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Diabetes Research and Clinical Practice 70 (2005) 8–12
DIABETES RESEARCH AND CLINICAL PRACTICE
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A comparison of the monofilament with other testing modalities for foot ulcer susceptibility

B. Miranda-Palma [a], J.M. Sosenko [a,*], J.H. Bowker [b], M.S. Mizel [b], A.J.M. Boulton [a]

[a] *Division of Endocrinology, Department of Internal Medicine, Diabetes Research Institute, University of Miami School of Medicine, P.O. Box 016960 (D-110), Miami, FL 33101, USA*
[b] *Department of Orthopedic Surgery, Diabetes Research Institute, University of Miami School of Medicine, P.O. Box 016960 (D-110), Miami, FL 33101, USA*

Received 19 November 2004; accepted 18 February 2005
Available online 28 March 2005

Abstract

We studied the number of testing sites and the proportion needed to be insensate for the optimal assessment of foot ulcer risk with the 10 g monofilament. Also, we compared the sensitivity and specificity of the 10 g monofilament with other methodologies. Fifty-two individuals with either a current foot ulcer, a history of a foot ulcer or the presence of Charcot neuroarthopathy and 51 individuals with no history of any of these conditions were assessed with the 10 g monofilament at four sites on each foot, the 128 Hz tuning fork at the halluces, the Biothesiometer at the halluces and the modified neuropathy disability score. Sensitivities and specificities were calculated for the various modalities. The Biothesiometer and the neuropathy disability score had the highest sensitivities (0.92 for both). The 128 Hz tuning fork tested only at the halluces (criterion: $\geq$1 insensate site) had the same sensitivity (0.86) as the 10 g monofilament tested at eight sites (criterion: $\geq$1 insensate site) with similar specificities (0.56 and 0.58, respectively). The Biothesiometer and the modified neuropathy disability score tend to be more sensitive than the 10 g monofilament for the assessment of individuals at risk for foot ulcers. The 128 Hz tuning fork tested at only two sites is as sensitive as the 10 g monofilament tested at eight sites. These data suggest that the 10 g monofilament may not be the optimum methodology for identifying individuals at risk of foot ulcers.

Keywords: Diabetes mellitus; Foot ulcer; Neuropathy; Monofilament

1. Introduction

Foot ulcers are the main cause of lower extremity amputation in patients with diabetes [1,2]. It has been estimated that 15% of patients with diabetes will develop a foot ulcer in their lifetime and that 85% of

* Corresponding author. Tel.: +1 305 243 6146; fax: +1 305 243 4484.
E-mail address: jsosenko@med.miami.edu (J.M. Sosenko).

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doi:10.1016/j.diabres.2005.02.013

all non-traumatic amputations are preceded by a non-healing foot ulcer [3]. The occurrence of a diabetic foot ulcer is the result of multiple contributing factors, but it is commonly accepted that peripheral neuropathy with the associated loss of protective sensation is most contributory [4]. It is therefore common clinical practice to assess the presence and extent of peripheral neuropathy in order to identify patients at risk for developing foot ulcers [4]. This is based on the rationale that individuals identified as being at high risk for foot ulcers may benefit from more frequent follow-up and from educational interventions [5,6].

Several instruments have been utilized to detect a lack of protective sensation [7]. The ideal instrument for this should be readily available, easy to use, and provide reproducible results with high sensitivity. In recent years, the 10 g monofilament has gained widespread use for assessing the loss of protective sensation, since it is available and simple to use [8]. However, there is no consensus as to the specific sites that should be tested and the minimum number of insensate sites required for the optimal prediction of foot ulceration [8].

A main objective of the present study was to determine the number of testing sites and the proportion needed to be insensate for the optimal assessment of foot ulcer susceptibility with the 10 g monofilament. Another objective was to compare the sensitivity and specificity of the 10 g monofilament with the vibration perception threshold (VPT) and the modified neuropathy disability score (NDS), other methods that have been shown to be useful predictors of foot ulcers [9–11].

2. Materials and methods

The study was approved by the Institutional Review Board of the University of Miami School of Medicine, and all subjects signed an informed consent prior to participation in the study.

2.1. Patients

One hundred and three patients were enrolled from the General Medical Clinic and the Diabetic Foot Clinic at Jackson Memorial Hospital. The diagnosis of diabetes had been made before enrollment. Patients were included in the foot ulcer group if they either had a previous or an active foot ulcer, a history of minor amputation (limited to one toe other than the hallux) and/or Charcot neuroarthropathy. Patients without a foot ulcer history, amputation or Charcot neuroarthropathy were included in the control group.

