Footboards: Indigenous and Novel Method of Screening for Diabetes Peripheral Neuropathy — A Pilot Study

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Abstract

Background: To validate the effectiveness of indigenously designed "footboard (FB)" in early diagnosis of diabetic peripheral neuropathy (PNP) by comparing it with Semmes–Weinstein monofilament (SWM) and vibration perception (VP). Materials and Methods: Two hundred and forty-four patients with diabetes were examined for PNP using SWM and 128 Hz tuning fork. The findings were compared with indigenously designed FBs with 1, 2, and 3 mm elevations. Results: Out of 108 patients who did not have protective sensation as per SWM, only 10 (9.2%) felt 1 mm board bearings, and out of 72 patients who did not feel vibration, only 8 (11.1%) felt 1 mm board bearings. Out of 136 patients who had protective sensation, 128 (94.11%) felt 2 mm elevated board bearings, and out of 172 patients who had VP, only 152 patients (88.3%) felt 2 mm board bearings. With SWM as standard, the sensitivities and specificities, respectively, were 63% and 90% (1 mm board), and 94% and 60% (2 mm board). With VP, the sensitivities and specificities, respectively, were 59% and 90% (1 mm board), and 88% and 61% (2 mm board). Conclusions: FB, which simultaneously tests touch and pressure sensation, shows a high level of performance in detecting at-risk feet. FB may be simple, time-efficient, and inexpensive test for detection of neuropathy and needs further validation in a larger study.

Keywords: Diabetes, Foot ulcer; India, Peripheral neuropathy: Foot board

INTRODUCTION

More than 135 million people worldwide have diabetes mellitus, and the World Health Organization estimates that this number will increase to 300 million by the year 2025.[1] Diabetic peripheral sensory neuropathy (DPN) and associated foot disease, a sequel of diabetes mellitus result in considerable morbidity.^[2] Peripheral neuropathy (PNP) increases the risk of complications such as foot ulcer and possible amputation resulting in marked economic loss.[3-5] In some developing countries, practice of walking barefoot during extreme weather may predispose to foot injury in patients with diabetes and PNP.^[6] Because of this, the annual amputation rate for people with diabetes is 15–40 times higher than nondiabetic individuals.^[7-9] To institute the preventive methods in high-risk patients with aim at reducing the incidence of foot complications, clinical practical guidelines recommend screening for neuropathy.[10,11] The amputation rates differ considerably depending on extent and severity of PNP and expertise of management team. [12] Impairment of touch, pressure, and temperature are common manifestations of DPN. Monofilament (touch and pressure) and tuning fork (vibration) tests are helpful in detecting at-risk

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patients for foot ulceration.^[13] The accurate use of these devices needs proper training of medical personal and understanding on the part of the patient.^[14,15] As shown in UK audit, less than one-third of patients with diabetes would get a proper foot examination done.^[16] The burden of disease, inertia on the part of the physician, and the need for trained personnel to use current devices debars many patients from the proper foot examination. Keeping these difficulties in mind, the use of a new simple, inexpensive, and user-friendly device would be required.

We present a new innovative method of testing DPN by use of an indigenously designed footboard (FB) and compare the results with standard testing in terms of sensitivity and specificity.

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MATERIALS AND METHODS

Description of cases and controls

Two hundred and forty-four patients with diabetes of varying duration attending diabetes clinic at a tertiary care hospital in North India comprised the patient population. They were clinically examined for parameters such as height, weight, body mass index, measurement of waist, hip, and presence of signs of insulin resistance. Systemic examination included an examination of peripheral pulses, looking for presence of retinopathy, and peripheral and autonomic neuropathy.

Testing for peripheral neuropathy

The 10 g monofilament (Semmes–Weinstein monofilament [SWM] Bills W. Long, Hansen's disease Centre, Carville, LA, USA) was used to determine the protective sensation in the feet by measuring patient's cutaneous pressure perception threshold. It was applied at seven sites on the feet until it buckled, which occurred at 10 g of linear pressure, and patient was asked for perception of its presence. If not felt on at least four out of seven sites, the protective sensation was considered lost. The patients were also tested for neuropathy using the tuning fork (128 Hz) for determining the vibration perception (VP) and light touch at the tip of great toe, malleoli, and tibial tuberosity.

