

Cultural adaptation and application of the IBS–QOL in China: a disease-specific quality-of-life questionnaire

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Abstract

Background Irritable bowel syndrome (IBS) is a chronic and episodic illness characterized by altered bowel habits and associated abdominal pain. At present, IBS is one of the most common functional gastrointestinal and motility disorders affecting countries around the world. Surveys have found that patients with IBS have a significantly lower health-related quality of life.

Objectives The aim of this study was to translate and examine the validity of the Irritable Bowel Syndrome–Quality of Life questionnaire (IBS–QOL) in patients suffering from IBS in China.

Methods A structured procedure was used for the translation and cultural adaptation of the original

English IBS–QOL into Chinese. The questionnaire was administered to 73 clinical patients with IBS and 70 healthy individuals. Psychometric testing for reliability, validity and responsiveness followed standardized procedures. Test–retest reliability (10–20 hours) was assessed using the clinical patients. Follow-up (4 weeks) was collected for 61 clinical patients. All enrolled patients also completed the Short Form-36 Health Survey (SF-36) at the baseline visit. Responsiveness to treatment (Venlafaxine and traditional Chinese herbal medicine) was assessed by one-way ANOVA methods.

Results The average length of time required to complete the questionnaire was short (5.63 min for IBS patients and 5.54 min for healthy subjects by self-administration). Internal consistency (Cronbach's alpha) values ranged from 0.722 to 0.914 for the Chinese IBS–QOL subscales and test–retest reliability coefficients were higher than 0.920 on all subscales. The convergent and discriminate validity results comparing the Chinese translation of the IBS–QOL overall score and the SF-36 subscales confirmed our predicted hypotheses. The Chinese IBS–QOL scores are more highly correlated with social functioning, vitality and general health (SF-36) and show weaker associations with physical functioning, role physical, mental health, and bodily pain (SF-36). The Chinese translation of the IBS–QOL was responsive to treatment.

Conclusion In general, the Chinese translation of the IBS–QOL, after cultural adaptation and revision, possesses good reliability, validity and responsiveness. It is a reliable and valid instrument to assess the quality of life in Chinese patients suffering from IBS and is an appropriate measure to use in further clinical trials or for related research projects in China.

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Keywords Chinese translation of the IBS–QOL · Quality of life · IBS · Reliability · Validity · Responsiveness

Introduction

Irritable bowel syndrome (IBS) is a chronic and episodic illness characterized by altered bowel habits and associated abdominal pain [1, 2]. At present, IBS is one of the most common functional gastrointestinal and motility disorders occurring in each country of the world [3]. Within China, the incidence has been found to range from 7.3% to 8.2% [4] affecting from 25% to 50% of the total outpatients [5].

Irritable bowel syndrome can have a substantial effect on a person's quality of life [6]. The Irritable Bowel Syndrome–Quality-of-Life questionnaire (IBS–QOL) developed by Patrick et al. [7] may be considered a gold standard in the assessment of QOL in patients with IBS. It consists of 34 items that produce an overall score and eight subscale scores including dysphoria, interference with activity, body image, health worry, food avoidance, social reaction, sexual, and relationships. Eight language versions have been widely used [8–11], but no officially approved Chinese version of the IBS–QOL has been validated. Therefore, following the recommended criteria [12, 13], we translated the original English IBS–QOL into Chinese and conducted a validation study.

Methods

Linguistic validation process

The license was obtained from the authors of the original IBS–QOL scale and Mapi Research Trust to develop this study. We followed the criteria of the linguistic validation process provided by Mapi [12] and the fundamental principles argued by Guillemin et al. [13] to carry out the IBS–QOL cultural adaptation and application.

Translation of the IBS–QOL

An initial forward translation step resulted in a translated version suitable for linguistic and cultural Chinese contexts. The original IBS–QOL measure has not been modified in any way except for addressing the differences in relationships, grammatical factors, Chinese ethnicity and general issues. This Chinese version

was then independently backward translated into English for content comparison. Consequently, some items in the forward-translated IBS–QOL were modified to better correspond to the meaning of the original item in the IBS–QOL. An expert committee was then asked to assess the comprehensibility of the Chinese version of the IBS–QOL, to highlight errors and suggest translation alternatives. The content of the final Chinese IBS–QOL was further verified by back translation procedure until both translated and back-translated versions were considered completely interchangeable, conceptually and linguistically.

