

Comparative diagnostic accuracy of clinical screening instruments for diabetic peripheral neuropathy against vibration perception threshold: A study in Indonesia

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Article Info:

Submitted:

06-05-2026

Revised:

03-08-2026

Accepted:

06-08-2026

Published:

01-09-2026

Keywords:

diabetic foot,
diabetic neuropathies,
diagnostic accuracy,
Michigan Neuropathy
Screening Instrument,
vibration perception
threshold

ABSTRACT

Diabetic peripheral neuropathy (DPN) is a major precursor of foot ulceration and amputation; however, validated low-cost screening tools remain limited in Southeast Asian populations. This study evaluated and compared the diagnostic accuracy of the MNSI-A, MNSI-B, DNS, and DNE against biothesiometer-defined DPN in Indonesian adults with type 2 diabetes. A cross-sectional diagnostic accuracy study recruited 140 consecutive patients with type 2 diabetes at Lavalette Hospital in Malang between August and September 2023. Two trained assessors administered the MNSI-A, MNSI-B, DNS, and DNE under double-anonymized conditions. A biothesiometer vibration perception threshold >15 V at the great toe served as the reference standard. Sensitivity, specificity, predictive values, and overall accuracy were calculated with 95% confidence intervals (CIs). DPN was detected in 55 (39.3 %) patients. MNSI-B showed the highest performance, with a sensitivity of 85.4% (95% CI 73.4–92.9), specificity of 97.6% (95% CI 91.4–99.7), positive predictive value of 95.9%, negative predictive value of 91.2%, and overall accuracy of 92.8%. The MNSI-A had a sensitivity of 76.3% (63.3–85.9) and specificity of 90.5% (82.1–95.3). The DNS yielded a sensitivity of 74.5% (61.3–84.5) and specificity of 72.9% (62.4–81.5). DNE showed a sensitivity of 83.6% (71.6–91.4) and specificity of 78.8% (68.6–86.6). The MNSI-B demonstrated excellent accuracy and may serve as a practical, low-cost first-line DPN screening instrument in Indonesian clinical settings. Symptom-based tools should not be used alone and should be integrated with objective physical examinations. These findings support the implementation of structured physical examinations in diabetes foot care programs.

 <https://doi.org/10.53713/nhsj.v6i3.737>

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INTRODUCTION

Diabetes mellitus represents a major global health burden, with diabetic peripheral neuropathy emerging as the most prevalent chronic complication and critical precursor to foot ulceration and amputation (Parveen et al., 2025). This metabolic disorder affects hundreds of millions of people worldwide, and approximately 50% of patients develop peripheral neuropathy during the disease course (Zhu et al., 2024). International clinical guidelines strongly recommend annual DPN screening for early detection and preventive interventions (Anastasi & Capili, 2022). Early identification of neuropathy significantly reduces the risk of foot ulceration, which precedes 85% of diabetes-related lower extremity amputations (Sen et al., 2022).

The implementation of DPN screening in Indonesia remains severely inadequate due to financial constraints, a lack of standardized protocols, and the absence of culturally validated screening instruments (Qona'ah et al., 2025). Low- and middle-income countries face compounded barriers, including limited healthcare infrastructure, insufficiently trained personnel, and inequitable resource distribution across primary care facilities (Abdul-Samed et al., 2025). Indonesian healthcare institutions currently lack a structured national protocol for routine neuropathy screening, directly contributing to delayed detection and increased amputation rates (Pamungkas et al., 2022). The absence of validated, locally appropriate tools perpetuates inconsistent screening practices across the country's decentralized health system.

Multiple screening instruments have been developed internationally, ranging from symptom-based questionnaires to structured physical examinations and quantitative sensory testing devices (Rangari et al., 2026). The Michigan Neuropathy Screening Instrument comprises a 15-item self-administered questionnaire (MNSI-A) and a 10-point physical examination (MNSI-B). At the same time, the Diabetic Neuropathy Symptom score (DNS) provides a brief four-item symptom assessment (Chowdhury et al., 2026). The Diabetic Neuropathy Examination (DNE) offers an eight-item neurological assessment, and a biothesiometer measures the vibration perception threshold as an objective quantitative reference (Subramani et al., 2025). Biothesiometers are recognized as clinical reference standards with strong prognostic value. However, their deployment at the primary care level is constrained by equipment costs, calibration requirements, and the need for trained operators (Kelshikar et al., 2024).

