

Patient Assessment of Constipation Quality of Life Questionnaire: Translation, Cultural Adaptation, Reliability, and Validity of the Persian Version

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What's Known

- Chronic constipation can influence the quality of life, work efficiency, and health system resources considerably.
- The Patient Assessment of Constipation Quality of Life (PAC-QOL) questionnaire was developed based on the literature, clinical expert interviews, and patient interviews to measure the health-related quality of life of constipated patients.

What's New

- There is no reported Persian version of the PAC-QOL yet.
- The purpose of this study was to systematically translate/culturally adapt the English version of the PAC-QOL for Persian speakers and to measure the reliability and validity of this version among Persian patients with constipation.

Abstract

Background: The Patient Assessment of Constipation Quality of Life (PAC-QOL) questionnaire is the most validated and the most specific tool for measuring the quality of life of patients with constipation. Over 120 million people live in countries whose official language is Persian. There is no reported Persian version of the PAC-QOL questionnaire yet. The aim of this study was to translate and culturally adapt the PAC-QOL questionnaire and to assess its reliability and validity among Persian patients with chronic constipation.

Methods: Following the translation and cultural adaptation of the PAC-QOL questionnaire to Persian, 100 patients (mean±SD age=40.51±13.67) with constipation were recruited for validity measurement and 20 patients were re-examined for reliability. Content validity was assessed based on the opinions of an expert committee and the floor/ceiling effect. Construct validity was evaluated according to the hypothesis test. The SF-36 questionnaire was used for concurrent criterion validity, intra-class correlation coefficient for reliability, and Cronbach's alpha for internal consistency.

Results: The content validity of the PAC-QOL questionnaire was proven, and there was no floor/ceiling effect. Construct validity also was confirmed based on the hypothesis test. The overall Cronbach's alpha of the PAC-QOL questionnaire was 0.92 (range=0.72–0.92), and the overall intra-class correlation coefficient of the questionnaire was 0.88 (range=0.69–0.87). The correlation between the SF-36 and PAC-QOL questionnaires was moderate.

Conclusion: The Persian version of the PAC-QOL questionnaire demonstrated good validity and reliability properties in chronic constipation. Accordingly, Persian researchers and clinicians can benefit from this questionnaire in further research and assessment of treatment outcomes.

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• Reliability • Validity

Introduction

Reported symptoms of difficult or incomplete evacuation, excessive straining during bowel movements, infrequent bowel movements, or hard stools constitute the clinical presentations

of constipation. Chronic constipation is characterized through the presentation of these symptoms for at least 3 months.¹ Chronic constipation may be secondary to colorectal cancer, hyperparathyroidism, hypothyroidism, diabetes mellitus, Parkinson's disease, medications' side effects, or other organic pathology. Constipation can also be caused primarily, which is known as functional constipation.² Generally, patients with impaired defecation can be allocated to 2 groups: those with structural defecation disorder and those with functional defecation disorder. Structural defecation can be caused by neoplasia, rectocele, enterocele, and hirschsprung's disease.³ Functional constipation is due to a lack of coordination between the relaxation of the pelvic floor muscles (puborectalis muscles) and the muscular movement of abdominal wall necessary for normal defecation.³

Chronic diseases impact on patients' and even their family and caregivers' life. Therefore, quality of life evaluation is necessary to assess patients' life and the services provided to them. A recent systematic review reported that constipation is a common problem in the world, with an epidemiology rate of between 0.7% and 79% (median=16%).⁴ In the general populations of Europe and Oceania, the mean value of the constipation rates was reported to stand at 17.1% and 15.3%, respectively.³ In a systematic review, the prevalence of constipation in Iran was reported to range between 1.4% and 37%, and the prevalence of functional constipation ranged from 2.4% to 11.2%.⁵ Chronic constipation can influence the quality of life,⁶ work efficiency,⁷ and health system resources⁸ considerably.

