Development and validation of a Taiwan version of the DN4-T questionnaire

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Abstract

Background: Neuropathic pain (NeP) is often under-recognized, resulting in poor pain management. Therefore, a Taiwan version of the 10-item Douleur Neuropathique 4 (DN4-T) questionnaire was developed to identify patients with NeP from a mixed population of patients with pain.

Methods: A prospective, nonrandomized, multicenter study was conducted in the Neurology Departments of four Taiwanese medical centers, to develop and validate the DN4-T questionnaire as a diagnostic tool for identifying patients with NeP. Patients who experienced pain for >30 days were classified as having neuropathic, nociceptive, or mixed pain. Patients and physicians also completed the DN4-T questionnaire. The DN4-T scores were assessed with the optimal cut-off score calculated using a receiver operating characteristics (ROC) curve, and sensitivity and specificity assessed and reliability determined statistically using the Cronbach alpha coefficient.

Results: Of the 318 patients who completed the DN4-T questionnaire, 189 patients were diagnosed with NeP, seven patients with mixed pain, and 122 patients with nociceptive pain. For statistical analysis, patients were categorized as having NeP (those with neuropathic pain and mixed pain) or non-neuropathic (nociceptive) pain (non-NeP). Using an optimum DN4-T cut-off score of ≥3 (ranging from 0 to 10, determined by a maximum c index value of 1.54), DN4-T scores provided a sensitivity of 0.77 and specificity of 0.78, for predicting NeP. The predictive power of DN4-T in diagnosing NeP was 0.83 (as determined by area under the curve of the ROC curve), and was significantly predictive of pain type ($p < 0.0001$) with a concordance of 0.785, a discordance of 0.129, and a Cronbach alpha coefficient of 0.7, suggesting that the DN4-T questionnaire is a useful predictive tool for diagnosing NeP.

Conclusion: The DN4-T questionnaire has been reliably translated into Mandarin Chinese and can be used as a diagnostic tool for NeP in conjunction with clinical evaluation.

Keywords: DN4; Neuropathic pain; Questionnaire; Taiwan

1. INTRODUCTION

Chronic pain is a debilitating condition that can affect approximately 5% to 8% of the world's population.[1] Accurate assessment and diagnosis are essential for determining treatment, particularly as this can be an underlying symptom of a number of debilitating diseases such as diabetes, arthritis, fibromyalgia, and other chronic inflammatory conditions. Patients may present with one of the three major pain categories: neuropathic, nociceptive, or mixed pain. Neuropathic pain (NeP) is caused by a lesion or disease to nervous tissues that affects the somatosensory system,[2,3] and is distinct from nociceptive pain, which is more easily classified as the pain signal is transmitted from injured tissue such as fractures, tissue injury, and inflammation. In contrast, mixed pain is caused by a combination of neuropathic and nociceptive pain, where the neuropathic component may initiate neural inflammatory processes leading to nociceptive pain.

There is currently no conclusive test for identifying NeP. Clinicians assess a combination of the patients' medical history, physical and neurological examinations, and radiological and electrodiagnostic findings to identify NeP.[1,4] There is a potential for improvement in identifying patients with NeP, which is currently under-recognized and under-treated.[5,6] Establishing accurate diagnoses of different pain categories is mandatory, so that targeted therapeutic interventions can be administered.[7]

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To help clinicians identify patients with NeP, several pain assessment questionnaires have been developed with varying levels of sensitivity and specificity. Pain is subjective and pain questionnaires based on verbal patients' description may provide a useful diagnostic tool.[8] Questionnaires can be used by pain specialists, general practitioners, and nurses to differentiate NeP from non-neuropathic pain, such as Leeds Assessment of Neuropathic Symptoms and Signs (LANSS), neuropathic pain questionnaire (NPQ), Pain DETECT, ID-Pain, STEP, McGill Pain Questionnaire and Brief Pain Inventory.[9–17]

