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Responsiveness and Minimal Clinically Important Differences after Cholecystectomy: GIQLI Versus SF-36

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Abstract
Introduction To compare responsiveness and minimal clinically important differences (MCID) between the Gastrointestinal Quality of Life (GIQLI) and the Short Form 36 (SF-36), we prospectively analyze 159 patients undergoing cholecystectomy at two tertiary academic hospitals.
Patients and Methods All patients completed the disease-specific GIQLI and the generic SF-36 before and 3 months after surgery. Scores using these instruments were interpreted by generalized estimating equation before and after cholecystectomy. The bootstrap estimation was used to derive 95% confidence intervals for differences in the responsiveness estimates.
Results and Discussion Mean changes in all GIQLI and the SF-36 subscales were statistically significant ($p<0.05$). Comparisons of effect size (ES), standardized response means (SRM), and relative efficiency (>1) indicated that the responsiveness of the GIQLI was superior to that of the SF-36. In the equivalence test, all lower or upper confidence limits presented no equivalence (>5), indicating good MCID. The ES and SRM for emotions and physical function in the GIQLI significantly differed from those of the SF-36 ($p<0.05$).
Conclusion The data in this study indicate that clinicians and health researchers should weight disease-specific measures more heavily than generic measures when evaluating treatment outcomes.

Keywords Responsiveness · Minimal clinically important differences · GIQLI · SF-36

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Introduction

Cholecystectomy is the most common procedure for treating symptomatic cholelithiasis or cholecystitis.[1,2] The procedure may be performed via open or laparoscopic approach. This intervention has proven safe and effective for improving health-related quality of life (HRQoL).[3–5]

HRQoL is a multidimensional measure derived by subjectively and objectively assessing physical, psychological, and social attributes, as well as overall life satisfaction.[5,6] Various HRQoL instruments have been used with increasing frequency during the past decade.[6] Disease-specific measures are traditionally administered in longitudinal studies to detect progressive changes in health and quality of life after interventions and tend to focus on physical function and pain. Conversely, generic measures are designed to assess the effects of any disease or condition and are usually adopted by health service researchers to assess overall quality of life. The Medical

Outcomes Study Short Form-36 Health Survey (SF-36) is a self-administered generic HRQoL instrument commonly used to assess overall outcome.[5] The Gastrointestinal Quality of Life Index (GIQLI) measures specific and general HRQoL by including measures of overall quality of life, such as psychosocial well-being, as well as items specifically related to gastrointestinal symptoms.[5]

"Responsiveness" is the accuracy of a measure in assessing longitudinal change in health status over time.[7] A highly responsive HRQoL instrument can detect significant treatment effects in a small sample size or in a single patient. The responsiveness of HRQoL instruments have been evaluated in several studies.[8,9] The minimal clinically important difference (MCID) examines differences at the individual patient level. The MCID is a vital measure given that statistically significant group changes may not exhibit statistical significance at the individual patient level.[9]

The HRQoL is currently weighted more heavily when evaluating health status, particularly regarding medical treatments and interventions. Nevertheless, it is easy to identify the statistical significance of any such changes, but it can be harder to determine whether these changes are clinically relevant. The MCID is one of the most effective and widely used methods of HRQoL assessment and can be used to provide an indication of the minimal change that is of clinical relevance. However, it is rarely used by gastroenterologists to compare responsiveness. Additionally, responsiveness estimates derived by the SF-36 and the GIQLI before and after cholecystectomy have not been clinically compared.

In this prospective cohort study, two well-known HRQoL instruments, the SF-36 and the GIQLI, were used to compare responsiveness and MCID in cholecystectomy patients.