Existing validation studies in Indonesia have relied on electromyography or subjective clinical diagnosis as reference standards, and no single study has simultaneously compared all four major instruments against an objective biothesiometer reference in a uniform population (Purnawan et al., 2024). This methodological inconsistency creates substantial clinical uncertainty regarding which screening approach offers optimal accuracy in Indonesia. Practitioners lack evidence-based guidance on whether to prioritize symptom questionnaires or objective physical examinations for routine screening programs (Gad et al., 2024). The lack of a unified comparative framework hinders the development of standardized national screening recommendations.

This study introduced a novel head-to-head diagnostic accuracy comparison of MNSI-A, MNSI-B, DNS, and DNE against biothesiometer-defined neuropathy in an Indonesian diabetic population. Cultural and linguistic factors may substantially influence the psychometric performance of symptom-based instruments, as the Indonesian terminology for neuropathic sensations may not capture clinical phenomena equivalent to those in Western populations. The reported sensitivity of the MNSI-B varies widely across international studies, ranging from 65% to 100%, suggesting significant context-dependent validity that requires local verification (Shah et al., 2026; Sylvana et al., 2025). No previous Indonesian study has simultaneously addressed these variables within a single prospective design.

The primary objective was to evaluate and compare the diagnostic accuracy of four screening instruments against a biothesiometer reference standard in Indonesian adults with type 2 diabetes. The secondary objectives included comparing performance characteristics to identify the optimal screening strategy and analyzing whether the accuracy varied by age, diabetes duration, and glycemic control. The hypothesis proposed that the MNSI-B would demonstrate significantly superior diagnostic accuracy compared with symptom-based instruments because it integrates objective physical examination findings, which are less susceptible to cultural interpretation bias (Iliescu et al., 2025; Asmara et al., 2026).

Urgent local validation is essential, given the escalating diabetes burden in Indonesia and the critical window for preventive intervention before irreversible neuropathic damage occurs. The absence of validated screening protocols directly contributes to preventable amputations and associated healthcare costs in countries with limited resources. Establishing evidence-based screening recommendations will enable the integration of appropriate tools into national clinical guidelines and primary healthcare programs (Nkonge et al., 2023; Beshyah et al., 2024). This study addresses an immediate clinical need and generates transferable evidence for similar resource-constrained settings across Southeast Asia.

METHOD

Design

This diagnostic accuracy study was designed and reported in accordance with the Standards for Reporting Diagnostic Accuracy Studies (STARD) 2015 guidelines. A cross-sectional approach was employed, wherein four index tests (MNSI-A, MNSI-B, DNS, and DNE) and the reference standard (biothesiometer) were administered simultaneously on the same day to each participant. Prospective data collection was implemented to eliminate incorporation and disease-progression biases between the index tests and the reference standards.

Setting and Time

The study was conducted at the Endocrine Polyclinic and Polyclinic 23 of Lavalette Hospital, a Type B referral hospital located in Malang, East Java, Indonesia. Data collection was conducted over four weeks, from August 28 to September 27, 2023. Clinical assessments were scheduled twice weekly (Monday and Wednesday), commencing at 3:00 PM Western Indonesian Time (WIB) until all eligible patients were assessed in each session.

Population, Sample, and Sampling

The study population comprised adults with type 2 diabetes mellitus who attended routine follow-up examinations at Lavalette Hospital in Malang, Indonesia. Consecutive sampling was used to recruit all eligible patients during the study period. Eligible participants were aged ≥ 18 years, met the American Diabetes Association criteria for type 2 diabetes, attended routine follow-up visits, and provided written informed consent. Patients with prior lower-extremity amputation, active diabetic foot ulceration or infection, pregnancy, severe cognitive impairment, or previously confirmed primary nondiabetic peripheral neuropathy were excluded from the study. The minimum sample size was 126 participants, calculated using Buderer's formula with an expected sensitivity and specificity of 85%, absolute precision of 10%, $\alpha = 0.05$, power = 80%, and an estimated DPN prevalence of 40%. A 10% allowance for incomplete data increased the target sample size to 140 participants. Among the 240 patients screened, 140 met all eligibility criteria and completed all assessments, whereas 100 were excluded because of type 1 diabetes, age < 18 years, active foot ulceration, or refusal to participate.