In 2005, the Douleur Neuropathique 4 (DN4) questionnaire was developed by the French Neuropathic Pain Group. This was a 10-item questionnaire completed in the presence of a clinician, who compared signs and symptoms in patients with chronic pain associated with neurological (peripheral or central)[16] or somatic tissue injuries. DN4 was a series of four groups of questions consisting of seven sensory descriptors (burning, painful cold, electric shock, tingling, pins and needles, numbness, and itching), and three signs related to a sensory physical examination of the painful area (tactile hypesthesia, pinprick hypesthesia, and allodynia).[16] The DN4 questionnaire was shown to be a useful tool for discriminating NeP from nociceptive pain in a French-speaking population. Nevertheless, for this questionnaire to be an effective tool globally, the 10-item questionnaire needs to be translated into other languages using a standardized process, whilst considering cross-cultural adaptation, psychometric validation, and colloquial terms used to describe pain.[18] The DN4 questionnaire has been culturally adapted and translated into several languages,[7,19–25] and a meta-analysis of NeP screening questionnaires showed that it was the most suitable for clinical evaluation of NeP.[26]

The aim of this current study was to develop and validate a Taiwanese version of the DN4 (DN4-T) questionnaire in a mixed pain patient population, across four Taiwanese medical centers for the diagnosis of NeP.

2. METHODS

2.1. Study design and methods

This was a prospective, nonrandomized, multicenter study conducted in the Neurology Departments of four medical centers in Taiwan, to evaluate the validity of an interview-based, DN4 questionnaire, and to determine whether this could be used as a diagnostic tool for NeP.

A pain specialist translated the DN4 questionnaire into Mandarin Chinese, ie, DN4-T, to be used in Taiwan. An independent bilingual researcher back-translated the questionnaire into English and compared it with the original version for comprehension and clarity. The Taiwan version of the DN4 questionnaire was then validated and finalized by an expert panel.

2.2. Patient inclusion and exclusion criteria

Patients recruited from the Neurology Departments were clinically assessed by performing general, neurological, and musculoskeletal examinations, to identify locations and characteristics of pain.

Patients with pain (other than headache) for >30 days were included in the study if they were over 18-years-old, had not within the past 30 days taken part in another pain study, were able to complete the DN4-T questionnaire, had no signs of psychosocial or unstable medical conditions, had no experience of piriformis-induced sciatica, lower back pain, nerve injury of undetermined location and etiology, or mixed origin pain (eg, cancer pain). The patient's pain was then classified as neuropathic, nociceptive, or mixed pain. Eligible subjects were enrolled after providing written informed consent following a thorough explanation of the purpose and detailed procedure of the study.

2.3. DN4-T questionnaire analysis

The subjects answered the seven questions regarding pain symptoms in the DN4-T questionnaire in the presence of a physician, with "Yes" answers giving a score of 1, and "No" answers scored as 0. The remaining three items were assessed by the clinician. The total scores ranged from 0 to 10, and higher scores were indicative of pain with a neuropathic component.

The clinical diagnoses were classified into NeP, nociceptive pain, and mixed pain. These three categories were further grouped into NeP (combining the neuropathic and mixed pain groups) and non-NeP (nociceptive) pain for statistical analysis.

2.4. Assessment of outcome measures and statistical methods

Analyses were performed to examine the association of the results from the DN4-T questionnaire with the clinical diagnosis, and to determine the optimal cut-off point using a receiver operating characteristics (ROC) curve for predicting the positive diagnosis of NeP. Index c was calculated from the sum of the sensitivity and specificity, with the maximum c value being the optimal cut-off point. NeP or non-NeP was predicted using the DN4-T questionnaire cut-off point, and the differences between physician's diagnosis and the DN4-T questionnaire was performed using χ^2 test.

Interitem consistency and reliability of the DN4-T questionnaire was measured by Cronbach's coefficient alpha.

