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Assessing the Reliability and Validity of the Persian Version of the Chronic Pelvic Pain Questionnaire in Women

Mirzaei Mahboubeh¹, Daneshpajooch Azar¹, Bagherinasabsarab Mohammadali^{1*}, Bahreini Fatemeh², Yazdanpanah Fatemeh²

1. Department of Urology, Kerman University of Medical Sciences, Kerman, Iran

2. Kerman University of Medical Sciences, Kerman, Iran

Abstract

Purpose: There is a need for developing a standard and approved tool to assess chronic pelvic pain (CPP) in Iranian women. The aim of this study was to investigate the reliability and validity of the Persian version of the pelvic pain and urinary/frequency (PUF) questionnaire in Iranian women with CPP.

Materials and Methods: This cross-sectional study was performed on 50 females with CPP referred to the urology clinic of Kerman University of Medical Sciences from 2018 to 2019. Initially, the PUF questionnaire was translated into Persian and then back translated into English. The face validity of the tool was evaluated by being tested on 50 patients who had different literacy levels to ensure its understandability and acceptability by patients. The construct validity was evaluated through both exploratory and confirmatory factor analyses. The internal consistency was also analyzed by determining Cronbach's alpha coefficient and test-retest method.

Results: The Persian version of the questionnaire was compatible with the original English version. The Kisser sampling adequacy index was calculated on the data before extracting the

factors indicating good factor accessibility of the questionnaire statements. The construct validity of the questionnaire was confirmed using exploratory and confirmatory factor analyses. The internal consistency parameters were also acceptable. Cronbach's alpha coefficient of the whole questionnaire, as well as the coefficients of the "signs/symptoms" and "unpleasant feelings" domains were 77%, 74%, and 78%, respectively.

Conclusion: The developed Persian version of the PUF questionnaire retrieved a good validity and reliability.

Keywords: Iran; Pelvic Pain; Reproducibility of Results; Surveys and Questionnaires; Women

INTRODUCTION

Chronic pelvic pain (CPP) is one of the most common women's health problems in today's society, especially at the reproductive age which seems to be more prevalent during this period. Any pelvic pain unrelated to pregnancy, menstruation, and intercourse lasting for at least six months or more is defined as CPP.⁽¹⁻³⁾ Diagnosis and treatment of CPP accounts for about 10% of visits by obstetricians and gynecologists.⁽²⁾ Although gynecological, urological, gastrointestinal, musculoskeletal, and socio-psychosocial parameters have been generally associated with this problem,^(1, 3, 4) more than 60% of CPP patients are not definitely diagnosed due to the complexity of the disease, especially in those with musculoskeletal problems.^(4, 5) The frequency of CPP in different communities has been reported between 3.8% and 39% according to the characteristics of study populations and methodology. There has been only one cross-sectional study in Iran which reported a high rate (10.2%) of CPP among women working in two medical centers.⁽⁶⁾

Recent studies suggest the necessity of therapeutic interventions in a significant number of patients with CPP. In fact, alleviating pain is one of the top priorities in all diseases.⁽⁷⁾ Primary evaluation of pain is of the most important aspects of pain management. As pain is a

psychological-clinical phenomenon, standard tools should be used for its evaluation. In fact, improper evaluation of pain may lead to bias in the physician's estimation of pain severity and ultimately impairment in the treatment process.⁽⁸⁾

The pelvic pain and urinary/frequency (PUF) questionnaire is a simple tool to diagnose interstitial cystitis or CPP syndrome in women.⁽⁹⁾ This questionnaire consists of two main dimensions (signs/symptoms and unpleasant feelings) consisting of 7 and 4 questions, respectively. The questionnaire has been widely used by researchers as it evaluates a wide range of clinical symptoms from urgency of urination and pelvic pain to symptoms of sexually transmitted diseases.⁽¹⁰⁾ In addition, the PUF questionnaire has been shown to be well-correlated with the results of the intravenous potassium allergy test which is positive in most patients with IC/PBS.⁽¹¹⁻¹⁵⁾ The PUF questionnaire which is used to assess pelvic pain also addresses symptoms related to sexually transmitted diseases, urinary tract obstruction, and interstitial cystitis.⁽¹⁵⁾

In order to use foreign-language questionnaire in another country, it is necessary to evaluate its validity (extent of target measurability) and reliability (reproducibility). Although the PUF questionnaire has been approved in English-language nations, it needs to be also translated and validated for Iranians,^(9, 16, 17) to determine if it has the same applicability as the original version to be used in target populations.⁽¹⁸⁾

Chronic pain usually affects individuals' attitudes toward life.⁽¹⁹⁾ and in some cases, theirs and their friends' and family members' quality of life.⁽²⁰⁾ Due to the clinical significance, high prevalence, and impact of CPP on patients' quality of life, and also the the lack of appropriate tools to screen and follow-up these patients in Iran and other Persian-speaking countries, this study was conducted to validate the PUF questionnaire as a simple and reliable tool to be used in clinic and research.