Today, health systems seek to manage not only the symptoms of patients but also the change in their quality of life after treatment, which is a main criterion for evaluating therapeutic services. Currently, the Patient Assessment of Constipation Quality of Life (PAC-QOL) questionnaire is the most validated and the most specific tool for measuring the quality of life of patients with constipation. The PAC-QOL questionnaire was developed based on the literature, clinical expert interviews, and patient interviews to measure health-related quality of life in constipated patients.⁹ It is a brief but comprehensive measure of the burden of constipation on patients' everyday life and is available in several languages.⁹ The translation and cultural adaptation of the PAC-QOL questionnaire have been validated in studies conducted in the United Kingdom, France, the Netherlands, Belgium, Canada, Australia, Japan, and Turkey.¹⁰⁻¹³ Health-related quality

of life is lower in patients with constipation.¹⁴ Goksel Bengi et al.¹² studied the validity and reliability of the PAC-QOL questionnaire for the Turkish population by recruiting 154 patients suffering from functional constipation and found that the patients were generally irritable because of the condition.

Over 120 million people live in countries whose official language is Persian. Despite the high prevalence of constipation among these people, there is no reported Persian Version of PAC-QOL questionnaire yet. The cultural adaptation of a questionnaire in a new country, culture, or language requires a unique and exact procedure for reaching a target equivalent form of the source language. Consequently, in linguistic terms, the items should be translated appropriately and culturally, the items should be adapted in a way to match the target cultural differences. In this way, the questionnaire can be perceived easily and appropriately in the target language. The aim of the present study was to translate and culturally adapt the PAC-QOL questionnaire and to assess its reliability and validity among Persian patients with chronic constipation.

Patients and Methods

One hundred patients with chronic constipation participated in this study for validity measurement and 20 patients were re-examined for reliability. The participants were recruited from patients who referred to Rasoul Akram Hospital, Tehran, Iran, based on convenient non-probability sampling. The participants were more than 16 years old, had the ability of writing and reading in the Persian language, and had a physician diagnosis of chronic constipation. The participants were excluded from the study if they had addiction, alcohol abuse, systemic disease, psychological disorders (e.g. dementia and perception impairments), severe septic disorders, neuropathy, myopathy, or tumor. Unwillingness to cooperate was another exclusion criterion. Before the experiment, the aim and the protocol of the study were explained to the participants, who thereafter filled an informed consent form.

Instruments

PAC-QOL

Marquis and colleagues developed the PAC-QOL questionnaire to evaluate the quality of life in constipation. The PAC-QOL questionnaire is a brief but comprehensive tool which evaluates constipation through daily individual health assessment and functioning. The contents of the PAC-QOL questionnaire are directly taken from the impact of constipation on a patient according

to the viewpoint of gastrointestinal specialists. The PAC-QOL questionnaire showed good validity in Europe and North America.¹³ This questionnaire consists of 28 self-reported items investigating the effects of constipation on the patient's quality of life in the recent 2 weeks. The PAC-QOL questionnaire is subcategorized to 4 items on physical discomfort, 8 items on psychosocial discomfort, 5 items on treatment satisfaction, and finally 11 items on worries and discomfort. Response choice is a Likert scale from 0 to 4. Higher scores mean higher negative effects on quality of life. Items 25, 26, 27, and 28 should be scored reversed because they are positive questions.

SF-36

The Short Form Health Survey (SF-36) contains 36 questions about the general health of people. These 36 items yield 8 subscales: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. The Persian version of the SF-36 was translated and culturally adapted by Montazeri et al.¹⁵

Systematic Translation

Forward translation

In this stage, the source version of the PAC-QOL questionnaire was translated into the target language (Persian) by 2 professional translators separately.

Synthesis

The synthesis is where the 2 translations were converted into a single agreed-upon translation. In this study, the synthesis was done within complete groups of translators, investigators, and experts. All the groups agreed on a common translation (Preliminary Common Forward Translation or the 1st Consensus Version) for each item and response choice labels.

