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UNMASKING THE SILENT EPIDEMIC: EVALUATING BIOTHESIOMETRY FOR EARLY DETECTION OF DIABETIC NEUROPATHY IN INDIA

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ABSTRACT –

Background: Due to the alarmingly high prevalence of type 2 diabetes mellitus (T2DM), India is experiencing a growing healthcare crisis. Diabetic peripheral neuropathy (DPN), one of the range of T2DM consequences, is particularly concerning, with prevalence rates in India ranging from 8% to 59%. DPN greatly increases the chance of serious side effects such gangrene, amputations, foot infections, and deformities. Factors like poor foot cleanliness, wearing the wrong shoes, and going barefoot all add to the intricacy of this problem.

Methods: This single-centre, hospital-based cross-sectional study spanned 18 months, involving 87 participants with confirmed T2DM. Data collection included anthropometric measurements, blood tests for glucose control and lipid profiles, urine sugar levels, and assessments for peripheral neuropathy using biothesiometry and nerve conduction velocity. Statistical analysis included mean values, percentages, chi-square tests, and t-tests.

Results: The study involved mostly male participants (64.4%) with an average age of 59.6 years and an average T2DM duration of 8.1 years. Notable findings included elevated fasting blood sugar (160.9 mg/dL), postprandial blood sugar (251 mg/dL), and HbA1c levels (7.1%). Approximately 49% of participants had high urine sugar levels, with 35.6% showing 4+ urine sugar. Nerve conduction velocity tests indicated peripheral neuropathy in 90.8% of cases. Biothesiometer assessments of the right foot revealed peripheral neuropathy in 78.2% of individuals, with varying severity. In contrast, left foot assessments indicated that 21.8% had no neuropathy. An association was found between HbA1c levels and neuropathy, and a significant difference existed between biothesiometer and

nerve conduction velocity results (p=0.021). When assessing neuropathy based on disease duration, nerve conduction velocity tended to identify more cases than the biothesiometer.

Conclusion: This study underscores the significance of early detection of peripheral neuropathy in T2DM patients. The biothesiometer proves to be a practical, non-invasive, and cost-effective tool for this purpose. Routine biothesiometer use is recommended for early detection of peripheral neuropathy in T2DM patients, providing a valuable contribution to managing this significant healthcare challenge in India.

Keywords: Type 2 diabetes mellitus, diabetic peripheral neuropathy, biothesiometer, nerve conduction velocity, India, prevalence, HbA1c, healthcare challenge.

INTRODUCTION –

India finds itself at the forefront of an imposing healthcare challenge, characterized by one of the world's most alarming prevalence rates of type 2 diabetes mellitus (T2DM). The foreboding projections indicate that by the year 2030, nearly 80 million Indians may grapple with T2DM, thrusting the nation's healthcare infrastructure into a relentless struggle (Dworkin et al., 2010). Yet, this looming crisis is not merely a matter of numbers; it is an imminent threat to the well-being of the nation's population (Ramachandran et al., 2007).

Among the manifold complications complexly woven into the fabric of T2DM, diabetic peripheral neuropathy (DPN) emerges as a particularly insidious opponent. Its prevalence within India presents a mosaic, with prevalence ranging from 8% to 59% across various studies (Hamid Zargar et al., 1999). Irrespective of these specific statistics, the consequences it entails remain consistently dire, significantly increasing the likelihood of severe issues like foot infections (Hamid Zargar et al., 1999), deformities (Hamid Zargar et al., 1999), gangrene (Deli et al., 2013), and, amputations (Armstrong et al., 1998).

The Indian context imparts a multifaceted complexity to this healthcare enigma. Factors encompassing suboptimal foot hygiene, inappropriate footwear choices, and the prevalent practice of barefoot ambulation serve to amplify the repercussions of peripheral neuropathy (PN). Tragically, the diagnosis of DPN is often delayed, constrained by a dearth of awareness and the absence of methodical screening programs (Abbott et al., 2005). This diagnostic inertia is disconcerting, as it potentially escalates the incidence of microvascular complications during the onset of T2DM (Dworkin et al., 2010). Additionally, well-documented ethnic disparities in the prevalence of diabetes-related complications underscore the nuanced nature of this crisis within the Indian population (Spijkerman et al., 2003).

