European Journal of Clinical Pharmacy
Print ISSN: 2385-409X **Online ISSN**: Applied
Website: https://farmclin.es/

Article

Prevalence and Determinants of Peripheral Neuropathy among Type II Diabetes Mellitus Patients in Urban Puducherry

Article History:
Received:11-11-2025

Revised: 25-11-2025

Accepted: 10-12-2025

Published: 30-12-2025

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Abstract: **Background:** Diabetic Peripheral Neuropathy (DPN) significantly affects the quality of life of individuals with Diabetes Mellitus (DM), and if left untreated, leads to increased rates of lower limb amputations. This study sought to determine the prevalence and risk factors of Peripheral Neuropathy among patients with Type 2 Diabetes Mellitus (T2DM) in urban Puducherry and to examine its association with socio-demographic and diabetes-related variables.
Methods: A community-based cross-sectional study was conducted among 225 individuals with T2DM in urban Villianur between January 2019 and May 2020. Diabetic Peripheral Neuropathy (DPN) was evaluated using the Semmes–Weinstein monofilament, and scores were calculated based on the Toronto Clinical Scoring System (TCSS).
Results: Most participants were female (72%) with a mean age of 58.7 ± 9.9 years. About 73% had been living with diabetes for 5 to 10 years. The estimated prevalence of Diabetic Peripheral Neuropathy (DPN) among the participants was 73%. Significant associations were observed between risk factors such as family history, duration of diabetes and HbA1c levels ($p < 0.001$), as well as socio-demographic variables including age, religion, and socio-economic status ($p < 0.001$). Multivariate logistic regression analysis further confirmed significant associations with duration of Diabetes Mellitus, HbA1c levels and age group ($p < 0.05$). **Conclusions:** The prevalence of Diabetic Peripheral Neuropathy among the participants was considerable, emphasizing the need for routine screening of all T2DM patients for complications during every visit to primary health centers to prevent further nerve damage.

Keywords: Diabetic Peripheral Neuropathy, Semmes Weinstein monofilament, Type 2 Diabetes Mellitus, Toronto Clinical Scoring System, Prevalence, risk factors

INTRODUCTION

Diabetes Mellitus (DM) is a long-term metabolic disorder marked by elevated blood glucose levels. Type 2 Diabetes Mellitus (T2DM) is the most prevalent form in adults and develops when the body becomes resistant to insulin or fails to produce adequate amounts of it. As per the World Health Organization (WHO), approximately 537 million people worldwide are currently living with diabetes, accounting for about 1.5 million deaths annually. By 2030, the global number of people living with diabetes is expected to rise to approximately 643 million, and may further increase to around 783 million by 2045. (1,2) The ICMR-INDIAB-17 study reported that India has 62.4 million individuals with

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diabetes, corresponding to an overall prevalence of 11.4%. The prevalence of diabetes varies significantly by state, ranging from 4.8% in Uttar Pradesh to 26.4% in Goa. In Puducherry, the reported rates are 7.3% among women and 7.5% among men. (3-5) Changes in lifestyle have been a major factor in the increasing prevalence of diabetes over the past few decades. Patients' quality of life is significantly impacted by poorly managed diabetes because of microvascular and macrovascular problems that can negatively affect the heart, blood vessels, eyes, kidneys and nerves. Major health issues like blindness, kidney failure, heart attacks, strokes and lower limb amputations might result from these complications. The most prevalent microvascular consequence associated with diabetes is Diabetic Peripheral Neuropathy (DPN). As per the Toronto Consensus, typical DPN is defined as a symmetrical, length-dependent sensorimotor polyneuropathy resulting from metabolic and microvascular changes caused by prolonged hyperglycaemia. Studies indicate that factors like advanced age, gender, duration of diabetes and dyslipidemia are associated with the onset of DPN, which in turn increases the risk of foot ulcers by sevenfold and the likelihood of lower limb amputations by fifteenfold. (6-9) A significant challenge with DPN is that, the symptoms are usually subtle and usually mistaken for typical signs of ageing, causing patients to overlook the signs of nerve damage, this neglect can over time adversely affect quality of life. Therefore, implementing a proactive screening approach is crucial for the early identification of DPN and the prevention of further nerve damage. (10) Several tests can be utilized to detect the loss of protective sensation in the feet of diabetic patients, including vibration perception tests, nerve conduction studies, electro-diagnostic tests, and the monofilament test. The Semmes-Weinstein monofilament test, is a simple, cost-effective, and portable method for assessing this loss. Several scoring systems are widely employed to diagnose and categorize DPN, including the Toronto Clinical Scoring System (TCSS), the Michigan Neuropathy Screening Instrument (MNSI), and the Neuropathy Impairment Score (NIS). Among these, the TCSS is regarded as the most reliable for diagnosing DPN, functioning effectively as a bedside screening tool. (11) In light of this, the present study was conducted to assess the prevalence and risk factors of diabetic peripheral neuropathy using an appropriate, simple, and cost-effective screening method that can be implemented at the community level.