Preliminary testing

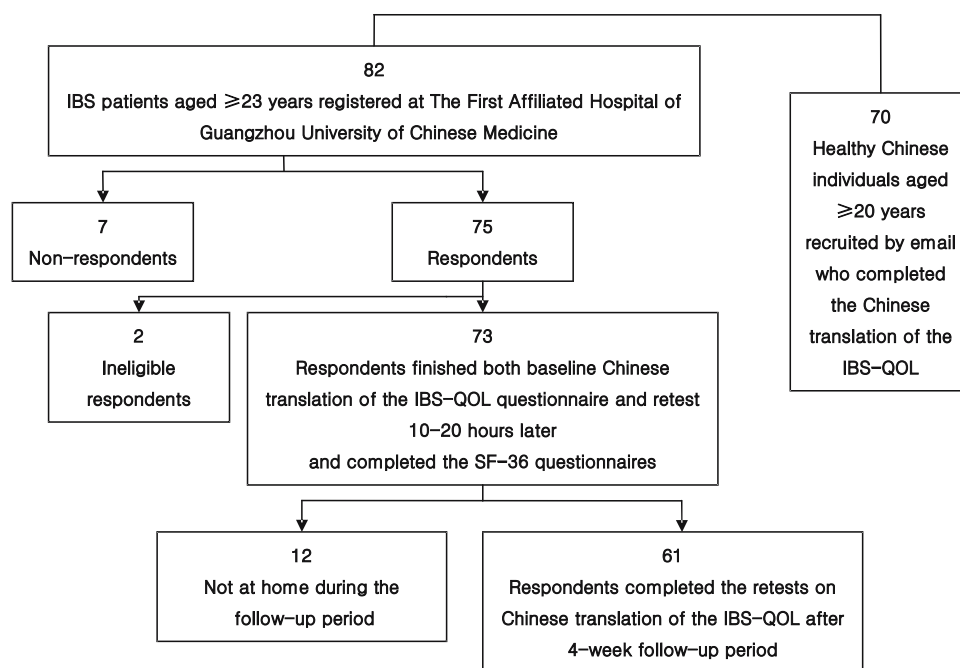
A sample of 12 IBS patients was recruited from a teaching hospital in China. All of these patients met the Rome Criteria II for IBS and comprised 4 each of three symptom types of IBS (constipation-predominant, diarrhea-predominant and alternating). Their ages ranged from 23 to 62 years, with a mean age across Chinese patients of 33.58 years (SD 11.43). The average time to complete the questionnaire was 15.33 min (SD 3.55). In the process, we have investigated if the patients had any difficulty in understanding the questionnaire and check the patient's interpretation of all items. Feedback from patients indicated that the wording of 34 items (9 pages following the original outline) was acceptable but the average time to complete was lengthy. The final Chinese version lists all items on a single page, which differs from the original version which has items spread over 9 pages.

Validation study

Subjects

Recruitment occurred between August and November of 2005 and included Chinese IBS patients coming into first contact with health care after a positive diagnosis of IBS. All of these patients met the Rome II criteria for IBS, regardless of the symptom types. A diagram of the study population is shown in Fig. 1. A healthy population was also recruited by email. Seventy healthy subjects completed the Chinese translation of the IBS–QOL by computer-linked access and sent the completed IBS–QOL questionnaire back. All the data from these questionnaires were documented to enable a check of the discriminatory power of the instrument. The procedure was the same as that applied during preliminary testing.

Fig. 1 Flow chart describing all enrolled patients with IBS in The First Affiliated Hospital of Guangzhou University of Chinese Medicine and healthy persons, Guangdong, China



QOL instruments

Every patient completed the Chinese translation of the IBS-QOL [7] and the SF-36 [14] at the baseline visit. Second administrations of the IBS-QOL were collected for all the patients 4 weeks after baseline.

The Chinese IBS-QOL produces a quality-of-life profile for people with IBS, using the same subscales as for the original English language version. All items are negatively framed with the greatest response scale equaling the worst quality of life. When scored, all items are reversed so that as IBS-QOL scores increase, quality of life increases.

Evaluation of the Chinese translation of the IBS-QOL psychometric properties

Psychometric testing of the Chinese IBS-QOL was conducted using standardized procedures [15] and instrument review criteria developed by the Scientific Advisory Committee of the Medical Outcomes Trust [16], also discussed in the recent Draft FDA PRO Guidance [17]. All psychometric analyses were based on data collected from patients in the clinical trial in order to test the construct validity, reliability and responsiveness of the Chinese IBS-QOL. All analyses were done with the SPSS 13.0 and SAS 9.0.