Backward Translation

The Preliminary Common Forward Translation of the PAC-QOL was translated into the source language again by a translator, who was totally blind to the original version. According to standards, the back-translator was an English-Persian bilingual, whose 1st language was American English as her mother tongue with complete fluency and whose 2nd language was Persian with sufficient reading, writing, and understanding skills. The backward translation was then reviewed and compared by researchers, experts, and the original developer for more comparison. This process constituted validity checking with a view to determining

whether the items reflected the same content as the source version. After the completion of the back translation of the PAC-QOL questionnaire, it was filed with forward translation records to be assessed by the Expert Committee and investigators.

Expert Committee and Equivalence

Assessment of the PAC-QOL:

The role of this committee was to consolidate all the versions of the PAC-QOL, to check for equivalence between the original version and the target version and between the original version and the back-translated version, and to develop what would be the pre-final version for field testing.

Statistical Analysis

Statistical Package for the Social Sciences (SPSS) was used for data analysis.

Content Validity

Content validity shows that an instrument has good example of items to demonstrate the favorite structure. An expert committee consisting of 4 experts was organized for the determination of content validity. Each expert scored each question from 1 to 4 (1=not related, 2=partly linked, 3=completely related, and 4=closely related). Then the item content validity index (I-CVI) was calculated. An I-CVI higher than 0.78 reveals good content validity.¹⁶ The ceiling/flooring effect was assessed. If more than 15% of the participants achieve the highest or lowest possible score, the ceiling/flooring effect can be confirmed.

Construct Validity

The hypothesis test was applied for construct validity. The following 4 hypotheses were stated:

1. Correlation between the total score of the SF-36 and the total score of the PAC-QOL is moderate to strong.
2. Correlations between the physical discomfort subscale of the PAC-QOL and the bodily pain and physical health subscales of the SF-36 are moderate to strong (convergent validity).
3. Correlation between the worries/concern subscale of the PAC-QOL and the mental health subscale of the SF-36 is moderate to strong (convergent validity).
4. Correlations between the physical discomfort and mental health and also between the satisfaction subscale and the SF-36 subscales are weak or with no correlation (divergent validity).

Concurrent Criterion Validity

Criterion validity was used to measure how much the PAC-QOL questionnaire correlated with another scale measuring the same theoretical content.¹⁷ The Pearson correlation coefficient between the PAC-QOL and the SF-36 questionnaires was computed to measure the concurrent criterion validity.

Internal Consistency

Internal consistency is the degree to which the items that comprise a specific scale measure the same attribute or construct. In other words, it is a value of the homogeneity of the items in a particular measure. The most common way to measure the internal consistency is Cronbach's coefficient alpha, which was used for the 28 items of the PAC-QOL in the present study. This statistical method measures the average correlation among all the items in a scale. Values range from 0 to 1, with the higher values indicating greater internal consistency.^{18,19} Nunnally and Bernestien²⁰ recommended an alpha level above 0.70 but not greater than 0.90 as an acceptable value. However, this is very dependent on the construct of the scale. Cronbach's alpha was calculated also for the PAC-QOL at the subscale levels.

Item internal consistency, also known as item-scale correlation, is an assumption that every item should have a substantial correlation to the concept which it is aimed to measure. This is done by a correlation between each item and the total score of all items in the scale (PAC-QOL), after correction for item-scale overlap. Item internal consistency is considered desirable if the measured correlation is around 0.40.²¹ For the 28 items of the PAC-QOL, item-scale correlation was used as an evaluation of the items' homogeneity. This was the criterion for the present test for the exclusion of items that did not contribute to the scale information.

Reliability

The test-retest reliability for the PAC-QOL was estimated by performing the same test on the same respondents after 7 days from the 1st test on 20 participants. The intra-class correlation coefficient (ICC) was used

to measure the test-retest reliability for the PAC-QOL. Because it is based on the actual magnitude of scores and agreement between them instead of correlation evaluation, the ICC is considered a more advantageous method than correlation coefficient for measuring reliability. ICC values above 0.70 to 0.75 indicate good reliability.¹⁹ The reliability measurement was conducted for the PAC-QOL subscales as well as the total score.

