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Cross-cultural adaptation and psychometric evaluation of the Turkish P4 pain intensity scale

Türkçe P4'ün kültürlerarası uyarlanması ve psikometrik değerlendirmesi

Kardem Ulaş[1], Nazemin Gilanlıoğulları[2], Murat Güçtekin[1]

[1]Department of Physiotherapy and Rehabilitation, Girne American University Faculty of Health Sciences, Kyrenia, Northern Cyprus, TR-10 Mersin, Türkiye
[2]Department of Physiotherapy and Rehabilitation, European University of Lefke Faculty of Health Sciences, Lefke, Northern Cyprus, TR-10 Mersin, Türkiye

Abstract

Objective: Pain assessment is "an important part of the healthcare system" as it contributes to improving patients' quality of life, especially for people who have chronic pain such as fibromyalgia. There are many tools that help to assess pain, but they have some limitations. The P4 pain intensity scale is a tool that helps assess pain using four questions that are easy to understand and use. However, it has not yet been translated into Turkish. This study aimed to cross-culturally adapt the P4 into Turkish and evaluate its psychometric properties in individuals with fibromyalgia.

Methods: Two phases were conducted to cross-culturally adapt and psychometrically test the Turkish version of P4 for people with fibromyalgia. In phase one, an expert panel meeting (n=8) and cognitive debriefing interviews (n=10) were conducted to translate P4 into Turkish and to make it understandable and relevant for people with fibromyalgia. In phase two, classical test theory (CTT) was used to assess the reliability and cross-cultural validity of the P4 in individuals with fibromyalgia (n=40) by comparing it with the visual analogue scale or the numeric pain rating scale.

Results: The expert panel meeting and cognitive debriefing interviews confirmed that the Turkish version of the P4 was understandable and relevant to individuals with fibromyalgia. CTT showed that the Turkish version of P4 has good reliability and validity for use in people with fibromyalgia, there is no gold-standard measure to compare its results.

Conclusion: The Turkish version of P4 has the ability to detect true daily pain intensity in people with fibromyalgia in a simple and inexpensive manner.

Keywords: P4, pain, fibromyalgia, cross-cultural adaptation, validity, reliability

Özet

Amaç: Ağrı değerlendirmesi, özellikle fibromiyaljiye bağlı kronik ağrısı olan kişilerde hastanın yaşam kalitesini iyileştirmeye yardımcı olması nedeniyle sağlık sisteminin önemli bir parçasıdır. Ağrıyı değerlendirmeye yardımcı olan birçok araç bulunmakla birlikte, bunların bazı sınırlamaları vardır. P4 ağrı şiddeti ölçeği, anlaşılması ve kullanımı kolay, dört soruyla ağrıyı değerlendirmeye yardımcı olan bir araçtır. Ancak Türkçeye çevirisi bulunmamaktadır. Bu çalışma, P4'ü Türkçeye kültürlerarası uyarlamayı ve fibromiyalji hastaları için psikometrik olarak test etmeyi amaçlamaktadır.

Yöntem: Fibromiyaljili bireyler için P4'ün Türkçe versiyonunu kültürlerarası uyarlamak ve psikometrik olarak test etmek amacıyla iki aşama yürütülmüştür. Birinci aşamada, uzman paneli toplantısı (n=8) ve bilişsel değerlendirme görüşmeleri (n=10) gerçekleştirilerek P4'ün Türkçeye çevrilmesi ve fibromiyaljili bireyler için anlaşılır ve anlamlı hale getirilmesi amaçlanmıştır. İkinci aşamada, fibromiyaljili bireyler (n=40) için P4'ün güvenilirliği ve kültürlerarası geçerliliği, klasik test teorisi (CTT) kullanılarak, görsel analog skala ve numerik ağrı derecelendirme skalası ile karşılaştırılarak değerlendirilmiştir.

Bulgular: Uzman paneli toplantısı ve bilişsel değerlendirme görüşmeleri, P4'ün Türkçe versiyonunun fibromiyaljili bireyler için anlaşılabilir ve uygun olduğunu göstermiştir. CTT, P4'ün Türkçe versiyonunun fibromiyaljili bireyler için kullanılabilecek iyi bir güvenilirlik ve geçerliliğe sahip olduğunu göstermiştir.

Sonuç: P4'ün Türkçe versiyonu fibromiyalji hastalarında günlük ağrı şiddetini pratik bir şekilde değerlendirmek için güvenilir şekilde kullanılabilir.

