

The Validity and Reliability Test of the Indonesian Version of Gastroesophageal Reflux Disease Quality of Life (GERD-QOL) Questionnaire

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ABSTRAK

Tujuan: mendapatkan kuesioner GERD-QOL yang andal dan sah untuk digunakan di Indonesia. **Metode:** sebagai tahap awal, kuesioner GERD-QOL terlebih dahulu diterjemahkan dengan metode back to back translation ke dalam bahasa Indonesia, dan dievaluasi oleh tim peneliti sehingga dihasilkan kuesioner GERD-QOL versi bahasa Indonesia. Sembilan puluh satu orang pasien yang telah didiagnosis GERD secara klinis sebelumnya berdasarkan kriteria Montreal, diwawancarai dengan menggunakan kuesioner GERD-QOL versi Indonesia dan kuesioner SF 36. Kesahihan dinilai menggunakan kesahihan konstruksi dan kesahihan eksternal dan keandalan dinilai melalui metode konsistensi internal dan tes ulang. **Hasil:** GERD-QOL berbahasa Indonesia memiliki keandalan konsistensi internal kuesioner yang baik (Cronbach alpha: 0.687–0.842) dengan keandalan tes ulang yang baik (intra class correlation coefficient: 0.756-0.936, $p < 0.05$). GERD-QOL juga terbukti memiliki kesahihan yang baik dengan korelasi setiap pertanyaan dengan SF-36 terbukti tinggi ($p < 0.05$). **Kesimpulan:** GERD-QOL berbahasa Indonesia terbukti sah dan andal untuk menilai kualitas hidup penderita GERD.

Kata kunci: GERD, kualitas hidup, GERD-QOL, kesahihan, keandalan.

ABSTRACT

Aim: to obtain a valid and reliable GERD-QOL questionnaire for Indonesian application. **Methods:** at the initial stage, the GERD-QOL questionnaire was first translated into Indonesian language and the translated questionnaire was subsequently translated back into the original language (back-to-back translation). The results were evaluated by the researcher team and therefore, an Indonesian version of GERD-QOL questionnaire was developed. Ninety-one patients who had been clinically diagnosed with GERD based on the Montreal criteria were interviewed using the Indonesian version of GERD-QOL questionnaire and the SF 36 questionnaire. The validity was evaluated using a method of construct validity and external validity, and reliability can be tested by the method of internal consistency and test retest. **Results:** the Indonesian version of GERD-QOL questionnaire had a good internal consistency reliability with a Cronbach Alpha of 0.687–0.842 and a good test retest reliability with an intra-class correlation coefficient of 0.756-0.936; $p < 0.05$). The questionnaire had also been demonstrated to have a good validity with a proven high correlation to each question of SF-36 ($p < 0.05$). **Conclusion:** the Indonesian version of GERD-QOL questionnaire has been proven valid and reliable to evaluate the quality of life of GERD patients.

Keywords: GERD, quality of life, GERD-QOL, validity, reliability.

INTRODUCTION

Gastroesophageal reflux disease (GERD) is a condition characterized by a reflux of gastric content into the throat causing symptoms such as epigastric pain and regurgitation and it may lead to complications. Several recent studies show an increasing GERD prevalence in Asia.^{1,2} However, no certain data has been available in Indonesia regarding the increasing prevalence of GERD in Asia. Based on the study conducted by Syam et al, it has been reported that the prevalence of GERD at Cipto Mangunkusumo Hospital has been increased from 5.7% in 1997 to 25.18% in 2002.³⁻⁶ Moreover, the most recent online survey conducted by Syam et al.⁷ between August 2013 and June 2015 reported that of 2045 subjects who participated the survey in Indonesia, there were 57.6% subjects with GERD.

