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THE EFFECTIVENESS OF THE BIOTHESIOMETER AND THE COMPREHENSIVE DIABETIC NEUROPATHY SCREENING ALGORITHM (CDNSA) IN DETECTING DIABETIC NEUROPATHY

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ABSTRACT
Diabetic neuropathy is a chronic complication of diabetes mellitus that often remains undetected in its early stages and may progress to foot ulcers and amputation. Early detection at the primary healthcare level is essential to prevent further complications. This study aimed to analyze the effectiveness of the Comprehensive Diabetic Neuropathy Screening Algorithm (CDNSA) compared with a biothesiometer as the reference standard in detecting diabetic neuropathy among patients with diabetes mellitus at Soromandi Primary Healthcare Center, Indonesia. This quantitative diagnostic test accuracy study used a cross-sectional approach. A total of 64 patients with diabetes mellitus who met the inclusion and exclusion criteria were recruited using consecutive sampling. Data were collected in 2025 through direct clinical assessments using both the CDNSA and a biothesiometer. The CDNSA assessed large-fiber function using a 10-g monofilament and a 128-Hz tuning fork and small-fiber function using pinprick and cold sensation tests, whereas the biothesiometer measured the Vibration Perception Threshold (VPT). Diagnostic performance was evaluated using sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), overall accuracy, and Receiver Operating Characteristic (ROC) curve analysis. CDNSA demonstrated a sensitivity of 94%, specificity of 100%, PPV of 100%, NPV of 80%, and overall diagnostic accuracy of 100%. The Area Under the Curve (AUC) was 97.1%, indicating excellent discriminatory ability in distinguishing patients with and without diabetic neuropathy. The CDNSA demonstrated excellent diagnostic performance and may serve as a practical and comprehensive screening method for the early detection of diabetic neuropathy in primary healthcare settings.

Keywords: biothesiometry; diabetes mellitus; diabetic neuropathies; early diagnosis

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INTRODUCTION

Globally, the prevalence of diabetes mellitus is projected to increase by 0.7% between 2030 and 2045 (International Diabetes Federation, 2021). In Indonesia, the number of individuals living with diabetes is estimated to reach 30 million by 2030 if unhealthy lifestyle patterns persist. Diabetes mellitus is currently the third leading cause of death after stroke and cardiovascular disease, affecting approximately 10 million people, with the number of cases expected to increase two- to threefold over the next decade (Ministry of Health of the Republic of Indonesia, 2020). Diabetes mellitus is associated with various chronic complications, including neuropathy, retinopathy, and nephropathy, all of which contribute to reduced quality of life and impaired physical and psychological well-being (Dewi, 2023). Among these complications, diabetic neuropathy is the most common in patients with type 2 diabetes mellitus and is characterized by dysfunction of the sensory, motor, and autonomic peripheral nerves (Hudiyawati et al., 2023).

Globally, the incidence of diabetic neuropathy is estimated at approximately 2.4% of the population and increases with advancing age. The highest prevalence has been reported in Asia, particularly Southeast Asia, including Malaysia (54.3%), the Philippines (58.0%), and Indonesia (58.0%) (Malik et al., 2020). Diabetic neuropathy is characterized by progressive damage to the peripheral nerves, typically beginning in the feet and presenting with symptoms such as tingling, burning pain,

stabbing sensations, and numbness. These manifestations substantially increase the risk of diabetic foot ulcers, infection, and lower-limb amputation (Rachmantoko et al., 2021).

The pathophysiology of diabetic neuropathy involves impaired nerve nutrition and the accumulation of sorbitol, which disrupts nerve conduction and slows the transmission of nerve impulses. Early detection is essential because diabetic neuropathy is often asymptomatic during its initial stages, resulting in delayed diagnosis until severe complications develop (Halmar et al., 2019; Febriyanti, 2023). Nurses and other healthcare professionals play a critical role in early neuropathy screening before clinical symptoms appear, thereby preventing diabetic foot ulcers through appropriate patient education and comprehensive foot care (Jones et al., 2023).

