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Translation and cross-cultural adaptation of the Malay version of the painDETECT Questionnaire

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Abstract

Background: The painDETECT questionnaire (PDQ) is a useful tool for screening of patients with neuropathic pain. This study aimed to translate the PDQ into the Malay language (PDQ-M) and to achieve cross-cultural adaptation of the questionnaire for use in Malaysia. *Methods:* The translation and cultural adaptation process of the English version of PDQ was performed based on international guidelines. Subsequently, 97 patients with neuropathic and nociceptive pain based on clinician's diagnoses were recruited to complete three-type numeric rating scale (NRS) of pain followed by PDQ-M. *Results:* On the basis of cognitive debriefing, several changes of the translated PDQ-M were made. A total of 53 patients with neuropathic pain and 44 with nociceptive pain (54.6% females, 45.4% males, mean age 52.4 years ± 14.2) were recruited into this study. The most common class of analgesia prescribed for patients with neuropathic pain was anti-convulsant, whereas co-analgesic therapy, which includes NSAID and COX-2 inhibitor, was the most prescribed for patients with nociceptive pain. Combination analgesia was used in 32.1% of those with neuropathic pain, and 11.4% of patients with nociceptive pain. The median time taken for respondents to complete the questionnaire was 420 seconds. In regression analysis, active smoking (beta 0.586, $p<0.001$) and female gender (beta -0.422, $p=0.008$) were associated with higher PDQ-M scores only among those with neuropathic pain.
Conclusions: The Malay version of the painDETECT questionnaire was translated and cross-culturally adapted for ease of understanding among the local population via careful face-to-face interview.

Keywords: Neuropathic pain; nociceptive pain; questionnaire; translation

INTRODUCTION

Neuropathic pain is typically described clinically as constant burning pain with spontaneous sharp exacerbations and somatosensory abnormalities.[1] It has an important negative impact on the quality of life in patients suffering from this disorder as it can lead to substantial disability in daily performance, leading to functional, psychological and social limitations. Chronic pain results in anxiety, depression, sleep disorders and interference of normal work and social activities.[2,3]

Early care and management of neuropathic pain is important to improve the quality of life of patients. To do this, early diagnosis is essential. Unfortunately, this remains a challenge as lesions of the somatosensory nervous system are not readily detectable, and therefore is widely underdiagnosed.[4] Moreover, neuropathic pain does not respond well to conventional analgesics compared to nociceptive pain. Therefore,

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effective screening tools play an important role in identifying neuropathic pain based on patient's presentations, especially in a busy clinic. The availability of a sensitive and specific patient-administered questionnaire to screen for this complication while awaiting to be seen by the clinician will not only save time but be helpful in achieving a timely diagnosis and subsequent management.

The painDETECT questionnaire (PDQ) is one of the reliable screening tools for painful neuropathy. It was first developed in Germany, with a sensitivity of 85%, specificity of 80%, and positive predictive accuracy of 83% for neuropathic pain.[5] This questionnaire has been translated into multiple languages, including Spanish, Dutch and Japanese.[6-8]

Since PDQ is a time-efficient, quick and economical method to screen for presence of painful neuropathy among patients, it would be beneficial for both clinicians and patients in Malaysia to have this patient-administered questionnaire translated and validated in the Malay language as majority of the population here speak this language. This will then reduce the comprehension barrier when patients attempt this questionnaire, thus increasing its usefulness as an instrument in detecting painful neuropathy among our patients. This will help clinicians more effectively screen for this complication and to institute early and appropriate care.

Hence, the objective of this study was to achieve a cross-cultural adaptation of the PDQ for use in Malaysia.

METHODS

Instrument

PDQ is an instrument comprising a main component and two additional components. In the main component, termed as "gradation of pain", there are 7 items to identify presence of pathological pain sensations, ie burning, tingling or prickling, tactile and thermal allodynia, electric shock-like sensations, numbness, and pressure-evoked pain sensation. The grading includes 0 = never, 1 = hardly noticed, 2 = slightly, 3 = moderately, 4 = strongly, and 5 = very strongly. This main component yields scores from 0 to 35 points.

