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Validation and reliability of the Malay version of the painDETECT questionnaire (PDQ-M) among patients with neuropathic and nociceptive pain

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Abstract

Background: Neuropathic pain is chronic and debilitating. Early and accurate diagnosis is important for appropriate management. The painDETECT questionnaire (PDQ) is an effective screening tool for presence of neuropathic pain. We tested the validity and reliability of the translated Malay version of PDQ (PDQ-M). *Methods:* This was a multi-center cross-sectional study conducted over 24 months. The original English version of PDQ was translated into Malay version following international guidelines. Subsequently, patients with chronic pain were administered PDQ-M and Malay version of SF36 at baseline and 2-4 weeks later. The reliability, construct and criterion validity of PDQ-M were evaluated. Clinician diagnoses were used as gold standard for comparison of diagnostic accuracy. Multiple regression analysis was performed to determine correlation between PDQ-M and SF-36 scores. *Results:* A total of 97 patients were included in the study (53 with neuropathic pain, 44 with nociceptive pain). The EFA of PDQ-M produced three factors which explained 58.3% of the variance. It exhibited fair consistency with Cronbach's alpha coefficient of 0.719 (for all 9 items) and 0.755 (for 7-item with Likert scale). PDQ-M is reliable with Cronbach's alpha coefficient of 0.719 and 0.852 for test-retest reliability. A score of ≥17 was the best cut-off value for discriminating between neuropathic and non-neuropathic pain in PDQ-M (79.2% sensitivity, 50.0% specificity). Multiple regression analysis exhibited total PDQ-M score to have significant negative correlation with all components of SF-36 scores except role limitation due to physical health.
Conclusions: PDQ-M is a reliable and valid self-administered screening tool for neuropathic pain.

Keywords: Neuropathic pain; nociceptive pain; questionnaire; validation; chronic pain; pain assessment; Malay

INTRODUCTION

Chronic pain is broadly classified into two main categories – neuropathic pain and nociceptive pain. Neuropathic pain is due to direct consequence of lesion or disease affecting the somatosensory system, whereas nociceptive pain is pain arising from direct damage to tissues.[1] Neuropathic pain is often chronic and debilitating[2], leading to reduced quality of life among patients suffering from this condition. One of the challenges is to differentiate neuropathic from nociceptive pain. Although there is considerable overlap in the patients' presentation between the two types of pain, early and accurate diagnosis is important so that appropriate management can be instituted correctly with favorable outcome as neuropathic pain is resistant to standard analgesic such as non-steroidal anti-inflammatory drugs.[3]

The diagnosis of neuropathic pain requires careful evaluation via detailed history and physical

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examination by managing physicians.[4] However, full neurological examination in determining this pain condition is time-consuming and is difficult in a busy primary care clinic. Hence, effective screening tools will be useful in detecting this condition and to differentiate it from nociceptive pain.

The painDetect Questionnaire (PDQ) was originally developed in Germany in detecting chronic low back pain. The reliability of this self-administered questionnaire has been validated with reported high sensitivity, specificity, and positive predictive value, as well as excellent internal consistency and fair to good criterion-related validity.[5] Due to its effectiveness and simplicity of use, it has been translated and validated into multiple languages. It consists of four domains, assessing pain in terms of intensity, course, radiation and 7-item sensory descriptors in Likert scale. Scores are calculated based on 7-item sensory descriptors, course of pain and presence of radiation pain, which maximum score of 38. A cut-off score of ≥19 is indication of probable neuropathic pain, score of ≤12 suggests otherwise, whereas a score in between the two indicates ambiguous result.

In Malaysia, patients from rural areas face more difficulty to access healthcare services compared to those from urban areas.[6] Furthermore, there is lack of trained personnel in detecting neuropathic pain.[7] As Malay language is the most used language in Malaysia, translation and validation of PDQ will be helpful to raise awareness among healthcare workers about neuropathic pain and provide them with a simple tool in detecting this condition. Hence the main objective of this study is to translate the questionnaire into Malay language (PDQ-M) and validate the questionnaire.

METHODS

Permission to translate the PDQ into Malay language was first obtained from the original researcher. The study was then approved by the local research ethics committee. All eligible participants gave written informed consent prior to recruitment.

