Biothesiometry in Diabetic Neuropathy: A Non-Invasive Tool for Screening, Diagnosis, and Monitoring Disease Progression

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Abstract:

Diabetic neuropathy (DN) is a prevalent and debilitating complication of diabetes mellitus, characterized by progressive nerve dysfunction that significantly affects the quality of life. Early detection and accurate monitoring of neuropathy progression are crucial for effective management and intervention. Biothesiometry, a non-invasive technique that measures vibratory perception threshold (VPT), has emerged as a valuable tool in screening, diagnosing, and assessing the severity and progression of diabetic neuropathy. This study explores the role of biothesiometry in diabetic neuropathy, focusing on its ability to detect early-stage neuropathy, classify the severity of nerve damage, and track disease progression over time. The biothesiometer measures VPT at multiple foot sites (e.g., big toe, arch, heel), with voltage levels ranging from 0-50 V, corresponding to different stages of neuropathy: normal (0-15 V), mild (16-20 V), moderate (21-25 V), and severe (>25 V). By assessing the response of Pacinian and Meissner corpuscles, which detect vibratory stimuli at specific frequencies, biothesiometry provides objective, reproducible data on sensory nerve function. Additionally, the method calculates a six-point average voltage, identifying areas of minimal and maximal nerve damage. This study demonstrates the diagnostic and prognostic value of biothesiometry in identifying subclinical neuropathy, monitoring progression, and evaluating treatment efficacy. Biothesiometry proves to be a reliable, non-invasive method for managing diabetic neuropathy and could be integrated into routine clinical practice to improve patient care and outcomes.

Keywords:

Biothesiometry, Diabetic Neuropathy, Vibratory Perception Threshold (VPT), Neuropathy Progression, Nerve Damage, Pacinian Corpuscles, Meissner Corpuscles, Screening Tool, Diagnostic Tool, Non-invasive Measurement, VPT Classification, Sensory Nerve Dysfunction.

Introduction:

Diabetic neuropathy (DN) is a prevalent microvascular complication of diabetes, affecting up to 50% of patients[1] and leading to sensory loss, foot ulcers, and increased risk of amputations[2]. Early detection is essential for effective management[3], but current diagnostic methods are often insufficient in identifying neuropathy at its onset[4]. Therefore, there is a pressing need for reliable, non-invasive diagnostic tools[5]. Biothesiometry, a technique that measures Vibration Perception Threshold (VPT), has emerged as a promising diagnostic method for assessing sensory nerve function in diabetic patients[6]. VPT represents the lowest intensity of vibration detectable by the patient, providing an early indicator of nerve dysfunction[7]. The biothesiometer delivers controlled vibratory stimuli, typically to the feet, and records the patient’s response to quantify nerve sensitivity[8]. This technique primarily reflects the function of large A-beta fibers, which are often the first to be affected in diabetic neuropathy[9]. As vibration sensitivity diminishes early in neuropathy, biothesiometry can detect subtle nerve changes before clinical symptoms, such as pain or numbness, manifest[10]. This early detection is crucial for initiating interventions that can slow disease progression.

Biothesiometry offers several advantages over conventional diagnostic methods: it is non-invasive, quick, and highly reproducible[11]. The device provides objective data that can be used to monitor neuropathy over time, enabling clinicians to track disease progression and assess the efficacy of therapeutic interventions[12]. By measuring VPT at multiple anatomical sites, biothesiometry also helps determine the extent and distribution of nerve damage, particularly in cases where neuropathy follows a distal-to-proximal pattern[13]. VPT values are categorized into severity levels: normal (0–15 V), mild (16–20 V), moderate (21–25 V), and severe (>25 V)[14]. The 6-point average voltage further refines the severity classification, offering a more precise assessment of nerve function[15]. These standardized thresholds aid in both diagnosis and ongoing monitoring of neuropathy. In clinical practice, biothesiometry plays an integral role not only in diagnosing DN but also in evaluating the effectiveness of treatments[16]. Regular VPT measurements allow clinicians to monitor nerve function, adjust treatment protocols, and mitigate the risk of complications such as foot ulcers[17]. In conclusion, biothesiometry represents a valuable, non-invasive tool for the early detection and longitudinal monitoring of diabetic neuropathy. Its ability to provide precise, reproducible data makes it an essential diagnostic asset in managing this complex and debilitating condition[18].

Materials and Methods

Study Design and Patient Selection

This prospective, cross-sectional study was conducted at Parul Institute of Ayurveda, Kayachikitsa Department, OPD No. 116, with the aim of evaluating the efficacy of biothesiometry in diagnosing and monitoring the severity of diabetic neuropathy. A total of 60 patients diagnosed with diabetic neuropathy were selected for the study, based on precise inclusion and exclusion criteria.

