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Non-adherence to foot-care activities and its associated factors among patients with type 2 diabetes mellitus in an urban area of South India: a cross sectional study

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) is the commonest metabolic disorder with prevalence of 8.3% in India. The prognosis largely depends on complications seen in natural course of illness. Stringent adherence to self-care activities is a mandatory step in management of T2DM. Hence, this study was done to assess non-adherence to foot-care activities among patients with T2DM for associated factors and also to report findings of foot examination among non-adherent participants.

Methods: A community based cross-sectional study was conducted in an urban area of Bengaluru. Using multi-stage sampling, 400 people with T2DM aged ≥18 years were selected. A pre-tested, semi-structured questionnaire was used to collect information regarding non-adherence to foot-care activities and foot examination was done for all the participants.

Results: Though all the participants were aware regarding the foot-care activities, 86.7% of participants were not adherent. Females and those with lower monthly income had 2.91 and 3.47 significantly higher odds of being non-adherent to foot-care activities, respectively.

Conclusions: The prevalence of non-adherence to foot-care activities among people with T2DM was observed to be high. Hence, more importance should be given to motivate people with T2DM in their follow-up visits regarding adherence to foot-care activities to avoid occurrence of complications.

Keywords: Non-adherence, Foot-care activities, Associated factors, Diabetes mellitus, Self-care

INTRODUCTION

The prevalence of type 2 diabetes mellitus (T2DM) has been increasing all over the world, in the past 30 years, particularly in India. According to International Diabetic Federation (IDF), 8.3% of the global population has T2DM (2014) and 4.9 million deaths occurred because of T2DM. The estimated prevalence of T2DM in India in 2014 is 8.63%. Successful management of T2DM is challenging. The physician should identify a target level of glycemic control for each patient and provide the

patient with the educational (nutrition and exercise, monitoring the level of glycemic control, foot-care) and pharmacologic (oral hypoglycemic agents, insulin or combination) resources necessary to reach this level. The patients should also be monitored and treated for T2DM-related complications.²

Most adults with T2DM end up with one or more micro or macro-vascular complications and also other comorbidities accounting for most of the morbidity and mortality.³ Macrovascular complications like

cardiovascular, cerebrovascular and peripheral arterial diseases and micro vascular complications like nephropathies, neuropathies and eye complications pose a significant health care burden, a deterrent to overall quality of life. Proportion of cardiovascular complications, ocular complications, neuropathy, peripheral arterial diseases, nephropathy cerebrovascular complications were 21.2%, 19.2%, 16.8%, 12.8%, 11.2% and 6.0% respectively. Complications like diabetic foot ulcers (DFU) and lowerextremity amputations result in physical limitations and decreased quality of life for patients causing major medical and economic threat to the society.⁵ The burden of diabetic foot disease is expected to increase consequent to the increasing global prevalence of T2DM. Worldwide, 3%–10% of people with diabetes have a foot ulcer with lifetime risk of developing DFU as high as 25%; and studies from different countries show that 15-27% of all ulcers result in amputations.^{6,7}

Simple self-care in diabetes helps individuals successfully manage the disease by themselves and prevent occurrence of complications. Active and voluntary involvement of the patient in adhering to the management of his or her disease by following a mutually agreed course of treatment and sharing responsibility between the patient and doctor is vital. Since diabetic foot is a predominant cause for hospitalization and amputation in those with diabetes and as it is preventable by regular foot-care, this study was undertaken to find non-adherence to foot-care activities among patients with T2DM, its associated factors and to describe the findings on foot examination among non-adherent participants.

METHODS

The study was a community-based cross-sectional study conducted from January 2016 to December 2016 in Mathikere, urban field practice area of M.S. Ramaiah Medical College, Bengaluru. Institution ethical clearance was obtained before the start of the study. Patients above 18 years of age diagnosed with T2DM prior to a minimum period of one year and who were residents of the study area for a minimum period of 6 months were included in the study. Patients with dementia, any other co-morbid illness or not on exclusive allopathic treatment were excluded from the study.

