Diabetic Foot Complications and Associated Factors among Diabetic Patients Who Attended Noncommunicable Disease Clinics in the Kollam District of South India-A Quality Improvement Project

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Abstract

Introduction: Diabetes mellitus has become a common metabolic disorder and a fast growing public health concern over the years. Among the diabetic complications, foot disorders lead to lower extremity infections and tissue breakdown, resulting in significant health and socioeconomic burden on the patients. When it comes to diabetic foot amputations performed in India 75% of them are done in neuropathic feet with a secondary infection that can be prevented. **Objective:** To assess the prevalence of Diabetic Foot Syndrome (DFS) and the associated risk factors among people with diabetes mellitus. **Methodology:** A healthy facility based cross-sectional study was conducted in randomly selected CHCs and PHCs of the Kollam district, India between the periods from March to August 2019. The sample size was 851 and was purposively selected. Data were collected using a structured interview schedule and screened for DFS using a micro ilament test. The collected data was analyzed using SPSS version 25. The analysis included descriptive analysis with frequency distribution calculated as necessary. **Result:** In mono ilament testing, 30.6% of participants screened positive for diabetic foot syndrome. The average duration of disease was 14.2 (SD 8.2) and (86.3%) of them reported having a family history of DM. Among the participants 69.1% detected with diabetic foot ulcers had 10+ years of diabetes mellitus. In our study, it was observed that 9.2% of patients had good knowledge of foot care practices and only 30% of diabetic foot ulcer patients do regular foot screening. **Conclusion:** The study stressed the signi icance of using screening tools and techniques for early detection, diagnosis, and treatment of foot ulcers and educating them about the need for foot care and lifestyle modi ications.

Keywords: Diabetic foot ulcer; Monofilament testing; Foot screening; Lifestyle modification; Public health

Introduction

Diabetes mellitus has become a common metabolic disorder and a fast-growing public health concern over the years. The Reports from the International Diabetic Federation (IDF) suggest that the incidence of DM was about 537M in 2015 and is expected to reach 643 million by 2030 [1]. The prevalence of diabetes mellitus has been rising rapidly in developed as well as developing nations. Among the diabetic complications, foot disorders are the most devastating and

costliest ones. Diabetic foot disorders lead to lower extremity infections and tissue breakdown, resulting in significant health and socioeconomic burden on the patients [2]. Diabetic foot ulcers lead to more than 50% of non-traumatic lower limb amputations and these amputations increase the mortality outcomes and result in prolonged hospitalization [3]. Peripheral neuropathy, Peripheral vascular diseases, and immune system dysfunction contribute to diabetic foot disease and impose a toll on the financial burden to patients.

IDF estimated that among the diabetic population, 80% live in low to middle-income countries like India. In 2021, China, India, and Pakistan were the nations with the highest proportions of people (20-79 years old) with diabetes. India is anticipated to have the second highest number of cases of diabetes worldwide, behind China, with 69.1 million people living with DM there. Recent prevalence statistics indicate that diabetes is becoming a bigger issue among rural populations as well, despite the fact that diabetes is already widely acknowledged as a public health priority in LMICs' urban areas. In the Indian scenario, it is also estimated that more than half of the diabetic patients remain undiagnosed. Foot disorders are one of the scariest complications of diabetes in developing nations and India, it is estimated that 85% of amputations are preceded by foot ulcers. 25% of diabetic patients are getting diagnosed with foot ulcers and among them, 20% of them are getting amputated [4]. In India, the prognosis of DFU is low and frequently leads to non-traumatic lower extremity amputations, life threatening complications, and even mortality. Different studies conducted globally indicate that the severity of diabetic foot disorders due to poor prognosis contributes heavily towards the increase in the number of lower extremity amputations. 80% of foot ulcers diagnosed in India results due to neuropathic lesions and the remaining 20% occur due to arterial disease [5]. When it comes to diabetic foot amputations performed in India 75% of them are done in neuropathic feet with a secondary infection that can be prevented [6]. Approximately 10000 legs getting amputated yearly in India manifests the need for early diagnosis and prevention. Additionally, it's believed that Indians have a higher level of insulin resistance and an increased genetic susceptibility to diabetes [7]. The management of diabetic foot disorders should be focused on preventive measures and effective treatment modalities. Effective foot care includes awareness about plantar offloading, footwear selection, foot hygiene, and infection control processes conducted by trained professionals.

The prevention of foot ulceration and amputation demands early screening and diagnosis and a need to focus on treatment interventions for foot disorder patients at risk [8]. The study evaluated the importance of foot screening practices in the early diagnosis of diabetic foot disorders. We conducted a clinical examination of patients by assessing sensation with Semmes Weinstein monofilament and evaluating vibratory perceptions using 128 Hz tuning fork apparatus. The findings of the study will help in the early diagnosis of diabetic foot ulcers and thereby reduce the risk of its devastating complications.

