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ORIGINAL ARTICLE

The proportion of undiagnosed diabetic peripheral neuropathy and its associated factors among patients with T2DM attending urban health clinics in Selangor

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Abstract

Introduction: Diabetic Peripheral Neuropathy (DPN), the most common complication of Diabetes Mellitus (DM), is often under-diagnosed and inadequately treated. This study identified the proportion of undiagnosed DPN and its associated risk factors among patients with established type 2 DM (T2DM) in community health clinics in the Gombak district.

Methods: A cross-sectional study was conducted in 2 community health clinics within the Gombak district between September and December 2017. Adults with T2DM were selected via systematic random sampling and screened using the Neuropathy Symptoms Score (NSS). Clinical records of participants' foot examinations were reviewed to identify positive findings of DPN and compared with the NSS.

Results: The study's sample comprised 425 patients. Most had co-morbidities, including hypertension, dyslipidaemia and pre-existing DM-related complications. About two-thirds of them performed no daily foot inspection and had no proper footwear. The proportion of patients with positive NSS was 49.4%. However, only 0.2% were diagnosed with positive DPN in their clinical foot examination record.

Conclusion: Although a positive NSS was identified in 1 out of 2 patients with established DM, only 0.2% of patients had DPN on their examination records. Most patients had never done daily foot inspections and lacked proper footwear. A positive NSS was associated with uncontrolled diabetes and lower BMI. Proper screening and examination for patients, especially those with uncontrolled diabetes and low BMI, is crucial in identifying DPN to ensure that these diabetic patients receive better preventative care, especially proper foot care and strict diabetic control, to prevent DPN-related complications.

Introduction

The World Health Organization has reported that about 422 million people worldwide have diabetes as of date. Moreover, the prevalence of this disease has been increasing over the past 3 decades.[1]

The National Health and Morbidity Survey 2019 revealed that the prevalence of diabetes in Malaysia has increased in recent years from 11.2% in 2011 to 18.3% in 2019.[1] According to the International Diabetes Federation, the prevalence of diabetes among Malaysian adults reached 16.8% in 2020.[2] Treatment for diabetes and its complications are costly, calculated to be at 5.6% of health GDP in 2013 in Malaysia.[3]

Diabetic peripheral neuropathy (DPN) is the commonest long-term complication, affecting an estimated 78.5% of diabetic patients[4]; moreover, its prevalence increases with the duration of diabetes. DPN is symmetric and predominantly sensory, starting distally and gradually spreading proximally in a glove-and-stocking distribution pattern. It causes substantial morbidity and increased mortality. DPN often leads to many hospitalisations and 50-75% of non-traumatic amputations, resulting in low quality of life[5,6] and an enormous economic burden.

DPN is often misdiagnosed and inadequately treated despite the implementation of foot screening programmes among diabetic patients, possibly due to the failure of physicians to diagnose DPN when using perception alone

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(instead of using a diagnostic tool).[7] Failure to diagnose DPN early leads to challenging complications, for example, neuropathic pain and diabetic foot ulcers.

This study aimed to identify the proportion of patients with DPN symptoms and associated factors among T2DM patients using the Neuropathy Symptom Score (NSS) questionnaire. Thus, this study provides the potential missed diagnosis of DPN and its associated factors, in turn helping clinicians to identify patients at risk of DPN. The recognition of a potential missed diagnosis is crucial since appropriate management following a diagnosis of DPN can prevent further complications.

Methods

This cross-sectional study was conducted on type-2 diabetes mellitus (T2DM) patients who attended diabetic follow-up appointments in 2 urban health clinics (KK Taman Ehsan and KK Hulu Kelang) in the Gombak district from September to December 2017. These clinics had a high prevalence of diabetic patients undergoing regular follow-up checks. A pilot study that was conducted yielded good outcomes. Participants were recruited via a systematic random sampling method. The first participant was selected randomly using the dice method; subsequently, every second patient from the registry who fulfilled the inclusion criteria were selected to participate in the study until the target number of samples was reached. Those who met the inclusion criteria were Malaysian citizens more than 18 years old with >5 years' history of T2DM. Patients with T2DM duration <5 years and/or who had pre-existing DPN were excluded from the study. The sample size of 425 participants was calculated using StatCalc Epi Info 7 while considering a 20% dropout rate. The study's response rate was 100%. Informed consent was collected before each interview.