The translation process of the PDQ adhered to the methodology recommended by the ISPOR Patient-Reported Outcomes Translation and Linguistic Validation Task Force guidelines.[8] Briefly, forward translation was performed by two independent Malay native speakers with medical background and informed about the concept of PDQ. Subsequently, backward translation was conducted by two independent Malay and English bi-lingual translators who were uninformed about the concept of PDQ. For both translation process, discrepancies were discussed and adjustments made accordingly. Cognitive debriefing was performed among ten participants with no medical background using the preliminary PDQ-M (pre-PDQ-M). Further modifications were made to the pre-PDQ-M based on the participants' suggestions. Finally, the translation is finalized and known as PDQ-M.[9]

The desired sample size to run an exploratory factorial analysis (EFA) is a ratio of five subjects per item as it served as one of the assumptions to be fulfilled. With the PDQ-M consisting of 9 items, it was ideal to have at least 45 subjects. Hence, the finalized PDQ-M was tested among 97 patients aged 18 years and above from 4 different hospitals in Malaysia. These patients had stable disease condition and pain of at least 4 weeks' duration. Those who were acutely ill, not able to understand or respond to the questionnaire or with cultural and language barrier were excluded. The patients' socio-demographic data and medical information were documented using a standardized data collection form.

At first, the patients were required to answer 2 sets of questionnaires in the following order: PDQ-M followed by Malay version of Medical Outcomes Study 36-item Short Form Healthy Survey (SF36). Subsequently, the patients were administered the same questionnaire 2-4 weeks after the first visit to determine test-retest reliability of the questionnaire.

Statistical analysis

Statistical analysis was performed using SPSS version 28 (IBM Corporation, Armonk, New York). Descriptive statistics were calculated. Suitability of PDQ-M data for factor analysis was verified using the Bartlett's test of sphericity and the Kaiser-Mayer-Olkin (KMO) measure of sampling adequacy. Construct validity was investigated by exploratory factorial analysis (EFA) with Promax rotation. A factor loading of >0.40 was used to determine the items for each factor. The internal consistency of the questionnaire was assessed using Cronbach's alpha test. Values of 0.7-0.9 are considered acceptable for reliability. The level of significance was set at 5% ($p<0.05$).

RESULTS

A total of 107 patients were recruited in this study. However, 10 patients were excluded as

they did not return for visit 2 for retest. A total of 97 patients were evaluated: 53 with neuropathic pain, 44 with nociceptive pain. The demographic characteristics of the patients included are presented in Table 1. Mean total PDQ-M score for those with neuropathic pain was 22.4±6.7, whereas mean for those with nociceptive pain was 17.3±6.4, p<0.001.

Internal consistency and test-retest reliability

PDQ-M is reliable with Cronbach's alpha coefficient of 0.719 (for all 9 items) and 0.755 (for 7-item with Likert scale). Cronbach's alpha coefficient is 0.716 for patients with neuropathic pain and 0.744 among patients with nociceptive pain in 7-item with Likert scale. Internal consistency did not improve by dropping any of the Likert-type items in main component of PDQ-M (Cronbach's alpha ranged from 0.711 to 0.740 for all samples; 0.656 to 0.700 for neuropathic pain and 0.687 to 0.736 for nociceptive pain) (Tables 2a and 2b).

There was also a good test-retest reliability in the overall sample, with Cronbach's alpha coefficient of 0.852 (for all 9 items) and 0.869 (for 7-item with Likert scale). Cronbach's alpha coefficient is 0.845 for patients with neuropathic pain and 0.862 among patients with nociceptive pain in test-retest reliability in 7-item with Likert scale. Similarly, there was no improvement of Cronbach's alpha coefficient with removal of any of the Likert-type items in main component of PDQ-M (Cronbach's alpha ranged from 0.856 to 0.868 for overall samples). Spearman rank correlation coefficient demonstrated a significant correlation of 0.691, 0.641 and 0.601 for all samples, those with neuropathic pain and

Table 1: 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, males (%)	26 (49.1)	17 (38.6)	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 (17.0)	1 (2.3)	
Secondary, n (%)	26 (49.1)	20 (45.5)	
Tertiary, n (%)	14 (26.4)	23 (52.3)	
No formal education, n (%)	3 (5.7%)	0 (0)	
Education level			0.034
Secondary and below, n (%)	37 (72.5)	22 (50.0)	
Tertiary, n (%)	14 (27.5)	22 (50.0)	
Body mass index, kg/m^2 (SD)	28.1 (6.7)	27.6 (8.5)	0.751
Duration of pain, weeks (range)	52 (4-1147)	25 (4-3152)	0.489
Diabetes mellitus			0.097
Yes (%)	27 (45.3)	17 (38.6)	
No (%)	26 (49.1)	27 61.4)	
Hypertension			0.669
Yes (%)	29 (61.7)	24 (55.8)	
No (%)	18 (38.3)	19 (44.2)	
Dyslipidemia			1.0
Yes (%)	20 (42.6)	18 (41.9)	
No (%)	27 (57.4)	25 (58.1)	
Smoking status			0.038
Yes (%)	8 (15.4)	1 (2.3)	
No (%)	44 (84.6)	42 (97.7)	

