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Diagnostic accuracy of bedside neurological examinations compared to biothesiometry for peripheral neuropathy: a community-based cross-sectional study

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Abstract: Peripheral neuropathy is a common but frequently underdiagnosed condition, especially in community settings. The diagnostic performance of four simple screening tests (vibration perception, temperature sensation, ankle reflex, and pinprick sensation) was examined against the biothesiometer as the reference standard for detecting peripheral neuropathy. This was a cross-sectional study conducted on those aged ≥18 years who visited retail pharmacies in Malaysia (March 2021 - May 2022). Four clinical examination tests, including the biothesiometer, were used to detect peripheral neuropathy. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value were computed in SPSS. The prevalence of peripheral neuropathy was 22.7% among 1,283 participants. Sensitivity was highest for ankle reflex (34.12%), followed by vibration testing (31.76%), pinprick (24.41%) and temperature sensation (6.76%). The specificity of all the tests was high (95.02 – 97.78%). The PPV was highest for vibration testing (83.72%). In non-clinical settings with limited time and equipment, vibration testing, together with ankle reflex, may serve as a reliable screening tool, given its high PPV and specificity. Given its low cost and ease of use, community health policy should consider early use of vibration and ankle tests to screen for peripheral neuropathy among at-risk groups, particularly among patients with diabetes and those over 50 years old.

Keywords: Peripheral neuropathy; Biothesiometer; Screening tool; Vibration; Malaysia

1.0 INTRODUCTION

Diabetes mellitus is a growing global epidemic and affects approximately 537 million adults in 2021 (Hossain et al., 2024). In Malaysia, the prevalence of diabetes has increased from 11.2% in 2011 to 15.6% in 2019, reflecting a significant 39.3% surge, as one of the highest rates in Southeast Asia (Institute for Public Health, 2024). A common complication of diabetes is peripheral neuropathy (PN), which affects 30-50% of patients and leads to chronic pain, foot ulcers, amputations and poor quality of life (Feldman et al., 2019; Pop-Busui et al., 2017).

In Malaysia, PN prevalence in diabetic patients reaches 49.4% among diabetic patients in primary care, but little is known at the community level (Lee et al.,2022). There are two types of peripheral neuropathy. Large fibre neuropathy often manifests with joint position and vibration sense sensory loss and sensory ataxia. Impairment of pain, temperature and autonomic functions will usually point to small fibre neuropathy (Misra et al., 2008)

Early detection and management of peripheral neuropathy are critical in preventing irreversible complications (Hicks and Selvin, 2019), but diagnostic challenges persist. Although the nerve conduction study (NCS) is the gold standard for diagnosing PN, it is costly and unavailable in non-clinical settings. Furthermore, there is a lack of consensus or guidelines on optimal bedside screening tools, particularly in community contexts where specialised equipment is unavailable (Jayaprakash et al., 2011; Petropoulos et al., 2018; Rolim et al., 2019).

This study focuses on four inexpensive and straightforward tests, all chosen to assess different neuroanatomical pathways, including vibration testing using a 128 Hz tuning fork to assess large myelinated fibre (Aα) function, which is a hallmark of PN because it tends to affect vibration sense before other modalities, including pinprick, as a hallmark feature of DPN (Feldman et al., 2019; Javed et al., 2015). The temperature sensation test assesses small, unmyelinated C-fibres and thinly myelinated Aδ-fibres involved in the perception of heat and cold; its dysfunction indicates small-fibre neuropathy (Shukla et al., 2005; Tesfaye et al., 2010).

The ankle reflex assesses the functional integrity of the deep tendon reflex arc, which contains large sensory (Ia afferent) and motor fibres; a decrease or loss suggests an advanced stage of large-fibre neuropathy or S1 nerve root involvement (Chan et al., 1992; Yang et al., 2018). Finally, the pinprick perception test assesses Aδ and C nociceptive-fibre functioning, the loss of sharp pain perception indicating a small fibre damage that predicts an increased risk factor for foot ulceration (Meijer et al., 2000; Sharma et al., 2023).

