

ORIGINAL ARTICLE

Prevalence of Diabetic Peripheral Neuropathy Among Type 2 *Diabetes mellitus* and Its Associated Factors in a Primary Care Clinic in Malacca: A Cross-sectional Study

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ABSTRACT

Introduction: Diabetes peripheral neuropathy (DPN) is the commonest diabetic complication. This study aimed to determine the prevalence of diabetic peripheral neuropathy among type 2 *diabetes mellitus* patients and its associated factors in a primary care clinic. **Materials and methods:** A cross sectional study was done in a government funded primary care clinic in Melaka involving type 2 *diabetes mellitus* patients aged 18 years and above using a systematic random sampling. Multiple logistic regression analysis was performed to identify its associated factors. **Results:** 493 respondents were involved in the study with a median age of 62 (IQR 14) and 43.4% per cent (n=214) male. The prevalence of DPN in this study was 58.4% per cent (n=288). Age (OR:1.05; 95% per cent CI: 1.04 – 1.07), insulin treatment (OR: 3.28; 95% per cent CI: 1.99 – 5.40), and presence of albuminuria (OR:1.74; 95% per cent CI: 1.17 – 2.60) were found to be significantly associated with DPN. **Conclusion:** The prevalence of DPN is high in primary care setting in Malaysia. To enhance detection of DPN, multimodal foot examination should be performed especially among patients aged >60 years old, those on insulin treatment and those with presence of albuminuria.

Malaysian Journal of Medicine and Health Sciences (2024) 20(5): 219-225. doi:10.47836/mjmhs20.5.28

Keywords: Diabetes, Peripheral neuropathy, Prevalence, Primary care, Malaysia, Factor

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INTRODUCTION

Diabetic peripheral neuropathy (DPN) is the commonest microvascular complication of type 2 *diabetes mellitus* (1). However, the prevalence of this condition was found to vary widely in previous studies. A study by Young et al. in hospital clinics in the UK found an overall prevalence of 28.5 per cent among type 1 and type 2 diabetic patients (2). This is comparable to another study published by the Korean Diabetes Association where 26.8 per cent of type 2 diabetes patients in Korean hospitals was reported to have diabetic peripheral neuropathy (3). In Malaysia, three studies done in tertiary hospitals reported prevalence of 79.1 per cent, 34.3 per cent and 54.3 per cent respectively (4–6).

The wide variation in reported prevalence of diabetic peripheral neuropathy (DPN) is due to the different criteria used to diagnose the conditions and the population where the studies were conducted. In Malaysia, most studies on DPN were done in tertiary

centres and there is limited published data on the prevalence of DPN at primary care level. This gap in data needs to be addressed as most diabetic patients are receiving care in government health clinics. Hence this study aims to determine the prevalence of diabetic peripheral neuropathy and its associated factors among type 2 diabetes patients in Klinik Kesihatan Tengker, a government-funded primary health care facility in Malaysia.

MATERIALS AND METHODS

Study design and study setting

A cross-sectional study was conducted between August and October 2021 on type 2 *diabetes mellitus* patients (T2DM) attending follow up in Klinik Kesihatan Tengker (KKT), Melaka, Malaysia. It was the busiest clinic in Melaka Tengah District with a daily attendance of around 700-800 cases. KKT has a total of 3,274 active *diabetes mellitus* cases undergoing follow up in the facility. Gender distribution among the active cases were 56.2 per cent female and 43.8 per cent male. Racially, the Chinese made up 51.2 per cent of the population while the Malays 43.8 per cent and Indians 5.1 per cent. This study was registered under the National Medical

Research Register (NMRR) (ID: NMRR-20-3250-57195). Ethical clearance was obtained from the Malaysia Medical Research and Ethics Committee (MREC).

Study population and sample size calculation

All patients aged 18 years old and above were included in the study. The exclusion criteria were type 1 *diabetes mellitus*, gestational diabetes, *diabetes mellitus* complicating pregnancy, patients with bilateral lower limb amputation, patients with known case of disease(s) that can cause peripheral neuropathy, and patients with known case of disease(s) that may impair with symptoms reporting such as advanced dementia. The patients were subsequently recruited using a systematic random sampling method. A written informed consent was obtained from all the participants.