Methodology

This community based cross-sectional study was conducted after obtaining the clearance from the Scientific Research and Institutional Ethical Committee [Ref: SVMC/IEC/2018-Nov/IEC 01] over a period of one year between January 2019 to May 2020 in Villianur commune, an urban area of Puducherry. Ambulant T2DM patients with duration of DM more than five years were included in the study, participants with history of chronic neurological diseases and on medications known to impair nerve function were excluded. Sample size was determined using Cochran's formula, n= $\frac{z^2pq}{d^2}$; taking the prevalence of DPN as 26.1% from previous study done by Pradeepa R et al. (9) in Chennai, Tamil Nadu, and absolute precision (d) of 7% and the sample size derived was 225. Simple Random Sampling method was adopted to select the wards in Villianur urban commune, Puducherry. Total four wards were selected, and each ward was considered as a cluster. Using Probability Proportional to Size Sampling (PPSS) technique, 56 Diabetes Mellitus patients were included from each ward and totally 225 Diabetes Mellitus patients were included for the study. House to house survey was conducted to contact the participants. After explaining the purpose of the study to the participants in local language, written consent and consent to publish also has been received from all the participants. Information regarding socio-demographic data, diabetic management history, family history of Diabetes Mellitus, physical inactivity, smoking habit, alcohol consumption, symptoms of sensory neuropathy, symptoms of autonomic neuropathy, use of footwear like Micro-Cellular Rubber/Micro-Cellular Polymer (MCR/MCP) were collected using a pre-designed questionnaire. Semmes Weinstein monofilament test was done to determine the prevalence of DPN and the same was graded by Toronto Clinical Scoring System (TCSS). TCSS includes the following parameters for scoring; presence of symptoms of DPN, presence/absence/reduced reflexes and abnormality in sensory tests. The resultant score was expressed as a range with a minimum of 0 to a maximum of 19 points. Six points were derived from symptoms, eight points from bilateral lower-limb reflexes and five points from sensory examination distally at the toes and graded as scores between 0-5 points suggests no neuropathy, 6-8 suggests mild neuropathy, 9-11 indicates moderate and scores between 12-19 accounts for severe neuropathy. Bilateral lower limb was assessed for sensations and reflexes. Anthropometric measures like height, weight, waist circumference and hip circumference were measured as per the guidelines. Venous blood sample (5ml) was also collected from the participants to estimate the HbA1c levels.

Data analysis:

Data collected was entered in Microsoft Excel Sheet and analyzed using SPSS version 23.0 (Armonk, NY: IBM Corp). Prevalence of DPN was expressed as rate, quantitative variables like age were expressed as mean and standard deviation, categorical variables like socio-economic status and classification of DPN were expressed in percentage. Association between socio-demographic variables and Peripheral Neuropathy was analyzed using Chi-

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Square test. Multivariate Logistic Regression analysis was done to calculate Odds Ratio (OR) to quantify the strength of association between socio-demographic factors, risk factors of DM and DPN. A p-value <0.05 was considered statistically significant.

RESULTS

In the current study, 225 patients with diabetes were enrolled, with a mean (SD) age of 58.7 (9.9) years (range: 48.8–68.6). Nearly two-thirds of the participants, 162 (72%), were female. A total of 52 (23%) had completed middle school education, while only 7 (3%) were illiterate. Most participants were married 207 (92%), 175 (77%) were Hindus and 94 (42%) belonged to Class III socioeconomic status as per the Modified Kuppuswamy Scale (2020 update). Almost half, 111 (49%), reported a positive family history of diabetes, 165 (73%) had diabetes for 5–10 years and 206 (92%) were taking oral hypoglycaemic agents. Also 91(40%) of the participants were in overweight category according to WHO Body Mass Index (BMI) classification and 45(90%) female participants and 16(25%) male participants were at high-risk Waist: Hip Ratio category. Blood pressure was measured as per JNC 7 classification and about 88(39%) participants were hypertensives and HbA1c levels shows, 127(56%), 49(22%) and 34(15%) of the participants had a poor, fair and good glycaemic control levels respectively. The overall estimated prevalence of DPN was 165(73%), and as per Toronto Clinical Scoring System for DPN 36(16%) of participants had severe neuropathy, 70(31%) had mild neuropathy and 59(26%) had moderate neuropathy.

