IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 24, Issue 12 Ser. 1 (December. 2025), PP 111-116
www.iosrjournals.org

Comparison Between Conventional Screening Tools with Nerve Conduction Study in Diabetic Peripheral Neuropathy in A Tertiary Care Hospital

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Abstract
Background: *Diabetic peripheral neuropathy (DPN) is a common microvascular complication of diabetes mellitus, leading to morbidity including foot ulceration and lower limb amputation. Early detection is critical, yet conventional screening tools vary in accuracy.*
Aim of the study: *To determine the diagnostic accuracy of conventional screening tools (128Hz Tuning fork, 10g-Monofilament and Biothesiometer) in detecting diabetic peripheral neuropathy.*
Methods: *A cross-sectional comparative study was conducted among 100 adult diabetic patients with suspected peripheral neuropathy at Dhaka Medical College Hospital from January 2023 to July 2024. Participants underwent DPN assessment using biothesiometer, tuning fork, and monofilament, with NCS as the reference standard. Sensitivity, specificity, and ROC-AUC were calculated.*
Result: *DPN prevalence by NCS was 21%. Biothesiometer demonstrated highest sensitivity 95.20% and moderate specificity 64.60%, with AUC of 0.882. Monofilament and tuning fork showed lower sensitivity 57.10% and 42.90% but higher specificity 89.30% and 86.40%, with AUCs of 0.24 and 0.305, respectively.*
Conclusion: *Vibration perception threshold using biothesiometer is a feasible and sensitive screening tool for DPN, though standardization and confirmation by NCS are recommended to reduce false positives.*
Keywords: *Diabetic peripheral neuropathy, Biothesiometer, Tuning fork, Monofilament, Nerve conduction study*

I. INTRODUCTION

Diabetes mellitus has become a global burden. The global diabetes prevalence in 20-79 years old in 2021 was estimated to be 10.5% (537 million), rising to 12.2% (783 million) in 2045. The total number of diabetic people is nearly 13.1 million in Bangladesh which is the 8th position the world. By 2045, it is projected to move the 7th position with 22.3 million people with diabetes [1]. The prevalence of diabetic peripheral neuropathy in Bangladesh was in female 18.7% and male was 19.7% [2]. Diabetic peripheral neuropathy (DPN) is a common microvascular complication of diabetes mellitus due to chronic hyperglycemia and presence of peripheral nerve dysfunction after exclusion of other causes [3]. Nearly 50% of adults with diabetes mellitus are affected by diabetic peripheral neuropathy during their lifetime and increasing morbidity including foot ulcer, disabling pain and lower limb amputation [4]. International standards from expert professional bodies advocate assessment for DPN starting at diagnosis of type-2 diabetes and 5 years after the diagnosis of type-1 diabetes and at least annually thereafter [5]. Commonly used neuropathy screening tools utilize pressure/touch sensation such as the 10 g Semmes Weinstein monofilament, and vibration perception (125 Hz tuning fork, Biothesiometer and Neurothesiometer) [6]. Use of the vibration perception threshold (VPT) is a simple way of detecting large-fiber dysfunction. The dietetic peripheral neuropathy can be detected by the use of Vibration perception threshold (VPT) measured by Biothesiometer [7]. Biothesiometer has a vibrating probe which is first applied to palmer aspect of feet to asses vibration perception. The vibration amplitude is measured in volts and can be changed manually [8]. The demonstration of Biothesiometer is easy and can be handled by non-professionals as well. For many years Biothesiometer is being used and have favorable sensitivity (SEN) 80% and around 70% specific (SPE) [9].

Biothesiometer measure Vibration perception on a scale from 0 to 50 by adjusting the amplitude which provides a quantitative measure of vibration sensation [10]. The 128 Hz tuning fork is the first tool to use vibration perception but its application is very limited. Because the 128-Hz tuning fork does not provide quantitative data on the degree of loss of vibration sensation [6]. Diabetic individuals have a 19-34% lifetime risk of getting a diabetic foot ulcer, and a lower limb is amputated in every 20s due to diabetic foot complication. Mortality is 2.5 times higher in diabetic individuals who does not have a foot ulcer [11]. The symptoms of DPN vary; nevertheless, it begins with sensory loss, which renders diabetes patients more prone to foot ulcers and increases the chance of leg amputation [12]. Early diagnosis of patients with diabetic peripheral neuropathy and development of awareness related to diabetic foot is necessary. The aim of the study was to determine the diagnostic accuracy of conventional screening tools (128Hz Tuning fork, 10g-Monofilament and Biothesiometer) in detecting diabetic peripheral neuropathy.