Results

Participants

One hundred patients with constipation participated in this study. The age mean±SD of the patients was 40.51±13.67, and 67% were female. All the patients had suffered constipation for more than 3 months. The PAC-QOL total score and item scores are presented in table 1. The average total score was 2.20±0.69, while the highest score of 2.80 belonged to the item satisfaction.

Content Validity

The I-CVI for all the items of the Persian PAC-QOL was 1.00 except for Item 5, which was 0.75. The Expert Committee was consulted about the problem, and the experts agreed that a revision of this item was necessary and the translated PAC-QOL was confirmed.

There was no ceiling/floor effect for the total score of the Persian PAC-QOL. Among the subscales of this questionnaire also there was no floor effect. The ceiling effect was 4% in the physical discomfort subscale, 2% in the worries/concerns subscale, and 6% in the satisfaction subscale. Based on these findings, there was no ceiling or floor effect among the PAC-QOL subscales.

Construct Validity

If hypotheses are specified in advance and at least 75% of the results correspond with these hypotheses, there is construct validity.²² This happened for our assumptions. The convergent validity in the 1st 3 assumptions was moderate to strong (P<0.01, R>0.5). The correlations between the satisfaction subscales of the

Table 1: Reliability and internal consistency of the PAC-QOL

| Subscale | Number of questions | Mean±SD | Minimum | Maximum | Cronbach's alpha | ICC |
|-------------------------|---------------------|-----------|---------|---------|------------------|------|
| Physical discomfort | 1-4 | 2.10±0.90 | 0.25 | 4 | 0.79 | 0.85 |
| Psychosocial discomfort | 5-12 | 1.64±0.92 | 0.13 | 3.63 | 0.81 | 0.87 |
| Worries and discomfort | 13-23 | 2.38±0.89 | 0.45 | 4 | 0.92 | 0.88 |
| Satisfaction | 24-28 | 2.80±0.79 | 0.80 | 4 | 0.76 | 0.69 |
| PAC-QOL | 1-28 | 2.20±0.69 | 0.82 | 3.57 | 0.92 | 0.88 |

PAC-QOL and all the subscales of the SF-36 were not significant.

Concurrent Criterion Validity

Table 2 demonstrates the correlation between the PAC-QOL total score. The correlation between the total score of the SF-36 and the PAC-QOL was significant in the moderate range. The correlation between the PAC-QOL and the physical health summary also was moderate,

Table 2: Pearson correlation between the PAC-QOL total score and the SF-36 subscales

| Subscale | P | Correlation |
|-------------------------|-------|-------------|
| Physical functioning | 0.19 | -0.30 |
| Role physical | 0.17 | -0.32 |
| Bodily pain | 0.000 | -0.74** |
| General health | 0.003 | -0.63** |
| Vitality | 0.01 | -0.55* |
| Social functioning | 0.02 | -0.51* |
| Role emotional | 0.20 | 0.30 |
| Mental health | 0.03 | -0.49* |
| Physical health summary | 0.004 | -0.63** |
| Mental health summary | 0.09 | -0.39 |
| Total SF-36 | 0.003 | -0.62** |

**Correlation is significant at the 0.01 level (2-tailed);
*Correlation is significant at the 0.05 level (2-tailed)

whereas the correlation with the mental health summary was not significant. The significant correlation between the subscales of the two questionnaires is shown in table 3.

Internal Consistency

The Cronbach's alpha was 0.92 for all the items of the PAC-QOL, with a range of 0.76 to 0.92 across all the subscales. These finding showed high internal consistency for the PAC-QOL questionnaire. According to table 4, the item internal consistency for all the items was desirable except the questions of the satisfaction subscale.

Reliability

The paired t-test showed no significant differences between the total scores of the test and the retest (P=0.22). The ICC for the PAC-QOL was 0.88, with a range of 0.69 to 0.87 across the subscales of the questionnaire.