DPN increases significantly with age, particularly among individuals over 50 years (p=0.003), both religion and socio-economic status also showed a significant association with DPN (p<0.05). Among diabetes-related risk factors, a significant relationship was observed with family history, the duration of diabetes, and HbA1c levels. Notably, the risk of DPN increases with the length of time a person has Diabetes Mellitus (p < 0.001) and also with inadequate glycaemic control (p = 0.037). (Table 1)

Participants with a duration of Diabetes Mellitus for more than 10 years had 4.01 times the odds of developing DPN (OR: 4.01, CI: 1.56-10.33, p=0.004) compared to those with a shorter duration of disease. Furthermore, individuals with poorly controlled HbA1c levels were nearly twice as likely to develop DPN (OR: 1.98, CI: 1.03–3.78, p = 0.038) compared to those with good glycaemic control. Likewise, older participants had 1.45 times the odds of developing DPN (OR: 1.45, CI: 1.05-2.00, p=0.024) compared to younger individuals (Table 2). The Linear Regression done between HbA1c levels and Diabetic Peripheral Neuropathy, shows that increase in HbA1c predisposes to Diabetic Peripheral Neuropathy (p = 0.017 with CI: 1.258-3.026). (Table 3)

TABLES AND FIGURES

Table I: Association between Diabetic Peripheral Neuropathy with various factors (n=225)

Variables	DPN		χ^2	p-value
	Present (n=165) n (%)	Absent (n=60) n (%)		
Age in years				
31-40	06 (86)	01 (14)	15.4813	0.003*
41-50	20 (57)	15 (43)		
51-60	53 (69)	24 (31)		
61-70	54 (74)	19 (26)		
>70	32 (97)	01 (03)		
Gender				
Male	42 (67)	21 (33)	1.989	0.158
Female	123 (76)	39 (24)		
Religion				
Hindu	137 (78)	38 (22)	14.709	0.0006*
Christian	07 (88)	01 (12)		
Muslim	21 (50)	21 (50)		
Marital status				
Married	152 (73)	55 (27)	0.012	0.911
Widow	13 (72)	5 (28)		
Socio-Economic Scale (Modified Kuppusamy Scale updated - 2020)				

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I	13 (87)	02 (13)	27.6876	0.00001*
II	55 (78)	14 (20)		
III	53 (56)	41 (44)		
IV	42 (95)	02 (05)		
V	02 (67)	01 (33)		
Family History of DM				
Present	110 (99)	01 (01)	74.3732	0.00001*
Absent	55 (48)	59 (52)		
Duration of DM				
5-10 years	108 (65)	57 (35)	19.641	0.00001*
>10 years	57 (95)	03 (05)		
Physical activity				
Practice	44 (78)	12 (21)	1.046	0.306
Don't practice	121 (72)	48 (28)		
Type of foot wear used				
MCR/MCP	28 (72)	11 (28)	0.057	0.811
Others	137 (74)	49 (26)		
BP status				
Normotensive	101 (74)	36 (26)	0.027	0.869
Hypertensive	64 (73)	24 (27)		
Body Mass Index				
Under weight	05 (83)	01 (17)	2.479	0.479
Normal	56 (67)	27 (33)		
Overweight	70 (77)	21 (23)		
Obese	34 (76)	11 (24)		
Waist: Hip Ratio				
Normal	50 (78)	14 (22)	1.050	0.403
High risk	115 (71)	46 (29)		
HbA1c levels				
Poor control (> 6.5)	100 (79)	27 (21)	4.359	0.037*
Good control (< 6.5)	65 (66)	33 (34)		

*p-valve <0.05, statistically significant

Table II: Multivariate logistic regression to find the strength of association between the significant correlates and diabetic peripheral neuropathy

Correlates	**B**	**Std. error**	**Wald**	χ^2	**Odd's ratio**	**95% Confidence Interval**	
						Lower Bound	Upper Bound
Duration of DM	4.292	1.232	12.142	<0.001			
	1.391	.482	8.332	0.004	4.019	1.563	10.337
HbA1c	0.684	.330	4.296	0.038	1.982	1.038	3.786
Age	0.372	.165	5.108	0.024	1.451	1.051	2.004
Family history	0.583	.328	3.167	0.075	1.792	0.943	3.406
Religion	0.332	.239	1.931	0.165	1.394	0.873	2.227
Socio-Economic Status	0.021	0.177	0.014	0.904	1.022	0.722	1.445

Table III: Linear regression analysis between HbA1c values and Diabetic PeripheralNeuropathy (n=225)

