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# Validity and Reliability of the Patient Assessment of Constipation: Symptoms (PAC-SYM ©) in the Indonesian Language

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**Abstract.** Introduction: Constipation is a very subjective symptom experienced by patients. Although ROME-IV could be used for diagnosis of functional constipation, it could not assess treatment response. The *Patient Assessment of Constipation – Symptoms* (PAC-SYM©) questionnaire was developed for this purpose. However, the PAC-SYM© had not been translated and adapted into Indonesian language.

Methods: The original PAC-SYM© questionnaire was translated and adapted based on the available guidelines. The final version of the translation was then used to perform validity and reliability analysis. A total of 64 patients with chronic constipation from the local community in Jakarta, Indonesia was used for the psychometric evaluation. Principal component analysis and structural equation modeling were also attempted.

Results: Most of the study subjects were female. The Cronbach's alpha for the overall average score was 0.869 which showed good internal consistency. The intraclass correlation coefficient for the overall score was 0.743 which showed good test-retest reliability. Content validity was considered to be sufficient by experts. Each domain correlated strongly with the total score. PAC-SYM© had moderate correlation with PAC-QOL which showed concurrent validity. The multi-trait analysis showed scaling success. Question 7 showed a very high floor effect (84.4%), and therefore omitted from the factor analysis. The principal component analysis revealed a new 'two-factors' structure, with question from the original 'rectal' domain combined into the 'stool' domain. The structural equation modeling indicated good model fit.

Conclusion: The Indonesian version of PAC-SYM© was valid and reliable to be used in clinical settings.

Keywords: constipation severity, symptoms, Indonesia, validity, reliability

## 1. Introduction

Constipation is a common condition encountered in daily practice. The reported prevalence across the literature are inconsistent because of the difference in the diagnostic criteria used. The pooled result from a meta-analysis estimated the global prevalence of constipation to be 14% when the constipation was diagnosed based on the frequency of bowel movements per week alone. However, when the more



stringent Rome III criteria were applied, the pooled prevalence decreased to 6,8%.<sup>1</sup> Most of the patients had primary constipation, especially normal-transit constipation (also known as functional constipation).<sup>2</sup> Although physicians may not consider functional constipation as a serious condition, it significantly decreases the patient's quality of life.<sup>3</sup>

Constipation is a symptom-based disorder. According to the Rome IV criteria of functional constipation, it is diagnosed when 3 criteria are met: 1) must include at least 2 of the following: fewer than 3 spontaneous bowel movements per week or straining, lumpy or hard stools, sensation of incomplete evacuation, sensation of anorectal obstruction, requiring manual maneuvers to facilitate defecations, all of which must occur at least 25% of defecations; 2) loose stools are rarely present without the use of laxatives; and 3) insufficient criteria for irritable bowel syndrome.<sup>4</sup> However, in daily practice, the definition of constipation differs for each patient.

Although the Rome IV criteria are useful for diagnosis, it is not intended to be used for evaluation of treatment response. The Patient Assessment of Constipation (PAC) questionnaire was developed to address this problem. The PAC consists of two separate scales, the PAC-symptoms (PAC-SYM©) and PAC-Quality of Life (PAC-QOL©). PAC-SYM© consists of 12-item measuring the severity of constipation symptoms in patients. The original psychometric evaluation of PAC-SYM© had been performed on 216 patients at 9 sites from US.<sup>5</sup> Since then, PAC-SYM© had been used in several clinical trials.<sup>6</sup> Yiannakou et al have calculated the minimally important difference at approximately -0,6, which is the threshold used to indicate a positive treatment response.<sup>7</sup> However, PAC-SYM© questionnaire has not been translated and validated in other countries, including Indonesia. The items of the questionnaire must not only be translated linguistically but should also consider the cultural aspect of the target population. Therefore, the aim of this study is to translate PAC-SYM© in Indonesian language and to perform the psychometric evaluation.

## 2. Methods

### 2.1. Description of PAC-SYM©

The original *Patient Assessment of Constipation – Symptoms* questionnaire (PAC-SYM) (Copyright©PAC-SYM, 1999 Mapi Research Trust, all rights reserved) is developed by Frank in 1999, which contained 12 items. Each item asked distinct symptoms that might be experienced by the patients. The patients were then asked to rate the severity of each symptom in a 5-point Likert scale (0-4; absent to very severe) during the past 2 weeks. The items were further categorized into 4 domains: abdominal symptoms (question 1-4), rectal symptoms (question 5-7), and stool symptoms (question 8-12). The mean score was then calculated to indicate the burden of the symptoms.

