

Short Report: Care Delivery

A pocket-sized disposable device for testing the integrity of sensation in the outpatient setting

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Abstract

Aims To compare the Ipswich Touch Test and the VibraTip with the Neuropathy Disability Score and the vibration perception threshold for detecting the 'at-risk' foot.

Methods We directly compared the Ipswich Touch Test and the VibraTip with both the Neuropathy Disability Score ≥ 6 and the vibration perception threshold ≥ 25 V indicating 'at-risk' feet in 83 individuals.

Results The vibration perception threshold and Neuropathy Disability Score tests exhibited almost perfect agreement with each other ($P < 0.001$). The VibraTip and Ipswich Touch Test results were identical ($P < 0.001$). The VibraTip and Ipswich Touch Test results also exhibited almost perfect agreement with the vibration perception threshold ($P < 0.001$) and the Neuropathy Disability Score ($P < 0.001$).

Conclusions These two simple and efficient tests are easy to teach, reliable and can be used in any setting, and neither requires an external power source. We conclude that both the VibraTip and the Ipswich Touch Test are reliable and sensitive tests for identifying the 'high-risk' foot.

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Introduction

Diabetic peripheral neuropathy, one of the most common chronic complications, may be asymptomatic in up to 50% of cases [1]. All patients with diabetes should therefore undergo a careful clinical examination of their feet at least once a year [2]. Current screening methods include the 10-g monofilament, the vibration perception threshold, the Neuropathy Disability Score and the recently described Ipswich Touch Test [3]. The VibraTip™ (McCallan Medical Limited, Nottinghamshire, UK) has been specifically designed to overcome barriers associated with other methods, such as the high cost for purchase and replacement, as well as training provision in device use [4]: when activated, it provides a stimulus of 128 Hz. Both the VibraTip and the Ipswich Touch Test can be used for testing the integrity of sensation in clinic and by the bedside. The Ipswich Touch Test requires no equipment, whilst the VibraTip (Fig. 1a and b) is easily portable with a rounded head that allows vibration sense to be assessed specifically and rapidly from

almost any angle. Manufacturer's guidelines report a maximum vibration of 35 min if the button is held down continuously, which in clinical terms should equate to several months usage allowing for approximately 10–20 s of vibration per patient. Thus, for the first time, we compared these two new tests with established screening tests for the 'at-risk' diabetic foot.

Patients and methods

The study included 83 individuals with varying neuropathy severity recruited from diabetes clinics: mean (\pm SD) age 62 ± 12 years, BMI 30.1 ± 8.1 kg/m² and diabetes duration 14.4 ± 10.6 years.

The study was performed in both the community and hospital settings and by eight different healthcare professionals.

The instructions for use of the VibraTip were as follows [4]: touch the patient's hallux twice with the rounded tip of the VibraTip, each time for approximately 1 s, explaining 'this is touch one' and 'this is touch two' whilst randomly activating the VibraTip on either the first or second touch.

The vibration perception threshold values were measured on the apices of both halluces using the Neurothesiometer. The

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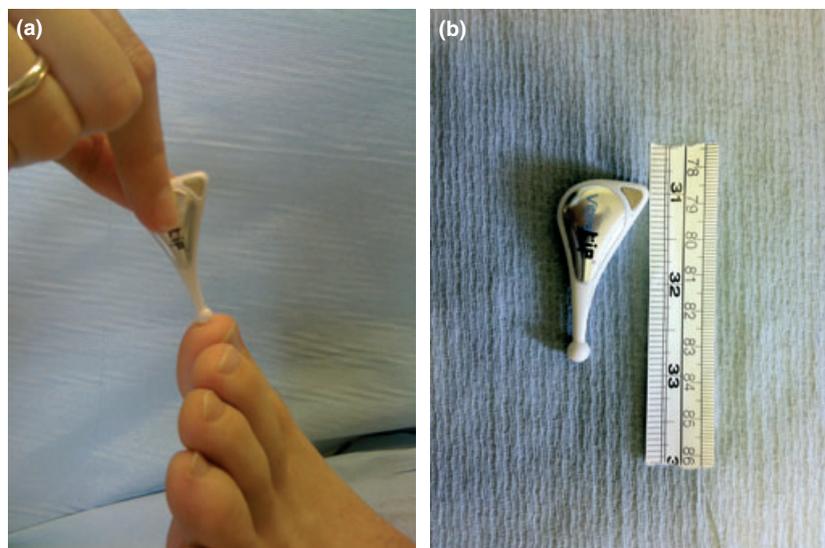


FIGURE 1 (a) VibraTip held between the thumb and forefinger, with rounded end placed lightly on the pulp of the hallux. Squeeze the device firmly between the fingers. (b) VibraTip pocket-size device measuring 2×1 cm.

