

Validation of the Persian Version of Inflammatory Bowel Disease Questionnaire in Patients Who Referred to Clinics and Hospitals of Birjand University of Medical Sciences, Iran

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Abstract

Background: Inflammatory bowel disease (IBD) questionnaire is a disease-specific questionnaire to measure the health related quality of life (QOL) in patients with inflammatory bowel disease.

Objectives: The current study aimed at assessing the validity of the Persian version of the QOL questionnaire in patients with inflammatory bowel disease referred to the clinics and hospitals affiliated to Birjand University of Medical Sciences, Iran.

Methods: The current cross sectional study included 87 patients who referred to the clinics and hospitals affiliated to Birjand University of Medical Sciences from 2014 to 2015; IBD diagnosis was confirmed in the subjects by the pathological analyses and accordingly they were asked to complete the Persian version of IBDQ. Data were analyzed by SPSS (15) using descriptive statistics, internal consistency reliability, construct validity (by the short-form 36), and factor analysis was used for the structural validity of the questionnaire.

Results: A total of 87 patients with the mean age of 38.80 ± 16.17 years enrolled in the study. Mean score of QOL based on IBDQ questionnaire, was 158.99 ± 24.9 out of 224. The factor analysis of the Persian version did not confirm the structural factor of the original questionnaire. Cronbach's alpha for the questionnaire was 0.94, in domains from 0.68 to 0.89. The correlation between the domains of QOL in IBDQ and SF-36 inventory were 0.44 to 0.69

Conclusions: Due to the high internal consistency and correlation coefficients with SF-36 inventory, it can be used in the studies to evaluate the QOL in the patients.

Keywords: Inflammatory Bowel Disease, Quality of Life, Validity, Reliability

1. Background

Inflammatory bowel disease (IBD) includes the Crohn disease and ulcerative colitis that affects about 10% to 20% of the world population (1). The prevalence of IBD is increasing in the world for unknown reasons (2). Crohn disease and ulcerative colitis affect males and females equally, with the peak age group of 10 to 40 years and the highest prevalence in Europe and North America. There are various symptoms such as diarrhea, fatigue, weight loss, and abdominal pain associated with IBD (3).

Ulcerative colitis and the Crohn disease have a chronic nature and are associated with inflammatory lesions and ulcers; the early onset affects the social aspects of patients life and quality of life (QOL) (4). IBD is chronic with intermittent periods of onset and remission. Chronic nature, severity and recurrence of symptoms, extraintestinal manifestations, drug and surgical effects and side effects, concerns about the possibility of cancer and other characteristics of IBD affect the daily life of patients and considerably

decrease their QOL (5).

Health-related QOL (HRQOL) is a dynamic subjective concept that according to the definition by the world health organization (WHO) is the people's perception of their position in life, goals, expectations, standards and priorities; it is completely personal, and is based on individuals' perceptions of various aspects of their lives (6).

The quality of life is assessed by several tools that are categorized as general and on specific diseases. General tools to measure the QOL, such as SF-36 inventory, are translated into Persian and validated in Iran (7).

IBDQ questionnaire is a specific QOL questionnaire in patients with IBD that is a validated, reliable, sensitive, and culturally adapted questionnaire and is often used in clinical trials and epidemiologic studies. This questionnaire was translated into more than 13 languages (5).

2. Objectives

According to the fact that IBD affects the QOL of patients in different aspects and due to lack of a proper and practical tool to assess the QOL of such patients, the current study aimed at assessing the validity of the Persian version of the QOL questionnaire in patients with IBD.

3. Methods

The current cross sectional, descriptive-analytic study included all patients who referred to the clinics and hospitals affiliated to Birjand University of Medical Sciences from 2014 to 2015; the subjects were recruited by the convenience sampling method and IBD diagnosis was confirmed in them based on the pathological analyses. The exclusion criteria were: lack of access to patients, non-compliance of patients to participate into the study, and the presence of other chronic diseases that affected their QOL. All participants were enrolled after signing the informed consent.

