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Original Research Article

Peripheral neuropathy and impaired sensation of feet among patients with type 2 diabetes mellitus: a descriptive cross-sectional study

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ABSTRACT

Background: Diabetic peripheral neuropathy (DPN) is the most prevalent consequence of type 2 diabetes mellitus (T2DM). Impaired sensation of feet due to DPN increases the risk of foot injury. Therefore, the objectives of this study were to assess the level of glycemic control, the prevalence of DPN and the impaired sensation of feet among the T2DM patients attending community clinics.
Methods: A descriptive cross-sectional study was conducted on 386 T2DM patients attending community clinics in Sri Lanka. The baseline data were collected by an interviewer-administered questionnaire. DPN was diagnosed by Michigan neuropathy screening instrument (MNSI) and monofilament test. Glycemic control was assessed by serum glycated hemoglobin (HbA1c) and fasting blood glucose (FBS).
Results: Among 386 T2DM patients, 265 (68.7%) were females, 179 (46.4%) had 1-5 years duration of disease. Poor long-term glycemic control (HbA1c) was observed in 292 (75.6%), while poor short-term glycemic control (FBS) was observed in 202 (52.4%). DPN was diagnosed in 68 (17.6%). Monofilament test assessed the touch sensation in 10 points of each foot. The ninth point (plantar central heel) of each foot was the commonest point with absent sensation. It was observed in 99 (25.6%) right feet and 94 (24.4%) left feet respectively.
Conclusions: High prevalence of DPN and impaired sensation in specific sites of foot indicate high risk for foot disease. Most patients with DPN had poor glycemic control. Urgent interventions to attain glycemic control and testing for impaired sensation regularly are essential to decrease progression of DPN and foot disease.

Keywords: Type 2 diabetes mellitus, Glycemic control, Diabetic peripheral neuropathy, Michigan neuropathy screening instrument

INTRODUCTION

Diabetes mellitus (DM) is the most common non communicable disease affecting more than 9% of the population of the world.[1] The commonest type of diabetes is type 2 diabetes mellitus (T2DM), responsible for over 90% of all diabetes cases globally.[2] Primarily, most adults with diabetes live in developing countries adding to the economic and social burden of these countries.[3] Attaining and maintaining glycemic control is recommended as the gold standard in the care of DM.[4] However, to attain the glycemic control and prevent the onset of complications, glycemic control should be accompanied with strategies to maintain multiple organ functions within a normal state. Thus, glycemic control as per the fasting blood glucose (FBS) and serum glycated hemoglobin (HbA1c) are mandatory to prevent or slow the progression of complications in T2DM.

Diabetic peripheral neuropathy (DPN) is the most prominent long-term neurological complication of diabetes.[5] Complications are more common and persistent

in patients with T2DM with poor glycemic control.[6] Early recognition and appropriate management are vital as it leads to serious outcomes for patients with T2DM. DPN has been linked to major complications such as numbness in the feet and impaired blood circulation in the feet, which can lead to foot ulcers, non-healing wounds, and amputations. Globally it is anticipated that 50% of patients with diabetes develop neuropathy.[7] Furthermore, 34% of patients with DPN end up with foot ulcers, 50% will become infected, and 20% will lead to amputations.[7] American Diabetes Association (ADA) recommends that improvement of glycemic control is vital to prevent or slow the progression of DPN amongst patients with T2DM.[5]

A decade ago, the prevalence of DPN was reported as 24% in Sri Lanka.[8] The male and female prevalence were 20% and 26.4%, respectively.[8] Further, a recent study done in a diabetic clinic of a tertiary care teaching hospital reported a higher prevalence of DPN of 62.6%.[9] However, there is a paucity of research findings on the burden of DPN amongst patients with T2DM attending community clinics in Sri Lanka. Thus, screening patients for DPN in the community using low-cost equipment that are simple and easy to use is vital for early identification. Most importantly, it can prevent injuries in numbed feet that are poorly sensitive to pain or injury.[5] Further it provides awareness to the patient of the extent of numbness of feet and would help in adopting early preventive measures.