A questionnaire guided the participants' interviews. Part 1 of the questionnaire collected details regarding their social demographic data, smoking status, alcohol intake, physical activity, footwear choices and performance of daily foot inspections. Participants were interviewed in person by researchers who were trained before starting data collection in both clinics.

Part 2 of the questionnaire, with results obtained from the patients' medical records, explored the clinical characteristics of the participants, including weight, height, blood pressure, latest fasting/random blood sugar, HbA1c, clinical history and list of medications.

Part 3 involved the use of the NSS questionnaire, a validated instrument used to aid in the diagnosis of DPN. The NSS has 82% sensitivity (indicating positive predictive value) and 67% specificity (referring to negative predictive value).[8] This tool was verified in a multicentre study in 118 UK hospitals in 1993,[8] where the NSS was combined with the neuropathy disability score (NDS) to establish the prevalence of DPN. The same tool was also used in a study conducted in 1998-1999 in a primary care clinic at UM hospital and Hospital Kuala Lumpur.[9]

Table 1. Neuropathy Symptom Score

Neuropathic Symptoms	Scores
1. Burning/ Numbness/ Tingling Fatigue/Cramping/Aching None of the above symptoms	2 1 0
2. Symptoms present in feet Symptoms present in calves Symptoms present elsewhere	2 1 0
3. Nocturnal exacerbation of symptoms Symptoms present day and night Symptoms present during daytime only	2 1 0
4. Symptoms wake patient up from sleep	1
5. Manoeuvres to reduce symptoms Walking Standing Siting/lying	 2 1 0
Total Score	

Note: Mild symptoms 3-4, Moderate symptoms 5-6, Severe symptoms 7-9

The presence of any symptoms was considered as a positive NSS indicating the probable presence of DPN.[9]

Part 4 of the questionnaire involved reviewing the clinical records of participants who had undergone foot examinations to identify positive findings of DPN.

The data were analysed using SPSS 25.0. Descriptive analysis was performed, and continuous variables were presented in terms of mean and standard deviation, while categorical data were presented in the form of numbers and percentages. The association of factors with a positive NSS was done using a chi-square test. P value<0.05 was considered statistically significant. Lastly, this study was approved by the Medical Research and Ethics Committee, NMRR-17-1065-35860 (IIR).

Results

In total, 425 diabetic patients were recruited for this study. The overall proportion of patients with a positive NSS was found to be 49.4%. As can be seen in **Table 2**, the sample population consisted largely of females >60 years old (66.8%). They mainly represented Malay (40%) and Chinese (44.9%) ethnicities and came from a low socioeconomic group (56.9%).

Most of the participants were non-smokers (87.3%), non-alcohol consumers (89.9%) and physically active (53.6%). More than half of them did not use proper footwear (60.5%) and did not perform a daily foot inspection (57.9%).

Table 2. Social Demographic Data of Patients

Demographic Data	N	%
Age		
<60 years old	141	33.2
>60 years old	284	66.8
Gender		
Male	141	33.2
Female	284	66.8
Ethnicity		
Malay	170	40
Chinese	191	44.9
Indian	64	15.1
Occupation		
Employed	114	26.8
Unemployed	311	73.2
Education level		
None	26	6.1
Primary	152	35.8
Secondary	216	50.8
Tertiary	31	7.3
Household income		
< RM1000/month	242	56.9
RM1001-3000/month	127	29.9
RM3001-6000/month	44	10.4
> RM6000/month	12	2.8
Marital status		
Single	15	3.5
Married	395	92.9
Others	15	3.5
Smoking status		
Smoker	54	12.7
Non-smoker	371	87.3
Alcohol status		
Alcohol drinker	43	10.1
Non-alcohol drinker	382	89.9
Physical activity		
Physically active	228	53.6
Physically inactive	197	46.4
Footwear		
Proper shoes	168	39.5
Improper shoes	257	60.5
Daily foot inspection		
Done	179	42.1
Not done	246	57.9

Table 3 reveals that the sample population consisted of patients with multiple co-morbidities, including hypertension (90.4%), dyslipidaemia (81.6%), overweight (83.3%) and pre-existing complications of diabetes (81.6%).

