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Validity and reliability of the patient assessment of constipation quality of life questionnaire for the Turkish population

INTESTINE

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Original Article

ABSTRACT

Background/Aims: There are few specific evaluation forms for evaluating the quality of life among patients with chronic constipation. Our study aimed to determine the validity and reliability of the translated Patient Assessment of Constipation Quality of Life (PAC-QOL) questionnaire for the Turkish population because evidence of its reliability and validity is required to justify its use in other studies and clinical practice.

Materials and Methods: This study included 154 patients with constipation who were treated at the Department of Gastroenterology, Dokuz Eylül University Hospital between January and June 2012. The translated PAC-QOL questionnaire was completed by patients at the clinic and also at a 2-week follow-up to test its reliability.

Results: Cronbach's alpha coefficient (internal consistency) was 0.91 (good) for the translated PAC-QOL questionnaire. Time validity was evaluated using the intraclass correlation coefficient (ICC) method, and the ICC value for all questions was confirmed as 0.68 at the 2-week follow-up. The validity of the tool in the study group was evaluated using factor analysis, and the results were highly significant (Kaiser–Meyer–Olkin value: 0.857; Bartlett's test: p=0.001). Questions were categorized according to six factors based on the factor analysis, and these factors explained 65.1% of the total variation. For hypothesis verification of the tool, the correlation coefficient for PAC-QOL and PAC Symptoms (PAC-SYM) was r=0.577 (p<0.001), whereas the correlation coefficient for PAC-QOL and constipation severity score was r=0.457 (p<0.001).

Conclusion: The PAC-QOL questionnaire was reliable, although not valid because of the limited sample group.

Keywords: Chronic constipation, validity, reliability, patient assessment of constipation quality of life, PAC-QOL

INTRODUCTION

Chronic diseases threaten patients' functional capability, cause recognizable changes, do not spontaneously resolve, and cannot be completely treated. These changes can substantially affect the patient's quality of life, which refers to how the patient subjectively perceives his/her own health within the sociocultural environment he/she lives in. The prevalence of chronic diseases has increased over the past decades because of various reasons, including changes in lifestyle, environmental factors, and increased life expectancy. Unfortunately, individuals with chronic diseases and their families are affected by physical and psychosocial issues, such as loss of self-esteem, unemployment, feelings of rejection and desperation, and economic losses. Furthermore, these adverse effects on individuals negatively impact the society.

Chronic constipation is characterized by long-term symptoms due to straining and irregular or absent bowel movements. Population-based studies in the United States have reported that the prevalence of chronic constipation is 19.2% among people who are 30–64 years old and 24.4% among those who are ≥65 years old (1). Uz et al. (2) reported that the constipation prevalence in our country is 20% and that 73% of patients are women, while 30% of them are >60 years old. Chronic constipation is occasionally diagnosed according to the

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number of times the patient defecates and other symptoms, such as a feeling of discomfort or difficulty in passing stools (3). On the basis of this information, the Rome III criteria were developed for the diagnosis of functional constipation, although they could not specify the severity of constipation. In addition to the Rome III criteria, many clinicians use the Constipation Scoring System (4) or Constipation Assessment Scale (5) to diagnose constipation and its severity. Unfortunately, the cost of constipation treatment is significant, and unemployment due to constipation is also significant.

Standardized patient assessment is necessary to accurately evaluate and treat chronic constipation. This will ensure better evaluation of patients and arrangement of more suitable treatments. Therefore, it is required to localize existing scales in Turkish with respect to their validity and reliability and to develop specific scales for the disease. However, there are few assessment forms that are specific to constipation and one of them is the Patient Assessment of Constipation Quality Of Life (PAC-QOL) questionnaire. Our study aimed to determine the validity and reliability of the translated PAC-QOL questionnaire in the Turkish population because evidence of its reliability and validity is required to justify its use in other studies and clinical practice.

MATERIALS AND METHODS

This study included all patients who fulfilled the Rome III chronic constipation criteria and were treated at the Department of Gastroenterology, Dokuz Eylül University Hospital between January and June 2011. The study was initiated after receiving the approval from the Ethical Committee of Dokuz Eylül University, and written informed consent was obtained from all patients. E-mail approval was received from Patrick Marquis for the translation of the PAC-QOL questionnaire into Turkish and for its use in Turkey. The target sample size was set at 140 patients [5×28 (the number of questions)], and a final sample of 154 patients were included in this study. Patients suffering from functional constipation for a reason, excluding all secondary constipation reasons, were included in the study. Because additional chronic diseases can affect patients' quality of life, only patients with one chronic disease (other than chronic constipation) were included in this study. The statistical package SPSS 15.0 for Windows (SPSS Inc., Chicago, IL, USA) was used for all statistical analyses.