Biothesiometry is a well-established and validated tool for assessing PN by measuring loss of vibration perception threshold (VPT) (Weintrob et al., 2007). Previous studies have demonstrated its high specificity and correlation with nerve conduction studies, supporting its validity as a gold standard (Bharucha et al., 1991). However, the accuracy of these tests (vibration testing, ankle reflex, temperature, and pinprick sensation) relative to the biothesiometer remains unclear, especially in Malaysia, due to a lack of real-world community-level validation.

2.0 MATERIALS AND METHODS

2.1 Study design and setting

This cross-sectional diagnostic study was conducted in seven retail pharmacies in Selangor State, Malaysia, from March 15, 2021, to May 5, 2022, as reported in a recent study (Mooi et al., 2024). The state of Selangor was chosen owing to its high population and diverse ethnic mix, thereby reflecting a real-world scenario for early detection of PDN in non-clinical settings.

2.2 Study population

Any Malaysian adults aged >18 years who had visited the pharmacies were included in the study. Pregnancy, severe illness, and cognitive disturbance were exclusion criteria.

2.3 Sample size calculation

The sample size was determined based on the prevalence of peripheral neuropathy in Malaysia (34.9%) (Feldman et al., 2019; Negida et al., 2019). With a sensitivity of 62.5% and a specificity of 95.3% (± 0.10 precision, 95% CI), we would require 258 for sensitivity and 27 for specificity. After accounting for a 30% loss to follow-up, the final desired number was 369. Nevertheless, this study was conducted as part of a larger epidemiological research to investigate the prevalence and associated factors with peripheral neuropathy (Ching et al., 2024). Having this larger sample increases the accuracy of our prevalence estimate and makes our diagnostic accuracy estimates in different subgroups more robust.

2.4 Data collection

A self-administered questionnaire was used to collect socio-demographic and relevant clinical data. All participants received index tests (ankle reflex, vibration sense, pinprick sensation, temperature sensation) and a reference standard (biothesiometer). Two trained physicians conducted assessments, and inter-rater reliability (0.71, good agreement) was calculated using the Cohen's kappa agreement (Kwiecien et al., 2011). Trained research assistants attended the data collection process and clarified any ambiguity that may have occurred to ensure accurate responses. The questionnaire was also piloted for comprehensibility and readability in a wide range of participants prior to final administration. These process help to reduce potential bias and enhance data reliability. The data collection details were shown in the **Table 1**.

2.5 Statistical analysis

Statistical Package for the Social Sciences version 26.0 was used to perform the statistical analysis. Mean and standard deviation (SD) were used for continuous data, and frequency and percentage for the categorical data. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the screening tests were calculated. A contingency table is constructed using the results of a screening test, such as ankle reflex, vibration testing, pinprick testing, and temperature testing, which were compared with the gold standard (biothesiometer test). Sensitivity, the proportion of true positives correctly identified, is calculated as True Positives / ((True Positives) + (False Negatives)).

Specificity, the proportion of true negatives correctly identified, is determined by (True Negatives) / ((True Negatives) + (False Positives)). PPV, which indicates the likelihood that a positive test result is accurate, is given by True Positives / ((True Positives) + (False Positives)). NPV, the probability that a negative test result is accurate, is calculated as (True Negatives) / ((True Negatives) + (False Negatives)).

2.6 Ethics

Ethical approvals were obtained from the Medical Research Ethics Committee, Ministry of Health Malaysia (NMRR-20-971-54860) and Ethics Committee for Research Involving Human Subjects, Universiti Putra Malaysia (JKEUPM-2020-367). Written informed consent was obtained from all participants.

Table 1. Data collection details.

Tool	Testing site	Procedure	Cutoff	Interpretation
Biothesiometer	Six sites on the sole	Vibration probe applied; voltage increased by 1V/second until perception. Mean of 3 readings recorded.	Age-stratified: >50y: Normal 1–15V, Mild 16–20V, Moderate 21–25V, Severe 26–50V; ≤50y: Normal 1–10V, Mild 11–15V, Moderate 16–20V, Severe 21–50V	Once the mean of 3 readings is above the cut-off value of any site, it indicates peripheral neuropathy (Adeleye et al., 2012; Chawla et al., 2013).
Ankle Reflex	Achilles tendon	Hammer tap with/without reinforcement; observed for calf muscle contraction.	Diminished/absent reflex	Suggests large fibre neuropathy or S1 nerve root involvement (Yang et al., 2018).
128Hz Tuning Fork	Bony prominences (toes, ankles, knees)	Participant indicates vibration perception.	Reduced/absent sensation	Impaired large fibre function (Yang et al., 2018).
Pinprick Test	Distal feet	Light pricking with a disposable stick; ascending gradient.	Diminished/absent sharp pain perception	Indicates small fibre damage (Yang et al., 2018).
Temperature Test	Plantar foot	Cold tuning fork applied; subjective differentiation assessed.	Inability to detect cold	Suggests small fibre neuropathy (Yang et al., 2018).