### 2.2. Questionnaire Adaptation

The adaptation process was based on guideline by MAPI Research Trust.<sup>8</sup> The forward Indonesian translation was performed by two independent translators. One of the translators was a doctor, and another was by an Indonesian professional translator without medical knowledge. Both translations were then synthesized into one Indonesian language questionnaire. The backward translation from Indonesian to the English language was performed by a professional translator with English as their mother tongue without expert medical knowledge. All of the translations were then reviewed by a panel consisting of gastroenterologists, methodologist, and language expert. The result was a pre-final questionnaire. The pre-final questionnaire was pretested on 10 patients with chronic constipation to assess their understanding of each question. The questionnaires were then reviewed and modified to clear any misunderstandings of the questions. The result was a final questionnaire, and psychometric evaluation was performed on the final version.

### 2.3. Study Population

The sampling method was convenient non-probability sampling. The minimum number of subjects for psychometric evaluation was 30 patients. The psychometric evaluation was primarily performed on patients from Petamburan Community Health Center in West Jakarta. Additional samples were also

obtained from college students in Jakarta to include younger patients. The questionnaires were administered through a direct interview or self-reported by the patients. The inclusion criteria were adult patient ( $\geq 18$  years old) who fulfilled the ROME IV criteria for chronic constipation. The exclusion criteria were those who were suspected to have an organic cause of constipation, drug-induced constipation, and who refused to complete the questionnaires. In addition, each patient also completed the PAC-QOL questionnaire for comparison to evaluate the concurrent validity. Informed consent was obtained from every subject.

#### *2.4. Validity Analysis*

The content validity was assessed by a panel of gastroenterologists who frequently encountered patients with constipation in daily practice. Each person was asked to judge every item regarding their clarity and relevance to the patients. Ceiling and floor effect for each question was also evaluated. Value  $> 50\%$  indicates significant ceiling and floor effect. The multi-trait analysis was performed to assess the convergent and divergent validity item-subscale correlation matrix. For item-subscale correlations, correlation  $\geq 0.4$  between each question and its respective domain showed convergent validity. In contrast, correlation  $\leq 0.4$  between domain and each question which do not belong to that domain indicate sufficient divergent validity.<sup>9</sup> Scaling success is defined the percentage of item-subscale correlation which exceeded the item-nonsubscale correlation.<sup>5</sup> Concurrent validity was assessed by comparing PAC-SYM© with PAC-QOL© for each domain and the overall score using Spearman's correlation coefficient. Exploratory factor analysis was also performed if sufficient criteria were met using principal component analysis. If a model was found, structural equation modeling was performed using SPSS AMOS 25 for Windows to test for model fit.

#### *2.5. Reliability Analysis*

The reliability of Indonesian PAC-SYM© was evaluated by the assessment of internal consistency and the reproducibility. The internal consistency was calculated using Cronbach's alpha, where the value of  $> 0.7$  was desired. The test-retest reliability was assessed by administering the questionnaires to the same subjects 1 week later and the intraclass correlation coefficient (ICC) was calculated. The interpretation of ICC in this study was: value  $< 0.5$  was poor,  $0.5-0.75$  was moderate,  $0.75-0.9$  was good, and  $> 0.90$  was excellent.<sup>10</sup> All analysis was performed on SPSS 20.0 for Windows statistical software.

### **3. Results**

#### *3.1. Questionnaire Translation and Adaptation*

After the forward and backward translation process, the pre-final version of the questionnaire was administered to 10 people with chronic constipation from the community health center. All questions were understood by the subjects, and the completion time was about 6 minutes. The final version for psychometric evaluation only had minor changes to correct the wording.

#### *3.2. Demographic Characteristics*

A total of 64 subjects were included in this study. The sociodemographic characteristics were shown in Table 1. Most of the subjects were female and were housewives. The median age was 39 (18-78) years old.

**Table 1.** Demographic Characteristics of Subjects

Characteristics	Number (n = 64)	Percentage (%)
Gender		
Female	58	90.4
Male	6	9.6
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	19	31.2
Unemployed	1	1.6

**a. Reliability****Internal Consistency**

Table 2. showed the internal consistency of the overall average score and each domain of PAC-SYM©.

