

Linguistic Validation of the Irritable Bowel Syndrome-Quality of Life Questionnaire for Iranian Patients

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Abstract- There is a growing interest of clinical and epidemiological researches in the field of functional gastrointestinal disorders in our society. Accordingly, validated and culturally adapted instruments are required for appropriate measurement of variables specially the quality of life. The aim of our study was the linguistic validation of the Irritable Bowel Syndrome-Quality of Life questionnaire (IBS-QOL) for Iranian IBS patients with Persian language. Following the standard forward-backward translation method, the IBS-QOL was translated into the Persian language and completed by 141 IBS patients. Patients also completed the IBS Symptom Severity Scale (IBS-SSS) and Hospital Anxiety and Depression Scale (HADS). One-week retest was performed on 30 randomly selected patients. Internal consistency and test-retest reliability were assessed using Cronbach's alpha and intraclass correlation coefficient (ICC), respectively. To analyze the discriminant validity, the IBS-QOL scores were correlated to the IBS-SSS and HADS scores. According to the results, reliability analyses were acceptable for all of the IBS-QOL domains (Cronbach's alpha=0.68 to 0.90 and ICCs=0.77 to 0.91). Discriminant validity was supported by the presence of correlations of the IBS-QOL scores with disease severity ($r = -0.628$), depression ($r = -0.692$), and anxiety ($r = -0.711$) scores; $P < 0.001$. These results indicate that the Persian version of the IBS-QOL is a reliable instrument with sufficient psychometric requirements to assess quality of life in Iranian IBS patients with Persian language.

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Introduction

Irritable bowel syndrome (IBS) is a common and chronic functional bowel disorder that is characterized by abdominal pain and/or discomfort accompanying with altered bowel habits in the absence of detectable structural abnormalities (1). The prevalence of IBS is about 10% to 15% in western (2) and 6% in Iranian general populations (3). With considerable amount of visits to primary-care physicians and also referrals to gastroenterologists, IBS imposes a substantial economic burden on both developed and developing countries (4). Associated morbidity can be devastating and quality of life of the patients is significantly impaired in almost all dimensions, comparable to severe organic gastroin-

testinal diseases (5). Measuring health-related quality of life (HRQL) is highly useful in clinical and epidemiological researches as well as in routine clinical practice (6). Among disease-specific measures of HRQL for IBS patients, the Irritable Bowel Syndrome-Quality of Life questionnaire (IBS-QOL), developed by Patrick *et al.*, has had better psychometric characteristics (7-9). The IBS-QOL has been adapted and validated for use in populations with different languages and validation reports are available for Japanese, Korean, and Chinese patients (10-12). These reports have shown that, after a standard linguistic validation method, the IBS-QOL can be administered in other populations with appropriate reliability and validity.

To the best of our knowledge, there is only one available report on validation of the IBS-QOL for Iranian IBS patients (13). However, the translation process in that study was not standard (only forward translation was done) and authors did not use appropriate methods to investigate the validity of the translated version. Therefore, following the standard linguistic validation method, this study was conducted to translate and culturally adapt the IBS-QOL in order to use in Iranian IBS patients.

Materials and Methods

Irritable bowel syndrome-quality of life questionnaire

The IBS-QOL comprises 34 items with 5-point response scales (0 to 4) that covers eight dimensions of HRQL: dysphoria (8 items), interference with activity (7 items), body image (4 items), health worry (3 items), food avoidance (3 items), social reaction (4 items), sexual concerns (2 items) and relationships (3 items). Higher values indicate better HRQL after converting the raw score on the IBS-QOL into 0 to 100 points. The IBS-QOL is designed as a self-administered instrument, but it can also be completed with interview (9).