Materials and Methods

A multicentric cross-sectional study was conducted on patients with type 2 DM who attended 7 healthcare centers in Kollam, Kerala. Consecutive sampling was done for the collection of data. The diagnostic criteria suggested by the American diabetic association were used for classifying diabetic patients [9]. Adult patients with type 2 DM for at least 12 months and who had visited the health centers during the study period of March to August 2019 were recruited for the study. Ethical approval for the research project was obtained from the directorate of health services in Thiruvananthapuram (SI.No 6/2014/2/19-GHEC). Diabetic patients who had undergone amputation, patients with cognitive impairment, and pregnant women were excluded from the study. Informed consent was obtained from the participating human subjects and participation was voluntary and they were allowed to withdraw from the study at any stage. The demographic and clinical data of the patients were collected using a structured data sheet. Monofilament and tuning fork tests were carried out for screening peripheral neuropathy and peripheral vascular diseases. The grade of ulcers was identified through observation and was classified using the Wagner nelson method. In this study, the sample size was determined, based on a previous study done on the prevalence of peripheral neuropathy by George H, et al., which reported the prevalence of neuropathy was 47% [10-15]. Thus, with 5% precision and a design effect of 2, the sample size of 766 was obtained at a 95% confidence interval. Considering the 10% non-response, the final sample size was 851.

Statistical analysis

A structured questionnaire was used for the assessment of socio-demographic characteristics and knowledge about diabetes and foot ulcers. The collected data were evaluated for completeness, entered in Microsoft Excel version 2016, and analyzed using SPSS version 25. The analysis included descriptive analysis with frequency distribution calculated as necessary. A *chi-square* test was done to find the predictor variables. Those variables which showed a significant association were included in the logistic regression.

Monofilament testing

A standardized 10 mg monofilament was used to assess the presence of peripheral neuropathy. Semmes Weinstein monofilament evaluation was performed on different sites of the foot, like plantar aspects of the greater toe, and first and fifth metatarsal regions, and was applied twice in each site. IWGDF guidelines were followed to carry out the technique [16]. If the patient responded affirmatively on at least 2 out of 3 applications in each site can be considered as free of neuropathy. Patients who did not perceive monofilament on any test sites might lack protective sensation and be at risk for a foot ulcer and neuropathy [17].

Visual examination

A general examination of the feet can be done for identifying the presence of blisters, calluses, ulcers, cracks or fungal infections, redness, the presence of gangrene, and foot injuries that don't start healing after a few days. Visual examination of feet helps in identifying feet at risk.

Results

The majority of the study participants were males (59%) and the mean (SD) age of the participants was 63.26 (10.0). Nearly 59% of the participants are males. Nearly half of the participants (53.2%) of them were unemployed, followed by 17.7% of them self-employed (Table 1).

Table 1: Socio-demographic characteristics of study participants.	
Age group	
Less than 45	35 (4.1)
45-59	236 (27.7)
60-74	463 (54.4)
75 and above	117 (13.7)
Gender	
Male	502 (59)
Female	349 (41)
Employment status	
Not employed	453 (53.2)
Retired	50 (5.9)
Self-employed	151 (17.7)
Farmer	98 (11.5)
Daily wage/others	99 (11.11.7)

All the study participants reported type 2 DM. Nearly 30.6% of them screened positive for diabetic foot syndrome with MF testing. The average duration of disease was 14.2 (SD 8.2) years among the participants (Table 2). The majority of the participants (86.3%) of them reported having a family history of DM. The most common comorbid condition was hypertension (56.8%) followed by hypercholesterolemia (41.6%). The majority of the participants were on the oral glycaemic drug (38.3%) followed by combination therapy of insulin and oral glycaemic medication (37.5%) and insulin (24.2%) alone. More than half (55.4%) of the participants checked their blood glucose regularly. Nearly two-thirds of the participants (64.5%) were aware of diabetic symptoms.

About three fourth (75.9%) of the participants use to skip their meals and nearly the same (72.9%) number of them do not follow a diet plan. Most of them (76.4%) follow a sedentary lifestyle. About 12.7% of walk without any footwear. Among the participants 61.9% detected with diabetic foot ulcers had 10+years of diabetes mellitus. Only 11.3% and 11.4% of them do their foot examination regularly and have a knowledge of foot care respectively. Less than 10% had a history of long standing non-healing ulcers. Those with a history of foot amputation were less than 5%. Only 17.9% of them reported having a habit (6.5% smoking, 5.3% drinking, 4.6% smokeless tobacco, and 1.5% both smoking and drinking.