The IBDQ was 1st translated into Persian by the researcher and 2 other experts in English translation, and then, the translated versions were compared and the questions were matched and the questionnaire again was back translated into English. The 2 versions of the questionnaire were compared by the researcher and any differences were discussed and resolved.

Finally, the Persian versions of IBDQ were matched with the original version, and the final Persian version was developed.

After preparation of the questionnaire, the researcher referred to the pathology clinics of Vali-Asr and Imam Reza hospitals and internal clinic in Vali-Asr Hospital and gastroenterologist clinics and the data of patients with IBD diagnosis were extracted. After referring to the medical records of patients, the address and phone numbers of the patients were collected and patients were contacted. Then, the researcher introduced the objectives and goals of the study to patients; those who were willing to cooperate were enrolled. When patients referred to the internal clinics, the questionnaire was completed through interview.

To collect data, the information checklist containing the study variables, and the IBDQ and SF-36 inventory were completed.

IBDQ specifically assesses the QOL inpatients with IBD; it includes 32 questions in 4 domains: bowel, systemic, emotional, and social. Each question has 7 options that the patients choose 1 of them according to their condition in the past 2 weeks. Each question has 7 points with the best as score 7 and the worst as score 1; scores ranging from 32 to 224 and the higher scores show better QOL. In this questionnaire, 10 questions assess the bowel symptoms,

12 questions the emotional status and 5 questions the social function. This questionnaire was translated into 13 languages, validated, and had high validity and reliability in clinical and epidemiological studies (5).

SF-36 inventory has 36 questions in 2 physical and mental domains and 8 subdomains. The score of each question is determined by a scoring system table of SF-36. SF-36 inventory is a tool to check the general QOL. The questionnaire includes the following domains: role limitations due to physical health (4 items), physical function (10 items), general health (6 items), pain (2 items), energy/fatigue (4 items), social functioning (2 items), emotional wellbeing (5 items), and role limitations due to emotional problems (3 items). The questionnaire was validated in Iran (7).

After completing the questionnaire, data were assessed by SPSS software (16). To examine the reliability and structural validity of the questionnaire, Cronbach's alpha coefficient and factor analysis were used for internal consistency.

To determine the structural validity of IBDQ, factor analysis was used by the varimax rotation method. Factors with Eigen value greater than 1 were designated as appropriate, variables loads greater than 0.5 were accepted as presentable variable in factors.

To assess convergent validity, the correlation between different aspects of IBDQ and SF-36 were analyzed using the Pearson correlation coefficient. To compare the mean scores of the variables, independent t test and ANOVA were used at a significant level of 0.05.

3.1. Ethics

The study protocol was approved by the ethics committee of Birjand University of Medical Sciences (code: Ir.bums.1394.14). The study objectives were explained to the patients prior to participation and if agreed, written informed consent was obtained from them.

4. Results

The current study included 87 patients with the mean age of 38.80 ± 16.17 years; 69 patients were diagnosed with ulcerative colitis (79.3%) and 16 patients (20.7%) with the Crohn disease. Mean duration of the disease was 90.96 ± 3.22 months that was 90.78 ± 3.47 in ulcerative colitis and 91.66 ± 1.87 in the Crohn disease. Table 1 presents the demographic and clinical characteristics of the patients with IBD.

Total mean score of QOL based on IBDQ was 158.99 ± 24.9 out of 224 (Table 2).

Mean score of QOL was 157.68 ± 25.8 in ulcerative colitis and 164 ± 20.8 in the Crohn disease that was higher in

Table 1. Frequency Distribution of Demographic Characteristics in the Study Subjects