Cronbach's *alpha* was calculated to assess internal consistency [18]. The criterion level for coefficient *alpha* was set at 0.70 or above [16, 18–21]. Test–retest reproducibility was examined by Pearson correlations.

Every patient completed the IBS-QOL at baseline and again between 10 and 20 hours later (we assumed that the QOL of each patient would not change in a single day).

Convergent validity was established using the SF-36 measures [7]. Pearson's correlation was computed to measure the association between the total scores of the Chinese IBS-QOL measure [20]. With justification from previous studies, a stronger correlation was considered to be 0.40 or above and a weaker correlation 0.39 or below [22].

Specifically, we hypothesized that Chinese IBS-QOL scores would be more highly correlated with *social functioning*, *vitality*, *general health* (SF-36), and *bodily pain* (SF-36) and show weaker associations with *physical functioning*, *role physical*, *role emotional* and *mental health*.

Also, we compared the total scores and subscales of the Chinese IBS-QOL between the IBS patients and the healthy population by the one-way ANOVA method in order to check the discriminate validity of the Chinese IBS-QOL.

The responsiveness of the Chinese IBS-QOL was assessed in an ongoing intervention study of the effects of Venlafaxine [23–25] in combination with traditional Chinese herbal medicine [26–30] on IBS patients (using Self-Contrast 61 with SPSS ($\alpha = 0.05$) [31]). Using data obtained from the clinical trial, total scores were calculated at the baseline visit and again at 4 weeks. For comparison, total and subscale quality of life scores were evaluated by paired-samples *t*-test in

order to test whether the Chinese IBS–QOL was sensitive to change.

Results

Group comparison

Seventy-three patients with IBS and 70 normal subjects were enrolled into the study. Sixty-one IBS patients completed the 4-week follow-up measurements. Mean ages of IBS ($N = 61$) and normal ($N = 70$) groups were 33.41 (SD 11.03) and 26.11 (SD 4.83) years, respectively. The average length of time required to complete the questionnaire was short (5.63 min for the IBS patients and 5.54 min for the healthy subjects by self-administration). Summarized clinical and demographic data are shown in Table 1. Compared with the 61 IBS patients who finished the total follow-up procedure, the healthy respondents had similar distributions of gender, age and educational level.

Internal consistency

The overall IBS–QOL showed a high internal consistency reliability as indicated by a Cronbach's alpha of 0.956. Each of the identified subscales had a high alpha value (0.722–0.914). Test–retest reliability coefficients were satisfactory ($r > 0.900$) (See Table 2)

Convergent and construct validity

Table 3 shows the predicted and actual strengths of correlation between the Chinese IBS–QOL questionnaire and the SF-36 using Pearson's product moment correlation coefficients. As predicted, scores on the IBS–QOL correlated strongly (0.40 or above) with the *social functioning*, *vitality*, and *general health* (SF-36) subscales. Only the *bodily pain* subscale of the SF-36 did not correlate as hypothesized. It was also hypothesized and confirmed that scores on the IBS–QOL would have weaker correlations with *physical functioning*, *role physical*, *role emotional* and *mental health* subscales of SF-36.

Table 1 Clinical and demographic data

Characteristics	IBS patients ($N = 61$)	Normal ($N = 70$)	P -value
Age (yr), Mean \pm SD	33.41 (11.03)	26.11 (4.83)	0.748
Men, n (%)	25 (41)	34 (49)	0.380
Education, n (%)			
≥ Bachelor degree	15 (25)	25 (36)	0.168

Table 2 Chinese IBS–QOL internal consistency and test–retest reliability

Chinese IBS–QOL	Cronbach's alpha coefficients (Time 1) ($N = 73$)	Test–retest reliability coefficients over 10–20 hrs ($N = 73$)
Overall scale	0.956	0.920*
Subscales:		
Dysphoria	0.911	0.927*
Interference with activity	0.844	0.927*
Body image	0.830	0.932*
Health worry	0.752	0.935*
Food avoidance	0.767	0.941*
Social reaction	0.840	0.928*
Sexual	0.914	0.932*
Relationships	0.722	0.920*

*Correlation is significant at the 0.05 level (2-tailed)

One-way ANOVA was used to measure the overall and subscale scores of Chinese IBS–QOL between the 61 IBS patients and the 70 healthy individuals at the baseline visit period. The Chinese IBS–QOL scores were highly discriminatory with P -values less than 0.001 (See Table 4).