Beyond its physical toll, neuropathy and neuropathic pain cast a profound shadow over the health-related quality of life for individuals grappling with T2DM. Simultaneously, the management of neuropathy, inclusive of the provision of adequate podiatric care, exacts a substantial economic toll on India's national healthcare framework (Dworkin et al., 2010, Brown et al., 2017). This financial encumbrance extends beyond the realm of direct medical expenditures, permeating into work-related absences, alterations in employment dynamics,

and even the specter of disability, thereby casting ripples that affect individuals and society at large (Perkins et al., 2001).

Amidst this backdrop, conventional methods for diagnosing DPN, such as nerve conduction studies and skin biopsies, have established their place in clinical practice (Jayaprakash et al., 2009). However, within primary care settings, clinical symptom scales and monofilament testing are the more frequently employed diagnostic modalities. Concurrently, the vibration perception threshold (VPT) test has secured its validation as a diagnostic tool for DPN. (Ramachandran et al., 2007)

In the receptacle of this multifaceted healthcare challenge, our study emerges as a beacon of inquiry and hope (Deli et al., 2013). While numerous international studies have rigorously scrutinized the reliability of biothesiometry in diagnosing diabetic neuropathy, India's contribution to this collective understanding remains notably deficient (Dworkin et al., 2010). The primary goal of this study is to examine and evaluate peripheral neuropathy in individuals with type 2 diabetes mellitus through the utilization of biothesiometry.

MATERIALS AND METHODOLGY -

This study was conducted as a single-centre, hospital-based cross-sectional study, employing an observational and descriptive approach. It spanned a duration of 18 months, starting in November 2020 and concluding in April 2022. The study was executed at a tertiary care hospital, with data collection occurring in both the medicine outpatient department (OPD) and ward.

The sample size for this study was determined through a calculated approach. A prior study had reported that approximately 31.33% of patients with type 2 diabetes mellitus exhibited peripheral neuropathy. To ensure statistical reliability, the sample size was calculated using the formula $N=4pq/e^2$, resulting in an estimated sample size of approximately 87 (n=87) participants. This sample size was selected with a 10% margin of error.

The study included individuals with a confirmed diagnosis of type 2 diabetes mellitus. However, certain exclusion criteria were applied. Participants under 18 years of age and those with insulin-dependent diabetes mellitus (type I diabetes), severe foot ulcerations, a history of alcoholism or smoking, known renal, cardiac, pulmonary, or hepatic diseases, a history of nerve compression, or other known causes of neuropathy were excluded from the study to ensure the homogeneity of the study population.

The study adhered to ethical principles and received formal approval from the institutional ethics committee, identified as IEC PROTOCOL NO: 048/2020-2021, underscoring its commitment to ethical research practices.

Diabetes mellitus was diagnosed based on multiple criteria, including fasting blood sugar level (FBS) exceeding 126mg/dl, 2-hour plasma glucose exceeding 200mg/dL during a glucose tolerance test, symptoms indicative of diabetes with random blood sugar levels (RBS) surpassing 200mg/dL, or a glycated haemoglobin (HbA1c) level exceeding 6.5%.

Data was meticulously collected from individuals diagnosed with type 2 diabetes mellitus. Anthropometric measurements were taken as part of the data collection process. Additionally, blood samples were routinely taken to measure the levels of glycated hemoglobin (HbA1c), fasting blood sugar, and post-meal blood sugar, all of which are critical indicators of blood sugar control.

The study also extended its examination to the lipid profiles of the participants. This encompassed the calculation of low-density lipoprotein (LDL) cholesterol levels using the Friedewald equation, as well as the assessment of high-density lipoprotein (HDL) cholesterol and very low-density lipoprotein (VLDL) cholesterol levels.