3.0 RESULTS

The study involved 1283 participants, with an average age of 40.6 ± 12.9 years. Most of the participants were of Chinese descent (54.1%), and almost half had completed tertiary education (43.4%). A large percentage of the participants did not drink alcohol (80.6%), were non-smokers (83.5%), and non-vegetarians (97.6%). Hypertension (21.8%) was more common than diabetes (12.9%) among the participants. Only a small number of participants had underlying neurological conditions (3.2%), and 7.3% reported having a family history of neurological problems (**Table 2**).

Table 2: Socio-demographic and clinical characteristics of the study population (n=1283).

Variables		n (%)
Age in years, mean ± SD		40.6 ±12.9
Gender	Male	648 (50.5)
	Female	635 (49.5)
Ethnicity	Malays	372 (29.0)
	Chinese	694 (54.1)
	Indian	161 (12.5)
	Others	56 (4.4)
Highest Education level achieved	Primary school and none	165 (12.8)
	Secondary school	446 (34.8)
	Pre-university and tertiary	6725 (52.4)
Personal monthly income in Ringgit Malaysia, mean ± SD		4246 ± 4403
Drink alcohol		249 (19.4)
Smoking		212 (16.5)
Vegetarian		31 (2.4)
Has hypertension		280 (21.8)
Has diabetes		166 (12.9)
Has neurological disorders*		41 (3.2)
Family history of neurological disorders		94 (7.3)
Complications among those with diabetes	Stroke	11 (6.6)
	Ischaemic heart disease	26 (15.7)
	Chronic kidney disease	15 (9.0)
	Retinopathy disease	43 (25.9)
	Foot ulceration	6 (3.6)

SD: standard deviation; *neurological disorders: Guillain-Barré syndrome and chronic inflammatory demyelinating polyneuropathy.

The biothesiometer test showed that 340 participants (26.5%) tested positive for peripheral neuropathy, while 943 participants tested negative. For ankle reflex, the majority (87.0%) of participants had a normal result, while only 13.0% had reduced or absent ankle reflex. For the vibration testing, most participants (89.9%) had normal results, while a small portion (10.1%) had abnormal results. For pinprick sensation, 91.1% of participants had normal pinprick sensation, while 8.1% had reduced pinprick sensation. For the temperature discrimination test, the majority of participants (94.5%) had normal results, while 5.5% had abnormal results.

Table 3 and **Figure 1** show the accuracy of ankle reflex, vibration testing, pinprick sensation, and temperature examination in detecting peripheral neuropathy compared with the biothesiometer test. The sensitivity of the ankle reflex is highest (34.12%), followed by vibration (31.76%), the pinprick sensation test (24.41%), and temperature (6.76%). The specificity of all tests is high, ranging from 95.02% to 97.78%. The positive predictive value is highest in vibration (83.72%), followed by pinprick sensation, ankle reflex and temperature.

Table 4 elaborates on the performance of 4 clinical tests (ankle reflex, vibration, pinprick, temperature) in diagnosing neuropathy among two age groups (<50 years old versus ≥50 years old), with the possibility of better excluding the presence of disease (high NPV: 87.55–89.62%) than detecting it. Sensitivity modestly increases with increasing age (maximally 40.65% for vibration), and PPV dramatically increases (e.g., PPV 88.5% for vibration), which may provide better means to confirm disease among the elderly. Temperature testing has the lowest sensitivity (7.32%>) with an absolute PPR in values (84–88.5%). More specifically, specificity diminishes slightly with age, presumably due to comorbidity. In general, these tests perform better in the setting of disease (high PPV) in older patients but exhibit poor screening characteristics due to low sensitivity.

