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Research Article

The Prevalence and Associations of Diabetes Peripheral Neuropathy Among Diabetic Patients Registered in Medical Clinics at the National Hospital of Sri Lanka

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Abstract

Introduction: Diabetic peripheral neuropathy (DPN) is the most common complication of diabetes, affecting up to 50%. DPN is associated with foot ulcers which can result in amputations. Early diagnosis is the key strategy to prevent foot ulcers.

Objective: This study aimed to determine the prevalence of DPN and its associated factors among patients with Diabetes mellitus (DM) registered in medical clinics at the National Hospital of Sri Lanka.

Methodology: This was a descriptive cross-sectional clinic-based study. We randomly selected 280 participants with diabetes. Michigan Neuropathy Screening Instrument (MNSI) was used to screen for DPN. MNSI is a simple validated clinical tool consisting of two parts: MNSI symptom score and MNSI examination score. An MNSI examination score of > 2 was taken as the cut-off point for defining DPN, which was 80% sensitive and 95% specific.

Results: Females were the majority (62.5%, n= 280). The mean age was 58.6 years, and the mean duration of diabetes was 8.6 years. Type 2 diabetes was the vast majority (96.1%). 120 patients (42.9%) had DPN according to the MNSI examination score. However, only 59 patients (21.1%) were diagnosed as having DPN. There was no significant difference in the incidence of DPN among different ethnic groups. However, the duration of diabetes was very significantly associated with DPN (p =0.001). Only 14 patients (5%) had an MNSI symptom score of 7 or more, but all of them had DPN (MNSI examination score > 2). The most common symptom was numbness of the feet (n=95); the sign was reduced vibration sensation (n=101, 36.07%). Nevertheless, a significant number of patients (26.3%) with feet numbness,36.7% with burning pain in the feet, and 26.7% with prickling sensation in the leg did not have DPN (MNSI examination score < 2). Conversely, 34 patients (28.3%) with DPN were asymptomatic There were 8 (0.03%) patients with leg ulcers, 7 of whom had DPN. The most common comorbidity in this study group was hypertension (n=205, 73.2%). Peripheral vascular disease (p=0.011) and retinopathy (p=0.016) were significantly associated with DPN.

Conclusion: DPN is a common and important complication of diabetes, however, a significant percentage of patients with DPN were not diagnosed at clinics. Many patients with DPN had no symptoms, therefore symptomatology in DPN is not a reliable clue to the diagnosis. Consequently, we reiterate the importance of annual assessment using a simple screening tool such as the MNSI examination score in patients with diabetes.

Keywords: Diabetic peripheral neuropathy, Michigan Neuropathy Screening Instrument

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Introduction

Diabetes mellitus (DM) is a major healthcare problem around the world. Type 2 DM is now found in almost every population, and epidemiological evidence suggests that, without effective prevention and control programs, its prevalence will continue to rise globally [1]. Sri Lanka is no exception to this rule; in fact, the prevalence of DM in Sri Lanka is up to 15% [2]. Neuropathy is the most common complication of DM, affecting up to 50% of patients with type 1 and type 2 DM [3]. The symptoms of diabetic neuropathy can be significantly troublesome, more importantly, neuropathy is associated with foot ulcers, which can lead to amputations. Early diagnosis and proper patient education are necessary to prevent foot ulcers. The screening for neuropathy should be done at diagnosis and annually thereafter by using simple clinical tests such as a pinprick, vibration sensation using a tuning fork, monofilament test, and ankle reflex [4]. The loss of monofilament sensation and reduced vibration sense predict foot ulcers [4]. Active surveillance is important as diabetic peripheral neuropathy (DPN) is asymptomatic in up to 50% of patients [4].

A community study performed in Sri Lanka reports a DPN prevalence of 24% [5]. However, the National Hospital Sri Lanka (NHSL) manages the most complicated patients as a tertiary care referral centre. Therefore, the prevalence of DPN may even be higher than that reported by the above study. Thus, the present study was designed to determine the prevalence of DPN among patients followed up at the National Hospital, Sri Lanka, so that early therapeutic interventions and preventive measures can be implemented to prevent later complications of neuropathy, such as foot ulcers, amputations, and infections. American Diabetes Association (ADA) guidelines recommend regular screening for neuropathy at diagnosis and annually thereafter using simple clinical tests [4]. Electrophysiological tests are rarely necessary, except when clinical features are atypical [4]. Therefore, we selected the Michigan Neuropathy Screening Instrument (MNSI), a simple clinical tool that can be used as a screening test to diagnose DPN. The MNSI consists of a 15-item questionnaire and a structured examination, a validated clinical instrument to diagnose DPN [6, 7].

