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painDETECT Questionnaire Filipino version: Transcultural adaptation and validation in two widely spoken regional languages (Tagalog and Cebuano)

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Abstract

Background & Objective: Chronic pain impacts the quality of life of patients, with neuropathic pain causing profound negative sequelae. Assessment of pain whether nociceptive or neuropathic is important to provide appropriate treatment. The objective of this study is to translate and validate the pain-DETECT Questionnaire (PDQ) to two widely spoken regional languages in Filipino. *Methods:* The PDQ, a self-administered questionnaire, was translated from English into the Filipino version, painDETECT Tagalog (PDQ-Tag) and painDETECT Cebuano (PDQ-Ceb). One hundred Filipino patients suffering from pain for at least three months were recruited in the out-patient clinics of a hospital and completed the questionnaire. The investigators, blinded to the subjects PDQ-Tag and PDQ-Ceb scores, examined the subjects using the standard clinical and neurological examination. The PDQ-Tag and PDQ-Ceb, scores were validated. Both questionnaires were administered to the same patient twice, two days apart by the same investigator. *Results:* Seventy subjects completed the (PDQ-Tag) and thirty subjects the (PDQ-Ceb). The sensitivity and specificity of PDQ-Tag were both 80% for an upper limit cut-off value of ≥ 17. The sensitivity and specificity of PDQ-Ceb were 62.5% and 80% respectively, for an upper limit cut-off value ≥ 18.0. Both questionnaires were reliable [Cronbach's alpha coefficient: 0.78 (PDQ-Tag) and 0.70 (PDQ-Ceb), good test-retest stability with intra-class correlation coefficient: 0.93 for PDQ-Tag and 0.99 for PDQ-Ceb]. Cohen's kappa were 0.64 and 0.61 for PDQ-Ceb and PDQ-Tag respectively, with P value<0.001 indicating a significant agreement on the assessment of neuropathic pain.
Conclusion: PDQ-Tag and PDQ-Ceb are reliable and valid self-administered screening tools to detect neuropathic pain among Filipinos.

Keywords: Neuropathic pain, pain assessment, questionnaire, Filipino, Tagalog and Cebuano

INTRODUCTION

Chronic pain with neuropathic component is associated with severe pain[1-3], a greater severity of co-morbidities[1,4], a reduced quality of life[1,4], and overall higher health care costs[3,4], compared with non-neuropathic pain. With its significant burden on the patient and society, the recognition and determination of the phenomenology of neuropathic pain is of the essence to achieve a favorable outcome of management. Neuropathic pain (NeP) is defined by the International Association for Study of Pain (IASP) as "pain caused by a lesion or disease of the somatosensory system.[5] Although there are recent attempts of sensory phenotyping for NeP, the outset challenge is actually the recognition, in that there are varied etiologies, yet signs and symptoms merge in the clinical setting. Hence, the formidable task of the clinician is to carefully screen those clinical manifestations of NeP, and this is best approached through valid screening instruments.

NeP screening tools are now gaining

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ground. These screening tools are intended to help clinicians identify patients with NeP notwithstanding that these tools will not replace good clinical examination and assessment. These screening tests have been assessed and developed and are now adapted in different languages. Fluctuating in frequency and intensity, a number of test instruments employ both NeP positive and negative symptoms as useful verbal descriptors, with or without physical examination. The positive symptoms are spontaneous pain, paresthesia and dysesthesia where patients complain of burning, tingling, lancinating pain, or pain from normal touch (allodynia) such as clothing brushing the skin. The negative symptoms are inability to feel, numbness, analgesia and anesthesia due to deficit function, including loss of balance from proprioceptive dysfunction. Screening tools such as the DN4 (Douleur Neuropathique 4)[6-12] and the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS)[13] require clinical examination but other instruments, such as a patient self-report version of the LANSS (S-LANSS)[14], and pain-DETECT Questionnaire (PDQ)[1] do not necessarily require clinical examination. The PDQ was developed and validated by Freynhagen in Germany for NeP in patients with chronic low back pain.[1] Its reliability has been established with high sensitivity, specificity and positive predictive accuracy and it has been validated to several languages.

