Patient assessment of constipation quality of life questionnaire: validity and reliability for Indonesian population

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ABSTRACT

BACKGROUND Constipation is a condition commonly encountered by physicians, causing a significant reduction in patients' quality of life. Therefore, successful management of constipation should also include increase the quality of life. The Patient Assessment of Constipation Quality of Life (PAC-QOL) questionnaire is a questionnaire developed to address this issue. However, this questionnaire had not been translated into the Indonesian language. This study was aimed to adapt PAC-QOL into Indonesian culture and perform the psychometric evaluation.

METHODS Translation and cultural adaptation were performed based on the linguistic validation guidelines by Acquadro et al in 2012. To perform the psychometric evaluation, a total of 64 subjects in Petamburan district in Jakarta, Indonesia, were recruited from February to March 2018. Test-retest reliability was assessed by completing the PAC-QOL twice with one-week interval. Subjects also completed the Short Form 36 (SF-36) Health Survey Questionnaire to assess concurrent validity. Internal consistency was analyzed with Cronbach's alpha value (>0.7) and the intraclass correlation coefficient.

RESULTS The mean (standard deviation) overall average score was 1.52 (0.66), while the Cronbach's alpha value for the overall average score was 0.910. Concurrently, the intraclass correlation coefficient for the overall score was 0.87. Simultaneously, several experts judged content validity to be adequate. All the questions had significant correlations with their respective domains. Moreover, each domain of PAC-QOL also had a significant correlation with several SF-36 domains.

CONCLUSIONS The psychometric evaluation performed in this study demonstrated that the Indonesian version of the PAC-QOL was valid and reliable, suggesting that this questionnaire can be used in daily clinical practice.

KEYWORDS constipation, Indonesia, reliability, quality of life, validation studies

Constipation is a major health problem that is often encountered by physicians and experienced by all age groups, even though it is more often experienced by women and elders. The prevalence reported around the world ranged from approximately 1 to >20%, depending on the diagnostic criteria used and the demographic factors.[1] A study conducted among female workers in Jakarta, Indonesia, observed that the prevalence of functional bowel disorders was 52.9% based on self-administered questionnaires.[2] Based on the Rome IV criteria, several signs and symptoms of constipation are as follows: the frequency of defecation <3 times a week, straining, dissatisfied feeling after defecation, hard stools, anorectal obstruction sensation, and requiring manual maneuvers to help in defecation. To establish a diagnosis of constipation, the patient must have >2 symptoms, lasting for >3 months.[3]

The occurrence of constipation causes significant physical and mental impacts, thereby affecting the quality of life of patients. Therefore, the quality of life of the patient is an important factor to be considered in the treatment of constipation. The management of the patient should not only be by treating the symptoms of constipation but also by improving the quality of life of patients.[1]

The Patient Assessment of Constipation Quality of Life (PAC-QOL) questionnaire, originally developed by Marquis et al[4] in 2005, is one of the most commonly used tools for evaluating the quality of life in patients with constipation. The questionnaire had been validated to be used in various countries, including the United States, Europe, Canada, Australia, Turkey, Japan, and Persia.[4–9] However, PAC-QOL has not been validated to be used in Indonesia. Therefore, this study was aimed to perform cultural adaptation, validation, and assess the reliability of the PAC-QOL questionnaire from the original English version into the Indonesian version to facilitate the clinical assessment of patients with constipation.

METHODS

Study population

In this study, the subjects from a community health center and the local community in Petamburan administrative village in Jakarta, Indonesia, were recruited from February to March 2018. Additional subjects were recruited from local colleges around Jakarta. The sampling method was convenient, non-probability sampling. The minimum number of subjects was 30. On the one group, adult patients (≥18 years old) who had chronic constipation which fulfilled the Rome IV criteria were included.[3] On the other group, the patients with constipation due to suspected organic cause and drug-induced constipation, unable to complete the questionnaire, and who had just experienced traumatic life events which could affect their quality of life at least 3 months before this study were excluded. Subsequently, informed consent was obtained from all subjects. This study has been approved by the Ethics Committee of the Faculty of Medicine, Universitas Indonesia (No: 0092/UN2.F1/ETIK/2018).