Table 2. Clinical Characteristics of Participants

Clinical characteristics	N	%
Family history of DM		
Yes	201	47.3
No	224	52.7
Hypertension (on antihypertensive medication)		
Yes	384	90.4
No	41	9.6
Dyslipidaemia (on lipid-lowering medication)		
Yes	347	81.6
No	78	18.4
Pre-existing DM complications (diagnosed retinopathy/ polyneuropathy/nephropathy)		
Yes	82	81.6
No	343	18.4
Blood pressure (<140/80)		
Controlled	185	43.5
Uncontrolled	240	56.5
Annual foot examination		
Done	411	96.7
Not done	14	3.3
Antidiabetic agent		
Monotherapy	85	20.0
Combination	158	37.2
Insulin	182	42.8
HbA1c		
<6.49 %	99	23.3
>6.5%	326	76.7
BMI		
<23kg/m2	71	16.7
>23kg/m2	354	83.3
Diabetic duration		
5-10 years	260	61.2
>10 years	165	38.8

Table 4 displays the sample population's NSS-related factors. A positive NSS was found to be associated with a higher HbA1c level P =0.041) and lower BMI (P =0.039). However, a positive NSS was not found to be associated with other social demographic factors, as shown in the table

Table 4. Factors associated with Positive NSS

Variable	NSS negative N(%)	NSS positive N(%)	*P* value
Age			0.45
<60 years old	75 (34.9)	66 (31.4)	
>60 years old	140 (65.15)	144 (68.6)	
Gender			0.09
Male	97 (45.1)	78 (37.1)	
Female	118 (54.9)	132 (62.9)	
Ethnicity			0.62
Malay	86 (40)	84 (40)	
Chinese	100 (46.5)	91 (43.3)	
Indian	29 (13.5)	35 (16.7)	
Education level			0.73
None	15 (7.0)	11 (5.2)	
Primary	72 (33.5)	80 (38.1)	
Secondary	112 (52.1)	104 (49.5)	
Tertiary	16 (7.4)	15 (7.1)	
Occupation			0.16
Employed	64 (29.8)	50 (23.8)	
Unemployed	151 (70.2)	160 (76.2)	

Variable	NSS negative N(%)	NSS positive N(%)	*P* value
Household income			0.94
< RM1000/month	122 (56.7)	120 (57.1)	
RM1001-3000/month	63 (29.3)	64 (30.5)	
RM3001-6000/month	23 (10.7)	21 (10.0)	
> RM6000/month	7 (3.3)	5 (2.4)	
Marital status			0.48
Single	6 (2.8)	9 (4.3)	
Married	203 (94.4)	192 (91.4)	
Others	6 (2.8)	9 (4.3)	
Smoking status			0.17
Smoker	32 (14.9)	22 (10.5)	
Non-smoker	183 (85.1)	188 (89.5)	
Alcohol status			0.94
Alcohol drinker	22 (10.2)	21 (10.0)	
Non-alcohol drinker	193 (89.8)	189 (90.0)	
Physical activity			0.79
Physically active	114 (53)	114 (54.3)	
Physically inactive	101 (47)	96 (45.7)	
Footwear			0.43
Proper shoes	81 (37.7)	87 (41.4)	
Improper shoes	134 (62.3)	123 (58.6)	
Daily foot inspection			0.61
Done	88 (40.9)	91 (43.3)	
Not done	127 (59.1	119 (56.7)	
Family history of DM			0.895
Yes	101 (47)	100 (47.6)	
No	112 (53)	110 (52.4)	
Hypertension			0.567
Yes	196 (91.2)	188 (89.5)	
No	19 (8.8)	22 (10.5)	
Dyslipidaemia			0.059
Yes	168 (78.15)	179 (85.2)	
No	47 (21.9)	31 (14.8)	
Pre-existing DM complications			0.111
Yes	35 (16.3)	47 (22.4)	
No	180 (83.7)	163 (77.6)	
Blood pressure			0.197
Controlled	87 (40.5)	98 (46.7)	
Uncontrolled	128 (59.5)	112 (53.3)	
Annual foot examination			0.964
Done	208 (96.7)	203 (96.7)	
Not done	7 (3.3)	7 (3.3)	
Antidiabetic agent			0.092
Monotherapy	46 (21.4)	39 (18.6)	
Combination	88 (40.9)	70 (3.3)	
Insulin	81 (37.7)	101 (48.1)	
HbA1c			0.041*
<6.49%	59 (27.4)	40 (19)	
>6.5%	156 (72.6)	170 (81)	
BMI			0.039*
<23kg/m^2	28 (13)	43 (20.5)	
>23kg/m^2	187 (87)	167 (79.5)	
DM duration			0.059
<10 years	141 (65.6)	119 (56.7)	
>10 years	74 (34.4)	91 (43.3)	

*A chi-square test was used to test the association of factors with a positive NSS.

