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Early detection of peripheral neuropathy and its correlation with retinopathy and HbA1c levels in type 2 diabetes mellitus patients

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ABSTRACT

Background: Screening of asymptomatic diabetes mellitus (DM) patients may reduce future complications. Despite having diabetic peripheral neuropathy (DPN), about 50% of type 2 diabetes mellitus (type 2 DM) patients are asymptomatic. If diabetic neuropathy is diagnosed early, the annual cost of treating diabetic neuropathy and associated complications can be decreased. The study objectives are to identify peripheral neuropathy at an early stage and to correlate peripheral neuropathy with diabetic retinopathy and HbA1c (glycated haemoglobin) in asymptomatic type 2 DM patients.

Materials and Methods: A cross-sectional analytical study was done during July and August 2022 using consecutive sampling on 105 patients who attended the General Medicine out-patient dept (OPD) at Pondicherry Institute of Medical Sciences and the Primary Health Centre (PHC) Kalapet in Puducherry, India. Patients over 18 years old with type 2 DM, who were asymptomatic for peripheral neuropathy, and had their HbA1c levels checked within the last two months were included. Patients have undergone Michigan Neuropathy Screening Instrument (MNSI) examination, biothesiometer and monofilament testing for neuropathy and Fundus examination for retinopathy.

Results: The average age of the study participants was 54.7±11.4 yrs, and they had a male-female ratio of 6:4. The retinopathy was present in 18.1% (95% CI:11.9-26.5). The prevalence of DPN by MNSI examination was 3.8% (95% CI:1.5-9.4), monofilament testing was 21.0% (95% CI:14.3-29.7) and biothesiometer was 98.1% (95% CI:93.3-99.5). A statistically significant association between DPN measured by a biothesiometer and HbA1c ($p<0.05$). There was no significant correlation between DR and HbA1c and between DPN measured by monofilament and HbA1c ($p>0.05$).

Conclusions: The objective assessment by the biothesiometer is the best tool for detecting peripheral neuropathy at an early stage in asymptomatic type 2 DM individuals than monofilament testing.

1. Introduction

Diabetes mellitus (DM) is a challenging health concern globally. DM affects about 425 million people globally, and by 2045 that number is predicted to increase to 628 million. Around 45% of type 2 diabetes mellitus (type 2 DM) patients are asymptomatic for diabetic peripheral neuropathy (DPN), with a prevalence that ranges from 21.3% to 34.5%.[1] Many systematic reviews have brought awareness to the rising expenses of individuals with complications of diabetic neuropathy in several health systems.[2] The diabetic treatment expenses and their related

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consequences exert an enormous economic burden on both the family and the entire nation.[3] One of the most significant predictors for the occurrence of ulcers in the foot, amputations, Charcot arthropathy, and other foot problems is peripheral sensory neuropathy. Despite having DPN, about 50% of type 2 DM patients are asymptomatic. DPN is a microvascular consequence of diabetes in which there are symptoms and signs of neuropathy and other causes of neuropathy have been ruled out.[4] It is also the most serious complication of diabetes, causing substantial disability and impairing the quality of life. It results in foot ulcers and limb numbness, which can progress to lower limb amputation and significant morbidity. If diabetic neuropathy is diagnosed early, the annual cost of treating it and its associated complications can be decreased. Therefore, early prevention of the complications of diabetic neuropathy is essential for these patients' rehabilitation. Consequently, early detection and effective action are prerequisites to stop the evolution of DPN.[5]

Diabetic retinopathy (DR) is a common challenge of uncontrolled diabetes mellitus, which leads to visual impairment due to damage to the retinal vessels. Out of the world's 50 million blind people, DR affects around 2.5 million individuals. With its vast spectrum of ocular manifestations, DR results in add-on socio-economic challenges on a global scale.[6] This study detects peripheral neuropathy in asymptomatic type 2 DM patients at an early stage through its association with diabetic retinopathy and HbA1c (glycated haemoglobin) levels so that preventive strategies can be implemented earlier.

The primary objective of the study is to measure the prevalence of peripheral neuropathy among type 2 DM patients who are asymptomatic for peripheral neuropathy using the Neuropathy Analyzer-Vibrotherm Dx (Biothesiometer) and monofilament testing. The secondary objective is to measure the correlation between peripheral neuropathy, diabetic retinopathy, and HbA1c levels.