Out of the 120 languages in the Philippines, the two most widely spoken native languages are Tagalog and Cebuano.[15] The objective of this study is to translate and validate the PDQ in "Tagalog" and "Cebuano"

METHODS

Study design and method

A cross-survey validation design was used in this study. A two-step protocol including translation and cross-sectional validation of the PDQ Filipino version instrument in two widely spoken Filipino regional languages, Tagalog and Cebuano, were performed. This was patterned after the report of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) task force for translation and cultural validation.[16]

Instrument

The PDQ questionnaire is a self-reported instrument by the patient without requiring a physical examination. It has 3 domains that address the quality of NeP symptoms. The first part has three items that assessed the intensity of pain and patient is asked to grade the actual pain level experienced, the maximum pain level experienced for the past four weeks and the average pain experienced in the past four weeks on a scale of 0-10 with 0= no pain, and 10 = maximum pain. This is not included in the scoring. The first domain is the main part which is about the gradation of pain, scored from 0-5 (never- 0; hardly noticed- 1; slightly- 2; moderately- 3; strongly- 4; and very strongly- 5). Five items ask about the following painful sensation: burning, tingling or prickling, tactile or thermal allodynia, electric shock-like sensations, numbness, and pressure-evoked pain. This domain provides scores between 0 and 35 points. The second domain asks about the pain course pattern, scored from -1 to 2 depending on which pain course pattern diagram is selected. The pattern of pain intensity course felt by the patient is represented in four visual graphs. The pain patterns are persistent pain with slight fluctuations (0 points), persistent pain with pain attacks (-1 point), pain attacks without pain between them (1 point), and pain attacks with pain between them (1 point). The third domain asks about radiation of pain, answered as yes or no and scored as 2 or 0 respectively. If the patient has pain, he will mark the pain zone in the drawing of a human figure showing the front and back (homunculus) and draw an arrow in the direction of radiating pain. Overall score is obtained by summing up the scores that may range from -1 to 38. A score $\leqslant$ 12 indicates that pain is unlikely to have a neuropathic component while a score $\geqslant$ 19 suggests that pain is more than likely to have a neuropathic component. A score between both values suggest that the result is uncertain and a more detailed examination is required to make a proper diagnosis.[1]

Linguistic validation

Translation process of the PDQ to Filipino version was done. Permission to use the English version of PDQ was obtained through an electronic mail communication with the first developers of the questionnaire. For forward translation, two native Filipino translators from the Institute of Linguistic Studies produced two forward translations each in Tagalog and Cebuano. The objective of the study was known to both translators. The two forward translations in Tagalog and Cebuano were analyzed and became the first intermediary versions of the questionnaire. The forward

translations in Tagalog and Cebuano were then back translated to English. Another professional translator from the Institute of Linguistic Studies did the back translation which was then compared to the original English version. A second version of the instrument was then produced. Once approved by the consultant investigator, a multidisciplinary review was done to deliberate on the second version. The Expert Committee was composed of a pain management specialist, endocrinologist, and neurologist. The committee members are all bilingual and understood the intent of the PDQ measure and concept. Modification of instructions was done. The qualifier term of intensity translated in Filipino to "*pinakamalakas*" was deemed inappropriate and was changed to "*pinakamatindi*."

Pretesting and cognitive debriefing

The next step was a committee review once again. The questionnaire was pre-tested for comprehensibility and ease of administration. The PDQ-Tag or PDQ-Cebwere pilot-tested in 18 pre-test subjects each from the University of Santo Tomas Hospital (USTH) Out-patient clinics. Face validity through cognitive debriefing was performed during pre-testing using guide questions.

Production of the final translation and questionnaire

The Expert Committee's review and additional insights from the pilot subjects provided refinement in the cultural adaptation and face validity of the final questionnaire. The final version of the Filipino PDQ, PDQ-Tag and PDQ-Ceb, were then completed. (Figure 1, 2)

Study setting

The study was carried out in the USTH Clinical Division out-patient clinics of Medicine, Orthopedics, Neurology, Dermatology and Pain Clinic.