Sample size

A study conducted at Puducherry in 2013 showed 80% had not followed good foot-care practices. Based on this, present study sample size was calculated to be 400 at 95% confidence levels with 5% relative precision and considering 5% as coverage error or non-response rate. From a study conducted in urban slums of Bengaluru in 2013, the prevalence of T2DM was 12.33%. Therefore, to obtain 400 people with T2DM, the population that needed to be screened was 3244 (400×100/12.33). Mathikere comprising of ward 17 and ward 36 has a population of 49,610 and 37,036 distributed in 107 and

70 Census Enumeration Blocks (CEB), respectively. To obtain this sample size, population probability proportional sampling (PPS) was done to select 5 and 3 CEBs from both wards using a random number table. Complete enumeration of all the households in each of the selected CEB was done. ¹¹

House to house survey was made by the investigator to identify patients with T2DM. After obtaining written informed consent to a pretested semi structured questionnaire was used for obtaining socio demographic details, details of T2DM and assessment of nonadherence to foot-care. The adherence part was developed by using 'The Summary of Diabetes Self Care Activities' (SDSCA). ¹² Foot examination was also done using Indian Council for Medical Research (ICMR) guidelines. 13 Participants were considered adherent to self-care activities of feet if they checked their feet for red spots, cuts, swellings or blisters especially between toes and pressure areas; inspected inside shoes for stones/foreign bodies or for any change in shape or heels of footwear; washed their feet after coming from outside and dry between toes after washing and used special footwear like microcellular rubber footwear on 5 to 7 days in the past 1 week. The other study participants who did not follow foot-care activities were considered nonadherent.

Descriptive statistics were employed to summarize the quantitative data such as age, duration of T2DM etc. Standard deviation was calculated as a measure of variation. Qualitative variables were expressed as percentages with 95% confidence interval. To test for differences in the two proportions, Chi-square test/Fisher's exact test were employed. Odd's ratios along with 95% confidence interval were estimated for various factors after dichotomizing the data into appropriate adherence and non-adherence to the diabetic foot-care self-care activities. Logistic regression analysis was employed to evaluate the independent determinants associated with adherence and non-adherence.

RESULTS

Socio demographic details of the study participants

Among the study participants, 211 (52.8%) were females. The mean age of the participants was 57.39 ± 13.67 years and 207 participants (51.8%) were aged \geq 60 years. Of the total study subjects, 117 (29.3%) were illiterate and 275 (68.8%) were unemployed. The mean age of diagnosis of diabetes mellitus was 49.28 \pm 11.79 years. Oral hypoglycemic agents (OHA) were taken by 377 (94.3%), insulin by 11 (2.8%) and insulin +OHA by 12 (3.0%) people with T2DM, respectively (Table 1).

Source of information regarding foot-care activities and health care seeking behavior of study participants

All participants were educated regarding foot-care activities by health care professionals. In addition, 91%

of study participants were also educated by television. Neighbors/relatives/family members (81%), newspaper/magazine (58.8%) and radio (5.3%) were other sources of information regarding foot-care activities. Among study participants, 49.3% were provided health-care by MBBS doctors and 50.7% by the Specialists. Government facilities were utilized by 9.5% and private health care facilities by 90.5% of the study population.

Table 1: Socio demographic profile of the study participants (n=400).

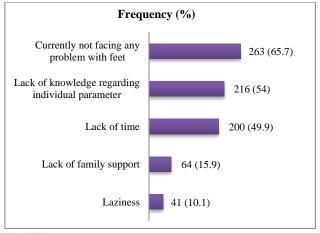
Characteristic	Frequency (%)					
Age (in years)						
18-39	55 (13.7)					
40-59	138 (34.5)					
≥60	207 (51.8)					
Gender						
Female	211 (52.8)					
Male	189 (47.2)					
Marital status						
Never married	1 (0.2)					
Currently married	319 (79.7)					
Widow/widower	71 (17.8)					
Separated/divorced	9 (2.3)					
Religion						
Hindu	279 (69.8)					
Muslim	41 (10.2)					
Christian	80 (20.0)					
Education						
Not literate	117 (29.3)					
Primary school	22 (5.5)					
Middle school	46 (11.5)					
High school	89 (22.2)					
Intermediate/diploma	65 (16.3)					
Graduate/post graduate	61 (15.2)					
Occupation						
Unskilled worker	2 (0.5)					
Semi-skilled worker	38 (9.5)					
Skilled worker	48 (12.0)					
Clerical/shop owner	13 (3.3)					
Semi- professional	21 (5.2)					
Professional	3 (0.7)					
Currently not working	275 (68.8)					
Monthly family income (INR)						
<10000	88 (22.0)					
10001-30000	119 (29.7)					
30001-50000	109 (27.2)					
50001-70000	37 (9.3)					
>70001	47 (11.8)					
Type of family						
Nuclear family	201 (50.3)					
Joint family	61 (15.2)					
Three generation family	120 (30.0)					
Others	18 (4.5)					