3. RESULTS

3.1. Patient demographics and baseline characteristics

In total, 330 patients were screened. Overall, 318 patients and their physicians completed the DN4-T questionnaire (three subjects failed screening, and nine subjects were excluded for missing at least one item). The participating patients were assessed by neurologists or pain specialists with 189 (59%) diagnosed with NeP, seven (2%) patients with mixed pain, and 122 (38%) patients with nociceptive pain. Pain diagnosis is summarized in Table 1. Postherpetic neuralgia (21%) was the most common diagnosis in the NeP group, while myofascial pain (65%) followed by osteoarthritis (34%) were the most common diagnoses in the nociceptive pain group.

To perform further statistical analyses, the patients were categorized into NeP group (consisting of patients with NeP and

Table 1

Diagnosis in the three pain groups of patients under DN4-T evaluation

Pain diagnosis	Neuropathic pain (N = 189)	Mixed pain (N = 7)	Nociceptive pain (N = 122)
Diabetes mellitus	33 (17%)	2 (29%)	0 (0%)
Osteoarthritis (arthropathy)	0 (0%)	2 (29%)	41 (34%)
Myofacial pain (soft tissue pain)	0 (0%)	1 (14%)	79 (65%)
Postherpetic neuralgia	39 (21%)	0 (0%)	0 (0%)
Trigeminal neuralgia	34 (18%)	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	14 (7%)	0 (0%)	0 (0%)
Others	46 (24%)	5 (71%)	4 (3%)

DN4-T = Douleur Neuropathique 4 questionnaire.

mixed pain) and non-NeP group (containing patients with nociceptive pain).

3.2. Correlation between clinical diagnosis and DN4-T questionnaire score

In the non-NeP group, the most frequent score was 0, while in the NeP group (mixed and neuropathic pain group), scores of 3 to 5 were the most commonly reported (Fig. 1). Variability in DN4-T scores across the three classifications of pain were similar.

The scores for the NeP group were significantly higher than those for the non-NeP group ($p < 0.001$; Fig. 2). Statistical analysis showed a higher frequency of DN4-T scores with a cut-off point ≥3 in the NeP group (150 [77%] of 196 patients) vs the non-NeP group (27 [17%] of 122 subjects; $p < 0.001$) (Table 2).

3.3. Calculating the cut-off score for predicting NeP using the DN4-T questionnaire

To determine the optimal cut-off score of the DN4-T questionnaire for predicting NeP, a ROC curve was used to predict a positive diagnosis of NeP expressed by sensitivity and specificity. The optimal cut-off point was determined using the maximum index c value (sum of sensitivity and specificity).[27,28] The optimal cut-off was a score of 3, as determined by a maximum c index value of 1.54. The predictive power of DN4-T for diagnosis of NeP was 0.83 as determined by the area under the curve (AUC) value.

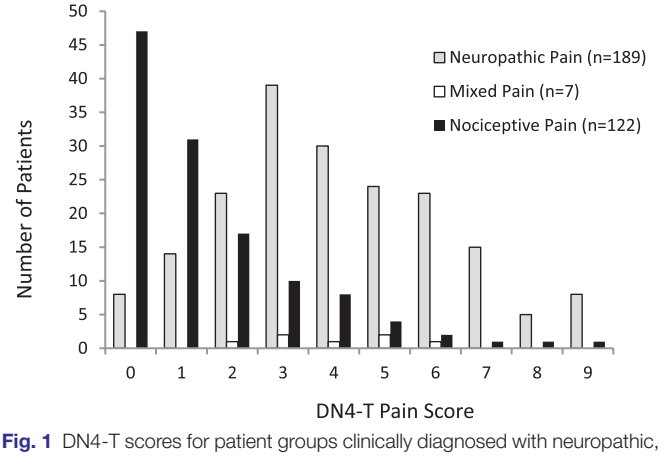

Fig. 1 DN4-T scores for patient groups clinically diagnosed with neuropathic, mixed, and nociceptive pain. Patients were clinically diagnosed and categorized into neuropathic, mixed, or nociceptive pain groups. The number of patients for each DN4-T score was presented for each pain group. In the neuropathic pain group, the highest incidence was in the Score 3 group, whereas in the nociceptive pain group, the highest frequency was in the Score 0 group. DN4-T, Taiwanese version of the Douleur Neuropathique 4 questionnaire.