2. Materials and Methods

We applied consecutive sampling to conduct a cross-sectional analytical study in individuals attending the General Medicine out-patient department (OPD) at the Pondicherry Institute of Medical Sciences and the Primary Health Centre (PHC) Kalapet in Puducherry, India, from July 2022–August 2022. All type 2 DM patients over the age of 18, who had asymptomatic peripheral neuropathy and had their HbA1c levels checked within the previous two months, were included. Patients with symptoms of peripheral neuropathy, patients with chronic kidney disease, hypothyroidism, pregnancy, alcoholic liver disease, pure vegetarians, and malignancies were excluded. The study instruments are the Michigan Neuropathy Screening Instrument (MNSI), the Neuropathy Analyzer-Vibrotherm Dx biothesiometer (Diabetik Foot Care India Pvt Limited, Chennai, India), monofilament testing using 10g Semmes-Weinstein monofilament for neuropathy, and indirect ophthalmoscopy for the retina. The study variables were age, gender, duration of type 2 DM, HbA1c level, co-morbid conditions (hypertension, coronary heart disease, and others), MNSI examination score, vibration perception threshold (VPT) by biothesiometer, touch sensation by monofilament testing, and fundus examination by indirect ophthalmoscopy.

2.1. Data collection procedure

The MNSI self-administered questionnaires were given to the patients. If the response was 'yes', it was counted as one point, and 'no', was counted as two points. The total score was 30. A score of less than or equal to 15 was considered abnormal.[7] A detailed history, including age, gender, duration of type 2 DM, HbA1c levels, and co-morbid conditions such as hypertension, coronary heart disease, and others (dyslipidemia, tuberculosis, and asthma) were taken. HbA1c levels were classified as good, fairly good, and poorly controlled if values were <6.5%, 6.5%-7.9% and ≥8.0% respectively. Foot sensations were tested, and a fundus examination was done and documented in the case study form.

The MNSI examination (Table 1) included inspecting both feet for neuropathic changes like dry skin, fissures, deformities, calluses, ulceration, prominent veins, nail lesions, and other abnormalities. The ankle reflexes were performed in the seating position. A brisk reflex was scored as zero. If there was no ankle reflex, Jendrassic manoeuvre was performed and documented as "present with reinforcement", and given a score of one. If there was no reflex, it was given a score of two. A 128 Hz tuning fork was placed over the great toe's dorsum on the distal interphalangeal joint and vibration perception at the great toe was examined. The patient was asked to inform when they lost the feel of the vibration. If the vibration was sensed within 10 seconds, it was assigned a score of zero. If it took more than 10 seconds, it was scored as one; if it was completely absent, it was scored as two. Monofilament testing was done using 10-gram Semmes-Weinstein monofilament; if the sensation was present in all 10 sites in the foot, it was scored as zero, if it was sensed at less than five sites in the foot, it was scored as one, and if it was absent in all sites, it was scored as two. The total score for the MNSI Examination was 16 points. A score of more than or equal to eight was considered abnormal.

2.2. Methods to elicit neuropathy

1. Monofilament testing: We used a 10-gram Semmes-Weinstein monofilament. It tests the sense of touch (large nerve fibre sensation). The patient was asked to indicate whether or not they felt anything when

Table 1: MNSI examination*

Physical Assessment	Scores for each foot
The appearance of the foot	Normal: Yes-0/ No-1
Ulceration	Absent-0/ Present-1
Ankle reflexes	Present-0/ Reinforcement-1/ Absent-2
Vibration Perception in the Great Toe	Present-0/ Decreased-1/ Absent-2
Monofilament testing	Present-0/ Reduced-1/ Absent-2
Total	Each foot gets 8 points. 16 points for both feet (≥ 8 is abnormal).

*Michigan Neuropathy Screening Instrument (MNSI)

the monofilament touched their foot. It was examined on both feet at 10 sites including the hallux plantar surface, the third toe, the fifth toe, the first, the third, and the fifth metatarsal heads, the medial instep, the lateral instep, the heel, and the dorsum of the foot. The maximum score was 10 for each foot, and it was graded accordingly, Grade 1 (a minimum of 20 sites, with one site reported as insensate). Grade 2 (a minimum of 20 sites, with two sites reported as insensate). Grade 3 (a minimum of 20 sites, with 10 sites reported as insensate by the patient).