Non-adherence to foot-care activities among study participants

Among the total study participants, 53 (13.3%, 95% CI: 9.9%-16.7%) were found to be adherent to all the footcare activities and the rest 347 were non-adherent (86.7%, 95% CI: 83.1%-89.7%). The proportion of study participants who did not check their feet, did not inspect inside shoes, did not wash feet after coming from outside, did not dry between toes after washing and did not use special footwear (microcellular rubber footwear) in more than 5 days of the past 7 days were 43.9%, 72.5%, 25.7%, 49.7% and 66.8% respectively. None of the study participants soaked their feet in water.

Factors associated with non-adherence to foot-care activities among the study participants

In univariate analysis, females were 2.44 times more non-adherent to foot-care activities and those with monthly family income of ≤Rs. 30,000=00 were 3.17 times more non-adherent to foot-care activities compared to males and those with greater family income, respectively. Other variables did not show any significant association with non-adherence to foot-care activities. Both these factors showed statistically significant association (p=0.003 and p<0.001 respectively). In multivariate analysis also, gender and monthly family income were statistically significantly associated with non-adherence to foot-care activities (Table 2). Other variables like education, occupation, consulting health care professional and consulting health care facility which were included in the analysis model were not found to be significant factors.



 $[*] Multiple\ responses.$

Figure 1: Perceived reasons by the study participants for non-adherence.

Among the study participants, 263 (65.7%) cited currently not facing any problem with their feet as the reason, followed by lack of knowledge regarding individual parameters and lack of time in 216 (54.0%) and 200 (49.9%) participants respectively (Figure 1).

Table 2: Factors associated with non-adherence among the study participants (n=400).

Variables	Categories	Non adherence n (%)	Adherence n (%)	χ²value	P value	Unadjusted OR (95% CI)	Adjusted OR* (95% CI)
Gender	Females	193 (91.5)	18 (8.5)	8.65	0.003	2.44 (1.33-4.47)	2.91 (1.35-6.29)
	Males	154 (81.5)	35 (18.5)			1.00	1.00
	Not literate	103 (88.0)	14 (12.0)		0.078	0.46 (0.15-1.46)	0.39 (0.12-1.30)
Education	Below high school	64 (94.1)	4 (5.9)	5.09		1.43 (0.74-2.78)	1.06 (0.49-2.30)
	High school and above	180 (83.7)	35 (16.3)			1.00	1.00
0	Currently not working	243 (88.4)	32 (11.6)	1.00	0.150	1.53 (0.85-2.78)	1.59 (0.72-3.49)
Occupation	Employed	104 (83.2)	21 (16.8)	1.99	0.158	1.00	1.00
Monthly family	≤Rs. 30,000=00	176 (93.1)	13 (6.9)	12.66 <0.00	رم مرم دم مرم	3.17 (1.64-6.13)	3.47 (1.61-7.47)
income	>Rs. 30,000=00	171 (81.0)	40 (19.0)		<0.001	1.00	1.00
Consulting health	MBBS doctor	174 (89.7)	20 (10.3)	2.02	3 0.092	1.66 (0.92-3.01)	1.16 (0.60-2.24)
care professional	Specialist	173 (84.0)	33 (16.0)	2.83		1.00	1.00
Consulting health	Government aided	35 (94.6)	2 (5.4)	2.18	0.140	2.86 (0.67-12.26)	1.40 (0.29-6.72)
care facility	Private	312 (86.0)	51 (14.0)			1.00	1.00
Age	≥60 years	179 (86.5)	28 (13.5)	0.03	0.866	0.95 (0.53-1.70)	
	<60 years	168 (87.0)	25 (13.0)			1.00	
Marital status	Others	71 (87.7)	10 (12.3)	0.07	0.788	1.11 (0.53-2.31)	
	Currently married	276 (86.5)	43 (13.5)			1.00	
Family type	Others	16 (88.9)	2 (11.1)	0.20	0.905	1.17 (0.25-5.40)	
	Nuclear family	173 (86.1)	28 (13.9)			1.30 (0.28-5.94)	
	Joint/ III generation family	158 (87.3)	23 (12.7)			1.00	•
Duration of DM	<10 years	240 (86.6)	37 (13.4)	0.01	0.924	1.03 (0.55-1.93)	
	≥10 years	107 (87.0)	16 (13.0)			1.00	

^{*}Adjusted for gender, education, occupation, monthly family income, consulting health care professional and consulting health care facility; p<0.05 - statistically significant.

