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Review

# The accuracy of VibraTip diagnostics in detecting peripheral neuropathy in diabetic feet: a scoping review

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## Abstract

Diabetes is a chronic metabolic disease in which pancreatic beta cells are damaged, leading to insulin resistance. One of the complications of diabetes is diabetic foot neuropathy. Early detection of neuropathy can reduce the risk of foot ulcers and related complications. VibraTip™ was created specifically to get over the drawbacks of the 128-Hz tuning fork. This review aims to decide the accuracy of VibraTip™ in recognizing peripheral neuropathy within the diabetic foot. This review used a scoping review approach involving searches of articles in three databases (ProQuest, Pubmed, and Google Scholar) using the PICOS framework. Article screening used the PRISMA method by removing duplicate articles and articles that did not meet the author's criteria. A PRISMA flowchart is provided to illustrate the search flow. Out of a total of 206 identified articles, five were found to be relevant and descriptive of the accuracy of VibraTip™ in detecting peripheral neuropathy in the diabetic foot. VibraTip™ is more sensitive than tuning forks in diagnosing diabetic peripheral neuropathy.

Keywords: diabetes, neuropathy, VibraTip™.

## Introduction

Diabetes can be an unremitting metabolic infection characterized by hyperglycemia caused by pancreatic cell damage, leading to a lack of insulin production or low insulin secretion [1, 2]. The Universal Diabetes Alliance (IDF) predicted that diabetes would affect approximately 463 million people worldwide and 96 million people in Southeast Asia in 2020. Among the 11 member states of Southeast Asia, Indonesia ranks first with the highest number of diabetes patients. According to the Basic Health Survey conducted in 2018, Indonesia's diabetes prevalence increased from 6.9% to 10.9%. The number of sufferers is expected to extend to 643 million and 783 million in 2030 and 2045 [1].

One of the complications of diabetes is diabetic foot neuropathy [3–5]. Neuropathy contributes to skin lesions and even wounds and infections in diabetic feet [4]. Several diagnostic tools have been introduced to facilitate early detection of diabetic peripheral neuropathy, one of which is the 128-Hz stimulation. The 128-Hz tuning fork has been used to test vibration sensitivity since the early 20th century. However, it has several drawbacks, such as its feeling cold, requiring pressure to produce vibrations, causing reduced variability and specificity, and being uncomfortable to use due to its size [6, 7]. VibraTip™ is a small, convenient device that is particularly designed to overcome the confinements of sound incitement by creating tender, non-stop vibrations [6, 7]. It has an advantage in its convenience and simplicity of use, and, when tried, it gives a more steady incitement than the 128-Hz tuning fork. Yet, its accuracy still needs an extensive assessment. Several studies have reported its superiority over the 128-Hz tuning form [6]. This review aims to determine the accuracy of VibraTip™ in detecting peripheral neuropathy in diabetic feet.

## Material and methods

This study employed the scoping review method. Article searches were conducted using the PICOS strategy [8] and the keywords "*diabetes* AND *neuropathy* AND *vibration*" with the Boolean operator "AND" to make it easier for the authors to find articles relevant and appropriate to the study material. The article was systematically searched by accessing the ProQuest, PubMed, and Google Scholar databases. The PICOS strategy used in this study is detailed in Table 1.

The rationale of this study was to find out whether VibraTip™ is more accurate than the 128-Hz tuning fork in detecting peripheral neuropathy in the diabetic foot. The inclusion criteria in this scoping review were articles in English, articles in the form of original research or literature reviews, and articles published between 2014 and 2023. The exclusion criteria were articles irrelevant to the topic, that is, the use of VibraTip™ and the 128-Hz tuning fork in detecting peripheral neuropathy.

The next step was to check titles, abstracts, and keywords against the inclusion and exclusion criteria. During the searches for articles that were appropriate to the purpose of this study, selections were made by reading articles in whole or in part with a consideration of their titles, backgrounds, methodologies, results, and conclusions in more detail. Articles meeting the inclusion and exclusion criteria were selected and analyzed utilizing the Preferred Reporting Items for Systematic Reviews and Meta-analyses or the PRISMA technique [9]. The article search process is illustrated in the PRISMA flowchart (Figure 1).

## Results

The searches in three databases yielded 206 articles, consisting of 22 articles from ProQuest, 13 from PubMed, and 171 from Google Scholar. The authors screened articles published between 2014 and 2023 and found 34 articles. The authors then screened appropriate titles and abstracts and obtained 25 articles. Afterward, duplicate articles were screened, with 6 articles being excluded. Of the 19 articles screened, 14 did not match the specified topic. Eventually, 5 articles appropriate to the present study's writing, namely, to discuss the use of VibraTip™ and the 128-Hz tuning fork in detecting peripheral neuropathy of the diabetic foot, were obtained. The articles finally selected are detailed in Table 2.