GERD is a chronic disease that often needs long-term treatment and it can affect quality of life by disturbing the quality of eating and drinking, physical activities and rest.^{6,8,9} Anxiety and depression in GERD patients are significantly higher compared to healthy subjects group. It demonstrates that GERD can affect mental and emotional aspects of an individual that eventually lower the quality of life.⁹⁻¹⁴ The socio-economic burden caused by GERD is also quite severe, which may need a special attention. The effect of GERD on the quality of life of patients who have experience the disease does not correlate with the lesion on mucosa as seen on endoscopy; therefore, improved quality of life has become another target of GERD management.^{10,11}

Many questionnaires have been developed to evaluate GERD, either the general questionnaires to evaluate quality of life or questionnaires that have been specifically developed for GERD. The SF-36 is a generic instrument that has been applied in various countries and has become the gold standard to evaluate quality of life; however, it is not specific to evaluate a certain disease and therefore, it is better to use it with another questionnaire, which is more specific in evaluating certain disease.^{9,12} Chan et al. have tried to developed an instrument to evaluate the quality of life of GERD patients in China before

and after having pharmacological treatment. The GERD-QOL questionnaire has also been tested for its validity and reliability, in which the results show that it is a relatively good instrument, but it has not widely applied.^{10,12,13}

The GERD-QOL questionnaire has been tested for its validity and reliability for Asian populations and it is considered to be a relatively good and specific instrument to evaluate the quality of life of GERD patients.¹⁰ The questionnaire evaluates the quality of life of Asian population before and after receiving proton pump inhibitor (PPI) treatment. It indicates that the questionnaire can also be used in Indonesia. Since Indonesia has different cultures, a study is required to test its reliability and validity before applying the GERD-QOL questionnaire for GERD patients in Indonesia.^{10,12}

METHODS

The study was a cross-sectional study to test the reliability and validity of the Indonesian version of GERD-QOL questionnaire involving 91 patients who had been diagnosed with GERD according to the Montreal Criteria. The involved patients were recruited by consecutive sampling. The inclusion criteria in the study were patients with GERD aged over 18 years old who visited the outpatient clinic of gastroenterology between July and August 2016; while the exclusion criteria were patients who were unwilling to participate in the study, illiterate or had any difficulty in communication.

The patients were informed about the aim of the study and their consent asked before the study was initiated. Patients were asked to fill in the GERD-QOL and SF-36 questionnaires. They dealt with the GERD-QOL questionnaire two weeks later. Characteristics data such as age, sex, last education level, body mass index, duration of GERD, treatment and other comorbidities were also obtained from each patient. The study had been approved by the Ethical Committee on Health Research, Faculty of Medicine, Universitas Indonesia - Cipto Mangunkusumo Hospital on June 13th, 2016 with a reference number of 482/UN2.F1/ETIK/2016.

Questionnaire

The GERD-QOL questionnaire is a specific questionnaire to evaluate the quality of life of GERD patients, which was filled in by the patients themselves (self-administered questionnaire). The questionnaire consisted of 16 questions, which were a combination of four domains, i.e. the daily activity (8 questions), treatment effect (3 questions), diet (3 questions) and psychological well-being (2 questions). Patients were asked to select their answer according to the symptoms felt by the patients within the last 7 days. Next, all answers were scored and the higher the score showed a better quality of life.¹⁰

Before conducting a reliability and validity test, the original version of GERD-QOL questionnaire was translated into Indonesian language using forward-backward translation method. Initially, the original questionnaire was translated by two certified translators into

Indonesian language; then, the results were evaluated by the investigator team. When there was no significant difference on the works between the two translators, the results were back-translated into English version by two native translators. The final result of translation was subsequently compared to the original version of questionnaire. Afterwards, a pretest stage was conducted in 20 patients and each patient was asked for their understanding of each question in the questionnaire. The stages of study can be seen in **Figure 1**.

