**VALIDATION: ITALIAN DN4 (DIABETIC POLYNEUROPATHY)**

**DOULEUR NEUROPATHIQUE EN 4 QUESTIONS (DN4)**

**ITALIAN TRANSLATION** (tested in patients with painful diabetic polyneuropathy)

**Bibliographic information for original (French) questionnaire**

*Reference*


**Bibliographic information for translated (Italian) questionnaire**

*Reference*


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**Properties of the translated questionnaire**

*Purpose*

Diagnostic/screening: To identify whether pain is likely to be neuropathic in origin in patients with diabetic polyneuropathy.

*Language*

Italian

*Translation process:*

No information on the translation process is provided. The Italian translation of the questionnaire was provided by Augusto Caraceni, Ernesto Zecca and Cinzia Martini.
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Changes from original questionnaire:
None stated

Assessment

SYMPTOMS (INTERVIEW):
Two questions addressing symptoms:
- Pain quality (presence of three symptoms assessed: burning, painful cold, electric shocks)
- Non-painful symptoms (presence of four symptoms assessed: numbness, tingling, itching, pins-and-needles)

SIGNS (CLINICAL EXAMINATION):
Two questions addressing sensory signs (requires a suitably trained person to administer the instrument):
- Assessments for mechanical hypoaesthesia (two modalities assessed: touch and pin-prick sensations)
- Assessment for mechanical dynamic allodynia (one modality assessed: brushing)

Scoring system
All items are answered in the affirmative (‘yes’) or negative (‘No’). All ‘yes’ responses are scored as 1, and ‘no’ responses are scored as 0. The individual item scores are summed and a total score calculated. A score of 4 or greater indicates that the pain is likely to be of neuropathic origin (based on the validation of the original French DN4).

If only the two questions dealing with sensory symptoms are completed, and no assessment of signs is made, then a total score of 3 of greater for the symptom component of the questionnaire indicates that the pain is likely to be of neuropathic origin (based on the validation of the original French DN4).

Scoring direction

Complete questionnaire
Score ≥ 4 indicate that the pain is likely to be neuropathic in origin

Assessment of symptoms only
Score ≥ 3 indicate that the pain is likely to be neuropathic in origin
Validation population

One-hundred and fifty-eight (158) adult Italian-speaking diabetic patients were recruited. Fifty (50) had painful diabetic polyneuropathy, 47 had non-painful diabetic polyneuropathy, and 61 had no diabetic polyneuropathy. Diagnosis of diabetic polyneuropathy required abnormalities in at least two of the following clinical findings: neuropathic symptoms, signs, vibration perception threshold, thermal perception thresholds or nerve conduction studies. Diagnosis of painful diabetic polyneuropathy required the additional presence of pain for more than 6 months in the same area and the same distribution as the findings used to diagnose the presence of diabetic polyneuropathy. Compared to the non-painful neuropathy group, the group with painful neuropathy had a greater proportion of women, and had greater HDL cholesterol and HbA1c. Both the neuropathy groups were older than the neuropathy-free group, and the group with painful neuropathy had had diabetes for a longer duration than the group who were neuropathy-free. Both neuropathy groups had worse neurological indices (vibration and thermal sensation thresholds) and nerve conduction study variables than the neuropathy-free group. The painful neuropathy group had higher scores on the Michigan Neuropathy Screening Instrument Questionnaire and the Michigan Diabetic Neuropathy Score than the non-painful neuropathy group. One investigator collected all the data required to make the diagnosis of diabetic polyneuropathy, and a second, independent investigator administered the DN4 questionnaire.

Psychometric properties

**Diagnostic validity of the 10-item questionnaire**

(using a threshold score ≥ 4)

Sensitivity: 80.0%
Specificity: 91.7%
Positive predictive value: 81.6%
Negative predictive value: 90.8%
Positive likelihood ratio: 9.6
Negative likelihood ratio: 0.2
Area under the curve of Receiver Operating Characteristic (ROC) curve of total score: 0.94

**Diagnostic validity of the 7-item questionnaire** (interview assessment of symptoms only)

(using a threshold score ≥ 3)

Sensitivity: 84.0%
Specificity: 84.2%
Positive predictive value: 71.2%
Negative predictive value: 92.0%
Validation: Italian DN4 (Diabetic Polyneuropathy)

Positive likelihood ratio: 5.3
Negative likelihood ratio: 0.2
Area under the curve of Receiver Operating Characteristic (ROC) curve of total score: 0.93

Construct validity
After correction for age, body mass index, type of diabetes and HBA1c, the following neurological indices and nerve conduction variables were correlated with the DN4 score:
- Michigan Neuropathy Screening Instrument
- Michigan Diabetic Neuropathy Score
- Vibration sense (hallux and maleolus)
- Cold detection threshold (foot) (negative correlation)
- Warm detection threshold (foot)
- Tibial/peroneal/sural amplitude (z score)
- Tibial/peroneal/sural conduction velocity (z score)
- Left Tibial F-wave latency (z score)

Convergent/criterion validity
Not assessed

Reliability
Not tested

Validation studies of translated questionnaire for specific pain conditions
n/a

Additional information
n/a