The second part is termed as "pain course pattern" and consists of a multiple choice pain chart where patients are required to quantify the pattern of experienced pain: persistent pain with slight fluctuations (0 point), persistent pain with pain attacks (-1 point), pain attacks without pain between them (1 point), pain attacks with pain between them (1 point). The third component asks patients if the pain radiates to other regions of the body (2 points), and if it does, to draw the direction in which the pain radiates.

A total score is then calculated by a sum of the scores from all three components. A high score of ≥19 indicates neuropathic pain component is likely. Scores of 13-18 indicate ambiguous result, but neuropathic pain component can be present. Scores of ≤12 suggest neuropathic pain component to be unlikely.

Translation and cultural adaptation process

The translation and cultural adaptation process of the English version of PDQ was performed based on the 10 steps described in the ISPOR Patient-Reported Outcomes Translation and Linguistic Validation Task Force guidelines (Figure 1).

Preparation

Firstly, the concepts of the study were explained by the project manager to the researchers after obtaining permission from the developer to use the original PDQ.

Forward translation and reconciliation

A forward translation of the source questionnaire was performed independently by two Malay native speakers (T1 and T2) with medical background and who were informed about the concept of PDQ. Special attention was given to the assessment of the semantic equivalence between the English version (source language) and the Malay version (target language) for each item. A conference call was made between T1, T2 and the project manager to discuss item by item linguistically and culturally following the forward translation. After discussion of the discrepancies, the translations were reconciled and combined into a new version, named T1-T2.

Backward translation and review

A back translation of the questionnaire was then conducted by another two independent translators who were bi-lingual in Malay and English (BT1 and BT2). Both BT1 and BT2 were uninformed about the concept of the PDQ. A conference call was made between BT1, BT2 and the project manager to discuss item by item linguistically and culturally. The best translation was adopted and combined into a new version, named BT1-BT2.