The study used SF-36 questionnaire, which the Indonesian version has been validated, as a comparator since the SF-36 is the gold standard questionnaire to evaluate quality of life.¹⁵⁻¹⁷ The questionnaire consisted of 8 domains, i.e. physical function, role limitations due to physical health problems, bodily pain, general health, vitality, social function, role limitations due to emotional problems and mental health.¹⁸

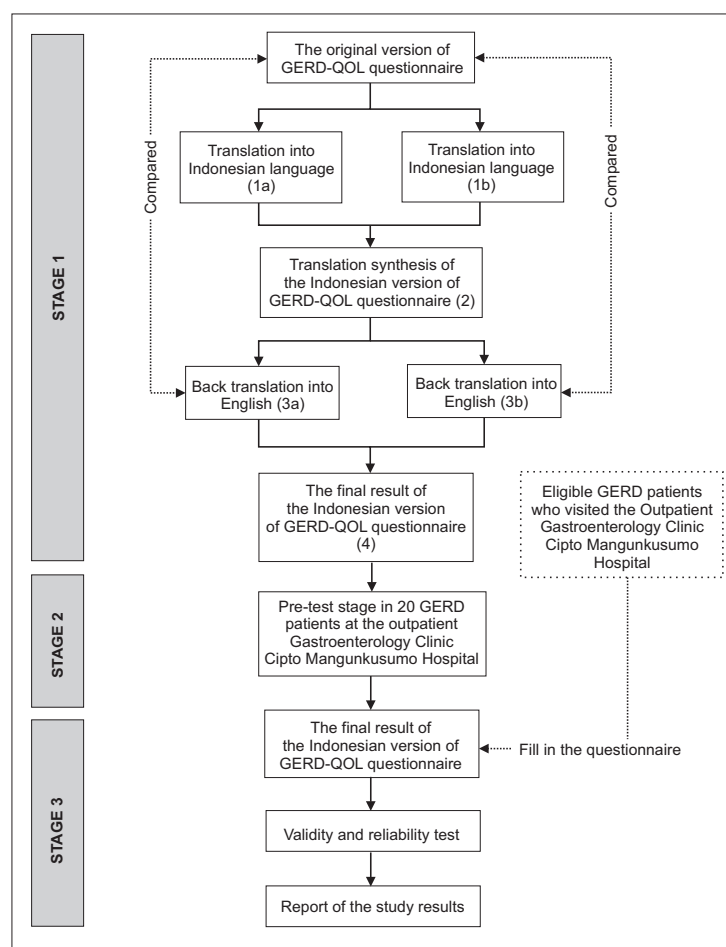


Figure 1. Study flow chart

Statistical Analysis

A valid instrument means that the instrument can be used to measure what it is supposed to; while a reliable instrument is an instrument that will produce exact data when the same object is measured repeatedly. Reliability can be tested by various methods and in the study, the method of internal consistency and test retest were used. Internal consistency was evaluated using the Cronbach Alpha coefficient. A value of Cronbach Alpha of more than 0.7 was considered as an indicator of good internal consistency and good reliability. The test and retest method were performed by presenting a test on a group of subjects twice within 14 days of time interval and subsequently evaluated the intra-class (ICC) coefficient. A coefficient of ICC over 0.70 was considered as a reliable result.¹⁹

The validity in the study was evaluated using a method of construct validity and external validity. The construct validity was aimed to evaluate the correlation between each question in the questionnaire against the total score of its domain. A questionnaire is considered to have a good construct validity when it has a high correlation when it is compared with the domain of the question and likewise, it has a low correlation when it is compared with a different domain. The construct validity was measured using a multitrait multimethod by convergent and discriminant method.

The external validity was measured by comparing the GERD-QOL questionnaire with the gold standard questionnaire, i.e. the SF-36. A value of Pearson correlation of $r > 0.6$ means that it has a good correlation. All of statistical tests were conducted using a two-tailed test and was considered as statistically significant when the $p < 0.05$. The calculation of Statistical Analysis was performed using the SPSS software version 23.0.

RESULTS

A total of 91 patients had fulfilled the inclusion criteria and they were involved in the study. The characteristics of all patients can be seen in **Table 1**.