Discussion

The aim of the current study was to translate and culturally adapt the PAC-QOL questionnaire and to assess its reliability and validity among

Table 3: Pearson correlation between the PAC-QOL and SF-36 subscales

| SF-36 subscale | Physical discomfort | Psychosocial discomfort | Worries/Concerns | Satisfaction |
|--------------------|---------------------|-------------------------|------------------|--------------|
| Bodily pain | -0.71** | -0.61** | -0.71** | -0.36 |
| General health | -0.51* | -0.51* | -0.67** | -0.24 |
| Vitality | -0.55* | -0.42 | -0.50* | -0.42 |
| Social functioning | -0.59** | -0.41 | -0.45* | -0.27 |
| Mental health | -0.34 | -0.39 | -0.58** | -0.04 |
| Physical health | -0.57** | -0.52* | -0.62** | -0.26 |

*Correlation is significant at the 0.05 level; **Correlation is significant at the 0.01 level

Table 4 : Cronbach's alpha and item statistics

| Question of the PAC-QOL | Corrected item-total correlation | Cronbach's alpha if item deleted | Squared multiple correlation | Question of the PAC-QOL | Corrected item-total correlation | Cronbach's alpha if item deleted | Squared multiple correlation |
|-------------------------|----------------------------------|----------------------------------|------------------------------|-------------------------|----------------------------------|----------------------------------|------------------------------|
| Q1 | 0.55 | 0.92 | 0.57 | Q15 | 0.63 | 0.92 | 0.77 |
| Q2 | 0.61 | 0.92 | 0.63 | Q16 | 0.55 | 0.92 | 0.68 |
| Q3 | 0.45 | 0.92 | 0.50 | Q17 | 0.64 | 0.92 | 0.64 |
| Q4 | 0.61 | 0.92 | 0.69 | Q18 | 0.60 | 0.92 | 0.67 |
| Q5 | 0.50 | 0.92 | 0.56 | Q19 | 0.72 | 0.91 | 0.77 |
| Q6 | 0.55 | 0.92 | 0.69 | Q20 | 0.65 | 0.92 | 0.73 |
| Q7 | 0.43 | 0.92 | 0.49 | Q21 | 0.67 | 0.92 | 0.71 |
| Q8 | 0.44 | 0.92 | 0.55 | Q22 | 0.57 | 0.92 | 0.61 |
| Q9 | 0.42 | 0.92 | 0.54 | Q23 | 0.71 | 0.92 | 0.78 |
| Q10 | 0.46 | 0.92 | 0.75 | Q24 | 0.44 | 0.92 | 0.63 |
| Q11 | 0.49 | 0.92 | 0.80 | Q25 | 0.22 | 0.92 | 0.67 |
| Q12 | 0.63 | 0.92 | 0.68 | Q26 | 0.30 | 0.92 | 0.73 |
| Q13 | 0.64 | 0.92 | 0.64 | Q27 | 0.32 | 0.92 | 0.73 |
| Q14 | 0.68 | 0.92 | 0.78 | Q28 | 0.12 | 0.92 | 0.42 |

Persian patients with chronic constipation. Findings showed that the Persian version of the PAC-QOL questionnaire is a valid and reliable tool for quality-of-life assessment in patients with chronic constipation and that the Persian version is comparable to the validated Turkish and Japanese versions.^{11,12}