Exclusion criteria:

1) Patients with secondary constipation
2) Patients with drug-induced constipation.
3) Patients without the mental capacity to complete the questionnaire.
4) Patients who could not read or write Turkish.
5) Patients who had experienced a major life event within the previous three months (e.g., the loss of an immediate family member).

Chronic constipation patient assessment quality of life questionnaire:

PAC-QOL questionnaire comprises 28 questions and depending on the factor analysis structure, the tool comprises four subscales, including "Physical discomfort (question 1–4)," "Psychosocial discomfort (question 5–12)," "Worries and concerns (question 13–23)," and "Satisfaction (question 24–28)." Similar to the Likert scale, each option is scored on a scale of 0–4 (least to the greatest effect), and higher scores indicate a worst quality of life. However, reverse coding was required in questions 18, 25, 26, 27, and 28 because they were positive questions, whereas the other 23 questions were negative ones.

Language equivalence of the translated PAC-QOL questionnaire:

The original PAC-QOL questionnaire was translated from English to Turkish using the translate–retranslate method. The Turkish translation was compared with the initial text, revised as required, and subsequently submitted for expert review to three gastroenterologists. After incorporating the revisions suggested by these experts, the tool was finalized for use in this study.

Validity and reliability analyses

1. Reliability

a) Stability over time: To assess the tool's stability over time, the test–retest method was used, which requires a minimum of 30 subjects to evaluate the tool's stability over time. In this study, a sample of 77 patients was re-evaluated at a 2-week follow-up. Because the patient was subject to diagnostic processes in this 2-week period between the test and re-test, no new treatment was applied and current treatments were continued. The correlation between the two measurements was calculated using the intraclass correlation coefficient (ICC) because the data was sequential and continuous.

b) Internal consistency: To assess the tool's internal consistency, we used the Cronbach's alpha coefficient. For sections analyses, Spearman's correlation coefficient was calculated to examine the correlation between the subject and total scores.

2. Validity

a) Validity of the content and scope: Three experts gave their opinions on the tool's understandability, expediency, and compatibility with the Turkish culture to confirm the tool's validity regarding content and scope.

b) Validity of structure and concept: To determine the tool's structural validity, confirmatory factor analysis and hypothesis testing were conducted. During the hypothesis testing, constipation symptoms were assessed using the PAC Symptoms (PAC-SYM) and Constipation Severity Scores (CSS) for the tool's validity. The correlation between PAC-SYM, CSS, and PAC-QOL average scores were evaluated using Spearman's correlation coefficient.

RESULTS

Sociodemographic characteristics of patients with chronic constipation

Among the 154 patients who participated in this study, the average age was 49.5±17.2 years (range, 18–85 years), 72% of participants were women, 65.6% were married, and 38.3% had only an elementary school education (Table 1). In addition, 43.5% of participants had a comorbid condition, 8.4% had diabetes, and 6.5% had cardiovascular heart disease. Among participants, 43.5% reported requiring care for another person, whereas 52.6% had someone to provide assistance when required.

Assessing the translated PAC-QOL questionnaire

The data obtained using the translated PAC-QOL questionnaire was examined under three categories (language equivalence, reliability, and validity) to analyze the tool's validity.

1. Language equivalence

During the pilot study, questions 10–12 (regarding the effects of chronic constipation on daily life) were not well understood by patients. Therefore, additional examples were added to provide a more clear understanding of the question; these examples were specific to daily life in the Turkish culture and did not exist in the original PAC-QOL questionnaire.

Table 1. The patients' sociodemographic characteristics

Characteristics	Number (n=154)	%
Sex		
Men	43	27.9
Women	111	72.1
Marital status		
Married	101	65.6
Single	27	17.5
Widower or divorced	26	16.9
Education		
Elementary school	59	38.3
Middle school	31	20.1
High school	54	35.1
University	10	6.5
Profession		
Self-employed	7	4.5
Public servant	20	13.0
Laborer	16	10.4
Housewife	51	33.1
Retired	39	25.3
Other	21	13.6
Working status		
Not working	104	67.5
Part-time	4	2.6
Full-time	46	29.9