Using a biothesiometer, the vibration perception threshold was determined. The participants in the study had both feet subjected to this gadget in a methodical manner. In order to interpret the findings, the thresholds were divided into categories, with normal studies (below 15 Volts), mild neuropathy (16–20 Volts), moderate neuropathy (21–25 Volts), and severe neuropathy (over 25 Volts) being the distinctions made.

The full evaluation of the study included a nerve conduction velocity test. In this test, electrodes were strategically placed on the skin to stimulate nerves, record muscle contractions, and allow for the measurement of nerve conduction velocity.

Statistical Analysis: Microsoft Excel was used for a thorough statistical analysis of the acquired data. The central tendency and dispersion of continuous data were revealed by the presentation of the data as Mean (+SD). To clarify the distribution of qualitative characteristics, categorical data was presented as percentages and proportions. When necessary, independent student t-tests for quantitative variables and chi-square tests for qualitative variables were used for statistical comparisons. For statistical significance, a p-value of 0.05 was used as the cutoff. Open Epi version 2.3.1 was used throughout the entire data analysis process to produce a solid and trustworthy statistical study.

RESULTS –

87 people who met the requirements and had been given a type 2 diabetes mellitus diagnosis were participated in the study. Males made up a larger percentage of the study cohort, with a male-to-female ratio of 1.8 showing a male predominance. The participants' ages ranged from 22 (25.2%) in the 40–50 age range to 26 (30%) in the 51–60 age range, with 39 (44.8%) representing the majority of the participants who were over the age of 60. The participants' average age was 59.6 years, with an 11.5-year standard deviation.

32 participants (36.8%) had type 2 diabetes mellitus for less than five years, 34 participants (39.1%) for five to ten years, and 21 participants (24.1%) for more than ten years. The participants' mean time with type 2 diabetes was 8.1 years, with a 6.1-year standard deviation. Newly diagnosed patients to those with a 30-year history of the illness were included in this time period. The study also evaluated various laboratory parameters, including fasting blood sugar (FBS), postprandial blood sugar (PPBS), HbA1c, total cholesterol (TC), triglycerides (TG), high-density lipoprotein (HDL), very low-density lipoprotein (VLDL), low-density lipoprotein (LDL), and urine sugar levels. Notably, 49% of the participants exhibited elevated urine sugar levels, with 35.6% displaying a high level of 4+ urine sugar, while 50.6% had normal urine sugar levels as shown in Table 1.

Table 1: Distribution of study population according to mean and standard deviation of numerical variables of laboratory parameters

Factors	Mean	SD (±)
Fasting blood sugar (FBS) (in mg/dl)	162.5	67.6

Post prandial blood sugar (PPBS) (in mg/dl)	250	113.8
HbA1c (%)	7.9	1.9
Total cholesterol (TC) (in mg/dl)	143.4	47.5
Triglyceride (TG) (in mg/dl)	144.8	115.8
High density lipoprotein (HDL) (in mg/dl)	38.8	25
Very low-density lipoprotein (VLDL) (in mg/dl)	34	24.5
Low density lipoprotein (LDL) (in mg/dl)	73.5	34.2

Nerve conduction velocity measurements were conducted for all 87 participants diagnosed with type 2 diabetes mellitus as depicted in Table 2. Among them, 8 (9.1%) had a normal study, 49 (56.3%) exhibited early changes of polyneuropathy, and 30 (34.5%) had established polyneuropathy. When evaluating peripheral neuropathy using the biothesiometer for the right foot, 24 (27.5%) participants had a normal study, 34 (39.1%) had mild peripheral neuropathy, 21 (24.1%) had moderate peripheral neuropathy, and 8 (9.1%) had severe peripheral neuropathy.

