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Nonrandomized Evaluation

Linguistic Adaptation, Validation and Comparison of 3 Routinely Used Neuropathic Pain Questionnaires

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Background: Neuropathic pain questionnaires are efficient diagnostic tools for neuropathic pain and play an important role in neuropathic pain epidemiologic studies in China. No comparison data was available in regards to the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS), the Neuropathic Pain Questionnaire (NPQ) and ID Pain within and among the same population.

Objective: To achieve a linguistic adaptation, validation, and comparison of Chinese versions of the 3 neuropathic pain questionnaires (LANSS, NPQ and ID Pain).

Study design: A nonrandomized, controlled, prospective, multicenter trial.

Setting: Ten pain centers in China.

Methods: Two forward translations followed by comparison and reconciliation of the translations. Comparison of the 2 backward translations with the original version was made to establish consistency and accuracy of the translations. Pilot testing and pain specialists' evaluations were also required. A total of 140 patients were enrolled in 10 centers throughout China: 70 neuropathic pain patients and 70 nociceptive pain patients. Reliability (Cronbach's alpha coefficients and Guttman split-half coefficients) and validity (sensitivity, specificity, positive and negative predictive values, receiver operating characteristic [ROC] curves and the area under the ROC curves) of the 3 questionnaires were determined. ROC curves and the area under the ROC curves of the 3 questionnaires were also compared.

Results: Chinese versions of LANSS, NPQ and ID Pain had a good reliability (Cronbach's alpha coefficients and Guttman split-half coefficients were greater than 0.7). Sensitivity, specificity, positive and negative predictive values of the Chinese versions of LANSS and ID Pain were considerably high (> 80%). The area under the ROC curves of LANSS and ID Pain was significantly higher than that of NPQ ($P < 0.05$). There was no statistically significant difference between the area under the ROC curves of LANSS and ID Pain ($P > 0.05$).

Limitation: The study was based on patients with a high school degree or above, which limited the application of the 3 neuropathic pain questionnaires to patients with lower educational levels.

Conclusion: The Chinese versions of LANSS and ID Pain developed and validated by this study can be used as a diagnostic tool in differentiating neuropathic pain in patients whose native language is Chinese (Mandarin).

Key words: Neuropathic pain, questionnaire, scale, LANSS, NPQ, ID Pain, reliability, validity.

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Neuropathic pain is intractable and costly. An epidemiology survey in the United Kingdom demonstrated that the prevalence of chronic pain from predominantly neuropathic origin was 8% (1). Schmidt et al (2) found that approximately 4% of the general adult population experienced back pain with a neuropathic component in Germany. There are no known or published data regarding morbidity or prevalence of neuropathic pain in China. Although neuropathic pain questionnaires have been employed in western countries to diagnose neuropathic pain for years, a valid diagnostic tool for neuropathic pain is lacking in China.

Neuropathic pain questionnaires are efficient diagnostic tools for neuropathic pain; they are easy to use, even for those who know little about neuropathic pain. Most neuropathic pain questionnaires have high sensitivity and specificity, therefore, they do not require special equipment or examinations, and are cheap in terms of cost. Thus, neuropathic pain questionnaires are highly efficient and cost effective. Neuropathic pain questionnaires will also play an important role in future epidemiologic studies, regarding the incidence of neuropathic pain in China. Unfortunately, as of today, no standardized Chinese neuropathic pain questionnaire is available for clinical use and consideration. Therefore, we translated, formulated, and validated Chinese versions of the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS), the Neuropathic Pain Questionnaire (NPQ), and ID Pain, allowing application in the Chinese Mandarin language for use in China as well as with Chinese in other countries. The English versions of LANSS, NPQ, and ID Pain have been proven to be of high sensitivity and specificity in various studies (3-7). However, no comparison data is available regarding these 3 questionnaires within and among the same population. In this study, using the basis of a same subject population group, we compared the validity of the Chinese versions of LANSS, NPQ, and ID pain.

Methods

The study protocol was approved by the Institutional Review Board of Peking University People's Hospital. Each patient provided informed consent before any study procedures were initiated.