Several screening instruments are currently available, including the Toronto Clinical Neuropathy Score (TCNS), Michigan Neuropathy Screening Instrument (MNSI), Total Neuropathy Score (TNS), and Neuropathy Disability Score (NDS). However, most of these tools rely on subjective clinical assessment and are influenced by examiner experience and competency. Simpler screening methods, such as the Semmes–Weinstein monofilament test and the Ipswich Touch Test, are practical and easy to perform but have limited sensitivity for detecting early-stage neuropathy. Ultrasonography (USG) can identify structural abnormalities of peripheral nerves, whereas nerve conduction studies (NCS) and electromyography (EMG) are considered the gold standard for diagnosing diabetic neuropathy. Nevertheless, these techniques require specialized equipment, trained personnel, and relatively high costs, making them less feasible for routine use in primary healthcare settings (Purwanti et al., 2024).

In this context, the biothesiometer has emerged as a more advantageous screening tool because it provides an objective, quantitative measurement of the Vibration Perception Threshold (VPT). It is highly sensitive, practical, rapid, portable, and suitable for implementation in primary healthcare centers. A VPT value of ≥25 volts is generally accepted as a diagnostic threshold for diabetic neuropathy, and the biothesiometer has demonstrated good accuracy in identifying the risk of diabetic foot ulcers by assessing large-fiber nerve function (Bowling et al., 2012; Hnit et al., 2022). In addition, the development of novel screening instruments, such as the Comprehensive Diabetic Neuropathy Screening Algorithm (CDNSA), represents an important innovation in the early detection of diabetic neuropathy. The CDNSA integrates assessments of both large- and small-fiber nerve function through structured evaluation of tactile sensation, vibration, temperature, and pain perception within a comprehensive screening algorithm. This integrated approach is expected to improve screening accuracy, facilitate earlier diagnosis, and support diabetic neuropathy screening in primary healthcare settings where diagnostic resources remain limited (Yeni et al., 2025). Despite the availability of several screening methods, early detection of diabetic neuropathy remains challenging in primary healthcare settings because many existing diagnostic tools are either subjective, insufficiently sensitive for early neuropathy, or require specialized equipment and trained personnel. Therefore, evaluating a practical, comprehensive, and accurate screening method such as the Comprehensive Diabetic Neuropathy Screening Algorithm (CDNSA) is important to support earlier identification of diabetic neuropathy and prevent its progression to diabetic foot ulcers and lower-limb amputation.. This study aimed to compare the effectiveness of the biothesiometer and the Comprehensive Diabetic Neuropathy Screening Algorithm (CDNSA) in detecting diabetic neuropathy among patients with type 2 diabetes mellitus.

METHOD

This study employed a quantitative descriptive-analytic design using a Diagnostic Test Accuracy (DTA) approach to evaluate the diagnostic performance of the Comprehensive Diabetic Neuropathy Screening Algorithm (CDNSA) against the biothesiometer as the reference standard. The study was conducted at Soromandi Primary Healthcare Center, Indonesia, in 2025. The study population comprised patients with diabetes mellitus receiving care at the healthcare center. The minimum sample size was calculated using G*Power version 3.1 (F-test, one-way ANOVA, effect size =

0.40, α = 0.05, power = 0.80, three groups), resulting in a minimum sample of 64 participants. Respondents were recruited using consecutive sampling based on predefined inclusion and exclusion criteria. After providing informed consent, participants underwent assessment using both the biothesiometer and the CDNSA. The biothesiometer measured the Vibration Perception Threshold (VPT), whereas the CDNSA assessed large-fiber function using a 10-g monofilament and a 128-Hz tuning fork, and small-fiber function using pinprick and cold sensation tests. Diagnostic performance was evaluated by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy based on 2 × 2 contingency tables. Receiver operating characteristic (ROC) curve analysis was performed to determine the Area Under the Curve (AUC) and the optimal cut-off point of the CDNSA.

