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ORIGINAL ARTICLE

Validation of the Ipswich Touch Test for Screening of Loss of Protective Sensation and Peripheral Neuropathy in Type II Diabetes

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Abstract

Introduction: Diabetic peripheral neuropathy (DPN) is a common complication of diabetes that significantly increases the risk of foot ulceration and amputation. Early detection of loss of protective sensation (LOPS) is critical, particularly in resource-limited settings. This study aimed to validate the Ipswich Touch Test (IpTT), a simple and non-invasive screening tool, against the 10 g monofilament (MF) and other neurological assessments in individuals with Type II diabetes.

Methods: A cross-sectional study was conducted among Type II diabetic patients from the XXX Diabetes (SeDia) Cohort. Participants underwent foot examinations using MF (reference standard), IpTT, and pinprick, vibration, and ankle reflex tests. Sensitivity, specificity, predictive values, likelihood ratios, and agreement (kappa coefficient) were calculated.

Results: Among 315 participants, the prevalence of LOPS/DPN was 14.6%. IpTT demonstrated 90.5% accuracy, with a sensitivity of 41.3% and specificity of 98.9% compared to MF. Agreement between IpTT and MF was moderate ($\kappa = 0.513$, $p < 0.001$). Vibration testing had the highest sensitivity, while pinprick showed the best specificity. Ankle reflex testing performed poorly.

Conclusion: IpTT is a highly specific and accurate screening tool suitable for use in low-resource settings. Despite limited sensitivity, it is a valuable adjunct to other neurological tests in detecting LOPS and DPN.

Keywords

Diabetic neuropathy, Impaired sensation, Global health, Medical economics, Primary care

Introduction

Diabetes mellitus (DM) is a major health concern in developing countries such as XXX. Current data indicate that by 2050, more than 180 million South-East Asians will be afflicted with the disease, exhibiting a 73% increase from 2024 [1]. The XXX Ministry of Health in 2020, through the National Diabetes Registry Report, reported the overall prevalence rate of raised blood glucose among adults at 18.3% [2]. This number is expected to rise annually unless drastic measures are taken to curtail it. Alarmingly, the state of XXX recorded the highest prevalence at 33.2% among adults aged 18 years and above [2]. To better understand this situation,

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the XXX Diabetes (SeDia) Cohort was established in 2023 through a collaboration between XXX University and Ministry of Health XXX. This 12-year longitudinal cohort study is aimed at examining the role of genetic, physiological, environmental, lifestyle, and psychosocial factors in developing Type II DM and its complications [3].

Among the complications of diabetes, diabetic polyneuropathy (DPN) and loss of protective sensation (LOPS) are particularly concerning due to their association with microtrauma, impaired proprioception, gait abnormalities [4], and increased risk of foot ulceration and lower limb amputation.

The 10 gm Semmes-Weinstein monofilament (MF) is widely accepted as the gold standard in LOPS detection in primary care [5-7] and is a key recommendation of the International Working Group for Diabetic Feet (IWGDF) [8]. Although it is relatively easy to conduct, there are still problems with equipment procurement and management, the training of healthcare professionals, and inaccessibility to family members for home surveillance [5,9,10]. The Ipswich Touch Test (IpTT), introduced by Gerry Rayman, offers a viable alternative, requiring only a light touch on specific foot areas. Its simplicity enables both clinical and home-based surveillance [7,9,11,12]. Several countries have validated and integrated IpTT into their diabetic screening programs [5,10,12,13-15], and XXX has incorporated it into the Clinical Practice Guidelines for DM management [16]. However, no local validation study among major ethnic groups (Malay, Chinese, and Indian) has been conducted, and its use is not widespread.

Using the SeDia project infrastructure, we aimed to validate the IpTT against the MF and other screening tools in detecting LOPS and DPN among Type II diabetic patients in the primary care setting.

Methods

This was a cross-sectional study performed between September 2023 and June 2024. Potential patients were recruited from the XXX Diabetes (SeDia) cohort subjects. Baseline and physical examination data were collected at recruitment from the subjects via face-to-face interviews. Additional clinical data were retrieved from medical records. Further information on the SeDia Cohort project may be obtained from its website, https://sedia.my.

The inclusion criteria were adults (≥ 18 years) with Type II DM who were physician-confirmed and can participate in foot examinations. Patients with Type I DM, gestational diabetes, active foot ulceration, previous amputation of digits, foot, or lower limb, and neuropathic conditions (past or resolving stroke, nerve root entrapment syndromes, Parkinson's, etc) were excluded. Institutional ethical approval was obtained, and all patients provided their written consent prior to the commencement of recruitment.