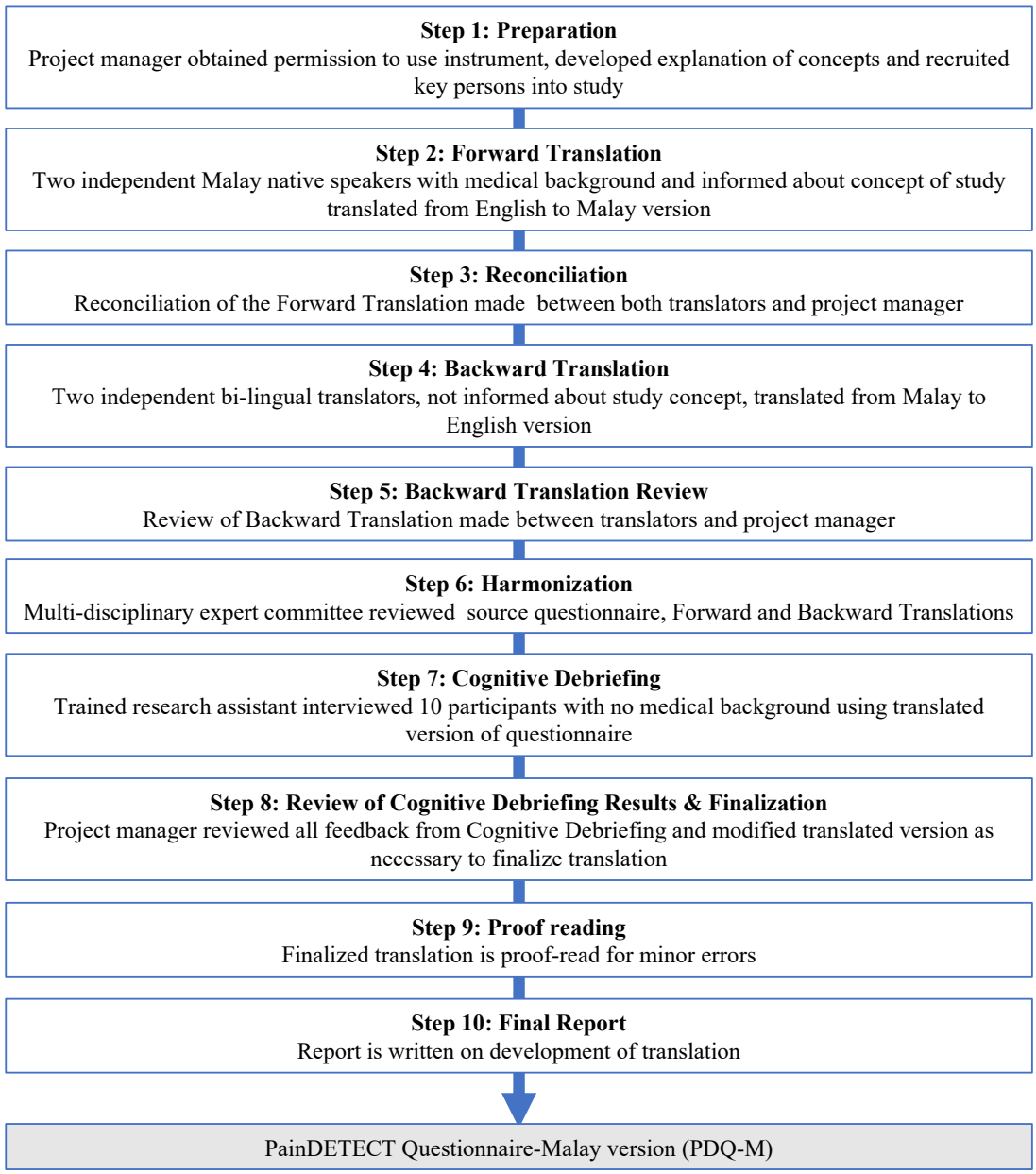

Figure 1. Translation and Cultural Adaptation Process

Harmonization

During the harmonization phase, the source questionnaire, the translations T1-T2, and translations BT1-BT2 were discussed item by item in a multi-disciplinary expert review committee, which consists of two physicians experienced in the treatment of neuropathic pain, one linguist (Malay native speaker and fluent in English), and the project manager, in close contact with both the forward and backward translators, to prepare the preliminary PDQ-M (pre-PDQ-M).

Cognitive debriefing

Following that, cognitive debriefing was performed among ten participants with no medical background by a trained research assistant. First, the participants were invited to fill in the pre-PDQ-M. A qualitative semi-structured interview was then conducted to ask the participants individually about the questionnaire and their understanding of the questions. The main purpose of this stage was to paraphrase the clarity, readability and comprehensibility of

the pre-PDQ-M.

Review and proof-reading

The feedback was reviewed by the project manager and translation modifications deemed necessary for improvement were identified. Items and response options were re-worded where the respondents' comments justified such changes. The translation was finalized and known as PDQ-M. The PDQ-M was checked for minor errors such as spelling mistakes and punctuations.

Testing of PDQ-M

After finalizing the questionnaire, the PDQ-M was tested among patients with neuropathic and nociceptive pain based on clinician's diagnoses. Patients aged 18 years and above, who were able to read and understand the Malay language, and agreeable to participate in the research were recruited. All the patients had to have stable disease condition and pain duration of at least 4 weeks. Those with acute illness, poor mental health status that prevented them from understanding or responding to the proposed questions, and cultural or language barrier were excluded. Patients' demographic data, cause of pain and co-morbidities were documented on a standard data collection form. They were then required to complete three sets of questionnaires, namely (i) PDQ-M, (ii) three-type numeric rating scale (NRS) of pain, and Medical Outcomes Study 36-item Short Form Healthy Survey (SF36) – Malay version. The time taken for patients to complete the PDQ-M was recorded.

Statistical analysis

Patients' socio-demographic data and clinical characteristics were reported using frequency for categorical variables and mean with standard deviation for continuous variables. Normality was assessed using Shapiro Wilk test and histograms for continuous variables. Data was compared between groups using chi-square test (for categorical variables) and t-test or Mann-Whitney's U test (for continuous variables). A p value of <0.05 is taken as statistically significant.

RESULTS

Cognitive debriefing was performed among ten participants (seven women, three men) with no medical background. The development of the translation was described in Table 1, containing every translation and choices made. The most frequent comment was that the questionnaire appeared congested, hence participants found it difficult to read. Suggestion made by participants during cognitive debriefing for a next version was to guide participants on how many sections were needed to be answered, by numbering each section. Other suggestions were to make it appear less congested and to increase the font size.