Table 5 describes the performance of 4 clinical tests (ankle reflex, vibration perception, pinprick sensation, and temperature assessment) in individuals with and without diabetes. In non-diabetic subjects, all tests have limited sensitivity (temperature 5.68%; ankle reflex 24.45%) but high specificity (95.16–98.09%) with better NPV (79.66–83.01%), suggesting that they are better for excluding neuropathy than for diagnosing true cases. Sensitivity is also significantly improved in diabetics (e.g. ankle reflex: 54.05%, vibration: 53.15%), where sensitivity is still suboptimal, whilst specificity is slightly lower (85.45–96.36%).

PPV is much higher in the diabetic population (96.72% for vibration vs. 72.06% for non-diabetic), indicative of the higher prior-like probability of true positives in a higher risk group. In contrast, NPV reduces significantly in diabetics (33·11–50·48%), indicating narrow-range tests to rule out neuropathy in diabetics. In general, vibration and ankle reflex are the best to confirm neuropathy among diabetics (high PPV), while all tests are poor screening tools because of low sensitivity, especially for non-diabetics. Temperature testing is least efficient in both groups. The results illustrate the effect of diabetes status on test performance and show that diabetics are likely to gain greater diagnostic value from these tests.

Table 3. Comparison of different screening tests in detecting peripheral neuropathy among the whole study population (n=1283).

	Sensitivity, % (95% CI)	Specificity, % (95% CI)	PPV, % (95% CI)	NPV, % (95% CI)
Ankle reflex	34.12 (29.09-39.43)	95.11 (93.62-96.34)	69.46 (62.62-75.54)	81.58 (80.38-82.72)
Vibration	31.76 (26.85-37.00)	97.77 (96.62-98.62)	83.72 (76.62-88.98)	79.90 (78.70-81.05)
Pinprick sensation	24.41 (19.94-29.34)	97.77 (96.62-98.62)	79.81 (71.34-86.26)	78.2 (77.14-79.23)
Temperature	6.76 (4.34-9.98)	95.02 (93.43-96.32)	32.86 (23.19-44.24)	73.87 (73.24-74.48)

PPV: Positive Predictive Value; NPV: Negative Predictive Value; CI: Confidence interval.

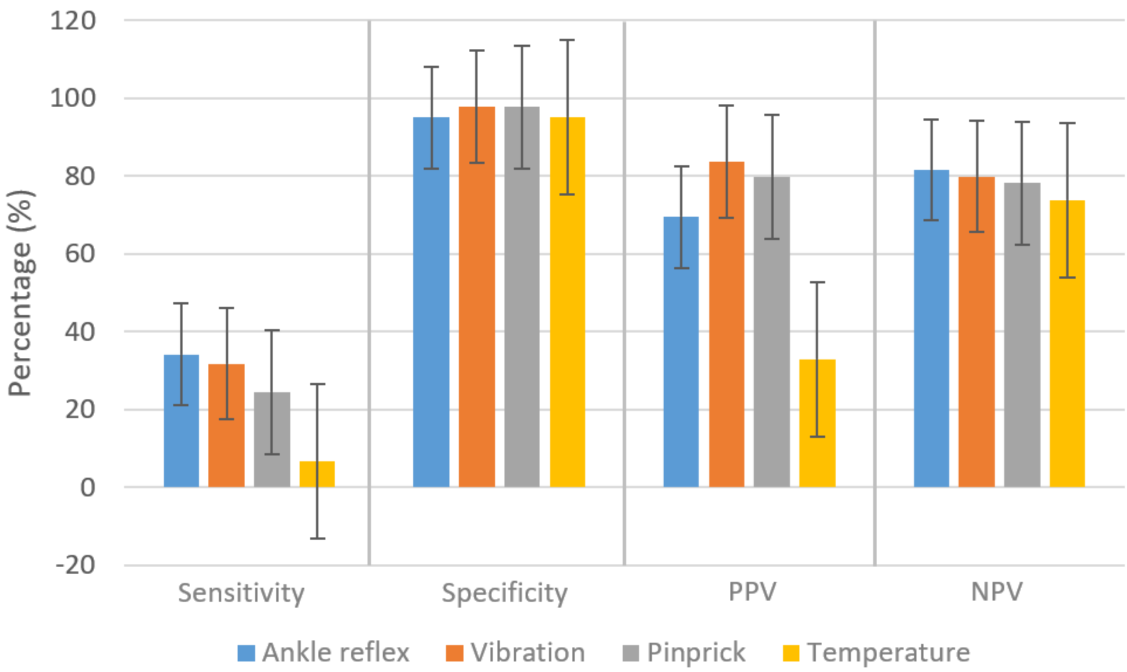

Figure 1: Bar chart comparison of different screening tests in detecting peripheral neuropathy among the whole study population (n=1283). PPV: Positive Predictive Value; NPV: Negative Predictive Value; Error bars: standard mean error.