We ascertained the required sample size using an online sample size calculator [17]. Based on an expected sensitivity of 75%, specificity of 98% (6,9,15), a LOPS prevalence of 25% [18], and allowing 5% dropout with 95% confidence and 1% precision, a final sample size of 310 was calculated.

The gold standard for LOPS evaluation is the MF test which is the most widely employed [19]. Using the protocol described by Boulton, et al. [20] the MF was placed perpendicular to the patient's skin overlying the plantar aspects of the hallux, 1st, 3rd and 5th metatarsal head for 2 seconds. Areas of callosities, scars, and hyperkeratosis were avoided. With their eyes closed, patients were instructed to indicate 'Yes' if sensation is felt. Each MF was allowed to rest for 10 minutes between patients and discarded after every 10 uses [20]. Inability to detect the sensation at 2 or more sites indicated the presence of LOPS.

The pinprick sensation is similarly tested using the method described by Boulton, et al. [20] A plastic tester or a wooden toothpick is applied to the skin of the big toe just proximal to the nail for 2 seconds, just enough to indent the skin. With the eyes closed, patients were required to indicate if the sensation was felt similarly.

After activation, a 128 Hz tuning fork was applied to the 1st metatarsophalangeal joint. With their eyes closed, patients were instructed to indicate if a sensation was felt when vibration was applied and stopped.

Lastly, ankle reflexes were tested using standard tendon hammer technique. Each patient is given a rest period of at least 15 minutes before proceeding with the IpTT.

With proper hand hygiene, the skin overlying the plantar aspect of the distal 1st, 3rd, and 5th toes are lightly touched for 2 seconds using the protocol described by Rayman [11,12]. Care was taken to ensure that no poking, prodding, or deep pressure takes place. Again, with eyes closed, the patients were instructed to indicate if the sensation was felt. The assessor was blinded to the results of the previous examinations. As proposed by Rayman, we regarded patients not able to detect the examiner's fingertip light touch 2 or more sites out 6 as positive for LOPS.

Data analysis was performed using IBM SPSS Ver 28.0 for accuracy, sensitivity, and specificity of the IpTT, predictive values, and likelihood ratios. Agreement between IpTT and MF tests was ascertained with kappa correlation.

Results

We examined 320 individuals from the SeDia Cohort subjects of which four were excluded from the

analysis: three with previous lower limb amputation (two multiple toes amputations, and one below knee amputation) and another with an evolving hemiplegic stroke. Another patient was removed from analysis because of incomplete data entry, leaving 315 patients available for analysis.

The mean age of our patients was 62.88 ± 10.98 years (range: 23-89) with 47.5% being males. 152 patients were Indians (48.3%), 110 were Chinese (34.9%) and 50 were Malays (15.9%). Other ethnicities constituted 0.9% of patients.

Our analysis showed that compared to 10 gm MF as a gold standard, the IpTT had an accuracy of 90.5% with a sensitivity of 41.3% and a specificity of 98.9%. We calculated the positive predictive value to be 86.4% with a negative predictive value of 90.8%. Patients with LOPS were 37.04 times more likely to be detected with a positive IpTT compared to patients without LOPS. Such patients with LOPS were 0.59 times likely to have a negative IpTT compared to those without LOPS. Our findings revealed a kappa coefficient of 0.513 ($p < 0.001$) indicating moderate agreement between the two tests (Table 1).

Based on our results, the prevalence of LOPS and DPN among our Type II diabetic patients is 14.6%. We next compared other neurological examinations using MF as the reference standard for LOPS and DPN. We wanted to compare the parameters shown by these techniques to that of IpTT. Our results are shown in table 2.

Our data indicate pinprick testing as showing the highest specificity when compared to MF as the gold standard while vibration testing yielded the highest sensitivity. Poor diagnostic performance was demonstrated by the ankle reflex. In terms of technique accuracy, using MF as the gold standard, the IpTT is slightly more accurate than pinprick, followed by vibration sense, and finally ankle reflex.

Table 1: Parameters of comparison of Ipswich touch test (IpTT) against monofilament (MF) as the gold standard.

	Ipswich Touch Test (IpTT) vs Monofilament (MF)
Sensitivity (%)	41.3 (95% CI: 28.29 - 55.66)
Specificity (%)	98.9 (95% CI: 96.77 - 99.62)
Positive predictive value (%)	86.4
Negative predictive value (%)	90.8
Likelihood ratio (+)	37.04 (95% CI: 11.42 - 120.15)
Likelihood ratio (-)	0.59 (95% CI: 0.47 - 0.76)
Accuracy (%)	90.5
kappa coefficient	0.513 ($p < 0.001$)

Table 2: Comparison of MF with other neurological examination techniques.

