

Research Article



Validity and Reliability of the Persian Version of the Comprehensive Constipation Questionnaire: A Cross-Sectional Study

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ABSTRACT

Introduction: Chronic constipation is one of the most common complaints of patients in developed countries, which affects 2 to 28% of the world's population and alters patients' quality of life extensively. This study aimed to determine the validity and reliability of the Persian version of the comprehensive constipation questionnaire.

Materials and Methods: The comprehensive constipation questionnaire was translated into Persian, and its back-translation was confirmed after evaluating the content validity ratio index (CVR) based on Lawshe table ($CVR \geq 0.62$). The content validity of the questionnaire was assessed by the content validity index, followed by examining its reliability by Cronbach alpha and test-re-test reliability using the intra-class correlation coefficient (ICC). A total of 100 patients with chronic constipation completed the questionnaire.

Results: Content validity was confirmed in the range of 0.84 to 1.00, and the Cronbach alpha values in the range of 0.90-1.00 were acceptable. In this questionnaire, was ICC in the range of 0.76-0.99 which indicates a level of good to excellent reliability of the questionnaire. Also, the results of the factor analysis were confirmed at a moderate level Kaiser Meyer Olkin test ($KMO > 0.6$) and Bartlett test ($P < 0.05$) by extracting a 1-factor solution.

Conclusion: The Persian version of the comprehensive constipation questionnaire had acceptable validity and reliability and seems to be an effective tool to evaluate patients with constipation.

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1. Introduction

Chronic constipation is one of the most common complaints of patients in clinical referrals, which affects 2-28% of the world population [1, 2]. Most studies revealed that constipation is highly prevalent among whites, children, and women [3]. The average rate of constipation among European and Australian populations has been reported 17.1% and 15.3%, respectively [4].

The prevalence of constipation is 1.4% to 37% in Iran [5]. According to the results of a systematic study, the average prevalence of constipation among adults was 16% while it was 33.5% in the elderly in the age range of 60-101 [3]. The prevalence of chronic constipation in the Iranian population is less than western countries, but it is predicted to be increasing with lifestyle changes, low fiber diet, immobility, and urbanization [6].

The risk factors of chronic constipation include low physical activity, some medications, pregnancy, surgery, depression, sexual and physical abuse along with stressful life, high caffeine intake, and low fiber diets [3]. Chronic constipation could result in physical, social, and mental limitations. Constipation affects the quality of life and productivity of patients and imposes a high cost on the healthcare system [1, 2, 5]. Therefore, proper treatment is very important. Besides, to have an effective treatment, we need a standard assessment tool to examine various dimensions of the disease.

Different tools are available for evaluating chronic constipation including questionnaires and diagnostic devices. Diagnostic modalities may include contrast imaging, colonoscopy or rectosigmoidoscopy, colon transit examination, anorectal manometry, balloon ejection test, and defecography [7, 8]. However, such diagnostic examinations would cost more than simple clinical examinations or questionnaires. Some available questionnaires to evaluate constipation include the Rome III, the KESS scoring system, the Bristol stool chart, patient assessment of constipation quality of life (PAC-QOL) [9], the Wexner scoring system, the comprehensive questionnaire, etc. [3].

The original English version of the comprehensive constipation questionnaire has been developed by Fairfax colon and rectal. This questionnaire assesses various dimensions such as bowel movements, stool consistency assessment by the Bristol questionnaire, KESS scoring system, drug or laxative use, mental state, illness or surgery, and incontinence.

The validity of Rome III, PAC-QOL, Bristol stool chart, and KESS score system has been evaluated in English [10]. However, the PAC-QOL questionnaire [11], the Wexner questionnaire [12, 13], and the Rome III have been validated in Persian [14]. In a study by Blake et al. in 2016, the Bristol stool form scale (BSFS) was assessed and showed concurrent validity and reliability [15]. Also, in the study of Wojtyniak et al. in 2018, the validity and reliability of the BSFS in Persian were acceptable [16]. Moreover, the KESS questionnaire was valid to help with the diagnosis of constipation [17].

The comprehensive constipation questionnaire includes 24 items in eight sections, providing a complete tool for evaluating patients with chronic constipation. Hence, this study aimed to evaluate the reliability and validity of the Persian version of the comprehensive constipation questionnaire in patients with chronic constipation.

2. Materials and Methods

Study population

The present cross-sectional study was conducted in 2018-2019 on 100 patients over 18 years of age with chronic constipation who referred to Sheikh Alraeis Clinic in Tabriz, Iran. After explaining the aim of the study to the participants, all of them provided written informed consent.

Patients with a history of chronic functional constipation were included in this study according to the ROM III criteria as follows: Chronic constipation or defecatory disorder for at least 3 months together with two or more of the following symptoms, fewer than three bowel movements (complete evacuation) in a week, lumpy and or hard stools, the sensation of incomplete evacuation and straining at defecation in at least a quarter of times.