Sample size estimation to calculate the prevalence of diabetic peripheral neuropathy was done using the Kish formula. To study factors associated with diabetic peripheral neuropathy, G*Power version 3.1.9.4 was used to calculate the sample size for two proportions. It was calculated with power of study 80 per cent with level of significance α of 0.05 and 95 per cent confidence interval. After accounting for 20 per cent non-respondents, the estimated sample size was 498 (7).

Sampling method

Respondents were recruited by systematic random sampling. The sampling interval of 6 is calculated based on the sampling fraction formula, which estimated study sample size divide by the total number of active diabetes patients attending follow up at the studied clinic. All diabetic patients who came for follow up for each day of data collection were registered at the main registration counter by the support staff for record retrieval. The patients received their diabetic records and then be directed to the diabetes room for assessment by the diabetic nurse educator. All patients registering for follow up for *diabetes mellitus* will be listed sequentially for each day of data collection. The first starting number between 1 to 6 was picked randomly by lottery method at the registration counter. After the first sample was picked, every six patients will be recruited into the study. If the person did not meet the inclusion and/or exclusion criteria or did not consent to, the next 6th patient was recruited.

Interview was performed by trained nurses. To reduce the interviewer bias, two nurses were briefed regarding the study and questionnaires by the principal investigator. The reason for different persons conducting the interview and foot examination was to reduce bias that the examiner might expect an abnormal foot examination if patients complained with significant symptoms.

Study instruments

A pre-designed questionnaires in Malay and English

were used in this study. The questionnaire contained five parts. Part one was to elicit the sociodemographic characteristics of participants. Part two and three contained the clinical data of participants which include diabetes status, current smoking status, and other confounding factors. Part four consisted of the Neuropathy Symptoms Score (NSS) and part five was made up of the modified Neuropathy Disability Score (NDS). The instruments were chosen as both had been validated to be used as diagnostic tool among middle age diabetic patients with 71.1 per cent sensitivity and 90 per cent specificity when compared with biothesiometer with positive predictive value of 57.14 per cent and negative predictive value of 94.23 per cent. (8)

NSS was used to assess neuropathic symptoms in the legs. A score of 2 was assigned if burning/numbness/tingling sensation was reported, score 1 if fatigue/aching/cramping was reported and score 0 if no symptom was reported. If the symptom occurred on the feet another 2 points were given, 1 point if symptom occurred on the calves and 0 if the symptom was experienced elsewhere. Another 2 points were assigned for nocturnal exacerbation, 1 point for both daytime and nocturnal exacerbation and 0 point if daytime exacerbation only. 2 points were assigned if the symptom was relieved by walking, 1 point if the symptom relieved by standing and 0 point if sitting or lying lead to resolution of the symptom. An additional 1 point was assigned if the participants had woken up from sleep due to the symptoms. A total score of 3-4 was considered mild symptoms, 5-6 as moderate and 7-9 as severe symptoms (2).

NDS was used to elicit abnormal sensation and ankle reflex. The sensory modalities (pin prick, temperature, and vibration) were scored 1 if absent/reduced and 0 if normal respectively. Normal ankle reflex was assigned 0 point, present with reinforcement was assigned 1 point and absent reflex was assigned 2 points. A total score of 3-5 was regarded as mild neuropathic signs. 6-8 as moderate, and 9-10 as severe.

The diagnosis of diabetic peripheral neuropathy (DPN) was made in the events of moderate signs with or without symptoms, mild signs with moderate symptoms, and severe signs i.e., NDS more than 6 or NDS more than 3 with combination of NSS more than 5 (2). This has a positive predictive value of 57.14 per cent and negative predictive value of 94.23 per cent (8). These scoring systems had been used by other researchers to study the prevalence of DPN thus increasing the comparability of the information obtained from this study.