Patient inclusion and exclusion criteria

Included in the study were patients age 18 years or over, natural-born Filipinos, able to read and understand the Filipino language (either Tagalog or Cebuano), with chronic NeP or nociceptive pain (NoP) for at least three months duration, with pain visual analog scale (Wong baker Face Scale with numerical coordinate) score of three or more, in stable medical condition and able to give consent. Excluded were patients with migraine, pain associated with mood disorders, substance abuse, illiterate, with cultural or language barrier, or with a poor mental health status that prevented them from understanding or responding to proposed questions. Informed consent was taken voluntarily.

painDETECT Questionnaire Filipino version (PDQ-Tag and PDQ-Ceb) analysis

The study protocol was approved by the USTH Institutional Review Board and Ethics Committee and each participant was provided with informed consent to participate in the study. Upon submission of their written informed consent, the subjects completed the Filipino version of the PDQ, either PDQ-Tag and PDQ-Ceb themselves in a waiting room and returned it to the physician in a sealed envelope. The study investigators were blinded to the subjects' PDQ-Tag *and* PDQ-Ceb scores. They examined the subjects using clinical and detailed neurological examination. Each patient's diagnosis was classified into neuropathic pain or nociceptive pain. The main investigator collected the socio-demographic and clinical data. Patients were then referred to the pain specialist who had used the criteria recommended by IASP and Neuropathic Pain Special Interest Group (NeuPSIG).[5] The PDQ Filipino version, PDQ-Tag if the patient spoke Tagalog or PDQ-Ceb if the patient spoke Cebuano, were administered to the same patient twice. The PDQ results were then compared with the results administered by the pain specialist. Time interval of 48 hours was given for the test-retest reliability testing.

Duration

The study duration was 3 years (September 2014 – 2016). The protocol was conceptualized in September 2014. The first phase which was the translation of the original PDQ was done from 2014-2015. The validation phase was done in 2016.

Outcome methods and statistical methods

Correlation between the investigator's clinical diagnosis and the PDQ Filipino version scores were measured. A receiver operating characteristic (ROC) curve was used to determine the cut-off point of both PDQ-Tag *and* PDQ-Ceb for correct prediction and positive diagnosis of NeP expressed through sensitivity and specificity. After determining the cut-off point, the results of the questionnaire were used to evaluate significant differences between NeP diagnosed clinically and

painDETECT

PAIN QUESTIONNAIRE

Petsa: ..... **Pasyente** **Apelyido:** ..... **Pangalan:** .....

Paano mo ihahambing ang nararamdaman mong sakit **ngayon**?

0 1 2 3 4 5 6 7 8 9 10

wala — pinakamatindi

Gaano katindi ang **pinakamasakit** na iyong naramdaman sa nakaraang apat na linggo?

0 1 2 3 4 5 6 7 8 9 10

wala — pinakamatindi

Gaano katindi ang sakit sa nakaraang apat na linggo kung pagsasamahin?

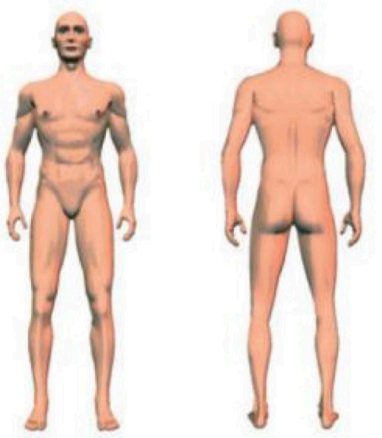
0 1 2 3 4 5 6 7 8 9 10

wala — pinakamatindi

Markahan ang larawan na nagpapakita ng nararamdamang sakit:

- **Tuloy-tuloy na sakit na may bahagyang pagbabago** ☐
- **Tuloy-tuloy na sakit na may pag-atake ng pagkirot** ☐
- **Pag-atake ng sakit na walang pagkirot sa pagitan nito** ☐
- **Pag-atake ng sakit na may pagkirot sa pagitan ng mga ito** ☐

Lagyan ng marka ang **lugar na masakit**



Ang sakit ba ay kumakalat o tumatagos sa ibang parte ng iyong katawan? ☐ Oo ☐ Hindi

Kapag oo, guhitan ng linya magmula sa parte ng katawan na masakit at kung saan ito tumatagos.