Instruments

Each subject in this study completed both the PAC-QOL and Short Form 36 (SF-36) Health Survey Questionnaire for the validation study. In 2005, Marquis et al[4] developed the PAC-QOL (Copyright©PAC-QOL, 2005 Mapi Research Trust) questionnaire to assess the quality of life of patients with constipation. Permission to adapt PAC-QOL into Indonesian language has been obtained from Mapi Research Trust, Lyon, France. The questionnaire consisted of 28 questions which were then categorized into four domains: physical discomfort, psychosocial discomfort, worries and concerns, and satisfaction. Each response to the question used a Likert scale as the scoring system, with a possible score ranging from 0 to 4. The higher score indicated a worse quality of life.

The SF-36 is a patient-reported general quality of life measurement tool. The SF-36 questionnaire contained 36 items which were categorized into eight domains: physical functioning, role-physical, role-emotional, vitality, mental health, social functioning, bodily pain, and general health. In this study, the validation study used the Indonesian version of SF-36 adapted by Salim et al. The Indonesian version of SF-36 was judged to have acceptable content validity, face validity, criterion validity, and construct validity from the study. The Indonesian version of SF-36 had a weak but statistically significant negative correlation with N-terminal pro b-type natriuretic peptide levels. All domains of SF-36 also showed good reliability (Cronbach alpha >0.7), except for the Social Functioning and the Vitality domains. Therefore, this version of SF-36 had acceptable validity and reliability to be used in this study.[10]

Translation and cultural adaptation

The methodology to conduct the linguistic validation in this study was based on the guidelines by Acquadro et al.[11] First, the original English questionnaire underwent forward translation by two different translators: one of them was a doctor, and another was a professional translator without a medical background. Both Indonesian translations were then combined into a single questionnaire. Second, the backward translation was performed by an English native speaker without a medical background. The backward translation was then compared with the original questionnaire, and a meeting was held between experts and translators to yield a pre-final questionnaire. Third, the pre-final questionnaire was then tested on ten patients with chronic constipation to obtain feedback. Then,

another meeting was held to yield the final version of the questionnaire.

Psychometric evaluation

There were three gastroenterologist experts who assessed the final version of the questionnaire to verify the content validity. To evaluate the concurrent validity, a minimum of 30 subjects were asked to complete the SF-36 questionnaire, and correlation studies were then performed with the PAC-QOL scores. Additionally, the item-total correlation was also performed to evaluate the validity of each question respective to their domains. The internal consistency was evaluated by calculating the Cronbach's alpha value, with the cut-off point >0.7 regarded as good internal consistency. To evaluate the test-retest reliability, a minimum of 30 subjects was asked to complete the PAC-QOL again with a 1-week interval, and, of note, they did not receive any interventions that could modify their symptoms. The intraclass correlation coefficient (ICC) was calculated, with value of <0.5 considered to be poor, 0.5–0.75 considered to be moderate reliability, 0.75–0.9 considered to be good reliability, and >0.9 considered to have excellent reliability.[12] SPSS software version 20 (IBM Corp, USA) for Windows was used in all statistical analysis performed.

RESULTS

Sociodemographic characteristics

Based on the Rome IV criteria,[3] a total of 64 subjects with chronic constipation were recruited. Table 1 shows the characteristics of subjects. The majority of the subjects were female and housewives, with the mean (SD) age of 37.9 (14.7) years. The level of education ranged from elementary school to college level.

Table 1. Characteristics of subjects

Characteristics	n (%) (N = 64)
Female sex	58 (90.4)
Age (years), mean (SD)	37.9 (14.7)
Education level	
Elementary school	15 (23.4)
Middle school	13 (20.3)
High school	18 (28.1)
College and University	18 (28.1)
Occupation	
Housewife	31 (48.4)
Student	12 (18.8)
Private sector	20 (31.2)
Unemployed	1 (1.6)

SD=standard deviation

Translation and adaptation process

After the forward and backward translation processes, the pre-final version questionnaire was tested on ten people with chronic constipation. Overall, the subjects could understand most of the questions. However, several questions were modified to better fit the situations. Originally, question number 10 and 11 asked about whether the subjects were embarrassed because they went to the bathroom frequently for a long duration of time when they were outside their home. However, many of the subjects rarely used toilets outside their homes, and, therefore, the questions were modified to include when they were using toilets inside their homes. In some questions, examples were added to further clarify the questions. For example, in question 12, the examples were modified to "having to go to the bathroom before going outside of home." In question 27, the question was further elaborated by adding "the length of time needed between having meals until bowel movement." Finally, since many

Table 2. Internal consistency of overall and domain scores (N = 64)