Characteristics	Ulcerative Colitis, N (%)	The Crohn Disease, N (%)	IBD, N (%)
Gender			
Male	45 (65.2)	10 (55.6)	55 (63.2)
Female	24 (34.8)	8 (44.4)	32 (36.8)
Age group			
< 30	29 (42)	4 (22.2)	33 (37.9)
30 - 40	21 (30.4)	4 (22.2)	25 (28.7)
> 40	19 (17.5)	10 (55.5)	29 (33.3)
Educational level			
Under high school diploma	17 (24.6)	11 (61.1)	28 (32.2)
High school graduated	52 (75.4)	7 (38.9)	59 (67.8)
Family history			
Positive	6 (8.7)	0 (0)	6 (6.9)
Negative	63 (91.3)	18 (100)	81 (93.1)
Marital status			
Married	55 (59.7)	16 (88.9)	71 (81.6)
Single	14 (20.3)	2 (11.1)	16 (18.4)
Smoking			
Yes	5 (7.2)	2 (11.1)	7 (8)
No	64 (92.8)	16 (88.9)	80 (92)
Phase			
Remission	56 (81.2)	14 (77.8)	70 (80.5)
Relapse	13 (18.8)	4 (22.2)	17 (19.5)

patients with the Crohn disease without significant difference (P value = 0.34) (Table 3).

Mean score of QOL had no significant difference based on the type of disease, gender, family history, and marital status (P value > 0.05) (Table 3).

Comparison of the QOL and its domains by age showed that people under 30 years had significantly higher QOL in intestinal (P value = 0.04) and systemic symptoms (P value = 0.01) than other age groups.

Cronbach's alpha for the whole questionnaire was 0.94 and in the domain of 0.68 to 0.89 (Table 2).

The factor analysis of the Persian version did not confirm the structural factor of the original questionnaire. In this method, 7 factors had Eigen value greater than 1 that described 69.43% of variance in the variables. Question 5

(bowel movements loose) was not included in any of the factors and question 12 (difficulty in leisure or sports activities) had the highest factor load in factor 3, but it was lower than 0.5 (0.48) (Table 4).

To assess the construct validity of the questionnaire, the correlation between the domains of QOL in IBDQ and SF-36 inventory were calculated. Correlation coefficients between the domains of the questionnaire showed the highest correlation coefficient between the general health of SF-36 inventory and the emotional status of IBDQ (0.69), and the physical functioning scale of SF-36 and the social function of IBDQ (0.67) (Table 5).

5. Discussion

The current study aimed at validating the Persian version of the QOL questionnaire in patients with IBD who referred to clinics and hospitals affiliated to Birjand University of Medical Sciences.

Factor analysis of the Persian version could not confirm the structural factor of the original questionnaire. In the study by Hjortswang H. et al., on validation of the Swedish version of IBDQ, the factor analysis did not support 4 domains in the Swedish version. The domains scores had high convergence, but low valid differentiation and homogeneity (8).

In the English version of the questionnaire, 5 domains were detected and the load factor for similar questions did not resemble the original version (9).

Pallis et al., evaluated the validity of IBDQ in 9 studies in Britain, the Netherlands, Spain, Korea, Sudan, Greece, and China, but only 2 studies supported the distribution of questions in 5 domains. Also, they showed that IBDQ had high reliability and validity in different nations and cultures (10).

In these studies, factor distribution of the questions in the questionnaire was not identical with the original version that is similar to the present study.

In the current study, Cronbach's alpha for the whole questionnaire was 0.94, ranged from 0.68 to 0.89. In the German (11) and Chinese (12) versions of IBDQ, similar Cronbach's alpha coefficients were reported in different domains.

In the current study, the mean score of QOL was 158.99 \pm 24.9 out of 224 that was higher in patients with the Crohn disease, but had no statistically significant difference in patients with ulcerative colitis. In the study by Pallis et al., to validate the health-related QOL in patients with IBD in Greece, the scores were higher than those of the current study, but there was no difference between the Crohn disease and ulcerative colitis (13), consistent with the present study.