Table 1. Subject characteristics at the final stage

Variables	Value
Sex (male), n (%)	34 (37)
Age (years), mean (SD)	48.6 (12.84)
Body Mass Index, median (min-max)	23.31 (14.19 - 41.09)
Duration of having GERD (months), median (min-max)	12 (1 - 360)
Comorbidities, n (%)	
- With comorbidities	51 (56)
- Without comorbidities	40 (44)
Therapy, n (%)	
- H2-antagonist	2 (2)
- PPI	75 (82)
- Sucralfate	10 (11)
- Prokinetics	15 (16)
- Rebamipide	23 (25)
- On Demand	9 (10)
Education level, n (%)	
- Elementary	5 (5)
- Junior High	6 (7)
- Senior High	42 (46)
- University (D1-S3)	36 (41)
Occupation, n (%)	
- Employed	45 (49)
- Housewives	29 (32)
- Students	1 (1)
- Unemployed	16 (18)
Endoscopic results, n (%)	
- Never had endoscopy	17 (19)
- Non-erosive	30 (33)
- LA grade A	27 (30)
- LA grade B	15 (16)
- LA grade C	-
- LA grade D	1 (1)

Reliability

Of 91 patients, 80 patients were selected, i.e. those who were stable and had received no change of treatment within 14 days. The eighty patients were asked to fill in the GERD-QOL questionnaire on the first day and on the 14th day in order to evaluate the consistency of their answers between the first and the 14th day. Results of Cronbach Alpha and ICC can be seen on **Table 2**. All domains in GERD-QOL questionnaire had Cronbach Alpha and ICC value of more than 0.7 except for the domain of diet.

Table 2. Cronbach Alpha of GERD-QOL questionnaire

Domain	Cronbach Alpha	ICC (n=80) (14-day interval)
Daily Activity	0.739	0.890
Treatment Effect	0.717	0.756
Diet	0.687	0.833
Psychological well-being	0.842	0.936
Total	0.822	0.880

Validity

The GERD-QOL questionnaire had a convergent and discriminant validity as each question was highly correlated when it was compared with its own domain and had a low correlation when it was compared with other domains.

The Pearson correlation between a total domain of GERD-QOL questionnaire and each domain of the SF-36 questionnaire showed a fair correlation ($r=0.19-0.40$, $p<0.001$). Results of construct validity can be seen on **Table 3**.

DISCUSSION

GERD-QOL questionnaire was firstly developed in China and it has been translated into English. The specific questionnaire is made to evaluate the quality of life before and after pharmacological treatment.¹⁰

Until now, many studies have been done to evaluate the quality of life in GERD patients and many questionnaire instruments have been developed; however, not all of them can describe the quality of life in multidimensional sense and can be used specifically in GERD patients. Different interpretations on GERD symptoms have also become a unique challenge to develop an appropriate questionnaire for certain population; moreover, the available questionnaire must be tested for its reliability and validity prior to the application.^{10,13}

In the era of international and multicenter studies, the instrument used in the studies measuring the quality of life of GERD patients must be appropriate with the studied population, either regarding the culture, language and social customs. A good instrument must have criteria such as sensitive to diagnose a disease, easily scored, easily understandable, easily translated into local languages, able to assess the disease comprehensively, including the typical and the non-typical symptoms and can be self-administered by the patients, economical as well as has been tested for its validity and reliability using psychometric tests.¹²

The study results showed that the Indonesian version of GERD-QOL questionnaire is a valid and reliable instrument to evaluate the quality of life of GERD patients in Indonesia.