Table 2: Evaluation of study population by biothesiometer of right foot

Biothesiometer evaluation	**(n = 87)**	**Percent**
Normal observations	24	27.5
Mild peripheral neuropathy	34	39.1
Moderate peripheral neuropathy	21	24.1
Severe peripheral neuropathy	8	9.1
Total	87	100

For the left foot, 26 (29.9%) participants had a normal study, 25 (28.7%) had mild peripheral neuropathy, 31 (35.6%) had moderate peripheral neuropathy, and 5 (5.7%) had severe peripheral neuropathy. The biothesiometer evaluation indicated that 68 (78.2%) participants had peripheral neuropathy, while 19 (21.8%) did not as shown in table 3.

Table 3: Evaluation of study population by biothesiometer of left foot

Biothesiometer evaluation	**(n = 87)**	**Percent**
Normal observations	26	29.9

Mild peripheral neuropathy	25	28.7
Moderate peripheral neuropathy	31	35.6
Severe peripheral neuropathy	5	5.7
Total	87	100

A biothesiometer was utilized to assess the vibration perception threshold (VPT) in the entire study cohort, consisting of 87 participants diagnosed with type 2 diabetes mellitus. Among these participants, 68 (78.2%) were found to have peripheral neuropathy, while 19 (21.8%) did not exhibit signs of peripheral neuropathy.

Participants were categorized based on their HbA1c levels. Among the total of 87 participants, as shown in table 4, 27 had HbA1c levels less than 6%, with 19 of them having peripheral neuropathy and 8 not having it. In contrast, 60 participants had HbA1c levels exceeding 6%, with 49 exhibiting peripheral neuropathy and 11 not having it.

Table 4 and 5 shows that both biothesiometer and nerve conduction velocity evaluations were conducted for the 87 participants for study population and type 2 diabetes mellitus patients respectively. On biothesiometer evaluation, 68 participants were diagnosed with peripheral neuropathy, while 19 were not. However, when assessing peripheral neuropathy using nerve conduction velocity measurement, 79 participants were diagnosed with it, and 8 were not. A chi-square test revealed a notable connection between the two assessment approaches, underscoring their concurrence in the diagnosis of peripheral neuropathy.

Table 4: Comparison of biothesiometer and nerve conduction velocity among the study population

Parameter	**Peripheral neuropathy present**	**Peripheral neuropathy Absent**	**Total**	**Chi square value- 5.3 DF-1 P value 0.021**
Biothesiometer	68	19	87	
Nerve conduction velocity	79	8	87	

Table 5. Comparison of peripheral neuropathy on nerve conduction velocity and biothesiometer based on duration of type 2 diabetes mellitus.

Duration in years	**Nerve conduction velocity**		**Biothesiometer**		**Total**
	Present	**Absent**	**Present**	**Absent**	
<5 years	25	7	20	12	32

5 to 10	33	1	29	5	34
>10	21	0	19	2	21
Total	79	8	68	19	87

DISCUSSION -

Our study cannot be directly compared to existing research due to the limited availability of literature regarding the utilization of the biothesiometer as a tool for assessing peripheral neuropathy. The current investigation was conducted with the aim of examining peripheral neuropathy in individuals with type 2 diabetes mellitus using the biothesiometer. It was a single-centre cross-sectional study conducted over an 18-month period, involving 87 patients diagnosed with type 2 diabetes mellitus. The diagnosis of diabetes mellitus was established based on previous diabetes history managed with or without medication, and it adhered to the ADA criteria, which include fasting blood sugar levels exceeding 126 mg/dL, random blood sugar levels surpassing 200 mg/dL, or HbA1c levels exceeding 6.5%.

Regarding the age distribution of our study participants, the average age was 59.6 years (with a standard deviation of 11.5 years). A significant proportion (44.8%) of the participants were aged above 60 years. In comparison, previous research conducted by Young MJ et al. [60] reported an average age of 51 years, with an age range from 30 to 80 years. Similarly, research by Nagaraja BS et al. noted a mean age of 41.1 years (with a standard deviation of 15 years), while Gill HK et al. found an average age of 47.6 years. Iyengar MF et al. reported an average age of 48.2 years. In contrast, Mettayil JJ et al. observed an age range spanning from 27 to 76 years in their study participants.