Patients and Methods

Patients and Data Collection

Two HRQoL instruments were used to survey all patients who underwent cholecystectomy performed by any one of three experienced surgeons (KT, HH, YH) at two tertiary academic hospitals in southern Taiwan between April and September, 2007. Twenty-two procedures performed by other low-volume surgeons were excluded from analysis. Patients with cognitive impairment (n=1), severe organ, or psychiatric diseases (n=2) were excluded. One hundred fifty-nine patients who completed preoperative and 3-month surveys after cholecystectomy were enrolled in the study. Immediately before surgery, a trained research assistant administered the SF-36 and the GIQLI in all subjects, and the same assistant used these instruments to assess HRQoL in the 3-month survey.

The study sample included 72 (45.28%) males and 87 (54.72%) females with a mean age of 56.08 years (standard deviation, 15.06 years; range, 22–86 years). Preoperatively, each patient exhibited an average of 0.56 comorbidities, and the principal comorbidities for the study population were hypertension, cardiovascular disease, chronic hepatitis, diabetes, and others, representing the relative frequency 33.7%, 22.5%, 19.1%, 12.4%, and 12.3%, respectively. The average length of stay was 5.25 days (standard deviation, 4.22 days). Patients who underwent laparoscopic cholecystectomies (n=145) and those who underwent open cholecystectomies (n=14) did not significantly differ in baseline age, gender, number of comorbidities, re-hospitalization within 30 days, SF-36 subscales, or GIQLI subscales.

Sample size analysis indicated the power of the present study between two time intervals approximated 100% across SF-36 and GIQLI subscales. This study was approved by the Institutional Review Board of Kaohsiung Medical University Hospital in Taiwan.

Outcome Measures

The two HRQoL survey instruments in this study were the generic Chinese version of the SF-36 and the Chinese version of the GIQLI. The SF-36 Health Survey, a widely used measure of generic HRQoL, includes 36 items for evaluating physical functioning, role limitations due to physical problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and mental health. Each SF-36 subscale was converted to a scale from 0 to 100; the higher the score, the better the HRQoL. A translated version of the SF-36 has been validated in Chinese populations.[10]

The GIQLI is recognized as a valid and reliable instrument for measuring HRQoL, especially in patients undergoing cholecystectomy.[11] Its 36 items include symptoms (19 items), emotions (five items), physical function (seven items), social function (four items), and the effects of medical treatment (one item). Each item is scored from 0 to 4, with a higher score indicating a better HRQoL. The total GIQLI scores range from 0 to 144. A Chinese version of the GIQLI has demonstrated validity.[11]

Statistical Analysis

The unit of analysis was the individual patient. To compare SF-36 and GIQLI subscales, raw scores were transformed and scaled from 0 to 100, with higher scores correlating with improved HRQoL.

The relationship between SF-36 and the GIQLI was first assessed by Pearson correlation preoperatively and at 3-month intervals to evaluate construct validity. Floor and

ceiling effects were estimated by proportional minimum and maximum scores for each HRQoL subscale measured preoperatively and 3 months after cholecystectomy. A floor effect occurs when a high proportion of the total respondents grade themselves at the minimum score. A ceiling effect, inversely, occurs when a high proportion of the total respondents grade themselves at the maximum score.

The generalized estimating equations (GEE) approach was employed to compare longitudinal changes in SF-36 and the GIQLI subscales before and 3 months after cholecystectomy. Each HRQoL subscale was used as a dependent variable as a function of time and covariates: age, gender, number of comorbidities, average length of stay, and laparoscopic/open surgery. Variables were entered into the GEE analysis as covariates because they were statistically significant in the univariate analysis and have proven to be consistent predictors of HRQoL in many previous studies.[12,13] Time was considered a categorical variable.