Anahtar Kelimeler: P4, ağrı, fibromiyalji, kültürlerarası adaptasyon, geçerlilik, güvenilirlik

Correspondence / İletişim: Kardem Ulaş Dr. Assist. Prof.,
Girne American University Faculty of Medicine, Kyrenia, Cyprus
E-mail: soyerkardem@gmail.com **ORCID ID:** orcid.org/0000-0002-6136-6124
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Introduction

The assessment and management of pain are recognized as crucial aspects of healthcare, and significant investment continues to be directed toward improving these processes.[1,2] The development of new tools that enable more accurate and efficient assessment of pain has been identified as a key target in this endeavor.[3,4]

Patients with fibromyalgia experience chronic widespread pain and tenderness. Fibromyalgia-related pain will change over time. Many people have good days and bad days. This fluctuating course of fibromyalgia often complicates pain assessment.[5]

There are many tools available to quantify pain. They range from a simple 1-10 verbal rating scale for intensity to the McGill pain questionnaire, which attempts to characterize the quality and intensity of pain in much greater depth.[6,7] Probably the most widely used and understood tool among those with fibromyalgia is the pain visual analogue scale (VAS) or the numeric pain rating scale (NPRS). This involves a 10 cm line with terminal descriptors "no pain" and "worst pain imaginable". Patients are asked to place a mark on the line to represent the overall intensity of their pain and to do the same to indicate pain "at its best". The difference between the two marks represents the perceived change in pain and is an indirect measure of pain relief.[6]

The VAS and NPRS allow good quantification of pain intensity and are relatively sensitive to changes over time. However, they have disadvantages. Some patients have difficulty understanding or using a 10-cm line. Those scales do not assess different components of pain (e.g., intensity, duration, and quality). This is important, as treatment may differentially affect these components. The VAS and NPRS are also criticized for a lack of clear categorization of pain intensity. This can render decisions based on baseline pain intensity unreliable, because changes in perceived pain intensity can be skewed across different levels of severity.[8-10]

Because the pain management system was effectively transitioned into a clinical practice setting and demonstrated a significant improvement in patient well-being, the P4 pain scale is to be used. It has great potential to supersede the NPRS and VAS scales.[11,12]

The first consideration regarding the scope of the P4 scale is that the panel must develop a scale capable of assessing pain in any situation, regardless of the severity or cause of the pain. Therefore, the scale needs to be simply worded and easily understood so that it can be used by a wide range of people, from patients to medical staff. The impact of this may be a wide-ranging standardization of pain assessment and improved recognition of pain.[12,13]

Our aim in this study was to translate the P4 into Turkish and to pave the way for its use among Turkish fibromyalgia patients, thereby shortening the decision-making process regarding pain during activities of daily living.

Materials and Methods

Recommended guidelines should be followed when conducting the cross-cultural adaptation and psychometric testing of a questionnaire.[14-16] Cross-cultural adaptation includes five steps: double translations, synthesis, reverse translation, expert panel review (including various members) to produce the pre-final version, and pretesting with the target population to assess the understandability of the items. As P4 was developed in another language, and after obtaining permission from the original developer of P4, recommended guidelines were followed to cross-culturally adapt P4 into Turkish and to make it understandable and relevant for people with fibromyalgia. Psychometric properties and pragmatic outcome measures are important for monitoring the success of implementation efforts and comparing the effectiveness of other rehabilitation techniques.[17] People aged over 18 who were able to write and speak Turkish, lived in Northern Cyprus, had a diagnosis of fibromyalgia, and could provide written consent were recruited for this study. After agreeing to participate in this study and providing written consent, participants were given three questionnaires to complete: the Turkish versions of the P4, VAS, and NPRS, to enable comparison of the P4 results with those of other questionnaires that aim to assess the same content.

Translation

The English version of the P4 was intended to be translated into Turkish to make the items understandable for people with fibromyalgia. After written permission was taken from the developers of P4, two translators used forward translation method to translate the English version of P4 into Turkish.[15] An expert panel, including the translator, synthesis recorder, healthcare professionals who work with people with fibromyalgia (such as a doctor, physiotherapist, and dietitian), research team members, and a lay person who spoke both Turkish and English, discussed the two forward translations for each item to ensure that they were understandable and agreed on a single Turkish version of the P4.

