

ORIGINAL ARTICLE

Early recognition of diabetic neuropathy: evaluation of a simple outpatient procedure using thermal perception

V Viswanathan, C Snehalatha, R Seena, A Ramachandran

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See end of article for authors' affiliations

Correspondence to:
Dr Vijay Viswanathan,
Diabetes Research Centre,
No 4, Main Road,
Royapuram, Madras 600
013, India;
dr_vijay@vsnl.com

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Objective: To determine the effectiveness of Tip-therm, a temperature discriminator, in making an early diagnosis of distal symmetrical polyneuropathy in diabetic patients and to compare its effectiveness with the Semmes-Weinstein monofilament and biothesiometry, which are established methods of diagnosing neuropathy in diabetic patients.

Patients and methods: From the diabetic subjects who came to the hospital for review, 910 consecutive cases were selected. All were tested with the Semmes-Weinstein monofilament (10 g monofilament) and biothesiometry and also by using the Tip-therm for comparison.

Results: Out of the 241 patients who had no sensation to the monofilament only four (1.7%) felt Tip-therm whereas 237 (98.3%) patients could not feel Tip-therm. Among 298 patients diagnosed as having neuropathy by biothesiometry, only eight (2.7%) patients exhibited sensation with Tip-therm while 290 (97.3%) patients could not feel it.

Conclusion: A simple device, Tip-therm, which tests for temperature discrimination, was compared with two validated methods for detection of neuropathy—a monofilament and biothesiometry. Tip-therm appears to be an inexpensive, highly sensitive, and specific device for detection of diabetic neuropathy when compared with biothesiometry and a monofilament.

Diabetic neuropathy is the most common and troublesome complication of diabetes mellitus. It also results in a huge economic burden for diabetes care.^{1,2}

The diabetic foot has traditionally been considered to occur because of the presence of peripheral vascular disease, peripheral neuropathy, and infection. Chronic sensory motor neuropathy is the commonest form of diabetic neuropathy and occurs in both type 1 and type 2 diabetes. It is the most common form of neuropathy in developed countries, accounting for more admissions to hospitals than all the other diabetic complications combined and is responsible for 50% to 75% of non-traumatic amputations.^{2,3}

Methods that are simple, but sensitive and specific, are required to evaluate sensory neuropathy. In distal symmetric neuropathy, an early symptom may be a failure to perceive variations in temperature.

Tip-therm (AXON GmbH Dusseldorf, Germany) is considered to be ideal for testing temperature sensitivity. It is a pen-like instrument with two flat sides. It is not dependent on external power sources, is practically indestructible, easy to handle, and small and light enough to fit in any jacket. Owing to its physical characteristics this simple instrument is easy to use and is known to give reproducible results in an ambient temperature of up to 23°C.

PATIENTS AND METHODS

M.V. Hospital in Madras is a large referral centre for diabetes care, and 910 consecutive patients who came to the foot department for routine screening for neuropathy were selected. There were 628 males and 282 females; the mean (SD) age of the patients was 53.7 (10.4) years and the mean (SD) duration of diabetes was 9.7 (8.0) years.

The patients were tested by the Semmes-Weinstein monofilament (10 g monofilament), biothesiometry, and also by using the Tip-therm for comparison.

All of them had been tested for neuropathy using the biothesiometer (Bio-Medical Instrument Co, Newbury, OH, USA) for determining the vibration perception threshold (VPT).

Three readings were obtained from each foot on the first metatarsal at different degrees of voltage increase and a mean was taken. Patients with a VPT of >25 V were considered to have significant neuropathy.⁴

The Semmes-Weinstein monofilament (Gills W Long, Hansen's Disease Center, Carville, LA, USA) determines the protective sensation in the feet. It consists of a series of graded pressure sensitive nylon filaments of increasing calibre that buckle at a reproducible stress and can measure the patient's cutaneous pressure perception threshold. The 10 g monofilament was used in this study. The filament is applied to at least five sites on the foot until it buckles, which occurs at 10 g of linear pressure, when the patient is asked to detect its presence. If it is not detected on at least three out of five times, then the protective sensation is considered to be lost.⁵ A new monofilament was used only for this study.