2. Reliability

In our version of the constipation assessment tool, question 13 had the greatest number of extremely and most of the time responses, whereas question 26 had the greatest number of not at all responses.

a) Internal consistency: Consistency was evaluated while considering all the questions and sections, and the results are summarized in Table 2. The responses for the questions and sections were consistent for this study group (all, >0.70). The internal consistency coefficient for the complete tool was 0.91 compared with 0.79 for "physical discomfort," 0.82 for "psychosocial discomfort," 0.89 for "worries and concerns," and 0.75 for "satisfaction."

b) Sections: The correlations between each question and its sub-group score and between each sub-group score and the tool's total score were evaluated. The subject with the lowest total test score correlation (0.50) was the "satisfaction" subgroup. The "worries and concerns" subject had the greatest correlation with the total score (0.89) (Table 3). However, question 18 was not correlated with the "worries and concerns" subgroup score, and question 24 only had a low level of correlation with the "satisfaction" sub-group score (Tables 4–7).

c) Stability over time (test–retest reliability): In the development phase for the original tool, its stability over time was evaluated using ICC. In our study, the ICC value for all questions was 0.68 with 0.66 for "worries and concerns," 0.61 for "physical discomfort," 0.79 for "psychosocial discomfort," and 0.46 for "satisfaction" (Table 8).

Table 2. Internal consistency of the constipation tool

Constipationtool sub-groups	Cronbach's alpha
All questions	0.910
Physical discomfort	0.794
Psychosocial discomfort	0.825
Worries and concerns	0.892
Satisfaction	0.755

Table 3. Correlations between the sub-group and total scores

Sub-group	Spearman's Rho	p value
Physical discomfort	0.744	<0.001
Psychosocial discomfort	0.774	<0.001
Worries and concerns	0.909	<0.001
Satisfaction	0.500	<0.001

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Table 4. Correlation between the total and physical discomfort question scores

	Spearman's Rho	p value
Question 1	0.848	<0.001
Question 2	0.846	<0.001
Question 3	0.771	<0.001
Question 4	0.638	<0.001

Table 5. Correlation between the total and psychosocial discomfort question scores

	Spearman's Rho	p value
Question 5	0.620	<0.001
Question 6	0.616	<0.001
Question 7	0.589	<0.001
Question 8	0.534	<0.001
Question 9	0.731	<0.001
Question 10	0.768	<0.001
Question 11	0.685	<0.001
Question 12	0.680	<0.001

Table 6. Correlation between the total and worries and concerns question scores

	Spearman's Rho	p value
Question 13	0.791	<0.001
Question 14	0.821	<0.001
Question 15	0.709	<0.001
Question 16	0.759	<0.001
Question 17	0.615	<0.001
Question 18	0.192	0.017
Question 19	0.747	<0.001
Question 20	0.769	<0.001
Question 21	0.779	<0.001
Question 22	0.757	<0.001
Question 23	0.638	<0.001

3. Validity

a) Content and concept validity: Three experts provided their opinions on the tool's understandability, expediency, and cultural compatibility to provide the validity of the content and scope.

b) Structural validity: The structural validity of the tool was tested using factor analysis (Table 9) that requires that the Kaiser–Meyer–Olkin measure be >0.50 and the p value for the Bartlett's test result be <0.05. For our data, the Kaiser–Meyer–Olkin measure was 0.857, and the Bartlett's test provided a value of (p<0.001); these results are highly significant and indicate that the data are suitable for factor analysis. In addition, the factor load of the questions was controlled, and the factors having >0.1 of factor load was specified. The questions were listed under the relevant factor along with the factor load, and these factors explained 65.1% of the total variance. Unfortu-

Table 7. Correlation between the total and satisfaction question scores

	Spearman's Rho	p value
Question 24	0.527	<0.001
Question 25	0.768	<0.001
Question 26	0.803	<0.001
Question 27	0.800	<0.001
Question 28	0.677	<0.001

Table 8. Intra-class correlation values for the tool's sub-groups

Sub-group	ICC	95% CI
Physical health	0.617	0.392–0.758
Psychosocial health	0.799	0.685–0.872
Worries and concerns	0.664	0.473–0.786
Satisfaction	0.460	0.153–0.656
Full tool	0.687	0.510–0.801