Table 2: Clinical and diabetic information of study participants.	
Disease related	
Duration of the condition	
5 or less	130 (15.3)
6-10	188 (22.1)
11-15	533 (62.6)
Family history of diabetes	
No	117 (13.7)
Yes	734 (86.3)

Presence of comorbidities

No	178 (20.9)
Yes	673 (79.1)

Type of medication use

Oral	326 (38.3)
Insulin	206 (24.2)
Both	319 (37.5)

Regular testing of glucose

No	379 (44.5)
Yes	470 (55.2)

Regular foot screening

No	755 (88.7)
Yes	96 (11.3)

History of diabetic foot ulcer

No	767 (90.1)
Yes	84 (9.9)

History of amputation

No	809 (95.1)
Yes	42 (4.9)

Current habits

No habits	699 (82.1)
Smoker	55 (6.5)
Smokeless tobacco	39 (4.6)
Alcohol use	45 (5.3)
Both alcohol and smoke/smokeless tobacco	13 (1.5)

Knowledge about diabetic symptoms

No	302 (35.5)
Yes	549 (64.5)

Knowledge about diabetic foot care

No	754 (88.6)
Yes	97 (11.4)

Follows a diet plan

No	620 (72.9)
Yes	231 (27.1)

Do regular exercise

No	650 (76.4)
Yes	201 (23.6)

Walk barefoot

No	743 (87.3)

Yes	108 (12.7)

Participant gender, participant age group, employment status, history of diabetics, type of medication, habits, checking glucose, regular checking of the foot, walking barefoot, knowledge about foot care, history of ulcer, history of amputation, duration of diabetics found to be significantly associated with screening positive for diabetic foot syndrome or testing positive for neuropathy using microfilament testing (Table 3).

Table 3: Factors associated with diabetic foot ulcer.		
Negative for neuropathy	Positive for neuropathy (DFU)	P value
Gender		
Male — 314 (46.9)	188 (27.7)	<.001
Female — 277 (53.1)	72 (72.3)	
Age group		
Less than 45 — 35 (5.9)	0	<.001
45-59 — 139 (23.5)	97 (37.3)	
60-74 — 327 (55.3)	136 (52.3)	
75 and above — 90 (15.2)	27 (10.4)	
Employment status		
Not employed — 339 (57.4)	114 (43.8)	<.001
Retired — 25 (4.2)	25 (9.6)	
Self-employed — 102 (17.3)	49 (18.8)	
Farmer — 56 (9.5)	42 (16.2)	
Daily wage/others — 69 (11.7)	30 (11.5)	
Family history of diabetes		
No — 107 (18.1)	10 (3.8)	<.001
Yes — 484 (81.9)	250 (96.2)	
Walk barefoot		
No — 560 (94.8)	183 (70.4)	<.001
Yes — 31 (5.2)	77 (29.6)	
Type of medication use		
Oral — 273 (46.2)	53 (20.4)	<.001
Insulin — 146 (24.7)	60 (23.1)	
Both — 172 (29.1)	147 (56.5)	
Regular testing of glucose		
No — 358 (60.8)	21 (8.1)	<.001
Yes — 231 (39.2)	239 (91.9)	
Regular foot screening		
No — 573 (97.0)	182 (70.0)	<.001
Yes — 18 (3.0)	78 (30.0)	
History of diabetic foot ulcer		
No — 587 (99.3)	180 (69.2)	<.001

Yes	4 (0.7)	80 (30.8)	
History of amputation			
No	591 (100)	218 (83.8)	
Yes	0	42 (16.2)	
Habits			
No habits	530 (89.7)	169 (65.0)	<.001
Smoker	36 (6.1)	19 (7.3)	
Smokeless tobacco	6 (1.0)	33 (12.7)	
Alcohol use	8 (1.4)	37 (14.2)	
Both alcohol and smoke/smokeless tobacco	11 (1.9)	2 (0.8)	
Knowledge about diabetic foot care			
No	539 (91.2)	215 (82.7)	<.001
Yes	52 (8.8)	45 (17.3)	
Duration of the condition			
5 years or less	113 (86.9)	17 (13.1)	
6-10	106 (17.9)	82 (31.5)	
11-15	372 (62.9)	161 (61.9)	

Discussion

One of the most dreaded complications of diabetes, diabetes foot ulcers significantly impact a person's quality of life. Unless the disease is treated and controlled, it will eventually cause total vascularity loss and tissue death. The consequences of diabetic foot ulcers have an impact on social, psychological, and financial crises in addition to physical well-being and thereby can pose a heavy burden on the patient. All facilities that provide care for patients with diabetes should strive to implement an inpatient diabetic foot screening service. Because early recognition of the factors that increase the risk of developing foot ulcers is crucial for the prevention mechanism.