2. Neuropathy Analyzer-Vibrotherm Dx Biothesiometer: Vibration perception threshold (VPT) is a quantitative method to assess the vibratory perception of the foot. The vibrator probe sends a vibratory stimulus that increases with the voltage. The probe was kept at various points on the patient's foot to check their vibration sensation, and the voltage at which the patient felt the vibration was recorded. VPT is regarded as the gold standard test for the early diagnosis of DPN according to a study that evaluated the application of VPT for early detection of DPN by biothesiometer.[8] The neuropathy was classified as mild (9.0-12.0 V), moderate (12.1-19.9 V), or severe (≥ 20.0 V) based on the threshold voltage.

2.3. To detect diabetic retinopathy

All the patients were subjected to a routine fundus examination by indirect ophthalmoscopy, using a 90D lens on a slit lamp, or fundus photography. Diabetic retinopathy was classified as per the ETDRS classification as non-proliferative diabetic retinopathy (NPDR), proliferative diabetic retinopathy (PDR), diabetic macular oedema (DME), and advanced diabetic eye disease.

2.4. Sample size and statistical analysis

The sample size was determined based on a study done by Mathiyalagen P et al.[9] considering the incidence of peripheral neuropathy to be 31.1% among type 2 DM patients, a 95% confidence level with an absolute precision of 9%. The desired sample size was calculated using the formula $4pq/d^2$= 102, and further, the sample size was rounded out to 105. The mean and standard deviation were applied for continuous variables, whereas proportions and percentages were employed to express categorical variables. A 95% confidence interval (CI) was estimated for the prevalence. Fisher's exact test was applied to discover the correlation between categorical variables. A value of ($p<0.05$) was regarded as statistically significant. Microsoft Excel 2019 was employed for data entry, and Statistical Package for the Social Sciences (SPSS) version 20.0 was utilised for data analysis.

2.5. Ethical consideration

The Institute Ethics Committee (PIMS, Puducherry) approved the study (IEC no.: RC/2022/02). Each participant was told about the study's details, the risks, and the benefits associated with it in a language comprehensible to them. All participants have read and signed the detailed informed consent voluntarily. Each participant's privacy and confidentiality were strictly maintained.

3. Results

Overall, 150 individuals took part in the study, 66 were from the hospital and 39 were from PHCs. The MNSI questionnaire was given, and 40 were excluded because they had an abnormal MNSI questionnaire (Score ≤15), indicating that they have symptoms of peripheral neuropathy. The remaining 110 patients were interviewed, and a detailed history was taken. Five were excluded from the analysis due to diabetic foot ulcers, chronic kidney disease, hypothyroidism, and megaloblastic anaemia. Finally, 105 participants were included in the evaluation of DPN and retinopathy. The participants were screened for neuropathy by monofilament testing and a biothesiometer and for retinopathy by fundus examination.

The mean age of 105 type 2 DM participants was 54.7±11.4 years. The majority of them were males, 63 (60.0%). The average duration of type 2 DM was 8.9±7.9 years with a duration of 3 months to 40 years.

The correlation between the duration of DM and DR was statistically significant ($p<0.05$); the longer the duration of DM, the more severe the retinopathy. There was no significant correlation between the duration of DM and neuropathy (MNSI examination, monofilament testing, and biothesiometer) ($p>0.05$).

Nine participants (8.6%) had good control of HbA1c <6.5%. 28 (26.7%) had fairly good control of HbA1c 6.5%-7.9%, and 68 (64.8%) had poorly controlled HbA1c ≥ 8%.

In this study, 33 (31.4%) were hypertensive, 10 (9.5%) had coronary artery disease (CAD), and 47 (44.8%) had no

associated co-morbid conditions.

All 105 patients were screened for peripheral neuropathy by MNSI examination, monofilament testing, and a biothesiometer.

The prevalence of neuropathy by MNSI examination was 3.8% (95% CI: 1.5-9.4). Out of 105 participants, 101 (96.2%) had scores of less than eight, which is normal. Four (3.8%) participants had a score of more than eight, which is abnormal and represents neuropathy.

The prevalence of neuropathy by monofilament testing was 21.0% (95% CI:14.3- 29.7). 83 (79%) participants had a score of 20, which signifies no neuropathy. Two (1.9%) patients had Grade 1 neuropathy (a minimum of 20 sites, with one site reported as insensate). One of the participants had Grade 2 neuropathy (a minimum of 20 sites, with two sites reported as insensate). 19 (18.1%) participants had Grade 3 (a minimum of 20 sites, with 10 sites reported as insensate by the participants).