Screening for DPN can be conducted using several methods. The Michigan neuropathy screening instrument (MNSI) includes two sections such as the Michigan neuropathy screening instrument questionnaire (MNSIQ) and Michigan neuropathy screening instrument examination (MNSIE). These two sensitive tests are recommended by the ADA and widely used in several studies to screen for DPN.[10,11] Further, the current study used the MNSI to determine neuropathy and the monofilament test to determine the sites of impaired sensation of each foot.

The recommendations of ADA emphasize that all patients with T2DM should be screened for DPN at the point of diagnosis and annually thereafter.[12] Furthermore, 10 g monofilament testing of the feet should be done every year to determine the risk for ulceration and amputation.[5] Despite the recommendation of the ADA, screening for neuropathy has not been implemented in busy community-based clinics with limited staff in Sri Lanka. Thus, based on the recommendations and the paucity of data, the current study aimed to assess the level of glycemic control, prevalence of DPN among T2DM patients and identify the sites of impaired sensation of feet in a community setting in Sri Lanka.

METHODS

A descriptive cross-sectional study was conducted for a period of one year (June 2020 to July 2021) in community clinics located in five randomly selected MOH areas in Colombo district, Sri Lanka. These community clinics provide free health care to patients affected with DM. In the current study, 386 patients with T2DM were studied for DPN. The patients were recruited using the systematic random sampling method. Every third T2DM patient of the clinic list fulfilling the inclusion criteria, was selected according to the clinic attendance appointment number. Ethical approval (ERC approval number: 19/17) was obtained from ethics review committee, Faculty of Medical Sciences, University of Sri Jayewardenepura. Voluntary informed written consent was obtained from each patient before recruitment to the study. Consenting T2DM patients with a disease duration of more than one year were included in the study.

Data collection

A pre-tested interviewer-administered questionnaire was used to obtain baseline socioeconomic information, social habits, diabetes-related information (duration of the disease, family history and current methods of treatment). The features of DPN were assessed by the MNSIQ, MNSIE and 10g Semmes Weinstein monofilament test.[13,14] Venous blood samples were taken to assess both short term glycemic control by assessment of the FBS and long-term glycemic control by the HbA1c. Good glycemic control was set at an FBS value ≤126 mg/dl and HbA1c ≤7%.[3]

Assessment of DPN and impaired sensation of the feet

The symptoms of DPN were assessed by MNSIQ and peripheral neurological functions were assessed by MNSIE. MNSIQ consists of 15 questions on foot sensation, including pain, numbness, and temperature sensitivity. In MNSIE, the physical examination included inspection of the feet, vibration perception at the great toe, and the presence of the ankle reflex. Several studies have confirmed that the MNSI correlates with the presence and severity of DPN.[10,13] The MNSI is a useful diagnostic tool and can be used as a low-cost easy method to screen diabetic patients for DPN.[13]

In the monofilament test, a standardized 10 g Semmes Weinstein monofilament was pressed against each part of the foot. Patients were asked to close their eyes while performing the test. Moreover, the patient's foot was supported during the examination. The monofilament was applied according to accepted standards, with the examiner maintaining a steady pressure until monofilament began to bow or buckle. When the filament bends, its tip is known to exert a pressure of 10 grams.[15]

The filament was applied in even pressure to the 10 sites of each foot as shown in Figure 1. The impaired sensation of feet was extensively assessed by considering the 10 sites of each foot.[15] T2DM patients were requested to respond when the sensation was felt at each site. Eight responses of positive sensation (out of 10 applications to each foot) were considered normal. Seven or less positive responses

indicated reduced sensation, and incorrect responses were translated into absent sensation.[14] Monofilament was not applied to areas with calluses or other structural abnormalities in the feet.