This study aimed to determine the prevalence of DPN and its associated factors among patients with DM registered in medical clinics at the National Hospital of Sri Lanka.

Methodology

Study design and sampling

This descriptive clinic-based study was done in the general medical clinics at the National Hospital, Colombo, Sri Lanka. Data was collected for a month from 1st August 2013. Two hundred and eighty patients with DM were recruited for this study using a stratified random sampling method. Patients with a known other cause for peripheral neuropathy (neuropathies due to vitamin deficiency, infections, connective tissue disorders, malignancy, and medications), those who have undergone lower limb amputations, and subjects with previous lower limb deformities due to any other causes were excluded from the study.

Study instruments and data collection

An interviewer-administered questionnaire comprising three parts was used. Part A included socio-demographic data, Part B had details about other co-morbid conditions, and Part C contained the MNSI. However, question number 7 in the symptom score section of the tool was modified to suit Sri Lankan culture. MNSI examination score of more than 2 was taken as the cut-off point to define the presence of DPN [6,7], which is 80% sensitive and 95% specific [6]. An MNSI symptom score of ≥ 7 has been suggested as abnormal in a study conducted in persons with type 1 DM [8]. However, when combined with the MNSI examination score, the MNSI symptom score did not further improve the DPN diagnosis, emphasizing the significance of the examination score [6]. Further, misleading information has been reported with the MNSI symptom score [9].

Each patient included in the study was interviewed by an experienced postgraduate trainee in medicine. Medical history was elicited, and previous medical records were examined to collect clinical data.

General information and details of disease-related complications were documented using parts A and B of the questionnaire. Each patient was interviewed to complete the MNSI symptom score. Foot inspection, vibration sense using a 128Hz tuning fork, monofilament test, and ankle jerk were performed to complete the MNSI examination score. Tamil-speaking patients were interviewed by a postgraduate trainee in medicine fluent in the Tamil language. Instructions about the questionnaire were given to the data collectors; consensus was reached regarding the time taken to administer the questionnaire and clarification. Responses to the questionnaire were added to obtain the total score. Responses of "yes" to items 1-3, 5-6, 8-9, 11-12, 14-15 were each counted as one point. A "no" response on items 7 and 13 counted as 1 point. Item 4 was a measure of impaired circulation, and item 10 was a measure of general asthenia, were not included in the scoring. The physical assessment was done as follows.

Foot Inspection:
The feet were inspected for evidence of excessively dry skin, callous formation, fissures, ulceration, or deformities.

Vibration sensation:
Vibration sensation was tested bilaterally using a 128 Hz tuning fork placed over the dorsum of the great toe. Participants, whose eyes were closed, were asked to indicate when they could no longer sense the vibration from the vibrating tuning fork. In general, the examiner should be able to feel the vibration from the hand-held tuning fork for 5 seconds longer on his distal forefinger than a normal subject could at the great toe. The vibration was considered normally present if the examiner felt a vibration on his finger for 10 seconds or less after the patient reported that the vibration at the toe had stopped. The vibration was considered reduced if the examiner felt the vibration for more than 10 seconds after the patient ceased to feel the vibration. Vibration was absent if the patient did not perceive with the tuning fork.

Muscle Stretch Reflexes:
If the reflex was obtained, it was graded as present. If the reflex was absent, the test was repeated after reinforcement. Reflexes elicited with the reinforcement were designated "present with reinforcement." If the reflex was absent, even after reinforcement, the reflex was considered absent.

Monofilament Testing:
The filament was applied perpendicularly and briefly (1-2 seconds) with an even pressure, which is enough to bend it. When the filament bends, a force of 10 grams is applied. The patient, whose eyes were closed, was asked to respond yes if he or she felt the filament. Eight correct responses out of 10 applications were considered normal, one to seven correct responses indicated reduced sensation, and no correct answers translated into absent sensation. How points were given for clinical examination is detailed in Appendix A.