Tip-therm examination procedure

The examiner places the two flat surfaces on the tip of the patient's great toe at irregular intervals and asks whether it feels cold or not so cold. The patient is asked to close his eyes during testing. Only if correct answers are given it is presumed that the patient's temperature perception is functioning satisfactorily. Patients can also use Tip-therm themselves in the course of regular pedicure treatment. The tests were done in an air conditioned room with a temperature range of 20–23°C.

RESULTS

Comparison of monofilament and Tip-therm

Among the patients who were tested with the monofilament, the sensation was present in 669 (73.5%) and in 241 (26.5%) patients the sensation was absent. Out of the 669 patients, Tip-therm was felt by 616 (92.1%) and in 53 (7.9%) patients it was not felt. Out of the 241 patients who had no sensation to the monofilament only four (1.7%) felt Tip-therm whereas 237 (98.3%) could not.

Comparison of biothesiometry and Tip-therm

In this study, biothesiometry was considered as the reference test for neuropathy. Among 298 patients diagnosed as having

Table 1 Comparison of Tip-therm with biothesiometry and monofilament

	Sensitivity (%)	Specificity (%)
Neuropathy by biothesiometry (n=298)	97.3	100
Loss of sensation by Tip-therm (n=290)	(290/298)	(612/612)
Loss of sensation by monofilament (n=241)	98.3	92.1
Loss of sensation by Tip-therm (n=237)	(237/241)	(616/669)

neuropathy by biothesiometry, only eight (2.7%) patients exhibited sensation with Tip-therm while 290 (sensitivity 97.3%) patients could not feel it. All 612 (specificity 100%) non-neuropathic patients were able to feel Tip-therm. Table 1 shows the comparison of Tip-therm with biothesiometry. It was interesting to find that the specificity of Tip-therm was 100% when compared with biothesiometry. Sensitivity of Tip-therm for neuropathy was better than that of the monofilament. With the monofilament, 241 out of the 290 neuropathy cases were picked up (sensitivity 83.1%). Among them 237 cases (sensitivity 98.3%) were Tip-therm positive.

DISCUSSION

In this study we have compared a simple device, Tip-therm, which tests for temperature discrimination, with a monofilament and biothesiometry, both of which have already been established as validated methods for detection of neuropathy. Tip-therm showed a high specificity and sensitivity when compared with these two devices.

Prospective trials have confirmed the role of both large and small fibre neurological deficit in the pathogenesis of foot ulceration.⁶ Small nerve fibre dysfunction usually occurs early and is often present without objective signs or electrophysiological evidence of nerve damage.⁷ It is manifested by early symptoms of pain and hyperalgesia in the lower limbs, followed by a loss of thermal sensitivity and reduced light touch and pin prick sensation.⁸

Temperature discrimination threshold is a measure of small fibre function. Warm sensation is mediated by the smallest non-myelinated C fibres and cold sensation by small myelinated A Δ fibres. Temperature discrimination threshold is particularly relevant for a number of reasons. First, temperature sensation may be the first to be affected in diabetic patients.⁹ Second, since small fibres also mediate pain sensation it was hypothesised that selective damage may have some relevance to positive painful symptoms of neuropathy.¹⁰ Finally lack of temperature sensation is of obvious clinical relevance since it may predispose to scalds, burns and other thermal injuries, although the degree of sensory loss required for this is actually quite large, which is approximately 10°C.¹¹

Most techniques for the detection of thermal or other temperature discrimination thresholds have used metal elements. They are based on the Peltier principle whereby they might be

Key points

- Tip-therm was used to find out temperature perception in type 2 diabetic subjects without neuropathy and with sensory neuropathy detected by abnormal biothesiometry and a monofilament.
- Tip-therm has high specificity (100%) and sensitivity (97.3%) in diagnosing diabetic neuropathy.
- It is suitable for screening sensation loss in the feet.
- It is a pen-like instrument, easy to use, and is known to give reproducible test results in an ambient temperature of up to 23°C.
- It can be used as an outpatient procedure for detecting foot problems in diabetes.

heated or cooled relatively quickly by changing the direction of flow of electric current through them. Results are often poorly reproducible, especially in disease states, and the equipment required is relatively cumbersome and expensive.

CONCLUSIONS

In this study the Tip-therm appears to be an ideal device for temperature testing with a high sensitivity and specificity compared with biothesiometry and a monofilament, which are established methods for the diagnosis of diabetic neuropathy.

Authors' affiliations

V Viswanathan, C Snehalatha, R Seena, A Ramachandran, Diabetes Research Centre, Madras, India

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