MATERIALS AND METHODS

This cross-sectional study was conducted in Kerman from 2018 to 2019. Considering the prevalence of CPP reported in similar studies, 50 patients referred to the urology clinic of Kerman University of Medical Sciences were enrolled in the study. The subjects consecutively entered the study, and verbal consent was acquired after explaining the purpose of the study to them. The 12-question PUF questionnaire was used to collect the data after being translated into Persian. In the first step, two Iranian native speakers who were fluent in English translated the tool into Persian. After that, the text was back-translated to English by two other people who had lived in English-speaking countries for more than 10 years and were professionally engaged in translating texts. In the first phase of translation, the word-to-word strategy was used, and in case of inapplicability and mismatches, the text was conceptually translated.⁽²¹⁾ To make sure that the questionnaire phrases were understandable, they were compared between the two English versions.

Inclusion criteria

These were a definite diagnosis of CPP, being native Persian-speaker, age over 18 years, and having ability to read and write.

Assessing validity

To do this, both face and construct validities of the questionnaire were assessed. The face validity assesses the audience's view on the appearance of the questionnaire's statements. The construct validity answers that to what extent the structure of the questionnaire is consistent with its primary purpose. Factor analysis was used to group variables and ascertain correlational patterns between them which are expected to follow a logical pattern.

The face validity of the instrument was assessed by filling the questionnaire by 15 patients with different literacy levels in order to determine if it was understandable and acceptable. To evaluate the construct validity, the factorial structure was examined by PAF analysis and Direct oblimin circulation. This method, which is a type of exploratory factor analysis, was performed

to determine the validity of the Persian version of the questionnaire. To ensure acceptable construct validity, confirmatory factor analysis (CFA) with a maximum estimated truthness approach was used.

Assessing reliability

The internal consistency of the questionnaire was measured to ascertain its reliability by calculating Cronbach's alpha coefficient and test-retest method. For this, the questionnaire was refilled by the participants after 7 days of the first test.

Statistical analysis

To analyze the data, statistical methods for assessing reliability and validity, as well as frequency and relative frequency were used. SPSS 20 software was utilized for this purpose.

RESULTS

A total of 50 women with CPP were examined. The patients' mean age was 39.81 ± 8.23 years, and the response rate was 98%. The translated questionnaire was approved by the translators in terms of agreement with the original version.

Construct validity

The Kaiser's measure of sampling adequacy (MSA) index which was calculated before extracting the factors was obtained as 0.89.

The two-factor model using the Eigenvalue values and the Scree chart was the best extractable model accounting for 65% of the total variance. The signs/symptoms and unpleasant feelings domains included 7 and 4 questions, respectively.

The mean scores of the signs/symptoms dimension were 7.41 ± 1.82 and 7.93 ± 2.32 at test and re-test phases, respectively. In the unpleasant feelings dimension, the mean scores were 3.92 ± 1.7 and 4.30 ± 1.78 at test and retest phases, respectively. The total mean scores were obtained as 11.4 ± 3.10 and 12.31 ± 3.71 at test and re-test, respectively (Table 1). Therefore, it seems that, under similar conditions, the questionnaire will deliver relatively similar scores.

The correlation coefficients between the questions were 0.924 ($p < 0.001$) in the signs/symptoms and 0.836 ($p < .001$) in the unpleasant feeling dimensions, as well as 0.905 in total scale ($p < .001$) (Table 2). Therefore, it can be said that the questions had the necessary correlations and alignments.

The two-factor model of CFA showed a Root mean square error of approximation (RMSEA) index of 0.92, the comparative fit index (CFI) of 0.95, and the chi-square/degree of freedom ratio of 2.6. All these indicated acceptable fitness.

Reliability

The internal consistency of the questionnaire was appropriate. The correlations between all the items were above 0.4 in both dimensions (signs/symptoms and unpleasant feeling). While the whole questionnaire's Cronbach's alpha coefficient was 77%, those of the signs/symptoms and unpleasant feeling dimensions were 78% and 74%, respectively.

The re-test phase also showed a high correlation between the questions indicating a good reliability. Both the Cronbach's alpha calculation and test-retest methods indicated acceptable internal compatibility and reliability of the questionnaire. In other words, the questions had necessary correlation and compatibility retrieving similar scores if being repeated under similar conditions.