Inclusion Criteria:

- Age: Between 40–70 years, inclusive.
- Gender: Both male and female patients.
- Diagnosis: Diagnosed cases of Diabetes Mellitus with clinically confirmed symptoms of diabetic neuropathy.
- Glycemic Control: Good to moderate glycemic control, defined as HbA1c levels between 6.5% and 8.5%.
- Altered Vibratory Perception: Patients exhibiting altered vibratory perception detected by the biothesiometer.

Exclusion Criteria: Exclusion was based on the presence of the following:

- Rheumatic diseases, vitamin deficiencies, substance abuse, and neurological disorders (e.g., Parkinsonism, cerebral vascular disease).
- Infectious or immune-compromised states (e.g., HIV/AIDS, leprosy).
- Acute diabetic complications and uncontrolled hypertension.
- Allergies to any components of the study medication.

Biothesiometry as a Diagnostic Tool

The biothesiometer was utilized to measure vibration perception thresholds (VPT), a non-invasive method for detecting sensory nerve dysfunction in diabetic neuropathy. This device is integral in providing an objective, quantifiable measure of peripheral nerve damage.

1. **Biothesiometer Device**: The **[Vibra Med, Medinza ABM:100]** was used, offering precise measurements of vibratory stimuli within the range of 0–50 V. This allows the device to detect even minor alterations in sensory function, which are often indicative of early neuropathic changes.
2. **Assessment Points**: The biothesiometer probe was applied at six distinct anatomical sites on both feet:

  - One point at the big toe.
  - Three points at the ball of the foot (medial, central, and lateral regions).
  - One point at the heel.
  - One point at the arch of the foot.
3. **Test Protocol**: Each site was assessed three times to ensure reproducibility. The device gradually increased the voltage until the patient reported sensation, and the voltage at which sensation was perceived was recorded as the vibration perception threshold (VPT).
4. **VPT Severity Classification**: The results were categorized to determine the severity of neuropathy:
  - Normal: 0–15 V
  - Mild Neuropathy: 16–20 V
  - Moderate Neuropathy: 21–25 V
  - Severe Neuropathy: >25 V

The maximum voltage threshold and minimum voltage threshold were also recorded for each patient, representing the most and least damaged nerve sites, respectively. The Biothesiometer's ability to measure these parameters is critical in providing an objective and quantifiable assessment of nerve function, which is crucial for diagnosing and monitoring the progression of diabetic neuropathy.

Data Analysis

Data were analysed using [SPSS], with descriptive statistics used to summarize baseline characteristics. Paired t-tests were applied to compare pre- and post-treatment VPT values. Correlation analysis was performed to investigate the relationship between glycemic control and VPT changes, with a significance level set at $p < 0.05$.

Results

The vibratory perception thresholds (VPT), measured using the biothesiometer, were assessed at two key time points—Visit 1 (Day 0) and Visit 6 (Day 90)—to track the progression of diabetic neuropathy in both trial and control groups. The biothesiometer proved to be a highly effective tool in assessing the changes in VPT over the 90-day period, providing an objective and quantifiable measurement of neuropathy severity. The following results illustrate the significant reductions in VPT values in both feet, highlighting the utility of the biothesiometer in monitoring neuropathy progression.

Right Foot Results:

- **Trial Group:** The biothesiometer demonstrated its sensitivity in detecting early changes in neuropathy. The average VPT in the trial group decreased significantly from 25.16 V (±6.93) at Visit 1 to 16.85 V (±3.92) at Visit 6, showing a 33% reduction over the study period. This reduction indicates that the biothesiometer can capture improvements in neuropathy severity.
  - Minimum VPT: The minimum VPT decreased from 21.06 V (±6.30) at Visit 1 to 15.67 V (±3.63) at Visit 6, reflecting a marked reduction in sensory nerve damage.
  - Maximum VPT: The maximum VPT for the trial group dropped from 29.74 V (±8.29) at Visit 1 to 18.22 V (±4.20) at Visit 6, further demonstrating the recovery of nerve function.

- **Control Group:** While the control group exhibited a reduction in VPT, the change was less pronounced, reinforcing the role of the biothesiometer in distinguishing between true therapeutic effects and natural disease progression. The average VPT decreased from 29.45 V (±10.39) at Visit 1 to 23.12 V

(±7.06) at Visit 6, indicating a 21.6% reduction over the 90-day period, suggesting less significant improvements compared to the trial group.

- Minimum VPT: The minimum VPT in the control group decreased from 25.35 V (±9.86) at Visit 1 to 21.48 V (±6.58) at Visit 6.
- Maximum VPT: Similarly, the maximum VPT decreased from 33.41 V (±11.08) at Visit 1 to 24.74 V (±7.78) at Visit 6.