	Hindi	Hindi kapansin-pansin	Bahagya	Katamtaman	Matindi	Lubhang matindi
Nakakaranas ka bà ng nasusunog na pakiramdam (hal. mahapding iritasyon) sa mga minarkahang bahagi ng katawan?	☐	☐	☐	☐	☐	☐
Nakakaramdam ka ba na parang tinutusok sa lugar na masakit (parang may gumagapang na langgam o kinukuryente)?	☐	☐	☐	☐	☐	☐
Nagdudulot ba ng sakit ang dampi ng (damit o kumot) sa lugar na ito?	☐	☐	☐	☐	☐	☐
Nakakaramdam ka ba ng biglaang sumpong ng sakit na parang kinukuryente sa lugar na ito?	☐	☐	☐	☐	☐	☐
Ang malamig o mainit na tubig pampaligo ba ay nagddulot ng sakit sa lugar na ito?	☐	☐	☐	☐	☐	☐
Ikaw ba ay naghihirap dahil sa matinding manhid na nararamdaman sa mga parte ng katawan na iyong minarkahan?	☐	☐	☐	☐	☐	☐
May sakit ka bang nararamdaman sa bahagyang salat sa isang parte ng katawan (hal. salat sa isang daliri ay masakit)?	☐	☐	☐	☐	☐	☐

(To be filled out by the physician)

Hindi	Hindi kapansin-pansin	Bahagya	Katamtaman	Matindi	Lubhang matindi
☐ x 0 = 0	☐ x 1 = ☐	☐ x 2 = ☐☐	☐ x 3 = ☐☐	☐ x 4 = ☐☐	☐ x 5 = ☐☐

Kabuuang iskor ☐☐ **mula sa 35**

R. Freynhagen, R. Baron, U. Gockel, T.R. Tölle, CurrMed ResOpin Vol 22, 2006, 1911-1920 ©Pfizer Pharma GmbH 2006 RBTLYR-13-95 Date of preparation: August 2013

Figure 1. painDETECT Tagalog questionnaire.