The significant associated factors were identified from $P<0.05$.

We found that 210 patients had symptoms of DPN; hence, we considered these individuals NSS positive in varying degrees of severity. Table 5 depicts severity scores reported by patients with a positive NSS.

Table 5. NSS Severity Reported by Patients

NSS severity (Score ranges)	Number of patients
None (0)	215
Symptom present (1-2)	7
Mild (3-4)	59
Moderate (5-6)	86
Severe (7-9)	58

A comparison was made between a positive NSS and positive clinical foot examination findings. Out of all participants, 14 patients (3.3%) were missing data on the clinical foot examination record. Nevertheless, the remaining results revealed that only 0.2% (n=8) of the patients were diagnosed with a positive clinical foot examination, compared to a positive NSS of 49.4%. The discrepancy between these 2 values was 49.2%.

Discussion

This study's findings demonstrated that 49.4% of the patients examined had a positive NSS. Moreover, a significant association of a positive NSS with higher HbA1c level and lower BMI emerged in the results.

Out of all our studied patients, 61.2% had been diagnosed with DM within 5-10 years and 96.7% had annual foot examinations done. However, their HbA1c was largely not optimised, with 76.7% of them having HbA1c>6.5%. Insulin usage was 42.8%. The latest Malaysian CPG T2DM has recommended an individualised HbA1c target; hence, a less stringent HbA1c target for many of our study participants who are in the age range > 60 years old should be considered.

A positive NSS result was seen in almost half of the patients. A previous local study reported similar findings, showing a 50.7% prevalence of DPN using the same NSS and NDS scores.[9] The reports of other studies regarding variations in the prevalence of DPN from 29.1%[10] to 56.2%[9,11,12] are probably due to using different criteria and scoring systems to diagnose DPN (for example, a translated version of the Michigan Neuropathy Screening Instrument). The gold standard of diagnosis for DPN is a nerve conduction study, which is scarce and costly.

In this study, a positive NSS was associated with a higher HbA1c. The high prevalence of DPN could be due to a higher percentage of patients (81%) who had poorly controlled diabetes with HbA1c>6.5% (P<0.041). This finding correlates with UK diabetes studies that have suggested improved glycaemic control is likely to prevent or delay DPN.[13] The development of diabetic neuropathy is also associated with a number of modifiable and non-modifiable risk factors, such as hypertension, dyslipidaemia, obesity, cigarette smoking and alcohol consumption. However, these factors were not significant in our study.

We found a significant association between a lower BMI and a positive NSS (P<0.039). Similar findings were reported in an African study that found a higher proportion of DPN among underweight and morbidly obese participants[14]. Although the finding was not significant, the researchers observed a trend where patients on insulin therapy had a higher percentage of DPN. Exogenous insulin use in T2DM might reflect an advanced stage in the natural progression of diabetes and could be associated with DPN.

Our study found that 56.7% of respondents with a positive NSS was found in individuals diagnosed with diabetes within the previous 5-10 years. This late diagnosis of diabetes could be explained by a late presentation, poor awareness of diabetes symptoms or not performing regular health screenings. Hence, more health screening campaigns should be implemented in adults above age 30, along with close follow-up on high-risk patients. Frequent audits and taking relevant remedial actions in medical practices would contribute to improving the standard of care for all diabetic patients.

Our study did not show a significant association between patients' demographic factors with the presence of DPN. Factors (such as age and DM duration) were not found to have significant associations with DPN in comparison to a Malaysian study done at a university.[8] This contrasting result could be due to differences in variables' cut-off point. As another possibility, some older adults may

attribute DPN symptoms to normal ageing. Regardless, raising diabetic patients' awareness of DPN symptoms is vital to enable the early detection of DPN.

