

Validation of Gastrointestinal Quality of Life Index in Swedish for Assessing the Impact of Gallstones on Health-Related Quality of Life

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ABSTRACT

Objective: The aim of the present study was to validate a Swedish translation of the Gastrointestinal Quality of Life Index (GIQLI) questionnaire in patients with gallstone disease.

Methods: Sensitivity to change, internal consistency, and test–retest stability were tested in 187 consecutive patients who underwent planned cholecystectomy. Construct validity was assessed by comparing the GIQLI score with the bodily pain scale of SF-36 and four single-item questions in a separate group of 104 patients.

Results: A significant increase in all five domains as well as in the overall GIQLI score 6 months after surgery (all $P < 0.05$) was seen.

All five domains correlated significantly with other measures of gallstone-related symptoms except one single-item question. Intraclass correlations ranged from 0.62 to 0.87. Cronbach's alpha ranged from 0.77 to 0.89.

Conclusion: The Swedish translation of GIQLI has a high validity and reliability for assessing the impact of gallstones on quality of life.

Keywords: cholecystectomy, gallstone, gastrointestinal symptoms, quality of life, reliability, validity.

Background

The prevalence of gallstones is very high throughout the Western world, especially in the older population [1]. The manifestation of gallstones varies from no symptoms at all to frequent attacks of intense biliary colic with a profound influence on the quality of life and potentially serious complications, such as acute cholecystitis, pancreatitis, and cholangitis.

As the indications for surgical treatment of gallstones is a matter of controversy, a reliable instrument for assessing gallstone-related symptoms is crucial. The Gastrointestinal Quality of Life Index (GIQLI) was developed in German and has been translated into English [2]. It includes 36 items divided between five domains: symptoms, physical dysfunction, emotional dysfunctions, social dysfunction, and a single-item question on the effect of medical treatment. Each domain includes 4 to 19 items. It has been applied in patients with various gastrointestinal disorders, including gastroesophageal reflux disease [3], gallstone-related symptoms [4], and irritable bowel syndrome [5].

The aim of the present study was to validate a Swedish translation of the GIQLI questionnaire as an instrument for assessing the impact of gallstone-related symptoms on health-related quality of life. The validation was performed by comparing the outcome from GIQLI with that from SF-36 and four single-item questions, by a factor analysis and by assessing the sensitivity to change of the instrument.

Material and Methods

The GIQLI includes 36 items with five answer categories for each item. By rating the answers from 0 to 4, a global score ranging from 0 to 144 can be estimated. Scores can also be counted for each of the domains.

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10.1111/j.1524-4733.2008.00396.x

The study was based on a translation of the GIQLI questionnaire from German into Swedish made by two independent persons with Swedish as their native language and with a fluent knowledge of German. The two versions were compared and a final version was produced, taking both versions into account. The Swedish translation was retranslated back to German by an independent translator. The retranslation into German did not show any major deviations from the original version. The retranslated version was also examined by Ernst Eypasch, the developer of GIQLI, who did not find any deviations of importance.

Tests for reliability and validity of the questionnaire were made on a cohort of patients aged 18 years or older undergoing elective cholecystectomy in the county of Uppsala, Sweden. The patients were requested to fill in the GIQLI questionnaire, SF-36, and four single-item questions before the operation and 6, 12, and 15 months postoperatively. In addition, they were requested to evaluate their pain using a visual analogue scale (VAS). The VAS has previously been validated as an instrument for measuring chronic pain [6].

Reliability

Test–retest stability was tested by asking the patients operated on between January 1 and August 31, 2005 to answer the questionnaire 3 months apart after 1 year had elapsed since surgery. The interval of 3 months was chosen as interval as the time elapsed since surgery was expected to provide a stable period disease activity. The interval was also long enough to ensure that the patient would not be able to recall the ratings at the two occasions.

Validity

Construct validity was tested by comparing the GIQLI score with the bodily pain scale in SF-36 and the four single-item questions in patients operated on in the period between October 15, 2005 and October 15, 2006. The four single-item questions were not

Table 1 GIQLI scores before surgery and 6 months postoperatively

Domain	Score before surgery (SD)	Score 6 months postoperatively (SD)	P-value
Symptoms	51.0 (12.7)	58.2 (11.4)	<0.001
Physical dysfunction	16.3 (5.9)	19.6 (5.7)	<0.001
Emotional dysfunction	11.8 (4.9)	14.8 (3.8)	0.001
Social dysfunction	11.7 (3.7)	13.5 (3.2)	0.002
Effect of medical treatment	4.3 (1.0)	4.6 (0.9)	0.017
GIQLI, overall	95.1 (24.8)	111.8 (20.1)	<0.001

GIQLI, Gastrointestinal Quality of Life Index; SD, standard deviation.

administered during the first half of 2005; we therefore performed the validity and reliability analyses on two separate cohorts. Construct validity was tested in the ratings before surgery.