Table 2. Descriptive Characters and Internal Consistency Coefficients of IBDQ and the Domains

Domains	Mean \pm SD	Range	Median	25th Percentile	75th Percentile	Cronbach's Alpha
Total IBDQ	158.99 \pm 24.9	66 - 210	166	144	176	0.94
Bowel symptoms	47.27 \pm 7.46	20 - 61	49	42	52	0.77
Emotional status	59.72 \pm 10.34	24 - 82	61	53	67	0.89
Systemic symptoms	23.98 \pm 4.28	10 - 32	25	21	27	0.75
Social function	28 \pm 4.65	12 - 35	29	26	31	0.68

Table 3. Comparison of QOL in the Study Subjects Based on the Study Variable

Characteristics	Mean \pm SD	P Value
Gender		0.47
Male	157.63 \pm 24.91	
Female	161.50 \pm 25.07	
Age group		0.03
< 30	166.88 \pm 21.45	
30 - 40	158.60 \pm 25.47	
> 40	150.34 \pm 25.90	
Family history		0.98
Positive	158.83 \pm 27.78	
Negative	159 \pm 24.86	
Marital status		0.05
Married	156.58 \pm 25.28	
Single	169.69 \pm 20.57	
Smoking		0.007
Yes	135 \pm 24.81	
No	161.09 \pm 23.93	
IBD		0.34
Ulcerative colitis	157.68 \pm 25.83	
The Crohn disease	164 \pm 20.83	
Phase		0.00
Remission	166.67 \pm 18.36	
Relapse	127.35 \pm 23.58	

The reason of differences between the results of different studies may be due to differences in sample size and supportive measures in various areas that can affect the QOL of patients. Also, various degrees of disease in patients could be another reason for the difference in the results.

In the current study, there was a high correlation between the domains of the 2 questionnaires, IBDQ and SF-36, which showed the high convergent validity of the Persian version. In most studies, to assess the convergence valid-

ity correlation between the domains of the questionnaire with those of the SF-36 questionnaire, a high correlation was found (13-15), consistent with the results of the current study.

The study by Leong et al., on validation of the Chinese version of IBDQ showed a high correlation with SF-36 in all 4 domains, activity index of the Crohn and colitis disease and visual analogue scale (14).

The study by Maleki et al., on 68 patients with ulcerative colitis compared the results of the SF-36 inventory and IBDQ, the results showed a high correlation between all domains of the questionnaires, except in the bowel symptoms (15).

In the study by Verissimo et al., the questionnaire was proven as a promising simple tool that can easily assess the QOL in patients with IBD (16).

The main limitation of the current study was small the sample size. The sample size was low for a validation study. Also, the association between QOL with the severity of the disease that can affect the QOL in patients with IBD was not assessed.

5.1. Conclusion

The factor analysis of the Persian version did not confirm the structural factor of the original questionnaire, but due to the high internal consistency and correlation coefficients with those of SF-36 inventory, it can be used in studies evaluating the QOL of such patients.

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Footnotes

Authors' Contribution: Bita Bijari: study design, writing of the manuscript, and statistical analyses; Behnam