Gender and ethnicity were not found to be strongly associated with the presence of DPN in our study. In contrast, another study done in California did show a statistically significant difference in DPN onset between genders, where males were shown to have a higher risk of foot ulcerations.[15] This difference in study results could be related to a higher proportion of female than male participants in our study. Nevertheless, all diabetic patients with DPN should be managed aggressively to prevent foot ulcerations and possible amputations.

For diabetic patients experiencing the complication of DPN, lifestyle modifications are essential. Although our study did not find any association between DPN and factors such as smoking, physical inactivity and alcohol intake, other studies have reported contrasting results. For example, a study set in Scotland[16] showed a higher prevalence of DPN in excessive alcohol (>3 alcoholic beverages) consumers. In the same vein, a Jordanian study found that patients who exercised moderately were at less risk for DPN.[10] The poor association linking DPN with smoking and alcohol intake in our study could reflect the lower percentage of smokers and alcohol consumers among our studied populations.

Another vital lifestyle modification demanding attention is the usage of proper footwear among diabetic patients. Our study showed that only 39.5% of patients wore suitable shoes, and only 42.1% performed a daily foot inspection. Improper footwear predisposes these patients to foot ulcerations, especially among those with DPN.[17] These figures underline the urgent need on wearing appropriate footwear and regular checking of their feet.

This study has several strengths. Using the NSS questionnaire to diagnose DPN was effective as well as less costly than conducting a nerve conduction study, which is not widely available. According to the data we collected, a positive NSS is almost equivalent in diagnosing probable DPN. The prevalence reported using the NSS was similar to that found in a Malaysia UM study that used NSS and NDS scoring.[8] We were also able to find a discrepancy between a positive NSS and clinical foot examination records among our patients (49.2%). Routine foot examinations did not detect most DPN, likely due to under-diagnosis of DPN during a routine clinical foot exam. The NDS information was taken from the clinical records. Even though 93% of the respondents had an annual foot exam, half of them were not detected as having DPN. Due to highly subjective nature of neurological examinations, foot examinations done by different healthcare providers might have been inconsistent.

This study also has various limitations. For example, as a cross-sectional study, this investigation did not assess the dynamic of the relationship between the variables evaluated. The studied population were limited to only 2 community clinics and may not represent diabetic patients from other settings, such as private clinics. Variations in a patient's response to the NSS questionnaire might have introduced potential bias. Furthermore, the NSS symptoms were non-specific and could have been caused by some other non-DM polyneuropathy. The scoring system also did not take into account the frequency of symptoms. Lastly, we did not examine differences in findings according to different HbA1c targets.

Conclusion

This study identified a high proportion of diabetic patients with a positive NSS. It revealed weaknesses in the early detection of DPN, especially in those with lower BMI, indicating advanced diabetes. The mismatch of positive DPN between using NSS questionnaires in this study and the medical records highlights the need to raise awareness and provide training for healthcare providers. The possibility of poor documentation in the patient's medical record also exists. According to the results of this study, implementing NSS in busy primary care clinics can be recommended, owing to its simplicity and low cost.

Recommendations

A focused, structured diabetes management programme should be implemented in all community health clinics. Currently, many obstacles stand in the way of optimising diabetes management in clinics, including treatment inertia, low patient acceptance, non-adherence to medications and inexperienced clinicians who are managing these patients. For example, compulsory annual foot examinations were incomplete.

The NSS offers a quick screening method for DPN among patients with diabetes as well as a cost-effective approach when used in the primary care setting. A team-based system is needed, where all healthcare workers involved should receive adequate training in using this tool. Additionally, a regular audit should be carried out to ensure that foot examinations are done properly and timely. Campaigns concerning DPN can also be carried out regularly to raise awareness among diabetic patients. Lifestyle and behavioural changes should be emphasised, especially in terms of healthy eating, regular exercise and proper foot care to prevent development and delay progression of DPN. Posters on diabetic foot complications and examples of suitable footwear can be displayed in waiting areas during diabetic follow-up. All of these efforts can contribute to detecting and managing DPN more effectively, benefiting a broad population of present and future diabetic patients.

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Conflicts of interest

The authors declare that they have no competing interests in the publication of this article.

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