The SF-36 is a generic instrument with 36 items. It yields an eight-scale profile of functional health and well-being scores as well as psychometrically based physical and mental health summary measures, and a preference-based health utility index. As the bodily pain scale is conceptually most closely related to gallstone-related symptoms, we used this scale for assessing construct validity. The four single-item questions were as follows:

1. Are you troubled by abdominal pain?
2. If you feel pain, please indicate with a cross in the picture where the pain is located.
3. Do you believe that your troubles are caused by gallstones?
4. Indicate with a cross on the scale below the intensity of the pain as you perceived it when it was most pronounced during the past week.

Two of the single-item questions have been presented in a previous report [7].

Sensitivity to Change

The sensitivity to change of GIQLI was tested in a single-group design [8] by determining the difference between the score before surgery and that 6 months postoperatively in the patients operated on during the period January 1 to August 31, 2005.

Statistics

The test-retest stability was assessed by calculating intraclass correlation. Intraclass correlation was assessed by comparing the ratings of each responder; the period elapsed between the responses was not included in the analysis. Internal consistence was assessed with Cronbach's alpha in the questionnaires recorded before surgery by the same patients. The correlation between GIQLI and the other symptom measures was tested with Spearman's rank correlation coefficient. A factor analysis with varimax rotation was performed to compare the factor loadings to the original subscale division.

Results

Response Rates

Altogether 187 patients underwent planned cholecystectomy during the period between January 1, 2005 and August 31, 2006 (125 women and 62 men, mean age 45.9 years, standard deviation [SD] 15.1 years). The response rate was 32% (59/187) for the preoperative questionnaire, 59% (110/187) for the questionnaire 6 months after surgery, 47% (87/187) for the questionnaire 12 months after surgery, and 23% (43/187) for the questionnaire

15 months after surgery. Thirty-three (18%) patients completed all the three follow-up questionnaires. Of the 311 patients who underwent planned surgery in the period October 15, 2005 to October 15, 2006, 104 (33%) responded to the questionnaire before surgery.

Reliability

Test-retest stability was determined from the responses 12 and 15 months after surgery. Intraclass correlation was 0.85 (95% confidence interval [CI] 0.73–0.92) for the global score, 0.87 (95% CI 0.76–0.93) for symptoms, 0.83 (95% CI 0.70–0.91) for physical dysfunction, 0.68 (95% CI 0.46–0.81) for emotional dysfunction, 0.63 (95% CI 0.40–0.79) for social dysfunction, and 0.62 (95% CI 0.38–0.78) for effect of medical treatment. Cronbach's alpha was 0.92 for the global score, 0.89 for symptoms, 0.84 for physical dysfunction, 0.83 for emotional dysfunction, and 0.77 for social dysfunction.

Validity

All domains as well as the overall GIQLI improved 6 months postoperatively as compared to the scores before surgery (Table 1). All domains correlated significantly with the bodily pain scale of SF-36 and the question regarding frequency of abdominal pain (Table 2). Nevertheless, they did not correlate significantly with the question regarding the patient's own conviction of the origin of the pain.

In a factor analysis, applying varimax rotation with 25 iterations, nine factors with eigenvalues greater than 1 accounting for 72% of the variance were found. The factor analysis was repeated with the number of factors restricted to five to compare the outcome to subscale division originally described for GIQLI [4]. This solution accounted for 58% of the variance. Although the division into five subscales explained less of the variance than the division into nine scales, this division allowed for a more comprehensive comparison with the original subscale division and gave a more coherent structure. The division into five factors could be interpreted as performance in physical role, large bowel function, performance in emotional role, upper gastrointestinal tract function, and meteorism, resembling the original subscale division. The large bowel function, upper gastrointestinal tract function, and meteorism in our analysis correspond to symptoms in the original subscale division, whereas physical role in our subscale division corresponds to emotions and social dysfunction in the original division. Items 1, 2, 8, 9, 15, 16, 17, 24, and 29 did not fall into subscales together with the same items as in the original subscale division.

Discussion

The high reliability and validity of GIQLI shown in the present study supports the value of this questionnaire as an instrument

Table 2 Correlations between GIQLI score and other measures of gallstone-related symptoms

	SF-36, bodily pain		VAS		Abdominal pain frequency		Patient's conviction on pain origin	
	Correlation coefficient	P-value	Correlation coefficient	P-value	Correlation coefficient	P-value	Correlation coefficient	P-value
Symptoms	0.52	<0.001	-0.44	<0.001	-0.57	<0.001	0.03	0.77
Emotions	0.53	<0.001	-0.43	<0.001	-0.45	<0.001	-0.18	0.08
Physical dysfunction	0.52	<0.001	-0.42	<0.001	-0.55	<0.001	-0.08	0.48
Social dysfunction	0.68	<0.001	-0.37	<0.001	-0.58	<0.001	-0.08	0.46
Effect of medical treatment	0.44	<0.001	-0.24	0.017	-0.36	<0.001	-0.11	0.29
Overall GIQLI score	0.63	<0.001	-0.50	<0.001	-0.60	<0.001	-0.08	0.49

GIQLI, Gastrointestinal Quality of Life Index; VAS, visual analogue scale.

for assessing the impact of gallstone-related symptoms on health-related quality of life. Further support is provided by results of previous studies in similar patient groups, which have shown that GIQLI is applicable in patients with gallstone disease and easy to administer [4,9,10]. As it covers a broad scale of gastrointestinal symptoms, the risk of overlooking any manifestations of gallstone-related syndrome is minimized. It may seem that a number of items included in the instrument do not obviously have bearing on gallstone-related symptoms and might hence reduce its specificity. Nevertheless, this has not resulted in a reduction of the sensitivity to change and correlation with other measures of gallstone-related symptoms, including three of the single-item questions and SF-36. The high test-retest stability confirms the reliability of GIQLI.