On the basis of cognitive debriefing, we changed "kesakitan antara serangan" to "kesakitan berterusan" as three out of ten participants found it confusing with the initial translated version. We also changed "dengan kesakitan antara serangan" to "di antara kesakitan berterusan". "Rasa sakit yang membakar" was changed to "rasa sakit seperti dibahang api" as five participants felt the latter better describes burning pain. We also removed stinging nettles as the example given for burning pain as it is not commonly known to the local community. The term "mengalami rasa kesemutan" was changed to "berasa semut-semut". We changed "sentuhan lembut" to "geseran" as four participants felt that they could comprehend better if it is described as slight friction caused by cloth or blanket.

Subsequently a total of 97 patients with chronic pain were enrolled in the study (53 neuropathic pain, 44 nociceptive pain based on clinician diagnoses). In order to better reflect the cultural diversity of Malaysia, patients were recruited from 4 different sites in Malaysia, namely Sarawak General Hospital, Penang Hospital, Putrajaya Hospital and Malacca Hospital. Patients were also recruited from various out-patient clinics to better capture pain due to a variety of disease, namely diabetes, orthopaedic, rheumatology, neurology and pain clinics.

The mean age of the respondents was 52.4 years ± 14.2 with a range of 21-75 years. A total of 54.6% were females and 45.4% males. Majority of the patients (75.3%) were on oral analgesia (88.7% for neuropathic pain, 68.2% for nociceptive pain). For patients with neuropathic pain, anti-convulsant is the most common class of analgesia prescribed, with Gabapentin the one most frequently used (70% of anti-convulsant group) followed by Pregabalin (12.5% of anti-convulsant group). As for patients with nociceptive pain, co-analgesic therapy, which includes non-steroidal anti-inflammatory drug (NSAID) and cyclooxygenase-2 (COX-2) inhibitor, is the most prescribed. Among those with neuropathic pain, 32.1% (n=17) required combination analgesia, whereas 11.4% (n=5) of patients with nociceptive pain were given

Table 1: Changes made in the harmonization phase after the cognitive debriefing of painDETECT questionnaire – Malay version (PDQ-M)

Preliminary PDQ-M	PDQ English version	PDQ-M	Remarks
Serangan sakit yang kuat tanpa kesakitan antara serangan	Pain attacks without pain between them	Serangan sakit yang kuat tanpa kesakitan berterusan	On the basis of the cognitive debriefing, we changed "kesakitan antara serangan" to "kesakitan berterusan" as three out of ten participants found it confusing with the initial translated version. When the researcher further described the pattern, they felt it is better comprehended if it is termed "kesakitan berterusan" which means "persistent pain"
Serangan sakit yang kuat dengan kesakitan antara serangan	Pain attacks with pain between them	Serangan sakit yang kuat di antara kesakitan berterusan	On the basis of the cognitive debriefing, we changed "dengan kesakitan antara serangan" to "di antara kesakitan berterusan" as three out of ten participants found it confusing with the initial translated version. When the researcher further described the pattern, they felt it is better comprehended if it is termed "di antara kesakitan berterusan" which means "in between persistent pain"
Adakah anda mengalami rasa sakit yang membakar (cth: sengatan) di kawasan yang telah ditanda?	Do you suffer from a burning sensation (e.g., stinging nettles) in the marked areas?	Adakah anda mengalami rasa sakit seperti dibahang api di kawasan yang telah ditanda?	On the basis of the cognitive debriefing, we changed "rasa sakit yang membakar" to "rasa sakit seperti dibahang api" as five out of ten participants felt "rasa sakit yang membakar" would be better understood if it is described as "rasa sakit seperti dibahang api" which means pain as though being burned. We also removed stinging nettles as the example as it is not commonly known to the local community.
Adakah anda mengalami rasa kesemutan atau menyucuk di kawasan kesakitan anda (seperti semut merangkak atau getaran elektrik)?	Do you have a tingling or prickling sensation in the area of your pain (like ants crawling or electrical tingling)?	Adakah anda berasa semut-semut atau menyucuk di kawasan kesakitan anda (seperti semut merangkak atau getaran elektrik)?	The word "tingling" could be translated to the Malay language as "kesemutan" or "semut-semut". On the basis of the cognitive debriefing, we changed "mengalami rasa kesemutan" to "berasa semut-semut" as five out of ten participants did not comprehend "kesemutan". When the researcher further described the sensation, they felt it is better to be termed as "semut-semut".
Adakah sentuhan lembut (kain, selimut) di kawasan ini menimbulkan kesakitan?	Is light touching (clothing, a blanket) in this area painful?	Adakah geseran (kain atau selimut) di kawasan ini menimbulkan kesakitan?	On the basis of the cognitive debriefing, we changed "sentuhan lembut" to "geseran" as four out of ten participants felt that they could comprehend better if it is described as slight friction caused by cloth or blanket.