Test	Sensitivity (%)	Specificity (%)	Accuracy (%)	Kappa
Pinprick vs MF	34.8 (22.72 - 49.24)	99.3 (97.30 - 99.84)	89.8	0.455*
Vibration vs MF	56.5 (42.32 - 69.92)	79.2 (73.92 - 83.61)	75.9	0.270*
Reflex vs MF	63.0 (48.62 - 75.51)	56.9 (50.90 - 62.69)	57.8	0.046

Discussion

We aimed to validate the usage of IpTT for the screening of LOPS and DPN of Type II diabetics amongst our population. No such validation study has been conducted in XXX despite being included as a diagnostic tool in our diabetic management guideline. 13 Our findings show that the IpTT is a highly specific and accurate tool in detecting LOPS. Although of moderate (41.3%) sensitivity, its specificity approached 99%, similar to the results of other authors [9,15].

Similar validation attempts were made in other countries. The Canadians validated its usage as a screening tool and showed strong interrater agreement for identifying LOPS [5]. Madanat, et al. examined 351 Saudi patients and found positive and negative predictive values of IpTT against MF that were almost similar to our own findings [10]. In Indonesia, Basir, et al compared the accuracy of IpTT against common neurological examination techniques including MF. They reported a sensitivity rate of 80%, concluding that there was no difference among the different techniques [13]. Bubun, et al. attempted to validate using IpTT as an early screening tool for DPN amongst diabetics in Indonesia, along with palpation of the dorsalis pedis pulse [14]. Dutra, et al. reported close agreement between IpTT and MF in their study amongst 250 Brazilian diabetics, with a kappa agreement index measuring 0.819 ($p < 0.001$) [15]. Bowling, et al. compared the IpTT and the Vibratip tool against a Neuropathy Disability Score (NDS) > 6 and the vibration perception threshold > 25V amongst 83 individuals with 'at-risk' feet. They concluded that both the former were reliable and sensitive methods of discerning feet at risk of LOPS and DPN [21].

On the other hand, comparing IpTT and MF against a vibration perception threshold of > 25V as the gold standard among 181 patients, Senthilkumar et al found that MF produced a better agreement with the vibration perception threshold compared to IpTT. Despite this finding, they concluded that the IpTT was an ideal alternative in resource-poor situations [22]. McIllhatton, et al. performed a systematic review and meta-analysis of 17 papers citing non-invasive screening tests and concluded that the reliability of certain neurological tests, IpTT included, was unclear. The use of vibration perception threshold, MF, and ankle reflex were more reliable for detecting and monitoring DPN [23].

Our findings demonstrated that the IpTT exhibited moderate agreement with the MF and showed promise as a primary screening tool. In terms of accuracy, IpTT rated better that pinprick, vibration sense, and ankle reflexes. Our findings are generally consistent with

previous reports, with sensitivity ranging between 41-93% and specificity from 68-100% [24-26]. Its relatively high positive and negative predictive values (86.4% and 90.8% respectively) lend further credence to its effectiveness. Its screening sensitivity could be further enhanced by combining it with other neurological tests.

Our findings further indicate IpTT is an acceptable substitute for MF, particularly in terms of economics. Given its zero cost, simplicity, and strong diagnostic performance, we recommend that IpTT be integrated more fully into community screening programmes and primary care practices [9,13,14,27] particularly in resource-impaired environments in Asia and Africa where diabetic complications are expected to increase [1]. This will invariably improve LOPS detection and prevention of non-traumatic amputations associated with Type II DM.

Conclusion

IpTT is shown to be a sufficiently accurate and highly specific alternative to MF particularly when resources are limited. Despite its moderate sensitivity, the IpTT's simplicity and zero cost support its use as an adjunct in diabetic foot screening programs. Combination with other tests may improve detection rates.

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Conflicts of Interest

The authors report no conflicts of interest.

Ethical Approval

This study was performed in accordance with the ethical principles outlined in the Declaration of Helsinki. The SeDia Cohort study protocol was approved by the Medical Research and Ethics Committee of the Ministry of Health XXX (NMRR ID-22-01568-0D2) and the XXX University Joint Committee for Research and Ethics (IMU R 228-2022). Each patient has provided written consent upon recruitment for the study.

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Author Contribution

Zairul Nizam Zainol Fithri - Conceptualization, Investigation & Data organization, Analysis, Data interpretation, Initial and Final draft preparation.

Lokman Hakim Sulaiman - Conceptualization, Review, Editing and Final draft preparation.

Ida Seriwati Ismail - Investigation & Data organization, Data interpretation.

Normy Narihan - Investigation & Data organization.

Shamini Nadaraja - Investigation & Data organization.

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