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The validation and cross-cultural adaptation of the PainDETECT questionnaire in osteoarthritis-related pain

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Abstract

Background Patients with knee osteoarthritis (KOA) often experience persistent pain and functional impairment after total knee arthroplasty (TKA), which presents challenges for pain management. Accurate preoperative assessment of pain characteristics is crucial for tailoring individualized treatment plans. The PainDETECT Questionnaire has been widely used to identify neuropathic components in chronic pain and has been validated for its reliability and validity across various cultural contexts. However, a culturally adapted version tailored to Chinese patients is currently lacking. This study aims to translate and culturally adapt PainDETECT for Chinese patients and evaluate its validity in TKA patients in China.

Methods This study followed international guidelines to translate and adapt the PainDETECT Questionnaire (PDQ) into Chinese (PDQ-CV). A cohort of 241 knee osteoarthritis (KOA) patients completed the PDQ-CV, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), EuroQol-5 Dimensions-5 Levels (EQ-5D-5 L), and Central Sensitization Inventory Chinese Version (CSI-CV). We assessed internal consistency using Cronbach's alpha and test-retest reliability via intraclass correlation coefficient (ICC). Construct and structural validity were evaluated through Pearson correlations and factor analyses.

Results The PDQ-CV demonstrated good acceptability among KOA patients, with no floor or ceiling effects observed. Internal consistency was high (Cronbach's $\alpha = 0.896$), and test-retest reliability was excellent (ICC = 0.994; 95% CI: 0.943–1.045). The PDQ-CV total score showed significant positive correlations with WOMAC ($r = 0.589$, $P < 0.01$), EQ-5D-5 L ($r = 0.533$, $P < 0.01$), and CSI-CV ($r = 0.776$, $P < 0.01$). Exploratory factor analysis (EFA) extracted two primary factors, corresponding to the sensory dimension (52.1% variance) and the affective dimension (16.3% variance), explaining a total variance of 68.4%.

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Conclusion The PDQ-CV demonstrated good feasibility, reliability, and validity in Chinese KOA patients, supporting its use in clinical practice and providing a foundation for future research.

Keywords Knee osteoarthritis, PainDETECT questionnaire, Pain assessment, Cross-cultural adaptation, Psychometrics, Total knee arthroplasty

Introduction

Both nociceptive and neuropathic pain components contribute to the experience of pain, necessitating different pain management strategies [1]. Neuropathic pain is a complex pain type that arises from damage to or dysfunction of the central or peripheral nervous system, commonly observed in patients undergoing total knee arthroplasty (TKA). This type of pain is often caused by conditions such as diabetic neuropathy, sciatica, or postoperative complications. Literature indicates that pre-existing neuropathic pain in TKA patients significantly affects postoperative pain management and rehabilitation outcomes [2, 3]. Therefore, differentiating pain characteristics prior to surgery is crucial for optimizing postoperative care and rehabilitation [4].

The PainDETECT Questionnaire is a self-report tool originally developed in German [5], specifically designed to identify neuropathic pain. It demonstrates a sensitivity of 85%, specificity of 80%, and positive predictive accuracy of 83% for detecting neuropathic pain (NeP) components in patients with lower back pain and other pain types [5, 6]. The tool has been validated as having high reliability and validity in distinguishing between different pain types [7]. Subsequently, it has been translated into approximately 30 languages and validated in patients with knee osteoarthritis (KOA), including English [8], Spanish [9], Japanese [10], and Korean [11]. In China, the PainDETECT Questionnaire has been utilized to assess the neuropathic components of pain in patients with postherpetic neuralgia, demonstrating good validity and reliability [12]. Despite its widespread international application, a culturally adapted version for Chinese patients with KOA has not yet been developed and validated. Given the substantial population of KOA patients in China, the development and validation of a Chinese version of the PainDETECT Questionnaire is crucial, as an accurate pain assessment tool will significantly enhance treatment efficacy and enable personalized treatment strategies.

This study aims to translate the PainDETECT Questionnaire into Chinese and conduct cross-cultural adaptation for KOA patients in China, evaluating its reliability and validity in this population. By validating the applicability of the PainDETECT Questionnaire, we hope to provide an effective tool for pain management in Chinese patients with KOA.