Data collection

The chief investigator was assisted by two diabetic educators (DE) during the data collection period. The DEs were briefed on the research and trained to help conduct the study. Diabetic patients coming for follow

up were directed to the diabetes room for assessment by the DE. Consented individuals were interviewed by the DE to complete part one to four of the questionnaire. The final part of the study was undertaken by the chief investigator to reduce bias if the researcher was aware of the patient's symptoms beforehand. The participants' medical records were reviewed to obtain the latest investigation results.

Study variables

The dependent variable in the study was the presence or absence of diabetic peripheral neuropathy (DPN) among the participants. This was determined by using the combination of either NDS more than 6 or NDS more than 3 with combination of NSS more than 5. The independent variables were sociodemographic (age, gender, ethnicity, level of education, and household income), diabetes profile (duration of diabetes, HbA1c value, whether the patient is on insulin treatment, BMI, blood pressure, lipid profile, renal function, and presence of albuminuria), and current smoking status.

Data analysis

IBM Statistical Package for Social Sciences (SPSS) version 26.0 was used for data analysis. Data cleaning and checking were done prior to running the analyses. All missing data was re-entered. For true missing data, the data was still used to ascertain the prevalence of diabetic peripheral neuropathy. However, the data was not used to study the associated factors of DPN. Categorical data were reported as frequencies and percentages. The non-normally distributed continuous data were reported as median and interquartile range (IQR). The result was considered significant if p value < 0.05 .

The univariate models considered all independent variables with possible association with diabetic peripheral neuropathy (DPN). The results were presented as crude odds ratio (OR) with 95 per cent confidence interval. Factors with p value < 0.20 were selected for the multivariate analysis to determine factors that are independently associated with DPN. The p value was set at higher value to allow more variables to be included in the multivariate model. The assumption for no multicollinearity was determined by no Variance Inflation Factor (VIF) > 10 and collinearity tolerance > 0.9 . The Goodness of fit of the multivariate model was tested by Hosmer-Lemeshow test, the classification table, and the Receiver Operating Characteristic (ROC) curve analysis. The results were presented in adjusted odds ratio (OR) with 95 per cent confidence interval.

Ethical approval

This study was registered under the National Medical Research Register (NMRR) (ID: NMRR-20-3250-57195). Ethical clearance was obtained from the Malaysia Medical Research and Ethics Committee (MREC).

RESULTS

Response rate and total prevalence of diabetic peripheral neuropathy

FOut of 501 patients that were approached, 493 fulfilled the inclusion and exclusion criteria, and consented for the study. This yielded a 98.4 per cent ($n=493$) response rate. Eight respondents were excluded as three did not consent, two had end-stage renal failures (ESRF) on regular haemodialysis, one had advanced dementia, one had severe bilateral hearing loss, and one had history of thalamic stroke with residual ipsilateral hyperaesthesia.

Respondent's characteristic

The median age of respondents was 62 with interquartile range (IQR) of 14. Female and male were distributed quite equally 56.6 per cent ($n=279$) and 43.4 per cent ($n=214$) respectively. Majority of respondents identified as Malay ethnicity (52.1 per cent, $n=257$) and attained secondary education (55.4 per cent, $n=273$). Most respondents also came from low-income group (85 per cent, $n=419$). Table I summarised the characteristics of respondents.

Table I: Characteristics of respondents (N = 493)