RESULT

Table 1.
Distribution of Diagnostic Test Results

Diagnostic Tests	f	%
Biothesiometer		
No Neuropathy	11	16.4
Neuropathy	53	79.1
CDNSA		
No Neuropathy	15	22.4
Neuropathy	49	73.1

Based on the table above, of the 64 respondents, the biothesiometer examination detected neuropathy in 53 (79.1%), while no neuropathy was detected in 11 (16.4%). Meanwhile, the CDNSA examination showed that 49 (73.1%) respondents had neuropathy and 15 (22.4%) respondents did not. These results indicate that both methods detect neuropathy at a high rate, with only a small difference. The difference in results is likely due to differences in testing principles: the biothesiometer quantitatively assesses vibration thresholds, while the CDNSA combines several aspects of clinical assessment. Overall, both methods have good potential as screening tools for diabetic neuropathy.

Table 2.
2x2 Diagnostic Test Table

	Biothesiometer (+)	Biothesiometer (-)	Total
CDNSA (+)	49	0	49
CDNSA (-)	3	12	15

Sensitivity	94%
Specificity	100%
PPV(Positive predictive value)	100%
NPV(negative predictive value)	80%

Based on the diagnostic test table between CDNSA and biothesiometer as a comparison standard in 64 respondents, 49 true positives, 0 false positives, 12 true negatives, and 3 false negatives were obtained. The analysis results showed a sensitivity of 94% for the CDNSA, meaning it was able to detect most cases of neuropathy confirmed by the biothesiometer. A specificity of 100% indicated that the CDNSA could identify all negative respondents without producing false positives, thus supporting a PPV of 100%.

An NPV of 80% indicates that a negative CDNSA result may actually be a positive case, and therefore, further clinical evaluation is still necessary for high-risk respondents. Overall, the CDNSA had an accuracy of 95.3%, concluding that it is an effective and reliable screening tool, particularly for confirming positive cases of diabetic neuropathy.

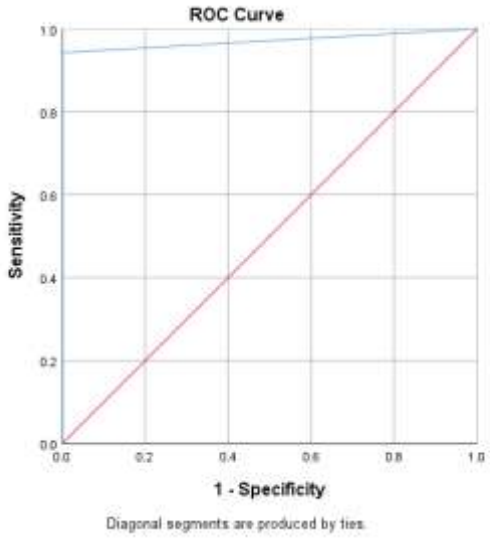

Figure 1. ROC curve

Based on the Receiver Operating Characteristic (ROC) graph, the CDNSA curve is near the upper left corner and well above the diagonal line (AUC = 0.5). This indicates that CDNSA has excellent discrimination ability. Sensitivity appears high when the false positive rate is very low, so CDNSA is able to detect neuropathy cases with minimal false positive errors. The shape of the curve indicates an AUC value close to 1, which means the CDNSA's diagnostic performance is almost perfect and has high agreement with the biothesiometer as the gold standard. Thus, CDNSA can be considered an accurate diabetic neuropathy screening tool and is suitable for use in clinical practice.

No.	Positive if Greater Than or Equal To [a]	Sensitivity	1 - Specificity	specificity	Youden
1	-1	1.00	1.00	0.00	0.00
2	0.5	0.942	0.00	1.00	0.942
3	2	0.00	0.00	1.00	0.00

Figure 2. Cut *Off* Point

A sensitivity value of 94% indicates that the CDNSA is capable of detecting nearly all cases of neuropathy confirmed by the biothesiometer, with a false-negative probability of approximately 6%. A specificity value of 100% at a cut-off of 0.5 indicates no false-positives, so all positive CDNSA results are consistent with the gold standard. A cutoff of 0.5 was considered optimal because it provided the best combination of sensitivity and specificity. Overall, the CDNSA had very high agreement with the biothesiometer and has the potential to be an effective screening tool, especially in primary healthcare settings with limited advanced diagnostic facilities.