Our study exhibited a notable predominance of male participants, constituting 64.4% of the total subjects, while females constituted a smaller percentage at 35.6%. This is in contrast to the findings of Young MJ et al., who found that 75 out of 100 patients in their study were female, with 25 being male. Similar findings were made by Nagaraja BS et al. who discovered that male participants comprised 64.7% of their study's participants while female participants made up 35.2%. In the study by Iyengar MF et al., 50.3% of the participants were female. These variations in gender distribution among the studies emphasize how important it is to consider demographic aspects when interpreting research results.

With a standard deviation of 6.1 and an average diabetes duration of 8.1 years, our study's findings reflect a wide range of experiences, from individuals who were only recently diagnosed to those who had the condition for up to 30 years. The majority of our participants, or 39.1%, had been taking care of their type 2 diabetes for five to 10 years, which is crucial to mention. As opposed to this, 26.13% of the respondents in Nagaraja BS et al.'s study had been controlling their sickness for more than 5 years. In contrast, the research cohort's mean time with diabetes in the Gill HK et al. study was 5.9 years, with a standard deviation of 8.2 years. These discrepancies in the length of diabetes among research highlight the variability of diabetic populations and imply that management and effects of the condition can vary greatly between people.

The study gave a thorough summary of all the important health metrics in our study sample. The average post-prandial blood sugar level (BSL) was 251, while the mean fasting BSL was

160.9. Additionally, random blood sugar levels were measured at an average of 226.9. The glycated haemoglobin (HbA1c) level, a critical marker for long-term glucose control, was found to be 7.1. In terms of lipid profile, the study observed an average total cholesterol (TC) level of 141.8, a triglyceride (TG) level of 146.8, high-density lipoprotein (HDL) at 39.7, very-low-density lipoprotein (VLDL) at 32, and low-density lipoprotein (LDL) at 77.5.

The investigation also examined urine sugar levels, with findings indicating that 49% of the participants had elevated urine sugar levels. Among those with elevated urine sugar, 35.6% exhibited a high presence of 4+ urine sugar.

Nerve conduction velocity assessments were a key component of the study, providing valuable insights into peripheral neuropathy among the study population. Notably, 56.35% of participants displayed early signs of polyneuropathy, while 34.5% exhibited sensory-motor polyneuropathy. A smaller proportion, 9.1%, had normal nerve conduction study results. Strikingly, a significant majority, comprising 90.8% of the participants, showed evidence of polyneuropathy based on nerve conduction velocity measurements.

Comparative references to other studies underscore the significance of these findings. For example, Ramu et al., reported a lower prevalence of neuropathy at 19.1%, while Nagaraja BS et al., Gill HK et al., Bansal et al., and Iyengar MF et al., recorded higher rates of diabetic peripheral neuropathy at 27%, 29.2%, 29.2%, and 89.5%, respectively. These variable numbers highlight the need for additional research and intervention techniques to comprehend and treat peripheral neuropathy in diabetes individuals.

The Biothesiometer assessments of the right foot in our study yielded valuable insights into the prevalence and severity of peripheral neuropathy among participants. Notably, 27.5% of the individuals exhibited a normal study result, indicating the absence of neuropathy. In contrast, 39.1% displayed mild peripheral neuropathy, signifying early-stage neuropathic changes, while 24.1% had moderate peripheral neuropathy, suggesting a more advanced level of nerve impairment. Additionally, 9.1% of the participants presented with severe peripheral neuropathy, reflecting the most severe degree of nerve damage on the right foot.

The Biothesiometer assessments extended to the left foot showed a slightly different distribution. A higher percentage, specifically 29.9%, had a normal study result for the left foot. Meanwhile, 28.7% exhibited mild peripheral neuropathy, 35.6% had moderate peripheral neuropathy, and 5.7% had severe peripheral neuropathy in the left foot. Overall, when considering both feet, the Biothesiometer results indicated that 78.2% of the participants had some form of peripheral neuropathy, while 21.8% did not exhibit signs of peripheral neuropathy.