Responsiveness is the capability of an instrument to detect clinically significant differences in health outcomes important to clinicians and patients.[9] Responsiveness estimates were evaluated in terms of change ratio (CR), effect size (ES), standardized response mean (SRM), and relative efficiency (RE).[14] The CR was calculated as the mean change score divided by baseline scores. The ES was calculated by dividing mean change score by the standard deviation of baseline scores. The SRM was calculated as the mean change score divided by the standard deviation of changed scores. The responsiveness of the CR, ES, and SRM was determined using the following equations:

$$\mathrm{CR} = \frac{\text{Mean Change Score}}{\text{Mean Baseline Score}} \times 100\%$$

$$\mathrm{ES} = \frac{\text{Mean Change Score}}{\text{Standard Deviation of Baseline Scores}}$$

$$\mathrm{SRM} = \frac{\text{Mean Change Score}}{\text{Standard Deviation of Changed Scores}}$$

RE was measured as the relative efficiency of HRQoL determined by each subscale at pre- and post-operation.[15] Therefore, in this study, RE was calculated relative to total SF-36 or GIQLI scores for each HRQoL subscale using the formula $\mathrm{RE}=(t1/t2)^2$, where $t1$ is the t value of a Student paired t test for each subscale, and $t2$ is the t value of a Student paired t test for the SF-36 or the GIQLI total scores. Generally, if RE equals 1, both HRQoL subscales/instruments are equally discriminatory. If RE exceeds 1, the subscale/instrument in the numerator is more efficient in differentiating HRQoL than the subscale/instrument in the denominator and vice versa if RE is less than 1.

The MCID has been defined as the smallest difference between baseline scores and the scores at 3 months in an instrument considered worthwhile or important.[16] The MCID was estimated with a 95% confidence interval at lower and upper limits (CL, CU) by the formula $(\mathrm{CL},\mathrm{CU}) = \left[\left(\overline{d} - t_{\alpha/2}S_{\overline{d}}, \overline{d} + t_{\alpha/2}S_{\overline{d}}\right)\right]$, where $\overline{d}$ is the mean change, $t_{\alpha/2}$ is the critical t value of a Student paired t test, and $S_{\overline{d}}$ is the standard deviation of the mean change scores. A 95% confidence interval at CL and CU indicates that if a patient exhibits a change in score equal to or exceeding the critical value for MCID, the change can be considered with 95% confidence to be reliable and not due to measurement error.[17] In this study, the critical value of MCID=5 (5% or 5 points) was used as the equivalence test to detect true change due to its postoperative 3-month survey. Therefore, a change in CL or CU score of less than −5 or greater than 5 can be interpreted as a true change.

Repeated assessment of a single patient can cause complications because of highly correlated observations within the same patient. To address these issues, the bias-corrected and accelerated bootstrap method with 2,000 replications was employed to compare the responsiveness estimates of the two HRQoL instruments.[18] Differences in ES and SRM between the GIQLI and the SF-36 were estimated, and the bootstrapping method was used to obtain 95% confidence intervals for these differences. All statistical analyses were performed using Stata Statistical Package, Version 9.0 (Stata Corp, College Station, TX, USA). A p value <0.05 was considered statistically significant.

Results

The Pearson correlation coefficients between the SF-36 and the GIQLI after cholecystectomy at preoperative and 3-month surveys were evaluated (Table 1). The GIQLI subscales revealed statistically significant associations with the SF-36 subscales. The Pearson correlation coefficients exhibited statistically significant for each subscale.

Analysis of floor and ceiling effects before and after cholecystectomy indicated the GIQLI outperformed the SF-36 (less than 15% of patients with the maximum or minimum possible scores for symptoms, emotions, and physical functioning subscales; Table 2). The measures of physical and emotional roles in the SF-36 revealed major floor and ceiling effects at preoperative and 3-month surveys. Additionally, the SF-36 exhibited increasing ceiling effects in physical function, social function, and bodily pain before and after cholecystectomy. Similarly, the ceiling effects of the GIQLI subscales were high after cholecystectomy.

