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Journal of the Chinese Medical Association 81 (2018) 12−17

www.jcma-online.com

Original Article

Development and validation of a Taiwan version of the ID Pain questionnaire (ID Pain-T)

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Received March 30, 2017; accepted June 24, 2017

Abstract

Background: Neuropathic pain (NeP) is distinct from nociceptive pain and has different underlying mechanisms requiring specific treatment strategies. To aid diagnosis, self-administered screening questionnaires (such as ID Pain) have been developed to help physicians identify patients with NeP. The aim of this study was to develop and validate a translated ID Pain questionnaire for Taiwanese subjects (ID Pain-T).
Methods: ID Pain, a 6-item self-administered questionnaire, score ranged from −1 to 5, was translated from English into Mandarin Chinese using local terms and back-translated by an expert panel. A prospective, non-randomized, multi-center study was performed in four medical centers in Taiwan. Patients aged over 18 years with pain other than headache for more than 30 days in either neurology or pain clinic were prospectively recruited. They completed the ID Pain-T questionnaire themselves. The study investigators, blinded to the subjects' ID Pain-T scores, examined subjects using a standardized clinical and neurological diagnostic procedure. The ID Pain-T questionnaire scores were verified and validated.
Results: A total of 317 patients completed the study. Clinical diagnosis of NeP was given for 189 (60%) patients, mixed pain diagnosed in 7 (2%) patients, and nociceptive pain in 121 (38%) patients. The reliability and consistency of the ID Pain-T were acceptable, with a Cronbach's alpha value of 0.6. Statistical analysis of the ID Pain-T questionnaire calculated an optimal cut-off score of ≥2 for determining NeP with 77% sensitivity and 74% specificity for predicting NeP. Ordinary least squares regression analysis showed significant predictive accuracy of the ID Pain-T questionnaire for NeP ($P < 0.0001$). These results are comparable to other studies that have translated the ID Pain questionnaire into other languages.
Conclusion: This study provides evidence that the ID Pain-T questionnaire is a valid and reliable self-administered screening tool to identify NeP in Taiwanese patients.

Keywords: Neuropathic pain; Questionnaire; Taiwan

Conflicts of interest: Dr. Shuu-Jiun Wang has served on the advisory boards of Pfizer (Taiwan), Daiichi-Sankyo and Eli Lilly and has received honoraria as a panel discussion moderator from local companies (Taiwan branches) of Pfizer, Eli Lilly, Bayer and Eisai. Other authors declare that they have no conflicts of interest related to the subject matter or materials discussed in this article.

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https://doi.org/10.1016/j.jcma.2017.06.019

1. Introduction

Neuropathic pain (NeP) affects millions of people worldwide, and may be caused by a range of different diseases, injuries, and interventions resulting in lesions in the somatosensory pathways of the peripheral or central nervous system, which becomes manifest as a spectrum of signs and symptoms. This is distinct from nociceptive pain, which has different underlying mechanisms and treatment strategies.[1] The diagnosis of NeP is made through physiological and neurological examinations, based on patient history (i.e. if there is an identifiable syndrome), analysis of neurologic etiology, and perturbations in sensory functioning. In many cases, the diagnosis is challenging, and this may lead to difficulties in selecting the best therapeutic strategy for patients with NeP.[2,3] If patients with NeP are not diagnosed accurately, they may suffer from insufficient pain relief.[4]

Dysfunction of the nervous system resulting in pain may be detected as abnormalities during electrodiagnostic or imaging studies, quantitative sensory testing, or pathological examination of tissues.[2,5−7] Yet, there is a poor correlation between these findings and patients' reported experiences, as severe NeP can occur even in the absence of identifiable neural pathology.[8]