combination pain relief. Based on clinician diagnoses, diabetic peripheral neuropathy is the most common cause of neuropathic pain, whereas osteoarthritis is the most common cause for nociceptive pain. The demography of the respondents and mean total scores of PDQ-M, NRS and SF36 are demonstrated in Tables 2 and 3 respectively.

The median time taken for respondents to complete the questionnaire was 420 seconds (45-14400). Only 1 participant did not answer the first question of PDQ-M, which is burning sensation in marked area. Eighteen of the 97 patients (18.6%) forgot to tick the box whether the pain was radiating to other regions of the body.

In regression analysis, active smoking (beta 0.586, p<0.001) and female gender (beta -0.422, p=0.008) were associated with higher PDQ-M scores only among those with neuropathic pain (Table 4).

DISCUSSION

This study presents the linguistic translation and cross-cultural adaptation of PDQ into Malay language for use in Malaysia. As PDQ is a reliable screening tool for painful neuropathy among patients, it has been widely translated into

Table 2: Baseline sociodemographic data of study participants

	Neuropathic pain (n=53)	Nociceptive pain (n=44)	p
Age, years (SD)	52.4 (15.1)	52.4 (13.3)	0.983
Gender, females (%)	27 (50.9)	27 (61.4)	0.315
Ethnicity			0.644
Malay, n (%)	25 (47.2)	25 (56.8)	
Chinese, n (%)	5 (9.4)	4 (9.1)	
Indian, n (%)	12 (22.6)	7 (15.9)	
Sarawak bumiputra, n (%)	11 (20.8)	7 (15.9)	
Others, n (%)	0 (0)	1 (2.3)	
Education level			0.008
Primary, n (%)	9 (17.3)	1 (2.3)	
Secondary, n (%)	26 (50.0)	20 (45.5)	
Tertiary, n (%)	14 (26.9)	23 (52.3)	
No formal education, n (%)	3 (5.8%)	0 (0)	
Body mass index, kg/m^2 (SD)	28.1 (6.7)	27.6 (8.5)	0.751
Employment status			0.752
Employee, n (%)	20 (37.7)	21 (47.7)	
Employer, n (%)	9 (1.7)	5 (11.4)	
Not employed, n (%)	10 (18.9)	7 (15.9)	
Retired, n (%)	13 (24.5)	11 (25.0)	
Smoking status			0.195
Active smoker, n (%)	8 (15.1)	1 (2.3)	
Ex-smoker, n (%)	5 (9.5)	5 (11.3)	
Non-smoker, n (%)	39 (73.6)	37 (84.1)	
Duration of pain, weeks (range)	52 (4-1147)	25 (4-3152)	0.489
Co-morbidities			
Hypertension, n (%)	29 (54.7)	25 (56.8)	
Diabetes mellitus, n (%)	27 (50.9)	17 (38.6)	
Dyslipidaemia, n (%)	20 (37.7)	18 (40.9)	
Others, n (%)	7 (13.2)	11 (25.0)	
Use of oral analgesia			0.013
Yes, n (%)	47 (88.7)	30 (68.2)	
No, n (%)	6 (11.3)	14 (31.8)	

Table 3: Baseline total PDQ-M, NRS of pain and SF-36 scores of study participants