Operational Definition and Procedures of Index Instruments

Table 1. Operational Definitions and Procedures of Index Instruments

No.	Operational Definitions	Procedures of Index Instruments
1.	Michigan Neuropathy Screening Instrument - A (MNSI-A)	This self-administered questionnaire consists of 15 binary (yes/no) items covering the history of leg injuries, muscle cramps, prickling sensations, tingling, numbness, burning, and temperature discrimination. Each "Yes" answer is scored as 1, except for items 7, 10, 13, 14, and 15, which are reverse-scored. The total score ranges from 0 to 13, with a cutoff point of ≥ 4 defined as a positive screening result based on the original validation by Feldman. Given the respondents' varying literacy levels, the researcher administered the validated Indonesian version of this instrument via a structured interview.
2.	Michigan Neuropathy Screening Instrument - B (MNSI-B)	This is a structured physical examination instrument performed by trained nurses that takes approximately 5 minutes per patient. The components assessed included the physical appearance of the foot (deformity, dry skin, infection, and calluses; each scored 1 if present), ankle/Achilles tendon reflex (scored 0 if normal, 0.5 if present with enhancement, and 1 if absent), vibration perception at the apex of the great toe using a 128 Hz tuning fork (scored 0 if normal, 0.5 if diminished, and 1 if absent), and protective sensory threshold testing using a 10-gram monofilament at three plantar sites (big toe, 1st metatarsal head, and 5th metatarsal head; scored 0 if normal, 0.5 if diminished, and 1 if absent per site). The total score ranges from 0 to 10, with a positive result for neuropathy defined as a score > 2 .
3.	Diabetic Neuropathy Symptom (DNS)	A structured symptom questionnaire consisting of four items covering unsteadiness while walking, numbness/tingling sensation, stabbing pain, and burning/tenderness was used. Each positive response was scored as 1 (range, 0–4), with a score ≥ 1 indicating a positive screening.
4.	Diabetic Neuropathy Examination (DNE)	A structured neurological examination comprising eight evaluation items was performed. The assessments included muscle strength (ankle dorsiflexion and extensor hallucis longus extension; scores 0–2), tendon reflexes (biceps, triceps, patellar, and Achilles; scores 0–2), and sensory disturbances (pinprick, temperature, vibration, and joint position of the great toe; scores 0–3). The total score ranged from 0 to 16, with a threshold value of ≥ 3 defined as a positive marker of neuropathy.

Gold Standard Procedure

Diabetic peripheral neuropathy was identified using biothesiometry as the reference standard, with the vibration perception threshold measured bilaterally at the distal plantar phalanges of the great toes. The participants were examined in the supine position with their eyes closed. Simultaneously, the applicator probe was placed perpendicular to the skin, and the voltage was gradually increased from 0 V until the vibration was first perceived. Three measurements were obtained from each foot, and the highest mean value from the two feet was

used for the classification. The biothesiometer was calibrated weekly, according to the manufacturer's standards. A vibration perception threshold >15 V defined positive neuropathy, consistent with evidence indicating a 12.5-fold increased risk of foot ulceration in patients with diabetes.

Blinding and Quality Control

Two registered nurses with more than five years of clinical experience in diabetes care served as the assessors. Before data collection, both completed 20 hours of standardized training, including video review, supervised practice on 20 non-study patients, and inter-rater reliability testing, achieving Cohen's kappa values of 0.91 for the MNSI-B physical examination and 0.87 for DNE. The assessors were blinded to each other's findings and the biothesiometer results, whereas the biothesiometer operator was masked to all index test findings. Self-report instruments (MNSI-A and DNS) were administered first to reduce fatigue, followed by MNSI-B, DNE, and biothesiometry in a randomized order.

