

Reliability and validity of the Persian version of patient assessment of constipation- quality of life (PAC-QOL) questionnaire

Marjan Mokhtare¹, Seyed-Mohammad-Sadegh Ghafoori², Mojtaba Soltani-Kermanshahi³, Amir-Hosein Boghratian⁴, Shahram Agah⁵, Mehrdad Sheikhvatan⁶

¹Assistant Professor, Colorectal Research Center, Rasoul Akram Hospital, Iran University of Medical Sciences, Tehran, Iran

²Medical Doctor, Colorectal Research Center, Medical Student Research Committee (MSRC), Faculty of Medicine, Iran University of Medical Sciences, Tehran, Iran

³Biostatistics Department, International Branch, Shahid Beheshti University of Medical Sciences, Tehran, Iran

⁴Colorectal Research Center, Rasoul Akram Hospital, Iran University of Medical Sciences, Tehran, Iran

⁵Professor, Colorectal Research Center, Rasoul Akram Hospital, Iran University of Medical Sciences, Tehran, Iran

⁶Clinical Research Development Center, Rasoul-e-Akram Hospital, Iran University of Medical Sciences, Tehran, Iran

ABSTRACT

Aim: The present study aimed to assess the reliability and validity of Persian version of patient assessment of constipation: quality of life (PAC-QOL) questionnaire in Iranian patients.

Background: Chronic constipation has significant effects on daily living, wellbeing and individuals' quality of life (QOL). Validated tools can help us to assessing QOL in affected ones and facilitating clinical management of them.

Methods: The English version of Patient Assessment of Constipation: Quality of Life (PAC-QOL) was translated into the Persian language and was confirmed by back-translation. One hundred and forty patients with functional constipation, according Rome III criteria, completed the questionnaires. The questionnaires were analyzed using Cronbach's Alpha internal consistency score to determine the reliability. Twenty medical experts were then asked to evaluate the PAC-QOL and the results were used to calculate the Content Validity Ratio (CVR) and Content Validity Index (CVI).

Results: Due to obtained value for Cronbach's α (0.975) and also for the subscale of physical discomfort (0.930), psychosocial discomfort (0.975) and worries and concerns (0.915), the internal consistency is established. According to medical experts' opinions, the value of CVR ranged from 0.5 to 0.8 and the value of CVI was 0.81.

Conclusion: The Persian version of PAC-QOL questionnaire is shown to have acceptable reliability and validity to be used for psychometric evaluation in Iranian patients complaining of functional constipation.

Keywords: Quality of life, Reliability, Validity, Persian, Constipation.

(Please cite as: Mokhtare M, Ghafoori SMS, Soltani-Kermanshahi M, Boghratian AH, Agah Sh, Sheikhvatan M. Reliability and validity of the Persian version of patient assessment of constipation- quality of life (PAC-QOL) Questionnaire. *Gastroenterol Hepatol Bed Bench* 2017;10(4):289-294).

Introduction

Chronic constipation is a common gastrointestinal complaint particularly in developed countries (1, 2). Constipation has undesirable effects on mental and physical aspect of the quality of life. According to the ROME III diagnostic criteria (3, 4), functional constipation presents as “determinedly difficult, infrequent, or incomplete

defecation”, without any abdominal pain, causative underlying disease and drug consumption. (5, 6). Functional constipation occurs in up to 27% of the general population and affects all age groups, but seems to be more prevalent in women and old age groups (7).

The prevalence of constipation is high in Iran. Though it is less than Western countries, latest alterations in behavioral and dietary life style, higher urban residency, industrialization and immobility can cause an enhance in the number of patients with constipation in the future.(8, 9).

Received: 12 July 2017 Accepted: 11 October 2017

Reprint or Correspondence: Shahram Agah, MD.
Department of Gastroenterology, Iran University of Medical Sciences, Iran.

E-mail: agah.shahram@yahoo.com

The estimated prevalence of constipation and functional constipation in Iran was 1.4-37%, and 2.4-11.2%, respectively (10-13).

The mean total direct and indirect costs during 6-months was approximately 147 PPP\$(purchasing power parity dollars) for patients with functional constipation in Iran and higher educated patients (189.75 PPP\$), age over 64 (373.42 PPP\$), BMI less than 18.5 kg/m² (510.84 PPP\$), and widowed persons (258.50 PPP\$) had the highest expenses (14,15).