The Assessment Committee of the Neuropathic Pain Special Interest Group (NeuPSIG) of the International Association for the Study of Pain (IASP) has provided guidance on the definition and diagnosis of NeP in primary care. This international group redefined NeP in 2011 as “pain arising as a direct consequence of a lesion or disease affecting the somatosensory system either at peripheral or central level,” replacing the previous definition of “dysfunction” with “disease.”[9] This change makes it crucial to distinguish NeP from neuroplastic changes caused by nociceptive stimulation. In addition, “somatosensory system” is included to replace the term “nervous system” to distinguish pain caused by lesions in other parts of the nervous system. Although this revised definition may assist clinical diagnosis of NeP, there remains no consensus on the best diagnostic approach.[10−13] It has been proposed that NeP can be classified according to its level of certainty (possible, probable, or definite) by using a history-derived working hypothesis, neurological examination for somatosensory defects, and a minimum of one positive confirmatory test.[9]

To help with the diagnosis, a screening questionnaire may alert a physician to identify a patient with NeP based upon described pain.[9] There are several questionnaires that have been developed and validated to assess patients with NeP, such as the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS),[14,15] Neuropathic Pain Questionnaire (NPQ),[16,17] Douleur neuropathique en 4 questions (DN4),[18] painDETECT,[19] and ID Pain.[20]

Validation of these questionnaires needs to be in the language of the patients to whom it will be applied, so that it may offer guidance for further diagnostic evaluation and pain management in that specific population.[9] ID Pain has been translated into Mandarin Chinese,[21,22] Italian,[23] and Thai,[24] while DN4 has been validated in French,[25] Spanish,[26] and Thai,[27] and translated into at least 15 other languages.

Effective screening questionnaires should be brief and easy to use, and help to identify patients with NeP without too much aid from a clinician in the primary care setting. ID Pain is a simple, patient-self-administered 6-item questionnaire that discriminates between neuropathic and nociceptive pain, consisting of five sensory items, and one item asking whether the pain is limited to the joints.[20] Its strength lies in the fact that it was developed in a mixed pain population that was large and very diverse, with patient samples drawn from university-hospitals and community-based populations, as opposed to single-center subjects experiencing NeP or nociceptive pain.[20] It has been well validated and widely used in the primary care setting for NeP screening.

The aim of this study was to develop a Taiwanese version of ID Pain (ID Pain-T) to identify NeP and validate it in Taiwanese subjects in a primary clinical care setting.

2. Methods

2.1. Study design and methods

This prospective, non-randomized, multicenter study was approved by the institutional review boards (IRBs) in the four medical centers in Taiwan where the study was conducted. A qualified nurse experienced in pain care translated the original English 6-item Identification (ID) Pain questionnaire into Mandarin Chinese using local terms. The translated version was then back-translated into English by an independent bilingual researcher who compared it with the original version for clarity and comprehension. The Mandarin Chinese version of the questionnaire (ID Pain-T) was finalized and validated by an expert panel.

2.2. Patient inclusion and exclusion criteria

Patients with pain other than headache for more than 30 days were included in the study if they were male or female aged over 18 years, were able to complete the ID Pain-T questionnaire, had not participated in another pain study within the past 30 days, had no evidence of unstable medical or psychosocial conditions, and had no experience of lower back pain, sciatica caused by piriformis, unclear identification of nerve injury, or mixed-origin pain (e.g. cancer pain).

2.3. ID Pain-T questionnaire analysis

Eligible subjects were enrolled into the Neurology or Pain Outpatient Clinic of each center to participate in the study. Subjects provided written informed consent after a thorough explanation of the purpose and detailed procedure of the study. The subjects completed the ID Pain-T questionnaire themselves in a waiting room, and returned it to the study nurse in a sealed envelope. In the ID Pain-T questionnaire, “Yes” answers to Questions 1−5 were given a score of 1, while a “Yes” answer to Question 6 scored −1. “No” answers were given a

score of 0. Higher total scores of the ID Pain-T questionnaire indicated the likelihood of a neuropathic pain component.

The study investigators were blinded to the subjects' ID Pain-T score, and examined subjects using a standardized clinical and neurological diagnostic procedure. Each patient's diagnosis was classified into neuropathic pain, nociceptive pain, or mixed pain. These three categories were grouped into neuropathic pain (NeP) (the neuropathic and mixed pain groups), and nociceptive (non-NeP) pain for further analysis.