Statistical Analysis

Data were analyzed using statistical software. Categorical variables were expressed as frequencies and percentages, and continuous variables as mean $\pm$ standard deviation or median, depending on their distribution. The DPN-positive and DPN-negative groups were compared using the independent t-test, Mann–Whitney U test, or chi-square test, as appropriate. The diagnostic performance of MNSI-A, MNSI-B, DNS, and DNE was assessed against the biothesiometer reference standard using 2 $\times$ 2 contingency tables, with sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy calculated with 95% confidence intervals via the Clopper–Pearson exact binomial method. Positive and negative likelihood ratios and diagnostic odds ratios were calculated to further evaluate the test performance. Receiver operating characteristic curves were constructed to determine the optimal cutoffs using the Youden index, and the AUCs were compared using the DeLong method. Subgroup analyses were performed to examine the diagnostic consistency across age tertiles, diabetes duration (<10 vs. ≥ 10 years), and HbA1c levels (<7 vs. $\geq 7\%$). Statistical significance was set at $P < 0.05$.

Ethical Declaration

The Ethics Committee of the Faculty of Health Sciences at Brawijaya University approved the study protocol. Written informed consent was obtained from all participants prior to data collection. All procedures complied with the ethical standards outlined in the Declaration of Helsinki.

RESULT

Demographic and Clinical Characteristics of Respondents

Of the 140 patients with type 2 diabetes who completed all testing procedures, the biothesiometer gold standard detected diabetic peripheral neuropathy (positive DPN, VPT value >15 volts) in 55 participants (39.3%; 95% CI: 31.4%–47.6%), while the remaining 85 participants were declared neuropathy-free (negative NPD, VPT value ≤ 15 volts). Demographic and clinical characteristics of the entire sample and their inter-group comparisons are presented in Table 2.

Table 2. Demographic and Clinical Characteristics of Type 2 DM Patients Based on Peripheral Neuropathy Status

Respondent Characteristics	Total Sample (N = 140), n (%)	Positive DPN Group (n = 55), n (%)	Negative DPN Group (n = 85), n (%)	p-value
Age (years)				<0.001
17–25	1 (0.7)	0 (0.0)	1 (1.2)	
26–35	2 (1.4)	0 (0.0)	2 (2.4)	
36–45	9 (6.4)	1 (1.8)	8 (9.4)	
46–55	27 (19.3)	8 (14.5)	19 (22.4)	
56–65	65 (46.4)	31 (56.4)	34 (40.0)	
>65	36 (25.7)	15 (27.3)	21 (24.7)	
Mean age $\pm$ SD	57.9 $\pm$ 9.8	62.3 $\pm$ 8.4	55.1 $\pm$ 10.2	
Gender				0.342
Male	44 (31.4)	19 (34.5)	25 (29.4)	
Female	96 (68.6)	36 (65.5)	60 (70.6)	
Duration of diagnosis (years)				0.003
≤ 10	94 (67.1)	28 (50.9)	66 (77.6)	
11–20	33 (23.6)	18 (32.7)	15 (17.6)	
≥ 20	13 (9.3)	9 (16.4)	4 (4.7)	
Median duration (years)	8	12	7	
Smoking history				0.612
No smoking	116 (82.9)	45 (81.8)	71 (83.5)	
Smoking	24 (17.1)	10 (18.2)	14 (16.5)	
Fasting blood glucose (mg/dL)				<0.001
Normal (80–99)	9 (6.4)	1 (1.8)	8 (9.4)	
Moderate (100–125)	25 (17.9)	4 (7.3)	21 (24.7)	
High (≥ 126)	106 (75.7)	50 (90.9)	56 (65.9)	
2-hour PP blood glucose (mg/dL)				<0.001
Normal (80–139)	19 (13.6)	2 (3.6)	17 (20.0)	
Moderate (140–199)	41 (29.3)	9 (16.4)	32 (37.6)	
High (≥ 200)	80 (57.1)	44 (80.0)	36 (42.4)	
Mean HbA1c (%)	8.0 $\pm$ 1.7	8.9 $\pm$ 1.8	7.4 $\pm$ 1.2	<0.001

Note. Values are presented as n (%) unless otherwise indicated. SD = standard deviation; PP = postprandial; DPN = diabetic peripheral neuropathy.