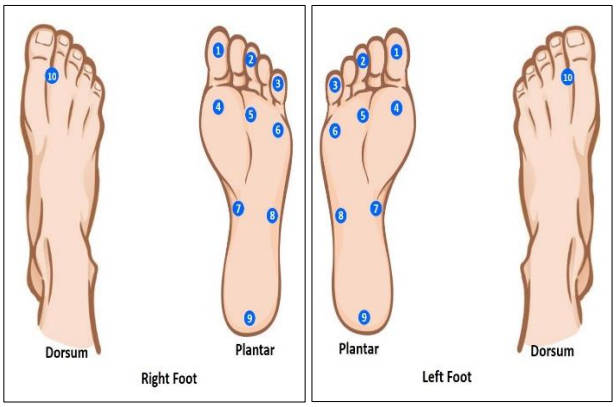

Figure 1: Monofilament examination sites of the foot.

The diagnosis of DPN was determined by the scores of MNSIQ (score of ≥4 as abnormal), MNSIE (score of ≥2.5 as abnormal), and monofilament test (score of ≤7 as abnormal).[13,14] DPN was confirmed by abnormal scores of all three tests.[16]

Data analysis

The IBM statistical package for the social sciences (SPSS) version 23 statistical software was used as the data analysis tool. Parametric and non-parametric tests were used as appropriate in analysis of data. Categorical variables were expressed as frequencies and percentages. Level of significance was set at $p<0.05$.

RESULTS

A total of 386 patients with T2DM were studied, 265 (68.7%) were female. Most of the patients 184 (47.7%) were aged between 48–63 years. Amongst them, 373 (96.6%) were of Sinhalese ethnicity. All smokers and alcohol consumers were male patients. Among the male T2DM patients, a few, 21 (5.4%) were identified as current cigarette smokers consuming <5 cigarettes per day. A similar finding was observed in the alcohol consumption pattern too. Current alcohol consumers, were 44 (11.4%). Almost all of them were occasional drinkers (Table 1).

The majority of T2DM patients, 179 (46.4%), had a disease duration of 1-5 years. Only 135 (35%) had a disease duration of >10 years. As expected, majority, 242 (62.7%), had a family history of the disease. Almost all, 376 (97.4%) attending the community clinics were on oral hypoglycemic drugs (Table 2).

As shown in Table 3, Long term glycemic control was poor, as determined by the HbA1c in 292 (75.6%) patients. Further, short term glycemic control (as determined by the FBS) was poor in 202 (52.4%) patients.

Table 1: Baseline characteristics of the T2DM patients.

Baseline characteristics	Number (n=386)	Percentage (%)
Gender		
Male	121	31.3
Female	265	68.7
Age (years)		
15–47 (young)	42	10.9
48–63 (middle age)	184	47.7
≥64 (elderly)	160	41.4
Ethnicity		
Sinhala	373	96.6
Tamil	8	2.1
Other	5	1.3
Level of education		
Not attended school	9	2.3
Up to grade 8	144	37.3
Up to O/L	164	42.5
Up to A/L	64	16.6
Diploma/graduate	5	1.3
Smoking status		
Never	314	81.3
Ex-smoker	51	13.2
Current smoker	21	5.4
Alcohol consumption status		
Non-alcoholic	306	79.3
Current alcoholic	44	11.4
Ex-alcoholic	36	9.3

Table 2: Diabetes related information.

Diabetes related information	Number (n=386)	Percentage (%)
Duration of diabetes (years)		
1–5	179	46.4
6–10	72	18.6
>10	135	35
Family history		
Yes	242	62.7
No	131	33.9
Do not know	13	3.4
Type of hypoglycemic treatment		
Oral hypoglycemic drugs	376	97.4
Insulin	7	1.8
Oral hypoglycemic and insulin	3	0.8

The responses of MNSIQ are tabulated Table 4. The most common symptoms observed by the majority are feeling weak all over most of the time 228 (59.1%), pain in legs while walking 226 (58.5%), and muscle cramps in leg or feet 222 (57.5%). Nearly half of the T2DM patients, 183 (47.4%), had numbness in their legs or feet. As depicted in the Table 5, the most frequent features of the MNSIE are the absent ankle reflex in 265 (68.6%) of left feet and 256

(66.3%) of right feet and absent vibration perception threshold in 236 (61.1%) of left feet and 230 (59.7%) of right feet. These findings indicate a high frequency of abnormal MNSIE parameters in this study population.

