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Screening for the loss of protective sensation in people without a history of diabetic foot ulceration: Validation of two simple tests in India

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ABSTRACT

The ability of the Ipswich touch test (IpTT) and Vibratip™ to detect loss of protective sensation (LOPS) was tested against a neurothesiometer in an outpatient diabetic population without a history for ulceration. Our results support the use of the IpTT as a screening tool for LOPS, but not of Vibratip™.

1. Introduction

People with diabetes can gradually lose the protective sensation of pain in their feet due to peripheral neuropathy. As a result, they tend to repeatedly overload and seriously injure them to cause diabetic foot ulceration (DFU). DFU is an open wound with limited capacity for healing, it can get infected and even lead to amputation. It is estimated that worldwide there is one amputation every 20 s due to diabetes [1]. Developing countries, like India, appear to be disproportionally affected by diabetes and diabetic foot complications [2].

Preventing the first-ever DFU is the most effective way to reduce the risk of amputations and to protect the quality of life of people with diabetes [3]. This is because 40% of people with healed first ulcers re-ulcerate within a year (60% re-ulcerate within three years) increasing significantly the risk for amputation [3]. The first-ever DFU is also associated with a 250% increase in the 5-year risk of death [4].

Methods used to prevent recurrent DFU are likely to be effective to prevent first ulcers, but their use across the entire diabetic population is practically impossible due to the sheer number of people at risk of first DFU [5]. There is a need to target preventative interventions at those people at imminent risk for first ulceration. Screening for the loss of protective sensation (LOPS) can play a key role to this end [6].

Simple and cost-effective tests such as the Ipswich touch test (IpTT) [7–13] and Vibratip™ [14,15] appear ideal candidate methods for LOPS screening in the community and in austere clinical environments. However, neither of them has been validated in populations without DFU history. In this context, the present study aims to directly assess the ability of IpTT and Vibratip™ to detect LOPS in a diabetic population without a history of DFU in India.

2. Research design and methods

2.1. Participants

252 adults with diabetes (Type 2) attending the diabetic outpatient clinic of Sri Ramachandra Medical College Hospital, Chennai, India were enrolled (Table 1). People with a history of DFU, Charcot foot or lower limb amputation were excluded. All participants provided written informed consent before data collection (Ethical approval reference number: IEC/22/FEB/169/06).

2.2. LOPS assessment

LOPS was assessed using vibration perception threshold (VPT) [16], the IpTT [8,13] and Vibratip™ [14,15]. Testing was done by three experienced clinicians which were blinded to each other's results. Each test was done by the same clinician for all participants.

VPT was measured according to standard clinical practice at the pulp of the hallux using a Neurothesiometer (Horwell Scientific,UK). The measurement was repeated three times per hallux and their average was

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Table 1
The demographic, anthropometric and relevant diabetes parameters of the recruited cohort.

Sex (male/ female)	57/ 195
Age (years)	58 ± 11
Height (m)	1.55 ± 0.78
Body mass (kg)	64 ± 12
Body mass index (kg/m^2)	27 ± 5
Duration of diabetes (years)	12.5 ± 9.5
Number of people with LOPS based on VPT (% of recruited population)	52 (21%)

used as the final VPT score for each foot. VPT > 25 V in at least one foot was considered indicative of LOPS [16].

During the IpTT the examiner lightly touched the apex of the hallux, 3rd and 5th toe in each foot with their index finger. The examiner was instructed not to poke, prod or tap to avoid creating a sensation other than light touch [13]. Patients were asked to close their eyes and say "left" or "right" when they perceived touch in their left or right foot respectively. Their ability (or not) to sense touching in each site was recorded. Two or more insensate sites across both feet were considered indicative of LOPS [13].

Vibratip^{TM} testing involved touching the apex of the hallux with the device's rounded tip for ≈1s [14,15]. This was done twice per hallux, but the device was randomly activated only once to provide a vibration stimulus. Inability to tell whether the device was activated for at least one hallux was considered indicative of LOPS [14,15]. For completeness, Vibratip^{TM} testing was repeated also for the 3rd and 5th toe in each foot. Ability/inability to sense whether the device was activated was recorded for each testing site.

2.3. Statistical analysis

Cohen's kappa was calculated to assess whether failing the IpTT or Vibratip^{TM} is a reliable indicator for LOPS. Alternative definitions of failing the IpTT or Vibratip^{TM} testing were also explored. In the case of the IpTT this involved changing the threshold for the minimum number of insensate sites. For Vibratip^{TM}, similar alternative definitions of failing the test were explored by considering the test's outcome for all six tested sites. All statistical tests were performed using SPSS v28 (IBM, Chicago, IL, USA).