2.4. Outcome measures and statistical methods

Correlation between the investigators' clinical diagnosis and ID Pain-T questionnaire scores was measured. A receiver operating characteristics (ROC) curve was used to determine the optimal cut-off point of the questionnaire for correct prediction and positive diagnosis of NeP expressed by sensitivity and specificity.

The c index is the sum of sensitivity and specificity, and the maximum c value was considered as the optimal cut-off point. After determining the cut-off point, the results of the questionnaire were used to evaluate significant differences between NeP diagnosed clinically and NeP identified by the ID Pain-T questionnaire based on chi-squared test. In addition, for the ROC curve, the area under the curve (AUC) was calculated to provide the predictive power of the questionnaire for the diagnosis of NeP.

The ability of the score to predict pain type (i.e. NeP and non-NeP) was assessed by regressing the scores on the diagnostic pain category using ordinary least-squares regression. The reliability and inter-item consistency of the ID Pain-T questionnaire was evaluated using Cronbach's alpha coefficient.

3. Results

3.1. Patient demographics and baseline characteristics

A total of 330 patients were screened at four medical centers. During the study, three subjects failed screening, while ten subjects left some items blank on the ID Pain-T questionnaire. Therefore, a total of 317 patients were considered eligible for the final analysis.

The neurologists or pain specialists diagnosed 189 (60%) of 317 patients as having neuropathic pain, 7 (2%) patients with mixed pain, and 121 (38%) patients with nociceptive pain. A summary of the pain diagnosis is provided in Table 1. The most prevalent pain diagnosis in the neuropathic pain group was post-herpetic neuralgia (22%). For the nociceptive pain group, the most common diagnosis was myofascial pain (64%), followed by osteoarthritis (34%).

3.2. Correlations between clinical diagnosis and ID Pain-T questionnaire total score

The most frequent score for the nociceptive pain group was 1, the most frequent score for the mixed pain group was 2, and the most frequent score for the NeP group was 3 (Table 2). Box plots of the three classifications of pain demonstrated the mean score for the neuropathic pain group being higher than that for mixed and nociceptive pain, with similar levels of variability (Fig. 1).

Table 1
Frequencies of clinical pain diagnosis by investigators.

Pain diagnosis	Neuropathic pain (N = 189)	Mixed pain (N = 7)	Nociceptive pain (N = 121)
Diabetic neuropathy	32 (17%)	2 (29%)	0 (0%)
Osteoarthritis (arthropathy)	0 (0%)	2 (29%)	41 (34%)
Myofacial pain (soft tissue pain)	0 (0%)	1 (14%)	78 (64%)
Post-herpetic neuralgia	41 (22%)	0 (0%)	0 (0%)
Trigeminal neuralgia	32 (17%)	0 (0%)	0 (0%)
Radiculopathy (spondylosis)	11 (6%)	0 (0%)	0 (0%)
Multiple sclerosis	8 (4%)	0 (0%)	0 (0%)
Stroke	6 (3%)	1 (14%)	0 (0%)
Small fiber neuropathy	15 (8%)	0 (0%)	0 (0%)
Others	46 (24%)	5 (71%)	4 (3%)

Table 2
ID Pain-T scores classified according to clinical pain diagnosis.

Score	Pain type		
	Neuropathic (N = 189)	Mixed (N = 7)	Nociceptive (N = 121)
−1	0 (0%)	0 (0%)	17 (14%)
0	14 (7%)	1 (14%)	32 (26%)
1	29 (15%)	1 (14%)	40 (33%)
2	45 (24%)	3 (43%)	20 (17%)
3	58 (31%)	2 (29%)	10 (8%)
4	26 (14%)	0 (0%)	2 (2%)
5	17 (9%)	0 (0%)	0 (0%)

The three pain categories designated by the neurologists or pain specialists were further grouped into neuropathic pain (NeP) (neuropathic pain and mixed pain), or non-neuropathic pain (non-NeP) (nociceptive pain) (Table 3).

3.3. Receiver operating characteristics (ROC) curve

The optimal cut-off was a score of 2, as determined by the maximum c index value of 1.51 (Table 4). The c index is a measure of discrimination and is a function of sensitivity and specificity, with the maximum of c considered the optimal cut-off point.[30,31] An area under the curve (AUC) value of 0.82 was considered as the predictive power of ID Pain-T for diagnosis of NeP. Therefore, patients who scored <2 were predicted to have non-NeP, and patients who scored ≥2 were predicted to have NeP (Fig. 2).