Longitudinal changes in all SF-36 and GIQLI subscales revealed statistically significant improvement ($p<0.05$) after adjustment for baseline age, gender, number of comorbidities, average lengths of stay, and laparoscopic/

Table 1 Pearson Correlation Coefficients between the SF-36 and the GIQLI

	SF-36								GIQLI			
	PF	RP	RE	SF	BP	VT	MH	GH	Symptoms	Emotions	Physical	Social
Before cholecystectomy												
PF	1	0.46**	0.45**	0.55**	0.35**	0.49**	0.45**	0.39**	0.56**	0.49**	0.57**	0.54**
RP		1	0.58**	0.49**	0.50**	0.42**	0.41**	0.34**	0.50**	0.45**	0.53**	0.53**
RE			1	0.54**	0.54**	0.46**	0.49**	0.37**	0.57**	0.61**	0.54**	0.60**
SF				1	0.51**	0.59**	0.55**	0.41**	0.57**	0.62**	0.68**	0.63**
BP					1	0.38**	0.38**	0.38**	0.48**	0.36**	0.49**	0.37**
VT						1	0.78**	0.49**	0.35**	0.41**	0.53**	0.41**
MH							1	0.35**	0.48**	0.65**	0.55**	0.53**
GH								1	0.36**	0.34**	0.45**	0.34**
Symptoms									1	0.72**	0.76**	0.71**
Emotions										1	0.69**	0.71**
Physical											1	0.77**
Social												1
After cholecystectomy (3 months)												
PF	1	0.41**	0.37**	0.48**	0.48**	0.41**	0.22*	0.39**	0.40**	0.43**	0.47**	0.42**
RP		1	0.78**	0.58**	0.55**	0.40**	0.37**	0.46**	0.46**	0.54**	0.65**	0.57**
RE			1	0.59**	0.56**	0.39**	0.36**	0.45**	0.46**	0.61**	0.61**	0.56**
SF				1	0.73**	0.51**	0.50**	0.45**	0.55**	0.65**	0.63**	0.64**
BP					1	0.42**	0.35**	0.40**	0.59**	0.61**	0.66**	0.60**
VT						1	0.82**	0.60**	0.51**	0.53**	0.49**	0.48**
MH							1	0.49**	0.44**	0.53**	0.38**	0.42**
GH								1	0.43**	0.56**	0.53**	0.48**
Symptoms									1	0.73**	0.68**	0.74**
Emotions										1	0.83**	0.83**
Physical											1	0.81**
Social												1

PF Physical functioning, *RP* role limitations due to physical problems, *RE* role limitations due to emotional problems, *SF* social functioning, *BP* bodily pain, *VT* vitality, *MH* mental health, *GH* general health, *Physical* physical function, *Social* social function
* $p<0.05$; ** $p<0.01$

open surgery (Fig. 1). The SF-36 and the GIQLI before and 3 months after cholecystectomy revealed improvement rates of from 6.76% to 60.83% and from 20.33% to 43.66%, respectively. Further, the GEE approach produced the highest mean scores for GIQLI symptoms 3 months after cholecystectomy. Specifically, as compared to a relatively low score of 51.26 before cholecystectomy, the mean SF-36 score for role limitations due to physical problems was 81.60 after cholecystectomy, an improvement of 59.20%. The mean SF-36 score for role limitations due to emotional problems changed from 51.90 to 83.08, indicating that the role limitations due to emotional problems was the most improved subscale, with an improvement rate of 60.83%. The least improved SF-36 subscale was general health, with an improvement rate of 6.76%.

Except for the general health subscale in the SF-36, all SF-36 and GIQLI subscales revealed considerable differences between responsiveness estimates calculated preoperatively and those calculated 3 months after cholecystectomy (Table 3). Further, equivalence test results revealed the 95% confidence interval of MCID scores (CL, CU) all exceeded 5, except for the SF-36 general health (CL=1.20). However, the estimated responsiveness and MCID in the GIQLI were generally higher than those of the SF-36 before and after cholecystectomy. Therefore, the correlation between the GIQLI and the SF-36 required use of the bootstrap method to analyze differences in responsiveness. Because the GIQLI subset symptoms cannot be compared with any SF-36 subset, we choose emotional, physical function, and social function for responsiveness differences comparison. Table 4 displayed statistical differences between the GIQLI and the SF-36 in responsiveness estimates of ES and SRM. The differences were considered statistically significant at confidence intervals other than zero. The emotional and physical function subscales statistically differed between the GIQLI and the SF-36, but the social functioning subscales did not. The GIQLI exhibited better responsiveness in the emotional and physical function subscales, whereas the SF-36 revealed better responsiveness in the social function subscale.