Translation and cultural adaptation phases for the Persian version of the PAC-QOL questionnaire were performed and a Persian version of the PAC-QOL was constructed. The Persian PAC-QOL questionnaire had good content validity. All the participants filled all the items of the Persian PAC-QOL questionnaire without any item non-response. For construct validity, 4 assumptions were defined. The results proved assumptions as well as the convergent validity (correlations were >0.5) and the divergent validity (there was no correlation) of the PAC-QOL questionnaire. These findings are similar to those reported by Tsundo et al.¹¹ The Turkish version of the PAC-QOL did not have acceptable construct validity.¹² Lack of validity in the Turkish version may be because of translation or may be because of differences in culture. The correlation between the total scores of the SF-36 and the PAC-QOL questionnaire was at an acceptable level for the concurrent validity of the translated PAC-QOL. This validity index was higher than that of the other published versions.^{11,12} The validity of the other versions of the PAC-QOL questionnaire was assessed with several tools such as the Constipation Scoring System (CSS), SF-36, and the Patient Assessment of Constipation Symptoms (PAC-SYM) and the results revealed that the overall correlation between the PAC-QOL and any one of these tools was significant. Bengi et al.¹² compared the PAC-QOL, PAC-SYM, and CSS and found a correlation of 0.577 ($P < 0.001$) between the PAC-QOL and the PAC-SYM and a correlation of 0.457 ($P < 0.001$) between the PAC-QOL and the CSS. Tsunoda et al.¹¹ compared the PAC-QOL and the CSS and found correlations of 0.05 to 0.28. The authors also found a significant correlation between the PAC-QOL and the CSS except for the satisfaction subscale and reported that the correlation between the Japanese PAC-QOL and the SF-36 was significant. In our study, while the correlation between the PAC-QOL and the total SF-36 was significant, the correlations between the PAC-QOL and some SF-36 subscales were not significant. The SF-36 is a general tool for the assessment of the quality of life, whereas the PAC-QOL questionnaire is a disease-specific tool; as a result, the correlation between these 2 tools may not be strong and significant in all the subscales. On the other hand, some subscales of these questionnaires

are irrelevant in content and construct, so it is obvious that the correlations between these subscales are not significant.

The Persian PAC-QOL questionnaire has good internal consistency and results illustrate that Cronbach's alpha for all the subscales and the total score is more than 0.75 in the Persian version, which is consistent with the other published versions.¹⁰⁻¹³ The findings as regards the item internal consistency (table 4) showed that all the Cronbach's alphas after the cancelation of each item did not affect the total Cronbach's alpha score, so no item showed a discrepancy with the rest of the questionnaire. Test-retest reliability is an important aspect of outcome assessment instruments and is designed to measure change over time. Reliability in the total score and all the subscales was more than 0.85 except in the satisfaction subscale. This level of ICC demonstrates the good stability of the questionnaire. The acceptably high ICC demonstrates that the PAC-QOL questionnaire is stable over time. In other versions, the overall ICC was also more than 0.8,^{10,11,13} with the exception of the Turkish version, in which the overall ICC was 0.68.¹² The ICC for the satisfaction subscale was the lowest in our study; this result chimes in with the results of the other versions.¹⁰⁻¹³ The satisfaction subscale may lack repeatability and may, thus, require reforming to improve its reliability. Good or improper treatment can change the participants' status and these may be the cause of the low ICC in the satisfaction subscale.

First and foremost among the limitations of our study is its small sample size in the test-retest group. Another drawback is that the cause of chronic constipation was not considered as a confounding item. For example, irritable bowel syndrome can result in chronic constipation; this type of chronic constipation is a disorder of brain/gut interaction; therefore, the quality of life may have been impaired differently from the other types of chronic constipation. In future studies, chronic constipation secondary to the irritable bowel syndrome should be excluded in order to make the study populations more homogenous. Moreover, other properties of the PAC-QOL questionnaire such as responsiveness can be drawn upon in the future research. Indeed, the correlations between the PAC-QOL questionnaire and constipation severity items can be assessed in future investigations. To explore dimensionality based on data and the theory behind the scale, we suggest that future studies be conducted on a proper sample size via exploratory factor analysis and confirmatory factor analysis.

Conclusion

The Persian version of the PAC-QOL questionnaire demonstrated good validity and reliability properties in chronic constipation. The psychometric properties of the Persian PAC-QOL questionnaire are comparable to those of the original version. Researchers and clinicians can utilize this questionnaire for over 120 million people living in countries whose official language is Persian. This questionnaire can also be used for further research or assessment of treatment outcomes.

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