Scale	Scores, median (range)	Cronbach's alpha
Physical discomfort (question 1–4)	1.50 (0.25–4.00)	0.722
Psychosocial discomfort (question 5–12)	0.87 (0–2.50)	0.688
Worries/concerns (question 13–23)	1.32 (0–3.82)	0.907
Satisfaction (question 24–28)	2.40 (0.40–4.00)	0.728
Overall	1.43 (0.43–3.46)	0.910

SD=standard deviation

Table 3. Test-retest reliability of the domains and the overall score

Scale	ICC (N = 31)
Physical discomfort (question 1–4)	0.711
Psychosocial discomfort (question 5–12)	0.611
Worries/concerns (question 13–23)	0.870
Satisfaction (question 24–28)	0.526
Overall	0.865

ICC=intraclass correlation coefficient

Table 4. Correlations between each domain and the overall score

Domain	*r*	*p*
Physical discomfort	0.501*	<0.001
Psychosocial discomfort	0.773*	<0.001
Worries/concerns	0.939†	<0.001
Satisfaction	0.674†	0.001

*Spearman's rho; †Pearson's correlation coefficient

of the subjects had not received any medication for their constipation, in question 28, any other attempts that the subjects had tried to relieve constipation (increasing intake of fruits, herbal medicine, juice, and others) were included.

Reliability analysis

Internal consistency

Table 2 shows the scores and Cronbach's alpha of each domain and the overall score. The internal consistency of the overall score and each domain exceeded the cut-off value for Cronbach's alpha (>0.7), except for the psychosocial discomfort domain.

Test-retest reliability

All subjects completed the PAC-QOL questionnaire again 1 week after the first completion. However, only 31 subjects were able to complete the retesting. Table 3 shows the ICCs (two-way mixed, absolute agreement, single rater). The overall score, physical discomfort, and worries/concerns domains had good reliability. Meanwhile, the psychosocial discomfort and satisfaction domains had moderate reliability.

Validity

Content validity

The expert panel (consisting of three gastroenterologists) agreed that the questions in the translated version were clear and relevant in assessing the quality of life of patients with chronic constipation.

Table 5. Correlations between each item and PAC-QOL domains

Domains	Questions	*r**	*p*
Physical discomfort	Q1	0.769	<0.001
	Q2	0.780	<0.001
	Q3	0.596	<0.001
	Q4	0.657	<0.001
Psychosocial discomfort	Q5	0.681	<0.001
	Q6	0.498	<0.001
	Q7	0.518	<0.001
	Q8	0.421	0.001
	Q9	0.681	<0.001
	Q10	0.695	<0.001
	Q11	0.513	<0.001
	Q12	0.467	<0.001
Worries/concerns	Q13	0.687	<0.001
	Q14	0.741	<0.001
	Q15	0.802	<0.001
	Q16	0.733	<0.001
	Q17	0.659	<0.001
	Q18	0.502	<0.001
	Q19	0.808	<0.001
	Q20	0.778	<0.001
	Q21	0.749	<0.001
	Q22	0.701	<0.001
	Q23	0.589	<0.001
Satisfaction	Q24	0.621	<0.001
	Q25	0.736	<0.001
	Q26	0.870	<0.001
	Q27	0.642	<0.001
	Q28	0.575	<0.001

PAC-QOL=the patient assessment of constipation quality of life
*Spearman's rho

Correlation studies

Table 4 shows the correlations between each domain and the overall score. The critical value for Pearson's correlation coefficient with degrees of freedom of 62 is 0.2075. All of the domains exceeded the critical value. The physical discomfort and satisfaction domain had a moderate correlation with the overall score, while the psychosocial discomfort and worries domain had a strong correlation with the overall score. Table 5 shows the correlation between each item and PAC-QOL domains.

Table 6. Correlation (r) between the PAC-QOL domains and the SF-36 domains

	Physical discomfort	Psychosocial discomfort	Worries/concerns	Satisfaction
Physical functioning	−0.198	−0.076	−0.157	0.103
Role-physical	−0.333*	0.042	0.007	0.033
Role-emotional	−0.203	0.061	−0.024	−0.187
Vitality	−0.340*	−0.117	−0.359*	−0.369*
Mental health	−0.096	−0.228	−0.267	−0.290
Social functioning	−0.089	−0.527†	−0.323	−0.127
Bodily pain	−0.521*	−0.125	−0.293	−0.217
General health	−0.611†	−0.262	−0.468*	−0.377*

PAC-QOL=the patient assessment of constipation quality of life; SF-36=short form 36
Spearman's rho: *significant at the 0.05 level; † significant at the 0.01 level

All questions in physical discomfort, worries/concerns, and satisfaction domains had moderate to strong correlation with the overall domain score. Almost every question in psychosocial discomfort domain had a moderate correlation with the domain score, except question number 6, 8, and 12 which had a weak correlation.