II. METHODOLOGY AND MATERIALS

This cross-sectional comparative study was conducted in the Outpatient Department of Endocrinology and Metabolism at Dhaka Medical College Hospital from January 2023 to July 2024 among adult patients with diabetes mellitus and suspected peripheral neuropathy. The study aimed to compare recommended conventional screening tools with nerve conduction studies for the assessment of diabetic peripheral neuropathy. A total of 100 participants were included in the study.

Inclusion Criteria:

- All adult (18 to 75) Patients with Diabetes Mellitus with suspected peripheral neuropathy

Exclusion Criteria:

- Patients with amputations, Charcot foot, foot infection, non-healing ulcer causing hindrance in test performance
- Chronic malnutrition, chronic kidney and liver disease, alcoholism
- Patient with acute hyperglycemic crisis within one month
- Patients with clinical evidence of lumbosacral radiculopathy and known peripheral vascular disease
- Cardiac pacemakers, rhythm abnormalities
- Patients unwilling for the test

Ethical Considerations

As per the rules of the Ethical Committee of Dhaka Medical College Hospital, Dhaka, participation in the study was voluntary. Informed consent was obtained from all respondents after providing a brief explanation of the study in Bangla or the local language. It was clearly explained that participants were free to take part in or withdraw from any part of the study at any stage without any obligation. All responses were kept confidential and were not disclosed without prior permission of the participants. Interviews were conducted at a suitable time and place convenient for the respondents. Refusal to participate or withdrawal from the study did not hamper or influence the treatment provided.

Data Collection

Data were collected using a structured pretested questionnaire and standardized clinical assessment procedures. Socio-demographic information including age sex and socioeconomic status was obtained through face-to-face interviews. Information on diabetes-related factors including duration of diabetes mellitus was also recorded. Clinical assessments were performed by trained investigators following standard protocols. Anthropometric measurements were taken to calculate body mass index and blood pressure was measured using appropriate techniques. Peripheral neuropathy screening was carried out using conventional tools such as the 128 Hz tuning fork the 10 g monofilament and vibration perception threshold measurement by biothesiometer following standardized procedures. Relevant laboratory parameters including hemoglobin erythrocyte sedimentation rate thyroid stimulating hormone random blood sugar glycated hemoglobin serum creatinine aspartate aminotransferase and alanine aminotransferase were recorded from hospital laboratory reports. Nerve conduction studies were performed by trained personnel using standard electrophysiological methods and served as the reference standard for diagnosing diabetic peripheral neuropathy. All data were collected ensuring privacy and confidentiality of the participants.

Statistical Analysis

The statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 27. Chi-squire test was used for testing the association between different variables. Sensitivity, specificity and area under curve (AUC) using receiver operating characteristic (ROC) curve analysis was done m and p-value of <0.05 was considered statistically significant.

III. RESULT

Most respondents were aged 45–54 years at 46.00% and 55–64 years at 34.00%, with a mean age of 51.26 ± 7.45 years. Females constituted 71.00%. Service holders accounted for 56.00%, business 7.00%, housewives 26.00%, and retired 7.00%. Graduates were 35.00%, those with class 5–10 education 30.00%, high-income earners 74.00%, lower-middle income 20.00%, smokers 21.00%, and non-smokers 79.00% shows in (Table 1). The mean BMI was 25.43 ± 3.22 kg/m², with average height 154.41 ± 16.09 cm and weight 62.29 ± 9.99 kg. Mean systolic and diastolic blood pressures were 119.90 ± 15.92 and 79.10 ± 5.87 mmHg. Glycemic markers showed RBS 12.25 ± 3.20 mmol/L and HbA1c 9.76 ± 1.68 examines in (Table 2). Among controlled HbA1c below 7%, neuropathy was absent in 2 and present in 0, while in uncontrolled cases it was present in 21 and absent in 77; p value 0.461 illustrates in (Table 3). Nerve conduction study was present in 21.00% and absent in 79.00%. Biothesiometry showed normal vibration perception in 29.00%, mild loss 26.00%, moderate loss 30.00%, severe loss 15.00%. Monofilament was present in 16.00% and absent 84.00%. Tuning fork was present 12.00% and absent 88.00% presents in (Table 4). Compared with NCS biothesiometry demonstrates 95.20% sensitivity 64.60% specificity 35.40% PPV and 96.60% NPV. Monofilament 57.10% sensitivity 89.30% specificity 42.90% PPV and 89.30% NPV. Tuning fork demonstrates 42.90% sensitivity 86.40% specificity 57.10% PPV and 96.20% NPV identifies in (Table 5). Finally, Table 6 demonstrates that validation with NCS showed biothesiometry had an AUC of 0.882, P<0.001, 95% CI 0.679–0.954. Monofilament had AUC 0.24, P<0.001, 95% CI 0.121–0.472. Tuning fork showed AUC 0.305, P<0.001, 95% CI 0.174–0.539.