Table 3: Findings of foot examination among study participants.

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Findings of foot examination	Among non-adherent participants, n=347	Among adherent participants, n=53					
	Frequency (%)	Frequency (%)					
Sensory							
Pin prick: absent	49 (14.1)	3 (5.7)					
Vibration: absent	30 (8.6)	2 (3.8)					
Motor							
Ankle reflexes: abnormal response	11 (3.2)	0 (0)					
Autonomic							
Dryness of skin	327 (94.2)	52 (98.1)					
Cracks on feet	338 (97.4)	47 (88.7)					
Vascular deformities	•						
Foot pulses: posterior tibial	21 (6.1)	1 (1.9)					
(Not palpable) dorsalis pedis	36 (10.4)	3 (5.7)					
Ulcers	22 (6.3)	2 (3.8)					
Claw foot	1 (0.3)	0 (0)					
Hallux valgus	113 (32.6)	26 (49.1)					
Prominent metatarsal heads	1 (0.3)	0 (0)					
Nails							
Thickened nails	47 (13.5)	5 (9.4)					
Deformed nails	24 (6.9)	1 (1.9)					

Foot examination

Foot examination performed during the study revealed that 52 (13.0%) participants had sensory impairment and 11 (3.2%) participants had motor impairment in feet. Posterior tibial and dorsalis pedis arteries were not palpable in 5.5% and 9.8% of participants respectively and 24 (6.0%) study participants had foot ulcers. Other findings of the foot examination both among non-adherent and adherent participants are enlisted in table 3. All foot findings were greater among the non-adherent participants except dryness of feet which was almost similar to those who were adherent and hallux valgus which was more among adherent participants.

DISCUSSION

T2DM is the commonest metabolic disorder and has a high prevalence in India. Its prognosis largely depends on the complications seen in the natural course of illness. Stringent adherence to self-care activities is a mandatory step in diabetes management to avoid the occurrence of all micro and macro vascular complications.

Non-adherence to foot-care activities

This study revealed 86.7% of the study participants were non-adherent to foot-care activities and the results are quite similar to the results of earlier mentioned study done at Puducherry which showed that 80% of study participants were not following good foot-care activities. The present study results are consistent with a similar study done using the same study tool among patients with diabetes in a rural area of Bangalore district, India (Suguna et al) where 4 out of 101 (4%) study participants adhered and the rest (96%) were non-adherent to foot-care activities. This shows that majority of patients with diabetes are not adhering to foot-care activities and it is of prime importance to educate and motivate all the patients with T2DM for every follow-up visit regarding self-care activities.

In a study by Rajasekharan et al done at a tertiary care hospital in Mangalore, Karnataka, 64.8%, 70.7%, 28.3% and 13.4% of patients with diabetes washed their feet, dried space between the toes, examined feet and inspected the inner surface of shoes on all days of the week. Another study examining the compliance to management of diabetes by patients attending an urban health center in South India done by Santhanakrishnan et al observed that 45.9% of participants were noncompliant to foot-care activities. This is contrary to the present study results where lower non-adherence rates were noticed as they were tertiary hospital based studies. It is possible majority of the patients who attended these settings would be more conscious about their health and would follow the self-care activities as instructed by the health care professional.

A Brazilian study which considered two parameters of the foot-care activities domain showed only 38.7% and 29% of the participants examined their feet and inspected the inside of shoes before wearing them on five to seven days a week and the rest were non-adherent to these two parameters.¹⁶ This study showed lower non-adherence rates as compared to the present study. A Sri Lankan study done in patients with chronic diabetic ulcer showed that regular foot observation was followed by 65.5%, but rest of the parameters were neglected by more than 50% of study sample. Use of scoring system also gives evidence for the poor commitment of patients for the practice of foot-careprinciples.¹⁷ Patients should be strongly encouraged to implement foot-care practices by the health care providers. Previous studies have found an increase in foot ulcers and amputations in those patients who did not adopt self-care practices. 18