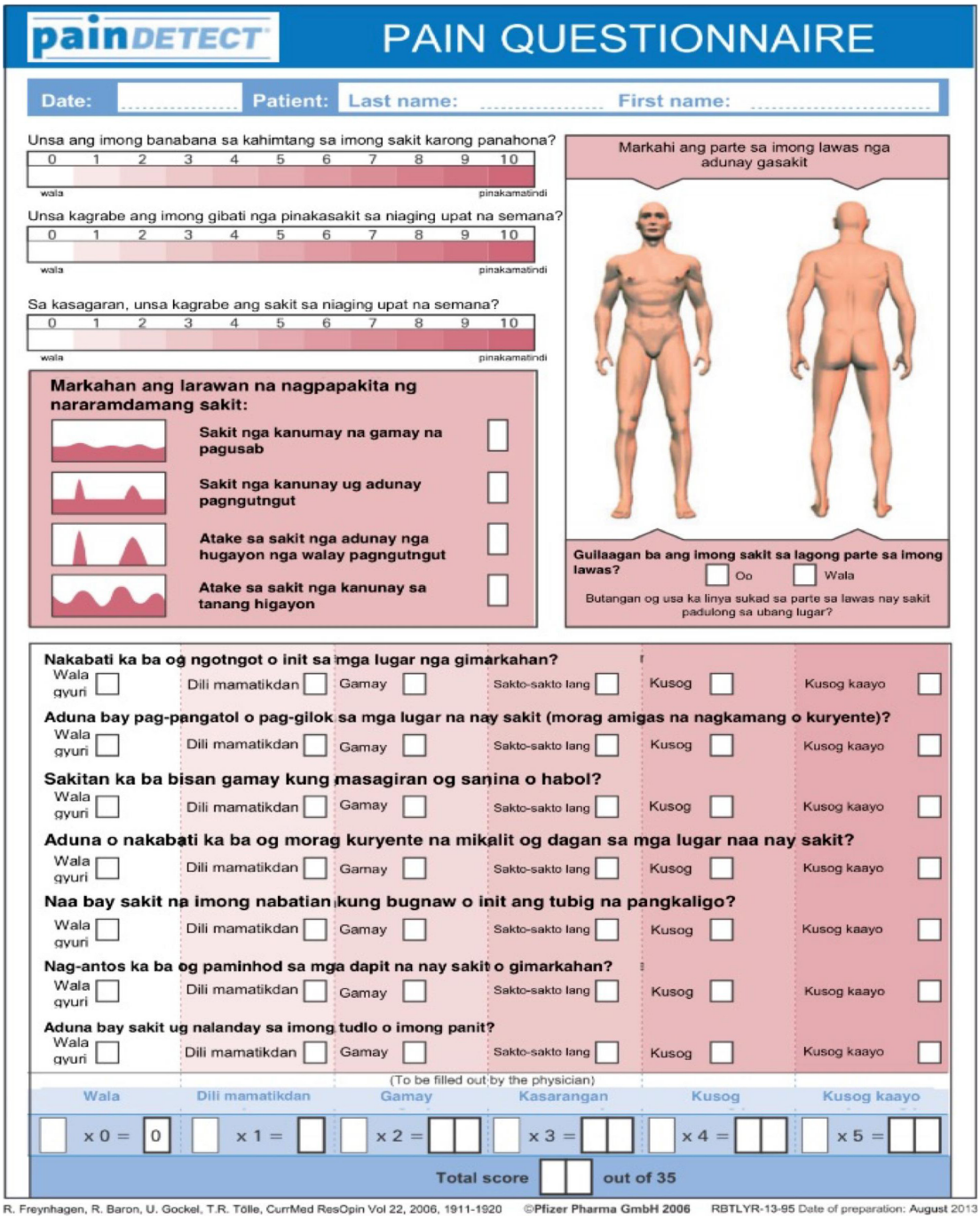


Figure 2. painDETECT Cebuano questionnaire.

NeP identified by the PDQ-Tag *and* PDQ-Ceb. The reliability and inter-item consistency of both PDQ-Tag and PDQ-Ceb were separately established by calculating Cronbach's alpha coefficient.

Inter-rater reliability was assessed by the agreement of the results obtained by raters 1 and 2 for each item and the total score of PDQ-Tagand PDQ-Ceb. Agreement was determined by calculating the Cohen's kappa coefficient. Inter-rater agreement which is determined by calculating the intra-class correlation coefficient of the total scores was also done. PDQ-Tag and PDQ-Ceb sensitivity and specificity indexes were computed for each total PDQ score and graphed in a receiver operating characteristic (ROC) curve. The ROC curve was used to determine

optimal cutoff PDQ-Tag and PDQ-Ceb scores for screening patients who present a neuropathic pain component. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS version 21.0) software.

RESULTS

Patient demographics and baseline characteristics

A total of 110 Filipino patients were enrolled in the study. Ten patients were excluded because of incomplete response to the questionnaire. A total of 100 patients were evaluated: 70 subjects answered the (PDQ-Tag) and 30 subjects the Cebuano version (PDQ-Ceb).

PDQ-Tag

The mean age of the respondents was 56 years +/- 12 with a range of 24-80 years. The majority (53%) belonged to the 41-60 years old age group. About 61% were females and 39% males. In terms of educational attainment, 33 subjects (47%) were college graduates. Eighty one subjects (81%) were non-smokers. Aside from the diagnosis of the etiology of chronic pain, patients had co-morbidities such as hypertension (11%), diabetes mellitus (59%) or both diabetes and hypertension (21%). The majority of the participants in the NeP group had diabetic neuropathy (50%) while the rest had radiculopathy, carpal tunnel syndrome, lumbar disc disease, sciatica, cervical stenosis, spinal cord syndrome and post-herpetic neuralgia as shown in Table 1. The prevalent diagnosis in the nociceptive pain group was osteoarthritis, visceral referred pain, myofascial pain syndrome, ankle sprain, rotator cuff injury, axillary lymphadenitis, and tendinitis (Table 2). Twenty-two participants (31.5%) were likely to have NeP, 33 subjects (47%) have no neuropathic component while 15 subjects (21.5%) have an inconclusive result.