The draft Turkish version of the P4 was then reverse-translated into English; the items were checked and compared with the original P4. Following the translation process, the items of the translated Turkish version of the P4 were discussed by the expert panel members to ensure that they were understandable to people with fibromyalgia, and the panel reached a consensus.

After the expert panel review, ten participants who were diagnosed with fibromyalgia using exactly the same criteria were recruited to assess whether the items of the Turkish version of the P4 were understandable and relevant to their condition. Finally,

after completing the Turkish version of the P4, participants were asked to take part in a cognitive debriefing interview to provide feedback on the relevance, understandability, ease of completion, and structure of the P4. The understandability and relevance of the items were evaluated using a five-point rating scale. In addition, open-ended questions were asked about the ease of completion, structure, and items of the questionnaire to obtain more detailed information about the P4. Following the completion of interviews, the P4 was edited, and the final version was sent back to the expert panel members to gain further advice on the final Turkish version of the P4.

Statistical Analysis

Participants with fibromyalgia were recruited to evaluate the psychometric properties of the P4 using classical test theory (CTT). This will include concurrent validity, acceptability, contrast validity, minimal detectable difference, and test-retest reliability. To obtain descriptive and meaningful data, the sample size needs to be large enough for CTT.[18] A rule of thumb for sample size calculation is to include ten participants per item for confirmatory factor analysis.[18] As the P4 includes four items, the rule of thumb was used, and 40 participants will provide sufficient information for assessing psychometric properties. Statistical analyses were performed using the Statistical Package for the Social Sciences for Windows (version 27.0; IBM Corp., Armonk, NY, 2020). Descriptive values for numerical demographic variables were expressed as mean ± standard deviation, and frequency (number and percent) for categorical variables. Statistical significance was set at p-values of <0.05 and <0.01.

Determination of Reliability

The intraclass correlation coefficient (ICC) and Cronbach's alpha were calculated as measures of internal consistency. Cronbach's alpha coefficient should be higher than 0.70 ($\alpha \geq 0.70$) to be accepted as very good.[19]

Determination of Validity

The Pearson correlation coefficient was calculated to determine the validity of the Turkish version of P4.

Ethical Consideration

Ethical approval was obtained from European University of Lefke Non-interventional Clinical Researches Ethics Board (approval number: BAYEK038.12, date: 28.12.2023). Before collecting the data, informed written consent was obtained from the participants. All data were anonymized and kept strictly confidential.

Results

First Phase

Recruitment for phase-one started after receiving ethics approval from the Ethics Committee and lasted three months. The expert panel included eight people: a methodologist, two translators, a lay person, a physiotherapist, a doctor, a psychologist, and a dietitian. As a result of expert panel meetings, the English version of the P4 was translated into Turkish, and all items were found to be relevant and understandable to people with fibromyalgia. After the expert panel meeting, the first draft of the Turkish version of the P4 was used in cognitive debriefing interviews.

In total, 10 people diagnosed with fibromyalgia were recruited. All participants were female and aged between 23 and 47 years. Overall, all participants found the P4 survey to be good and relevant to their condition. They reported that there was nothing they would like to change or add. Only one participant thought that the date on the questionnaire, which is given as (year/month/day), could be reordered as (day/month/year), as this is the common format used in North Cyprus. This was edited after obtaining agreement from the expert panel members. The results of the cognitive debriefing interview were shared with the expert panel members, and the panel reached a consensus to use the translated version of the P4 for the second phase of the research to assess its psychometric properties.

Second Phase

Psychometric Properties

To assess the psychometric properties, 40 participants were recruited for this study. Table 1 provides a summary of the participants' demographic details. To quantify the reliability and validity, each participant was asked to complete VAS, NPRS and P4 twice (two weeks apart).[20] The VAS first measurement and the NPRS first measurement mean scores of the participants were 4.30 ± 1.40 and 4.0 ± 1.35 respectively. The VAS second measurement and the NPRS second measurement mean scores of the participants were 3.81 ± 1.2 and 3.51 ± 1.16 respectively. Participants' responses to P4 items for the first and second measurements are listed in Table 2.

Reliability

The test-retest reliability for the first measurements of the P4 total score was 0.81 [95% confidence interval (CI)]. Table 3 demonstrates Cronbach's alpha values for each item. The ICC value was calculated as a mean of 0.98 (0.979 to 0.994), $p<0.001$, which was above the acceptable level of 0.70.