Linguistic validation

Permission was obtained from the original questionnaire developer and MAPI Research Trust (Lyon, France) to develop this study. We followed the recommended process of the MAPI Research Trust (14) as well as the principles ordered by the Translation and Cultural Adaptation working group (15). The standard forward-backward translation was done; two health professionals did the forward translation independently and backward translation was done by two professional translators separately as well. In each translation step, sessions were conducted by translators and a gastroenterologist (MHE) to evaluate the translations. The report of each session, regarding any discrepancy and/or difficulty in translating items, were sent to the original questionnaire developer and further editions were made based on the developer's comments. Then, the Persian version of the IBS-QOL was tested in a pilot study by administering to 15 adult IBS patients for "cognitive debriefing" and to five gastroenterologists for "clinician's review" (14). According to the results of the pilot study and feedbacks from the developer, the questionnaire was edited more and the final Persian version of the IBS-QOL (IBS-QOL-P) was produced.

Subjects

Adult IBS patients referring to the clinics of gastroenterology at Poursina Hakim Research Institute (Isfahan, Iran) were recruited from November 2008 to April 2009. IBS and its subtypes, including diarrhea-predominant (IBS-D), constipation-predominant (IBS-C), mixed bowel habit (IBS-M), and unsubtyped IBS, were diagnosed on the basis of the Rome III criteria and necessary workups. The study was approved by the Ethics Committee of Isfahan University of Medical Sciences and informed consent was obtained from patients.

Psychometric validation

The following criteria were used to identify probable problematic items: a ceiling effect of an item in which >50% of patients circled "Not at all" in their response; an item with >5% missing data; an item with an item-to-total correlation of <0.40 indicating that it may measure a different construct; and pairs of items with an inter-item correlation of >0.70 indicating redundancy of measurement (9).

We used Cronbach's alpha and intraclass correlation coefficient (ICC), respectively, to evaluate the internal consistency and reproducibility of data from the IBS-QOL-P. Thirty patients were randomly selected and completed the IBS-QOL-P twice with a 7-day interval. Those with stable symptoms based on the IBS-Global Assessment of Improvement scale (16) were included in ICC analysis.

To analyze the discriminant validity, the IBS-QOL-P scores were correlated to the IBS Symptom Severity Scale (IBS-SSS) and Hospital Anxiety and Depression Scale (HADS) scores. The IBS-SSS comprises 5 items that scores severity and frequency of abdominal pain, severity of abdominal distension, satisfaction with bowel habits, and quality of life. Each item is scored from 0 to 100 using a visual analogue scale and the total score ranges from 0 to 500 that can be graded as mild (<175), moderate (175-299), or severe (>300) according to the original study (17). As reported in a review of outcome measures by Bijkerk *et al.*, the IBS-SSS is considered to be the best choice for a detailed IBS symptom assessment (18). The HADS evaluates anxiety and depression symptoms in non-psychiatric outpatients with two 7-question sets, each question is scored from 0 to 3 (19). We anticipated that the IBS-QOL-P scores would decrease as the IBS-SSS and HADS scores increase. In addition, we compared the IBS-QOL-P scores among the three levels of IBS severity.

Validation of IBS-QOL for Iranian patients

The SPSS for Windows, Version 16.0 (Inc., Chicago), was used for statistical analyses. Internal consistency was calculated by Cronbach's alpha and test-retest reproducibility by intraclass correlation coefficient (ICC). Pearson correlation was also applied to assess the validity of the IBS-QOL-P with respect to the IBS-SSS and HADS. Analysis of variance was applied to compare the IBS-QOL-P scores among the three levels of symptom severity.

Results

Subjects

The IBS-QOL-P was completed by 141 IBS patients. Mean age was 30.8±7.0 years, 81.6% were females, and 72.3% were married. Regarding education levels, 4.2% were illiterate, 14.1% were below diploma, 46.0% had diploma, and 35.4% have been educated to university levels. Disease subtypes included IBS-D 16.3%, IBS-C 32.6%, IBS-M 47.5%, and unsubtyped IBS 3.5%. According to the IBS-SSS, 22.7%, 48.9%, and 28.4% of the patients had mild, moderate, and severe IBS, respectively.