Materials and methods

Translation and cross-cultural adaptation

This study adhered to established guidelines for translation and cross-cultural adaptation, comprising five steps [13]. First, two native Chinese speakers fluent in English independently translated the original English version of the PainDETECT Questionnaire into Simplified Chinese. One translator was an orthopedic surgeon, and the other was a professional translator. After comparing the two translations, a preliminary consensus version of the Chinese Questionnaire (PDQ-CV) was developed. In the next step, the translators and the authors held a consensus meeting to address issues related to linguistic expression and cultural differences, resulting in the first draft of the PDQ-CV. In the third step, two bilingual translators fluent in Chinese (with a medical background) independently back-translated the first draft of the PDQ-CV into English. These back-translations were then reviewed to reach a consensus. Independent experts compared the back-translated versions with the original English version, providing feedback to develop the second version of the PDQ-CV. In the fourth step, the research team held another consensus meeting to resolve any remaining linguistic differences and ensure consistency in cultural adaptation and conceptual equivalence between the Chinese and English versions, finalizing the PDQ-CV. Finally, a pilot test of the finalized PDQ-CV was conducted on 50 KOA patients. Feedback was collected to refine the questionnaire, addressing any issues from the pilot test, and finalizing the version for clinical validation (as detailed in Additional file 1: Appendix A).

Patient recruitment and data collection

To comprehensively assess reliability parameters, 241 KOA patients were recruited, adhering to the guideline that each questionnaire item should have at least 10 participants [14]. Patients were recruited between January 2023 and December 2023 at the outpatient clinic of the Honghui Hospital in Shaanxi Province. Inclusion criteria were as follows: (a) age ≥ 18 years, (b) adequate cognitive ability to complete the questionnaires, and (c) fluent in Mandarin. Exclusion criteria were: (a) history of other vascular or musculoskeletal diseases that could affect activity or pain symptoms, and (b) severe conditions affecting daily life, such as heart disease, respiratory disorders, or psychiatric illnesses. Post-hoc power analysis was conducted using G*Power software (Düsseldorf, Germany) to verify the statistical power of the results.

The significance level was set at $P < 0.05$. All participants provided written informed consent, and the study was approved by the Institutional Ethics Committee of Honghui Hospital, Xi'an Jiaotong University (Approval number: No.202209022).

Questionnaires

All patients were required to complete the questionnaires as briefly described below.

Demographic information

Every participant was required to fill out the general demographic information questionnaire, which included age, body mass index, gender, employment status, living situation, and educational level.

PainDETECT questionnaire (PDQ)

The PainDETECT Questionnaire (PDQ) is a standardized tool for comprehensively assessing a patient's pain condition, divided into four sections. The first section evaluates pain intensity using a 0–10 numeric rating scale. The second section assesses pain patterns through four graphical representations. The third section requires identifying pain locations and radiating pain. The fourth section includes seven weighted sensory descriptors to evaluate pain intensity and dysesthesia. The total score ranges from 0 to 38; a score of ≤ 12 suggests that pain is very unlikely to be present, a score of ≥ 19 indicates that pain is very likely to be present, and a score between 12 and 19 denotes an unclear diagnosis [5].

Western Ontario and McMaster universities osteoarthritis index (WOMAC)

The WOMAC is a reliable assessment tool widely used in clinical studies of patients with osteoarthritis [15], covering three domains: stiffness, pain, and joint function, with each item scored from 0 to 4.

EuroQoL five-dimensions questionnaire (EQ-5D-5 L)

The EQ-5D-5 L is a multi-dimensional health-related quality of life (HRQoL) measurement tool widely used for HRQoL assessment in Chinese populations [16], evaluating health status across five dimensions, each with five levels.

Chinese version of the central sensitization inventory (CSI-CV)

The CSI-CV is a rigorously validated tool for quantifying characteristics of central sensitization in the central nervous system, suitable for Chinese populations [17, 18], providing a comprehensive description of the sensitization phenomenon.

Psychometric assessment and data analyses

The Kolmogorov-Smirnov test was used to assess the normal distribution of the questionnaire total scores. Continuous data are reported as mean ± standard deviation, and categorical data are presented as frequencies and percentages. Statistical analyses were performed using SPSS 26.0 software, with a significance level set at $P < 0.05$.