Variables	Frequency, n (%)	Median (IQR)
Age (years)		62(14)
HbA1c (%)		7.4(2.2)
Lipid profile		
Total cholesterol (mmol/L)		4.7 (1.31)
Serum triglyceride (mmol/L)		1.35 (0.86)
Gender		
Male	214 (43.4)	
Female	279 (56.6)	
Ethnicity		
Malay	257 (52.1)	
Chinese	209 (42.2)	
Indian	19 (3.9)	
Others	8 (1.6)	
Level of education		
No formal education	44 (8.9)	
Primary education	122 (24.7)	
Secondary education	273 (55.4)	
Tertiary education	54 (11.0)	
Monthly household income		
B40 (<RM4,850)	419 (85.0)	
M40 (RM4,850-RM10,959)	60 (12.2)	
T20 (>RM10,959)	14 (2.8)	
Duration of diabetes (years)		
<1 year	21 (4.3)	
1-5 years	179 (36.3)	
6-10 years	134 (27.2)	
>10 years	159 (32.3)	
Insulin treatment		
Yes	121 (24.5)	
No	372 (75.5)	
BMI category	N = 485	
Underweight	7 (1.4)	
Normal weight	60 (12.2)	
Overweight	163 (33.1)	
Obese	255 (51.7)	

CONTINUE

Table I: Characteristics of respondents (N = 493). (CONT.)

Variables	Frequency, n (%)	Median (IQR)
Blood pressure		
Controlled (<140/80)	94 (19.1)	
Uncontrolled (≥140/80)	399 (80.9)	
eGFR (mL/min/1.73m ²)	N = 488	
≥90 (CKD stage 1)	189 (38.3)	
60-89 (CKD stage 2)	200 (40.6)	
30-59 (CKD stage 3)	91 (18.5)	
≤29 (CKD stage 4 and 5)	8 (1.6)	
Presence of albuminuria	N = 480	
No	278 (56.4)	
Yes	202 (41.0)	
Current smoking status		
Yes	73 (14.8)	
No	420 (85.2)	

HbA1c: glycosylated hemoglobin, BMI: body mass index, eGFR: estimated glomerular filtration rate, CKD: chronic kidney disease

Factors associated with diabetic peripheral neuropathy are presented in Table II. diabetic peripheral neuropathy (DPN) was significantly associated with age (p<0.001), Indian ethnicity (p=0.02), duration of diabetes 6-10 years (p=0.044), duration of diabetes >10 years (p=0.009), patient on insulin treatment (p<0.001), eGFR 60-89 (p=0.042), eGFR 30-59 (p<0.001), and presence of albuminuria (p=0.006).

Table II: Simple logistic regression analysis between the sociodemographic and clinical characteristics with diabetic peripheral neuropathy (N=493)

Variable	Unadjusted coefficient (b)	Crude OR (95% CI)	Wald statistic	p value
Age (years)	0.04	1.00(1.03,1.06)	25.43	<0.001
Gender				
Female	ref	1		
Male	-0.14	0.87 (0.61, 1.25)	0.55	0.46
Ethnicity				
Malay	ref		7.88	
Chinese	-0.15	0.86 (0.60,1.25)	0.63	0.43
Indian	1.77	5.87 1.32,25.95)	5.45	0.02
Others	-0.88	0.41 (0.10,1.77)	1.41	0.24
Level of education				
No formal education	ref		9.60	
Primary education	-0.01	0.99 (0.47,2.08)	0.00	0.99
Secondary education	-0.64	0.53 (0.27, 1.04)	3.40	0.07
Tertiary education	-0.54	0.58 (0.25,1.34)	1.62	0.20

CONTINUE

Table II: Simple logistic regression analysis between the sociodemographic and clinical characteristics with diabetic peripheral neuropathy (N=493). (CONT.)