Comparative references to other studies underscore the significance of these findings. For instance, Young MJ et al., reported their observations on the Biothesiometer, noting that out of 100 patients, 21 had normal values, 35 exhibited grade I neuropathy, and 44 displayed grade II neuropathy. Similarly, Mettayil JJ et al., conducted Biothesiometer assessments and found that among their participants, 26 had normal values, 50 had grade 1 neuropathy, and 24 had grade 2 neuropathy. These comparisons emphasize the varying degrees of peripheral neuropathy observed in different studies and highlight the importance of early detection and intervention to manage this condition effectively.

Our study provided important information on the association between peripheral neuropathy and HbA1c levels. Specifically, among the participants, 19 cases with peripheral neuropathy

and 8 cases without peripheral neuropathy exhibited HbA1c levels below 6. On the other hand, 49 individuals with peripheral neuropathy and 11 without it had HbA1c levels above 6. These results strongly imply a significant link between elevated HbA1c levels and the existence of peripheral neuropathy. A study by Gill HK et al. yielded comparable findings regarding the connection between HbA1c and peripheral neuropathy, emphasizing the critical role of controlling blood sugar levels in addressing neuropathic issues.

In terms of comparing the assessments conducted with the Biothesiometer and nerve conduction velocity, our analysis yielded statistically significant results with a chi-square test, resulting in a 'p' value of 0.021. This statistical significance indicates that the Biothesiometer and nerve conduction velocity measurements are not entirely concordant, implying variations in their ability to detect peripheral neuropathy.

When we compared the results of nerve conduction velocity and the Biothesiometer to the duration of type 2 diabetes mellitus, we observed that the majority of cases had a disease duration ranging from 5 to 10 years. Interestingly, among this group, nerve conduction velocity tests tended to yield more positive results for peripheral neuropathy compared to the Biothesiometer assessments.

Furthermore, when we compared the outcomes of peripheral neuropathy assessment between the Biothesiometer and nerve conduction velocity, we discovered differences. Out of the 87 participants, 68 were identified as having peripheral neuropathy through Biothesiometer assessments, while, in contrast, nerve conduction velocity testing indicated that 79 were identified as having peripheral neuropathy, and 8 were not.

These findings underscore the complexity of diagnosing peripheral neuropathy and suggest that different assessment methods may yield varying results. It is essential to consider these variations when diagnosing and managing peripheral neuropathy in clinical practice.

Moreover, insights from previous studies support our findings. Gill HK et al. [63] stressed the importance of screening for diabetic peripheral neuropathy at the time of diabetes diagnosis, especially among older individuals. Similarly, Bansal et al. [63] emphasized the value of timely screening, early detection, and intervention in preventing the progression of neuropathy. The utilization of vibration perception threshold assessments with the Biothesiometer emerged as a simple yet sensitive tool for the early detection of significant diabetic peripheral neuropathy in an outpatient setting. Madhavi Latha's research further supported the reliability of diagnosing diabetic neuropathy using the Biothesiometer and its potential to aid in the early detection of the condition.

Thus, our study sheds light on the connection between HbA1c concentrations and peripheral neuropathy, highlights discrepancies between the Biothesiometer and nerve conduction velocity assessments, and underscores the significance of early screening and intervention in managing diabetic peripheral neuropathy.

CONCLUSION –

This cross-sectional study aimed to assess peripheral neuropathy in type 2 diabetes mellitus patients using the biothesiometer and nerve conduction velocity tests. Notably, 80% of patients with peripheral neuropathy displayed biothesiometer-detected evidence. The biothesiometer is useful for detecting early peripheral neuropathy in people with type 2 diabetes mellitus and is non-invasive, quick, and affordable. In order to detect early peripheral neuropathy in type 2 diabetic patients, we advise routine biothesiometer use.

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