Feasibility assessment

This study evaluated the feasibility of the questionnaire survey, documenting the difficulties encountered by respondents and the average time taken to complete the questionnaire.

Floor and ceiling effect analysis

The distribution of PDQ scores was analyzed to identify floor and ceiling effects. An effect is considered present if more than 15% of participants achieve the lowest or highest possible scores.

Reliability

Internal consistency and test-retest reliability

Internal consistency, which measures the interrelatedness of a set of items as a single construct, is typically assessed using Cronbach's alpha coefficient. For the purposes of this study, we deemed coefficients below 0.70 as poor, those ranging from 0.70 to 0.79 as adequate, those from 0.80 to 0.89 as good, and those of 0.90 or above as excellent [14]. To ascertain the test-retest reliability, a random sample of 60 patients was drawn from a larger cohort of 241 participants. The intraclass correlation coefficient (ICC), calculated using a two-way random effects model analysis of variance, served as the metric for this assessment. An ICC between 0.5 and 0.75 suggests moderate reliability, while values between 0.75 and 0.9 indicate good reliability, and those above 0.9 suggest very high reliability [19]. Adhering to the recommended interval of 1–2 weeks for repeated measurements [14], we selected a 7-day interval for the re-administration of our questionnaire.

Measurement error

Standard error of measurement (SEM) is an indicator of absolute reliability [14]. The most common calculation method for this statistic is the following equation: $SEM = SD \cdot \sqrt{(1 - R)}$, where SD = the sample standard deviation and R = the calculated ICC [20].

Construct validity

The psychometric properties of the Simplified Chinese versions of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the five-level EuroQol five-dimension questionnaire (EQ-5D-5 L), and the

Table 1 Demographic data of participants

Items	Participants (*N* = 241)
Age (years, mean + SD)	65.0 ± 7.2
Sex, number(%)	163(67.6)
Women	78(32.4)
Men	160.7 ± 6.2
Height (cm, mean ± SD)	64.3 ± 10.3
Weight (kg, mean ± SD)	24.9 ± 3.3
Body mass index (mean ± SD)	102(42.3)
Educational level, number (%)	94(39)
Primary school and below	35(14.5)
Junior high school	10(4.1)
High school	27(11.2)
University or above (including junior college)	182(75.5)
Residence status, number (%)	32(13.3)
Live alone	154(63.9)
Living with partner	20(8.3)
Living with children	67(27.8)
Employment, number (%)	4.9 ± 2.8
Farming	
Unemployed	
Retirement (including no longer farming)	
Sickness time (mean ± SD)	
side, number (%)	130(53.9)
Right	111(46.1)
Left	

Central Sensitization Inventory-Central Version (CSI-CV) have been extensively validated within the Mainland Chinese population. This study aimed to evaluate the construct validity of the PainDETECT Questionnaire Chinese Version (PDQ-CV) by determining the Pearson correlation coefficients with the aforementioned instruments. Correlation strengths are categorized as none or very weak (0-0.2), weak (0.21–0.4), moderate (0.41–0.60), strong (0.61–0.80), or very strong (0.81-1.0) [21]. Our a priori hypothesis was that the PDQ-CV would demonstrate substantial correlations with the WOMAC, EQ-5D-5 L, and CSI-CV, indicative of its construct validity in this patient cohort.

Structural validity

Due to the differential factor structure of the PainDETECT Questionnaire across various disease states, we used exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) to evaluate the structural effectiveness and determine the optimal number of factors. We employed the Kaiser-Meyer-Olkin (KMO) measure and Bartlett's test of sphericity to assess the suitability of our data for factor analysis. Bartlett's test confirmed the presence of sufficient correlations among the variables for factor analysis. We proceeded with principal component analysis, employing Kaiser's normalization and Varimax rotation to simplify the factor structure. A factor loading cutoff of 0.6 was applied to retain items, in line with standard practices to ensure that only items that significantly contribute were included in the final factor solution.