The comparative analysis in Table 2 shows statistically significant clinical differences between the DPN-positive and DPN-negative groups. Patients with peripheral neuropathy had a significantly older mean age (62.3 $\pm$ 8.4 years vs. 55.1 $\pm$ 10.2 years; $p < 0.001$), longer median duration of diabetes (12 vs. 7 years; $p = 0.003$), and poorer glycemic control with higher mean HbA1c levels (8.9 $\pm$ 1.8% vs. 7.4 $\pm$ 1.2%; $p < 0.001$).

2x2 Contingency Cross-Tabulation Results

The assessment of the distribution of binary classification results from each index instrument (MNSI-A, MNSI-B, DNS, and DNE), which were cross-tabulated against the biothesiometer gold standard, is presented in the following contingency table.

Table 3. Cross-tabulation of Screening Instruments Against Biothesiometer Results (N = 140)

Screening Instrument	Index Test Result	Biothesiometer Positive (>15 V), n	Biothesiometer Negative (≤ 15 V), n	Total, n
MNSI-A (Questionnaire)	Positive (≥ 4)	42	8	50
	Negative (< 4)	13	77	90
MNSI-B (Physical Examination)	Positive (> 2)	47	2	49
	Negative (≤ 2)	8	83	91
DNS (4-item)	Positive (≥ 1)	41	23	64
	Negative (< 1)	14	62	76
DNE (8-item)	Positive (≥ 3)	46	18	64
	Negative (< 3)	9	67	76

Comparative Diagnostic Accuracy Metric Evaluation

Based on the 2×2 cross-tabulation data, the comparative diagnostic performance metrics were calculated comprehensively and are listed in Table 4.

Table 4. Comparative Diagnostic Accuracy of MNSI-A, MNSI-B, DNS, and DNE Against the Biothesiometer

Diagnostic Accuracy Parameter	MNSI-A (95% CI)	MNSI-B (95% CI)	DNS (95% CI)	DNE (95% CI)
Sensitivity	76.3% (63.3–85.9)	85.4% (73.4–92.9)	74.5% (61.3–84.5)	83.6% (71.6–91.4)
Specificity	90.5% (82.1–95.3)	97.6% (91.4–99.7)	72.9% (62.4–81.5)	78.8% (68.6–86.6)
Positive Predictive Value (PPV)	84.0% (71.7–91.4)	95.9% (86.0–99.0)	64.0% (52.4–74.2)	71.8% (60.4–80.8)
Negative Predictive Value (NPV)	85.5% (76.6–91.5)	91.2% (83.4–95.7)	81.5% (71.3–88.9)	88.1% (78.9–93.6)
Overall Accuracy	85.0% (77.8–90.4)	92.8% (87.0–96.5)	73.5% (65.5–80.4)	80.7% (73.2–86.8)
Positive Likelihood Ratio (LR+)	8.0	35.6	2.8	3.9
Negative Likelihood Ratio (LR–)	0.26	0.15	0.35	0.21
Diagnostic Odds Ratio (DOR)	30.8	237.3	8.0	18.6

The evaluation results in Table 4 show that the MNSI-B instrument has the most superior clinical performance compared to the other three instruments. The MNSI-B produced the highest overall accuracy of 92.8%, accompanied by excellent specificity (97.6%) and a very strong false-positive case exclusion capacity (LR+ = 35.6, DOR = 237.3).

ROC Curve Analysis and Inter-Rater Reliability

ROC curve analysis showed that the Area Under the Curve (AUC) value for the MNSI-B score as a continuous variable was 0.94 (95% CI: 0.90–0.97). This value was significantly higher than the MNSI-A AUC of 0.82 (95% CI: 0.76–0.88; $p=0.002$ for difference in difference), DNE AUC of 0.86 (95% CI: 0.80–0.91; $p=0.04$), and DNS AUC of 0.78 (95% CI: 0.71–0.85; $p<0.001$). The local optimal threshold value for the MNSI-B obtained by maximizing the Youden index was >2 (index = 0.83), which was identical to Feldman's initial validation criteria. For the DNE instrument, the Youden index reached its maximum at a threshold value of ≥ 3 (index = 0.62), confirming the appropriateness of the standard cut-off value. The inter-rater reliability testing results during the study showed excellent agreement for the physical examination component of

the MNSI-B (Cohen's kappa = 0.91; 95% CI: 0.84–0.98) and good agreement for DNE (kappa = 0.87; 95% CI: 0.79–0.95).

