

Diagnostic accuracy of the VibraTip in detection of diabetic peripheral neuropathy

HISHAM NIZAR,¹ NEIL MUNRO,^{1,2,3} PETER NIGHTINGALE,⁴ MICHAEL D FEHER^{1,2,3}

Abstract

Aims: Clinical assessment of peripheral neuropathy can be performed by testing vibration sense using a tuning fork and cutaneous sensation using a 10g monofilament. The VibraTip® is a novel device which produces a constant vibratory stimulus and therefore assesses vibration sense. This study evaluated the diagnostic accuracy of the VibraTip compared to the tuning fork.

Methods: From 100 patients with diabetes, 50 patients had confirmed peripheral neuropathy (PN +ve) and 50 were confirmed to have no peripheral neuropathy (PN -ve) as assessed by neurothesiometer. Both groups were then assessed using both the VibraTip and tuning fork. The sensitivity, specificity, predictive values and likelihood ratios for diagnosing peripheral neuropathy were calculated.

Results: A statistically significant difference in sensitivity (52%) ($p < 0.001$) between the VibraTip and tuning fork results was observed for PN +ve subjects. However no statistically significant difference in specificity (6%) ($p < 0.25$) was seen for PN -ve subjects.

Conclusion: This study confirms that the VibraTip is comparable to the neurothesiometer, and superior to the tuning fork, in the detection of peripheral neuropathy and could be a useful screening tool in clinical practice.

Key words: VPT, peripheral neuropathy, VibraTip

Introduction

At the beginning of the 20th century the ability to detect vibration sense was recognised as a specific sensory modality.¹⁻³ Tuning forks applied directly to the skin have been used to assess vibration sense. There are several drawbacks to the use of tuning forks in clinical practice. There is little agreement about the op-

Abbreviations and acronyms

HbA _{1c}	glycated haemoglobin
NPV	negative predictive value
PPV	positive predictive value
PN+ve	peripheral neuropathy +ve
PN-ve	peripheral neuropathy -ve
VPT	vibration perception thresholds
V	volts

imal vibration frequency to be used. The coldness of the metal tuning fork and the pressure required to impart vibration can impair the specificity of the test. In terms of utility, tuning forks tend to be rather bulky and not easily carried discreetly. Additionally, tuning forks produce a set pitch rather than a set amplitude and vary in vibration intensity depending on the force with which they are struck and the time that elapsed since they were struck.⁴ These features may collectively lead to confusion and increase the time required to make diagnoses. Importantly, there is no precedent for cleaning or autoclaving tuning forks, and there may be increased risk of infection. There is no agreement about an optimal pitch of vibration or consistent guidelines on the use of tuning forks in clinical practice.

By comparison, the Horwell neurothesiometer⁵ is a device, which provides a constant source of vibration to assess this specific sense (Figure 1). The amplitude can be adjusted as needed. It is considered the "gold standard" tool for assessing vibration sense to confirm peripheral neuropathy. However, it has significant limitations including non-portability and dependency on electricity or overnight charging for usage.

In recent years Professor Andrew Levy and colleagues from University of Bristol have developed a novel device for measuring vibration sense, the VibraTip.⁶ The VibraTip is a key fob-sized device that has been specifically designed to overcome the limitations of tuning forks, by providing a constant source of gentle vibration using a vibrating motor (as used in mobile phones and vibrating wet razors) powered by a mercury- and lithium-free button cell in a clean, sealed, disposable unit (Figure 2).

To date there have been only two studies^{7,8} evaluating the VibraTip. The first study⁷ assessed agreement between perception of the VibraTip, tuning fork and 10g monofilament. This study revealed correlation of results with all the above three devices. The second study⁸ assessed the VibraTip, neurothesiometer, Neurotip, tuning fork and 10g monofilament where the threshold for identifying peripheral neuropathy by the neurothesiometer was set at 25Volts. There has been no comparative evaluation with the neurothesiometer set at 20Volts to assess peripheral neuropathy.

¹ Beta Cell Diabetes Centre, Chelsea & Westminster Hospital, London, UK.

² Diabetes Therapy Evaluation Network, London, UK.

³ CSRI, Warwick University, Warwick, UK

⁴ University Hospital Birmingham NHS Foundation Trust, Wellcome Trust Clinical Research Facility, Birmingham, UK.

Address for correspondence: Dr Hisham Nizar

Beta Cell Diabetes Centre, Chelsea & Westminster Hospital, 369 Fulham Road, London, SW10 9NH, UK

Tel: +44 (0)20 3315 5843

E-mail: nnizar@nhs.net

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Figure 1. Horwell Neurothesiometer.

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Figure 2. VibraTip is a key fob sized device (a) which is used to assess sensitivity to vibration (b)**(a) VibraTip**

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(b) Use of VibraTip to assess vibration sense

Reproduced courtesy of Professor Andy Levy, University of Bristol

Aims

The aim of our study was to assess the sensitivity and specificity of the VibraTip compared with that of a tuning fork in those patients with peripheral neuropathy confirmed by neurothesiometer set at 20Volts.