## Discussion

The compact, lightweight, key-fob-sized VibraTip™ evaluates vibration as a signal of diminished protection. It was invented by Andy Levy, Professor of Neuroendocrinology, consultant, and inventor of the School of Clinical Sciences of the University of Bristol. It was chosen by the Medical Technologies Advisory Committee (MTAC) for evaluation through the National Institute for Health and Care Excellence (NICE) [7, 10, 11]. VibraTip™ evaluates the vibration sensation in the hallux by giving a 128-Hz vibration stimulus at each activation, indicating the loss of protective sensitivity, with battery life sufficient for several months of normal use [7, 12–15]. It comprises a micro-vibrating motor powered by mercury, sealed, and disposable [7]. It is an important alternative for emitting consistent amplitude and offering increased diagnostic accuracy [16].

To perform a vibration test, the rounded tip of the VibraTip™ device is gently touched twice to the skin of each big toe, and the tool is then firmly pressed between the hallux and the index toe for half a second while making one of two vibrator pulses. It provides a quick and accurate assessment of vibration sensor integrity [7, 13]. The researcher would notify the subject during a test about the first and second touches [16]. A patient is diagnosed with diabetic peripheral neuropathy if he/she does not experience any vibration in

Table 1: PICOS strategy.

| Elements | Key Words |
|---|---|
| **P (Problem)** | Diabetic peripheral neuropathy |
| **I (Indicator/Intervention)** | Inspection with VibraTip |
| **C (Comparison)** | 128-Hz tuning fork |
| **O (Outcome)** | Accurate in detecting neuropathy |
| **S (Study Design)** | Literature study, cross-sectional study, case-control study |


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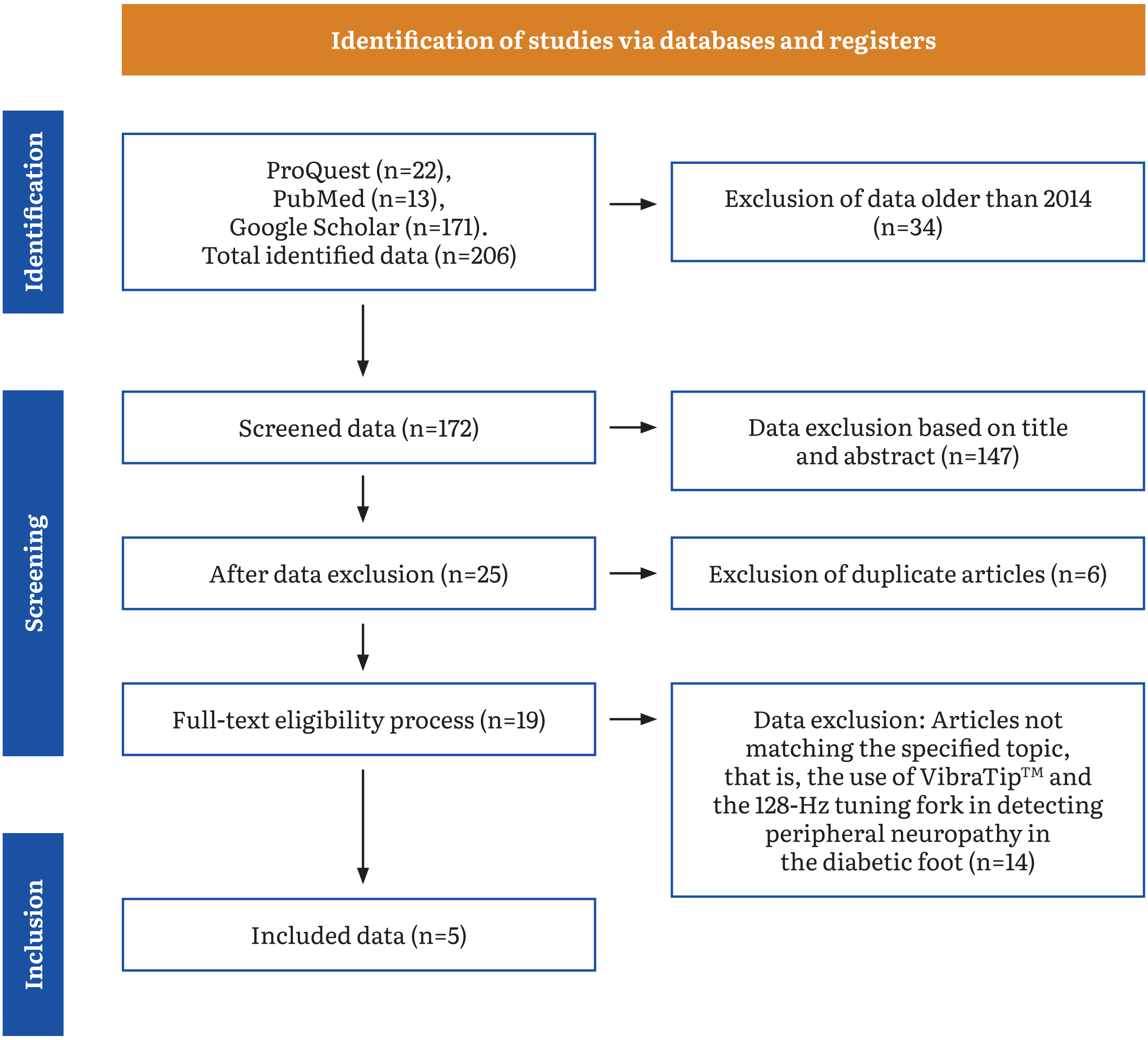