Development of the Chinese versions of LANSS, NPQ, and ID Pain

With permission and authorization received from the original authors, 2 translators, native Chinese speakers fluent in English, independently translated the LANSS, NPQ and ID Pain questionnaires into Chinese (Mandarin). These 2 translation versions were integrated into the first Chinese version. Two other translators, native English speakers fluent in Mandarin Chinese, independently did a reverse translation, translating the first Chinese version back to English, followed by a comparison of the original versions of the LANSS, NPQ and ID Pain with the translated English versions of them. Each discrepancy was carefully analyzed, and the first Chinese version was modified to obtain a second improved Chinese version. Five native Chinese patients with neuropathic pain were invited to fill out the second Chinese version in a pilot test to evaluate its reliability and wording as well as public acceptance of the translated questionnaires. The third Chinese version was created according to feedback received from clinicians and patients. Pain specialists from 10 major research centers in China discussed the professionalism, practicability, and accuracy of the third Chinese version; the fourth Chinese version was available after appropriate modification, which was the final translated version (8).

Validation of the Chinese versions of LANSS, NPQ and ID Pain

From March 2010 through July 2010, a total of 140 patients were enrolled into the validation study to analyze and test run our Chinese translations of the 3 neuropathic pain questionnaires; 70 neuropathic pain patients and 70 nociceptive pain patients were enrolled. A total of 10 pain centers from 10 different hospitals and institutes throughout China took part in our study; 7 neuropathic pain and 7 nociceptive pain patients were enrolled from each participating pain center. LANSS was filled out by trained investigators, while patients independently completed both NPQ and ID Pain themselves. Questionnaires were explained to the patients by trained investigators when necessary.

Inclusion criteria:

1. Patients suffering from pain for 3 or more months (persistent and/or recurrent pain)
2. Education level : high school degree or above, be able to understand Mandarin
3. Have one of the following neuropathic or nociceptive pain diseases:
   * Neuropathic pain:
     * Diabetic peripheral neuropathy (DPN)
     * Postherpetic neuralgia (PHN)

    * Primary trigeminal neuralgia (TN)
    * Primary glossopharyngeal neuralgia (GPN).
  * Nociceptive pain:
    * Lateral epicondylalgia
    * Knee osteoarthritis
    * Plantar fasciitis
    * Costal cartilage inflammation.
4. Patients were enrolled only after confirmation by 2 pain clinicians with consistent diagnosis (in reference to international diagnostic criteria).

Exclusion criteria:

1. Patient without disposing capacity (such as schizophrenia, Alzheimer disease, et al)
2. Unable to read and write Chinese
3. Patients with mixed pain.

Statistical methods

SPSS for Windows 13.0 (SPSS, Inc., Chicago, IL) was used for statistical analysis. The reliability (Cronbach's alpha coefficients and Guttman half coefficients were used for the analysis of internal consistency) and validity (sensitivity, specificity, positive predictive value, negative predictive value, and the area under the receiver operating characteristic [ROC] curve) were analyzed. Generalized U-statistics were used to compare the areas under the ROC curves of the 3 questionnaires (9). A P value < 0.05 indicated statistical significance.

Results

The patients' sex and age distribution are as indicated in Table 1. The diagnosis distribution of neuropathic pain and nociceptive pain are as indicated in Tables 2 and 3.

Reliability

Cronbach's alpha coefficients and Guttman half coefficients of all 3 questionnaires are as shown in Table 4; both coefficient values were greater than 0.7.

Validity

1. Face validity: the face validity of all 3 questionnaires was confirmed to be good after the discussion among pain specialists from all 10 recruited pain centers.
2. The area under the ROC curve of all 3 questionnaires is as indicated in Table 5. The area under the ROC curve of NPQ was significantly lower than that of LANSS and ID Pain (P < 0.001). There was no statistically significant difference between the area under the ROC curve of LANSS and ID Pain (P > 0.05). The ROC curves of all 3 questionnaires are

Table 1. *Sex and age of patients.*

	Men	Women	Age
Neuropathic pain	36	34	64.27 ± 14.37
Nociceptive pain	23	47	59.54 ± 12.19