	Neuropathic pain (n=53)	Nociceptive pain (n=44)	p
Total PDQ-M score (SD)	22.4 (6.7)	17.3 (6.4)	<0.001
NRS of pain score			
Current pain (SD)	4.2 (2.4)	3.9 (2.2)	0.494
Strongest pain (SD)	7.0 (2.3)	6.0 (2.3)	0.040
Average pain (SD)	5.6 (2.0)	4.9 (2.2)	0.090
SF-36			
Physical functioning (SD)	47.0 (24.7)	53.0 (26.3)	0.252
Role limitations due to physical health (SD)	6.1 (18.9)	12.5 (28.3)	0.189
Pain (SD)	44.5 (26.3)	49.4 (15.8)	0.286
General health (SD)	48.7 (17.2)	58.5 (18.6)	0.008
Role limitations due to emotional problems (SD)	18.9 (33.7)	28.0 (40.0)	0.223
Energy fatigue (SD)	52.1 (20.5)	58.6 (19.4)	0.111
Emotional well-being (SD)	66.3 (19.0)	75.5 (17.4)	0.016
Social functioning (SD)	67.5 (27.1)	72.2 (23.6)	0.370

PDQ-M painDETECT questionnaire – Malay version; NRS three-type numeric rating scale; SF-36 Medical Outcomes Study 36-item Short Form Healthy Survey

multiple languages. It was originally developed to detect neuropathic pain components especially in low back pain but is now widely used for many other chronic pain conditions. PDQ can be self-administered by patients with ease and may not necessarily require clinical examination. Moreover, PDQ is a time-efficient screening tool. This is reflected by the time taken to answer the questionnaire by the study participants, with median time of 7 minutes. The questionnaire consists of four domains – first domain assesses intensity of pain, second domain determines course of pain, third domain regarding radiation of pain whereas fourth domain addresses sensory descriptor items of pain using Likert scale. In the original PDQ, a cut-off score of ≥19 indicates probable neuropathic pain whereas a score of ≤12 suggests neuropathic pain to be unlikely.

One of the challenges in clinical practice and research is the availability of patient-reported outcome measures or patient-administered questionnaire of good quality to detect and quantify the presence of a disease. Patient-reported outcome measurement plays an important role in health care and understanding health outcomes of individual patients.[9] They are widely used in research and clinical practice and are relatively inexpensive compared to diagnostic tests.[10] Due to globalization of research, there is an increasing need to translate and culturally adapt the patient-reported outcome measurements.[11] Therefore, to ensure our translated questionnaire is of a high quality, internationally accepted methodology procedure was performed. The ISPOR Patient-Reported Outcomes Translation and Linguistic Validation Task Force guidelines outlined the principles of good practice in translation and cultural adaptation via 10 steps as described above. The use of these guidelines improves the linguistic and cultural equivalence.[12]

Table 4: Multilinear regression analysis

Predictors	Neuropathic pain (n=53)		Nociceptive pain (n=44)	
	b	p	b	p
Gender	-0.422	0.008	0.016	0.931
Education	-0.111	0.427	-0.009	0.961
BMI	-0.029	0.830	-0.126	0.488
Employment	-0.013	0.929	0.233	0.247
Smoking	0.586	<0.001	-0.124	0.496
Analgesia use	0.217	0.114	0.257	0.201

Although one of the comments during cognitive debriefing was that the questionnaire appeared congested with small fonts making reading difficult, a change in the questionnaire formatting may produce variations in response, hence we opted to maintain the same layout as the original version. The cognitive debriefing phase was crucial to determine how the translated questions were interpreted and perceived. Based on the interview, we made several changes for a better culturally-adapted translated questionnaire.

Neuropathic pain is pain caused by lesion or disease of the somatosensory nervous system, either at peripheral or central level; whereas nociceptive pain is an unpleasant sensory experience associated with tissue damage. Neuropathic pain causes suffering and disability for many patients but is often under-diagnosed and sub-optimally treated.[4] However, the development of simple questionnaires for neuropathic pain has improved diagnosis of this condition.[13] The availability of PDQ-M will raise awareness among healthcare practitioners about neuropathic pain and allow for easy screening of diagnosis and subsequently prompt and appropriate management. This is particularly useful for screening by non-specialists due to its ease of use, providing immediately available information.

