Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 4 No. 12 (2023): December 2023 Issue
https://doi.org/10.51168/sjhrafrica.v4i12.973
Original Article

A CROSS-SECTIONAL STUDY OF USING BEDSIDE SCREENING TECHNIQUES FOR EVALUATION OF PREVALENCE AND INCIDENCE OF DIABETIC PERIPHERAL NEUROPATHY.

Sudhir Chandra Jha[a], Naween Kumar[b,], Purushottam Kumar[c], Amit Kumar Yadav[c]*
[a]Professor, Department of Medicine, Darbhanga Medical College, Darbhanga, Bihar, India
[b]Assistant Professor, Department of Medicine Darbhanga Medical College, Darbhanga, Bihar India
[c]Junior Resident, Department of Medicine, Darbhanga Medical College, Darbhanga, Bihar, India

ABSTRACT

Introduction

Peripheral neuropathy is frequently observed in patients with diabetes mellitus who have persistently high blood sugar levels. Diabetic peripheral neuropathy can cause symptoms such as loss of feeling, numbness, or even very upsetting experiences. Significant neuropathic deficits may exist in certain circumstances yet remain undetected. Thus, the aim of this research is to evaluate diabetes mellitus patients in order to promote early peripheral neuropathy screening.

Methodology

This study included 110 diabetes mellitus patients who visited the Darbhanga Medical College within 2022-2023. A diabetes symptom and examination questionnaire, the tuning fork test, the biothesiometer, the monofilament test, and other bedside screening methods are used in the evaluation.

Results

The results show that people with poor management of their diabetes (51%), subsequent to those with fair control (31%) and good control (18%), are most likely to develop diabetic neuropathy. Notably, there is a correlation between blood sugar levels and the severity of peripheral neuropathy. Considering how common diabetic peripheral neuropathy is, it is clear that these individuals' morbidity is still significant.

Conclusion

A major adverse effect of diabetes is diabetic peripheral neuropathy. New treatments like tricyclic anti-depressants or anti-convulsant and proper glycemic control can improve results for these individuals, thus early identification and management are crucial. Initial detection of DPN is crucial for foot ulcer prevention. These folks need extensive preventive treatment and education.

Recommendations

The study suggests that diabetics, especially those with poorly managed blood sugar, should be screened for peripheral neuropathy often. Early detection of neuropathic impairments should prompt therapy and actions to reduce foot ulcer risk. Optimizing glycemic management as part of diabetes patients' regular therapy can lower peripheral neuropathy severity and incidence. To reduce diabetic peripheral neuropathy, patient education should emphasize self-monitoring and foot care.

Keywords: *Type 2 Diabetes Mellitus, Peripheral Neuropathy, Biothesiometer, Bedside Screening, Monofilament, Tuning Fork Test*
Submitted: 2023-12-22 Accepted: 2023-12-23

Corresponding Author: *Naween Kumar[b,*], Assistant Professor, Department of Medicine Darbhanga Medical College, Darbhanga, Bihar India.*
Email: naween.arya@gmail.com

INTRODUCTION

Diabetes is a disease that is becoming more and more common worldwide, particularly in poorer nations. In 2005, the WHO released a report approximating that there were 171 million diabetics globally; by 2030, that figure is projected to rise to 366 million. The number of people with diabetes in India alone was 31.7 million in 2000, and by 2030, it is expected to rise to 79 million [1]. About 90% of instances of diabetes are thought to be type 2 diabetes mellitus [2]. Type 2 diabetes affected an estimated 250 million individuals in 2010, and estimates suggest that number could rise to roughly 300 million by 2025. India is now officially recognized as the "Diabetic Capital of the World" [3].

Diabetes mellitus, a chronic metabolic disorder, is characterized by hyperglycemia resulting from impairments in insulin secretion, insulin action, or a combination of both. Diabetic peripheral neuropathy is one of the complications that arise from these issues (DPN). Up to 50% of diabetes cases have DPN, which can cause excruciating pain, limited movement, and a higher risk of foot ulcers and amputations [4]. According to studies conducted in the US, over 70% of

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diabetics experience neuropathic pain, with 60% of those with severe neuropathy reporting unpleasant symptoms [5].