Validity

The Pearson's r values were 0.824 for the P4 total score at the first measurement, 0.839 for NPRS and VAS at the first measurement, and 0.806 and 0.741 for the second measurements, respectively. Table 4 presents the analysis of item validations.

Discussion

The Turkish version of P4 used in the current study was considered statistically reliable and valid for measuring pain intensity in patients with fibromyalgia. Although not all questions needed to be adapted, changed, or removed for the 4th item, activity might affect pain changes in fibromyalgia patients, so Pearson's r was found to have fair validity.

Our goal in translating the P4 into Turkish was to obtain a practical clinical measure that is as sensitive as the single-item NPRS and VAS, yet more sensitive at indicating changes throughout the day and across activities. Norman[21] has shown that the test-retest reliability of a measure affects its sensitivity to change. Spadoni et al.[12] developed the P4 to measure pain intensity and change. They also examined whether the test-retest reliability and validity of the P4 were higher than those of the single-item NPRS. They found that the reliability and longitudinal validity of the P4 were statistically higher than those of the NPRS.[13] Similarly, our initial findings showed that the test-retest reliability and validity of the P4 were both statistically significant and higher than those of the NPRS and VAS.

In their research, they investigated patients not labelled as having chronic pain. In our research, we prefer to assess P4 in fibromyalgia patients because we can obtain a brief report. We believe that most of the questionnaires and scales for fibromyalgia are quite long and sometimes confusing.

No gold standard exists for pain assessment, and investigators must rely on a construct validation process. When we examine the reliability and validity of VAS [ICC=0.99 (95% CI 0.989 to 0.992)] and NPRS (r=0.79-0.96), they are both highly reliable and valid tools for measuring pain intensity.[22,23] However, the most important disadvantage is that they are single-item. For example, during the assessment of pain, when we ask the patients to score their pain with VAS and/or NPRS, they sometimes experience difficulty to detect exact value and ask "In general the severity of my pain is 3/10 but at nights it rises to 6/10, so which one should I circle?". Our study has shown, through item validation, that P4 serves to resolve that dilemma.

Previous studies have shown that the Turkish versions of the VAS and NPRS are reliable tools for assessing pain.[24,25] However, unlike VAS and NPRS, the P4 provides a more multidimensional assessment of pain by helping to analyze pain levels at different times of the day. For example, patients may experience low pain in the morning but significant pain in the evening. This cannot be captured using the VAS or NPRS, as they assess a single time point. However, this kind of detailed information can help healthcare professionals adapt the rehabilitation timeline or guide people with fibromyalgia to self-manage their daily activities by adapting those activities according to their pain, which can vary throughout the day.

Table 1. Participant descriptive

	n (40) n ± SD	n (40) n (%)
Age	33.4±13.3 years	
Gender		
Female		34 (85%)
Male		6 (15%)
Duration of disease	4.4±2.9 years	

n: Number, SD: Standard deviation, %: Percentage

Table 2. Descriptive of items

	n ± SD		n ± SD
NPRS* (first*)	4.0±1.35	**NPRS (second)**	3.51±1.16
VAS* (first)	4.3±1.40	**VAS (second*)**	3.81±1.2
P4*.1 (first)	5.37±2.31	**P4.1 (second)**	4.95±2.3
P4.2 (first)	4.35±2.0	**P4.2 (second)**	4.47±1.9
P4.3 (first)	4.7±2.18	**P4.3 (second)**	5.35±2.2
P4.4 (first)	2.65±2.38	**P4.4 (second)**	2.19±1.9
P4. score (first)	16.98±6.77	**P4. score (second)**	16.95±6.7

First indicates test measures, second indicates re test measures, n: Number, NPRS: Numeric pain rating scale, P4: Pain intensity scale, SD: Standard deviation, VAS: Visual analogue scale

Table 3. Cronbach's alpha analyses of P4

	Cronbach's alpha analysis	
Items	**Total correlation**	**Cronbach's alpha if item deleted**
Item 1	0.892	0.744
Item 2	0.939	0.753
Item 3	0.769	0.775
Item 4	0.416	0.832
Total score	0.999	0.825

Cronbach's alpha of total scale: 0.817, P4: Pain intensity scale

Study Limitations

The study has several limitations. There is no other linguistic translation of P4, so we were not able to compare and discuss from the perspective of cross-cultural validation. Moreover, the sample size was limited because the number of fibromyalgia cases in TRNC is not known exactly, so it had to be determined using the rule of thumb. In addition, most participants were female, as fibromyalgia is more common in women. However, these limitations made it difficult to generalize the results, and further studies should be conducted with a larger sample of fibromyalgia patients and should include more detailed demographic information, such as participants' education level, to allow analyses across different subgroups.