2.2. Patient selection

All patients had a history and a limited physical examination. Foot ulceration was defined as a complete break of the skin distal to the malleoli. Charcot neuroarthropathy was defined by at least two of the following: unilateral swelling, temperature differential of $\geq 2\,^{\circ}C$ between the two feet, bony deformity and radiographic changes [12]. Patients with major foot amputation proximal to the toe areas as well as a hallux amputation were excluded. Other exclusion criteria included evidence of peripheral vascular disease assessed by absent foot pulses, a history of claudication and/or peripheral bypass surgery, a history of cerebro-vascular disease or any other neurological disease that could be associated with abnormal sensory findings, and a history of alcohol abuse defined as >21 units per week.

2.3. Procedures

The following objective measures of peripheral nerve function were assessed:

(1) Ten gram monofilament evaluation

All patients were assessed using the Bailey 10 g monofilament (Baileys Instruments Co., Chorlton, Manchester, UK), chosen because they had previously been assessed to be accurate at assessing pressure at 10 g when the filament buckled [13]. Testing was performed at four different sites in each foot: the plantar surface of hallux, and the first (MTH1), third (MTH3), and fifth (MTH5) metatarsal heads, according to the recommendations of Mayfield and Sugarman [8]. With eyes closed, the patients were required to provide a ''yes/no'' response to monofilament pressure and in addition identify correctly the site of contact. Each filament was placed against a plantar surface of the four sites in a perpendicular fashion so that it bent with a constant force.

(2) Modified neuropathy disability score (NDS)

Originally described by Young et al. [14], this score (maximum 10) is derived from abnormalities of pain sensation using a neurotip, vibration sensation using a 128 Hz tuning fork, dorsal temperature sensation using warm and cold rods and Achilles tendon reflexes using a tendon hammer. For one foot, each sensory test scored zero for normal sensation or one for abnormal sensation: ankle reflex scored zero if present, one if present with reinforcement or two if absent. Pain and temperature sensation were assessed on the dorsal surface of the great toe after the stimuli were demonstrated at a proximal, normal site. Vibration perception was assessed using the 128 Hz tuning fork over the apex of the hallux. The Achilles tendon reflex was assessed with the patient supine on a couch as previously described [11,14]. The maximum score for the two feet is 10, with a score of $\geq$6 indicating moderate to severe neuropathy [14].

(3) Vibration perception threshold (VPT)

This was measured using a Biothesiometer (Biomedical Instrument Company, Newbury, OH). This handheld device was balanced so that the vibrating stylus rested on the apex of the hallux. The normal sensation of vibration was demonstrated on a proximal site and then over the testing site of the hallux. Three consecutive measures were then taken at variable speeds of voltage increase and the median of the three was taken as the final result for each foot.

2.4. Statistical methods

The *t*-test for the comparison of independent means and the chi-square test were used to compare characteristics between the foot ulcer patients and those without foot ulcers. *P*-values are two-sided. Sensitivities and specificities were calculated after cutoff values were determined according to the criteria indicated below.

3. Results

Of 103 patients that were screened, 10 patients were excluded due to the presence of peripheral vascular disease as determined by absent pulses and/or the presence of a hallux amputation. Of those included in the study, 52 patients (50%) had either a past or present ulcer, a history of a minor amputation (one digit excluding hallux) or Charcot neuroarthropathy. Ninety-three percent of the patients had type 2 diabetes mellitus (defined as treatment with diet or an oral hypoglycaemic agent, or the institution of insulin treatment at least two years after diagnosis) and 56% were male. The vast majority of the patients were Hispanic (60%) or African–American (30%). In the ulcer group there was a predominance of male patients (73%).

Testing with the 10 g monofilament was assessed according to different cutoff points for positivity (Table 1). We examined the sensitivities and specificities of the 10 g monofilament for detecting foot ulceration with positivity cutoffs of $\geq$1 insensate sites of 8, $\geq$2 insensate sites of 8 and $\geq$4 insensate sites of 8. We found that the sensitivities of the monofilament ranged from 65 to 86%, while the specificities ranged from 58 to 71%.

Sensitivities and specificities at individual sites of the foot were also assessed with an abnormal site defined as at least one foot being insensate at that site (Table 2). In general, the individual sites had low sensitivities (range: 65–77%). The highest sensitiv-

Table 1
Sensitivity and specificity of the 10 g monofilament according to the number of insensate sites

Test	Sensitivity	Specificity
Monofilament $\geq$1/8	86	58
Monofilament $\geq$2/8	77	63
Monofilament $\geq$4/8	65	71

52 of 93 tested had either an ulcer, an amputation or Charcot neuroarthropathy.