Left Foot Results:

- **Trial Group:** The left foot results followed a similar trend, with the biothesiometer reflecting a substantial reduction in neuropathy severity over time. The average VPT dropped from 25.45 V (±8.28) at Visit 1 to 16.35 V (±3.78) at Visit 6, marking a 35.7% reduction in sensory perception.
    - Minimum VPT: The minimum VPT decreased from 21.48 V (±6.58) at Visit 1 to 15.29 V (±3.42) at Visit 6, further highlighting the role of the biothesiometer in detecting subtle changes in nerve function.
    - Maximum VPT: The maximum VPT showed a decrease from 28.70 V (±9.34) at Visit 1 to 17.93 V (±4.47) at Visit 6.

- **Control Group:** Similar to the right foot, the control group exhibited a reduction in VPT values, but to a lesser extent. The average VPT decreased from 29.45 V (±10.58) at Visit 1 to 23.45 V (±7.51) at Visit 6, representing a 20.4% reduction.
    - Minimum VPT: The minimum VPT in the control group decreased from 25.38 V (±9.96) at Visit 1 to 21.38 V (±6.95) at Visit 6.
    - Maximum VPT: The maximum VPT decreased from 32.48 V (±11.04) at Visit 1 to 25.83 V (±8.35) at Visit 6.

Summary Table: Vibratory Perception Threshold (VPT) Measurements

Foot	Group	Visit 1 (Day 0) Average VPT (V)	Visit 6 (Day 90) Average VPT (V)	Visit 1 Minimum VPT (V)	Visit 6 Minimum VPT (V)	Visit 1 Maximum VPT (V)	Visit 6 Maximum VPT (V)
Right	Trial	25.16 (±6.93)	16.85 (±3.92)	21.06±6.30	15.67±3.63	29.74±8.29	18.22±4.20
	Control	29.45 (±10.39)	23.12 (±7.06)	25.35±9.86	21.48±6.58	33.41±11.08	24.74±7.78
Left	Trial	25.45 (±8.28)	16.35 (±3.78)	21.48±6.58	15.29±3.42	28.70±9.34	17.93±4.47
	Control	29.45 (±10.58)	23.45 (±7.51)	25.38±9.96	21.38±6.95	32.48±11.04	25.83±8.35

Statistical Analysis:

- The average VPT values showed a statistically significant decrease in the trial group for both feet ($p < 0.01$), indicating a clear improvement in vibratory perception.
- The control group demonstrated a minor decrease in average VPT, with no significant changes observed in minimum and maximum VPT values (NS).

Discussion

Diabetic neuropathy is a prevalent and debilitating complication of diabetes mellitus, characterized by progressive sensory, motor, and autonomic nerve dysfunction. The gradual onset of these symptoms severely impacts the quality of life of affected individuals. Early detection, accurate assessment, and monitoring of neuropathy severity and progression are essential for effective intervention and management. Biothesiometry, a non-invasive method measuring the vibratory perception threshold (VPT), has become an invaluable tool in screening, diagnosing, and assessing the progression of diabetic neuropathy.

Screening and Early Diagnosis with Biothesiometry

One of the greatest strengths of biothesiometry lies in its ability to detect early-stage neuropathy, often before clinical symptoms manifest. Traditional methods such as clinical assessments and neuropathy questionnaires are subjective and reliant on patient-reported symptoms, which may not always reflect the true extent of nerve damage. Moreover, many patients with early neuropathy do not exhibit noticeable symptoms, making these traditional methods less effective for early detection. Biothesiometry provides an objective and quantitative measure of sensory nerve function, specifically assessing the integrity of the sensory nerves. By measuring VPT, it can detect subclinical neuropathy in patients who may not yet exhibit any overt symptoms. In our study, VPT values measured at various foot sites—such as the big toe, ball of the foot, heel, and arch—served as reliable markers for sensory nerve function, with early elevations in VPT indicating the onset of neuropathy. Establishing baseline VPT ranges allows for the identification of individuals at risk, enabling early intervention and preventive measures.

The non-invasive nature of the biothesiometer, combined with its ability to assess multiple foot sites simultaneously, makes it an ideal tool for routine screening in diabetic populations. By detecting subclinical neuropathy, biothesiometry can identify at-risk individuals before they develop overt symptoms, allowing clinicians to take preventive actions to slow the progression of neuropathy.

Diagnostic Utility of Biothesiometry

Beyond screening, biothesiometry serves as a highly effective diagnostic tool. The VPT values correlate directly with the degree of nerve impairment, allowing for the classification of neuropathy into different stages—normal, mild, moderate, and severe. In our study, patients with higher baseline VPT values were found to have more advanced neuropathy, and reductions in VPT following therapeutic intervention were indicative of improved nerve function. The significant reduction in average VPT values in the trial group over the 90-day period demonstrated the therapeutic effect of the intervention, suggesting not only a slowdown in neuropathy progression but also potential reversal of nerve damage.