According to our understanding, this study is the first to be conducted in the Kollam district of Kerala to determine the prevalence of risk factors for diabetic foot ulcers and knowledge of foot care among patients. We are aware that the most frequent contributing factor to diabetic foot ulceration was peripheral neuropathy. Regular screening of this population was crucial because neuropathy was commonly asymptomatic. Test using 10 g monofilament is considered the best technique for detecting foot ulcers. Ankle reflexes, VPT, and 128 Hz tuning fork vibration sensing are some of the other methods routinely used during the screening. Our study screened peripheral neuropathy using a 10 g monofilament plus tuning fork test to improve specificity and sensitivity. For peripheral arterial disease, Ankle-Brachial Index (ABI) is a typical procedure used in diagnosis. It contrasts the ankle's blood pressure with the arm's blood pressure. In our study, we didn't evaluate PAD which can be considered a drawback of our study. From the SWF test on PN, we observed that around 30.6% of patients were diagnosed positive with peripheral neuropathy which is comparable with other studies conducted in India, 26.1% and 32.8% respectively. The most important point of the study was the high prevalence of risk factors for foot ulceration. In the selected sample 16.2% had a history of ulceration and/or amputation and therefore were at very high risk of (re)ulceration. This group had a significant prevalence of comorbidities or complications related to diabetes. According to our study, 79.3% of participants had at least one complication, such as hypertension, hyperlipidemia, or retinopathy. Factors like obesity, lack of physical activity, smoking, and alcohol intake had a significant correlation with diabetic foot ulcers and are confirmed by previous studies.

It was commonly recognized that patients with diabetes for at least ten years are at greater risk of ulcers and lower limb amputations. The result of our study suggested that 61.9% of participants detected with diabetic foot ulcers had 10+ years of diabetes mellitus which was in line with the study conducted in Sudan. The cause may be that people with diabetes mellitus are exposed to hyperglycemia for a longer period of time, and this cumulative glycaemic burden can have harmful effects on all parts of the body, including the skin and feet. The severity of DFU was evaluated on the basis of Wagner's grade of classification, grades 0, 1, 2, and 3 were (34%), 12%, and 2% respectively, and was in line with a study conducted in Ethiopia and India. Among the practices, it was observed in the case of participants walking barefoot frequently that the risk of neuropathy was high as

they were exposed more to injuries with sharp objects, thermal injuries, and rat bites, and cultural and socioeconomic factors contributed to the same. Poor glycaemic control and poor testing of blood sugar levels were found to be significant risk factors for the development of diabetic foot ulcers in our study. When compared to those who had good glycaemic control, those with poor glycaemic control were more likely to develop diabetic foot ulcers.

The outcomes of this study indicated that many diabetic patients had limited knowledge of diabetic foot care. These shortcomings result from a lack of knowledge about the benefits of therapeutic footwear, the requirement for podiatrist consultation for diabetic foot, the significance of regular dressing and cleaning, of wounds, the application of emollients to prevent cracks, etc. Similarly, diabetic foot care practice and regular foot screening are significant in the management of diabetic foot ulcers. In our study, it was observed that 9.2% of patients had good knowledge of foot care practices and only 30% of diabetic foot ulcer patients do regular foot screening. This is in line with studies conducted in Nigeria and Saudi Arabia, 10.2% and 8.2% respectively. Shortfalls in daily foot inspection, washing, and drying of wounds, walking barefoot, selection of footwear, etc. may contribute to the development and worsening of diabetic foot ulcers. Patients should receive foot care learning from health professionals to improve and maintain their adequate practice of foot care because patient awareness of foot care is a key factor in preventing diabetic foot ulcers.

Conclusion

In India, the prevalence of diabetes and its complications, such as foot disorders, is rising alarmingly quickly. In our study, it was observed that foot care knowledge gaps and risk factors for developing foot ulcers were common among the study population. Peripheral neuropathy, foot deformities, barefoot walking, poor glycaemic control, prolonged duration of diabetes, the use of ill-fitting shoes, and poor practice of foot self-care were all significantly linked to the development of diabetic foot ulcers. The study stressed the significance of using screening tools and techniques for early detection, diagnosis, and treatment of foot ulcers and educating them about the need for foot care and lifestyle modifications.

Limitations

I used the SWF test diagnosis of diabetic foot ulcers. When compared to SWF, vibrating perception threshold, measurements have demonstrated superior peripheral neuropathy detection in numerous studies. In my study, I evaluated only peripheral neuropathy I should have also taken peripheral arterial disease into account when evaluating diabetic foot ulcers in my research. Use of techniques like the ankle brachial pressure indexes for the detection of PAD should have been used. The study participants were mainly from rural areas so there might be bias regarding the contributing factors, such as socioeconomic and cultural factors to foot ulcers.

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