There are very little information exist to concern about the natural history, quality of life and risk factors of constipation in Iran. Selecting the best treatment for patients with functional constipation depends on how it can relief individual symptoms and improve quality of life. The original English version of a Patient Assessment of Constipation: Quality of Life (PAC-QOL) (Copyright©PAC-QOL, 2005 Mapi Research Trust, All rights reserved) that developed and validated by Marquis et al (15) in 2005, is a self-reported questionnaire frequently used to measure QOL in patients. PAC-QOL questionnaire can facilitate clinical assessment of this complaint in patients.

PAC-QOL questionnaire has been translated and validated in majority of different languages all around the world. The present study aim to assess the reliability and validity of the translated Persian version of PAC-QOL tool in Iranian patients.

Methods

Description of PAC-QOL

The original PAC-QOL paper contains 28 items grouped into 4 subscales covering: Worries and concerns (11 items), Physical discomfort (4 items), Psychosocial discomfort (8 items), and Satisfaction of treatment (5 items).

A 5-point Likert response scale, ranging from 0 (Not at all / none of the time) to 4 (Extremely / All of the time), is used over a 2-week recall period (A higher score indicating worse QOL due to constipation).

Total score and the scores for each subscale were calculated according to the original PAC-QOL paper (16).

Linguistic and semantic equivalence

The linguistic validation of the PAC-QOL into Persian aimed to obtain a conceptually equivalent version and easily understood by our patients.

Forward Persian translation was done by three translators (two gastroenterologists and a professional translator). Back translation to English was performed by two other experienced translators. Slight discrepancy was found in Items 18 and an expression in this item was corrected.

However, to complete the linguistic and cultural adaptation we decided to perform a clinical review and a cognitive debriefing with patients. Both were considered a means to test the instrument's content validity, *i.e.*, to evidence its suitability to the specific purpose. So, for a clinical review, we first asked a committee composed by a forward translator, six gastroenterologists, a biostatistician and an epidemiologist to clinically improve the Persian translated version. This gave a minor changes in translated version to improve the clarity of the questions in Persian. The questionnaire was filled by 6 series of patients for pilot test with the purpose of finding any problem of clarity, misunderstandability and redundancy of each item (17, 18).

Study population

Once piloted, the Persian version was then tested for reliability and validity. For this second phase we selected 140 patients with functional constipation (according to Rome III criteria) and age over 18 who referred to gastrointestinal clinic of Rasoul-e-Akram educational hospital. The patients over 18 years with a history of chronic constipation or evacuator disorder for at least 3 months alternately also with two or more of the following symptoms: fewer than three bowel movements (complete evacuation) in a week, lumpy and/or hard stools at least a quarter of the time, the sensation of incomplete evacuation at least a quarter of the time, and straining at defecation at least a quarter of the time were included. The patients with constipation dominant irritable bowel syndrome and/or secondary specific etiology (associated to underlying disease and drug) for constipation and inability to completing the QOL questionnaire were excluded. Four Gastroenterologists gave the questionnaires to the patients. All of participants filled informed consent form.

The sample size is considered an acceptable number for validation studies and for factor analysis (19, 20). Data were collected during a period of 5 months, starting in October 2014.

Validation methods

The psychometric features of the PAC-QOL were determined in terms of reliability, content validity, and construct validity as described below (21).

Reliability

Internal consistency and reproducibility were investigated to evaluate reliability of the PAC-QOL. Internal consistency examines the complementary nature of items by searching for contradictions and measurement errors. Internal consistency of overall score and only three subscales calculated with Cronbach's alpha. A high positive value for Cronbach's alpha (0.7) suggests that the PAC-QOL is scoring consistently (10). To evaluate the reproducibility, a two week test-retest study was performed on 30 patients by comparing PAC-QOL scores obtained at the time of each patient's first visit with those at the second visit, when an evacuation proctography and/or colonic transit study were undertaken without any treatment recommended between two visits. Comparisons were made using intra-class correlation coefficients (ICC) and a high positive correlation coefficient (0.7) was taken as evidence of reproducibility (3).

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). Since the numbers of specialists were 20, Cut Point for CVR was considered to be 0.42.

To test the construct validity, we used the factor analysis from 140 patients with functional constipation. Kaiser-Meyer-Olkin (KMO) measure of adequate sampling and Bartlett's test of sphericity were considered before analysis.

Statistical analysis

Mean \pm SD used for data expression. Statistical analyses were performed using SPSS version 18.0 by Cronbach's alpha, intraclass correlation analysis, F test, and independent T test. P-value<0.05 was considered significant.