Table 4. Comparison of different screening tests in detecting peripheral neuropathy between the study population aged 50 and above and below (n=1283).

	Sensitivity (%)		Specificity (%)		Positive predictive value (%)		Negative predictive value (%)	
Variables	<50 y.o	≥50 y.o	<50 y.o	≥50 y.o	<50 y.o	≥50 y.o	<50 y.o	≥50 y.o
Ankle reflex	22.34	38.62	96.18	90.97	45.65	78.51	89.62	63.44
Vibration	8.51	40.65	98.78	95.49	50	88.5	88.27	65.32
Pinprick sensation	9.57	30.08	98.93	95.14	56.25	84.09	88.4	61.43
Temperature	5.32	7.32	95.57	93.75	14.71	50	87.55	54.22

y.o: year old.

Table 5. Comparison of different screening tests in detecting peripheral neuropathy between the study population with and without diabetes (n=1283).

	Sensitivity (%)		Specificity (%)		Positive predictive value (%)		Negative predictive value (%)	
Variables	No DM	Have DM	No DM	Have DM	No DM	Have DM	No DM	Have DM
Ankle reflex	24.45	54.05	95.16	85.45	56.57	88.24	83.01	47.96
Vibration	21.4	53.15	97.86	96.36	72.06	96.72	82.84	50.48
Pinprick sensation	17.9	37.84	98.09	92.73	70.69	91.3	82.25	42.5
Temperature	5.68	9.01	95.27	90.91	23.64	66.67	79.66	33.11

DM: Diabetes mellitus.

4.0 DISCUSSION

The prevalence of peripheral neuropathy identified in this study was 26.5%, which is lower and within an acceptable range compared to another local study among patients with underlying diabetes in a primary care setting, where the prevalence of PN was reported as 49.4% (Lee et al.,2022). The possible cause of PN in this study could be due to ageing and other factors. Study reported that up to 30% of PN cases are idiopathic, particularly in older adults (Bouche, 2020). This study reported higher PN rates among participants ≥50 years. Other causes could be due to vitamin deficiencies, alcohol and hypertension (Bouche, 2020). Future studies should screen for prediabetes and metabolic syndrome, assess nutritional status, especially vitamin B12, and rigorously evaluate alcohol intake and environmental toxins.

The findings of this study provide important insights into the diagnostic performance of clinical tests for detecting peripheral neuropathy across different population subgroups. Our results demonstrate that temperature discrimination had the lowest sensitivity among the clinical examinations (6.76%). Our finding was similar to that of Bhabhor and Vidja (2019), who reported a sensitivity of 10.52% for cold discrimination using the thermal perception sensitometer. The thermal perception sensitometer has lower sensitivity but higher specificity in detecting peripheral neuropathy (Bhabhor and Vidja et al., 2019).

Similarly, a study by Viswanathan (2002) also shows the same findings as our study: they found that using the Tip-therm examination had a sensitivity as low as 2.7% and a high specificity of 97.3% compared with the biothesiometer in detecting peripheral neuropathy (Viswanathan et al., 2002). The vibration testing showed the best overall performance with 83.72% PPV, supporting its inclusion in diagnostic protocols as recommended by the American Family Physician Association (Castelli et al., 2020; Onde et al., 2008).

Age-stratified analysis revealed important diagnostic differences, with tests performing better in older adults (≥50 years). The PPV of 88.5% for vibration testing in patients ≥50 years suggests particular utility for confirming neuropathy, consistent with previous findings (Bouche, 2020; Ching et al., 2024). However, the modest sensitivity (40.65%) emphasises the need for complementary testing.