According to the diagnostic criteria, DPN was confirmed in 68 (17.6%) T2DM patients, as shown in Table 6. The frequency of DPN amongst males and females were 27 (22.3%) and 41 (15.5%) respectively (Table 6, p=0.262).

Table 3: Glycemic control of the T2DM patients with FBS and HbA1c.

Glycemic control	Male (n=121) n (%)	Female (n=265) n (%)	Total (n=386) n (%)	P value
FBS (mg/dl)				
≤126 (glycemic controlled)	59 (48.8)	125 (47.2)	184 (47.6)	0.794
>126 (glycemic uncontrolled)	62 (51.2)	140 (52.8)	202 (52.4)	
HbA1c (%)				
≤7 (glycemic controlled)	35 (28.9)	59 (22.3)	94 (24.4)	0.287
>7 (glycemic uncontrolled)	86 (71.1)	206 (77.7)	292 (75.6)	

Chi-square test

Table 4: Positive and negative responses of MNSIQ.

Responses	Number (n=386)	Percentage (%)
Positive responses		
Are your legs or feet numb?	183	47.4
Do you ever have any burning pain in your legs or feet?	139	36
Are your feet very sensitive to touch?	142	36.8
Do you get muscle cramp in your leg or feet?	222	57.5
Do you ever have any prickling feelings in your legs or feet?	118	30.6
Does it hurt when the bed covers touch your feet?	15	3.9
Have you ever had an open sore on your foot?	66	17.1
Has your doctor ever told you that you have diabetic neuropathy?	11	2.8
Do you feel weak all over most of the time?	228	59.1
Are your symptoms worse at night?	126	32.6
Do your legs hurt when you walk?	226	58.5
Is the skin on your feet so dry that it cracks open?	133	34.5
Have you ever had an amputation?	3	0.8
Negative responses		
When you get into the tub or shower are you able to tell the hot water from cold water?	0	0
Are you able to sense your feet when you walk?	11	2.9

Table 5: MNSIE parameters.

MNSIE parameters	Left	Right
	Number (n=386) n (%)	**Number (n=386) n (%)**
Appearance of feet		
Abnormal	123 (31.9)	122 (31.7)
Ulceration		
Present	5 (1.3)	2 (0.5)
Ankle reflex		
Absent	265 (68.6)	256 (66.3)
Vibration perception threshold		
Absent	236 (61.1)	230 (59.7)

Table 6: Diagnosis of diabetic peripheral neuropathy.

DPN	Male (%)	Female (%)	Total (%)	P value
All three tests normal	26 (21.5)	61 (23)	87 (22.5)	0.262
One test abnormal	37 (30.6)	75 (28.3)	112 (29)	
Two tests abnormal	31 (25.6)	88 (33.2)	119 (30.8)	
Three tests abnormal	27 (22.3)	41 (15.5)	68 (17.6)	

Chi-square test

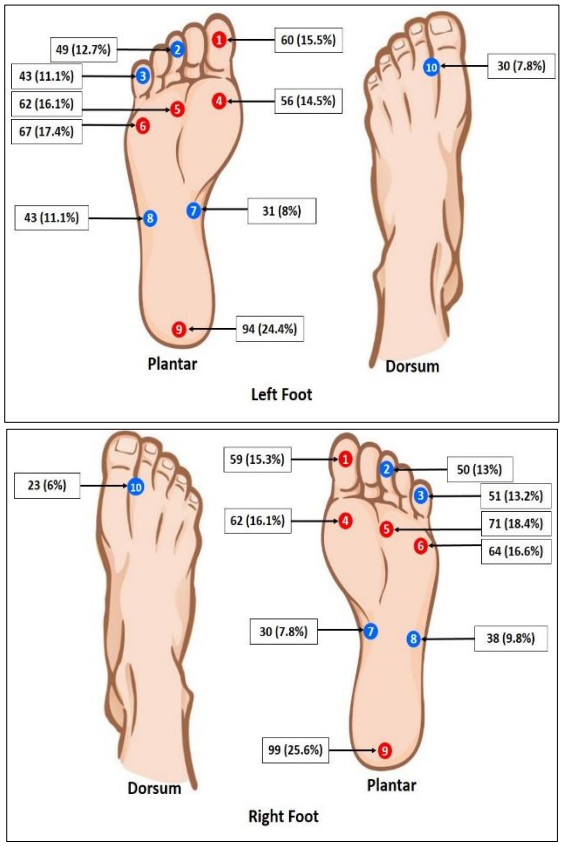

Figure 2: The absent sensation in monofilament test points (plantar and dorsum aspect of the left and right foot).

