 – 5.895, p<0.05); Pre-existing foot deformities (OR = 14.857, 95% CI = 3.1825 – 69.3585, p<0.05); history of past foot ulcer OR = 45.63, 95% Ci = 5.7342 - 36.090, p<0.05) were significant risk factors for diabetic foot ulcer.

Table 5. Logistic regression analysis for significant risk factors for foot ulcer development						
Parameters		OR	95% CI	p Value		
Dyslipidemia		1.9740	1.0525-7.4155	<.005		
Knowledge of foot care practices	Self-examination of foot	0.1342	0.0398- to 0.453	<.01		
	Type of footwear: chappals, shoe	0.2798	0.092 to 0.847	<.05		
	Barefoot walking	11.4300	2.379 to 5.895	<.05		
Pre-existing foot deformities		14.8570	3.1825 to 69.358	<.05		
History of past foot ulcer		45.6300	5.7342 to 36.09	<.05		

IV. Discussion:

The aim of this study was to determine the prevalence and the risk factors of Diabetic foot ulcer (DFU) at a tertiary care hospital in Navi Mumbai. In order to find the prevalence and risk factors of DFU, a prospective cross-sectional study was conducted among 130 study subjects. Baseline characteristics, demographic variables, and the risk factors of DFU were compared among the patients having and not having DFU.

Based on the results of the multivariate analysis, the independent significant risk factors of DFU development were smoking, alcohol, tobacco chewing, and a combination of smoking, tobacco chewing, and alcohol, Family history of diabetes, Dyslipidemia, knowledge about foot care practices, pre-existing foot deformities and history of previous DFU or amputation.

The prevalence of diabetic foot ulcer was higher among males (16.4%) as compared to females (5.3%). Smokers had a higher prevalence of DFU (32.1%) as compared to non-smokers. Few studies reported outcomes in patients without any active or past foot ulcer (6). The prevalence of DFU in the present study was about 11.54% among diabetic patients, which is comparable to that of other studies (4).

The prospective study conducted by Leese et al. study showed 4.7% DFU prevalence in a study conducted among diabetic study participants.(7) Abbott et al. reported a 2.2% prevalence of DFU.(8) Crawford et al.'s study reported 1.93% new foot ulcer during an average 1-year follow-up, (9) while Ramsey et al.'s study reported DFU prevalence to be 5.8% over 3 years of observation (10). A prospective study by Hurley et al., involving 18 months' follow-up of 563 patients, reported the same prevalence, but the patients included in this study had a lesser duration of diabetes (11). Jiang et al.'s study, a cohort in China with 678 patients, reported DFU prevalence to be 8.1% in a study conducted over a period of 1 year, which was closer to that in our study and that of western countries according to their own report. (12)

The extensive literature review suggests that the risk factors associated with the DFU vary from one study to another, but many factors are common among these studies. Like the results of the other studies, the variables like smoking, alcohol, tobacco chewing, and combination of smoking, tobacco chewing and alcohol, Family history of diabetes, Dyslipidemia, knowledge about foot care practices, pre-existing foot deformities and history of previous DFU or amputation were the most associated risk factors of DFU in our study (4,5,9,11).

Among these factors, the most associated factors were knowledge about foot care practices, pre-existing foot deformities, and history of previous DFU or amputation. This is reasonable because patients with poor knowledge about foot care practices and a history of ulceration may be predisposed to different micro- and macrovascular dysfunctions or peripheral neuropathy.

The results of this study also confirm that the diabetic patients treated with insulin were more susceptible to diabetic foot ulcer than those treated with oral glycemic agents or lifestyle modification alone. One of the reasons behind this might be that when patients are advised to start insulin, they may already have diabetes for a very long time with greater associated complications. This finding of the current study is compatible with a few studies (5,7,11). In a systematic review by Monteiro-Soares M et al, which included 16 studies, 7 studies out of 16 reported a statistically significant association between DFU and insulin therapy (6). It is needed to conduct further studies in order to elaborate on the relationship between DFU and insulin therapy by eliminating the possible confounding factors and providing more accurate details.