Table 3.
Area under the curve (AUC)

Test Result Variable(s): CDNSA				
Area	Std. Error [a]	Asymptotic Sig. [b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.971	.020	.000	.932	1,000

Based on the ROC analysis, the CDNSA AUC value was 0.971 (SE = 0.020; p = 0.000; 95% CI: 0.90–1.00) with the biothesiometer as the gold standard. This AUC value indicates that the CDNSA has excellent discrimination ability in differentiating neuropathic and non-neuropathic patients. The confidence interval is well above 0.5 and the small standard error indicates stable and precise results. Clinically, an AUC of 0.971 means that the CDNSA has a 97.1% chance of giving a higher score to patients who actually have neuropathy compared to those who do not. Thus, the CDNSA is considered to have excellent diagnostic performance and is suitable for use as a diabetic neuropathy screening tool, with an accuracy level almost equivalent to the biothesiometer, so H0 is accepted (there is no difference in detection ability between the two tools).

DISCUSSION

The findings of this study demonstrated that the Comprehensive Diabetic Neuropathy Screening Algorithm (CDNSA) has excellent diagnostic performance compared with the biothesiometer as the reference standard. The area under the receiver operating characteristic (ROC) curve (AUC) was 0.971 (95% CI: 0.90–1.00; $p < 0.05$), indicating an almost perfect ability to discriminate between patients with and without diabetic neuropathy and meeting the criteria for excellent diagnostic accuracy (Hajian et al., 2020). The CDNSA achieved a sensitivity of 94% and a specificity of 100%. The perfect specificity indicates the absence of false-positive results, thereby minimizing the risk of misdiagnosis, while the high sensitivity demonstrates that most cases of diabetic neuropathy can be identified, supporting early detection and reducing the risk of delayed diagnosis and subsequent complications (Selvarajah et al., 2023).

The biothesiometer has long been recognized as a reliable instrument for measuring vibration perception threshold and is strongly associated with the risk of diabetic foot ulcers and the progression of diabetic neuropathy, making it an appropriate reference standard (Busui et al., 2022). The high diagnostic accuracy observed for the CDNSA suggests that it may serve as an effective screening alternative, consistent with previous studies reporting that well-validated and reliable clinical scoring instruments can achieve diagnostic performance comparable to established reference methods (Callaghan et al., 2020). Furthermore, the positive predictive value (PPV) of 100% indicates that all positive CDNSA results were confirmed by the biothesiometer, whereas the negative predictive value (NPV) of 80% suggests a small possibility of false-negative findings. Therefore, patients at high risk of diabetic neuropathy should undergo further clinical evaluation when neuropathy is clinically suspected despite negative screening results (Tesfaye et al., 2021). Overall, the CDNSA demonstrated excellent diagnostic validity and represents a practical, efficient, and cost-effective screening tool for the early detection of diabetic neuropathy, particularly in primary healthcare settings where access to advanced diagnostic equipment is limited.

CONCLUSION

Based on the findings of this study conducted at Soromandi Primary Healthcare Center, the Comprehensive Diabetic Neuropathy Screening Algorithm (CDNSA) demonstrated excellent diagnostic performance and a high level of agreement with the biothesiometer as the reference standard for detecting diabetic neuropathy among patients with diabetes mellitus. The CDNSA achieved a sensitivity of 94% and a specificity of 100%, indicating a high ability to identify neuropathy cases without producing false-positive results. A positive predictive value (PPV) of 100% confirmed that all positive CDNSA results were consistent with the biothesiometer, whereas a negative predictive value (NPV) of 80% indicated a small possibility of false-negative results. Furthermore, receiver operating characteristic (ROC) analysis yielded an area under the curve

(AUC) of 0.971 ($p < 0.001$; 95% CI: 0.90–1.00), demonstrating the CDNSA's near-perfect discriminatory ability.

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