Table 1: Disease Entities with Neuropathic Pain

	Neuropathic Pain	
	PDQ-Tag	**PDQ-Ceb**
Diabetic Neuropathy	11	4
Compression Fracture	1	
Carpal Tunnel Syndrome	2	
Lumbar Disc Disease	2	1
Sciatica	1	
Cervical stenosis	1	
Spinal Cord Syndrome	1	
Post-herpetic Neuralgia	1	
Metastatic Cancer	2	

PDQ-Ceb

The mean age of the respondents was 60 years +/- 12 with a range of 33-83 years. Majority (47%) belonged to the 41-60 years old age group. About 60% were females and 40% males. In terms of educational attainment 16 subjects (53%) were college graduates. Ten respondents (33%) were smoker while 20 respondents (67%) were non-smokers. The following co-morbidities noted in our subjects were hypertension (17%), diabetes mellitus (23%) and both hypertension and diabetes in (7%). The majority of respondents in NeP group were diagnosed with peripheral neuropathy (80%) while the prevalent diagnosis in nociceptive pain group was osteoarthritis (Table 1, 2). Five subjects (17%) were likely to have NeP, 17 subjects (56%) have no neuropathic component while 8 subjects (27 %) have an inconclusive result.

Table 2: Disease Entities with Nociceptive Pain

	Nociceptive Pain	
	PDQ-Tag	**PDQ-Ceb**
Osteoarthritis	8	9
Visceral Referred pain	3	1
Myalgia	2	1
Tenosynovitis	2	
Rotator cuff injury	1	
Axillary lymphadenitis	1	
Myathenia Gravis	1	
Osteoporosis	3	
Tendinitis	1	1
Gouty arthritis	1	
Psoriatic arthritis	1	
Cellulitis	2	1
Metastatic Cancer	1	
Infection (UTI, carbuncle)	4	3
Urolithiasis	1	
Post traumatic Arthritis	1	
Ankle Sprain		1

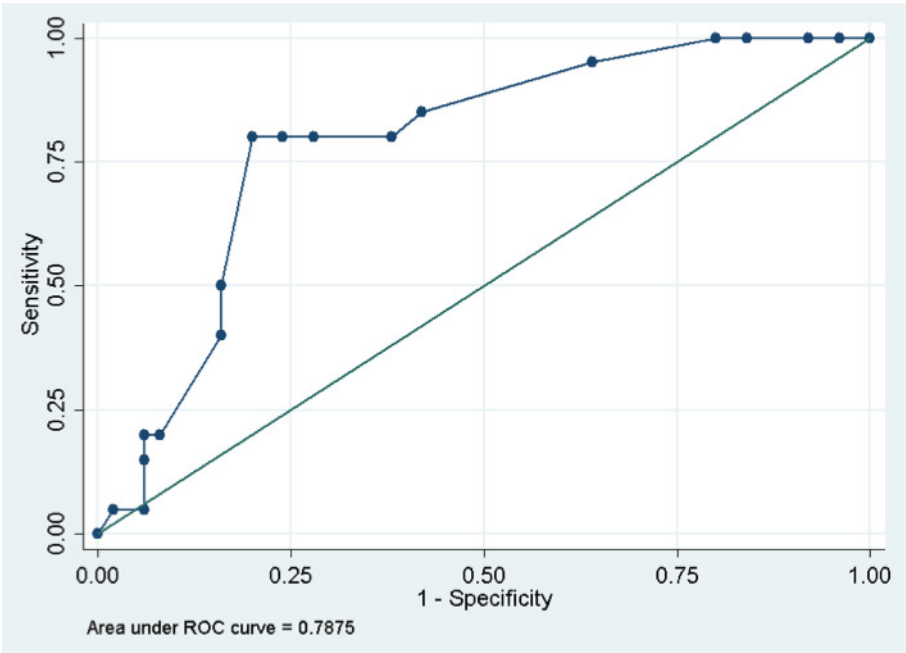


Figure 3. ROC curve of patients and specialists scores with PDQ-Tag.