Further to the DPN diagnostic criteria, the monofilament test was used to extensively assess the protective sensation in 10 points of each foot. The absent sensation of each monofilament test points results was shown in Figure 2. The 9th point of each foot was identified as the most common point with absent sensation. The results showed that 99 (25.6%) and 94 (24.4%) had absent sensation in the 9th point in the right and left foot, respectively. Apart from the 9th point, the most affected other points were the 1st, 4th, 5^{th,} and 6th points as shown in the Figure 2. These most affected sites of the foot are the most typical sites for foot ulceration in patients with T2DM (Figure 2).

DISCUSSION

In the present study, 386 patients with T2DM were studied. Nearly half of the patients with T2DM, 46.4% were within 1-5 years duration of the disease, indicating the early stages of the disease. Poor long-term glycemic control as determined by HbA1c was observed in 75.6% T2DM patients. Further poor short-term glycemic control was observed in 52.4%. Similar to the current study findings, poor glycemic control for HbA1c was observed in 78.2% of the T2DM patients in India.[17] However, the Indian study was conducted in a teaching hospital, and the findings revealed that most patients (70.3%) were on insulin therapy or combined therapy. However, in the current study, majority (97.4%) of patients were on oral hypoglycemic drugs. The timing and compliance to medication, timing of meals and composition of food play a large part in attaining short term and long-term glycemic control.[18] Previous studies in Sri Lanka have shown that patients who have poor glycemic control often do not comply with dietary advice or time their meals with regular medication adherence.[18,19] Thus, nutrition information, dietary and medication adherence advice should be regularly provided to reinforce the knowledge and motivate compliance.[20] Often these practices are not adhered by health care personnel managing very busy community diabetic clinics in the country. Usually, in Sri Lanka, patients with uncontrolled glycemia are referred to the hospital diabetic clinics for management and follow-up by a larger health care team. However, since referral of all these poor glycemic control patients is not practical, the clinics should establish a visiting dietician or nutritionist to address these patients and motivate glycemic control on an individual basis. Individualized personalized diabetic care is an unmet need amongst T2DM patients in Sri Lanka.[20]

Further, another study conducted in Sri Lanka a decade ago, also revealed poor glycemic control.[18] Although diabetic care in Sri Lanka has expanded in many ways through the last decades, poor glycemic control is still a serious health issue among T2DM, as confirmed by the present study. Since the majority were detected to have uncontrolled glycemia, these patients are more prone to develop complications of diabetes such as diabetic neuropathy.[4] Sri Lankan patients eat a large portion of rice (usually white rice) and they consume the meal with small portions of vegetables and plant/animal protein.[18] This should be addressed when providing dietary advice and thus patients should be motivated to attain glycemic control.[18,19]

Nerve conduction studies are the gold standard in detecting diabetic peripheral neuropathy.[14] However, these gold standard methods considered are not practical in the community clinical settings. In order to administer nerve conduction studies, specially trained staff, expensive

equipment and extra time are required.[14] Therefore, several neurological associations have recommended easy to administer noninvasive tools to detect DPN in clinical and primary care settings.[14,21] Those tools have been widely used to assess DPN in different settings.[21-23] The current study used the MNSI, a simple, noninvasive, and valid tool that consists of MNSIQ and MNSIE[13]. Moreover, it is recommended for primary diagnosis of DPN too.[24] The Korean Diabetic Association too recommends the use of MNSI as a tool to assess DPN.[14] Therefore, the MNSI can be applied in the Asian context where foot wear is not worn indoors in many households. Thus, the current study used the MNSI as the diagnostic tool for DPN along with the monofilament test.