One of the main causes of foot issues, such as walking difficulties and amputations, is DPN. It is the main reason for amputations that are not traumatizing. According to research, neuropathy affects 19.1% of South Indian patients with type 2 diabetes [6]. It is noteworthy that a large number of neuropathy assessment instruments were created and assessed in developed nations with common foot care practices. Contrarily, a large number of people in developing countries like India continue to walk barefoot and neglect their feet. This can change how neuropathy symptoms appear and have an impact on the reliability of diagnostic instruments like the Diabetic Neuropathy Examination (DNE) score, the 10-gram Semmes-Weinstein monofilament test, the Diabetic Neuropathy Symptom (DNS) Score, the 128 Hz tuning fork vibration testing, the ankle reflex assessment, and others.

The growing prevalence of diabetes worldwide emphasizes how crucial it is to test for diabetic peripheral neuropathy and identify it early. Early detection lowers the risk of serious complications like amputations and ulcers by giving diabetes individuals the critical chance to control their blood sugar levels and adopt improved foot care practices. Clinical practice guidelines encourage neuropathy screening as a result of screening procedures that have been demonstrated in clinical studies to reduce the frequency of such problems. However, because of disparate lifestyles and foot care customs, it can be difficult to adapt these screening measures for underdeveloped nations, which could have an impact on diagnostic accuracy.

The objective of this study was to evaluate the utilization of the aforementioned modalities in a community with limited adherence to foot care practices, employing the conventional and extensively validated screening method of quantifying vibration perception threshold (VPT) with a biothesiometer.

The aim of this study is to evaluate the presence of both subclinical in nature and symptomatic diabetic peripheral neuropathy among patients diagnosed with Type II diabetes mellitus. This assessment will be conducted using bedside screening methods at a Tertiary Care Hospital.

METHODOLOGY

Study Design:

A cross-sectional study

Study Setting:

Darbhanga Medical College, Darbhanga, Bihar, India

Study Duration:

July 2022- June 2023

Study size:

Following the application of stringent inclusion and exclusion criteria, the final study cohort comprised 110 participants.

Participants:

The study included a cohort of 110 participants.

Inclusion Criteria:

The present study focuses on individuals who have been previously diagnosed with Type 2 Diabetes Mellitus (DM) as well as those who have recently received a new diagnosis of this condition. Patients of both genders seeking medical care in both the inpatient department (IPD) and outpatient department (OPD), within the age range of 34 to 70 years.

Exclusion Criteria:

Exclusion criteria encompass individuals with pre-existing or known neuromuscular pathology, peripheral arterial disease, or a significant medical ailment. The patient presents with a diagnosis of diabetic foot and has undergone limb amputation as a result of DPN.

Bias:

Potential bias was mitigated at the onset of the study by ensuring uniform dissemination of information to all participants and concealing group allocation from the data-collecting nurses.

Variables

Variables included demographic details, clinical symptoms, laboratory parameters, and treatments.

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Methodology:

Every participant provided their signed consent, relevant clinical assessment data, and a thorough medical history. The data was carefully recorded using a pre-designed data collection form.

The patients' medical history was thoroughly investigated, covering the length of time they had had diabetes, any family history of the disease, and any symptoms that would have pointed to peripheral neuropathy.

Patients presenting at our medical facility with an initial diagnosis of T2 DM were categorized as recently diagnosed T2 DM patients, as per the assessment of clinical manifestations and laboratory results.

Bedside screening techniques:

When DPN was identified, the following bedside approaches were used to carefully document the degree of neuropathy. The following bedside screening techniques were used to assess peripheral neuropathy, and each patient's results were carefully documented:

1. Monofilament test by Semmes and Weinstein

2. A biothesiometer, which measures a subject's threshold for vibrating perception.

3. To evaluate vibration perception, use the tuning fork test.

Statistical analysis:

Frequency and percentages were calculated of all the variables.