**Table 2.** Internal consistency of PAC-SYM©

Scale	Cronbach's alpha (n=64)
Abdominal symptoms (Question 1-4)	0.754
Rectal symptoms (Question 5-7)	0.642
Stool symptoms (Question 8-12)	0.776
Overall	0.869

The overall average score and all domains except 'rectal symptoms' exceeded 0.7 which is commonly used as the acceptable cut off value.

**Test-Retest Reliability**

After one week, the same group of subjects completed PAC-SYM© for the second time to test the stability over time. Only 30 subjects were able to complete the questionnaire for the second time. Table 3. showed the intraclass correlation coefficient (2-way mixed, absolute agreement, single rater) of each domain and overall average scores.

**Table 3.** Test-retest Reliability of PAC-SYM©

Scale	ICC (n=30)
Abdominal symptoms (Question 1-4)	0.750
Rectal symptoms (Question 5-7)	0.465
Stool symptoms (Question 8-12)	0.659
Overall	0.743

The abdominal symptom domain and the overall score had good reliability, the rectal symptom domain had poor reliability, while the stool symptom domain had moderate reliability. The overall score had moderate test-retest reliability.

**b. Validity****Content Validity**

Three gastroenterologists evaluated the final version for the clarity and relevance of each question. All of them agreed that each question was clear and represented the symptom spectrum of chronic constipation.

### Ceiling and Floor Effect

Table 4. showed the ceiling and floor effects of each question, as well as their mean scores.

**Table 4. Ceiling and Floor Effects of Each Question**

Items	Ceiling (%)	Floor (%)	Mean (SD)
Q1	7.8	15.6	1.59 (1.08)
Q2	3.1	50.0	0.98 (0.50)
Q3	6.3	26.6	1.38 (1.15)
Q4	6.3	65.6	0.67 (1.15)
Q5	4.7	34.4	1.27 (1.16)
Q6	4.7	37.5	1.23 (1.18)
Q7	0.0	84.4	0.27 (0.72)
Q8	4.7	14.1	1.48 (0.98)
Q9	9.4	17.2	1.73 (1.17)
Q10	3.1	20.3	1.47 (1.04)
Q11	10.9	14.1	1.88 (1.21)
Q12	7.8	14.1	1.70 (1.15)

No ceiling effect was observed in all questions. However, floor effect was detected in question 4 and especially in question 7. The mean score was also the lowest in question 7.

### Correlation Studies

Table 5. showed the correlation between the four domains of PAC-SYM© and the average overall score.

**Table 5.** Correlation between PAC-SYM© domain scores and average overall scores

Domain	Median scores	Spearman's rho	p-value
<b>Abdominal symptoms</b>	1.00 (0-4.00)	0.818	<0.001
<b>Rectal symptoms</b>	0.67 (0-3.33)	0.785	<0.001
<b>Stool symptoms</b>	1.60 (0.20-4.00)	0.904	<0.001
<b>Average overall scores</b>	1.17 (0.08-3.67)		

All of the domains had a strong correlation with the average overall score. Table 6 showed the multi-trait analysis which included the inter-item and item-subscale matrices.

**Table 6.** Results of Multi-Trait Analysis

Domain	Question	TOTAL		
		ABD	REC	STO
ABD	1	<b>0.78*</b>	0.51*	0.49*
	2	<b>0.70*</b>	0.44*	0.41*
	3	<b>0.75*</b>	0.31*	0.41*
	4	<b>0.58*</b>	0.33*	0.41*
REC	5	0.45*	<b>0.85*</b>	0.57*
	6	0.58*	<b>0.88*</b>	0.60*
	7	-0.02	0.34*	0.14
STO	8	0.30*	0.34*	<b>0.60*</b>
	9	0.51*	0.49*	<b>0.80*</b>
	10	0.26*	0.53*	<b>0.63*</b>
	11	0.49*	0.49*	<b>0.78*</b>
	12	0.50*	0.36*	<b>0.67*</b>

\* indicates significant correlation ( $p < 0.05$ )

The inter-item correlations showed that all questions had sufficient convergent validity, except question 7 ('rectal bleeding or tearing during bowel movement'). From the item-subscale correlation, each question had significant moderate to strong correlation with their respective domains (except question 7). Question 7 also had a significant correlation with the 'rectal symptom' domain, but it was weak. However, all questions except question 8 seemed to lack divergent validity because they also had correlation  $\geq 0.40$  with a domain which it did not originally belong to. Despite that, scaling success was achieved because 100% of all questions had better correlation with their respective domains than nondomain.