The prevalence of neuropathy by biothesiometer was 98.1% (95% CI: 93.3-99.5) which was higher than the other two screening methods. 103 participants had neuropathy screened by a biothesiometer. Two (1.9%) had a normal vibration perception threshold (<9 V), eight (7.6%) had mild (9.0-12.0 V) neuropathy, 22 (21%) had moderate (12.1-19.9 V) neuropathy, and most of the participants 73 (69.5%) had severe (≥ 20.0 V) neuropathy. (Figure 1).

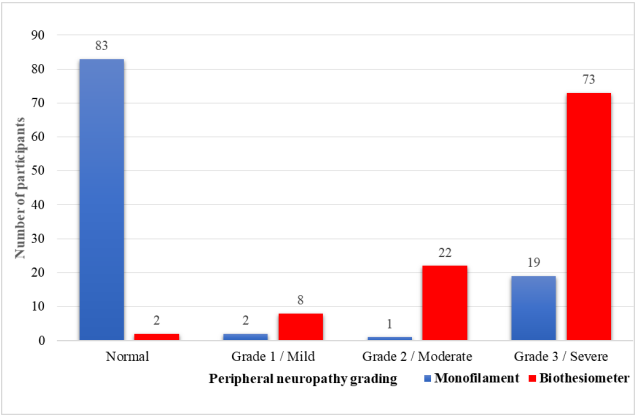

Figure 1: Frequency distribution of peripheral neuropathy found by monofilament testing and biothesiometer (n =105)

The prevalence of DR was 18.1% (95% CI:11.9-26.5). 86 (81.9%) had no signs of retinopathy, 14 (13.3%) had NPDR, and five (4.8%) had both PDR and maculopathy.

Eight participants with mild (9.0-12.0 V) neuropathy had a normal fundus. Of the 22 participants with moderate (12.1-19.9 V) neuropathy, one had NPDR, while the others had a normal fundus. A total of 73 participants had severe (≥ 20.0 V) neuropathy, of whom 13 (17.8%) had NPDR and five (6.8%) had both PDR and maculopathy. Our study could not detect any significant correlation between retinopathy and neuropathy by biothesiometer ($p > 0.05$). (Table 2).

There was no correlation between monofilament testing and HbA1c levels ($p > 0.05$). Whereas, there was a correlation between biothesiometer and HbA1c levels ($p < 0.05$).

The correlation between monofilament testing and HbA1c levels showed that 15 participants with poorly controlled HbA1c levels had grade 3 neuropathy and one had grade 2 neuropathy.

The correlation between biothesiometer and HbA1c levels showed that 51% of participants with poorly controlled HbA1c levels had severe (≥20.0 V) neuropathy, 11 had moderate (12.1-19.9V) neuropathy, two had mild (9.0-12.0V) neuropathy. (Table 3)

4. Discussion

We used consecutive sampling to conduct a cross-sectional analytical study in individuals attending the General Medicine OPD at the Pondicherry Institute of Medical Sciences and the Primary Health Centre (PHC) Kalapet in Puducherry. In our study, male and female participants were 60% and 40% respectively, which was similar to a study by Rasheed R et al.[10] The average age and duration of Type 2 DM patients were 54.7±11.4 years and 8.9±7.9 years, in accordance with a study done by Mathiyalagen P et al.[9]

An additional finding in our study is that the correlation between the duration of DM and DR was statistically significant ($p<0.05$); the longer the duration of DM, the more severe the retinopathy equivalent to a study done by As R et al.[11]

The prevalence of neuropathy by MNSI examination in our study was 3.8% (95% CI:1.5-9.4) whereas, in other studies, it was 31.1%,[9] and 52.9%,[12] respectively. The former study included participants with symptomatic diabetic neuropathy.

The monofilament testing detected neuropathy in 22 (21.0%) (CI:14.3-29.7) participants similar to a study by Shrestha S et al.[13] where it was 27.1%.

The prevalence of DPN by biothesiometer detected neuropathy in 103 (98.1%) (CI:93.3-99.5) whereas it was in contrast to other studies 71.8%[10] and 38%.[14] Bansal D et al.[15] at Chandigarh in 2014 found the combined prevalence of DPN by monofilament and biothesiometer to be 29.1% (95% CI: 27.2–31.2). The difference is because of the inclusion of symptomatic participants in other studies, whereas our study included all the asymptomatic participants.