Table 2 Distribution of PDQ-CV scores, ceiling and floor effects, and internal consistency reliability

	Mean + SD	%Floor[1]	%Ceiling[2]	Cronbach's a[3]
PDQ-CV	12.2 ± 6.3	0.4	0.4	0.896
Sensory dimension	7.6 ± 5.4	0.8	0	0.969
affective dimension	6.1 ± 2.7	5.4	0	0.885

[1]% scoring worst possible value (0)

[2]% scoring best possible value (10)

[3] Internal consistency reliability

PDQ-CV, PainDETECT Questionnaire Chinese Version

Results

The demographic data of all the participants are shown in Table 1.

Feasibility Assessment

No missing data were recorded during the administration of the PDQ-CV and the other questionnaires. The average completion time for the PDQ-CV was 3.5 min (SD 0.5), demonstrating its practicality and efficiency in clinical settings. Post-hoc power analysis revealed that, at an alpha level of 0.05, the statistical power to detect differences between patients with neuropathic pain and those without neuropathic pain was 87.9%.

Reliability analysis

As presented in Table 2, the Cronbach's α coefficient of the PDQ-CV indicates good internal consistency among the items (0.896). Test-retest reliability analysis with 60 participants (24.9%) over a one-week interval yielded mean scores of 13.1 (SD = 7.2) and 13.0 (SD = 6.9), reflecting high consistency. The Pearson correlation coefficient between the two measurements was 0.994 ($P < 0.001$, 95% CI 0.943–1.045), confirming a strong positive correlation over time. The standard error of measurement (SEM) was 0.6 and 1.0, respectively, supporting the temporal stability of the PDQ-CV in assessing neuropathic pain.

Floor and ceiling effect analysis

Table 2 details the mean, standard deviation, and analysis of the floor and ceiling effects for the PDQ-CV. No significant floor or ceiling effects were noted in patients with knee osteoarthritis. The mean total score of the PDQ-CV was 12.2 (SD ± 6.3), with mean scores of 7.6 (SD ± 5.4) for the sensory dimension and 6.1 (SD ± 2.7) for the affective dimension. The Cronbach's α for the PDQ-CV was 0.896, with no floor (0%) or ceiling (0%) effects observed for the total score. For the sensory and affective dimensions, the Cronbach's α coefficients were 0.969 and 0.885, respectively, calculated after item removal. These findings indicate robust internal consistency, validating the scale's effectiveness in assessing pain perception variations among participants.

Construct validity

To evaluate construct validity, 241 patients were included, with 40 (16.6%) diagnosed with neuropathic pain (PDQ-CV score ≥ 19) and 201 (83.4%) diagnosed with nociceptive pain [22, 23]. Bivariate correlation analysis was conducted between the PDQ-CV and the WOMAC, EQ-5D-5 L, and the Chinese version of the Central Sensitization Inventory (CSI-CV) (see Table 3). A strong positive correlation was found between the PDQ-CV (mean 12.2, SD = 6.3) and the WOMAC total score (mean 51.4, SD = 12.0, $r = 0.589$, $P < 0.01$). In the nociceptive pain group, the mean WOMAC score was 49.0(SD = 8.7, $r = 0.412$, $P < 0.01$), while in the neuropathic pain group, it was 63.3 (SD = 17.9, $r = 0.659$, $P < 0.01$). The positive correlation between the PDQ-CV and the EQ-5D-5 L score (mean 13.3, SD = 3.3, $r = 0.533$, $P < 0.01$) indicates significant negative impacts of neuropathic pain on health-related quality of life. The EQ-5D-5 L total scores were 12.7(SD = 3.1, $r = 0.325$, $P < 0.01$) for nociceptive and 16.3(SD = 3.1, $r = 0.782$, $P < 0.01$) for neuropathic pain groups. The high correlation with the CSI-CV (mean 24.8, SD = 13.5, $r = 0.776$, $P < 0.01$) underscores the close relationship between neuropathic pain and central sensitization, with CSI-CV scores of 20.0(SD = 8.6, $r = 0.292$, $P < 0.01$) for nociceptive and 48.7 (SD = 6.0, $r = 0.800$, $P < 0.01$) for neuropathic pain groups (see Table 4).