ICC: intra class correlation; CI: confidence interval

Table 9. Factor structure for the chronic constipation quality of life tool

Factors	Question number	Factor load	Variance explained by factor (%)
Factor 1	15	0.789	16.83
	16	0.783	
	14	0.781	
	17	0.669	
	22	0.652	
	13	0.612	
	20	0.582	
	21	0.542	
	19	0.531	
Factor 2	1	0.710	13.62
	2	0.693	
	24	0.652	
	4	0.607	
	23	0.590	
	3	0.566	
Factor 3	26	0.911	10.89
	27	0.885	
	25	0.856	
	28	0.641	
Factor 4	11	0.794	10.81
	10	0.749	
	12	0.702	
	5	0.661	
Factor 5	8	0.803	7.91
	6	0.756	
	9	0.570	
	7	0.491	
Factor 6	18	0.632	5.06

nately, this indicates that validity is problematic in this group; thus, questions were grouped under six factors.

Hypothesis Testing

The relationships between PAC-QOL, PAC-SYM, and CSS were analyzed. The correlation coefficient for PAC-QOL and PAC-SYM was 0.577 (p<0.001), whereas the correlation coefficient for PAC-QOL and CSS was 0.457 (p<0.001). A significant and weak-to-moderate relation was observed (Table 10).

Table 10. The correlation between the average PAC-QOL, PAC-SYM and CSS

	Rho	p
PAC QOL vs PAC SYM	0.577	<0.001
PAC QOL vs CSS	0.457	<0.001

PAC QOL: patient assessment of constipation–quality of life
PAC SYM: patient assesment of constipation symptoms
CSS: constipation scoring system
p<0.001 for all correlations.

DISCUSSION

The original PAC-QOL questionnaire was developed by Marquis et al. (6) in 2003 to measure the effects of chronic constipation on the quality of life and activities of daily living using a simple structure and scoring system. Our study aimed to determine the validity and reliability of the translated PAC-QOL questionnaire in the Turkish population because evidence of its reliability and validity is required to justify its use in other studies and clinical practice.

Among patients who were included in the present study, the average age was 49.45 years. However, patients may have encountered difficulties answering the test questions because the ages ranged from 19 to 85 years with a bias towards more elderly patients. Consistent with the literature, we found that 72.1% of patients with chronic constipation were women. In addition, 38.3% of participants were elementary school graduates that may have affected their ability to understand and accurately answer the questions.

During the pilot study, questions 10–12 (regarding the effects of chronic constipation on daily life) were not well understood by patients. Therefore, additional examples were added to provide a more clear understanding of the question; these examples were specific to daily life in the Turkish culture and did not exist in the original PAC-QOL questionnaire. Because of this modification, questions became clearer and patients were able to easily and completely explain their situation. Moreover, it appears necessary to add small examples or make small modifications to achieve a more usable scale by abiding to its original version.

It is unlikely that any of our patients correctly reported a total score of 0 because we selected patients based on the Rome III criteria that indicates that patients were not satisfied with the quality of life; these complaints should have been reflected on the score of the translated PAC-QOL questionnaire. Therefore, we question whether patients provided accurate and diligent responses. We found that question 26 (regarding satisfaction with the regularity of bowel movements) had the highest number of "not at all" responses (100 patients, 64.9%). In addition, question 13 (regarding whether the patient felt irritable because of his/her condition) had the highest number of "extremely" or "quite a bit" responses (35 patients, 22.7%). These results indicate that patients with chronic constipation are more affected by the irregularity of the bowel movements and that they are generally irritable.

The median total score for the initial PAC-QOL questionnaire was 1.85, and the "satisfaction" sub-group had the greatest negative effect on the quality of life; we observed a similar result. Furthermore, the Cronbach's alpha coefficient for the translated PAC-QOL questionnaire was 0.91 that indicates that our components were consistently homogeneous and measured the same feature. For the original PAC-QOL questionnaire, the Cronbach's alpha coefficient for the whole tool was 0.93 with 0.83 for "worries and concerns", 0.86 for "physical discomfort", 0.91 for "psychosocial discomfort," and 0.81 for "satisfaction" (6). The average Cronbach's alpha coefficient for all questions was 0.94, and this value is above the 0.8 value that has been reported for sub-groups in validation studies that were performed in France, the United Kingdom (UK), the Netherlands, Belgium, Canada, and Australia. When the Cronbach's alpha coefficients of the translated PAC-QOL questionnaire's components were examined, "satisfaction" had the lowest value (0.75), and Marquis et al. reported similar results for the original PAC-QOL questionnaire. A previous study by Dedeli et al. (7) revealed that PAC-QOL's Cronbach's alpha coefficient was 0.91, whereas the Cronbach's alpha coefficient of each subscale was between 0.76–0.88; thus, making it sufficiently reliable.