DISCUSSION

Many epidemiological and interventional studies are concerned with determining frequency and monitoring progression of CPP.⁽²²⁾ Instruments designed to measure CPP should have three characteristics: 1) being clinically applicable, 2) having good validity, and 3) having acceptable reliability. A short and simple translation makes the tool understandable and increases its applicability. On the other hand, the high level of participation of the studied population can be in favor of the acceptance of questionnaire by patients.⁽²³⁾ So far, studies have been conducted on the validity and reliability of Persian versions of other questionnaires. For example, a study

by Hajebrahimi et al. in 2012 validated the Persian version of the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UISF) as a simple and valid tool in patients with urinary incontinence.⁽¹⁹⁾ Another study in 2015 by Sari-motlagh et al. showed that the Persian version of the International Questionnaire Consultation on Incontinence Questionnaire in Over Active Bladder (ICIQ-OAB) can be a strong and simple tool for researches to monitor Persian-speaking patients.⁽²⁰⁾

In the present study, the PUF questionnaire was validated as a brief questionnaire in which queries are juxtaposed in a relatively identical format. Because of having a few descriptive words and a simple language structure,⁽²²⁾ the Persian translation of the original questionnaire was relatively easy and fluent. The translations of this questionnaire into other languages including Spanish⁽²²⁾ and Brazilian⁽²³⁾ were also reported to be easy. In our study, the mean scores of the signs/symptoms and unpleasant feeling dimensions were obtained as 7.93 and 4.30, respectively. The total mean score was also recorded as 12.31 which was almost the same as the study of Minaglia et al. who validated the Spanish version of the questionnaire in 2005.⁽²²⁾ In 2015, Victal et al. also validated the Brazilian version of the questionnaire reporting good validity and reliability.⁽²³⁾

The CFA and EFA approaches were used to determine construct validity of the questionnaire. The EFA method was used to extract the constituents of the questionnaire retrieving two factors consistent with the those proposed by the developers of the questionnaire. In some studies; however, the extracted factors were not the same as those of the original version.⁽⁷⁾ In the CFA method, the questionnaire dimensions proposed by its developers were re-evaluated to check if they met the required criteria and to confirm the construct validity of the translated questionnaire. In the present study, the CFA highlighted one indicator.

A good-fitness in a model is met when the RMSEA is not larger than 0.2, the CFA is > 0.9 , and the chi-square/degree of freedom ratio is less than 3 or even 5. In this study, using the AMOS

software, the data showed a good fitness in the two-factor model. Most studies have used the EFA method to determine the construct validity of the CPP questionnaire.⁽²²⁾ However, other experts have noted that the CFA may be more appropriate to test the proposed model.⁽²²⁾ Overall, one of the strengths of this study was using a variety of methods to evaluate the validity and reliability of the questionnaire.

The reliability of the PUF questionnaire was analyzed by two methods (i.e. Cronbach's alpha calculation and test-retest method). This indicated appropriate internal compatibility and reliability of the tool. In other words, the questions had adequate correlation and alignment retrieving relatively similar scores after being retested under similar conditions. The results of this study were parallel to the studies on Spanish and Brazilian versions of the questionnaire which reported good validity and reliability.^(22, 23) Considering the above-mentioned, it seems that the developed Persian version of PUF questionnaire can be used for clinical and research purposes.

CONCLUSIONS

Considering the comprehensibility, as well as acceptable validity and reliability of the developed Persian version of the PUF questionnaire, it can be used by Iranian researchers in related fields.

ETHICAL APPROVAL

The study was approved by the Ethics Committee of Kerman University of Medical Sciences (IR.KMU.AH.REC.1397.084).

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CONFLICTS OF INTEREST

None declared.

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Corresponding Author:

Mohammadali Bagherinasabsarab, M.D.

Department of Urology, Kerman University of Medical Sciences, Kerman, Iran.

Tel: +98 34 32239188

Fax: +98 34 32239188

E-mail: ma_bagherinasab_md@yahoo.com

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Table 1. The mean scores of the questions and dimensions of the pelvic pain and urinary/frequency questionnaire

Questions/Dimensions	Test		Re-test	
	Mean	SD	Mean	SD
Question 1	0.24	0.04	0.3	0.04
Question 2a	1.06	0.08	1.18	0.08
Question 2b	0.90	0.08	0.84	0.08
Question 3	1.10	0.03	1.10	0.03
Question 4a	0.68	0.06	0.71	0.06
Question 4b	0.64	0.06	0.78	0.06
Question 5	1.12	0.05	1.12	0.05
Question 6	0.79	0.07	0.82	0.07
Question 7a	1.53	0.06	1.51	0.05
Question 7b	0.91	0.06	0.95	0.07
Question 8a	1.40	0.05	1.45	0.06
Question 8b	1.18	0.08	1.24	0.07
Signs/Symptoms	7.41	1.82	7.93	2.32
Unpleasant feeling	3.92	1.70	4.30	1.78
Total	11.40	3.10	12.31	3.71

Table 2. Internal correlation coefficients between questions of the two dimensions of pelvic pain and urinary/frequency questionnaire at two time points (test/retest)

Questions/dimensions	Correlation Coefficient	P value
Question 1	0.756	<0.001
Question 2a	0.931	<0.001
Question 2b	0.940	<0.001
Question 3	1	<0.001
Question 4a	0.883	<0.001
Question 4b	0.905	<0.001
Question 5	0.849	<0.001
Question 6	0.888	<0.001
Question 7a	0.813	<0.001
Question 7b	0.921	<0.001
Question 8a	0.821	<0.001
Question 8b	0.885	<0.001
Signs/Symptoms	0.924	<0.001
Unpleasant feeling	0.836	<0.001
Total	0.905	<0.001