Sensitivity and specificity of Filipino version

ROC curve analysis identified a score of 17 as the best cut-off value discriminating between neuropathic and non-NeP in PDQ-Tag that has 80% sensitivity and 80% specificity. The PDQ-Ceb has a higher cut-off score of "18" that has 62.5% sensitivity and 80% specificity.

Internal consistency, inter-rater agreement and test-retest reliability

Our study demonstrated that both PDQ-Tag and PDQ-Ceb were reliable with Cronbach's alpha coefficient: 0.788 (PDQ-Tag) and 0.702 (PDQ-Ceb). Values of 0.6-0.7 are considered acceptable for reliability. The inter-rater agreement coefficient: 0.9 (PDQ-Tag) and 0.8 for (PDQ-Ceb) showed significant agreement and good

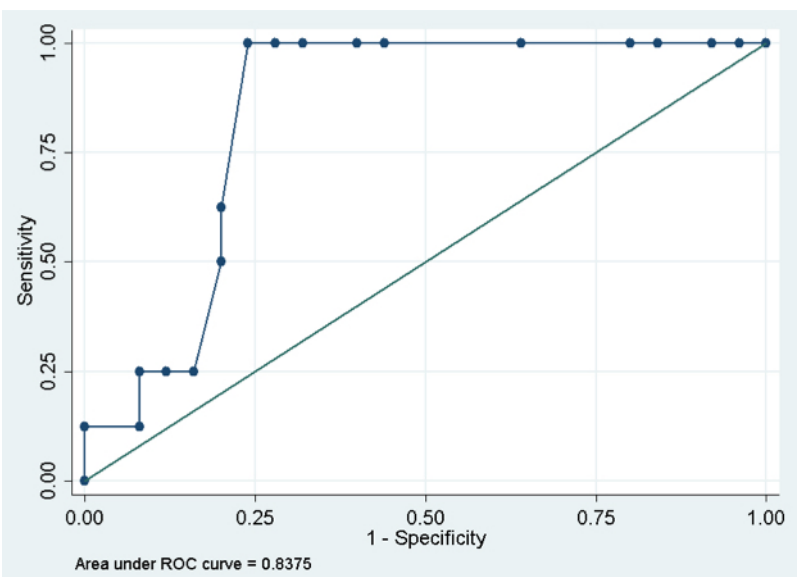


Figure 4. ROC curve of patients and specialists scores with PDQ-Ceb.

test-retest stability with intra-class correlation coefficient: 0.93 (PDQ-Tag) and 0.99 (PDQ-Ceb). Calculation of the Cohens kappa coefficients supported the inter-rater agreement with a value of 0.64 and 0.61 for PDQ-Ceb and PDQ-Tag respectively, indicating a significant agreement on the assessment of neuropathic pain. The area under the ROC curve for PDQ-Tag and PDQ-Ceb were 0.78 and 0.83 respectively when the patient's and specialist's scores were compared. (Figure 3, 4).

The Spearman's Rho Correlation Coefficient was used for both PDQ-Tag and PDQ-Ceb with correlation significance at p-values 0.001. Each item was tested for its correlation. (Table 3) Moderate to strong correlation was noted with PDQ-Tag verbal descriptors (questions) 1, 2, 3, 4, 6 and 7 which meant that these items which describe the quality of NeP have significant relationship to the total score. (Table 3) The lowest correlation was noted in item #5 "Ang malamig o mainit na tubig pampaligo ba ay nagdudulot ng sakit sa lugar na ito" (will hot or cold shower cause pain?) which had a weak relationship to the total score. With PDQ-Ceb, moderate to strong correlation was noted in Block 4 questions 2, 3, 4,5 and 6. (Table 3).

DISCUSSION

The PDQ was originally designed as a self-administered screening tool to help in detecting presence of neuropathic pain component in patients with chronic low back pain. In this present validation study, the original questionnaire was translated into two widely spoken regional languages, Tagalog and Cebuano using local terms, then back-translated and validated by an expert panel to enable its applicability to Filipino subjects. The results from this study demonstrated that both PDQ-Tag with 80% sensitivity and 80% specificity and PDQ-Ceb with 62.5% sensitivity and 80% specificity were valid. These suggest that the PDQ-Tag and PDQ-Ceb are statistically as good as clinical diagnosis by neurologists or pain specialists for accurate discrimination of NeP and NoP. This is comparable with the original version by Freynhagen *et al*.[1] with a sensitivity of 85%, specificity of 80%, and positive predictive accuracy of 83% with a suggested cut-off value of 19 points or higher.