Data analysis
Data was analyzed using the SPSS 20 package. Socio-demographic characteristics and disease characteristics were described using descriptive statistics. Chi-square statistics were used to look for associations of DPN. A p-value of less than 0.05 was considered significant.

Definitions
Coronary artery disease (CAD) was defined as the presence of a history of typical angina, myocardial infarction, or coronary artery bypass graft, and cerebrovascular disease (CVD) as the presence of a history of transient ischaemic attack (TIA) or a stroke. Patients were considered to have peripheral vascular disease (PVD) if they had a history of intermittent claudication or gangrene. Nephropathy (DN) was diagnosed when they had either micro or macroalbuminuria or eGFR< 60mL/min/1.73m2. Having an LDL cholesterol concentration > 100mg/dL or being on lipid-lowering medications was taken as dyslipidaemia (DL). Diabetic retinopathy (DR) was defined as having either pre-proliferative or proliferative retinopathy or a history of laser treatment.

Results

Two hundred eighty patients were recruited for the study, of which 62.5% were females. The mean age was 58.6 years, and the mean duration of diabetes was 8.6 years. The study group was predominantly comprised of patients with type 2 DM (96.1%). There were 9 (3.2%) patients with type 1 DM, however, only 2 (0.7%) patients had secondary DM. Most patients (65.4%) had only primary education, and about 50% had a low income of less than 20,000 Sri Lankan rupees (Table 1).

Table 1. Demographic characteristics of the study population.

Variable		Number (%)
Sex	Male	105 (37.5)
	Female	175 (62.5)
Type	Type 1 DM	9 (3.2)
	Type 2 DM	269 (96.1)
	Secondary DM	2 (0.7)
Education	Primary	183 (65.4)
	Secondary	96 (34.2)
	Tertiary	01 (0.4)
Income	< LKR 20000	144 (51.4)
	LKR 20000 – 40000	132 (47.2)
	>LKR 40000	4 (1.4)

One hundred twenty patients (42.9%) had an MNSI examination score of more than 2, and they were considered to have DPN. According to the defined cut-off of the MNSI examination score, 40% of females (n=70) and 47.6% of males (n=50) were found to have DPN (Table 2).

However, according to the clinical records, only 59 patients (21.1%) were diagnosed as having DPN. Two-thirds of patients with DPN had an age range of 51 to 70 years, and more than 50% of patients with an age of over 70 years had neuropathy. The prevalence of DPN among Sinhalese, Muslim, and Tamil patients was 42.85%, 39.62%, and 45.94%, respectively. However, there was no statistically significant difference among ethnic groups (p=0.636). DPN was more common in patients with only primary education (58/115, 50.43%) than in those with secondary education (61/164, 37.19%), respective values were 50.43% and 37.19% (Chi-square, p=0.046). Nevertheless, other sociodemographic factors did not show a statistically significant difference in the prevalence of DPN.

Our study group was predominantly comprised of patients with type 2 diabetes (96.1%), and there was no statistically significant difference in the incidence of DPN among subtypes of diabetes. However, the duration of diabetes was very significantly associated with DPN (p =0.001).

Only 14 patients (5%) had an MNSI symptom score (MNSI symptom score) of more than 7, but all of them had DPN (MNSI examination score > 2). The most common symptom was numbness of the feet (33.9%), followed by burning pain in the feet (31.1%) and prickling pain in the legs (25.4%). Nevertheless, a significant number of patients (26.3%) with foot numbness,36.7% with burning pain in the feet, and 26.7% with prickling sensation in the leg did not have DPN (MNSI examination score < 2). Conversely, 34 patients (28.3%) with DPN were asymptomatic (symptom score =0). Approximately 1/3 of patients without neuropathy had a symptom score of up to 6. The commonest physical sign was absent or reduced vibration sensation (36.07%), followed by an abnormal monofilament test (31.07%). There were 8 (0.03%) patients with leg ulcers, 7 of whom had DPN.