Ethics

This study was approved by the ethics committee of Iran University of Medical Sciences (study ID NO. 1941 /documented at 19/Aug/2014). Informed consent form was completed by all participants.

Results

The Sample

172 consecutive patients presented at our clinic with a chief complaint of constipation .32 patients were excluded from our study group because of various reasons (IBS-Constipation dominant, drug consumption, underlying disease such as diabetes mellitus), thus data from 140 patients were analyzed. All the patients had been suffered from constipation for more than 3 months. Table 1 shows the distributions of the demographic, anthropometric and socioeconomic characteristics of the patients with constipation. Accordingly, the mean (SD) of age was 40.7 (10.2) and regarding the education only 51.2% had academic education. Also 77.4 % of patients were married. The liquid consumption was not differed among females and males (P-value=0.503).

Table 2 presents the distribution of the domains of PAC-QOL in patients. Accordingly, 58.6% of patients had severe constipation.

Feasibility

The mean PAC-QOL completion time was 16.2 ± 2.280 minutes, ranging from 14 to 20 minutes. All items were filled. Table 3 shows the PAC-QOL domains value for patients. Our sample showed a group of patients with very severe levels of constipation. It might be due to referral center.

Reliability

Due to obtained value for Cronbach's α (0.975) and also for the subscale of physical discomfort (0.930), psychosocial discomfort (0.975) and worries and concerns (0.915), the internal consistency is established. It maintains excellent even if we delete an item, as shown in Table 4. Moreover, all items showed high test-retest correlation coefficients and intra-class correlation coefficients (0.974).

Validity

According to medical expert's opinions, the value of content validity ratio (CVR) ranged from 0.5 to 0.8 and the value of content validity index (CVI) was 0.81. Table 5 shows the sensitivity of PAC-QOL index over the different value of the socio-demographic variables. Accordingly, there was no significant difference of PAC-QOL index regarding gender, age, education and smoking status. We also evidenced significant lower PAC-QOL score and better health, for single and those with more liquid consumption.

Table 1. Demographic, anthropometric and socioeconomic characteristics of the patients

Variable	Value	N	%
Gender	Female	84	60.0
	Male	56	40.0
Age	Mean (SD)	40.7(\pm 10.2)	-
	Min-Max	18-68	
Education	Less than diploma	43	30.7
	Diploma	20	14.3
	University degree	77	55.0
Family Status	Single	33	23.6
	Married	107	76.4
Smoking Status	Yes	17	12.1
	No	123	87.9
Alcohol Status	Yes	9	6.4
	No	131	93.6
Drug Status	Yes	18	12.9
	No	122	87.1
Liquid Consumption Status	1-2 glass per day	43	30.7
	2-4 glass per day	80	57.2
	4-6 glass per day	15	10.7
	6-8 glass per day	2	1.4
Activity Status	Daily activity	120	85.7
	Professional	20	14.3

Table 2. Distribution of the domains of the PAC-QOL

Domains	Items Number	Severity	Frequency	Percent
Physical Discomfort	4	Mild	22	15.7
		Moderate	35	25.0
		Severe	83	59.3
Psychosocial Discomfort	8	Mild	30	21.4
		Moderate	26	18.6
		Severe	84	60.0
Worries and Concerns	11	Mild	31	22.1
		Moderate	27	19.3
		Severe	82	58.6
Total	23	Mild	30	21.4
		Moderate	28	20.0
		Severe	82	58.6

To test the construct validity, we also found Kaiser-Meyer-Olkin measure of sampling adequacy index value 0.930 and Bartlett's index value 4843.584 (P-value < 0.001). Then we performed a principal component factor analysis and evidenced the desirable triple dimensional structure, corresponding to 83.536% of explained variance. These results confirm the PAC-QOL domains.

Discussion

We showed strong internal consistency for the total Persian PAC-QOL score and across all three subscales in our study patients. In particular, Cronbach's alpha coefficients in the overall score and subscales were higher than 0.9, demonstrating a high level of internal consistency.

The overall score showed good reproducibility, during 2 week interval between the first and second visits same as the original PAC_QOL version evaluation (16).

Chronic constipation has significant effects on different components of individuals' QOL such as; negative economic impact, reducing quality of life, Healthcare system disturbances, Nocebo/side-effects of medicalization. We need validated tools to assess QOL in order to facilitate clinical management of constipated patients. PAC-QOL questionnaire is a self-reported questionnaire frequently used to measure QOL in constipated patients.