Description of foot board

FB is an indigenous innovation and comprises two wooden plates in the shape of the right and left foot each, cut out to the sizes of an average adult feet. Each board is 19 mm thick, fitted with twenty ball bearings of 8 mm in diameter at 1, 2, and 3 mm elevation on three different boards to address for sensation perception at pressure points [Figures 1 and 2]. Authorities recommend that measurements be taken at ten sites of the foot to detect neuropathy.^[18] These include the first, third, and fifth digits plantarly, the first, third, and fifth metatarsal heads plantarly, plantar midfoot medially and laterally, and plantar heel and distal first interspace dorsally. However, testing just four plantar sites on the forefoot, namely, the great toe and base of the first, third, and fifth metatarsals

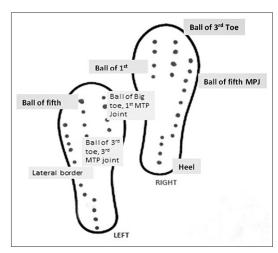


Figure 1: Diagrammatic representation of foot boards

identifies 90% of patients with loss of protective sensation.^[19] In FB, ball bearings are kept in such a way that these test pressure points plantarly at the first, third, and fifth digits; the first, third, and fifth metatarsal heads, lateral midfoot, and the plantar heel. Thus, during the test, all vital areas are included to detect sensory neuropathy. Each pair of FB consumes a floor space approximately equal to that of a weighing machine. The average time required assessing sensations in a patient by monofilament and vibratory method was approximately 15 min and about 5 min using the FBs.

Testing for peripheral neuropathy with foot board

Patients were explained the nature and function of FBs and asked to put their feet on 3, 2, and 1 mm boards serially while standing. The results of perception (or no perception) of ball bearings under the feet in each case were noted separately for each board and comparison with monofilament and VP was noted.

Statistical analysis

Data were entered and subsequently analyzed using R software. Statistical Package R 2.10.1 version h(R-2.10.1 Statistics Windows). Sensitivity, specificity, positive, and negative predictive values of FBs were calculated comparing with SWM and VP.

RESULTS

Two hundred and forty-four patients with diabetes were tested for the presence or absence of neuropathy (in the form of loss of protective sensation) with the help of 1, 2, and 3 mm FBs and compared with 10 g monofilament and 128 Hz tuning fork. Sensitivity, specificity, positive, and negative predictive value were calculated for 1, 2, and 3 mm FBs compared with the monofilament and tuning fork test.

Comparison with monofilament

Of 244 patients who were tested with the monofilament, protective sensation (felt filament at four or more out of seven sites) was present in 136 patients (55.7%) and absent in 108 patients (44.2%). Out of 108 patients who did not have protective sensation, 56 patients (22.9%) had some sensation (felt monofilament at 2 or 3 sites out of 7) and 52 patients (21.3%) had no sensation to monofilament. Comparison of monofilament with the results of FB testing is

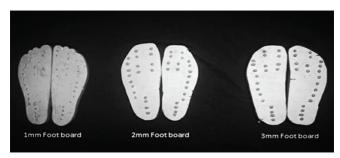


Figure 2: Footboards with 20 (8 mm diameter) ball bearings on each board

detailed in Figure 3. Out of 136 patients who had protective sensation, 86 (63.2%) felt 1 mm, 128 patients (94%) felt 2 mm and all 136 patients (100%) felt 3 mm elevated board bearings. Out of 108 patients with loss of protective sensation on SWM, only 10 (9.2%) felt 1 mm board. Sensitivity, specificity, positive, and negative predictive values of different FBs comparing with monofilament are given in Table 1. Overall, 3 mm FB had the highest sensitivity and 1 mm FB had the highest specificity.

Comparison with vibration

Among 244 patients, VP was present in 172 patients (70.4%) and absent in 72 patients (29.5%). Out of 172 patients who had VP, 102 (59.3%) patients felt 1 mm board, and 152 (88.3%) patients felt board with 2 mm elevated board bearings. Out of 72 patients who did not feel vibration, only 8 (11.1%) felt 1 mm boards. Comparison of VP with the results of FB testing is detailed in Figure 4. Table 1 gives the sensitivity, specificity, positive, and negative predictive values of 1, 2, and 3 mm FB comparing with VP. Overall, 3 mm FB had the highest sensitivity, and 1 mm FB had the highest specificity.