Table 2: The relationship between DPN, duration, type of DM, and demographic characteristics

Variable	Neuropathy Present	Neuropathy Absent	X^2	P
Type				
Type 1	1	8		
Type 2	118	151	3.85	0.145
Secondary DM	1	1		
Duration (yrs)				
<1	4(30.7%)	9(69.3%)		
1-5	23(27.7%)	60(72.3%)		
5-10	41(48.2%)	44(51.8%)	21.67	**0.001**
10-15	23(42.6%)	31(57.4%)		
15-20	13(52.0%)	12(48.0%)		
>20	16(80.0%)	04(20.0%)		
Age (yrs)				
21-40	2	2		
41-60	18	29	0.56	0.754
>60	90	127		
Gender				
Male	50	55	1.55	0.212
Female	70	105		
Ethnicity				
Sinhala	81	108		
Muslim	21	32	1.70	0.636
Tamil	17	20		
Education				
Primary	58	57		
Secondary	61	103	6.17	**0.046**
Tertiary	01	0		

The most common comorbidity in this sample was hypertension (n=205, 73.2%), followed by DL (n=165, 58.9%) and CAD (n=115, 41.1%). According to the above data,116 (41.4%) patients and 20 patients (7.1%) were not screened for DN and DL respectively (Table 3). Further, 87.6% of patients who were not screened for DN and all of those who were not screened for DL had a lower income (< LKR 30,000). Therefore, it is likely that those patients could not spend money on the urine protein

creatinine ratio and lipid profile. Both these tests were unavailable in the National Hospital of Sri Lanka during the study period. However, another significant proportion of patients (n=64, 22.9%) had not been screened for diabetic retinopathy, a free service at the National Eye Hospital. Fifty-four per cent of those who were not screened for retinopathy had diabetes for over 5 years, and 27% had diabetes for over 10 years. Out of comorbidities, PVD (p=0.011) and DR (p=0.016) were significantly associated with DPN (Table 4).

Table 3. Comorbidities of the study group.

Comorbidity	Absent	Present	Not screened
Diabetic retinopathy	153 (54.6%)	63 (22.5%)	64 (22.9%)
Diabetic neuropathy	79 (28.2%)	85 (30.4%)	116(41.4%)
Coronary artery disease	165 (58.9%)	115 (41.1%)	
Cerebrovascular disease	252 (90%)	28 (10%)	
Peripheral vascular disease	241 (86.1%)	39 (13.9%)	
Hypertension	75 (26.8%)	205 (73.2%)	
Dyslipidaemia	95 (33.4%)	165 (58.9%)	20(7.1%)

Table 4: The relationship between comorbidities and DPN.

Variable (comorbidity)	Neuropathy		X^2	P
	Absent	Present		
Coronary artery disease	61	54	1.339	0.247
No Coronary artery disease	99	66		
Cerebrovascular disease	13	15	1.458	0.227
No cerebrovascular disease	147	105		
Peripheral vascular disease	15	24	6.457	**0.011**
No peripheral vascular disease	145	96		
Diabetic neuropathy	46	37	1.493	0.222
No diabetic neuropathy	54	25		
Diabetic retinopathy	26	37	10.279	**0.016**
No diabetic retinopathy	98	55		
Hypertension	111	94	2.806	0.094
No Hypertension	49	26		
Dyslipidaemia	92	73	0.483	0.785
No dyslipidaemia	57	38		

Discussion

This study was carried out to determine the prevalence of DPN and its associated factors among patients with DM registered in medical clinics at the National Hospital of Sri Lanka. Two hundred eighty patients were studied using an interviewer-administered questionnaire and physical examinations. We used the MNSI to screen the patients.

According to defined criteria, the overall prevalence of DPN in our study was 42.9%, which was higher than that reported by some European clinic-based studies. A study in Italy reported a prevalence of 32.3% [10], whereas a similar study conducted across 16 countries in Europe reported a prevalence of 28% [11]. However, the above two studies used slightly different criteria to diagnose DPN. Another clinic-based study done in Turkey [9] used MNSI to diagnose DPN, which reported a DPN prevalence of 40.4%, which was comparable to the prevalence of DPN in our study. Therefore, the difference in the prevalence of DPN between our study and some European countries may be attributed to the use of slightly different diagnostic criteria in those studies. However, there may be many reasons for this difference, like the duration of DM, the level of glycaemic control, and ethnic differences. Although a community-based study done in Sri Lanka reported a DPN prevalence of 24%, a higher prevalence can be expected among clinic patients from a tertiary care centre.