Ethical considerations:

The study protocol underwent approval by the Ethics Committee, and informed consent in writing was obtained from all participants involved in the study.

Table 1: Baseline characteristics of participants

Variables	Frequency	Percent
Neuropathy		
Yes	82	75
No	28	25
Age group		
34 to 40 yrs	20	18
41 to 50 yrs	34	31
51 to 60 yrs	13	11
61 to 70 yrs	27	25
More than 70 yrs	16	15
Gender		
Female	65	59
Male	45	41
HbA1C		
Fair (5.7%)	20	18
Good (5.8 to 6.4%)	34	31
Poor (>6.4%)	56	51
Duration of diabetes		
1 to 5 yrs	13	12
6 to 10 yrs	25	23
11 to 15 yrs	19	17
16 to 20 yrs	35	32
More than 20 yrs	18	16
Treatment of diabetes		
Insulin	9	8
OHA	20	18
OHA + insulin	81	74

RESULTS

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Table 1 shows the data collected from the study participants revealed various variables. Regarding neuropathy, 75% of participants reported having it, while the remaining 25% did not. The age distribution among the participants was as follows: 18% were in the 34 to 40 years age group, 31% in the 41 to 50 years age group, 15% in the 51 to 60 years age group, 11% in the 61 to 70 years age group, and 25% were above 70 years old.

In terms of gender, 59% of participants were female, and 41% were male. When assessing HbA1C levels, 18% fell within the "Fair" range (5.7%), 31% in the "Good" range (5.8 to 6.4%), and 51% in the "Poor" range (>6.4%).

Concerning the duration of diabetes, 12% had been living with it for 1 to 5 years, 23% for 6 to 10 years, 17% for 11 to 15 years, 32% for 16 to 20 years, and 16% for over 20 years. Lastly, the treatment of diabetes showed that 8% were on insulin, 18% on oral hypoglycemic agents (OHA), and a significant majority of 74% was using a combination of OHA and insulin for management.

Table 2: Comparing the Tuning Fork, Biothesiometer, and Monofilament

	Monofilament Test	**Tuning Fork**	**Biothesiometer**
True positive	43	40	98
False negative	29	18	7
False positive	14	22	5

Table 2 presents a comparison between the results of three diagnostic tests: the Monofilament Test, Tuning Fork Test, and Biothesiometer Test. In the evaluation of diabetic peripheral neuropathy using three different screening techniques, the results revealed varying numbers of true positives, false negatives, and false positives. The monofilament test identified 43 cases as true positives while showing 14 cases as false positives. However, it missed 29 cases, leading to false negatives. The tuning fork test demonstrated 40 true positives, along with 22 false positives and 18 false negatives. The biothesiometer displayed the highest number of true positives at 98, with only 5 false positives and 7 false negatives. These findings emphasize the varying performance of these screening methods in identifying diabetic peripheral neuropathy cases, highlighting the importance of selecting the most appropriate technique for accurate diagnosis and early intervention. Additionally, it was also examined how well three screening tests—the tuning fork test, the biothesiometer, and the monofilament test—diagnosed neuropathy. When it came to detecting neuropathy, the biothesiometer showed the highest levels of sensitivity (92.98%), specificity (96.86%), positive predictive value (95.30%), negative predictive value (95.48%), and accuracy (95.41%). The monofilament test exhibited a sensitivity of 58.04%, specificity of 76.86%, positive predictive value of 60.25%, negative predictive value of 75.22%, and accuracy of 68.85%. The tuning fork test yielded an accuracy of 81.06%, positive predictive value of 84.71%, negative predictive value of 85.76%, sensitivity of 77.31%, and specificity of 83.29%.