The procedures used to determine whether the components measure a specific feature are called subject analyses. If the correlation of a subject with the total score is low, the subject is thought to measure a different feature than the other subjects. Because low subject correlation reduced the tool's reliability, the subjects in question should be removed from the tool. In the present study, 18 questions had the question-to-total score correlation p values of >0.005, indicating that they were insignificant. The lowest sub-group-to-total score correlation was for the "satisfaction" sub-group that had a value of 0.50. When the subject analyses are examined as a whole, the correlation between the questions and sub-groups to which they belonged was moderate-to-good. The strong correlation between all the sub-group scores (except "satisfaction") and total test score makes this tool consistent and reliable.

The translated PAC-QOL questionnaire had good stability over time. During the original tool's development, stability over time was analyzed using the ICC method (an ICC value of 0.82 at two weeks), and no change in constipation severity was observed at the 2-week follow-up (5). French and Dutch validation studies reported ICC values of >0.7 in all sub-groups except for the

"satisfaction" sub-group. When we evaluated the ICC value for the translated PAC-QOL questionnaire, an even higher value was observed (0.79).

After modifying the translated PAC-QOL questionnaire on the basis of the opinions of our expert reviewers, the tool was used for the data of 10 patients (who were not included in this study's analysis), and the Cronbach's alpha coefficient (internal consistency) was calculated to be 0.91. The tool was also shaped by asking participants regarding their understanding of expressions, ability to read, and complete the questions. Despite all these adjustments, we found that question 18 (regarding whether the subjects felt in control of their situation) was not well understood by patients. It would be useful to arrange this question in a more understandable way that is illustrated with examples.

Our analysis of the translated PAC-QOL questionnaire indicated that the questions were grouped under six factors. However, no questions had a factor load of <0.30, therefore, none of the questions was removed from the tool. In contrast, the original PAC-QOL questionnaire was grouped under four factors. For the translated PAC-QOL questionnaire, factors explained 65.1% of the total variance. However, the factor structure of our translated tool was not comparable with the factor structure of the original tool.

In the original PAC-QOL questionnaire, a significant positive correlation between PAC-QOL and constipation severity measures, including weekly defecation, stomachache, and observer and clinical observation of the patient) was observed (6). The original PAC-QOL questionnaire was developed in English by Marquis et al. for the American population, and the same team also evaluated the tool in French and Dutch to demonstrate its reliability and validity in the UK, France, the Netherlands, Belgium, Canada, and Australia. In our study, the translated PAC-QOL questionnaire was reliable, although not valid in our patient sample. However, it would be incorrect to generalize our results (from a sample of 154 patients) to the general Turkish population.

The causes of this lack of validity for the translated PAC-QOL questionnaire are as follows: patients were a heterogeneous group (18–85 years old), majority of the sample comprised older patients, and majority of the sample had only graduated elementary school. Patients with lower educational and older patients are unlikely to understand and accurately answer the questions. Other possible causes may have been the translation into Turkish and the lack of explanatory examples for various questions. Patients may also have incorrectly answered the questions because of a lack of supervision, insufficient time, and lack of diligence. It is possible that the in-person interviews may have generated different results, although patients are easily manipulated using that method, and it is also not practical for use in the clinic. Although the contents of this tool are suitable for European and American patients, they are not suitable for the Turkish population. Therefore, additional modifications (e.g., in the contents, language, or clarity) and a more specific patient group (e.g., younger, more educated patients) are required to implement and analyze this tool. We should perhaps develop our own new questionnaire that would suit the education level in Turkey rather than try to adopt the English PAC-QOL questionnaire. The facts that the correlation between the 2-week follow-up and original measurements was poor and that the answers of the "satisfaction" sub-group were worse than those for the general tool indicate that patients did not receive sufficient and efficient treatment.

As the tool comprises sub-groups ("physical discomfort," "psychosocial discomfort," "worries and concerns," and "satisfaction"), it can guide clinicians in making appropriate diagnoses and selecting effective treatments. When used with the severity and symptom scoring for patients with chronic constipation, the translated PAC-QOL questionnaire may be useful in clinical applications because it provides a holistic approach to patient assessment by simultaneously using two subjective and objective measurement tools.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Dokuz Eylül University Ethics Committee on December 15, 2012 (approval number 638).

Informed Consent: Written informed consent was obtained from patiens who participated in this study.

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