Table 3 Bivariate correlation results between PDQ-CV and related scales($N = 241$)

Variance	Mean (SD)	Pearson Correlation Coefficient	*P*-value
Womac	51.4(12.0)	0.589	<0.01
EQ-5D-5 L	13.3(3.3)	0.533	<0.01
CSI-CV	24.8(13.5)	0.776	<0.01

WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; EQ-5D-5 L, 5-level EuroQoL Group's 5-dimension questionnaire; CSI-CV, Central Sensitization Inventory Chinese Version

Structural validity

Exploratory Factor Analysis

Principal component analysis (PCA) with varimax rotation confirmed the factor structure of the PainDETECT Questionnaire. The Kaiser-Meyer-Olkin (KMO) value was 0.833, and Bartlett's test of sphericity was significant (χ^2 = 704.2, $P < 0.001$), indicating the suitability of the data for factor analysis. Two factors were extracted, explaining 52.1 and 16.3% of the variance, with a cumulative variance of 68.4%. Factor 1 represented the sensory dimension (neuropathic pain characteristics), while Factor 2 related to the affective dimension (pain occurrence pattern). The rotated component matrix indicated high loadings on respective factors, suggesting good internal consistency (see Table 5). This factor structure aligns with the two-factor model observed in other language versions of the PainDETECT Questionnaire, supporting its psychometric properties during cultural adaptation.

Table 5 Pattern matrix of factor analysis

Items	Sensory dimension	Response dimension
Burning sensation	**0.826**	0.000
Tingling pain or prickling pain	**0.845**	0.000
Dysesthesia	**0.814**	0.000
Pain attacks	0.000	**0.647**
Temperature-induced pain	**0.734**	0.000
Numbness	**0.647**	0.000
Pressure-induced pain	0.000	**0.887**

Bold items represent loading on a factor

Confirmatory factor analysis

Confirmatory factor analysis (CFA) evaluated the structural validity of the PDQ. The overall model fit was good, with fit indices showing a Goodness of Fit Index (GFI) of 0.902, a Comparative Fit Index (CFI) of 0.900, and a Root Mean Square Error of Approximation (RMSEA) of 0.149. Although the CMIN/DF ratio was 6.329, slightly above the recommended value of 5, the overall model fit was supported by the performance of the other indices (see Table 6). Comparisons with independent models showed significantly lower GFI and CFI values, affirming the robustness of our two-factor model.

Table 4 Bivariate correlation results between PDQ-CV and related scales in nociceptive and neuropathic pain populations

Variance	Mean (SD)		Pearson Correlation Coefficient		*P*-value	
	Nociceptive pain($N = 201$)	Neuropathic pain($N = 40$)	Nociceptive pain ($N = 201$)	Neuropathic pain($N = 40$)	Nociceptive pain ($N = 201$)	Neuropathic pain($N = 40$)
WOMAC Total Score	49.0(8.7)	63.3(17.9)	0.412	0.659	<0.01	<0.01
WOMAC Pain Subscale	14.1(4.4)	13.4 (6.7)	0.482	0.651	<0.01	<0.01
WOMAC Function Subscale	31.9(7.4)	44.6 (14.2)	0.160	0.500	<0.05	<0.01
WOMAC Stiffness Subscale	3.0(1.6)	5.3 (2.1)	0.188	0.199	<0.01	0.219
EQ-5D-5 L Total Score	12.7(3.1)	16.3 (3.1)	0.325	0.782	<0.01	<0.01
CSI-CV	20.0(8.6)	48.7 (6.0)	0.292	0.800	<0.01	<0.01

WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; EQ-5D-5 L, 5-level EuroQoL Group's 5-dimension questionnaire; CSI-CV, Central Sensitization Inventory Chinese Version

Table 6 Goodness-of-fit indices for the PainDETECT questionnaire Model

Fit Index	CMIN	DF	*P*	GFI	CFI
Default Model	82.280	13	<0.01	0.902	0.900
Independence Model	713.585	21	<0.01	0.446	0.000
RMSEA	0.149				
CMIN/DF	6.329				

CMIN, Chi-Square Statistic; DF, Degrees of Freedom; P, P-value; GFI, Goodness of Fit Index; CFI, Comparative Fit Index; RMSEA, Root Mean Square Error of Approximation

Discussion

This study successfully translated and culturally adapted the PainDETECT Questionnaire (PDQ) into Chinese, demonstrating that the PDQ-CV version exhibits robust psychometric properties for patients with KOA.