The high correlation between the GIQLI score and the other measures of gallstone-related symptoms gives support to the construct validity of GIQLI (Table 2). The pain was also significantly more often localized in the right upper quadrant, although there was no association between the localization of the pain and the GIQLI score (Table 3).

The factor analysis gave five factors the resembled those devised by the instrument developers, although the factor loadings were slightly different (Table 4). As originally devised, subscales with predominantly physical and emotional items could be identified. We also found three subscales with gastrointestinal symptoms (large bowel function, upper gastrointestinal tract symptoms, and meteorism). The differentiation into three different gastrointestinal subscales may reflect the specific characteristics of symptoms in gallstone disease.

Whereas large bowel function symptoms and meteorism are very common in the whole population, they are not associated with gallstones. The items that fell in the upper gastrointestinal tract symptoms are generally considered more strongly associated with the presence of gallstones. There was, however, a paradoxically stronger correlation between the bodily pain score of SF-36 and social dysfunction than between bodily pain and symptoms (Table 2). Although all correlations were significant, the strong association between the purely physical items in SF-36 and the items related to social dysfunction in GIQLI is difficult to

Table 3 Pain localization

Quadrant	Patients with pain		Patients without pain		P
	n	GIQLI score (±SD)	n	GIQLI score (±SD)	
Right upper	63	96 (±21)	22	96 (±26)	0.23
Left upper	13	101 (±18)	72	95 (±23)	0.16
Right lower	13	84 (±22)	72	99 (±22)	0.86
Left lower	5	87 (±20)	80	97 (±22)	0.81

GIQLI, Gastrointestinal Quality of Life Index; SD, standard deviation.

Table 4 Subscale division and factor loadings after factor analysis with varimax rotation

GIQLI item no.	Components	Loading
Component 1 (physical role)		
1	Pain	0.51
18	Appearance	0.74
19	Physical strength	0.71
20	Endurance	0.58
21	Feeling unfit	0.54
22	Daily activities	0.72
23	Leisure activities	0.71
24	Bothered by treatment	0.68
25	Worsened relations	0.60
26	Impaired sexual life	0.62
29	Dysphagia	0.60
	Eigenvalue	6.2
	Variance (%)	17.3
Component 2 (large bowel function)		
6	Abdominal noises	0.54
7	Bowel frequency	0.55
30	Bowel urgency	0.78
31	Diarrhea	0.73
34	Blood in stool	0.58
36	Uncontrolled stools	0.66
	Eigenvalue	4.7
	Variance (%)	13.0
Component 3 (emotional role)		
8	Enjoyed eating	0.59
10	Coping with stress	0.65
11	Sadness	0.65
12	Nervous	0.60
13	Happy with life	0.45
14	Frustrated	0.76
15	Fatigue	0.54
16	Feeling unwell	0.56
	Eigenvalue	4.4
	Variance (%)	12.2
Component 4 (upper gastrointestinal tract function)		
2	Fullness	0.42
9	Restricted eating	0.37
17	Wake up at night	0.66
27	Regurgitation	0.58
28	Eating speed	0.51
32	Constipation	0.70
33	Nausea	0.43
35	Heartburn	0.52
	Eigenvalue	3.2
	Variance (%)	9.0
Component 5 (meteorism)		
3	Bloating	0.65
4	Flatus	0.72
5	Belching	0.43
	Eigenvalue	2.5
	Variance (%)	6.9

GIQLI, Gastrointestinal Quality of Life Index.

explain. It may be that frequent attacks of biliary colic may interfere with the social role as well.

Although the response rate was relatively low in the follow-up questionnaires as we did not send any reminders, we do not believe that this has biased the outcome because there is no obvious reason for a selection mechanism. The patients were sampled from a population-based register; inclusion was not dependent on any circumstances related to the extent of symptoms or decision to undergo surgery.

In conclusion, the Swedish translation of the GIQLI questionnaire has high reliability and validity. The German and English versions are already well established, showing that it is applicable to various populations with gallstone-related symptoms. It can therefore readily be used as a basis for monitoring the outcome after gallstone surgery and for clinical trials.

Acknowledgments

The authors thank Johanna Lönngrén, Eberhard Varenhorst, and Christoph Varenhorst for helping with the translation and retranslation of the German questionnaire. Gudrun Berglund and Gertie Roman made the study possible by assembling all data. The study was supported by a grant from the Bengt Ihre Foundation.

Supplementary materials for this article can be found at: <http://www.ispor.org/publications/value/ViHsupplementary.asp>

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