DISCUSSION

In the present study, the hospital-based descriptive study used bedside screening methods to evaluate DPN in patients with Type II diabetes, both subclinical and symptomatic. According to the findings, patients with poor diabetes control had the highest prevalence of DPN (51%), followed by those with fair control (31%) and good control (18%). Notably, there was a correlation between blood sugar levels and the degree of peripheral neuropathy, with greater blood sugar levels being linked to more severe neuropathy. This emphasizes how crucial blood sugar control is for diabetic people in order to lower their risk of DPN.

The study participants were distributed across various age groups, providing a diverse representation of the population. A significant proportion of the participants, constituting 18% of the total, fell within the 34 to 40 years age bracket. In the 41 to 50 years age group, 31% of the participants were included, reflecting a substantial presence in this category. Furthermore, 15% of the participants were aged between 51 and 60 years, while 11% belonged to the 61 to 70 years age group. The study also included a notable segment of older individuals, with 25% of the participants aged above 70 years. This wide age distribution ensured that the study encompassed a broad spectrum of age-related factors, contributing to a comprehensive understanding of the research findings. DPN was discovered to be more prevalent after the age of fifty, which is consistent with findings from other studies [7,8].

Regarding the duration of diabetes among the study participants, it was found that a diverse range of experience existed. Specifically, 12% of individuals had recently been diagnosed and were living with diabetes for a period

spanning 1 to 5 years. A larger proportion, constituting 23% of the cohort, had been managing their diabetes for duration of 6 to 10 years. Additionally, 17% of participants had a history of diabetes spanning 11 to 15 years, signifying a significant portion of the population with a relatively long-standing condition. A substantial 32% of individuals reported managing their diabetes for 16 to 20 years, reflecting a considerable portion of the study group. Finally, 16% of participants had the longest experience, with a diabetes duration exceeding 20 years. These findings underscore the heterogeneity of diabetes duration within the study population, highlighting the need for tailored approaches to diabetes management and care. Based on the length of diabetes, the study did not uncover any statistically significant changes in DPN prevalence. This is in line with other studies that show a direct relationship between the length of diabetes and the prevalence of peripheral neuropathy [7, 9].

Additionally, the evaluation of diabetic peripheral neuropathy using three different screening techniques yielded diverse outcomes in terms of true positives, false negatives, and false positives. The monofilament test identified 43 true positives but also yielded 14 false positives, missing 29 cases (false negatives). The tuning fork test identified 40 true positives, 22 false positives, and 18 false negatives. The biothesiometer demonstrated the highest true positives at 98, with only 5 false positives and 7 false negatives. These results underscore the varying effectiveness of these screening methods in identifying cases of diabetic peripheral neuropathy, underscoring the need to select the most suitable technique for accurate diagnosis and timely intervention.

Furthermore, the diagnostic performance of the three screening tests—tuning fork, biothesiometer, and monofilament test—was assessed. The biothesiometer exhibited the highest sensitivity (92.98%), specificity (96.86%), positive predictive value (95.30%), negative predictive value (95.48%), and accuracy (95.41%) in detecting neuropathy. The monofilament test displayed a sensitivity of 58.04%, specificity of 76.86%, positive predictive value of 60.25%, negative predictive value of 75.22%, and accuracy of 68.85%. Meanwhile, the tuning fork test achieved an accuracy of 81.06%, positive predictive value of 84.71%, negative predictive value of 85.76%, sensitivity of 77.31%, and specificity of 83.29%. These findings emphasize the varying diagnostic capabilities of these tests, with the biothesiometer demonstrating the highest overall performance in detecting diabetic peripheral neuropathy.

The main goals of treatment for diabetic peripheral neuropathy with symptoms are to reduce neuropathic pain, delay the disease's progression, and avoid complications like diabetic foot. Neuropathic pain can be managed with antidepressants, anticonvulsants, pregabalin, and gabapentin, among other drugs. Changing one's lifestyle to include regular foot care routines, antidiabetic medication adherence, and stringent blood sugar management are all essential for managing diabetic neuropathy. These include washing your feet in lukewarm water, making sure the water temperature is safe, checking your feet every day, carefully trimming your nails, avoiding going barefoot, checking your footwear for potential problems, attending to cuts, blisters, redness, swelling, and nail problems right away, abstaining from smoking, and selecting moisture-wicking socks without elastic tops. When taken as a whole, these actions help to effectively manage diabetic peripheral neuropathy and prevent further problems.