Variable	Unadjusted coefficient (b)	Crude OR (95% CI)	Wald statistic	p value
Monthly household income				
B40 (<RM4,850)	ref		1.42	
M40 (RM4850 – 10959)	-0.31	0.74 (0.43,1.27)	1.22	0.27
T20 (>RM10.959)	0.22	1.24 (0.41,3.77)	0.15	0.70
Duration of diabetes				
<1 year	ref		16.91	
1-5 years	0.45	1.57 (0.62,3.98)	0.91	0.340
6-10 years	0.97	2.65 (1.03,6.82)	4.04	0.044
>10 years	1.27	3.54 (1.38,9.09)	6.92	0.009
Latest HbA1c	0.05	1.06 (0.95,1.17)	1.03	0.310
Insulin treatment				
No	ref	1		
Yes	0.99	2.70 (1.70,4.27)	17.83	<0.001
BMI category				
Underweight	ref		1.02	
Normal	0.36	1.30 (0.27,6.33)	0.10	0.749
Overweight	0.12	1.13 (0.25,5.23)	0.03	0.875
Obese	-0.01	0.99 (0.22,4.51)	0.00	0.988
BP control (mmHg)				
<140/80	ref	1		
≥140/80	-0.17	0.85 (0.53,1.34)	0.52	0.473
Serum cholesterol	-0.14	0.87 (0.72,1.04)	2.43	0.119
Serum triglyceride	0.025	1.03 (0.83, 1.27)	0.05	0.818
eGFR (mL/min/1.73m ²)				
≥90	Ref		13.26	
60-89	0.42	1.52 (1.01,2.27)	4.12	0.042
30-59	0.98	2.67 (1.55,4.56)	12.62	<0.001
≤29	0.52	1.68 (0.39,7.25)	0.49	0.484
Presence of albuminuria				
No	ref	1		
Yes	0.527	1.69 (1.17,2.46)	7.61	0.006
Current smoking status				
No	ref	1		
Yes	-0.24	0.79 (0.48,1.30)	0.88	0.349

ref = reference group, CI = confidence interval. Significant p value <0.05

Determinants of diabetic peripheral neuropathy based on multivariate logistic regression

Table III showed the factors that are independently associated with diabetic peripheral neuropathy (DPN).

We identified there are three factors, which are age (adjusted OR 1.05 [95 per cent CI 1.04-1.07], $p < 0.001$), insulin therapy (adjusted OR 3.28 [95 per cent CI 1.99-5.40], $p < 0.001$) and presence of albuminuria (adjusted OR 1.74 [95 per cent CI 1.17-2.60], $p = 0.006$). Table 3 illustrates the findings from multiple logistic regression analysis.

Table III: Multiple logistic regression of diabetic peripheral neuropathy with the sociodemographic and clinical characteristics of respondents (N=493)

Variable	Regression coefficient (b)	Adjusted OR (95% CI)	Wald statistic	p value
Age	0.053	1.05 (1.04,1.07)	32.02	<0.001
Insulin therapy				
No	ref	1		
Yes	1.19	3.28 (1.99,5.40)	21.75	<0.001
Presence of albuminuria				
No	ref	1		
Yes	0.56	1.74 (1.17,2.60)	7.47	0.006

Forward LR Multiple Logistic Regression model was applied. Multicollinearity was checked and not found. Hosmer-Lemeshow test, ($p = 0.922$), classification table (overall correctly classified percentage 68.5%) and area under the ROC curve (70.3%) were applied to check the model fit. Significant p value <0.05

DISCUSSION

Prevalence of diabetic peripheral neuropathy and its associated factors

The prevalence of diabetic peripheral neuropathy (DPN) in this study is 58.4 per cent. This number is higher compared to other studies done in primary care but was almost the same with studies done in Malaysian university hospitals (6,9). The authors of previous local studies attributed the high prevalence rate to the study setting – university hospitals catering to more complicated diabetes cases. One possible reason behind this discrepancy is the higher median age (62, IQR=14) of the study population. As almost all local studies employed the same tool (NSS and NDS) to diagnose diabetic peripheral neuropathy, it is possible to compare the prevalence rate between these studies.

Age was found to be an independent factor associated with diabetic peripheral neuropathy (DPN). Normal aging process causes axonal degeneration and the presence of *diabetes mellitus* accelerate the process. Higher age could also mean the person had live with diabetes for longer period as shown in this study where only 40 per cent of the study population had diabetes for less than 5 years. This is in line with the finding that duration of diabetes is significantly associated with DPN although the association could be compounded by age (10).