Furthermore, patients with constipation due to irritability bowel syndrome (IBS), alcohol and drug use, systemic diseases, psychiatric and psychological disorders, and those who were not fluent in Farsi were excluded.

The comprehensive constipation questionnaire

The constipation comprehensive questionnaire contains 24 items in eight subsections: Section 1 involves defecation times, and bowel movements, section 2 is related to stool consistency using Bristol's criterion, section 3 includes the Wexner scoring system scored in the range of 0-30 indicating a normal status as 0 and the most severe form of chronic constipation as 30 as well

as digitation, section 4 is related to medications used by the patient during the recent three months, section 5 is about the delivery and menstrual status, section 6 is depression evaluation, section 7 is related to medical or surgical history, and finally section 8 is related gas or stool incontinence.

Linguistic and semantic equivalence

First, the questionnaire was translated into Persian. Then, this translation was compared with the translation of a professional medical translator and necessary corrections were made. Next, the Persian translation of the questionnaire was backward translated into English by another translator and then compared with the main English version [18]. The required modifications were made to the Persian version. The final version of the Persian questionnaire was given to 10 experts in gastroenterology and colorectal surgery to identify the level of difficulty, ambiguity in expressions and terms, and inadequacy of the words' meanings. After receiving the experts' comments, necessary corrections were made to make the questions simpler, clearer, and more understandable.

Content validity

In this questionnaire, factor analysis was used to check all aspects of the behavior of the questionnaire items to determine its content validity. To test the content validity, we asked 20 medical experts to evaluate the PAC-QOL and the results were used to calculate the content validity ratio (CVR) and content validity index (CVI).

CVR was used for quantitative evaluation of the content validity and to ensure choosing the most important and correct content (item necessity). Accordingly, the expert panel was asked to examine each item based on three options: "it is necessary," "it is effective but not necessary" or "it is not necessary." Then, content validity coefficients were estimated using Lawshe's formula, and the items with a content validity of ≥ 0.62 were confirmed considering the number of experts [18].

Additionally, CVI was used to ensure that the items of the questionnaire were designed for the proper measurement of the content. Hence, the expert panel ($n=10$) was asked to identify the simplicity, specialty, and clearness of each item on a four-point Likert scale. Content validity of more than 0.79 was considered acceptable [19].

Construct validity

To test the construct validity, we used factor analysis from 130 patients with functional constipation. Kaiser-Meyer-Olkin (KMO) measure of adequate sampling and Bartlett's test of sphericity were considered before the analysis.

Moreover, the KMO index was used to evaluate the adequacy of the sample size. KMO values of 0.5 to 0.7 indicate moderate factor analysis, 0.7 to 0.8 balanced, 0.8 to 0.9 acceptable, and greater than 0.9 shows excellent factor analysis. Bartlett test was also used to investigate the correlation between questionnaire items and data appropriateness for exploratory factor analysis.

Reliability

Reliability means the strength of reproducibility, continuity of measurement, and effectiveness of the tool. To determine the reliability of the questionnaire, test-re-test stability and internal consistency were used. To determine the reliability of the questionnaire, re-test stability and internal consistency were used. An interval of 2 days was considered to determine the stability of the test-re-test [20]. The questionnaire was filled by 20 randomly selected patients and the intra-class correlation index (ICC) and confidence interval were calculated for each factor and the whole questionnaire. To determine the internal consistency, the Cronbach alpha coefficient was calculated for each factor and the whole instrument, which aims to examine the degree of correlation between the variables that make up the structure or scale. In this study, the Cronbach alpha value for reliability was 0.789 [21].

Statistical analysis

Statistical analysis was performed using SPSS software, version 26 (SPSS Inc. Chicago, IL, The USA) and a $P < 0.001$ was considered statistically significant.

3. Results

One hundred thirty patients with constipation were included in this study; 30 of them were excluded from the study for various reasons. Then, data from 100 patients were analyzed. All patients had chronic constipation for more than 3 months. The Mean \pm SD age was 38.13 (12.02), 38% of participants were male and 62% were female.

Validity

To evaluate the construct validity of this questionnaire, the value of the KMO index was 0.642 and the Bartlett index was 361.276 ($P < 0.05$). The results of the factor analysis were confirmed at a moderate level Kaiser Meyer Olkin test ($KMO > 0.6$ and Bartlett test $P < 0.05$) by extracting a 1-factor solution (Table 1).

Reliability

The correlation of the items was estimated using the Cronbach alpha index, and its value for the reliability of the 24 items of the questionnaire was 70-99% in the test-re-test, showing excellent reliability and validity of the questionnaire items (Table 2).