Table 2
Sensitivity and specificity of the l0 g monofilament according to the location of testing ($\geq$1 of the two sites tested was considered positive)

Testing site	Sensitivity	Specificity
Hallux	73	68
MTH1	71	63
MTH3	65	63
MTH5	77	68

52 of 93 tested had either an ulcer, an amputation or Charcot neuroarthropathy.

Table 3
Sensitivity and specificity according to methodologies used to assess insensitivity

Test	Sensitivity	Specificity
VPT $\geq$ 25	92	39
NDS $\geq$ 6	92	53
Monofilament $\geq$1/8	86	58
128 Hz tuning fork[a]	86	56

52 of 93 tested had either an ulcer, an amputation or Charcot neuroarthropathy.
[a] $\geq$1 of the two sites tested was considered positive.

ities were at the hallux and MTH5. When these two sites were combined ($\geq$1 of 4 being positive), the sensitivity was 81% with a specificity of 63%.

We compared the 10 g monofilament with two other procedures for detecting decreased sensitivity, the measurement of the VPT using a biothesiometer and a modified NDS (Table 3). A VPT $\geq$25 [9,10] and a modified NDS $\geq$6 [11] were used as cutoffs for positivity. The VPT and the modified NDS both demonstrated sensitivities of 92% for detecting patients with foot ulceration with respective specificities of 39 and 53%. Both tests had higher sensitivies than the 10 g monofilament test.

The 128 Hz tuning fork component of the NDS (insensitivity of one of the halluces was considered a positive test) was also compared with the monofilament with a cutoff of $\geq$1 insensate site of 8 tested. Testing with the tuning fork at the halluces alone had the same sensitivity 86% and nearly as high a specificity (56% versus 58%) as that of the 10 g monofilament.

4. Discussion

The 10 g monofilament is now commonly used [5,7,8], yet there are few rigorous data available with regard to how it is best utilized to detect foot insensitivity and its resultant foot ulcer risk. Although a number of studies have utilized monofilaments for the assessment of neuropathy, there are no substantive data that support any one standard method of application of the 10 g monofilament [8]. It is therefore not surprising that its optimal capacity to detect insensitivity is not known. In examining different methods of application of the 10 g monofilament and in comparing the performance of the monofilament to other instruments, this study has raised questions as to whether its widespread use is warranted. The appropriate cutoff for the number of insensate sites is dependent on screening objectives; however, the data appear to indicate that requiring more than one insensate site would lead to an unacceptable number of false negatives. Even using a cutoff of one or more insensate sites of eight tested had only moderate sensitivity.

The 10 g monofilament did not compare favorably with the other testing modalities. The sensitivities of the VPT and the modified NDS were both higher than that for the 10 g monofilament. The performance of the 128 Hz tuning fork at two sites was even comparable to the 10 g monofilament at eight sites.

Although the use of the VPT and the NDS would apparently lead to higher sensitivities than the 10 g monofilament, their specificities would be lower. One cannot definitively say which performance characteristic would be preferable from a public health perspective; however, it would appear that there is more to lose by a failure to initiate preventive interventions in those who would benefit than the alternative.

A rationale for using the 10 g monofilament is that it is available, inexpensive and easy to use [8]. However, if at least eight sites are required for its use, it does require some time for testing. In fact, the use of the 128 Hz tuning fork at two sites (the halluces) would take less time than the 10 g monofilament tested at eight sites and provide comparable accuracy. The graduated tuning fork has also been shown to be a useful, accurate and reproducible method of assessing peripheral sensation [15].

There are other questions regarding the use of the 10 g monofilament apart from those raised by this study. It has been shown that a number of monofilaments purported to be testing 10 g pressure actually fail to do so [13]. Also, it is entirely possible that monofilaments smaller in size would perform better.

There are certain limitations with this study. We were testing the various modalities to detect foot ulcers in individuals who already had previous or existing ulcers, whereas the real issue is how the modalities are able to predict the future development of foot ulcers. The number of participants in this study was relatively

small and differences were not statistically significant. Until a prospective study with sufficient power is performed to compare these various testing modalities, definitive conclusions cannot be drawn.

Despite the above limitations, this study does serve to show that one must question the use of the 10 g monofilament as a standard. Its sensitivity might be insufficient, even with testing at multiple sites. The tuning fork had been a staple in the clinic setting for assessing insensitivity before the 10 g monofilament became popularized. Until more definitive information is obtained about the use of the 10 g monofilament, alternatives should include the modified NDS or even the 128 Hz tuning fork.

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