The ability of biothesiometry to monitor changes in VPT over time makes it an essential tool for diagnosing and tracking the course of diabetic neuropathy. The progressive increase in VPT values observed in the control group, which did not receive any therapeutic intervention, underscores the ongoing neurodegeneration typical in untreated diabetic neuropathy. In contrast, the trial group, which received treatment, exhibited a more favorable response with reduced VPT levels, highlighting Biothesiometer's ability to both diagnose neuropathy and assess the effectiveness of treatment.

Assessing Neuropathy Progression

Biothesiometry plays a crucial role in assessing the progression of diabetic neuropathy. The ability to track subtle changes in sensory nerve function over time makes it an invaluable tool for monitoring disease progression, particularly in patients with long-standing diabetes. In many cases, neuropathy may advance silently without overt clinical symptoms. VPT measurements provide a sensitive, reproducible, and objective means of detecting these changes, enabling clinicians to monitor the course of the disease.

Our study demonstrated that biothesiometry could detect even slight changes in nerve function. The trial group, which received therapeutic intervention, showed a reduction in VPT values over the 90-day period, reflecting positive changes in nerve conduction. The control group, which did not receive treatment, exhibited a progressive increase in VPT, signaling worsening neuropathy. This longitudinal tracking capability emphasizes Biothesiometer's sensitivity to neuropathy severity, making it a reliable marker for disease progression. Additionally, Biothesiometer's ability to assess both the average and site-specific VPT values provides valuable information on the spatial distribution of sensory deficits, which can be useful in localizing nerve damage and tailoring treatment strategies.

Mechanism of Biothesiometer and Its Diagnostic Relevance

The biothesiometer operates by delivering vibratory stimuli at varying voltage levels, with a range of 0-50 V. These voltage levels correlate with different stages of neuropathy:

- **0-15 V**: Normal sensory function
- **16-20 V**: Mild neuropathy
- **21-25 V**: Moderate neuropathy
- **>25 V**: Severe neuropathy

Biothesiometry evaluates the function of Pacinian and Meissner corpuscles, mechanoreceptors responsible for sensing vibration. These corpuscles react to vibratory stimuli at different frequencies, with Pacinian corpuscles, located deeper in the skin, responding to higher frequencies (125 Hz), and Meissner corpuscles, located near the surface, responding to lower frequencies. This frequency-dependent response enables biothesiometry to assess the integrity of these sensory receptors and gauge the degree of neuropathic damage.

In addition, the biothesiometer measures the six-point average voltage at specific foot sites, including the big toe, ball of the foot, arch, and heel. The voltage readings from each site are compared, with the minimum voltage indicating areas of least nerve damage and the maximum voltage pointing to the most severely affected regions. This localized assessment allows clinicians to track the progression of neuropathy across different foot sites and aids in identifying areas with more severe nerve damage. By assessing the distribution of VPT values across multiple foot sites, biothesiometry offers detailed insights into the spatial progression of neuropathy and helps guide treatment decisions.

Limitations and Future Scope

Biothesiometry has certain limitations, primarily its sensitivity in detecting early-stage diabetic neuropathy. It may miss subtle neuropathic changes in the initial phases, leading to delayed diagnosis. The lack of standardized testing protocols and reference ranges can result in inconsistencies, and external factors like temperature and skin type may introduce variability. The method primarily assesses sensory nerve function, limiting its ability to evaluate motor and autonomic nerve involvement. Additionally, patient variability due to age, comorbidities, and health status can affect results, leading to false positives or negatives. There is also a need for more long-term studies to validate its role in tracking neuropathy progression.

Future advancements could enhance Biothesiometer's diagnostic capabilities. Improved sensitivity, standardization of testing protocols, and integration with other diagnostic tools, such as nerve conduction studies, would provide a more comprehensive assessment. Incorporating machine learning could offer predictive models for personalized care. Biothesiometer's non-invasive, cost-effective nature makes it ideal for resource-limited settings, and establishing population-specific norms could improve diagnostic accuracy. With further development, biothesiometry has the potential to revolutionize early detection, monitoring, and management of diabetic neuropathy.

Conclusion

In conclusion, biothesiometry stands as a highly promising tool for the screening, diagnosis, and monitoring of diabetic neuropathy. Despite its current limitations, its advancements and integration with other diagnostic technologies, coupled with the development of standardized protocols, will only enhance its clinical utility. As we look toward the future, biothesiometry could become an integral component of comprehensive diabetic care, allowing for early diagnosis, timely intervention, and more precise tracking of neuropathy progression, ultimately improving patient outcomes and reducing the burden of diabetic neuropathy on healthcare systems worldwide.

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Conflict of Interest

The authors declare that there is no conflict of interest.

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