Sample size calculations indicated that a minimum of 247 people were needed for this study (assumed LOPS prevalence: 20% [9], maximum acceptable width of 95% confidence intervals: 10%, anticipated sensitivity/specificity: 76%/90% [13], a = 0.10) [17].

3. Results

LOPS was diagnosed in 21% of participants based on VPT (gold standard). Cohen's kappa (k) indicated fair [18] agreement between VPT and the IpTT ($k = 0.382$, $p < 0.001$) when the threshold for failing the IpTT was defined according to literature (i.e. ≥ 2 insensate sites). The achieved sensitivity and specificity were 71% and 76% respectively and the positive, negative predictive value of the IpTT were 44%, 91% respectively. The established threshold of ≥ 2 insensate sites offered the best compromise between sensitivity and specificity (Fig. 1a). Lowering this threshold to ≥ 1 insensate site maximised sensitivity to 83% but reduced specificity to 62%.

For Vibratip^{TM}, Cohen's kappa (k) also indicated fair [18] agreement with VPT ($k = 0.396$, $p < 0.001$) when failing the test was defined according to the literature (i.e. insensate hallux) [15]. Vibratip^{TM} achieved 37% sensitivity, 96% specificity, 70% positive predictive value and 85% negative predictive value. Changing the criterion for failing the test as having at least one insensate site, regardless of where this is detected, increased sensitivity to 50% and marginally reduced specificity to 92%.

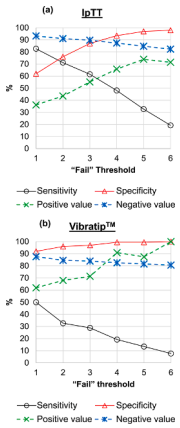

Fig. 1. The effect of different definitions of failing (a) the IpTT and (b) Vibratip^{TM} testing on their sensitivity, specificity, positive and negative predictive value. The failure threshold corresponds to the minimum number of insensate sites that constitutes a "failure" regardless of where these sites are observed.

In this case, a threshold of one insensate site (regardless of where this is detected) appears to offer the best compromise between sensitivity and specificity (Fig. 1b).

4. Discussion

The IpTT achieved sensitivity similar to relevant literature [9,13] and a high negative predictive value. These mean that failing the IpTT signals, with satisfactory certainty, the need for more specialised care while passing the IpTT effectively rules out LOPS. Combined these two characteristics make the IpTT a good candidate tool for screening. At the same time, IpTT's specificity was relatively lower than relevant literature [9,13], which means that a higher number of false positives is expected. Even though false positives are not necessarily a major problem for screening [19], their potential impact on the cost-effectiveness of interventions for the prevention of first-ever DFU should be considered in future research.

On the other hand, Vibratip^{TM} achieved specificity similar to relevant literature [15] but it was significantly less sensitive than relevant literature [15] or the IpTT. The performance of the test improved when three sites were tested per foot and "failure" was defined as one insensate site regardless of where this was detected. However, its capacity to detect LOPS remained unsatisfactory for screening in the recruited population.

The above deviations from relevant literature [9,13,15] may be due to differences between the tested populations. The present study is the first to focus on people without DFU history. As a result, the recruited population had a lower risk for DFU (IWGDF risk groups 0–2 [6]) relative to relevant literature [9,13,15]. Participants were also asked about their footwear habits. They all indicated that they walked barefoot indoors and wore sandals outdoors. Predilection for barefoot walking can lead to thicker and harder skin in the foot and might affect sensitivity to the specific stimuli of the tests used here [20].

A key limitation of this study is that IpTT or Vibratip^{TM} were not directly linked to ulceration. People diagnosed with LOPS based on VPT are known to have a significantly increased risk for DFU [16]. Further research is needed to directly assess the predictive value of LOPS diagnosed using IpTT or Vibratip^{TM} for ulceration. Potential modifications to the test and direct comparison against the 10gm monofilament could also provide additional insight into its effectiveness.

5. Conclusions

High sensitivity and high negative predictive value highlight the

IpTT as a useful screening tool for LOPS in people without a history of DFU. Its simplicity, its ease-of-use even for non-professionals [8] and the fact that it is practically cost-free makes it ideal for community testing and for testing in austere clinical environments. Our results do not support the use of Vibratip™.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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