4. Discussion

This study aimed to evaluate the reliability and validity of the comprehensive constipation questionnaire in Persian. This study showed good internal consistency for the Persian version of the comprehensive constipation questionnaire as the Cronbach alpha value for all items was 0.7, which indicates a high level of internal consistency.

The overall reliability score of this questionnaire was acceptable.

Chronic constipation has many adverse effects on the quality of life and imposes high expenses on the health-care system. Therefore, a valid tool for the clinical evaluation of constipation is required. The comprehensive chronic constipation questionnaire consists of several questionnaires, which can evaluate different aspects of constipation. Additionally, it includes both qualitative and quantitative questions compared to other related questionnaires.

The Bristol stool form and the KESS scoring system of the comprehensive constipation questionnaire are valid and reliable in English but only the Bristol stool form has been validated in Persian.

This study was the first investigation to validate the reliability of the comprehensive constipation questionnaire in Persian. We showed that the translated questionnaire has good content validity and internal consistency. Similar studies conducted to determine the reliability and validity of Bristol's questionnaire reported an acceptable Kappa index. From 320 items, the general Kappa index

Table 1. Factor analysis

Component Matrix	
Component	1
Q7	0.785
Q3	0.696
Q4	0.683
Q6	0.648
Q5	0.638
Q8	0.638
Q1	0.577
Q10	0.470
Q9	0.402
Q2	0.389
Q18	
Q13	
r_Q15	

Extraction method: Principal component analysis. a. 1 component extracted.

Table 2. Internal consistency and test-re-test reliability

Questions	Test-re-test Correlation Coefficient	Question	Test-re-test Correlation Coefficient
Q1	0.989	Q13	1.000
Q2	0.994	Q14	1.000
Q3	1.000	Q15	0.984
Q4	0.992	Q16	1.000
Q5	0.907	Q17	1.000
Q6	0.991	Q18	1.000
Q7	0.956	Q19	1.000
Q8	0.984	Q20	1.000
Q9	0.983	Q21	0.994
Q10	1.000	Q22	1.000
Q11	1.000	Q23	1.000
Q12	1.000	Q24	1.000

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(95%-CI: 0.77- 0.73, 0.75) was at the desirable level for 80 participants, also the Kappa index (95%-CI 0.91-0.87) was 0.89 in test-re-test for 170 participants [16].

Another study evaluated the KESS scoring system in 71 patients with chronic constipation. In this study, linear discriminant analysis was used. The total symptom score was strongly correlated with the Cleveland clinic score ($r=0.9$). The mean total score in patients with constipation was 20 (range, 31-35) compared to the mean of 2 in the control group (ranged 0-6). Discriminatory analysis using cross-validation estimated that pathophysiology can be correctly predicted for 55% (95% confidence interval=67-43%) of patients using only five symptoms. Distinctive function seldom misdiagnoses patients with rectal drainage disorder as slow-moving constipation and vice versa, but cannot effectively distinguish patients with single and mixed pathologies. This new scoring system is a valid technique to assist in the diagnosis of constipation and is the first study using an appropriate statistical methodology to demonstrate the discriminatory ability of multiple symptoms in constipation [17].

According to the acceptable validity and reliability of the Persian version in our study, this tool can assess various aspects of the disease and the severity of constipation. This questionnaire can also be an available and inexpensive tool for clinical trials and control of the treatment process by therapists and researchers.

One limitation of the present study was the lack of investigation of the structural validity of the questionnaire. The evaluation of structural validity using an exploratory factor analysis considering a higher number of questions in this questionnaire (24 items) requires a large sample size, which was impossible in the limited time of the present study.

However, the present study was the first to determine the validity and reliability of the constipation comprehensive questionnaire, which can eliminate the shortcomings of other questionnaires and evaluate constipation severity in patients from different aspects. Moreover, it is suggested to use the present questionnaire as a reliable and valid tool in future investigations for diagnostic and therapeutic purposes. This questionnaire can also be used to assess the treatment process including the effectiveness of medications or physiotherapy.

5. Conclusion

The Persian version of the constipation comprehensive questionnaire had acceptable reliability and validity, which can be used as a complementary tool along with other evaluation tools for patients with constipation.

Ethical Considerations

Compliance with ethical guidelines

All of the ethical codes were considered in this study and it was confirmed by the Regional Research Ethics Committee of [Tabriz University of Medical Sciences](#) (Code: IR.TBZMED.REC.1398.251).

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Authors' contributions

Conceptualization: Tuba Mahmoudzadeh and Fariba Ghaderi; Supervision: Fariba Ghaderi; Data collection: Tuba Mahmoudzadeh, Fariba Ghaderi and Bita Sepehri; Statistical analysis: Mohammad Asghari Jafarabadi; Manuscript writing: Tuba Mahmoudzadeh, Fariba Ghaderi and Hakimeh Adigozali.

Conflict of interest

All authors declare no conflict of interest.

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