Our study found no significant sex difference in the prevalence of DPN, which was consistent with previous studies done in Europe [11] and Asia [12]. Furthermore, the latter study found that DPN was more common in individuals with lower incomes; this finding was also reported in a community-based study conducted in Sri Lanka [5]. A possible explanation for this disparity is that individuals from low-income backgrounds are less likely

to access healthcare services, which can result in delayed diagnoses and a higher risk of complications at the time of diagnosis [5]. However, we could not say if there was a difference in glycaemic control between those two groups as HbA1C was not available for the vast majority. Our study also revealed that the prevalence of DPN was significantly higher in patients with only a primary education. However, 95% of those patients had a lower income, which can explain the difference. The duration of the disease was strongly associated with DPN. This has been reported by previous local and overseas studies [5, 13].

It was found that only 5% of patients had neuropathy when the MNSI symptom score was used to diagnose DPN. This means that 37.9% of patients would go undiagnosed. A study conducted at Michigan University also reported the unreliability of the MNSI symptom score, highlighting the greater importance of the MNSI examination component [6]. The commonest symptom in our study group was numbness of the feet. This was consistent with the findings from a Sri Lankan study [5], but a previous study done in the United Kingdom [13] reported painful neurological symptoms as the most common symptom. The reason for this disparity is not clear, but the longer duration of diabetes in our study group and previous Sri Lankan studies may be a reason, as numbness tends to occur later in the disease. Approximately one-third of our study group had painful neuropathic symptoms. The study done in the United Kingdom reported a similar proportion of painful neuropathic symptoms [13]. Our study also found that approximately one-third of patients with DPN were asymptomatic, which was within the expected value, as up to 50% of patients with DPN can be asymptomatic [4]. Conversely, a similar proportion of patients without neuropathy were symptomatic. This indicates the unreliability of symptoms in either diagnosing or excluding DPN. The commonest abnormal physical sign in our study group was reduced vibration sense. A previous study in Italy reported the same physical sign as the commonest abnormality in patients with DPN [10]. However, the percentage of patients with reduced vibration sense was different, 36% in our study and 59% in the Italian study. The reason for the difference is not clear.

It was observed that a significant percentage of patients with DM were not screened for DN and DL, since they were registered in the clinics. However, the guidelines recommend annual screening [4]. The most likely reason would be the unavailability of these tests in the National Hospital of Sri Lanka during the time of study. The vast majority of patients who were not screened had a lower income; therefore, they would not have been able to pay for these tests from the private sector. However, nearly one-quarter of patients were not screened for DR, though it was a free service offered by the National Eye Hospital of Sri Lanka.

We used Chi-squared statistics to look for associations between comorbidities and DPN. It was found that the presence of DR was significantly associated with DPN. A previous multicentre study in Europe [11] and another study in Turkey [9] had reported a significant association between DR and DPN. The latter study in Turkey used the same diagnostic criteria as ours (MNSI examination score). The reason for this association is not clear. However, this might represent an advanced stage of DM with microvascular complications. We also observed that PVD was significantly associated with DPN. There is only scanty evidence for this association, except for one study [14]. Therefore, further research is necessary to explore this association. Nevertheless, this association is alarming as both increase the risk of foot ulceration. We found no association between DPN and microalbuminuria, even though a previous study had demonstrated a significant association [11]. The reason for the discrepancy is not clear; however, a considerable proportion of patients in our study group had not been screened for microalbuminuria. Therefore, our findings concerning microalbuminuria may be unreliable.

Limitations

Our study had several limitations. We could not assess the impact of glycaemic control on the presence of DPN as HbA1c was not available for most of the patients. A significant number of patients were not screened for some comorbidities; therefore, those were excluded from the analysis. Results would have been different if we had had all the data. We were dependent on medical records and history taking to diagnose some associated conditions; therefore, asymptomatic patients would have been missed, and the reliability of some data depends on the quality of documentation in clinic notes. Further, the exclusion of patients with lower limb amputations for an accurate MNSI examination score, which needs examination of both lower limbs, would have affected the MNSI symptom score.

Conclusions and recommendations

DPN neuropathy is a common and important complication of diabetes; however, a significant percentage of patients with DPN were not diagnosed at the clinics. Many patients with DPN have no symptoms, and symptomatology in DPN is not a reliable clue to the diagnosis. Therefore, we reiterate the importance of

annual assessment using a simple screening tool such as the MNSI examination score in patients with diabetes.

Ethical statement

Ethical clearance for this study was obtained from the ethical review committee of the National Hospital of Sri Lanka. Informed written consent was taken from participants. All data was anonymized and stored securely.

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