Responsiveness

The responsiveness of the Chinese IBS–QOL is illustrated in Fig. 2. It shows the effect of treatment on QOL at baseline and after the 4-week follow-up in IBS patients. Using paired-samples t -test, IBS–QOL scores showed a significant improvement after treatment in each subscale and overall score ($P = 0.000$ – 0.003) with the exception of *food avoidance* score ($P = 0.567$) and the *sexual* score ($P = 0.330$).

Table 3 Predicted versus actual correlation strength between the Chinese IBS–QOL and the SF-36

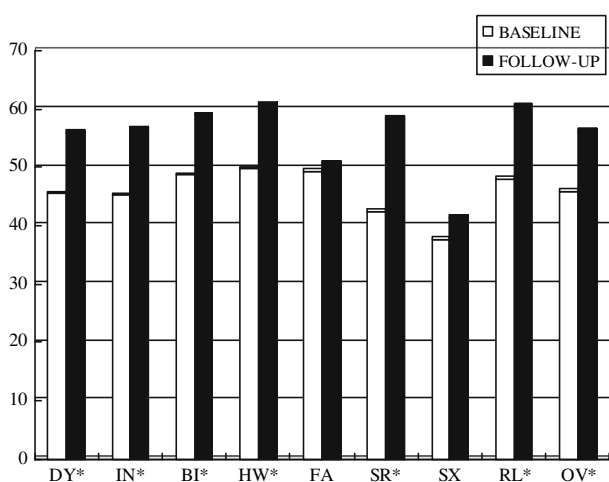
	Chinese IBS–QOL		
	Predicted	Actual	Correct (y/n)
SF-36			
Physical functioning	Weaker	0.329	Yes
Social functioning	Stronger	0.864	Yes
Role physical	Weaker	0.338	Yes
Role emotional	Weaker	0.364	Yes
Mental health	Weaker	0.182	Yes
Vitality	Stronger	0.420	Yes
Bodily pain	Stronger	–0.014	No
General health	Stronger	0.683	Yes

Weaker correlation: <0.40

Stronger correlation: ≥ 0.40

Table 4 Comparison of the total and subscale scores of Chinese IBS–QOL between IBS and healthy subjects

Chinese IBS–QOL	Mean and SD of overall and subscale scores				F	P-value
	IBS patients (N = 61)		Healthy subjects (N = 70)			
	Mean	SD	Mean	SD		
Overall	45.96	20.86	95.50	6.73	352.878	<0.001
Dysphoria	45.54	23.46	96.61	5.07	314.986	<0.001
Interference with activity	45.26	22.99	95.51	8.13	292.840	<0.001
Body image	48.67	29.47	94.64	9.41	152.618	<0.001
Health worry	49.73	26.04	93.57	10.63	166.692	<0.001
Food avoidance	49.32	20.88	90.00	17.92	144.032	<0.001
Social reaction	42.52	28.11	97.14	8.15	241.294	<0.001
Sexual Relationships	37.70	34.87	99.29	2.92	216.781	<0.001
	48.09	24.74	96.43	8.10	238.236	<0.001

**Fig. 2** Mean Chinese IBS–QOL domain scores at baseline and 4-week follow-up. DY = Dysphoria, IN = Interference with activity, BI = Body image, HW = Health worry, FA = Food avoidance, SR = Social reaction, SX = Sexual, RL = Relationships, OV = Overall. *Significant difference between baseline and 4-week follow-up score is based on paired-samples *t*-test

Conclusion

In research and practice, valid measurement instruments are needed to assess quality of life in Chinese patients with IBS. As the IBS–QOL was not available in Chinese, we translated the instrument into Chinese and tested it on a sample of Chinese patients with IBS. Our findings showed that the instrument had good internal validity, reliability, and was sensitive to treatment differences. It is easy for patients to use and it covers the most important areas of quality of life that are influenced by altered bowel habits and associated abdominal pain. We conclude that the Chinese translation of the IBS–QOL is well suited for quality of life

assessment in patients suffering from IBS in healthcare setting. The results of the assessment of content validity, criterion-related validity and construct validity indicated that the Chinese IBS–QOL questionnaire appears to measure what it is intended to measure and that its items are selective and non-redundant. The results presented are of particular interest given that results of hospital- or treatment centre-based studies are prevalent in China. The results of this study indicate that the Chinese IBS–QOL is a valid and reliable instrument for assessing the quality of life of patients with IBS. It also provides us with an important instrument to assess the effects of complex interventions in clinical trials or related research.

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