3.4. Sensitivity and specificity of ID Pain-T questionnaire

There were 151 patients who were diagnosed with NeP with a score of ≥2 both clinically by a physician, and with the ID Pain-T questionnaire, giving a sensitivity of 77%. In comparison, there were 89 patients who were diagnosed with

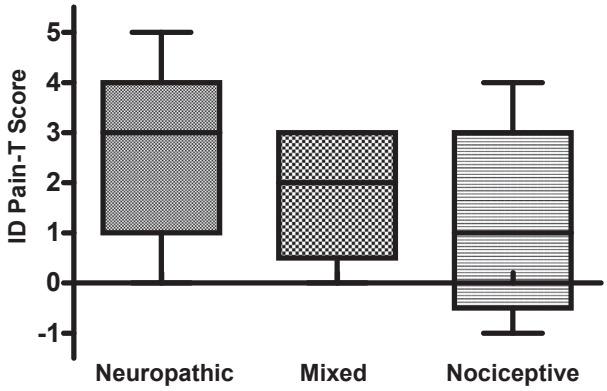

Fig. 1. Box plots of ID Pain-T Scores for patient groups clinically diagnosed with neuropathic, mixed, and nociceptive pain. Patients were diagnosed clinically and categorized into neuropathic, mixed, or nociceptive pain groups. The mean (±SD) ID Pain-T scores were presented for each group. The mean score for the neuropathic pain group was higher than those for the mixed pain group and the nociceptive group.

Table 3
The distinction between neuropathic and non-neuropathic pain diagnosis for different ID pain-T scores.

Score	Pain type		P^a
	NeP	Non-NeP	
−1	0 (0%)	17 (14%)	<0.001[a]
0	15 (8%)	32 (26%)	
1	30 (15%)	40 (33%)	
2	48 (24%)	20 (17%)	
3	60 (31%)	10 (8%)	
4	26 (13%)	2 (2%)	
5	17 (9%)	0 (0%)	
Total	196 (100%)	121 (100%)	

NeP = neuropathic pain.
[a] Chi-square test was used for categorical variables.

Table 4
ROC curve analysis to determine optimal cut-off score for ID pain-T.

Total score	Sensitivity	Specificity	Index c	AUC
−1	1.00	0.00	1.00	0.82
0	1.00	0.14	1.14	
1	0.92	0.40	1.33	
2	0.77	0.74	1.51	
3	0.53	0.90	1.43	
4	0.22	0.98	1.20	
5	0.09	1.00	1.09	

AUC = area under the curve.

non-NeP both clinically and by the ID Pain-T questionnaire, giving a specificity of 74%. These results suggest that the ID Pain-T questionnaire is statistically as good as clinical diagnosis by neurologists or pain specialists for accurate discrimination of NeP and non-NeP (Table 5).

The ability of the ID Pain-T questionnaire score to predict pain type (i.e. NeP and non-NeP) was assessed by regressing the scores on the diagnostic pain category using ordinary least-squares regression. Analysis revealed that the ability of the ID Pain-T score to predict the pain types was statistically significant ($P < 0.0001$), and the concordance was 0.746, with discordance of 0.115. These results indicate that the ID Pain-T provides statistically significant prediction accuracy.

The reliability and inter-item consistency of the ID Pain-T questionnaire was evaluated using Cronbach's alpha coefficient. The ID Pain-T proved to be reliable as indicated by a Cronbach's alpha value of 0.6 (values of 0.6–0.7 are considered acceptable for reliability).

4. Discussion

The ID Pain questionnaire is specifically designed as a self-administered screening tool to aid in the identification of patients suffering from NeP. As the ID Pain questionnaire was originally developed in English, there may be cultural and language differences, as well as potential differences in clinical characteristics that need to be considered.