Table 2. *Percentage of neuropathic pain diagnosis.*

	DPN	PHN	TN	GPN	Total
Neuropathic pain	2	43	25	0	70
Percentage(%)	2.9	61.4	35.7	0	100

DPN = diabetic peripheral neuropathy; PHN = postherpetic neuralgia; TN = primary trigeminal neuralgia; GPN = primary glossopharyngeal neuralgia

Table 3. *Percentage of nociceptive pain diagnosis.*

	Lateral epicondylalgia	Knee osteoarthritis	Plantar fasciitis	Costal cartilage inflammation	Total
Nociceptive pain	13	43	13	1	70
Percentage(%)	18.6	61.4	18.6	1.4	100

Table 4. *Cronbach's alpha coefficients and Guttman split-half coefficients.*

	LANSS	NPQ	ID pain
Cronbach's alpha coefficient	0.824	0.809	0.755
Guttman split-half coefficient	0.842	0.765	0.740

Table 5. *Area under ROC curves of the 3 questionnaires.*

*	LANSS	NPQ	ID pain
Area under the ROC curve	0.963 ± 0.015	0.823 ± 0.035*	0.954 ± 0.015^
95% CI	0.934 - 0.993	0.754 - 0.891	0.924 - 0.984

*compared with LANSS P < 0.001, ^compared with NPQ P < 0.05

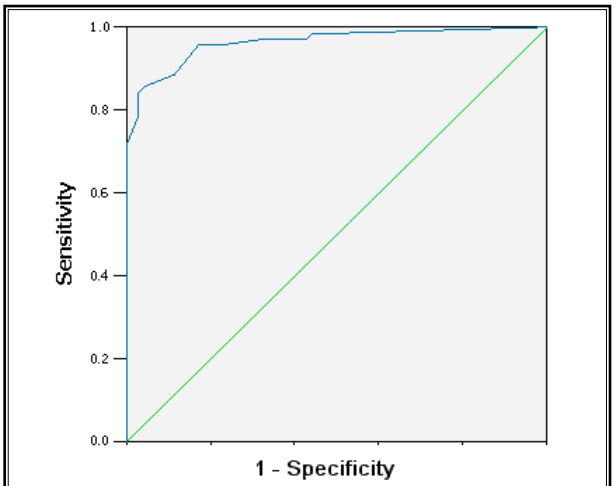

Fig.1. *ROC curve of LANSS.*

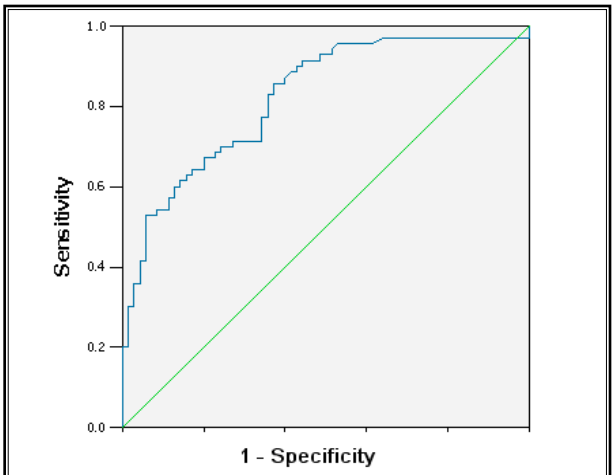

Fig.2. *ROC curve of NPQ*

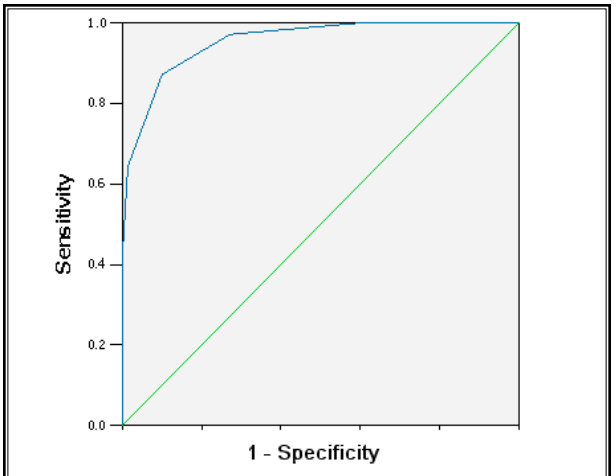

Fig.3. *ROC curve of ID pain.*

shown in Figs. 1-3.