Table 2 Floor and Ceiling Effects before and 3 Months after Cholecystectomy

	Before cholecystectomy		After cholecystectomy (3 months)	
	Floor effect (%)	Ceiling effect (%)	Floor effect (%)	Ceiling effect (%)
SF-36				
PF	4.40	29.56	1.26	48.43
RP	21.51	44.65	16.35	67.99
RE	26.54	48.43	15.09	69.25
SF	0.63	31.45	0.63	46.54
BP	1.89	10.69	1.26	28.93
VT	0.63	1.89	0.63	2.89
MH	2.52	1.89	0.63	2.52
GH	2.52	3.77	1.26	3.14
GIQLI				
Symptoms	0.63	3.14	0.63	11.38
Emotions	0.63	5.66	0.63	12.70
Physical	0.63	1.26	0.63	4.59
Social	1.26	27.67	0.63	35.91

PF Physical functioning, *RP* role limitations due to physical problems, *RE* role limitations due to emotional problems, *SF* social functioning, *BP* bodily pain, *VT* vitality, *MH* mental health, *GH* general health, *Physical* physical function, *Social* social function

Discussion

Based on the assessments of the GIQLI and the SF-36, this comparative study yielded systematic and comprehensive data regarding responsiveness and MCID in patients undergoing cholecystectomy.

Preoperative and 3-month postoperative Pearson correlation analyses revealed significant correlation between the SF-36 and GIQLI. Thus, these two measures demonstrated construct validity, which is consistent with previous studies.[6,11]

An ideal HRQoL instrument should produce neither floor nor ceiling effects. Regarding the floor and ceiling effects of the SF-36 and the GIQLI, there seems to be room for improvement in these two measures. As Wyrich et al.[19] pointed out, 15% would be a critical value for the largest proportion of patients who should score the maximum or minimum possible scores. In this study, the GIQLI revealed no floor or ceiling effects before or after cholecystectomy, but the social functions subscale revealed a remarkable significant notable ceiling effect. Before cholecystectomy, the SF-36 exhibited a floor effect in role limitations due to physical and emotional problems and a ceiling effect in physical functioning and social functioning, as well as role limitations due to physical and emotional problems. After medical intervention and treatment management, the floor effect decreased at 3-month survey. However, as cholecystectomy is widely performed and has a high success rate, the ceiling effect is extremely problematic in postoperative outcome measurement. Therefore, discriminating between patients presenting a ceiling effect and determining the impact of underestimating its effect after cholecystectomy may be extremely difficult.

Analysis of longitudinal changes indicated the role limitations due to physical and emotional problems of the SF-36 exhibited the highest improvement rate. Before cholecystectomy, the mean scores for physical and emotional roles were relatively lower than those for other scales, probably because these roles were limited by the physical and emotional function of patients. The patients could resume their role limitations immediately after cholecystectomy. Conversely, the areas of pain relief and symptom functions revealed relatively greater improvement