Table 1: Socio-demographic characteristics of the respondents (N=100)

Variables	Frequency (n)	Percentage (%)
Age (years)		
≤34	2	2.00
35-44	15	15.00
45-54	46	46.00
55-64	34	34.00
≥65	3	3.00
Mean±SD	51.26±7.45	
Gender		
Male	29	29.00
Female	71	71.00
Occupation		
Day laborer	4	4.00
Service Holder	56	56.00
Business	7	7.00
Housewife	26	26.00
Retired	7	7.00
Education		
Class 1 to 4	6	6.00
Class 5 to 10	30	30.00
SSC	7	7.00
HSC	22	22.00
Graduate and above	35	35.00
Income (BDT per month)		
High (≥50,000)	74	74.00
Upper middle (30,001-49,999)	4	4.00
Lower middle (10,001-30,000)	20	20.00
Low (<10,000)	2	2.00
Smoking status		
Smoker	21	21.00
Non-smoker	79	79.00

Table 2: Physical measurements and Biochemical characteristics of the study population

Variables	Mean±SD
BMI(Kg/m^2)	25.43±3.22
Height (cm)	154.41±16.09
Weight (Kg)	62.29±9.99
Systolic blood pressure (mmHg)	119.90±15.92
Diastolic blood pressure (mmHg)	79.10±5.87
Hemoglobin (Hb g/dl)	11.76±1.49
Erythrocyte sedimentation rate (ESR mm/hour)	8.87±5.79
Thyroid stimulating hormone (TSH mIU/L)	1.96±0.84

RBS mmol/L	12.25±3.2
Glycated haemoglobin (HbA1c %)	9.76±1.68
Serum creatinine (mg/dL)	1.01±0.17
Aspartate aminotransferase (AST units/L)	35.58±8.55
Alanine aminotransferase (ALT units/L)	31.57±8.03

Table 3: Association of HbA1c with diabetic peripheral neuropathy (n=100)

HbA1c	Peripheral Neuropathy		P value
	Present	Absent	
Controlled (<7 %)	0	2	0.461
Uncontrolled (>7%)	21	77	

Table 4: Distribution of neuropathy assessment findings among participants

Variables	Frequency (n)	Percentage (%)
NCS		
Present	21	21.00
Absent	79	79.00
Biothesiometry		
Vibration perception normal	29	29.00
Mild loss	26	26.00
Moderate loss	30	30.00
Severe loss	15	15.00
Monofilament		
Present	16	16.00
Absent	84	84.00
Tuning fork		
Present	12	12.00
Absent	88	88.00

Table 5: Comparison of Biothesiomitry, Monofilament and Tuning fork with Nerve Conduction Studies (NCS)

Comparison with NCS	Sensitivity	Specificity	PPV	NPV
Biothesiometry	95.20	64.60	35.40	96.60
Monofilament	57.10	89.30	42.90	89.30
Tuning fork	42.90	86.40	57.10	96.20

Table 6: Validation of Biothesiometry, Monofilament and Tuning fork with Nerve Conduction Studies (NCS)

Variables	Area under the curve (AUC)	P-value	95% Confidence Interval	
			Lower band	Upper band
Biothesiomitry	0.882	P<0.001 (0.000)	0.679	0.954
Monofilament	0.24	P<0.001 (0.023)	0.121	0.472
Tuning fork	0.305	P<0.001 (0.109)	0.174	0.539