Correlates	B	Std. Error	T	p value	95% Confidence Interval	
					Lower Bound	UpperBound
Constant	1.489	0.097	15.390	0.000	1.298	1.680
HbA1c	0.142	0.059	2.412	0.017	1.258	3.026

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DISCUSSION

From this community-based cross-sectional study the prevalence of DPN, measured using the Toronto Clinical Scoring System, was 73%. This finding is consistent with the results reported by Amour et al. (12) in Tanzania. However, studies from various regions in India, including Andhra Pradesh, Chandigarh, Mangalore, Lucknow, Tamil Nadu, West Bengal and Karnataka, as well as those from Nepal and Ethiopia, found lower prevalence rates of DPN, ranging from 5% to 50%. (13-24) Discrepancies in DPN prevalence across studies could be attributed to a variety of factors, including differences in diabetes duration, as the current study included participants with diabetes for more than 5 years. The use of various screening instruments and scales for identifying and categorizing DPN, variances in the degree of hyperglycemia, dietary practices, or regional variations across the studies could all be additional contributing variables.

The present study found a statistically significant link between DPN and being over 50 years old ($p = 0.003$). Also, the risk of developing neuropathy increases by 1.45 times for each additional year of age compared to younger individuals. Similar findings were reported in studies by Darivemula et al. (13), Bansal D et al. (14) and Gill HK et al. (15). The results suggest that age is an important non-modifiable risk factor for the development of DPN, with the likelihood of losing protective foot sensation increasing as individuals age compared to younger people. The current study also found a statistically significant association between religion, socio-economic status, and DPN ($p < 0.001$). Similar findings were reported by Corsi DJ et al. (16) and Houle J et al. (17) in their studies done in India and in Canada respectively. Religion influences biological, cultural, psychological and interpersonal factors; all of which can play a role in the development of disease complications. Patients from lower socioeconomic backgrounds may be less knowledgeable about the condition, its complications, how to take good care of themselves and how important glycemic control is in preventing DPN. This study discovered a strong correlation between the development of neuropathy and a family history of diabetes mellitus ($p < 0.001$). Similar results were reported by Geetha A et al. (18) and Young MJ et al. (19). These findings suggest that genetic predisposition may increase the risk of developing DM and subsequently DPN.

There was a significant association observed between DPN and the duration of DM ($p = 0.00001$). Multinomial logistic regression analysis revealed that participants with duration of diabetes over 10 years had 4.01 times higher odds of developing DPN compared to those with a shorter duration. Similar results were reported in studies by Gill HK et al. (15) Bansal D et al. (14). Conversely, a study by D'Souza et al. (20) in Mangalore found no association between the duration of diabetes mellitus and DPN. This could be due to the fact that having diabetes for a long time often leads to persistent high blood sugar levels, which plays a major role in the onset of complications.

In the current study, among the patients with poor glycemic control the prevalence of DPN was higher with a statistically significant association ($p = 0.037$). Patients with uncontrolled HbA1c levels have 1.98 times the odds of developing DPN compared to those with controlled HbA1c levels, according to multinomial logistic regression analysis, while patients with greater HbA1c levels are more likely to develop neuropathy, according to linear regression analysis. Similar results were reported in studies by Venguidesvarane AG et al. (21) in Tamil Nadu, Darivemula et al. (13) in Andhra Pradesh, Bansal D et al. (14) in Chandigarh and Morkrid J et al. (22) in Bangladesh. These findings highlight that prolonged uncontrolled glycemic levels increase the risk of complications, accelerating the onset of DPN. While, contrasting findings were reported by Gill HK et al. (15) which could be attributed to inclusion of newly diagnosed DM patients and also could be due to participants' age, as the complications of DM often take several years to develop, and older patients might overlook symptoms, leading to differing results of the studies.

CONCLUSION

DPN was assessed by a valid, easy to use bedside tool but nerve conduction testing which is the gold standard to detect Neuropathy was not used. Prevalence of DPN was high among the participants and it was associated significantly with age, religion, SES, Family history of DM, longer duration of the disease and HbA1c levels. This highlights the need to adopt intensive health education programmes to create awareness and also to screen for complications at all health facilities.

ACKNOWLEDGEMENT

I thank the participants who consented to participate in this study, I also extend my thanks to the Medico Social Worker and Health Inspector who had supported me during house-to-house visit for data collection. I express my heartfelt thanks to ICMR for providing MD/MS fund.

SOURCE OF FUNDING

This work was funded by ICMR MD/MS grants [Ref. No.3/2/March-2019/PG-Thesis-HRD (7)]

CONFLICT OF INTEREST

None declared

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