Neuropathy Disability Score was derived from examination of pain sensation using a Neurotip™ [5], vibration sensation using a 128-Hz tuning fork, temperature sensation on the apices of the hallux and ankle reflex using a tendon hammer [7]. Sensory modalities were scored for each side as either present (score of 0) or reduced/absent (score of 1) for each side. Reflexes were recorded as normal (score of 0), present with reinforcement (1) or absent (2) per side. The maximum score is 10, indicating sensory loss to all modalities and absent ankle reflexes, whereas a score of 0 represents intact sensation [6]. Patients were diagnosed as having ‘at-risk’ neuropathic feet when Neuropathy Disability Score was ≥ 6 [7].

The Ipswich Touch Test involves lightly touching/resting the tip of the index finger for 1–2 s on the apex of the hallux and the 3rd and 5th apices of the lesser digits [3].

Examiners were instructed not to poke, prod or tap in case this may elicit a sensation other than light touch. Patients were asked to close their eyes and give a simple yes when they perceived touch.

A vibration perception threshold of ≥ 25 V and a Neuropathy Disability Score ≥ 6 were used as cut-offs for detecting the ‘at-risk’ foot [5,7]. We directly compared the Ipswich Touch Test and the VibraTip with both of the above.

Statistical analyses

All analyses were performed using SPSS version 16.0 (SPSS Inc., Chicago, IL, USA) and Microsoft Excel 2007. Cohen’s kappa was calculated to estimate diagnostic reliability between the VibraTip and the Ipswich Touch Test, and to compare with the vibration perception threshold and the Neuropathy Disability Score [8]. Interpretation of the degree of diagnostic reliability was based on the standard scale of Landis and Koch (1977), with $0.61 < \kappa < 0.80$ corresponding to ‘substantial

agreement’ and $0.81 < \kappa < 1.0$ corresponding to ‘almost perfect agreement’. The sensitivity, specificity, negative predictive value, positive predictive value, negative likelihood ratio and positive likelihood ratio were also measured for each test, using the method of Altman and Bland [9].

Ethical approval

The protocol for undertaking neuropathy assessment was approved by the local research ethics committee of the North Manchester Health Authority (LREC).

Results

Vibration perception threshold and Neuropathy Disability Score tests exhibited almost perfect agreement with each other ($\kappa = 0.948$, $P < 0.001$). VibraTip and Ipswich Touch Test results were identical ($\kappa = 1.0$, $P < 0.001$). Thus, statistical results are presented for each established test comparison to avoid unnecessary redundancy.

The VibraTip and the Ipswich Touch Test results exhibited almost perfect agreement with the vibration perception threshold ($\kappa = 0.973$, $P < 0.001$) and the Neuropathy Disability Score ($\kappa = 0.921$, $P < 0.001$).

Sensitivity between the VibraTip and the Ipswich Touch Test was 100% for both vibration perception threshold and Neuropathy Disability Score. Very high specificity was found between the new tests and the vibration perception threshold (96.6%) and the Neuropathy Disability Score (90.3%), respectively. Very high positive predictive value was found between the new tests and both the vibration perception threshold (98.2%) and the Neuropathy Disability Score (94.5%). The new tests exhibited 100% negative predictive value relative to both vibration perception threshold and

Neuropathy Disability Score. The tests showed high positive likelihood ratio compared with vibration perception threshold (29.0) and Neuropathy Disability Score (10.3). Finally, the new tests showed a negative likelihood ratio of 0 for both vibration perception threshold and Neuropathy Disability Score.

Discussion

Our results confirm a high concordance between two new and simple tests: the VibraTip and the Ipswich Touch Test when compared with the vibration perception threshold and the Neuropathy Disability Score, which are established tests for identifying patients at 'high risk' of foot ulceration. The VibraTip and the Ipswich Touch Test exhibited almost perfect agreement with each other and the diagnosis results were identical. Both of these simple and efficient tests can be used in an inpatient or outpatient setting, and particularly in areas where funding or training is limited; neither require an external power source. Although not demonstrated in the study, the application of light touch by a clinician may vary greatly in its execution between clinicians. The advantage of the VibraTip is the fact that it uses vibration rather than pressure, thereby providing a stimulus that remains constant between patients. We conclude that both the VibraTip and the Ipswich Touch Test are reliable and sensitive tests for identifying the 'high-risk' foot and may be included in future algorithms for the comprehensive diabetic foot examination [10].

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None.

Competing interests

Nothing to declare.

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