Methods

This study was a cross sectional observational design. Patients with either Type 1 diabetes or Type 2 diabetes were recruited from a secondary care specialist diabetes outpatient clinic. The following demographic details of each patient were recorded: duration of diabetes, type of diabetes, diabetes specific complications (retinopathy, nephropathy, neuropathy, ischaemic heart disease, cerebrovascular disease), latest HbA_{1c} measurement, current diabetes therapy and alcohol consumption.

The study had ethical approval and all those recruited gave written informed consent.

Clinical assessment

The presence of peripheral neuropathy was confirmed by the neurothesiometer set at 20Volts. The first clinical assessment was with the neurothesiometer to determine the presence of peripheral neuropathy. Following this, both the tuning fork and VibraTip were used to evaluate peripheral neuropathy and the results with each device were recorded.

We tested each patient first without the device activated and then with activation. Patients acknowledging the presence of vibration sense while the device was inactive were considered malingering. This helped us identify malingering patients who were excluded from the study. The vibration sense with all three devices was first demonstrated on the patient's forehead and then later used on the feet to assess for peripheral neuropathy.

All devices were tested on the same anatomical site, which was located on the left or right medial malleoli. Due to practical considerations, if this site could not be used then an alternative site was located on the lateral aspect of the first metatarsal head.

Data analysis

Patients were categorised into two groups according to the presence of peripheral neuropathy (PN +ve) or absence of peripheral neuropathy (PN -ve) based on the assessment by the neurothesiometer set at 20Volts. These two groups were then assessed with the VibraTip and a tuning fork. Data were evaluated to confirm the diagnostic accuracy of the presence of peripheral neuropathy.

In order to achieve statistical significance and adequate power, the sample size required was 100. These sample sizes provided 95% confidence that the estimates of sensitivity and specificity (expressed as percentages) are within 15 of the true values. The requirement was 50 PN +ve subjects and 50 PN -ve subjects as identified by neurothesiometer.

Results

From the two clinical groups assessed, PN +ve patients were slightly older and had longer duration of diabetes than PN -ve patients (Table 1).

Table 1 Demography of patients assessed for peripheral neuropathy determined by neurothesiometer (20V)

	Peripheral neuropathy +ve (n=50)	Peripheral neuropathy -ve (n=50)
Age (yrs)	Mean 67 (range 40-90)	Mean 51 (range 17-85)
Gender	Female n=13; Male n=37	Female n=19; Male n=31
Body mass index	Mean 30.6 (range 17-44)	Mean 29.5 (range 18-52)
Type 1 diabetes	n=10	n=20
Type 2 diabetes	n=40	n=30
HbA_{1c} (mmol/mol)	Mean 69 (range 39-130)	Mean 70 (range 37-151)
Duration of diabetes (yrs)	Mean 20.5 (range 1-55)	Mean 16.35 (range 0.08-50)

The results of the clinical assessment using the VibraTip and the tuning fork are shown in Table 2. The assessments were stratified according to the presence (+ve) or absence (-ve) of peripheral neuropathy as determined by the neurothesiometer.

The sensitivity, specificity, positive predictive and negative predictive values and positive likelihood ratios for VibraTip and tuning fork are shown in Table 3.

In PN +ve subjects a significant difference in sensitivity of 52% (92-40) ($p < 0.001$) between the VibraTip and tuning fork was noted. However no significant difference in specificity 6% (100-94) ($p < 0.25$) was seen for PN -ve subjects.

Discussion

Vibration sensation has been described to be the first modality of sensation to be lost in the development of diabetic peripheral neuropathy. This study has confirmed the diagnostic accuracy of the VibraTip in comparison to the tuning fork in the diagnosis of diabetic peripheral neuropathy. Both of these methods assess vibration sense, which is the clinical assessment of large fibre neuropathy, an early clinical sign in diabetic peripheral neuropathy. In comparison, small fibre neuropathy is clinically manifested by dysfunction or pain and temperature (Table 4).

Our study has assessed the devices (i.e. VibraTip, tuning fork and neurothesiometer) testing only vibration sense. We used a lower threshold of 20Volts for the confirmation of peripheral neuropathy compared to 25Volts used in the previous study.⁸ This loss of vibration sense could therefore be recognised at a much earlier stage, providing opportunity to prevent complications.

The VibraTip has clear utility advantages which include being portable, discreet to carry, and providing a constant source of vibration at a set amplitude. These utility advantages overcome several drawbacks encountered with the use of a tuning fork.

Two previous studies have evaluated the VibraTip.^{7,8} The pre-

Table 2 Assessment for peripheral neuropathy with (a) VibraTip and (b) tuning fork in subjects with neurothesiometer confirmed presence (+ve) or absence (-ve) of peripheral neuropathy.