Table 4. Item validation

		P4.1 (first)	P4.2 (first)	P4.3 (first)	P4.4 (first)	P4.score (first)	P4.1 (second)	P4.2 (second)	P4.3 (second)	P4.4 (second)	P4.score (second)	NPRS (first)	NPRS (second)	VAS (first)	VAS (second)
P4.1 (first)	r		0.750**	0.852**	0.188	0.899**	0.932**	0.787**	0.971**	0.032	0.862**	0.897**	0.868**	0.969**	0.910**
	p		0.000	0.000	0.227	0.000	0.000	0.000	0.000	0.839	0.000	0.000	0.000	0.000	0.000
P4.2 (first)	r			0.567**	0.500**	0.913**	0.864**	0.925**	0.782**	0.492**	0.950**	0.700**	0.721**	0.673**	0.613**
	p			0.000	0.001	0.000	0.000	0.000	0.000	0.001	0.000	0.000	0.000	0.000	0.000
P4.3 (first)	r				-0.195	0.709**	0.720**	0.611**	0.818**	-0.167	0.633**	0.715**	0.731**	0.878**	0.862**
	p				0.211	0.000	0.000	0.000	0.000	0.286	0.000	0.000	0.000	0.000	0.000
P4.4 (first)	r					0.518**	0.292	0.540**	0.176	0.840**	0.552**	0.289	0.212	0.096	0.068
	p					0.000	0.058	0.000	0.258	0.000	0.000	0.060	0.173	0.541	0.664
P4.score (first)	r						0.902**	0.932**	0.890**	0.415**	0.977**	0.824**	0.801**	0.839**	0.791**
	p						0.000	0.000	0.000	0.006	0.000	0.000	0.000	0.000	0.000
P4.1 (second)	r							0.781**	0.944**	0.194	0.922**	0.855**	0.829**	0.874**	0.825**
	p							0.000	0.000	0.213	0.000	0.000	0.000	0.000	0.000
P4.2 (second)	r								0.762**	0.451**	0.924**	0.790**	0.792**	0.746**	0.661**
	p								0.000	0.002	0.000	0.000	0.000	0.000	0.000
P4.3 (second)	r									0.047	0.872**	0.828**	0.819**	0.921**	0.862**
	p									0.767	0.000	0.000	0.000	0.000	0.000
P4.4 (second)	r										0.498**	0.137	0.126	-0.039	-0.015
	p										0.001	0.382	0.422	0.806	0.922
P4.score (second)	r											0.821**	0.806**	0.794**	0.741**
	p											0.000	0.000	0.000	0.000
NPRS (first)	r												0.929**	0.931**	0.855**
	p												0.000	0.000	0.000
NPRS (second)	r													0.894**	0.838**
	p													0.000	0.000
VAS (first)	r														0.937**
	p														0.000
VAS (second)	r														
	p														

First indicates test measures, second indicates retest measures, *: $p<0.05$, correlation is significant at the 0.05 level, **: Correlation is significant at the 0.01 level, NPRS: Numeric pain rating scale, P4: Pain intensity scale, r: Pearson correlation coefficient, VAS: Visual analogue scale

Conclusion

The validity of measures intended to assess symptom-related quality of life and pain will always be incomplete because there are no gold standards for these attributes. The current study demonstrates P4's ability to detect true daily pain intensity in a simple and inexpensive manner.

Ethics

Ethics Committee Approval: Ethical approval was obtained from European University of Lefke Non-interventional Clinical Researches Ethics Board (approval number: BAYEK038.12, date: 28.12.2023).

Informed Consent: Before collecting the data, informed written consent was obtained from the participants.

Footnotes

Authorship Contributions

Surgical and Medical Practices: K.U., N.G., M.G., Concept: K.U., N.G., M.G., Design: K.U., N.G., Data collection and analysis: M.G., Analysis or Interpretation: K.U., Literature Search: K.U., N.G., M.G., Writing: K.U., N.G.

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