Table 3. Inter scale reliability indicators

Question	α if item deleted	Test-retest correlation coefficient
Q1	0.972	0.663
Q2	0.972	0.677
Q3	0.972	0.839
Q4	0.973	0.830
Q5	0.971	0.867
Q6	0.971	0.896
Q7	0.972	0.844
Q8	0.971	0.867
Q9	0.972	0.944
Q10	0.972	1.000
Q11	0.971	1.000
Q12	0.971	1.000
Q13	0.971	0.951
Q14	0.972	0.992
Q15	0.972	0.978
Q16	0.972	0.975
Q17	0.972	0.910
Q18	0.984	0.823
Q19	0.972	0.932
Q20	0.972	0.967
Q21	0.972	0.982
Q22	0.972	0.844
Q23	0.973	1.000

Up to now, PAC-QOL translated and formally validated in many languages in which it is now available (4). The original English PAC-QOL tool, were studied in France (n= 30), Netherlands (n = 33), Belgium (n= 20), and Canada (n= 55), with demonstrated internal consistency, reliability, and reproducibility (16). The number of patients were low in these studies in comparison with the original English study (n= 223).

In this study we had not satisfaction subscale because

our study was done only before treatment but the satisfaction subscales that reported in the original study was 0.66 and in the Japanese Version was 0.46.

In an evaluation study of the PAC-QOL psychometric features, Dubois et al. (5) validated a 1-point improvement in the PAC-QOL score as a relevant definition of significant response for treatment. Furthermore, in the Marquis et al. study (16) estimation of 0.5 – point change was recommended as the minimum important difference in overall score on the basis their effect size. According to these two reports, difference of <1 or 0.5 does not have clinically meaning.

Attention to concurrent validity, PAC-QOL is the best gold standard constipation-specific QOL questionnaire. The original English study, the PAC-QOL scores were compared with the “clinical severity” to assess cross-sectional validity (16).

Formal linguistic validation was performed in our study as a translation–back translation method or a linguistic consensus board in comparison with the recent Japanese PAC-QOL version validation.

However, in translating to Persian, language cultural and lifestyle differences between the two societies were considered.

First limitation of our study was three subscales analysis without treatment satisfaction item. However, all of the patients completed 23 questions in the Persian version of PAC-QOL questionnaire, as follows: 140 patients (100%) in the internal consistency evaluation;

Table 4. Relationship between PAC-QOL Index and socio-demographic variables

Variable	Value	PAC-QOL Index	t/F	sig
Gender	Female	2.974	1.532	0.128
	Male	2.722		
Age	Less than 30 years	2.522	2.171	0.118
	Between 30 & 59 years	2.902		
	60 or more years	3.583		
Education	Less than diploma	2.931	0.197	0.822
	Diploma	2.927		
	University degree	2.827		
Family Status	Single	2.446	3.016	0.003
	Married	3.005		
Smoking Status	Yes	2.850	0.110	0.913
	No	2.877		
Liquid Consumption Status	1-2 glass per day	3.055	4.260	0.007
	2-4 glass per day	2.899		
	4-6 glass per day	2.467		
	6-8 glass per day	1.000		

t: Student's t, F: F test, sig: significance (P-value)

30 (21%) in the test–retest.

And second limitation was a difference between our patients group with constipated general population, because Rasoul-e-Akram Hospital is a referral center.

The results of this study might be generalized to Iranian constipated patients according to other studies anywhere in the world.

The PAC-QOL, is the best gold standard constipation-specific QOL questionnaire available now. Moreover, the PAC-QOL has been used more and more frequent in many high-quality studies (6). The Persian version of PAC-QOL questionnaire had acceptable reliability and validity. It can be used for Iranian patients complaining of chronic constipation all over the world.

The availability of the PAC-QOL in a variety of languages would make it feasible and easy to compare international studies and to do multicenteral researches.

Conflict of interests

The authors declare that they have no conflict of interest.