Studies have shown that the most common symptom indicating neuropathy was the presence of numbness of feet as measured in MNSIQ. In a study conducted in Sri Lanka, this was observed in 37% whereas the current study observed it in 47.4%.[8] Thus, it shows an increase in prevalence of DPN amongst T2DM patients. The appearance of the feet as assessed in the MNSIE was abnormal in over 31% of the current study group while ulceration was present only in less than 1.5%. However, the ankle reflex was impaired in over 66%. In a previous study in Sri Lanka, ankle reflex was found to be diminished or absent in 28.2%, whereas in the current study ankle reflex was absent in over 66% of patients.[8] Similarly, vibration sense was found to be absent in 26.1% in a previous study whereas in the current study, vibration perception was absent in over 61%.[8] This indicates that there is an increase in the prevalence of DPN among Sri Lankans within the last few years. Moreover, loss of the ankle reflex is one of the earliest signs of the changes of DPN.[25] In the current study, loss of ankle reflex was observed in 68.6% of left feet and 66.3% of right feet indicating a high prevalence of absent ankle reflex. This is a serious cause for concern as absent ankle reflex has been associated with DPN indicating a high level of undetected DPN in this study population.[26]

As per the criteria of all three tests being abnormal, DPN was confirmed in 17.6% of T2DM patients in the current study. Perhaps this cutoff level may be set too high. When the criteria of at least two test results being abnormal was used to confirm DPN; it was observed that the prevalence of DPN was as high as 48.4%. These results are comparatively higher than in other studies conducted in the Asian region.[27,28] Moreover, the DPN prevalence among the male and female T2DM patients in the current study was similar, i.e. 47.9% and 48.7%, respectively (with at least two tests being positive). These findings indicate a high prevalence of DPN among T2DM patients attending community clinics. A previous study in Sri Lanka to identify the prevalence of DPN across the country revealed an overall DPN prevalence of 24% among already diagnosed diabetic patients.[8] In comparison, the prevalence among males and females were 20% and 26%, respectively.[8] Further a study conducted in a major tertiary care hospital in Sri Lanka reported a high prevalence for DPN as 62.6%.[9] The high prevalence of DPN in a hospital-based study may be due to the study site being a major tertiary care hospital diabetic clinic, with over 400 patient turnovers daily from Colombo and its suburbs. Community clinics are the caregiving centers for T2DM patients without complications. Usually, the T2DM patients with complications are referred to the tertiary care hospital diabetic clinics and are being treated and monitored by a consultant working in collaboration with a large health care team. Moreover, most of the patients with T2DM in this study were in the early stages of diabetes (i.e., duration of disease was 1-5 years). However, the high community prevalence of DPN is a cause for concern. It needs to be addressed by health care providers and health policy makers as this undiagnosed group would be the patients that would subsequently develop complications and require referral to the tertiary health care centers in the future. Thus, the early diagnosis of DPN and monitoring of glycemic control in the community clinics are essential measures to overcome these problems.

Globally, the prevalence of DPN varies in different regions in the world. Developing countries of Latin America and the Caribbean nations report a high estimated prevalence of DPN of around 46.5%.[29] Other developing countries such as India (31.1%), Bangladesh (38.1%), Pakistan (39.8%) also have nearly similar values in accordance with the current study thus showing a similarity within the South Asian region.[27,28] However, developed countries such as Germany (42.2%), Korea (33.5%), USA (62.2%; national average is 28-45%) also report a higher prevalence for DPN.[30,31] In these developed countries foot ware is worn at all times in contrast to the Asian populations where foot ware is not worn indoors.[32,33] A study conducted in India shows the prevalence of DPN as 45.4%, in concordance with the findings of the current study (with two tests being positive).[34] The prevalence of DPN had nearly similar findings for most countries globally, despite the status as a developed or a developing country. Currently, diabetes and its complications are a global pandemic, contributing to the higher prevalence reported across the globe.