The diabetes status analysis yielded particularly striking results. While test specificity remained high in non-diabetics (95.16-98.09%), the dramatic PPV increase in diabetics (vibration: 96.72%) supports the clinical value of these tests in high-risk populations. These findings corroborate the previous study, whereby patients with diabetes are at risk of peripheral neuropathy (Galiero et al., 2023). The poor NPV in diabetics (33.11-50.48%) underscores the importance of regular monitoring.

Even though vibration testing has low sensitivity, as shown by this study (i.e., 31.76% for the whole population), it can still be a valuable tool for detecting peripheral neuropathy, especially in patients with diabetes mellitus, as it is among the first sensations lost (Galiero et al., 2023). This aids in the timely diagnosis of diabetic peripheral neuropathy, which, if untreated, may lead to serious complications such as foot ulcers and amputations (Ministry of Health Malaysia, 2020).

In essence, tests that aim for high PPV often do so at the cost of sensitivity. Therefore, high PPV is often achieved by raising the threshold for a positive test result. This reduces false positives, thus increasing PPV, but also increases false negatives. PPV is prevalence-dependent, while sensitivity is not. Therefore, to maintain high PPV, screening is often restricted to high-risk populations, which inherently reduces the sensitivity for the general population (Humphrey et al., 2004).

One of the strengths of this study is the large sample size (n = 1,283) and the community-based setting, which provides insights into the performance of these screening tools in a real-world, non-clinical environment. There are several limitations in this study. First, the cross-sectional design precludes assessment of the temporal relationship between test performance and other variables. Second, the characteristics of our study population may limit generalizability to other ethnic groups. Third, there was no gold-standard confirmation using nerve conduction studies in this study, so we need to interpret the results cautiously. Forth, despite the biothesiometer being a validated and well-correlated instrument for detecting DPN, the lack of confirmation by the gold-standard NCS is a major limitation.

Using biothesiometry instead of NCS as a reference standard would be confounded by the poor performance, high variability, and subjective nature of the reference test itself, rather than reflecting the true capability of the test being evaluated. Thus, the reader needs to interpret our findings in light of this methodological limitation.

This value of high PPV and low sensitivity has clinical relevance for a population-based 'screen-and-refer' approach. An especially accurate test, such as vibration testing, is appropriate for verifying a disease, since the PPV was 83.7 in the general population and 96.7 in diabetes. For example, if a patient's symptoms are classic for DN and their vibration test is positive, this provides strong evidence in favour of the diagnosis. In those patients with obvious disease, it is not necessary to perform a more expensive and complex confirmatory test, such as nerve conduction studies (NCS), on everyone (Selvarajah et al., 2019). This effectively allows the limited healthcare resources to be allocated so that only those who will benefit are treated.

On the other hand, the low sensitivity of these tests is a major limitation in excluding the disease. A normal result does not offer a reliable rule-out of peripheral neuropathy, especially among high-risk groups such as diabetics with NPV ranging from 33.11 - 50.48%. Therefore, these tests cannot be used for ruling out neuropathy. By the same reasoning, given that a ‘screen-and-refer’ programme with the tools studied would need to be supported by protocols and guidance stating that negative results do not exclude neuropathy, and requiring ongoing surveillance and periodic re-evaluation, we believe our findings are of value for an optimal design of a diagnostic screening pathway.

5.0 CONCLUSIONS

The prevalence of peripheral neuropathy was 26.5% based on the biothesiometer test and 10.1% based on the vibration test. While conventional clinical tests show limited sensitivity for neuropathy screening, their high specificity and PPV make them valuable confirmatory tools, particularly in older adults and individuals with diabetes. These findings support current recommendations for multimodal assessment and highlight the need for more sensitive screening methods in low-risk populations.

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Author Contributions:

S.M.C., H.L. and A.H.K.Y.K. conceived and designed the study, with S.M.C., N.K.D., A.T.C., S.V. and X.H.T. performed the data extraction. Y.J.L., F.K.H., W.A.W.S., and M.P. analysed the data, S.M.C., W.C.L., Y.F.P. and V.R. evaluated the quality, and S.M.C. and V.R. drafted the manuscript. All authors have reviewed and critically provided feedback on the manuscript.

Conflicts of Interest:

The authors declared no conflict of interest.

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