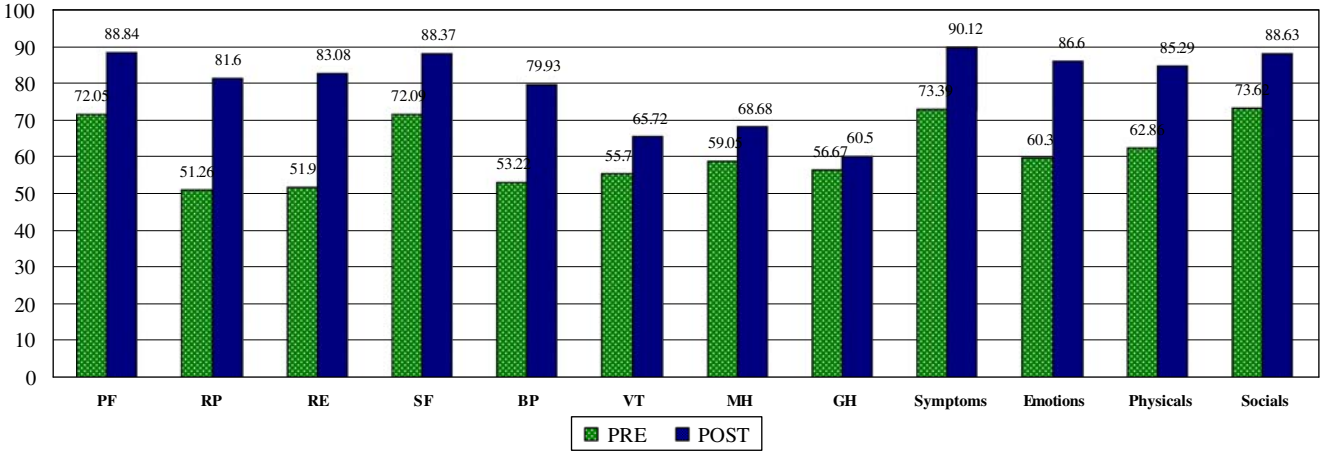

Figure 1 Longitudinal changes in each subscale of the SF-36 and the GIQLI before and 3 months after cholecystectomy. Domains: *PF* physical functioning, *RP* role limitations due to physical problems, *RE* role limitations due to emotional problems, *SF* social functioning, *BP* bodily pain, *VT* vitality, *MH* mental health, *GH* general health, *Symptoms*, *Emotions*, *Physical* function, *Social* function. All *p* values denote statistically significant differences between preoperative and 3-month postoperative baseline scores for age, gender, number of comorbidities, average lengths of stay, and laparoscopic versus open surgery.

Table 3 Estimated Responsiveness and MCID for the SF-36 and the GIQLI

	Responsiveness estimates				MCID	
	CR (%)	ES	SRM	RE	CL	CU
SF-36						
PF	23.29	0.53	0.55	0.30	12.03	21.54[a]
RP	59.20	0.64	0.61	0.37	22.59	38.10[a]
RE	60.83	0.64	0.57	0.33	22.73	39.64[a]
SF	22.58	0.63	0.64	0.41	12.33	20.22[a]
BP	50.19	1.04	0.93	0.86	22.25	31.17[a]
VT	17.99	0.52	0.53	0.28	7.11	12.93[a]
MH	16.30	0.47	0.52	0.27	6.73	12.52[a]
GH	6.76	0.17	0.23	0.05	1.20	6.46[a]
GIQLI						
Symptoms	22.79	0.86	0.87	0.76	13.75	19.70[a]
Emotions	43.66	1.12	1.10	1.20	22.59	30.05[a]
Physical	35.70	1.01	0.91	0.82	18.61	26.27[a]
Social	20.33	0.62	0.60	0.36	11.09	18.87[a]
Total scores	28.13	1.02	1.00	1.00	16.41	22.44[a]

MCID Minimal clinically important differences, *PF* physical functioning, *RP* role limitations due to physical problems, *RE* role limitations due to emotional problems, *SF* social functioning, *BP* bodily pain, *VT* vitality, *MH* mental health, *GH* general health, *Physical* physical function, *Social* social function, *CR* change ratio, *ES* effect size, *SRM* standardized response means, *RE* relative efficiency, *CL* 95% confidence interval at lower limit, *CU* 95% confidence interval at upper limit

[a] No equivalence (good responsiveness)

than other functions. Taken together, perhaps this might imply that cholecystectomy improves role limitations due to emotional or physical problems by relieving bodily pain and emotional burdens that accompany cholecystitis/symptomatic cholelithiasis. Consequently, improved role limitations, pain relief, and symptom function might improve physical, emotional, and social functions, as well as overall quality of life. However, minor improvements in physical function, vitality, and mental health were found immediately after cholecystectomy, which may explain the poorest improvement rate in the SF-36 general health subscale. This might implicate that symptomatic cholelithiasis or cholecystitis is not a severe disease to such a patient group.