References

1. Irvine EJ, Ferrazzi S, Pare P, Thompson WG, Rance L. Health-related quality of life in functional GI disorders: focus on constipation and resource utilization. *Am J Gastroenterol* 2002;97:1986-93.
2. Wald A, Scarpignato C, Kamm MA, Mueller-Lissner S, Helfrich I, Schuijt C, et al. The burden of constipation on quality of life: results of a multinational survey. *Aliment Pharmacol Ther* 2007;26:227-36.
3. Chassany O, Sagnier P, Marquis P, Fullerton S, Aaronson N. Patient-reported outcomes: the example of health-related quality of life—a European guidance document for the improved integration of health-related quality of life assessment in the drug regulatory process. *Drug Inf J* 2002;36:209-38.
4. Nomura H, Agatsuma T, Mimura T. Validity and reliability of the Japanese version of the Patient Assessment of Constipation Quality of Life questionnaire. *J Gastroenterol* 2014;49:667-73.
5. Dubois D, Gilet H, Viala-Danten M, Tack J. Psychometric performance and clinical meaningfulness of the Patient Assessment of Constipation-Quality of Life questionnaire in prucalopride (RESOLOR) trials for chronic constipation. *Neurogastroenterol Motil* 2010;22:e54-63.
6. Mueller-Lissner S, Kamm MA, Wald A, Hinkel U, Koehler U, Richter E, et al. Multicenter, 4-week, double-blind, randomized, placebo-controlled trial of sodium picosulfate in patients with chronic constipation. *Am J Gastroenterol* 2010;105:897-903.

7. Longstreth GF, Thompson WG, Chey WD, Houghton LA, Mearin F, Spiller RC. Functional bowel disorders. *Gastroenterology* 2006;130:1480-91.
8. Agachan F, Chen T, Pfeifer J, Reissman P, Wexner SD. A constipation scoring system to simplify evaluation and management of constipated patients. *Dis Colon Rectum* 1996;39:681-5.
9. Jun DW, Park HY, Lee OY, Lee HL, Yoon BC, Choi HS, et al. A population-based study on bowel habits in a Korean community: prevalence of functional constipation and self-reported constipation. *Dig Dis Sci* 2006;51:1471-7.
10. Pourhoseingholi A, Safaee A, Pourhoseingholi MA, Moghimi-Dehkordi B, Habibi M, Vahedi M, et al. Prevalence and demographic risk factors of gastrointestinal symptoms in Tehran province. *JPH* 2010;8:42-6.
11. Honarkar Z, Baladast M, Khorram Z, AkhondiSh AM, Masoodi M. An analysis of gastrointestinal symptoms in causalities of catastrophic earthquake of Bam, Iran. *SEMJ* 2005;6:2.
12. Sorouri M, Pourhoseingholi MA, Vahedi M, Safaee A, Moghimi-Dehkordi B, Pourhoseingholi A, et al. Functional bowel disorders in Iranian population using Rome III criteria. *Saudi J Gastroenterol* 2010;16:154-60.
13. Massarrat S, Saberi-Firoozi M, Soleimani A, Himmelmann GW, Hitzges M, Keshavarz H. Peptic ulcer disease, irritable bowel syndrome and constipation in two populations in Iran. *Eur J Gastroenterol Hepatol* 1995;7:427-33.
14. Moghimi-Dehkordi B, Vahedi M, Pourhoseingholi MA, Khoshkrood Mansoori B, Safaee A, Habibi M, et al. Economic burden attributable to functional bowel disorders in Iran: a cross-sectional population-based study. *J Dig Dis* 2011;12:384-92.
15. Mohaghegh Shalmani H, Soori H, Khoshkrood Mansoori B, Vahedi M, Moghimi-Dehkordi B, Pourhoseingholi MA, et al. Direct and indirect medical costs of functional constipation: a population-based study. *Int J Colorectal Dis* 2011;26:515-22.
16. Marquis P, De La Loge C, Dubois D, McDermott A, Chassany O. Development and validation of the Patient Assessment of Constipation Quality of Life questionnaire. *Scand J Gastroenterol* 2005;40:540-51.
17. Acquadro C, Jambon B, Ellis D, Marquis P. Language and translation issues. In: Spilker B, editor. *Quality of Life and Pharmacoeconomics in Clinical Trials*. Philadelphia: Lippincott-Raven Publishers 1996:575–85.
18. Acquadro C, Conway K, Giroulet C, Mear I. *Linguistic Validation Manual for Health Outcome Assessments*. Lyon: Mapi Institute 2012.
19. De Vet HCW, Terwee CB, Mokkink LB, Knol DL. *Measurement in Medicine*. Cambridge: Cambridge University Press 2011.
20. Gorsuch RL. Exploratory factor analysis: its role in item analysis. *J Pers Assess* 1997;68:532-60.
21. Chronbach LJ. Coefficient alpha and the internal structure of tests. *Psych* 1951;16:297-334.