Table 2a: Corrected item-total correlations and Cronbach's alpha values if an item is deleted in the PDQ-M among patients with neuropathic pain

PDQ-M components	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Squared multiple correlation	Cronbach's alpha if item deleted
Item 1	18.31	32.780	0.443	0.340	0.679
Item 2	17.86	31.121	0.536	0.412	0.656
Item 3	19.1	33.330	0.376	0.371	0.695
Item 4	17.71	32.692	0.397	0.342	0.691
Item 5	18.67	33.347	0.359	0.211	0.700
Item 6	17.78	31.413	0.470	0.347	0.672
Item 7	18.57	32.770	0.406	0.392	0.688

Table 2b: Corrected item-total correlations and Cronbach's alpha values if an item is deleted in the PDQ-M among patients with nociceptive pain

PDQ-M components	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Squared multiple correlation	Cronbach's alpha if item deleted
Item 1	14.02	27.325	0.566	0.373	0.687
Item 2	13.95	29.114	0.440	0.347	0.720
Item 3	15.07	33.507	0.457	0.271	0.722
Item 4	14.20	29.701	0.464	0.365	0.712
Item 5	14.27	29.412	0.514	0.340	0.701
Item 6	14.16	31.346	0.357	0.250	0.736
Item 7	13.86	30.167	0.454	0.299	0.715

nociceptive pain respectively, between test and retest scores (all p<0.001) (Tables 3a-3c).

Criterion validity

Considering the diagnosis of neuropathic or nociceptive pain by managing clinician as the gold standard, the area under the curve of receiver operating characteristic (ROC) was 0.712 (95% confidence interval 0.609 to 0.814, p<0.001) for the total PDQ-M score (Figure 1). Coordinates of the curve identified a score of ≥17 as the best cut-off value discriminating between neuropathic and non-neuropathic pain in PDQ-M, that has 79.2% sensitivity and 50.0% specificity, positive predictive value of 69.8% and negative predictive value of 54.5%.

Predictive validity

Multiple regression analysis exhibited total PDQ-M score to have significant negative correlation with all components of SF-36 scores except role limitation due to physical health (Table 4).

Construct Validity

The KMO Measure of Sampling Adequacy (MSA) value of 0.782 (>0.6) was good, indicating that the sample was appropriate for factor analysis.[10,11] The Bartlett's test proved to be significant as correlations were present with a p value of <0.001.

Three factors of formal importance (eigenvalue≥1.0) were identified in PDQ-M, which explained 58.3% of the variance, namely Hyperesthesia, Radiculopathy and Course of Pain. The first factor (Hyperesthesia) explained 25.9% of the total variance and includes items 1, 3, 5 and 7 of the 7 Likert-type items, with factors loading ranging between 0.470 to 0.751. The second factor (Radiculopathy) explained 8.9% of total variance, with factor loading ranging between 0.308 to 0.874. The third factor (Course of pain) explained 3.0% of total variance, with factor loading of 0.40 (Table 5).

DISCUSSION

This current study examined the internal consistency, concurrent and predictive validity

Table 3a: Pearson's Correlation for Test-Retest Validity of PDQ-M for all samples

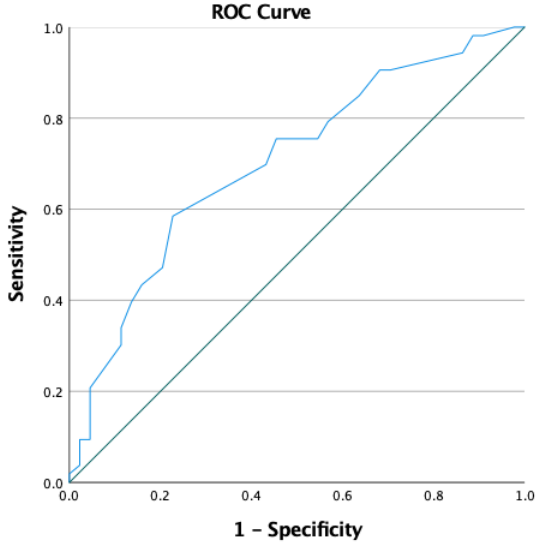
		Baseline total PDQ-M scores	Retest total PDQ-M scores
Baseline total PDQ-M scores (all samples)	Correlation Coefficient	1	0.691
	Sig. (2-tailed)		<0.001
	N	97	97
Retest total PDQ-M scores (all samples)	Correlation Coefficient	0.691	1
	Sig. (2-tailed)	<0.001	
	N	97	97