The prevalence of diabetic retinopathy in our study was 18.1% (95% CI: 11.9-26.5) similar to the prevalence of DR reported by Sivaprasad S et al.[16] which had 17.4% (95% CI 15.1%, 19.7%). In another study by Zegeye AF et al.,[17] the prevalence was high at 36.3% (95% CI:29.8-47.6).

The monofilament detected 22 neuropathy patients out of them only ten had retinopathy and the biothesiometer detected 103 neuropathy patients out of them 19

Table 2: Correlation of diabetic retinopathy and diabetic peripheral neuropathy by biothesiometer (n = 105)

Biothesiometer	Fundus*			Total	p-value
	Normal	NPDR**	PDR** & Maculopathy		
Normal (<9 Volts)	2	0	0	2	0.403
Mild (9.0-12.0 Volts)	8	0	0	8	
Moderate (12.1-19.9 Volts)	21	1	0	22	
Severe (≥20.0 Volts)	55	13	5	73	
Total	86	14	5	105	

*Number of participants with normal fundus, non-proliferative diabetic retinopathy, proliferative diabetic retinopathy, and maculopathy.
**NPDR: non-proliferative diabetic retinopathy; PDR: proliferative diabetic retinopathy

Table 3: Association between HbA1c and other screening tools of peripheral neuropathy (n=105)

Variables	HbA1c*			Total	p-value
	Good control (<6.5%) (n = 9)	Fairly good control (6.5-7.9%) (n = 28)	Poor control (≥ 8.0%) (n = 68)		
MNSI Examination					
Normal (score < 8)	8	28	65	101	0.236
Abnormal (score ≥8)	1	0	3	4	
Monofilament Grading					
Normal (score 20)	7	24	52	83	0.193
Grade 1 (score 19)	1	1	0	2	
Grade 2 (score 18)	0	0	1	1	
Grade 3 (score 0-17)	1	3	15	19	
Vibration Perception Threshold (Biothesiometer)					
Normal (< 9 Volts)	0	1	1	2	0.005**
Mild (9.0 - 12.0 Volts)	0	6	2	8	
Moderate (12.1 - 19.9 Volts)	5	6	11	22	
Severe (≥ 20.0 Volts)	4	15	54	73	

*Number of participants with good control, fairly good control, poor control of HbA1c levels.
**p (<0.05) is significant.
MNSI: Michigan Neuropathy Screening Instrument, HbA1c: glycated haemoglobin

had retinopathy. The association between DPN by biothesiometer and DR in our study was not of significance (p>0.05), although a study done by Rasheed R et al.[10] showed a statistically significant association between DR and DPN (95% CI: 1.97–35.99). The duration of diabetes mellitus in the above study was more than fifteen years, whereas it was 9 years in our study.

In our study, out of 68 poorly controlled patients, 14 had retinopathy (10 NPDR; 4 PDR), out of 28 fairly good control patients, four had retinopathy (3 NPDR; 1 PDR), and out of nine good control patients, only one had NPDR. The DR and HbA1c associations were not significant. Whereas, other studies Mersha GA et al.[18] (AOR=4.76, 95% CI:2.26-10.00) and Rasheed R et al.[10] (95% CI:1.57–8.60) had a statistically significant association between DR and HbA1c. This may be because of participants with shorter duration of diabetes mellitus in our study.

A significant association (p<0.05) between neuropathy by biothesiometer and HbA1c suggests that participants with poorly controlled HbA1c levels had severe neuropathy, which is equivalent to a study done by Maiya AG et al.[19] (95% CI:3.67-4.39) and Hafeez et al.[20]

The study was limited by the small sample size and it was a hospital-based study. The community-based study will reflect the actual burden of peripheral neuropathy in asymptomatic diabetic individuals.

5. Conclusion

The prevalence of DPN detected in asymptomatic participants by biothesiometer was 98.1% (95% CI:93.3-99.5) compared to 21.0% (95% CI:14.3- 29.7) monofilament testing. Thus, objective screening using a biothesiometer is better at detecting peripheral neuropathy in asymptomatic diabetic individuals than monofilament

testing.

Early detection using a biothesiometer, intensive glycemic control, and early intervention in diabetic neuropathy and retinopathy may slow the progression of these microvascular complications and aid in the better health of Type 2 DM patients. We plan to replicate this study in a larger sample size before recommending practice changes.

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7. Conflict of Interest

None.

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