DISCUSSION

Several clinic- and population-based studies show surprisingly similar prevalence rates for distal symmetrical neuropathy affecting 30% of all the people with diabetes. In India, up to or more than 37% of patients with diabetes have clinical or subclinical neuropathy and the incidence rises as the duration of diabetes increases.^[20] As PNP is a pivotal element in both

foot ulceration and amputation, selecting a quick, inexpensive, and accurate instrument to evaluate high-risk patients is essential for any preventive strategy to be implemented.

The most frequently used modality for detecting neuropathy in clinical practice is the nylon SWM and inability to perceive it is associated with clinically significant large, fiber neuropathy. The reported sensitivity and specificity for monofilament sensation is up to 95% and 82%, respectively. [21,22] The 128 Hz tuning fork is an inexpensive test of vibration sensation and is a test for large fiber neuropathy. The sensitivity and specificity of vibration testing for PNP is estimated to be 53% and 99%, respectively.^[23] Both these techniques are operator-dependent and time-consuming, as multiple sites need to be evaluated individually. Given the magnitude of the problem and the number of patients visiting diabetic clinics, we rarely see the feet being evaluated for PNP.[16] Therefore, the need of the hour is to devise a test, which is less labor and time-consuming and at the same time quite reliable. In this study, we have compared the device - FBs fitted with 8 mm diameter metallic ball bearing at pressure points, elevated at 1, 2, and 3 mm above board level in 3 different sets of boards. As the patient keeps his barefeet on FBs, touch-pressure sensation is tested according to what the patient feels under the feet. The weight of the patient and the density of sensory receptors are different in different patients, but these factors act individually in each patient. In our study, we found the sensitivity and specificity of 2 mm boards in detecting PNP to be 94% and 51%, respectively, as compared to SWM, and 88% and 61% as compared to 128 Hz tuning fork. Thus, we infer that the FBs are reliable in

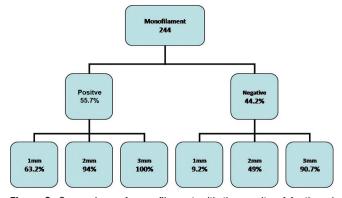


Figure 3: Comparison of monofilament with the results of footboard testing

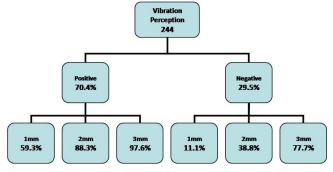


Figure 4: Comparison of vibration perception with the results of footboard testing

Table 1: Sensitivity, specificity, positive, and negative predictive value of 1, 2, and 3 mm footboard against monofilament and vibration perception

Footboard	Parameter					
	Against monofilament (mm)			Against vibration perception (mm)		
	1	2	3	1	2	3
Sensitivity (%)	63	94	100	59	88	98
Specificity (%)	90	51	9	89	61	22
Positive predictive value (%)	90	71	58	93	84	75
Negative predictive value (%)	66	87	100	48	69	80

detecting PNP. Two mm elevated board bearing has a very high sensitivity in detecting patients having intact sensation whereas as 1 mm board has high specificity (around 90%) in detecting patients who do not have protective sensation. We can use these FBs easily in office setting to detect clinical neuropathy and guide the patients accordingly. Patients need to enter office barefooted and stand on 2 mm board if they perceive it, some sensation is present. Then, they are asked to move to 1 mm board, and if they perceive it, protective sensations are present and if not, then protective sensations are not present and patients are advised accordingly. If patients do not perceive 2 mm board, sensation is lost and then they can move to 3 mm board, and if they do not even perceive this, then sensory loss is profound. In our study, 2 mm board correlated very closely with patients having loss of sensation and occurred in about 26% of evaluated patients. FBs can be used in office setting as well as at home by patients with the high standard of accuracy to detect PNP.

Conclusions

FB tests touch-pressure sensation and its absence on 1 mm FBs have high specificity for detecting at-risk feet. FB is inexpensive, simple to use, less time, and labor-consuming device to test PNP. These can be used easily in clinics by physicians and at home by patients to get a quick idea of sensory loss.

Limitations

FB tests only the planter aspect of feet as a single unit. Thus, only sensation along the distribution of tibial nerve is tested.

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Conflict of interest

There are no conflicts of interest.

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