Psychometric analyses, reliability, validity, and responsiveness

A ceiling effect of an item was found for items 10, 17, 26, and 31. Detailed analysis showed that only the item 26 remained with ceiling effect in patients with severe symptoms (IBS-SSS score > 300). Ten items has missing data, all of them related to only one patient and thus no items had >5% missing data. An inter-item correlation of >0.70 was found between items 12 and 20, and between items 7 and 9. The IBS-QOL-P overall score demonstrated high reproducibility (ICC, 0.93, $p < 0.001$) and internal consistency (Cronbach's alpha, 0.94); Table 1.

Item-subscale scores correlations were acceptable for all items. Items 12 and 21 had item-total scores correlation of <0.40 ($r = 0.318$ and 0.374 , respectively; $P < 0.001$). All subscales scores had acceptable correlations with total score ($r=0.438$ for relationships to 0.919 for dysphoria; $P < 0.001$). Regarding the discriminant validity, the IBS-QOL-P overall and subscales scores (except sexual concern subscale) decreased with increasing IBS-SSS and HADS scores (Table 2) and also significantly discriminated among different levels of IBS severity (Table 3).

Table 1. Reliability for the overall and subscale scores on the IBS-QOL-P

IBS-QOL	Mean ± SD	Cronbach's alpha	ICC*
Overall scale	67.1 ± 16.6	0.94	0.93
Subscales			
Dysphoria	69.0 ± 20.8	0.90	0.91
Interference with activity	62.9 ± 17.4	0.75	0.90
Body image	73.2 ± 20.1	0.70	0.79
Health worry	61.0 ± 23.8	0.70	0.77
Food avoidance	53.2 ± 20.1	0.68	0.79
Social reaction	72.4 ± 22.1	0.77	0.82
Sexual concerns	62.1 ± 36.8	0.88	0.88
Relationships	57.8 ± 23.6	0.73	0.81

* ICC: Intraclass correlation coefficient; $P < 0.001$

Table 2. Correlation between the IBS-QOL-P overall and subscales scores and the IBS-SSS, depression, and anxiety scores

	IBS-SSS	Depression	Anxiety
Overall score	-0.628	-0.692	-0.711
Subscales			
Dysphoria	-0.572	-0.629	-0.645
Interference with activity	-0.581	-0.615	-0.577
Sexual	-0.169 *	-0.324	-0.315
Health worry	-0.649	-0.585	-0.607
Food avoidance	-0.457	-0.358	-0.345
Social reaction	-0.515	-0.625	-0.634
Relationships	-0.483	-0.428	-0.449
Body image	-0.337	-0.431	-0.545

All correlations (Pearson's correlation coefficient) were significant at $P < 0.001$ except * $P > 0.05$

Table 3. Discriminant validity of the IBS-QOL-P according to IBS severity and subtypes

	IBS Severity			P*
	Mild	Moderate	Severe	
Overall score	77.6 ± 11.3	71.7 ± 11.4	52.7 ± 18.0	<0.001
Subscales				
Dysphoria	81.9 ± 14.1	73.5 ± 13.9	53.5 ± 25.3	<0.001
Interference with activity	73.3 ± 13.4	66.6 ± 13.0	50.4 ± 19.7	<0.001
Sexual	67.7 ± 33.9	66.2 ± 36.5	51.5 ± 37.8	0.151
Health worry	75.4 ± 15.3	69.0 ± 17.3	39.1 ± 23.1	<0.001
Food avoidance	61.8 ± 16.0	57.7 ± 17.5	40.1 ± 20.7	<0.001
Social reaction	81.9 ± 15.5	79.4 ± 14.7	54.2 ± 25.9	<0.001
Relationships	70.1 ± 23.4	59.7 ± 21.3	47.2 ± 23.9	0.002
Body image	79.2 ± 17.4	76.5 ± 16.9	63.8 ± 23.9	0.005

Data are shown as Mean ± SD

* ANOVA

Discussion

Measuring and monitoring HRQL is highly useful in routine clinical practice as well as clinical researches of IBS (21). According to a systematic review by Bijkerk *et al*, the IBS-QOL questionnaire is the most extensively validated of all disease-specific HRQL measures for IBS (18). Our study presented the appropriate trans-cultural adaptation and validation of the IBS-QOL for Iranian IBS patients with Persian language. According to the results, items on the IBS-QOL-P were well understood by Iranian IBS patients demonstrating an overall acceptable translation process.