Table 7. showed the correlation matrix between the domains of PAC-SYM© and the domains of PAC-QOL©.

**Table 7.** Correlation matrix between PAC-SYM© and PAC-QOL© domains

	Physical Discomfort	Psychosocial Discomfort	Worries/ concerns	Satisfaction
Abdominal symptoms	0.559**	0.446**	0.451**	0.322**
Rectal symptoms	0.260*	0.218	0.326**	0.281*
Stool symptoms	0.382**	0.225	0.371**	0.535**

\* Significant at 0.05 level

\*\* Significant at 0.01 level

The physical discomfort domain of PAC-QOL© had a moderate correlation with 'abdominal symptom' and only weak correlation with 'rectal' and 'stool symptoms'. The psychosocial discomfort domain only had a weak correlation with 'abdominal symptom'. The worries and concerns domain had a weak correlation with 'abdominal', 'rectal', and 'stool symptoms'. Meanwhile, the satisfaction domain had a moderate correlation with 'stool symptom', and only weak correlation with 'abdominal' and 'rectal symptoms'. Finally, the overall average score of PAC-SYM© had a moderate correlation with the overall PAC-QOL© scores ( $r = 0.586$ ).

### Structural Validity

Exploratory factor analysis was performed using Principal Component Analysis (PCA) to evaluate the structural validity. The Kaiser-Meyer-Olkin measure was 0.849, which showed sampling adequacy. The Bartlett's test of sphericity was significant ( $<0.001$ ) which allowed PCA to be performed. Question 7 was omitted from this analysis because the KMO value for that question in the anti-image correlation matrix was  $<0.5$ . Based on the Kaiser's criterion (eigenvalues  $>1$ ) and the scree plot, two factors were extracted which explained 55.6% of the total variance. The original study by Frank utilized orthogonal rotation to maximize simple structure.<sup>5</sup> Therefore, this study used a varimax rotation method. Table 8. showed the factor loadings after the rotation. The question with factor loading  $<0.3$  was suppressed.

**Table 8. Factor Loadings of Each Question after Rotation**

Factor	Question	Factor Load	Variance explained (%)
Factor 1 (New Abdominal)	1	0.818	29.92
	2	0.733	
	3	0.788	
	12	0.602	
Factor 2 (New Stool)	4	0.432	25.75
	5	0.687	
	6	0.653	
	8	0.574	
	9	0.715	
	10	0.747	
	11	0.742	

We thought that factor 1 represented the 'New Abdominal' domain, and factor 2 represented the 'New Stool' domain. To test for model fit, confirmatory factor analysis in the form of structural equation modeling was performed to test the model fit. In this bifactor model, we allowed both factors to be correlated. The estimated covariance between the 'New Abdominal' and 'New Stool' domain was 0.78. The estimation method was maximum likelihood. The CMIN/df of the model was 1.170 and the p-value was  $>0.05$  (0.206) which was good. The other absolute fit indices were<sup>11</sup>: GFI 0.877 (borderline), RMSEA 0.052 (good), SRMR 0.061 (good). The value for incremental fit indices were<sup>11</sup>: TLI 0.961 (good) and CFI 0.969 (good). Overall, this bifactor model seemed to fit the data adequately.

### 4. Discussion

This was the first study to adapt PAC-SYM© into Indonesian language and also to perform validity and reliability tests. Most of the subjects in this study were female (90.4%) which was similar to the subject demographic of the original study by Frank (93.5%) and the subjects used for confirmatory factor analysis by Neri et al (female 82.1%).<sup>5,12</sup> This phenomenon was corroborated by a meta-analysis by Soares which observed that the prevalence of chronic idiopathic constipation was indeed higher in female (OR 2.22).<sup>1</sup> The education levels of subjects in this study were variable and well distributed, from elementary school level to those who had attended college and university.