Table 3. Correlation between each question and the domains of GERD-QOL questionnaire

	Daily activity	Treatment effect	Diet	Psychological well-being	GERD-QOL total
Q2, Q4, Q5, Q8, Q10 – Q13 (DA)	0.49 – 0.68	0.04 – 0.31	0.16 – 3.23	0.10 – 0.38	0.29 – 0.45 ($p<0.001$)
Q3, Q7, Q14 (TE)	0.09 – 0.037	0.74 – 0.78	0.16 – 0.27	0.30 – 0.38	0.44 – 0.57 ($p<0.001$)
Q1, Q6, Q9 (DI)	0.21 – 0.37	0.11 – 0.29	0.74 – 0.81	0.23 – 0.43	0.50 – 0.59 ($p<0.001$)
Q15, Q16 (PW)	0.31 – 0.37	0.36 – 0.43	0.37 – 0.41	0.92 – 0.93	0.74 – 0.79 ($p<0.001$)

Table 4. Correlation between total score of GERD-QOL domains and specific domain of SF-36

	SF-36 domain							
	Physical functioning	Physical role	Bodily pain	General health	Vitality	Social functioning	Emotional role	Mental health
GERD-QOL	0.309	0.352	0.276	0.402	0.319	0.192	0.326	0.286
p-value	0.000	0.000	0.000	0.000	0.000	0.010	0.000	0.000

The characteristics of 91 patients were similar to those in the original questionnaire conducted in Hong Kong that found greater number of female respondents than male. The mean age of patients in the study was 48.6 years with a standard deviation (SD) of 12.84 mimicking the characteristic of respondent age in the original study.¹⁰

In the study, the test retest method was used to evaluate reliability and the interval used was 2 weeks by involving 80 patients with stable condition and who did not have any change in their treatment. The two-week interval was selected as there were not many changes of the patients' clinical condition within the interval. The ICC results found in each domain of the study were within a range of 0.756-0.936, which was similar to the original questionnaire conducted by Yawen et al in Hong Kong that found ICC between the first and second test ranged between 0.73–0.94, with $p < 0.001$.¹⁰

Internal consistency was evaluated by measuring the Cronbach Alpha. Of the four domains in the GERD-QOL questionnaire, the domain of Daily Activity, Treatment Effect and Psychological Well-being have a Cronbach Alpha of more than 0.7; however, the domain of diet had a Cronbach Alpha of 0.687 (**Table 2**).

There is no certain measurement on the number of questions suggested for each domain. Some available studies suggest that the Cronbach Alpha would be found lower than the actual value when the questions of each domain are less than four. On the other hand, too many domains will also affect the Cronbach Alpha value to be lower. Moreover, the Cronbach Alpha is also affected by other factors, such as the number of sample, homogeneity of the respondents, the poor association of each question in each domain.²⁰

Table 3 shows that each item of questions in the GERD-QOL questioner is convergently valid. When the item of question in daily activity domain was compared to different domains, i.e. the domain of diet, treatment effect and psychological well-being, a value of $r < 0.4$ was found. Likewise, the questions in the domain of treatment effect had a low correlation when compared to the domains of daily activity, diet and psychological well-being. In diet domain,

there were questions with $r > 0.4$ when they were correlated with the domain of in psycholological well-being; however, when the value of r was compared to the domain of diet itself, we found a lower r value. It indicates that each item of questions in the GERD-QOL questionnaire is discriminantly valid.

The external validity evaluated the correlation among similar domains between GERD-QOL and SF-36 questionnaires. The correlation is considered good when the questionnaire is valid and the correlation value found is $r > 0.4$. In the present study, we found a correlation ranged between 0.192 and 0.402. GERD-QOL has a good correlation with SF-36 domains, i.e. physical functioning, physical role, general health and emotional role. The weakest correlation was found in the domain of social functioning, i.e. 0.192. (**Table 4**). The findings of domains with $r < 0.3$ did not always mean that the GERD-QOL questionnaire has a weak correlation, but it may occur as the compared domains between both questionnaires were incomparable or the study did not evaluate the same domain.⁴

The limitation of the study is that it only involved the GERD patients in the outpatient clinic. It did not correlate the education level and did not evaluate the effect of treatment, the presence of comorbidities as well as the disease severity on the quality of life.

CONCLUSION

GERD-QOL questionnaire is a reliable and valid instrument to evaluate the quality of life of GERD patients in Indonesia.

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