Figure 1: The Scoping Review's Flowchart Based on PRISMA 2020.

one or both feet [13]. This vibration is designed to get beyond the limitations of tuning forks by providing a gentle, continuous vibration source with stable adequacy and repetition, similar to a 128 Hz calibrated fork vibration source [7, 17]. VibraTip™ has been shown to correlate well with 128-Hz tuning forks and neurosensory measurements. A study evaluating the diagnostic performance of atrial fibrillation in European patients found a fibrillation detection threshold of 25 volts or higher using a neurosensory meter, the gold standard for diabetes detection, with sensitivity and specificity values of 79% and 82%, respectively [14]. VibraTip™ was found to have a high diagnostic performance in detecting peripheral neuropathy [11].

Tuning forks positioned at the pores and skin have been used to evaluate vibration sensitivity. Numerous drawbacks accompany their usage in medical procedures, foremost among them being the cold metal of the tuning fork and the stress required to provide vibration, which may jeopardize the test's specificity. From a practical point of view, tuning forks are quite large and inconvenient to carry. In comparison, VibraTip™ has advantages. For instance, it is very small, pocketable, easy to use and carry, and capable of convenient and rapid neurological evaluation in an outpatient setting [6, 7, 13–15]. The advantages of this device offset some of the disadvantages of tuning forks [6].

Nizar (2014) showed that VibraTip™ sensitivity is more than twice that of tuning forks, indicating that it is more reliable than tuning forks in assessing vibration sensitivity in diabetic peripheral neuropathy. It manages color incitement to hit upon diabetic peripheral neuropathy in sufferers with type 1 or type 2 diabetes [6]. Dr. Willits affirmed that VibraTip™ had a

Table 2: Characteristics of the selected articles.

| No. | Author/year/ country | Goals and subjects | Population/sample | Design | Conclusion |
|---|---|---|---|---|---|
| **1.** | (Nizar *et al.*, 2014)/ English | To assess the demonstrative accuracy of VibraTip™ compared to the tuning fork | In a population of 100 diabetics, 50 sufferers had peripheral neuropathy (PN-ve), which was evaluated using neurosensory measurements. The use of a VibraTip™ device and a tuning fork was examined. | An observational study with a cross-sectional design | In patients with peripheral neuropathy (PN-ve), there was a measurably critical contrast in sensitivity (52%) ($p<0.001$) between the VibraTip™ and the turning fork. In any case, there was a measurably noteworthy distinction in specificity (6%) ($p<0.25$). This affirmed that VibraTip™ is comparable to other neurosensory tools, notably tuning forks, in recognizing peripheral neuropathy and may be a valuable screening device in clinical settings. |
| **2.** | (Willits *et al.*, 2015)/English | To decide the symptomatic prevalence of vibration compared to 10-g monofilaments and 128-Hz tuning forks | The population portrayed comprised grown-ups and children with type 1 or type 2 diabetes mellitus who underwent routine foot-care checks by primary and secondary care providers. | Literature study | VibraTip™ could save the NHS (National Health Service) around £50,000 compared to 10-g monofilaments and £40,000 compared to 128-Hz tuning forks. Increased use of VibraTip™ could reduce ulcers by 1% and save £6,430,000 in costs compared to 10-g monofilaments and £6,350,000 compared to 128-Hz tuning forks. |
| **3.** | (Pasangha *et al.*, 2021)/India | To assess the application of VibraTip™ singly and in combination with assessing the lack of protective sensation | Seventy-five treated patients with diabetic foot ulcer (DFU) were included in the study. Clinical examination of the contralateral foot was performed to check the temperature perception, pinprick sensation, vibration, neuropathy disability score, and Achilles tendon reflex. Tests were also performed on a 10-g monofilament, a VibraTip™ device, and a biothesiometer. The biothesiometer was used as a reference standard and compared against three bedside tests (10-g monofilament, 128-Hz tuning fork) and VibraTip™ singly and in combination. | Cross-sectional study | Diabetic peripheral neuropathy cannot be identified by VibraTip™ alone. The sensitivity of the 10-g monofilament was essentially improved from 50% to 62.5%. Including a third device, a 128-Hz tuning fork, the sensitivity increased by an extra 2%. VibraTip™ performed exceptionally well compared to the biothesiometer, with a positive predictive value of 90.3% and a specificity of 84.2%. However, the sensitivity was 50%. The finest combination was VibraTip™ and 10-g monofilament, which expanded the sensitivity to 62.5%. Combining all three (biothesiometer, VibraTip™, and 10-g monofilament) increased the sensitivity to 64.3%. |