Generalizability:

The generalizability of the study's findings is supported by its hospital-based design using bedside screening methods to assess Diabetic Peripheral Neuropathy (DPN) in Type II diabetes patients, reflecting real-world clinical settings. The inclusion of participants spanning various age groups, diabetes durations, and the use of three distinct screening techniques enhances the applicability of the results to a diverse patient population. The study's focus on diagnostic performance, with the biothesiometer demonstrating superior sensitivity and specificity, provides valuable insights for healthcare providers in selecting suitable screening methods. Additionally, the emphasis on treatment goals, including pain management and lifestyle modifications, aligns with broader healthcare objectives for managing DPN, making the study's recommendations widely relevant.

CONCLUSION

The prevalence and incidence of DPN and its related complications, such as the formation of trophic ulcers and more serious problems requiring amputation, can be greatly decreased by early detection of DPN in individuals with long-standing diabetes through straightforward bedside techniques and appropriate counseling on foot care by treating physicians. When compared with tuning fork and monofilament testing among these bedside procedures, the Biothesiometer is the most specific and sensitive tool for diagnosing neuropathy. It is important to remember, though, that the Biothesiometer is a slightly more costly device, and doctors need to be trained to use it properly. Consequently, all diabetes patients should have regular check-ups regarding neuropathic symptoms, be evaluated by simple bedside techniques for early diagnosis and treatment, and

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Original Article

receive thorough foot care advice, especially from those with subclinical symptoms. This method can lessen the effects of diabetic neuropathy and greatly enhance patient outcomes.

Limitations:

The study is subject to certain limitations, notably the inclusion of a relatively small sample population. The generalizability of the study's findings to a broader population is limited. Moreover, the absence of a comparison group presents a constraint on the findings of this study.

Recommendations:

In light of the study's findings, it is recommended that healthcare providers prioritize regular screening for peripheral neuropathy in patients with diabetes mellitus, particularly those with poorly controlled blood sugar levels. Early identification of neuropathic deficits should trigger prompt management and interventions to mitigate the risk of complications, such as foot ulcerations. Additionally, healthcare professionals should focus on optimizing glycemic control as part of the standard care for diabetic patients to reduce the severity and incidence of peripheral neuropathy. Educational initiatives aimed at patients should emphasize the importance of proactive self-monitoring and foot care practices to minimize the impact of diabetic peripheral neuropathy.

Acknowledgement:

The authors express their gratitude to the participants, as their invaluable contribution was indispensable in the successful completion of this study. We express our gratitude to the dedicated supporting staff of our esteemed medical institution who actively participated in the provision of comprehensive patient care for the study cohort.

List of abbreviation:

DPN- Diabetic peripheral neuropathy
DNE- Diabetic Neuropathy Examination
DNS- Diabetic Neuropathy Symptom
WHO- World Health Organization
T2DM- Type 2 diabetes mellitus
VPT- Vibration perception threshold
IPD- Inpatient department
OPD- Outpatient department

Source of funding:

No funding received.

Conflict of interest:

The authors have no competing interests to declare.

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Vol. 4 No. 12 (2023): December 2023 Issue
https://doi.org/10.51168/sjhrafrica.v4i12.973
Original Article

Publisher details

SJC PUBLISHERS COMPANY LIMITED

Category: Non-Government & Non-profit Organisation
Contact: +256775434261(WhatsApp)
Email: admin@sjpublisher.org, info@sjpublisher.org or studentsjournal2020@gmail.com
Website: https://sjpublisher.org
Location: Wisdom Centre Annex, P.O. BOX. 113407 Wakiso, Uganda, East Africa.