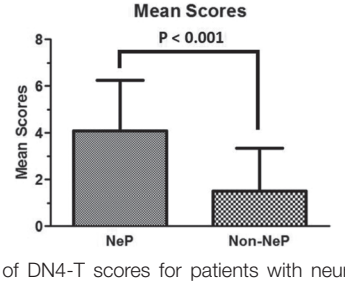

Fig. 2 Box plots of DN4-T scores for patients with neuropathic and non-neuropathic pain. Patients were clinically diagnosed and categorized into NeP (neuropathic and mixed pain), or non-NeP (nociceptive) pain groups. The mean DN4-T score for the NeP group was significantly higher than that for the non-NeP group. DN4-T, Taiwanese version of the Douleur Neuropathique 4 questionnaire.

Table 2

The distribution of DN4-T score between neuropathic and non-neuropathic pain diagnoses

	Pain type		
Score	NeP	Non-NeP	*p*
0	8 (4%)	47 (39%)	<0.001*
1	14 (7%)	31 (25%)	
2	24 (12%)	17 (14%)	
3	41 (21%)	10 (8%)	
4	31 (16%)	8 (7%)	
5	26 (13%)	4 (3%)	
6	24 (12%)	2 (2%)	
7	15 (8%)	1 (1%)	
8	5 (3%)	1 (1%)	
9	8 (4%)	1 (1%)	
10	0 (0%)	0 (0%)	
Total	196 (100%)	122 (100%)	

DN4-T = Taiwanese version of the Douleur Neuropathique 4 questionnaire; NeP = neuropathic pain; Non-NeP = non-neuropathic (nociceptive) pain.
*χ^2test or Fisher's exact test was used when appropriate.

3.4. Sensitivity and specificity of the DN4-T questionnaire

The DN4-T questionnaire was shown to be reliable as indicated by a Cronbach alpha coefficient of 0.7 (values of 0.6 to 0.7 are considered acceptable for reliability). When a DN4-T score of ≥3 was used to determine NeP, the sensitivity was 0.77 and specificity was 0.78 (Table 3). Ordinary least-square regression showed that the DN4-T questionnaire score was significantly predictive of NeP vs non-NeP ($p < 0.0001$), with a concordance of 0.785 and discordance of 0.129, suggesting that it is a useful predictive tool for determining NeP and non-NeP, similar to clinical diagnosis by neurologists or pain specialist.

4. DISCUSSION

Clinical evaluation of NeP is a complex process requiring a combined assessment of a patients' medical history, along with a number of neurological and physical examinations. The development and implementation of questionnaires such as DN4 are very useful in the diagnosis and treatment of NeP. There are a number of other different self-administered and healthcare professional-guided pain questionnaires, but in a meta-analysis study, the DN4 questionnaire was identified as the most suitable pain questionnaire for the clinical diagnosis of NeP, giving a relatively high sensitivity and specificity.[26] The results from this large, multicenter study of 318 evaluable patients showed

Table 3

Significant correlation between clinical diagnosis and DN4-T questionnaire scores ≥3 for neuropathic pain

	Clinical diagnosis		
DN4-T score ≥ 3	NeP	Non-NeP	*p*
NeP	150 (77%)	27 (22%)	<0.001*
Non-NeP	46 (23%)	95 (78%)	

DN4-T = Taiwanese version of the Douleur Neuropathique 4 questionnaire; NeP = neuropathic pain; Non-NeP = non-neuropathic (nociceptive) pain.
*χ^2 test.