Factors associated with non-adherence

Gender and monthly family income were the two factors that were found to be associated with non-adherence to foot-care activities. There was no association between duration of T2DM and non-adherence observed in the present study but a study by Rajasekharan et al revealed that regarding the foot-care component, adherence to drying between the toes after washing of feet was found among participants with duration of T2DM ≥10 years. ¹⁴ Similar study done in a rural area of Bangalore did not find any association between any of the variables (gender, education and per-capita income) and adherence to foot-care activities. ⁸

Barriers for non-adherence

As self-care is important in management of diabetic foot, it is vital to establish reasons for the poor adherence. Majority of the participants neglected foot-care activities as they were currently not facing any problem with their feet and the complications would start to occur in due course of the illness. Lack of knowledge regarding each of the parameters in the foot-care activities domain was another major barrier. Poor T2DM-related foot-care knowledge and foot-care skills have been associated with foot injuries and ulceration. This lack of knowledge has been recognized as a contributing factor to people not undertaking foot self-care activities. It is widely accepted that additional education will lead to improved knowledge, self-care activities, and thus resulting in a reduction of foot complications. ^{19,20} Funnel et al noted that this additional education should be customized and tailored to individual needs and beliefs of the person with T2DM.²¹ Studies have shown that these educational interventions have the ability to lower rates of lower extremity amputations by 85%. Ollendorf et al noted that educational interventions aimed at foot self-care behavior and skills may offer the highest economic benefit in the reduction of lower extremity amputation rates.²²

Foot examination

Among those who were non-adherent to foot-care activities, 14.1% and 3.2% of participants showed sensory and motor impairment, respectively. Posterior tibial and dorsalis pedis arteries were not palpable in 6.1% and 10.4% of non-adherent participants respectively. Also, 22 (6.3%) study participants who were non-adherent to foot-care activities had foot ulcers. The foot examination performed among all participants revealed that more findings were present among non-adherent participants than among adherent participants.

CONCLUSION

Among the 400 study participants with T2DM, 86.7% were non-adherent to foot-care activities and females and those with low family income were significantly more non-adherent. The most common reasons stated by the study participants for being non-adherent was that currently they were not facing any problem with their feet and lack of knowledge about individual parameters of foot care. Majority of the participants were non-adherent to self foot care which is an important activity to prevent major complications. The variety of reasons stated by the participants for non-adherence can be tackled by health care professionals by giving health education, creating awareness and motivating them in every follow-up visit regarding self-care activities in diabetes management.

Strengths of the study

The present study had a large sample which helped to study the effect of several confounding factors like various socio-demographic variables and also to make more precise estimates by efficiently distributing data in the categories of the adjustment variables. Setting and adhering to operational definitions and criteria from standard validated questionnaire (SDSCA) and ICMR guidelines ensured reduction of misclassification and measurement biases in the present study. The findings of the present study can be extrapolated to similar populations because appropriate sampling methods and techniques were employed while conducting the study. Being a community based study, the present study holds a major strength than when compared to any other hospital based study in assessing the actual adherence among patients with DM. This is because all the patients who do not visit the hospital were also included and addressed in the present study and they are the people who are at most risk for non-adherence to the self-care activities.

Participants with DM were identified based on self-reporting of the illness. It is likely that some of the patients with DM did not report their diabetes status. Such people might also have poor adherence to self-care activities. If they have not been included in the study, it is likely that the prevalence of non-adherence to self-care activities could be an under-estimate and may reduce the generalisability of the study results. While interpreting

factors associated with adherence to self-care activities, it should be borne in mind that the odds ratios calculated are prevalence odds ratios. They are subject to the 'prevalence effect', i.e. it is difficult to establish a temporal sequence.

It is very important to create awareness and motivate the patients about being adherent to self-care, with emphasis on demonstration of foot-care and examination of the foot, among people with T2DM immediately after being diagnosed. Training and continuous education for interdisciplinary teams, working together with people with T2DM and civil society is needed. Repeated reminders of foot-care principles to improve motivation, having support schemes, health education and financial assistance are necessary to promote adherence to foot care practices. Specialized wound care centers need to be instituted in remote health care facilities. Psychological assistance, involvement of family members and care givers in foot-care management will be helpful. The practice of foot-care activities is critical for the prevention of foot ulcers leading to gangrenous lesions which progress to lower limb amputations, disability and handicap.

Future research on developing a standardized foot self-care program across multiple populations will help achieve reduction of complications associated with T2DM. This potential intervention will have the ability to expand the scope to not only include foot-care, but also other components of self-care to combat and halt the complications associated with T2DM.

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