In this study, the questionnaire was translated into Mandarin Chinese using local terms, then back-translated and validated by an expert panel, with the aim of applying it to Taiwanese subjects. The results from this large multi-center study in 317 evaluable patients (the largest study to date for a Chinese translation of the ID-Pain questionnaire, where previous studies by Li et al.[21] and Chan et al.[22] recruited 140 and 92 subjects, respectively), demonstrated that the ID Pain-T was valid, with a sensitivity of 77% and specificity of 74% when a cut-off score of ≥2 was applied.[22] This was comparable when a similar cut-off score of ≥2 provided 87% sensitivity and 90% specificity for a Mandarin Chinese version (Mainland China) of the ID Pain questionnaire.[21] In the Chinese ID Pain questionnaire study conducted in Hong Kong with a cut-off score of ≥3,[22] the results gave a 81% specificity and 65% sensitivity. Assessment of Cronbach's alpha coefficient to test for reliability demonstrated a score of 0.6 for this current study, which is within the acceptable range (0.6–0.7) for reliability and was marginally lower than the value of 0.76 for the Hong Kong study. These results are similar to those of studies on other ID-Pain questionnaire translations into Thai and Italian, where similar sensitivity and specificity levels were obtained.[23,24] Reliability and validity measurements are used to confirm the validation of questionnaires. Cronbach's alpha coefficient values above 0.7 are considered good reliability scores for ID Pain questionnaires. As the ID Pain questionnaire is intended as a screening tool, it may be more desirable to take a more cautious approach, and set a lower cut-off score to increase the sensitivity of the questionnaire and reduce the likelihood that a patient with NeP is not identified.

Other questionnaires available for screening patients with NeP involve an interview with a physician, but this can introduce bias. The ID Pain-T questionnaire has shown specificity and sensitivity for identifying NeP comparable with those of the LANSS Pain Scale[14,32] and Neuropathic Pain Questionnaire (NPQ).[33] The NPQ is a 12-item self-questionnaire that does not include a sensory examination and contains questions that may be less specific for NeP, which may explain the modest sensitivity and specificity values associated with this questionnaire.[33] Indeed, a direct comparison between ID Pain, NPQ and LANSS questionnaires with a Chinese version demonstrated that the

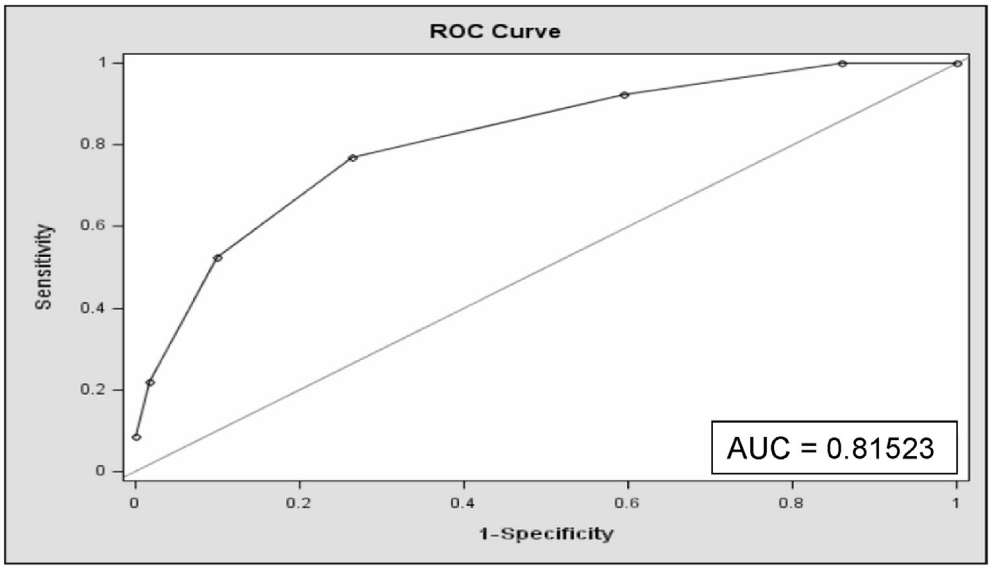

Fig. 2. Receiver operating characteristics (ROC) curve for ID Pain-T questionnaire. A receiver operating characteristics (ROC) curve was used to determine the optimal cut-off point of the ID Pain-T questionnaire. The ROC curve illustrates the difference between the performance of the ID Pain-T questionnaire and a theoretical toll representing chance alone plotted along a 45° diagonal. Results show an AUC value of 0.81523.