3. Sensitivity, specificity, positive predictive value, and negative predictive value of the 3 questionnaires are shown in Table 6.
4. Canonical discriminant function coefficients of the Chinese version of NPQ are shown in Table 7.

Discussion

As an independent pain category, neuropathic pain is different from nociceptive pain both in etiology and clinical manifestation. The clinical manifestations of neuropathic pain are complex and variable, differing in the same patient at different stages of the disease. Early diagnosis and treatment often mean a better prognosis. However, current existing examinations, such as nerve conduction velocity and somatosensory evoked potential, do not have high specificity. Quantitative sensory testing with high specificity requires expensive equipment, while skin biopsy is not easily accepted by patients due to its traumatic feature. Clinicians need examinations that are easy to use and have high sensitivity and high specificity to diagnose neuropathic pain. Therefore, many neuropathic pain questionnaires such as LANSS, NPQ, ID Pain, DN4 (10), and others have been developed in recent years because they meet the requirements mentioned above.

Pain clinicians know that patients with neuropathic pain often describe their pain with very specific adjectives and descriptions, such as tingling pain, stabbing pain, electric pain, burning pain, etc. This population often presents with specific signs, such as allodynia and hyperalgesia. The investigation of Dubuisson and Melzack (11) and Boureau et al (12) confirmed that some vocabularies or questions describing pain could very accurately identify neuropathic pain, thus providing a theoretical basis for the development of questionnaires consisting of patients' symptoms and/or signs to diagnose neuropathic pain. In 1997, Galer and Jensen (13) developed the Neuropathic Pain Scale (NPS); however, it only differentiated postherpetic neuropathic pain from other pain diseases, and was unable to completely differentiate neuropathic pain from nonneuropathic pain. Since 2001, various questionnaires for diagnosing neuropathic pain have been developed and published. Some questionnaires simply contain symptoms; some other questionnaires also cover physical signs. Questionnaires that include both symptoms and signs have higher sensitivity and specificity, such as LANSS and DN4. These questionnaires can be filled out within a few minutes, do not require special tools and cost very

Table 6. *Sensitivity, specificity, positive and negative predictive values of the 3 questionnaires.*

	LANSS (score ≥ 12)	NPQ (score ≥ 0)	ID pain (score ≥ 1)	ID pain (score ≥ 2)	ID pain (score ≥ 4)
Sensitivity	80.0% (56/70)	52.9% (37/70)	97.1% (68/70)	87.1% (61/70)	41.4% (29/70)
Specificity	97.1% (68/70)	91.4% (64/70)	72.9% (51/70)	90.0% (63/70)	100% (70/70)
Positive predictive value	96.6% (56/58)	86.0% (37/43)	78.2% (68/87)	89.7% (61/68)	100% (29/29)
Negative predictive value	82.9% (68/82)	66.0% (64/97)	96.2% (51/53)	87.5% (63/72)	63.1% (70/111)

little. The sensitivity and specificity of most questionnaires range from 70% to 90% (3-5), similar to other examinations. However, all neuropathic pain questionnaires mentioned above were developed and validated in non-Chinese environments (English, French, etc.). Chinese versions should be developed and validated if the questionnaires are to be used with Chinese patients.

Before commencing our study, we obtained authorization from the original authors of LANSS, NPQ, and ID Pain. In China, the Chinese dialect varies, inclusive of the national Mandarin, between northern and southern regions in China. Culture and language differences throughout China enforced the decision to select 10 pain centers from all around China to cover and represent the various regions from north to south China; hence, the Chinese versions of the questionnaires developed and validated will be more reliable in terms of representation when applied across China in the future.

"Forward translation" and "backward translation" were strictly implemented during the development process of the Chinese versions of questionnaires to reduce deviation from the original questionnaires. During this process, a consensus was reached in terms of various confusing vocabularies. In addition, because of issues relating to skin pigmentation, descriptives such as "red or pink" can be understood by the appearance of respective rashes in paler skin tones, while "pink" would normally be overlooked and almost unobservable in skin with more yellowish hues; hence, the term "pink" was excluded from the final version.