To determine the concurrent validity, the correlations between each domain of PAC-QOL and SF-36 were calculated. A total of 36 subjects completed both questionnaires. Table 6 shows the correlation matrix. The physical discomfort domain of PAC-QOL had a weak correlation with physical role limitation and vitality domains, and also a moderate correlation with pain and general health domains of SF-36. Further, the psychosocial domain had a moderate correlation with social function domain of SF-36. Furthermore, the worries/concerns domain had a weak correlation with both vitality and general health domain of SF-36. The satisfaction domain also had a weak correlation with both vitality and general health domain of SF-36. Finally, the correlation between the overall score of PAC-QOL and SF-36 was weak and statistically not significant ($r = -0.275$).

DISCUSSION

This was the first study to translate PAC-QOL into Indonesian language and perform psychometric validation. The majority of the subjects in this study were females (90%), which was similar to the population in the original study (94% female) and other countries. During the pretesting, some of the questions needed to be modified, to better fit the situations, and examples were added, especially from the psychosocial and satisfaction domains. This might reflect the difference in culture since the original study was validated in some Western countries including the United States, Europe, Canada, and Australia.[4] Moreover, studies from Turkey, Japan, and Persia also had modified several questions especially in the psychosocial domain that was more suitable to the local culture.[5–9]

The mean overall score in this study (1.52) was also similar to the original study (1.85), which was about in the middle range of the scores.[4] The higher mean score (2.20) in the Persian study was more likely because the subjects were recruited from a referral hospital.[8] In contrast, the subjects in this study were recruited from the community health center and the local community, which possibly had less severe cases of constipation. Also, the highest score in this population was from the satisfaction domain, which was also similar to the original study and other countries. This showed that constipation significantly affected patients' satisfaction.[4–9]

The internal consistency of the translated questionnaire was pretty high (0.910), and the internal consistency of each domain also exceeded the cut-off value, except for the psychosocial domain which was slightly under 0.7. However, on further analysis, none of the questions increased the Cronbach's alpha value if deleted. Therefore, none of the questions in this domain were deleted. The test-retest reliability of the overall score was also good (0.865), which was similar to the original study (0.82) and higher than the validation study performed in Turkey (0.687).[4,5] However, the satisfaction domain only had moderate reliability (0.526). This pattern was also seen across the original and studies from Turkey, Japan, and

Persia.[5–9] One of the possible reasons was that after the time interval between completion of the first and second questionnaires, the persistence of the symptom without any intervention could lead to more dissatisfaction from the subjects.

All of the domains had a moderate to strong correlation with the overall score, with the highest from the "worries" domain and the lowest from the "physical discomfort" domain (range 0.5–0.9). The validation study from Turkey also found the highest correlation with the worries and concerns domain (0.909).[5] All of the questions also had significant correlations with their respective domains. To demonstrate the concurrent validity, a correlation matrix between the PAC-QOL and SF-36 domains was performed. The results were quite similar to the study by Nikjooy et al[6] in Persia and Tsunoda et al[8] in Japan. For example, the physical discomfort domain of PAC-QOL had a significant correlation with physical role limitation, vitality, pain, and general health, which showed that constipation also affected that area of the quality of life. The psychosocial discomfort caused by constipation also correlated well with the social functioning aspect of the quality of life. Also, no correlation was observed between the psychosocial discomfort domain and the "role-emotional" and "mental health" domains of SF-36. One possible explanation is that the SF-36 was a questionnaire developed to assess the quality of life in general. Thus, using the SF-36 to evaluate constipation was not specific and might not be appropriate.

Still, there were several limitations to this study. First, the number of subjects were not adequate to perform a confirmatory factor analysis in assessing the structural validity of the questionnaire. Nevertheless, future studies could be performed with a larger number of subjects (ratio of 5–10 subjects per item) to perform this analysis. Besides, the responsiveness to treatment using this questionnaire were not assessed because the authors wanted the subjects to be free of any intervention to assess the test-retest reliability. In the subsequent study, standard treatment could be given to the subjects and was followed up to calculate the mean score change and detect the minimally important difference.

In conclusion, the psychometric evaluation performed in this study demonstrated that the Indonesian version of PAC-QOL was a valid and reliable tool, suggesting that this questionnaire can be used in clinical settings.

Conflict of Interest

The authors affirm no conflict of interest in this study.

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