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Original Article

Validation of neuropathic pain assessment tools among Chinese patients with painful diabetic peripheral neuropathy

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ABSTRACT

Objective: This study aims to evaluate the reliability and validity of neuropathic pain assessment tools among Chinese patients with painful diabetic peripheral neuropathy (PDPN).

Methods: One hundred patients with PDPN and 70 patients with non-neuropathic pain were recruited from five grade III general hospitals in Guangzhou. Pain was assessed using the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS), Douleur Neuropathique 4 questionnaire (DN4), and Brief Pain Inventory for Painful Diabetic Peripheral Neuropathy (BPI-DPN). Reliability was evaluated by internal consistency of the Cronbach's α coefficient and Guttman split-half. Construct validity was analyzed by factor analysis and Spearman correlation coefficients. Sensitivity and specificity were also assessed.

Results: The Cronbach's α coefficients of the LANSS, DN4, and BPI-DPN were 0.735, 0.750, and 0.898, respectively. The Guttman split-half coefficients of the LANSS, DN4, and BPI-DPN were 0.660, 0.726, and 0.849, respectively. The cumulative contributions of the LANSS, DN4, and BPI-DPN to the total variance were 61.945%, 57.010%, and 66.056%, respectively. The items of the LANSS, DN4, and BPI-DPN presented high factorial loads, ranging from 0.387 to 0.841, 0.137 to 0.948, and 0.487 to 0.953, respectively. The LANSS and DN4 exhibited sensitivities of 58.0% and 82.7%, respectively, and specificity of 97.1%.

Conclusions: The LANSS or DN4 can be used to detect neuropathic pain in Chinese patients with PDPN. The BPI-DPN can be employed to monitor the effectiveness of pain intervention.

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1. Introduction

Diabetes mellitus (DM) is a common chronic disease and could lead to diabetic peripheral neuropathy (DPN) [1]. DPN could affect up to one-third of adults with diabetes [2]. Symptoms of DPN include numbness, burning, pins and needles, and sometimes allodynia. Painful diabetic peripheral neuropathy (PDPN) is caused by abnormalities of the peripheral nervous system in patients with diabetes [3]. The prevalence of PDPN varies from 14.0% to 65.3% [4,5]. China has the highest human population worldwide; of which, approximately 114 million patients suffer from DM [6]. However, the prevalence of PDPN in China has been rarely investigated.

PDPN affects the quality of life of patients, and the pain severity of this disease is associated with anxiety and depression [2,7,8]. Patients with PDPN exhibit significantly higher healthcare resource utilization and costs than patients with diabetes only [9]. Early detection of the presence of PDPN contributes to treatment outcome. In addition, effective pain assessment tools can be used to diagnose PDPN.

PDPN is difficult to diagnose. Gold diagnostic criteria for PDPN have not been established clinically. Assessment tools can be used to distinguish PDPN from other types of pain. Several neuropathic pain assessment tools are available and include the most widely used Leeds Assessment of Neuropathic Symptoms and Signs (LANSS), Douleur Neuropathique 4 questionnaire (DN4), and Brief Pain Inventory for Painful Diabetic Peripheral Neuropathy (BPI-DPN). The LANSS was developed by Bennett [10] and has been translated into Portuguese [11,12], Spanish [13,14], Turkish [15,16], and other languages. The Chinese version of the LANSS was translated and validated by Li et al. [17]. This version is reliable and valid. The DN4 was designed by a French pain expert group in 2005 [18] and has been translated into Arabic [19], Dutch [20], Greek [21], and several other languages. However, the Chinese version of the DN4 has not been reported. The LANSS and DN4 are used to differentiate neuropathic pain from non-neuropathic pain, but not for Chinese patients with PDPN specifically. The Brief Pain Inventory (BPI) was developed by Cleeland and Ryan [22], and the Chinese version of this tool is widely used to assess acute, chronic, and cancer pain. The BPI-DPN was revised by Zelman et al. [23] to assess patients with PDPN, but this version has not been reported in China.

This study aims to evaluate the reliability and validity of the LANSS, DN4, and BPI-DPN among Chinese patients with PDPN.

2. Methods

2.1. Sample

A convenience sample was recruited at inpatient and outpatient departments of endocrinology, inpatient department of pain, and outpatient department of orthopedics from five grade III general hospitals in Guangzhou from May 2014 to January 2015. Inclusion criteria were as follows: a) age $\geq$ 18; b) complaint of pain for over 3 months (persistent and/or recurrent pain); c) having one of the following diagnosis: neuropathic pain (PDPN), or non-neuropathic pain (low back pain, myofascial pain syndrome, ankylosing spondylitis, shoulder arthritis, headache, osteoporosis, carpal tunnel syndrome, rib cartilage inflammation, osteoarthritis, etc.); and d) willing and able to complete the questionnaire. The exclusion criteria included the presence of neuropathic pain from other causes or with mixed pain, history of foot ulcers or severe comorbidities or lower limb amputation, and inability to communicate and complete the questionnaire.

Based on sample size estimation, 100 subjects were required for a two-sided test with 80% power of the test ($1-\beta$) at a significance level α of 0.05. In previous studies, sample sizes ranged from 42 to 123 and from 52 to 80 for neuropathic pain and non-neuropathic pain, respectively. On the basis of sample size estimation and previous studies, the sample sizes for neuropathic pain (PDPN) and non-neuropathic pain used for the present study were 100 and 70, respectively.

2.2. Measures

2.2.1. *Leeds assessment of neuropathic symptoms and signs (LANSS)*

The LANSS [10] was developed to distinguish neuropathic pain from nociceptive pain. The LANSS consists of pain questionnaire and sensory testing with seven items, and the highest overall score is 24. Pain questionnaire includes sensations, such as pricking, tingling, pins and needles, skin discoloration, light touch pain, electric shocks, jumping and bursting, and feeling of altered skin temperature, including hot and burning. Sensory testing includes allodynia and altered pinprick threshold. If the pain symptom is consistent with the description, the subjects answer "yes," and the items are scored 5, 5, 3, 2, 1, 5, and 3, respectively. If the pain symptom is inconsistent, the subjects answer "no," and the item is scored 0. The cut-off value is 12. If the total score is $\geq$12, neuropathic mechanisms could contribute to the pain experienced by the patient. The Chinese version of the LANSS used in this study was translated by Li et al. with a Cronbach's α value of 0.824; this version exhibits high sensitivity, specificity, and positive and negative predictive values (>80%) [17].

2.2.2. *Douleur neuropathique 4 questionnaire (DN4)*

The DN4 [18] consists of four questionnaires in two parts, namely, interview and examination, of the patient with a total of 10 items. DN4-interview questions include burning, painful cold, electric shocks, tingling, pins and needles, numbness, and itching. Examination of the patient includes hypoesthesia to touch, hypoesthesia to prick, and brushing. Each item is scored "yes" or "no." Each "yes" item is scored 1, and "no" is scored 0, with a total possible score of 10. The cut-off value is 4. Total score $\geq$4 indicates neuropathic pain. The Chinese version of the DN4 was translated by the first author and another nursing master candidate and then back-translated by the corresponding author.

2.2.3. *Brief pain inventory for painful diabetic peripheral neuropathy (BPI-DPN)*

The Brief Pain Inventory (BPI) [22] includes pain intensity and pain interference on a 0–10 numeric rating scale (NRS). Pain