Table 5
Statistical analysis comparing clinical diagnosis and ID Pain-T Questionnaire for neuropathic pain.

Predictive result	Diagnosis		
	NeP	Non-NeP	*P*
NeP	151 (77%)	32 (26%)	<0.001[a]
Non-NeP	45 (23%)	89 (74%)	

NeP = neuropathic pain.
[a] Chi-square test.

LANSS and ID Pain questionnaires were significantly better screening tools than NPQ.[21] The question relating to the color of the skin in the painful area has the highest weighting, but this may be inaccurate if the questionnaire is used in patients with variations in skin coloration.[14] The S-LANSS questionnaire was developed as a self-assessed shortened version of the LANSS questionnaire, and showed sensitivity ranging from 74% to 78%, depending on the cutoff score, which was similar to the results obtained for ID Pain-T.[32] The S-LANSS questionnaire has been translated for patients in Turkey[34] and Libya,[35] both translations yielded results comparable to those of the original S-LANSS questionnaire. The painDETECT questionnaire is another brief, self-administered questionnaire that has been successfully translated into Spanish[28] and Dutch.[29] The advantages of using self-administered questionnaires are that they can provide a quick and simple screening process to aid physicians' diagnosis of NeP and, for research purposes, may be a useful tool in determining NeP in the wider population as they can be completed and returned by post by patients from home.

Our study showed that the ID Pain-T questionnaire was a useful screening tool for identifying patients with NeP, but it is important to note that the diagnosis of NeP requires clinical examination and testing. With a revised definition provided by the NeuPSIG of the IASP, a consensus approach may be developed in defining and diagnosing NeP in the clinic.[9] Other diagnostic tools may be available to the physician, such as quantitative sensory testing, nerve conduction velocity, somatosensory evoked potential, imaging, electrodiagnostic evaluation, and skin biopsies,[2,5−7] although these may only be available in medical centers with state-of-the-art facilities.

In conclusion, the results from this study provide evidence that the translated Taiwan version of the ID Pain questionnaire is a valid and reliable self-administered screening questionnaire to identify NeP in Taiwanese patients, especially when used in conjunction with a combination of clinical and laboratory examinations for identifying damage to the somatosensory pathway for a conclusive diagnosis. The ID Pain-T may be particularly useful as a routine self-administered screening tool, increasing awareness of NeP and facilitating communication between patients and clinicians. In this study, although there were adequate numbers of patients in the NeP and non-NeP groups to provide statistical analyses, there were fewer patients in the mixed-pain group (n = 8). Further studies with a larger mixed-pain patient population would be beneficial to understand the usefulness of the ID Pain-T questionnaire in this population.

4.1. Future prospects for the ID Pain-T questionnaire

NeP is typically classified according to the underlying cause of the disorder, the anatomical pain of the specific lesion, or its level of uncertainty (possible, probable, or permanent).[9,36] Diabetic neuropathic pain is the most common form of neuropathic pain.[37] Numerous questionnaires have been developed for evaluating patients with NeP, such as the DN4,[38] ID Pain,[20] LANSS,[14,15] NPQ,[16,17] and painDETECT.[19] However, a reliable guideline for the screening and diagnosis

of diabetic neuropathy or neuropathic pain in Taiwan remains lacking. In light of the increasing prevalence of diabetes in Taiwan, developing an effective guideline for screening diabetic neuropathy warrants immediate attention. The ID Pain questionnaire is advantageous in the primary care setting because it is brief, simple, and easy to understand and can be completed by patients alone without help from a physician. The results of this study showed that the translated Taiwan version of ID Pain demonstrates favorable validity and reliability, making it a promising instrument for the screening and diagnosis of diabetic neuropathy in clinical applications.

Acknowledgments

This study was sponsored by Pfizer, Taiwan. The study code is A0081175 (TWN-2008-CNS-001). The authors are responsible for all of the study results.

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