However, it is important to note that pain in a region with nerve injury may not necessarily be entirely neuropathic origin, as nerve injury may lead to concomitant nociceptive pain, thereby affecting the scores of PDQ.[14] Moreover, due to the complexity of sensory aberrations, even positive (allodynia and hyperalgesia) or negative (hypoesthesia and hypoalgesia) sensory phenomenon have been reported in non-neuropathic pain conditions during clinical examination.[14] This may explain the PDQ-M scores in our patients with nociceptive pain, although those with neuropathic pain had significantly higher scores than patients with nociceptive pain.

Majority of our patients with neuropathic pain have moderate-intensity pain as reflected by the mean NRS scores of 4.2, 7.0 and 5.6 for current pain, strongest pain and average pain components respectively. NRS is commonly used to assess the present intensity of acute pain and is preferred due to its administration simplicity and reliability.[15] It has shown high correlations with other pain-assessment tools.[16,17] A score of 4 and above on the 11-point NRS (NRS-11) is generally considered the cut-off for moderate pain.[18]

Three drug classes have received strong recommendations as first line therapy in neuropathic pain management guidelines, ie tricyclic antidepressants especially amitriptyline, serotonin-norepinephrine reuptake inhibitors such as duloxetine, and anticonvulsants gabapentin and pregabalin.[19] In this regard, anticonvulsant particularly gabapentin is the most used analgesia among our patients with neuropathic pain.

In our cohort of study participants with neuropathic pain, higher PDQ-M score was correlated with active smoking and female gender. Current smoking status and higher nicotine dependence have been reported to be associated with neuropathic pain secondary to chronic radiculopathy[20], foot and ankle injury[21], burn injury[22], HIV/AIDS[23], spinal cord injury[24], diabetes[25] and post-herpetic infection.[26] A dose-response relationship was observed in prospective cohort studies of smoking with chronic painful conditions.[27,28] In addition, smokers complain of greater pain intensity and functional impairment.[29-32] The mechanisms of chronic pain in smokers are multi-factorial; including altered pain processing, interaction with opioids, structural damage of other systems, psychosocial factors and presence of depression.[33] Females are at higher risk for many common pain conditions and use analgesia more often, even without significant difference in pain frequency and severity compared to males.[34,35] Among patients with diabetes, although nerve injury and polyneuropathy are more common in males, females report greater pain intensity.[36]

We assessed health-related quality of life (HRQoL) among our study participants as they report the impact of the disease on the patients' physical, psychological and social functioning. It is well known that patients with neuropathic pain have reduced quality of life. Patients with neuropathic pain are shown to have greater reduction in HRQoL scores compared to non-neuropathic pain although this effect is not consistent as this may be affected by the severity of pain. The SF36 is extensively used and validated in chronic pain conditions. In our patients, those with neuropathic pain have consistently lower SF36 scores across all categories compared to patients with nociceptive pain, although the difference was statistically significant only in the Emotional well-being category.

As for limitation of this study, screening tools are known to miss about 10-20% of patients with clinician-diagnosed neuropathic pain indicating that these questionnaires offer guidance for

further diagnostic evaluation but cannot replace clinical judgement.[14] Furthermore, this study was performed among clinic attendants with clinician-diagnosed neuropathic pain, hence the ability of this questionnaire to detect neuropathic pain in the general population is not fully elucidated. However, our study recruited patients with different aetiologies of neuropathic and nociceptive pain origins, from different centres in Malaysia, hence reflects a diverse population of different ethnicity.

In conclusion, we developed the Malay version of the painDETECT questionnaire which was cross-culturally adapted for ease of understanding among the local population. This was done via careful face-to-face interview during the cognitive debriefing phase. A subsequent validation study will be useful to assess the psychometric properties of PDQ-M.

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DISCLOSURE

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Conflict of interest: None

Ethics: The protocol was approved by the National Medical Research Registration Ethical Committee (NMRR-19-3805-51803). All patients gave informed consent to participate in this study and for publication.

Availability of data and materials: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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