Insulin treatment is another factor that was found to have an independent association with diabetic peripheral neuropathy (DPN). The proportion of participants on insulin in this study (25 per cent, $n = 122$) was similar to the national insulin usage as reported in the National

Diabetes Registry 2020 (24 per cent) (11). However, diabetic peripheral neuropathy was found to be higher in those on insulin as compared to those not on insulin (68.4 per cent vs. 31.6 per cent). Low insulin utilization may be due to patients' perception that insulin causes numerous negative side effects as highlighted in a qualitative study on barriers of insulin therapy (12). Additionally, patients on insulin usually had poor glycemic control or had advanced renal disease (13).

Neuropathy and nephropathy are manifestation of microvascular complications of *diabetes mellitus* with shared mechanism of vascular injury (14). The earliest sign of nephropathy is albuminuria. Hence, discovering an independent association between presence of proteinuria with diabetic peripheral neuropathy is expected.

In conclusion, the prevalence of DPN is high in primary care setting in Malaysia. The increasing numbers of diabetic individuals have a negative impact on the overall national healthcare expenditure. Almost 70 per cent of the patients receive treatment in government health clinics (15). Hence, we strongly recommend the primary care doctors to always perform the multimodal foot examination to elicit the signs of neuropathy to all diabetic patients particularly among patients aged 60 years old and above, those on insulin treatment and those with presence of albuminuria. Around 50 percent of diabetic peripheral neuropathy is asymptomatic, hence annual screening is very important for early detection.

Our study has several limitations that must be considered. As this study was conducted in a single government clinic, the result cannot be extrapolated to other populations. Due to financial and timing constraint, the measure of glycaemic control and lipid profile in this study were extracted from the respondents' medical record. The latest HbA1c, serum cholesterol and serum triglyceride values within the past 1 year were recorded into the study. However, HbA1c only portrays glycaemic control for the past 3 months. Additionally, a single HbA1c reading is insufficient to ascertain level of control especially among newly diagnosed patients where treatment was recently initiated. The relationship between LDL and HDL were not investigated as these tests were not routinely done unless specifically ordered by the doctors. Another factor that was not studied is vitamin B12 deficiency as possible cause of peripheral neuropathy. Vitamin B12 deficiency is a known side effects of long-term metformin ingestion especially with a dose of >1500g/day. This study also did not exclude medical conditions that may mimic peripheral neuropathy such as radiculopathy or peripheral vascular disease. Finally, this is a descriptive cross-sectional study and any significant associations found are not found to be causal.

Despite these limitations, from our limited search, this study is among few published studies on prevalence of diabetic peripheral neuropathy (DPN) in a government-funded primary care centre in Malaysia. Previously published studies were done in either specialised diabetic/endocrine clinic in the hospital or in university centres. Additionally, this study had achieved a very good response rate of 98.4 per cent.

Secondly, the diagnostic tools used in this study were also employed in other local studies. The combination of NSS and NDS has a sensitivity of 71.1 per cent and specificity of 90 per cent, hence providing a simple and accessible method to diagnose DPN in settings with limited resources.

Recommendations for future research

Future research in diabetic peripheral neuropathy should include factors that are missing in this study such as serum vitamin B12 level. Besides that, incorporation of nerve conduction study result in the future study are also recommended to support the diagnosis of DPN. Cohort study to determine causality will be very helpful. A larger study involving multiple private and government healthcare facilities should be conducted in the future to get a clearer picture on the prevalence of diabetic peripheral neuropathy in the community.

CONCLUSION

In conclusion, the prevalence of diabetic peripheral neuropathy (DPN) is high at primary care level in Malaysia. At 58.4%, the prevalence reported in this study is comparable with studies done in secondary or tertiary centres. From this study, increasing age, insulin treatment and presence of albuminuria were found to be independently associated with DPN. To enhance detection of DPN, a multimodal foot examination should be performed such as the Neuropathic Disability Score (NDS) used in this study. The examination should be targeted to diabetic patients age >60 years old, those on insulin treatment and those with presence of albuminuria.

ACKNOWLEDGEMENT

We would like to express our gratitude to the staffs of KKT for their assistance with data collection and to all respondents for their time and participation in this study.

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