Table 4. Factor Analysis: Factor Load for the Core Domain of IBDQ

Rotated Component Matrix		Component						
		1	2	3	4	5	6	7
Q2	Feeling fatigue or being tired	0.57	0.34	0.26	0.14	0.29	-0.11	0.66
Q6	Energy	0.52	0.21	0.18	-0.17	0.19	0.13	0.45
Q16	Avoid attending events where there was no bathroom at hand	0.57	0.25	0.43	0.14	0.11	0.28	0.07
Q29	Troubled by feeling sick to your stomach	0.53	0.35	0.22	0.18	0.21	0.35	0.04
Q30	Felt irritable	0.74	0.11	0.17	0.27	0.14	0.09	0.13
Q31	Felt a lack of understanding others	0.70	0.05	0.08	0.32	0.25	0.17	0.13
Q32	Satisfied, happy, or pleased in personal life	0.71	0.23	0.10	0.10	0.21	0.24	0.04
Q3	Felt frustrated, impatient, or restless	0.46	0.52	0.12	0.23	-0.04	0.18	0.30
Q4	Unable to attend school or work	0.23	0.61	0.28	0.34	0.10	-0.02	0.25
Q9	Troubled by cramps in your abdomen	0.14	0.79	0.09	0.12	0.29	0.07	-0.04
Q10	Felt generally unwell	0.23	0.51	0.46	0.03	0.22	0.18	-0.01
Q11	Troubled due to fear of not finding a bathroom	0.44	0.54	0.34	0.10	0.17	0.10	0.08
Q13	Troubled by pain in the abdomen	0.23	0.74	0.11	0.24	0.11	0.10	0.10
Q21	Felt relaxed and free of tension	-0.004	0.65	0.03	-0.05	0.18	0.47	0.22
Q7	Feel worried about the possibility of the for a surgery	-0.14	0.12	0.58	0.25	0.29	-0.03	0.27
Q8	Delay or cancel a social engagement	0.22	0.09	0.80	0.07	0.20	0.00	-0.03
Q12	Difficulty with doing leisure or sports activities	0.28	0.25	0.48	0.16	0.43	0.11	0.02
Q14	Problems getting a good night sleep	0.32	0.16	0.69	0.15	-0.10	0.15	0.12
Q18	Problem with maintaining or getting to the weight	0.31	0.14	0.02	0.59	0.44	0.00	0.07
Q19	Worries about getting cancer, never feeling better, and having a relapse	0.41	0.41	0.14	0.63	-0.03	-0.02	-0.02
Q22	Problem with rectal bleeding	0.08	0.07	0.18	0.63	0.09	0.28	0.41
Q24	Troubled by a feeling of having to go to the bathroom even with empty bowels	0.28	0.26	0.22	0.51	0.25	0.30	0.23
Q26	Troubled by accidental soiling of your underpants	0.24	0.16	0.35	0.58	-0.07	0.35	-0.11
Q17	Problem with passing large amounts of gas	0.26	0.10	0.16	0.03	0.74	0.14	0.09
Q20	Troubled by a feeling of abdominal bloating	0.17	0.23	0.11	0.03	0.78	0.06	0.10
Q23	Felt embarrassed as the result of soiling or an unpleasant odor	0.09	0.36	0.18	0.44	0.52	0.18	0.28
Q15	Felt depressed or discouraged	0.40	0.31	0.16	-0.12	-0.08	0.60	0.29
Q25	Felt tearful of upset	0.33	0.18	0.06	0.24	0.32	0.56	0.05
Q27	Felt angry as a result of your bowel problems	0.27	0.15	0.27	0.31	0.04	0.64	0.01
Q28	Limited sexual activity	0.06	0.00	-0.05	0.08	0.08	0.76	-0.08
Q1	Frequent bowel movements	0.12	0.28	0.02	0.14	0.29	-0.11	0.66

Soltani: study design, data collection, and writing of the manuscript.

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Table 5. Correlations of IBD Domains With Short-Form 36 Domains^a

SF-36	IBD			
	Bowel Symptoms	Systemic Symptoms	Emotional Status	Social Function
Physical functioning	r = 0.57 ^b	r = 0.62 ^b	r = 0.63 ^b	r = 0.67 ^b
Role limitations due to physical health	r = 0.63 ^b	r = 0.64 ^b	r = 0.66 ^b	r = 0.51 ^b
Role limitations due to emotional problems	r = 0.53 ^b	r = 0.50 ^b	r = 0.59 ^b	r = 0.49 ^b
Energy/ fatigue	r = 0.50 ^b	r = 0.54 ^b	r = 0.56 ^b	r = 0.49 ^b
Emotional well being	r = 0.44 ^b	r = 0.52 ^b	r = 0.61 ^b	r = 0.41 ^b
Social functioning	r = 0.44 ^b	r = 0.48 ^b	r = 0.50 ^b	r = 0.50 ^b
Pain	r = 0.58 ^b	r = 0.61 ^b	r = 0.64 ^b	r = 0.59 ^b
General health	r = 0.58 ^b	r = 0.59 ^b	r = 0.69 ^b	r = 0.54 ^b

^ar: Pearson correlation (2-tailed test).^bP value < 0.001.

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