The internal consistency of the overall average score, the 'abdominal', and 'stool' domains was good (Cronbach's alpha  $>0.7$ ). The internal consistency of the 'rectal' domain was slightly under 0.7 (0.634). However, if question 7 was deleted the Cronbach's alpha value increased to 0.763. The test-retest reliability of the overall score was also good. The ICC was also the lowest in the rectal domain. Similar to these results, the study by Neri and Slappendel also found that the internal consistency of the rectal domain was the lowest, although the value was above 0.7 in those studies.<sup>9,12</sup> In contrast, the original study by Frank showed that all domains had good internal consistency, with the lowest value in 'stool symptoms' domain.<sup>5</sup>

The content validity was judged to be adequate by the experts. In this data, we observed a very high floor effect on question 7 (84.4%) and less on question 4. This effect was similar to the original study,



which found that more than 50% of the subjects reported 'absent' for question 7 (rectal tearing or bleeding).<sup>5</sup> Study by Neri also observed high floor effect on question 7 (61.7%) and question 4 (50.30%).<sup>12</sup> Another study by Slappendel for opioid-induced constipation also observed that floor effect was observed in 58% of the scores for rectal domain.<sup>9</sup> Frank in his study decided to retain question 7 to identify patients with the most severe constipation.<sup>5</sup>

Scale-total correlations were strong in all domains. The observed correlation coefficient was higher in this study than in the original study (0.53 for rectal, 0.59 for abdominal, and 0.69 for stool symptoms). However, the similarity was that the lowest correlation was from 'rectal' domain, and the highest was from the 'stool' domain. The multi-trait analysis showed that all questions except question 7 had sufficient convergent validity. A study by Neri also found that question 3, 4, 5, 7, 8, and 9 might have a lack of convergent validity through inter-item correlation.<sup>12</sup> In this study, all questions except question 8 showed a lack of divergent validity which meant that the questions were highly correlated with each other. This further suggested that the 'three factors' model from the original study might not be true for this set of data. In spite of that, scaling success was still achieved because the item-subscale correlation with the appropriate domains was still higher than the non-domains. The correlation between PAC-SYM© and PAC-QOL was moderate, which was appropriate because even though they were correlated, they were designed to measure different constructs. Each domain of PAC-SYM© did have a significant correlation with several PAC-QOL domains which demonstrated concurrent validity.

Results from the principal component analysis revealed a 'two factors' model using the data in our study. Question 7 was omitted in this analysis for various reasons stated above (improvement of internal consistency in the rectal domain, very high floor effect, lack of convergent validity, KMO value <0.5). In the confirmatory factor analysis performed by Neri, question 7 was also deleted because of the high floor effect and question 7 was only included in the original study because of expert opinion, not based on the evidence. The two factors observed in our study ('new abdominal' and 'new stool') was similar to the bifactor model of Neri. Neri's model found that question 5 and 6 which originally belonged to the 'rectal' domain were combined into 'stool' domain, resulting in 'modified-stool' domain.<sup>12</sup> In our study, question 5 and 6 also had stronger loadings in the 'new stool' domain. However, question 12 (feeling like you had to pass a bowel movement but could not) had stronger loading in the 'new abdominal' domain and vice versa, question 4 (stomach cramps) had stronger loading on the 'new stool' abdomen. Perhaps the reason was that stomach cramps were more likely to be associated with the straining because of difficulty in passing stools.

The results from structural equation modeling showed that our 2 factors model fulfilled the cut-off criteria for fit indexes proposed by Hu and Bentler, except for the GFI which was slightly below the cut-off value.<sup>13</sup> This showed that our model was fit for the data from this study population.

This study did have several limitations. First, the number of samples was lower than the original validation study and other studies. However, the ratio of patient to the number of questions was 5:1, which was sometimes used as the minimum ratio. In addition, the KMO measure during principal component analysis showed sampling adequacy. The second limitation was that the results from confirmatory factor analysis might not be appropriate because the number of samples was too low. The general rule of thumb was the minimum number of sample size was 200, or 5-20 times the number of parameters to be estimated, or 10 cases per variable. However, Wolf in his study argued that the minimum number of samples could actually range from as small as 30 to 460, depending on several factors.<sup>14</sup> Despite that, our model seemed to fit well with the data.

Overall, our study showed that the Indonesian version of PAC-SYM© was both valid and reliable. Although question 7 was omitted during the statistical analysis, we decided to retain it in the questionnaire to identify patients who need more careful attention. The structural validity in our study did differ from the original. However, a much larger sample size was needed to confirm the factor structures. In the future, confirmatory factor analysis using the Indonesian version of PAC-SYM© could be rerun and by comparing different theorized models. In addition, the responsiveness of the scale could be assessed by observing the response to intervention, and the minimally important difference could also be calculated.

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