Both neuropathic pain and nociceptive pain could suggest various diseases, sometimes making a clear diagnosis of neuropathic pain extremely difficult. Therefore, in our study design we selected 8 common and typical diseases for neuropathic pain and nociceptive pain to facilitate the research's quality control.

Table 7. *Canonical discriminant function coefficients of the Chinese version of NPQ.*

NPQ question number	Canonical discriminant function coefficients
1	0.010
2	0.015
3	-0.007
4	0.009
5	0.008
6	0.006
7	-0.013
8	-0.013
9	0.002
10	0.000
11	0.012
12	-0.006
Constant	-0.934

The validation of questionnaires is usually verified from 2 aspects, namely reliability and validity. Reliability refers to the degree of credibility of the questionnaires' testing results. The internal consistency of items in the questionnaires should also be high for better reliability. The commonly used testing indexes for reliability include Cronbach's Alpha coefficients and Guttman split-half coefficients. The higher the coefficients are, the higher the internal consistency will be. Normally, the value of coefficients should be above 0.7 to show

sound reliability. The values of both Cronbach's alpha coefficients and Guttman split-half coefficients for the Chinese versions of the LANSS, NPQ, and ID Pain questionnaires were all above 0.7, indicating that the reliability of all 3 questionnaires is good.

The validity of questionnaires could be analyzed from 2 aspects, namely face validity and content validity. The face validity usually means that experts from related areas will discuss the accuracy, professionalism, and practicability of the questionnaires. Pain experts from 10 research centers discussed and concluded that the face validity of 3 of our Chinese version questionnaires is good. The commonly used indicators for content validity include the area under the ROC curve, sensitivity, specificity, positive predictive value, and negative predictive value. The sensitivity and specificity won't be affected by the incidence rates, and the value ranges from 0 to 1. Values closer to 1 demonstrate better diagnostic accuracy. The positive predictive value refers to the percentage of patients truly suffering from related diseases among the positive test results, while the negative predictive value refers to the percentage of those who were not found suffering from related disease among the negative test results. Values for both range from 0 to 1. Generally, tests of higher sensitivity produce higher negative predictive value, while tests of higher specificity produce higher positive predictive value.

Completed by doctors, LANSS contains descriptors for both symptoms and physical signs. The Chinese version of LANSS (total score ≥ 12) had very high sensitivity and specificity (80.0% and 97.1%, respectively). The sensitivity and specificity of the English version of LANSS were 83% and 87%, respectively (3). The sensitivity and specificity of the Turkish version of LANSS were 89.9% and 94.2%, respectively (14). Currently Troponin I is a well-respected diagnostic indicator for acute myocardial infarction, with high sensitivity (about 75-80%) and specificity (about 86-88%). The Chinese version of LANSS has a much higher sensitivity and specificity than Troponin I (15). We can see that LANSS is an excellent tool for the diagnosis of neuropathic pain under multiple language environments.

Apart from a pain site marking diagram, there are only 6 questions in ID Pain, which is very quick and simple for patients to fill out, but the scoring standard is more complex. The scores are divided into 4 parts in the English version: very likely (score = 4 or 5); likely (score = 2 or 3); possible (score = 1); unlikely (score = 0 or –1)(5). We analyzed the sensitivity and specificity, taking scores of 1, 2 and 4 as the cut-off points (Table 7). The specificity was 100% when the score was ≥ 4 (score = 4 or 5), while the sensitivity was low, only 41.4%. The sensitivity (87.1%) and specificity (90.0%) were both high when the score was ≥ 2 (score = 2-5), while the sensitivity was high (97.1%) when the score was ≥ 1 (score = 1-5); specificity was slightly lower (72.9%). Our results generally coincided with the evaluation method of the original ID Pain; therefore, evaluation methods from the original scale could still be used in the Chinese version of the ID Pain scale.