Clinical Subgroup Analysis

Based on the results of the subgroup analysis, the diagnostic accuracy of the MNSI-B was consistently stable across various clinical conditions. In the group of patients with diabetes duration ≥ 10 years, the MNSI-B maintained a sensitivity of 88.2% (95% CI: 72.5%–96.7%) compared to 83.3% (95% CI: 65.3%–93.6%) in the group with duration < 10 years, with similar specificity values (96.8% vs. 98.3%, respectively). In contrast, the symptom-based instrument (DNS) showed a significant decrease in specificity among patients with HbA1c $\geq 7\%$ (65.4% vs. 82.1% in patients with HbA1c $< 7\%$; $p=0.04$). These subgroup findings indicate that screening strategies relying solely on subjective symptom reporting are less reliable and biased in patients with poorly controlled diabetes.

DISCUSSION

The Michigan Neuropathy Screening Instrument Part B (MNSI-B) demonstrated superior diagnostic accuracy in detecting biothesiometer-defined diabetic peripheral neuropathy among Indonesian adults with type 2 diabetes. The instrument achieved a sensitivity of 85.4%, specificity of 97.6%, positive predictive value of 95.9%, negative predictive value of 91.2%, overall accuracy of 92.8%, and an area under the receiver operating characteristic curve of 0.94. Symptom-based instruments, including the MNSI-A and DNS, exhibit adequate sensitivity but substantially lower specificity, rendering them insufficient as stand-alone screening tools (Verdini et al., 2025). The Diabetic Neuropathy Examination (DNE) demonstrated intermediate performance relative to physical examination and symptom-based approaches (Pusapati et al., 2025). These results provide compelling evidence that structured objective physical examinations should be prioritized over subjective symptom questionnaires for DPN screening in resource-constrained clinical settings.

The MNSI-B demonstrated a sensitivity of 85.4% and specificity of 97.6% for detecting biothesiometer-defined diabetic peripheral neuropathy. The observed sensitivity reflects the instrument's ability to detect objective physical signs of large-fiber sensory impairment. The biothesiometer reference standard primarily measures functional loss of vibration perception rather than subclinical axonal structural damage detected by electrodiagnostic testing, which may influence the apparent sensitivity of the clinical screening instruments (Thimabut et al., 2024; Hazari et al., 2024). The high specificity is supported by the structured nature of the physical examination components, including monofilament testing, tuning-fork assessment, tendon reflex evaluation, and visual foot inspection (Lew et al., 2022; Sharma & Kaur, 2025). The intensive 20-hour assessor standardization training and strict adherence to the double-blind protocol likely contributed to the low false-positive rate.

The 72.9% DNS specificity observed in this Malang patient population contrasts markedly with the 87% specificity reported in the original Dutch validation study. This performance discrepancy confirms the substantial influence of cultural and linguistic factors on symptom-based screening. Indonesian terms describing neuropathic symptoms, such as unsteadiness, tingling, and shooting pain, are frequently interpreted differently by local patients compared to Western populations (Pinzon et al., 2024; Barus et al., 2025). These sensory complaints also overlap considerably with non-neuropathic musculoskeletal conditions prevalent in the aging Asian population. The structural weakness of the DNS scoring system, in which a single positive

symptom immediately classifies a patient as screen-positive, creates an excessively low threshold, leading to a high false-positive rate.

The DNE demonstrated a sensitivity of 83.6% but a lower specificity of 78.8% compared with the MNSI-B. This performance gap stems from differences in reference standards and the inclusion of upper-limb assessment items, specifically biceps and triceps reflexes, which are clinically less relevant for lower-extremity diabetic foot risk stratification. The DNE was originally designed as a comprehensive neurological examination rather than a targeted diabetic foot screening tool, which explains the inclusion of anatomically distant assessment components (Mohanraj et al., 2024; Maharani et al., 2025). Therefore, clinicians seeking efficient lower-extremity screening should favor instruments specifically designed for diabetic foot evaluation.