In addition to the diagnostic criteria of DPN, the 10 g monofilament test was also used for the assessment of impaired sensation in the foot. The present study measured sensation on 10 sites by the monofilament test for better accuracy since testing more sites would be more sensitive in identifying DPN and risk of foot ulceration.[35] Furthermore, studies have shown that foot ulcer risk is independently related with impaired sensation measured with 10 g monofilament test.[36] Other studies have also used the ten sites because it is a quick, non-invasive and inexpensive test.[37] However, some studies have recommended three sites and four sites instead of ten sites.[38] The present study results showed that the most commonly affected sites were 1st, 4th, 5th, 6th, and 9th points in both feet (Figure 2). The sensation was impaired in 15.5%, 14.5%,16.1%, 17.4%, 24.4% in left foot and 15.3%, 16.1%, 18.4%, 16.6%, 25.6% in right foot,

respectively, in T2DM patients. These findings are unique in a study population with poor glycemic control where footwear is not worn indoors by most T2DM patients (74.4%) in the current study. To the best of the knowledge of the authors, this is the first study where monofilament sites have been extensively assessed in a community group of T2DM patients in Sri Lanka. Moreover, the present study showed that the highest affected point of both feet was the 9th point. However, the 9th point is not included in the testing protocols using three and four test sites.[38] The present study highlights the importance of performing the monofilament testing on ten sites for greater accuracy and early identification of risk of foot ulceration.[39]

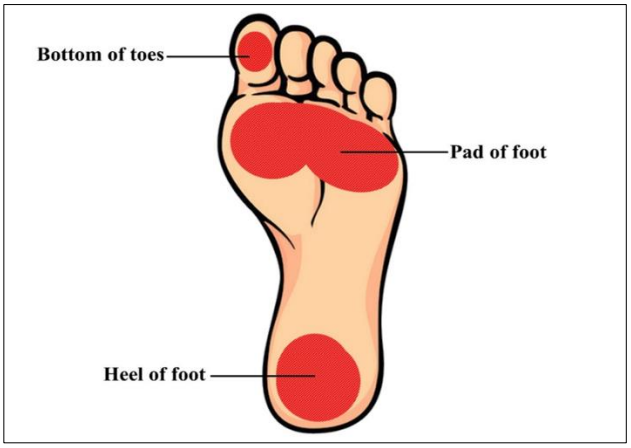

Figure 3: Common sites for foot ulceration in a diabetic foot.

Furthermore, the most affected sites of both feet (1st, 4th, 5th, 6th and 9th) are the most typical sites for foot ulceration in patients with T2DM as shown (Figure 3).[40] Since 25% of patients with T2DM in the current study showed impaired sensation, appropriate advice on preventive foot care should be given to this community population. This is required as these patients with impaired sensation are more prone to injury, which can lead to foot ulceration and amputation. Furthermore, in Sri Lanka, many patients with T2DM do not wear footwear at home. Thus, when sensation of the feet is impaired, injuries to the feet might be not observed and easily neglected. Therefore, it is essential that all T2DM patients be advised to wear footwear at all times at home or outdoors.

CONCLUSION

In this study, poor long-term glycemic control as determined by the HbA1c was observed in 75.6% of the population. Poor short-term glycemic control as measured by FBS was seen in 52.4% of the population. Both the FBS and HbA1c indicate that glycemic control is poor amongst this population. Therefore, urgent measures to attain glycemic control should be implemented in this population. Moreover, the prevalence of DPN is observed in 17.6% of the population. However, early DPN was observed in 48.4% as determined by at least two positive tests among MNSIQ, MNSIE and 10g monofilament test. It is a major cause for concern in this group of patients with uncomplicated T2DM attending community diabetic clinics**.** Furthermore, the results of monofilament test sites showed absent sensation in most common sites of foot ulceration in considerably high number of T2DM patients indicating the risk of foot ulceration among this population. Thus, glycemic control should be attained to prevent further progression of DPN. All the above essential measures were found sadly lacking in the current study indicting the urgent need for them in prevention against DPN. Urgent measures to overcome this progression should be implemented by proper dietary habits, proper foot care measures, regular exercise, and glycemic control.

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