IV. DISCUSSION

Diabetic peripheral neuropathy (DPN) is a chronic and devastating complication of diabetes that affects motor, sensory and autonomic nerve fiber [13]. Clinical assessment should have standardized using validated NPQ (Neuropathic Pain Questionnaire) Neuropathic Pain Symptom Inventory (NPSI) and Douleur Neuropathique 4 (DN 4), in our study we use Diabetic neuropathy symptom score (DNS) [14]. We conducted present study for detection of diabetic peripheral neuropathy, among the participants 46.00% were aged between 45- 54 years and most of participants were female. Among the participants 21 subject were smoker and all were nonalcoholic. In this study most 98.00% of our subjects having HBA1c above 7% having symptom of DPN, which is similar from other study of Nozawa et al. [15]. Screening tools, such as pinprick and temperature sensation, 128Hz Tuning fork,10g monofilament (protective sensation), vibration perception (large fiber function) testing can be used according to American Diabetes Association and clinical practice guidelines [16]. In this study screening was done with Biothesiometer, 128Hz Tuning fork,10g monofilament and gold standard test NCS. Among our study population 21.0% patients having peripheral neuropathy with gold standard test NCS. Biothesiometer,128Hz Tuning fork,10g Monofilament test detect peripheral neuropathy in 71.00% ,12.00% and 16.00% participants respectively. Joseph et al. reported that VPT is gold standard for early detection of diabetic peripheral neuropathy [17]. In this study has shown more sensitivity 95.20% and less specificity 64.60% of VPT with Biothesiometer considering NCS as gold standard. There were clinical studies which prove the efficiency of VPT by showing sensitivity and specificity of 82.1 % and 78.7% respectively [18]. Vibration perception threshold yields a sensitivity of 86% and specificity of 76% according to Mythili et al. [19]. These variations may be because of the use of Biothesiometer probe of varying frequencies and the sites of examination also varied between studies. Some guidelines suggest that a VPT threshold of 25V strongly predicts future foot ulceration risk [20]. The ADA guidelines have recommended the 10-g monofilament test to detect loss of protective sensation (LOPS) because of its favorable evidence in predicting risk of foot ulceration. The current study 10-g Monofilament test shows higher specificity of 89.30%, lower sensitivity of 57.10%, positive predictive value 42.90% and negative predictive value 89.30% in comparison to gold standard test NCS. Shrestha et al. study showed that the sensitivity, specificity, positive predictive value and negative predictive value of monofilament were found to be 92.0%, 95.8%, 88.5% and 97.1% respectively [21]. The International Working Group on the Diabetic Foot (IWGDF) guidelines, in suspected high risk cases additional screening of Tunning fork or Biothesiometer when a monofilament test does not show any loss of protective sensations [5]. Our study suggests that the inclusion of VPT testing can identify additional cases of DPN. The 128-Hz Tuning fork provides an easy and inexpensive test of vibration sensation used to assess DPN. Interpretation done by comparing how long the patient detects vibration in comparison with an examiner. It determines whether vibration sense is normal, impaired or absent. The sensitivity and specificity of vibration testing for peripheral neuropathy have been estimated to be 53 and 99 per cent respectively [22]. The present study shows lower sensitivity 42.90%, and specificity 86.40% of 128Hz tuning Fork test considering NCS as gold standard. In other study they show more sensitivity 70% and specificity 90% in detecting sever neuropathy [23]. Receiver operating characteristic (ROC) curve was plotted to compare the diagnostic performance of Biothesiometer, 128Hz Tuning fork ,10g Monofilament with NCS diagnosed DPN and the area under the curve (AUC) was determined. Area under the curve (AUC) was higher for the biothesiometer 0.882 and both monofilament and tuning fork the AUC was lower. Nahm et al. categorized result of area under curve as Fail (0.5 -0.59), Poor (0.6-0.69), Good (0.80-0.89) and excellent (> 0.90) [24]. Consequently, it is plausible that there is overestimation of diabetic peripheral neuropathy in Biothesiometery. Further research can validate the diagnostic accuracy of Biothesiometer and find out a optimal VPT cut off for our populations. The advantage of VPT testing is its ability to quantified vibration perception values, which can be utilized to actively monitoring the disease progression over an extended period [25]. Which can offer sub-substantial time efficacy for medical practitioners.

Limitations of study: The sample was collected purposively, so bias might have occurred. There was no control group. The target sample size was not reached. Additionally, the biothesiometer is not yet a validated diagnostic tool.

V. CONCLUSION AND RECOMMENDATIONS

In the present study, Vibration perception threshold (VPT) exhibited suitable efficacy for screening of DPN and these results support the feasibility of VPT with Biothesisometer as tool in clinical practice. But there is high chance of false positivity, so this should be further confirmed by clinical finding and nerve conduction study.

Recommendations:

As nerve conduction study is not widely available, a biothesiometer could be an alternative. However, better standardization of the biothesiometer may be needed. A large-scale, primary health care center-based study may also be helpful.

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