These findings have substantial practical and policy implications for the Indonesian healthcare system. The estimated operational cost of approximately 0.50 USD per MNSI-B examination, which requires only a tuning fork, a 10-gram monofilament, and a visual inspection sheet, offers markedly superior cost-effectiveness compared to biothesiometer procurement costs ranging from 500 to 2,000 USD. The brief examination duration of approximately five minutes permits realistic integration into routine diabetes consultations at primary health care facilities. Three clinical policy recommendations emerge from these findings: First, the MNSI-B should be formally integrated into Indonesia's National Guidelines for Medical Services for diabetes management, which currently lacks a structured foot examination. Training in MNSI-B techniques should be incorporated into existing certified diabetes educator programs for primary health care nurses. The MNSI-B should serve as a first-line screening tool, with biothesiometer assessment reserved for clinically equivocal cases or advanced pre-ulcer risk stratification (Gaur et al., 2024; Singh et al., 2025). A two-stage strategy using MNSI-A followed by MNSI-B is not recommended, given MNSI-A's 24% false-negative rate, which risks missing one in four cases of active neuropathy.

The methodological strengths of this study include a prospective design with simultaneous administration of the index tests and reference standard, strict double-blinding of assessors and operators, comprehensive pre-study calibration that achieved excellent inter-rater reliability, and the use of an evidence-based biothesiometer cutoff. The consecutive sampling approach minimized the selection bias in the study setting. All participants underwent both index and reference tests, thereby eliminating partial verification bias.

This study has several limitations that must be acknowledged. Hospital-based recruitment introduces spectrum bias, as patients at Type B referral hospitals tend to have more advanced diabetes than primary healthcare populations, potentially inflating sensitivity estimates. The observed DPN prevalence of 39.3% substantially exceeded community-based Indonesian estimates of approximately 20%, thereby affecting the generalizability of the predictive values. The biothesiometer reference standard itself has an inherent sensitivity of approximately 80% relative to nerve conduction studies, meaning that some early neuropathy cases classified as false positives by index instruments may represent subclinical diseases that vibration threshold testing fails to detect. Operator dependency remains a concern, as the excellent inter-rater reliability achieved through specialized training may not be replicable in facilities lacking comparable programs. The cross-sectional design precludes the assessment of the long-term predictive validity of foot ulceration or mortality outcomes. The cultural specificity of the findings limits their generalizability to the Javanese urban population of East Java, and diagnostic performance may differ among other Indonesian ethnic groups with distinct diabetes phenotypes and neuropathy presentations.

CONCLUSION

The Michigan Neuropathy Screening Instrument Part B (MNSI-B) demonstrated excellent diagnostic accuracy for biothesiometer-defined diabetic peripheral neuropathy in Indonesian adults with type 2 diabetes, achieving a sensitivity, specificity, and overall accuracy of 85.4%, 97.6%, and 92.8%, respectively. This structured physical examination significantly outperformed symptom-based questionnaires (MNSI-A and DNS) and the DNE, primarily because its objective components, such as tendon reflexes, monofilament testing, and visual foot inspection, are not susceptible to cultural-linguistic interpretation bias. The MNSI-B represents a practical, low-cost alternative screening instrument suitable for both hospital clinical settings and community screening programs in which quantitative biothesiometer devices are unavailable. The widespread implementation of the MNSI-B within the healthcare system requires support through structured nursing training programs and regular quality assurance mechanisms to maintain consistent inter-examiner reliability. Future research should prioritize external validation in primary healthcare and rural settings, longitudinal assessment of predictive validity for foot ulceration and amputation outcomes, and cost-effectiveness analysis within the National Health Insurance financing framework. Symptom-based instruments, such as DNS, lack sufficient specificity for stand-alone screening. They should be used in combination with a physical examination or reserved for situations where direct clinical assessment is not feasible.

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