Reliability and validity measurements were used to confirm the validation of questionnaires. Assessment of Cronbach's alpha coefficient to test for reliability demonstrated a score of 0.788 and 0.702 for PDQ-Tag and PDQ-Cebfor this current study which indicated good reliability scores for both questionnaires. The inter-rater agreement coefficient showed significant agreement with good test-retest stability. The Cohens kappa coefficients supported the inter-rater agreement with a value of 0.64 and 0.61 for PDQ-Ceb and PDQ-Tag indicating a significant agreement on the assessment of NeP. Our study demonstrated that the Filipino versions, PDQ-Tag and PDQ-Ceb are reliable and valid. It confirmed that the discriminative properties of the sensory descriptors were helpful in distinguishing NeP.[1,16-22] In general, all the domains of PDQ-Ceb and PDQ-Tag scores showed satisfactory results.

Our study demonstrated the validity and reliability of the PDQ-Tag and the PDQ-Ceb as simple, self-administered screening tools in the two most widely spoken languages in the Philippines for the detection of neuropathic pain in patients with chronic pain conditions. The need for a good history-taking and a thorough clinical examination and testing is then warranted for the diagnosis of neuropathic pain as prescribed by the NeuPSIG of the IASP.

The caveats of this study lie on the small sample size and the lack of representation as this was

Table 3: Spearman's Rho Correlation of PDQ-Tag and PDQ-Ceb

	PDQ-Tag	P-Value	PDQ-Ceb	P-Value
Item #1	0.463	0.001	0.313	0.092
Item #2	0.630	0.001	0.73	0.001
Item #3	0.489	0.001	0.605	0.001
Item #4	0.716	0.001	0.805	0.001
Item #5	0.194	0.107	0.483	0.007
Item #6	0.515	0.001	0.518	0.003
Item #7	0.453	0.001	0.247	0.188

performed in a single center only. However, the participation of various experts in the field during the multi-step validation and cultural adaptation process may have been critical in arriving at an acceptable sensitivity and specificity for both the majority spoken languages in the country. Further studies on larger sample sizes and in homogeneous clinical pain conditions are needed to determine the applicability of the PDQ-Tag and PDQ-Ceb as screening tools for neuropathic pain in Filipino patients.

In conclusion, the Filipino versions of the (PDQ-Tag and PDQ-Ceb) are reliable and valid self-administered screening tools that can be easily used by clinicians, and culturally adaptable for ease of understanding among the targeted patient population for the assessment of NeP.

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DISCLOSURE

Financial support: None

Conflict of Interest:

Raymond Rosales has participated in local and regional advisory boards for Pfizer, received speaker fees from Pfizer, Abbott, Novartis, Ipsen, Boehringer, Otsuka, Sun and Menarini, and received honoraria as a clinical trial investigator from Pfizer, Novartis, and Ipsen. In no way is Dr. Rosales, nor his family, has personal stakes/ownerships in any of the aforementioned companies.

Maria Honolina S. Gomez has participated in local advisory boards for Boehringer Ingelheim, Novo-Nordisk and Pfizer; received honoraria as a clinical trial investigator from Takeda; Sanofi-aventis and Glaxo Smith Kline; received speaker fees from Boehringer Ingelheim, Pfizer, Novo-Nordisk and Torrent Pharma. In no way is Dr. Gomez, nor her family, has personal stakes/ownerships in any of the aforementioned companies.

Jocelyn C. Que has participated as local advisory board for Abbott, A. Menariniand Mundipharma; received honoraria as a clinical trial investigator from Abbott, Janssen and Mundipharma; and speaker honoraria from Abbott, Janssen (Johnson & Johnson), Mundipharma, A. Menarini, Pfizer, and Hospira. Neither Dr. Que nor her family has personal stakes/ownerships, in any of the aforementioned companies.

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