NPQ is a questionnaire filled out by patients. The Chinese version of NPQ (score ≥ 0) had a sensitivity of 52.9% and a specificity of 91.4%, which was not so promising. The sensitivity and specificity of the English version of NPQ were 66.6% (which was higher than that of the Chinese version of NPQ) and 74.4% respectively (4). The reason may be that the final English version of NPQ consisted of 12 questions chosen from 32 questions, and that discriminant analysis was conducted for the 12 questions to calculate the canonical discriminant function coefficients of each question. The corresponding coefficients should be multiplied on the score of each question, substituted into the formula for calculation, and then the final score calculated to determine if the patient suffers from neuropathic pain. The coefficients and formula of the English version of NPQ were used in the score calculations of the Chinese version of NPQ; therefore, the low sensitivity of the Chinese version of NPQ is probably because the coefficients and the formula of the English version of NPQ were not applicable to Chinese patients. We have recalculated the discriminant coefficients for the Chinese version of NPQ (Table 7). When the cutoff point was set to 0.016, sensitivity and specificity based on the study population were 72.9% and 95.7% respectively. More samples are needed to further evaluate the sensitivity and specificity of the Chinese version of NPQ; however, generally they may be a little lower than the currently calculated values (72.9% and 95.7%). We presume that the sensitivity of the Chinese version of NPQ should be a little lower than those of the Chinese versions of LANSS and ID Pain, which need to be verified by further study.

The ROC curve reflects the balance between sensitivity and specificity. The area under the ROC curve is also an important indicator of the test's acuracy; the value ranges from 0.5 to 1. If the area under the ROC curve of is 0.5, it is deemed to be useless for diagnosis, which is also called reference line. The ideal value for the area

under the ROC curve is 1. Generally, it is believed that when the area under the ROC curve is between 0.5 and 0.7, its usefulness for diagnosis is low; when it is 0.7-0.9, it is of medium diagnostic value; when it is above 0.9, it has great diagnostic value (9). Mean values of the areas under the ROC curves of the Chinese versions of LANSS and ID Pain were both larger than 0.9, indicating the diagnostic value of the Chinese versions of LANSS and ID pain were high. The mean value of the area under the ROC curve of the Chinese version of NPQ was between 0.7 and 0.9, indicating that the diagnosis value of the Chinese version of NPQ was moderate. The closer the ROC curve is along the left line and the upper line, the higher the trial accuracy. The closer the ROC is along the opportunity line (45°diagonal), the lower the trial accuracy. The ROC curves of LANSS and ID Pain were closer to the left line and upper line, while the ROC curve of NPQ was closer to the opportunity line (Figs. 1-3). The areas under the ROC curves of LANSS and ID Pain were larger than that of NPQ ($P < 0.001$), while the difference between LANSS and ID Pain was not statistically significant ($P > 0.05$). All of the above suggested that the accuracy of the Chinese versions of LANSS and ID Pain was higher than that of the Chinese version of NPQ.

Considering the morphology of the ROC curves of the 3 questionnaires and the pair-wise comparison of the areas under the ROC curves (the areas under the ROC curves of LANSS and ID Pain were larger than that of NPQ, $P < 0.001$), our opinion is that as a diagnostic tool the current Chinese version of NPQ is not ideal enough. Further improvement of this questionnaire is desired. This part of our work will be reported in a later article.

The study was based on patients with high school degrees or above, which limited the application of the 3 neuropathic pain questionnaires in patients with lower education levels. Validation of LANSS, NPQ, and ID Pain in patients of various education levels needs to be performed in the future.

In summary, the Chinese versions of LANSS, NPQ, and ID Pain developed by this study have good reliability and face validity, and the content validity of the Chinese versions of LANSS and ID Pain were proven to be good by validation in multiple centers. The Chinese versions of LANSS and ID Pain are more reliable than NPQ when used for the diagnosis of neuropathic pain in Chinese patients. The validity of the Chinese version of NPQ needs to be reassessed.

Conclusion

The Chinese versions of LANSS and ID Pain developed and validated by this study can be used as a diagnostic tool in differentiating neuropathic pain in patients whose native language is Chinese (Mandarin).

Disclosures

Conflict of Interest: None.

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