(a)-VibraTip	Peripheral neuropathy +ve	Peripheral neuropathy -ve
VibraTip +ve	46	3
VibraTip -ve	4	47
(b)-Tuning Fork	Peripheral neuropathy +ve	Peripheral neuropathy -ve
Tuning Fork +ve	20	0
Tuning Fork -ve	30	50

Table 3 Sensitivity, specificity, positive predictive and negative predictive values and positive likelihood ratios of peripheral neuropathy assessed by Vibratip and tuning fork.

	VibraTip	Tuning fork
Sensitivity (95% CI)	92% (80.8-97.8%)	40% (26.4-54.8%)
Specificity (95% CI)	94% (83.4-98.7%)	100% (92.9-100%)
PPV	94%	100%
NPV	92%	63%
Positive likelihood ratios	15.3	Infinity

Table 4 The clinical features of both large and small fibre neuropathy.

LARGE FIBRES (myelinated fibres)	SMALL FIBRES (unmyelinated fibres)
<i>Clinical features</i> Weakness Wasting	<i>Clinical features</i> Pain Autonomic Thermal
Impaired vibration Loss of joint position sense Loss of reflex	Normal strength & reflexes

liminary study⁷ assessed several clinical devices including the VibraTip, 10g monofilament and tuning fork. There was good correlation of results among all three devices. However, the study⁸ did not differentiate between the presence or absence of diabetic peripheral neuropathy. Hence the diagnostic accuracies were not specific to clinical neuropathy. In the second study,⁸ the VibraTip was further compared with the neurothesiometer, which is considered the gold standard for assessment of peripheral neuropathy. The study used receiver operating characteristic curves to compare results between the neurothesiometer and those of

the VibraTip, tuning fork, monofilament and Neurotip. The results were then compared using the intra-rater reliability. The strength of this study⁸ is that all sites commonly used for testing for vibration as part of screening for diabetic peripheral neuropathy were evaluated. Hence by constructing receiver operating characteristic curves, the best performance of each of the bedside tools was known prior to comparison with the neurothesiometer set at 25Volts.⁹ However the weakness of this study⁸ is the comparison of devices assessing different modalities of sensory loss (vibration, touch, pain) in peripheral neuropathy.

The sensitivity of the VibraTip is more than double that of the tuning fork in PN +ve subjects. This suggests VibraTip is more reliable than the tuning fork in bedside evaluation of peripheral neuropathy. Although the tuning fork has a higher specificity than the VibraTip, these values are not statistically significant. Hence the VibraTip would have a better utility compared to the tuning fork in the assessment of loss of vibration sense from diabetic peripheral neuropathy.

Conclusions

The results of the present study support those of previous studies.^{7,8} The VibraTip has diagnostic accuracy comparable to the neurothesiometer. It can be used in daily clinical use for screening for diabetic peripheral neuropathy. However correlation with other signs would be needed for completeness. Nerve conduction studies would confirm diagnosis.

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Conflict of interest None

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Patient consent Informed consent obtained



Key messages

- VibraTip has greater sensitivity than the tuning fork in diagnosing diabetic peripheral neuropathy
- This study confirms previous reports on the utility of vibratip
- There are distinct advantages with the use of VibraTip over the tuning fork in the clinical setting

References

1. Rumpf H. Uber einen Fall von Syringomyelie nebst Beitrag zur Untersuchung der Sensibilitat. *Neurologisches Zentralblatt* 1889.
2. Lewandowsky M. *Handbuk der Neurologie*. Bd 1. Allg. Neurologie 11. Berlin: Springer, 1910: 499-502.
3. Freeman C, Okun, M S. Origin of the sensory examination in neurology. *Semin Neurol* 2002;**22**:399-407. <http://dx.doi.org/10.1055/s-2002-36762>
4. Juma A, Mandal A. Vibration sensitivity testing with tuning fork: 256 Hz or 512 Hz? *Eur J Plastic Surg* 2007;**30**:5-6. <http://dx.doi.org/10.1007/s00238-007-0125-y>
5. Bril V, Kolic J, Ngo M, et al. Comparison of a neurothesiometer and vibration in measurement of vibration perception thresholds and relationship to nerve conduction studies. *Diabetes Care* 1997;**20**:1360-2. <http://dx.doi.org/10.2337/diacare.20.9.1360>
6. www.vibratip.com (Accessed February 2014).
7. Levy A. Preliminary data on Vibratip, a new source of standardized vibration for bedside assessment of peripheral neuropathy. *Br J Diabetes Vasc Dis* 2010;**10**:284-6. <http://dx.doi.org/10.1177/1474651410390741>
8. Bracewell N, Game F, Jeffcoate W, Scammell BE. Clinical evaluation of a new device in the assessment of peripheral sensory neuropathy in diabetes. *Diabet Med* 2012;**29**:1553-5. <http://dx.doi.org/10.1111/j.1464-5491.2012.03729.x>
9. Bowling FL, Abbott CA, Harris WE, Atanasov S, Malik RA, Boulton AJ. A pocket size device for testing the integrity of sensation in the outpatient setting. *Diabet Med* 2012;**29**:1550-2. <http://dx.doi.org/10.1111/j.1464-5491.2012.03730.x>