Table 3b: Pearson's Correlation for Test-Retest Validity of PDQ-M for neuropathic pain

		Baseline total PDQ-M scores	Retest total PDQ-M scores
Baseline total PDQ-M scores	Correlation Coefficient	1	0.641
	Sig. (2-tailed)		<0.001
	N	53	53
Retest total PDQ-M scores	Correlation Coefficient	0.641	1
	Sig. (2-tailed)	<0.001	
	N	53	53

Table 3c: Pearson's Correlation for Test-Retest Validity of PDQ-M for nociceptive pain

		Baseline total PDQ-M scores	Retest total PDQ-M scores
Baseline total PDQ-M scores	Correlation Coefficient	1	0.601
	Sig. (2-tailed)		<0.001
	N	44	44
Retest total PDQ-M scores	Correlation Coefficient	0.601	
	Sig. (2-tailed)	<0.001	
	N	44	44



Area under ROC curve = 0.712

Figure 1. ROC curve for total PDQ-M score

Table 4: Correlation between PDQ-M scores and SF-36 scores

SF-36 components	Correlation coefficient with total PDQ-M scores	p
Physical functioning	-0.232	0.022
Role limitations due to physical health	-0.071	0.491
Pain	-0.396	<0.001
General health	-0.358	<0.001
Role limitations due to emotional problems	-0.235	0.021
Energy fatigue	-0.261	0.01
Emotional well-being	-0.341	<0.001
Social functioning	-0.312	0.002

of PDQ-M. The findings from this study indicate that PDQ-M has good psychometric properties in patients with neuropathic pain. It is a reliable and valid instrument to assess neuropathic pain in a Malay-speaking population. In this study, PDQ-M exhibited good internal consistency, which is consistent with other versions of PDQ, ie Japanese (PDQ-J), Filipino (PDQ-Tag and PDQ-Ceb), Hindi (Hi-PDQ), Brazilian and Arabic versions. To date, this is the first study in translating questionnaire in screening for neuropathic pain in Malaysia and it demonstrates that PDQ-M has good Cronbach's alpha coefficient as the English version and other translated versions of PDQ.

Criterion validity determines how well a measure predicts an outcome for another measure. It includes concurrent validity and predictive validity. Concurrent validity measures how a test compares against a criterion or "gold standard", which in this case, is the clinicians' diagnosis. With this regard, PDQ-M demonstrated good sensitivity, specificity, positive and negative predictive value. This suggests that PDQ-M is statistically as good as clinical diagnosis for accurate discrimination between neuropathic pain and nociceptive pain. Intraclass correlation coefficient (ICC) was calculated between test and retest scores from our patients. ICC of greater than 0.80 is considered to indicate excellent reliability. The test-retest reliability of PDQ-M was significantly high (ICC=0.869), indicating good reliability and repeatability, comparable to other version of PDQ – Hindi (ICC=0.94), Japanese (ICC=0.94), and Arab (ICC=0.970).

Predictive validity is the degree to which a test accurately predicts a future outcome, which in this case, is assessed by SF-36 scores. Our analysis demonstrated negative correlation between PDQ-M scores and SF-36 except for role limitation due to physical health. Patients with chronic pain have lower quality of life.[12] Our study indicated that our cohort of patients with elevated PDQ-M scores result in profound impairment of both physical and mental quality of life, although the pain condition may not have limited their roles in everyday conditions.

Our study is not without limitations. First, the samples were recruited from outpatient clinics using convenience sampling, thus may raise concern about generalizability. Secondly,

Table 5: Exploratory Factor Analysis of PDQ-M using alpha factoring

	Component		
Item	**Component 1**	**Component 2**	**Component 3**
1	0.470		
2		0.613	
3	0.550		
4		0.385	
5	0.643		
6		0.874	
7	0.751		
Radiating pain		0.308	
Course of pain			0.400

our study was cross-sectional in nature, hence causality could not be determined through this study. However, we included patients of different ethnicities and varied diagnoses from multiple centers which can then better reflect the Malaysian population. Furthermore, this is the first study on validating PDQ-M in Malaysia, which will be beneficial in future research among patients with neuropathic pain. As majority of Malaysians are of the Malay ethnicity, the use of this translated and validated questionnaire will be helpful in clinical setting in screening for presence of neuropathic pain.

In conclusion, PDQ-M is a reliable and valid self-administered screening tool for neuropathic pain among Malaysians. The use of this questionnaire for the assessment of patients with suspected neuropathic pain should be encouraged among healthcare workers in Malaysia.

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DISCLOSURE

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.

Data availability: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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Conflict of interests: None

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