Geng et al. emphasized the significant impact of KOA on patients' quality of life, presenting a considerable challenge to global public health [24]. Additionally, Li et al. offered insights into the global burden and socioeconomic effects of KOA [25]. Although the etiology of KOA remains complex, current treatment strategies primarily focus on symptom relief and slowing disease progression. A key innovation of this research is the precise assessment of pain characteristics, which provides a scientific foundation for developing targeted therapeutic interventions. This enhancement of our understanding of KOA management holds crucial clinical relevance [26, 27]. The PDQ has been adapted into several languages, including Brazil [28], Dutch [29], English [8]and Spanish [9] with validations supporting its effectiveness across various cultural contexts.

Research on the PDQ in China has largely focused on patients with herpes zoster [12] and chronic pain [30], underscoring the need to validate its reliability and validity specifically for KOA patients. Our findings indicate that the PDQ-CV displays excellent discriminative ability, with no ceiling or floor effects observed [8, 29]. The Cronbach's α coefficient was 0.896, consistent with Spanish-validated language versions [9]. Moreover, the intraclass correlation coefficient (ICC) of 0.994 further affirms the scale's reliability.

Additionally, our study reveals significant positive correlations between the PDQ-CV and established scales such as WOMAC, EQ-5D-5 L, and CSI-CV (correlation coefficients of 0.589, 0.533, and 0.776, respectively, all $P < 0.01$). Notably, the correlation between the PDQ-CV and WOMAC total score highlights its effectiveness in assessing pain severity and functional impairment, consistent with findings from Polish studies [10, 31, 32]. These results affirm the PDQ-CV as a valid tool for evaluating neuropathic pain and its implications for health-related quality of life.

Exploratory factor analysis (EFA) confirmed the PDQ-CV's construct validity, revealing strong factor loadings for pain descriptors. The sensory dimension included "burning sensation" (0.826) and "prickling pain" (0.845), while the reactive dimension comprised "pain attacks" (0.647) and " pressure-induced pain " (0.887). These findings align with the original design of the PDQ, which aims to differentiate neuropathic from non-neuropathic pain. These results are consistent with those of Samuel Lapkin et al., who also confirmed the two-factor structure of the PainDETECT Questionnaire [33].

Despite the strengths of our study, several limitations warrant discussion. The lack of longitudinal data may hinder a thorough evaluation of the responsiveness of the PDQ-CV. Furthermore, the sample, primarily drawn from central and western China, may not fully represent the national patient population, potentially limiting the generalizability of our findings. Although the sample size was adequate for the study's primary objectives, we acknowledge that larger, more diverse cohorts would further enhance the robustness and generalizability of the findings. The self-report nature of the PDQ-CV could also introduce response bias. Future research should consider implementing a multicenter design that includes diverse geographic regions and patient demographics to address these limitations effectively.

In conclusion, the PDQ-CV provides a reliable and valid tool for assessing pain in KOA patients. By highlighting the importance of accurate pain assessment, this study lays a solid foundation for future research and clinical applications, offering valuable insights into pain management strategies that could considerably improve patient care and treatment decisions.

Abbreviations

KOA	Knee Osteoarthritis
TKA	Total Knee Arthroplasty
PDQ-CV	PainDETECT Questionnaire Chinese Version
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
EQ-5D-5L	5-level EuroQoL Group's 5-dimension questionnaire
CSI-CV	Central Sensitization Inventory Chinese Version
CMIN	Chi-Square Statistic
DF	Degrees of Freedom
P	P-value
GFI	Goodness of Fit Index
CFI	Comparative Fit Index
RMSEA	Root Mean Square Error of Approximation

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

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Author contributions
CX and JBM conceived and designed the experiment. XFC, SXY, and JW collected data. XFC, CX, and JBM analyzed and interpreted the data. XFC, SXY and JW wrote the manuscript. LS and JBM modifed the manuscript. All authors participated in the translation and cross-cultural adaptation of the scale. All authors read and approved the final manuscript.

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Data availability
The datasets generated and/or analyzed during the current study are not publicly available because they are still being used in subsequent studies, but can be obtained from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This study was approved by the Ethics Committee of the medical ethics committee of Honghui Hospital, approval number (No.202209022). Written informed consent was obtained from all participants.

Consent for publication
Consent to publish was obtained from all the patients.

Competing interests
The authors declare no competing interests.

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