Table 4

Comparisons of different languages of DN4 cut-off scores for evaluation of neuropathic pain

Language	Total number of evaluable patients	DN4 cut-off score (10 items)	AUC	Sensitivity	Specificity
Mandarin (Taiwan)[a]	318	3	0.83	77	78
Spanish[7]	158	4	0.85	79.8	78
Arabic[19]	195	5	0.97	93	95.8
Korean[20]	83	4	0.95	87.1	94.1
Farsi[21]	175	4	0.97	90	95
Dutch[22]	248	5	0.82	75	79
Portuguese[23]	101	4	0.97	100	93.2
French[16]	160	4	0.92	82.9	89.9
Greek[24]	237	4	0.89	89	78
Turkish[25]	180	4	0.97	95	96.6

[a]DN4-T results from the current study.

AUC = area under the curve; DN4-T = Taiwanese version of the Douleur Neuropathique 4 questionnaire.

that when patients were grouped according to the presence or absence of NeP, there was a significantly higher DN4-T score in NeP patients than in those with non-NeP ($p < 0.001$), with a sensitivity of 0.77 paired with a specificity of 0.78 at a cut-off score of ≥3. The DN4-T questionnaire was shown to have good reliability according to the Cronbach alpha score of 0.7, indicating its usefulness as a diagnostic tool for the clinical diagnosis of NeP.

Our study results were similar to those obtained from other DN4 questionnaires translated into Spanish, Arabic, Korean, Farsi, Dutch, Portuguese, Greek, and Turkish.[7,19–25] High levels of specificity and sensitivity were observed in all these translated DN4 questionnaires, showing its robust ability to be translated, and its effectiveness at diagnosing NeP across multiple languages (Table 4). Even when different cut-off DN4 scores were taken (there was one country with a cut-off Score of 3, seven countries with a Score of 4, and two countries with a Score of 5 [Table 4]), the sensitivity and specificity of the DN4 questionnaire for distinguishing between NeP and non-NeP remained high (ranging from 75% to 100% and 78% to 95.8%, respectively).[7,19–25]

The variation in the range of specificity and sensitivity recorded for the translated DN4 questionnaires may be due to a number of factors involved in the validation process. Translation of a questionnaire from languages of widely different cultures requires expertise from healthcare professionals and linguistics experts, as well as validation by clinical researchers, pain management specialists, and physicians for both the translated and back-translated languages.

Differences in the recruitment and inclusion criteria of the patient populations in these studies may influence DN4 questionnaire outcomes. In some studies, patients were exclusively recruited from pain clinics,[7,20,21] whereas in others, the patients were attending pain clinics for the first time.[19,22,23] Patients who had been evaluated and followed by pain specialists may have been more familiar with NeP terminology and respond to the DN4 questions more accurately than those patients who were included at their first visit. This may introduce bias into the overall DN4 questionnaire scores.

NeP has been previously defined as "pain arising as a direct consequence of a lesion or disease affecting the somatosensory system" by the International Association for the Study of Pain.[3] A recent review of the literature in 2016 proposed that NeP can be classified using a revised grading system, and the clinical diagnoses of NeP may be classified as possible, probable, or definite, according to the extent of the clinical evaluation.[29] NeP can be confirmed if diagnostic tests confirm a lesion or disease of the somatosensory nervous system as the cause of pain.[29] Ideally, a gold standard diagnosis for NeP would be readily available; however, the most appropriate criteria for defining NeP remains to be determined.

One of the limitations of the present study is the lack of a diagnostic algorithm consistent across different study sites. Ideally, the diagnosis of NeP would rely on a comprehensive diagnostic evaluation, including clinical history, neurologic examination, quantitative sensory testing, and additional diagnostic tools, such as electrodiagnostic studies, magnetic resonance imaging, and appropriate laboratory tests. However, this is sometimes not feasible due to time and resource constraints. Second, intra- and inter-rates reliabilities were not evaluated in the present study. Nevertheless, these were confirmed in prior studies, and should not be an important concern in the implementation of DN4-T in the clinical setting.

In conclusion, the results in this study demonstrated that the DN4-T questionnaire can be reliably translated into Mandarin Chinese for use in Taiwan, and this may be more widely used as a diagnostic tool for the screening and assessment of NeP, in conjunction with clinical assessment by a healthcare professional specialized in NeP.

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