

## **Evaluation of the Self-administered Indicator Plaster Neuropad for the Diagnosis of Neuropathy in Diabetes**

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## ABSTRACT

*Objective:* To evaluate the inter-rater reliability between patient and healthcare provider of the indicator plaster neuropad (IPN) in the diagnosis of peripheral neuropathy (PN) and the feasibility of the IPN.

*Research Design and Methods:* 56 patients with diabetes were examined. At the same visit the IPN was evaluated by the healthcare provider. Afterwards, the IPN with written instructions for its use and evaluation for self-testing at home were provided together with a questionnaire asking for the easiness of the IPN.

*Results:* Neuropathy was diagnosed in 56.9% of the participants by the healthcare provider. The  $k$  statistic to measure overall agreement between patient and healthcare provider of the IPN was very good: 0.88 (95% CI: 0.85-0.91). The indicated instructions and the IPN were evaluated as easy by the patients.

*Conclusions:* The high degree of reliability and the easiness of the IPN suggest that it is proper for self-testing for the identification of PN.

Chronic peripheral sensorimotor neuropathy (PN) is a common complication of diabetes (1). Clinical examination is the mainstay for the diagnosis of PN and prevention of foot problems (1). Sudomotor dysfunction develops early in the course of PN (2). Recently, a new test assessing sudomotor dysfunction, the indicator plaster neuropad (IPN), has been introduced for the diagnosis of PN (3,4). The IPN has a high sensitivity for the diagnosis of PN (3-5) and excellent reproducibility (6). Another advantage of the IPN is its simplicity. This study evaluated the inter-rater reliability between patient and healthcare provider of the IPN in the diagnosis of PN and the feasibility of the IPN.

#### RESEARCH DESIGN AND METHODS

A total of 156 consecutive subjects were recruited from the outpatient diabetes clinic of our hospital (Table 1). Subjects were included if they were able to read and understand the written instructions for the use and evaluation of the IPN. Patients with dyschromasia, severe visual loss, treated with medications affecting sweating, known allergy to cobaltium, and critical limb ischemia were excluded.

Participants were assessed for neuropathy at first visit in the clinic. Diagnosis of neuropathy was based on clinical examination using the neuropathy symptom score and the neuropathy disability score (7). The IPN was applied for 10 min in the sitting position at both feet and evaluated as normal (pink colour bilaterally) or abnormal (blue colour or any other combinations of colours bilaterally) by the doctor at the same visit. Afterwards, the IPN for self-testing at home in the sitting position together with written instructions for its use and evaluation were provided. Additionally, a questionnaire was given asking for the easiness to understand the instructions for the use of the IPN, the

easiness to use the IPN, and the easiness to evaluate the result of the IPN (visual analogue scales 0-10, with 0 the most difficult and 10 the easiest for each question). Moreover, patients were asked to report if they required any help for self-examination. Participants were instructed to return the results of the IPN and the completed questionnaires in a second visit to another participating doctor, who was blind to results of the tests of the first visit.

#### RESULTS

All patients returned the result of the IPN and the completed questionnaires to the healthcare provider. Neuropathy was diagnosed in 93 subjects (56.9%). Neuropathy by both clinical examination and IPN was diagnosed in 87 cases; in 50 cases, both clinical examination and the IPN were normal; in 13 cases the IPN was abnormal while clinical examination was not diagnostic for PN; and in 6 cases the IPN was normal while clinical examination revealed PN. The performance of the IPN for the diagnosis of PN was as follows: sensitivity 0.87 (95% CI: 0.81-0.92); specificity 0.66 (0.58-0.73); positive predictive value 0.94 (0.90-0.97); and negative predictive value 0.79 (0.72-0.85).

The agreement between patient and healthcare provider in the evaluation of the IPN as normal (n=92) or abnormal (n=49) was 90.3%. The *k* statistic to measure overall agreement between patient and healthcare provider as normal or abnormal was very good (0.88 [95% CI: 0.85-0.91]). The evaluation of the instructions and the test by the patients (median values, interquartile range) was as follows: easiness to understand the instructions for the use of the IPN 10.0 (9.0-10.0), easiness to use the IPN 10.0 (9.0-10.0), and easiness to evaluate the test as normal or abnormal 10.0 (8.0-10.0).

Noteworthy, 32 patients (20.5%) reported that they requested help to perform self-testing.

They were older ( $69.8 \pm 7.8$  vs.  $61.5 \pm 9.4$  years,  $P < 0.001$ ) and reported more often kinetic (53.1% vs. 3.1%,  $P < 0.001$ ) and visual problems (50% vs. 7.6%,  $P < 0.001$ ); sex, neuropathy status and presence of foot ulceration were not associated with difficulty in self-testing. No any adverse event has been reported.

## **CONCLUSIONS**

All tests and questionnaires provided were returned completed implying that patients have a strong interest in the care of their feet. We found a very good agreement between patient and healthcare provider in the evaluation of the IPN. In 8 cases the test was characterized normal by the patients but abnormal by the doctor while in 7 cases the test was characterized abnormal by the patient and normal by the doctor; all these 15 patients reported visual problems. This means that 5.2% of the patients may evaluate an abnormal test as normal and they may be misclassified as having normal sensation if they self-tested with the IPN alone. Our finding of an excellent sensitivity but a lower specificity of the IPN in the diagnosis

of PN agrees with previous data (3-5, 8). False negative results with the IPN were found in 6 cases and false positive results in 13 cases. The later finding is expected as sudomotor dysfunction occurs early in the course of PN, even when nerve conduction studies may be normal (2). However, false negative results of a screening test are a limiting factor.

Noteworthy, 20% of the patients, particularly the older and those with kinetic and/or visual impairment reported that they requested help by another person for self-testing. This limitation should be considered when the IPN is administered to patients. Participants evaluated the indicated instructions and the test as very easy, confirming that the IPN is a simple test.

In conclusion, the high degree of reliability and the easiness of the IPN suggest that it is proper for self-testing for the identification of PN when clear instructions for its use and evaluation are provided. However, older patients and those with visual and/or kinetic impairment may not be able to perform self-examination.

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**TABLE 1. Demographic and clinical characteristics of the study subjects**

n	156
Age (years)	59.6 ± 15.5
Male/female n (%)	82 (52.6)/74 (47.4)
Type 1/type 2 diabetes n (%)	7 (4.5)/149 (95.5)
Duration of diabetes*	14.0 (5.0-20.0)
Antidiabetic treatment n (%)	
Diet only and/or tablets	93 (59.6)
Insulin	63 (40.4)
Neuropathy (yes/no) n (%)	93 (59.6)/63 (40.4)
Foot ulcer n (%)	50 (32.1)
Active ulcer n	18
Ulcer in the past	32
Classification of the ulcer n	
Neuropathic	44
Neuroischemic	6
Ischaemic	0
Neuropathy symptom score*	6.0 (3.0-7.0)
Neuropathy disability score*	4.0 (1.0-6.0)
Ankle brachial index (right)	1.03 ± 0.19
Ankle brachial index (left)	1.05 ± 0.18

Data are means ± SD or n (%). \*Median values (interquartile range).