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Table 2: COntinued.

| No. | Author/year/ country | Goals and subjects | Population/sample | Design | Conclusion |
|---|---|---|---|---|---|
| **4.** | (Lasca, Tăut, and Vereşiu, 2016)/ Romania | To assess three screening methods, VibraTip™, 128-Hz tuning fork, and 10-g Semmes-Weinstein monofilament, for predicting neuropathic ulcerations in diabetic patients | A total of 90 subjects were divided into three groups. Group A comprised 30 diabetic subjects with one or more active neuropathic ulcerations at one foot, group B comprised 30 diabetic subjects without ulcerations, and group C comprised 30 healthy subjects. | Case-control study | Ninety subjects were divided into 3 groups: group A comprised 30 diabetics with one or more active neuropathic ulcerations at one foot, group B comprised 30 diabetics without ulcerations, and group C comprised 30 healthy subjects. |
| **5.** | (Goddard *et al.*, 2018)/ United Kingdom | To study the diagnostic accuracy of 5 standard peripheral neuropathy tests, *i.e.*, VibraTip™, Ipswich Touch Test (IpTT), 10-g monofilament, 128-Hz tuning fork, and neurothesiometer, compared to the reference test of sural nerve conduction velocity (SNCV) | Adults with type 2 diabetes and without foot ulcerations attending a routine follow-up health center | Cross-sectional study | This study primarily compared 5 simple tests of diabetic peripheral neuropathy and addressed the uncertainty surrounding the superiority of VibraTip™ to other checks. |

sensitivity of 0.79 (95% CI 0.69–0.90) and a specificity of 0.82 (95% CI 0.74–0.90) [15]. According to Lasca (2016), the VibraTip™ had a sensitivity of 76.66% and a specificity of 77.5%, the 10-g monofilament had a sensitivity of 71.67% and a specificity of 91.67%, and the 128-Hz tuning fork had a sensitivity of 60% and a specificity of 89.17% [18]. VibraTip™ showed the maximum sensitivity in this case, while the 10-g monofilament showed the most specificity [16].

Additionally, it was shown that the use of a 10-g monofilament and a 128-Hz tuning fork simultaneously helped enhance the detection of diabetic peripheral neuropathy [10]. VibraTip™ use in combination with a 10-g monofilament could boost sensitivity from 50% to 62.5%. A 128-Hz tuning fork added as a third device would increase the sensitivity by 2%. VibraTip™, by itself, might not be able to diagnose every patient with an at-risk foot. Ath-risk feet are almost always associated with abnormal results, and to treat foot ulcers, patients need to be examined and educated [10]. With vibration recognition, often on the inside of the hallux, the VibraTip™ can be a handy, pocket-sized tool for predicting diabetic peripheral neuropathy [13, 14].

## Conclusion

Clinical users may utilize VibraTip™ regularly to test and screen diabetic peripheral neuropathy. In addition, it is more accurate in identifying diabetic peripheral neuropathy than tuning forks. It yields considerable diagnostic outcomes in individuals with type 2 diabetes, making it extremely beneficial as a screening tool. It is dependable, clean, and capable of highlighting a vibration location edge, much like 128-Hz tuning forks. The advantage of the VibraTip™ is that it is more convenient to carry and use and gives additional steady incitement within the course of examination compared to 128-Hz tuning forks.

## Conflict of interest

The authors declare no conflict of interest.

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