In our study, we found four items with ceiling effect and the item 26 remained with ceiling effect even in patients with severe symptoms. Park *et al.*, in their study in Korea found nine items with ceiling effect including items 10 and 26, similar to our findings. However, as Park and colleagues also mentioned, these items were highly correlated with scores of their domains and also with the overall IBS-QOL score (10), and thus they are not seem to be problematic. By the way, we believe that, in the item 26, our translation of the word “unclean” might be understood as “morally impure” according to religious backgrounds in our population that could result in patients responding to it as “Not At All”. Hence, this item must be re-translated with more emphasis on “cognitive debriefing” in the cultural adaptation process.

An inter-item correlation of >0.70 was found between items 12 and 20 (sexual subscale), and items 7 and 9 (dysphoria subscale). According to the socio-cultural characteristics of our population, patients may avoid expression of sexual concerns which can justify these findings. Regarding items 7 and 9, eliminating these items resulted in a decrease in internal consistency

of the related subscale. Also, these items were highly correlated with other domain items as well as with overall IBS-QOL-P score. Therefore, we believe that these items are not really inappropriate for our population. The inter-item correlation was not described in the results of other studies and therefore no data was available for comparison.

In our study, two items had item-total scores correlation <0.40; item 12 (sexual concerns subscale) and item 21 (body image subscale). The item-total score correlation <0.40 was also reported by Kanazawa *et al.* for item 12 (0.30) and also for items 5 (related to body image) and 32 (related to health worry) (12). However, Park and colleagues found an acceptable item-total score correlation for all items (10). Differences between studies can be related to several factors including differences in the proportion of patients with severe symptoms, IBS subtypes, and cultural differences. Nevertheless, further studies with larger sample sizes are needed to confirm whether cross-cultural differences in patients' concerns are associated with these results.

Reliability analyses demonstrated high internal consistency and reproducibility of the IBS-QOL-P for the overall as well as for subscales scores that was comparable to the original study (Cronbach's alpha = 0.95, ICC = 0.86) (9) and also to other validation studies (Cronbach's alpha = 0.95 to 0.97, ICC = 0.92 to 0.97) (10-12). Strong correlation of the overall as well as subscales scores (except the sexual concern subscale) with symptom severity and psychological status confirmed the discriminant validity in our study. Applying the same method, Kanazawa *et al.* also found acceptable discriminant validity of the Japanese version of the IBS-QOL (12). However, other investigators used the Short-Form Health Survey (SF-36) to assess the

convergent validity of the IBS-QOL (10,11). Anyway, results of these studies showed that IBS-QOL has a good construct validity (either discriminant or convergent) in different populations.

There are some limitations related to our study. Patients in our study were included from outpatient clinics of gastroenterology which may have higher socio-economic state and it is important for linguistic validation studies to include patients from different socio-economic states equally. Also, according to this selection bias, factor analysis and finding out the current state of quality of life in Iranian IBS patients were not possible. In conclusion, the IBS-QOL-P appears to be a reliable instrument with sufficient psychometric requirements to assess the disease-specific HRQL in Iranian IBS patients with Persian language. Further validation studies are warranted to investigate the reliability and validity of the IBS-QOL-P after editing some of the translated items. Also, evaluation of the current state and influencing factors of HRQL in Iranian IBS patients in different cities in Iran is worthwhile.

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