The prevalence of DFU among males was observed to be significantly higher as compared to females. This is one of the important findings of this study, which was consistent with other studies (11). This possible reason behind this increased prevalence among males could be explained by the fact that men are more involved in outdoor activities as compared to females, and this may lead to higher foot exposure to different risks and more plantar pressure on their feet. Few more studies observed that the males have a higher association with DFU when analyzed univariately, but when multivariate analysis was conducted, it was not significant (6,10,11).

Pre-existing Foot deformities were another significant risk factor of DFU observed in this study, which is comparable with some other studies (5,9,12). In a conducted by Al-Rubeaan K. et al, it was significant only when the univariate analysis was done. In our study, 13 patients out of 15 DFU patients had pre-existing foot deformities like hallux valgus, hammer toe, prominent metatarsal head, bunion, and just one Charcot joint. (13)

Recent studies reported that among only 30% of the patients with DM-2, foot inspection has been reported as preventive care for ulceration.(14) Similar results have been reported in another this study, which demonstrates that the limited involvement of healthcare personnel concerning the earlier detection of DFU and related complications. It may be due to lack of time, lack of knowledge, and lack of interest, which is finally not helpful in reducing the existing rates of ulceration and amputation. (15,16)

Ultimately, this creates an opportunity for nursing, that can help in establishing foot ulcer prevention programs at the primary care level, considering the examination of the foot, training of patients, and timely referral to tertiary care for preventing further complications. (17,18) In this regard, it is necessary to highlight the fact that the little education on diabetes received by the participants, that it was not explicitly for foot care, and was not given by the nurses, and other healthcare professionals whose potential could be used for the positive effect regarding the DFU. (17,19)

In our study, we observed that risk factors like age and BMI were not significantly associated with DFU. Our study and a few more studies concluded that some of other factors like smoking, alcohol consumption, and tobacco chewing, are significant risk factors for DFU. (4,5,10,11,17) In this study, the small number of patients developing foot ulcer may have led to this result.

Al-Rubean et al. conducted a study and reported a significant association between the duration of diabetes and DFU occurrence. The results of the study reported that 88.99% incidence of DM in the study for more than 10 years, and further analysis reported that smokers have 1.15 times higher chances of developing gangrene, increasing the incidence of amputation. (4,7,13)

Another study conducted by Ledoux et al. studied the obesity paradox theory and reported that for every 5kg/m2 increase in BMI, the risk of DFU reduces. (11) Sohn et al., also reported similar findings and reported that overweight and obese patients have a reduced risk of DFU. Biasucci et al. concluded that wound healing among obese study subjects was improved because of an increase in the endothelial progenitor cell levels which functions as a protective vascular factor against atherosclerosis. (20)

Our study has a number of limitations. First, although this study was performed prospective cross-sectional study, the patients included in the study were from a tertiary care hospital, and this may affect the results by selection bias. However, the effect of this bias will be minimal as the hospital where this study was conducted was a tertiary care referral hospital and the focal point of diabetes in the area, and this is the major strength of this study to have different patients with different conditions. Another shortcoming of this study is the small size of subgroups in analysis which may lead to lesser precision in prevalence estimates. Another limitation of this study is that some of the potential confounding factors like health care provision level and patient behavioral factors were ignored in the occurrence of new foot ulceration. Finally, the differences in methods of neuropathy assessment may affect the results to be compared with those of other studies.

V. Conclusion:

All diabetes patients need to undergo a foot examination every year to identify risk factors for foot ulceration. The results of this study support this suggestion to reduce the prevalence of DFU. It is also needed to have a cost-effective way of annual screening of diabetic patients.

This study seeks to shed light on the prevalence and risk factors for foot ulcers in patients with Type 2 Diabetes Mellitus. By uncovering key determinants of foot ulcer development, this research could lead to improved patient care, better outcomes, and reduced healthcare burden associated with diabetes-related foot complications.

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