This study is the first to compare the GIQLI and the SF-36 for responsiveness and MCID in cholecystectomy patients treated at two medical centers. The data derived by this study can help clinicians and health researchers decide which measure is most effective for evaluating HRQoL before and after cholecystectomy. The responsiveness estimates for the GIQLI generally exceeded 0.5, which can be interpreted as medium change.[20] The SF-36 also presented good results in all subscales except mental and general health, which revealed improvement after surgery. Additionally, ES and SRM estimates were conceptually similar, which is consistent with an earlier finding reported by Zou.[21]

Schmitt and Di Fabio[9] suggested that statistically significant group changes may not exhibit statistical significance at the individual level. Based on the patient outcomes reported in that study, MCID is an essential measure for comparing two HRQoL instruments. In a subsequent study of patients undergoing total knee replacement,[7] MCID ranged from 14.52 (stiffness) to 22.87 (pain) on the Western Ontario and McMaster Universities Osteoarthritis Index, and SF-36 ranged from 11.56 (physical functioning) to 16.86 (bodily pain). In the 6-month survey of another study of patients with obstructive sleep apnea, the SF-36 vitality scores were 20.7–24.2 points. At the 18-month survey, scores for role limitation due to physical problems, social functioning, vitality, and general health were 2.5–7.5, 5.5–6.6, 7.5–8.7, and 13.5–15.5 points, respectively.[22] A comprehensive literature review reveals no other reports of GIQLI to calculate the MCID.

The 95% confidence interval of the MCID (CL, CU) for each subscale of the GIQLI or the SF-36 in this study

Table 4 Comparative Responsiveness Estimates of Effect Size and Standardized Response Mean of the GIQLI and the SF-36

Subscale	GIQLI–SF-36 (estimate [95% CI])[a]	
	Effect size	Standardized response mean
Emotional	0.48 (0.12, 0.84)	0.53 (0.21, 0.85)
Physical function	0.48 (0.22, 0.74)	0.36 (0.13, 0.59)
Social function	−0.01 (−0.33, 0.31)	−0.04 (−0.34, 0.26)

[a] Differences are presented in effect size and standardized response mean (95% confidence interval obtained by bootstrapping).

Table 5 Comparative Effectiveness of HRQoL Instruments Reported in Previous Studies

Authors (publication date)	Country	No. of subjects	Measurement time intervals	Instrument	Findings
Shi HY et al. (present study)	Taiwan	159	Preoperative and 3-month surveys	GIQLI, SF-36	GIQLI revealed greater overall effectiveness than the SF-36 between preoperative and 3-month surveys
Drossman D et al. (2007)26	USA	402	Preoperative and 3-month surveys	IBS-QOL, SIP	IBS-QOL exhibited treatment responsiveness superior to the SIP; meaningful clinical improvement was 2.8 points for SIP and 14 for IBS-QOL
Finan KR et al. (2006)27	USA	55	Preoperative and 17.1-month surveys	GISS, SF-36	GISS was relatively more effective for GI symptoms than the SF-36
Quintana JM et al. (2005)5	Spain	650	Preoperative and 3-month surveys	GIQLI, SF-36	GIQLI was relatively more effective than the SF-36 for those who were considered appropriate candidates for cholecystectomy
Quintana JM et al. (2001)28	Spain	353	Preoperative and 3-month surveys	GIQLI, SF-36	Responsiveness of the GIQLI, as measured by mean standardized response, ranged from 0.45 to 0.82, which was superior to that of the generic questionnaire SF-36 (0.20 to 0.56)

GIQLI Gastrointestinal Quality of Life Index, *SF-36* Medical Outcomes Study Short Form-36 Health Survey, *IBS-QOL* Irritable Bowel Syndrome-Quality of Life, *SIP* Sickness Impact Profile

exceeded 5 (except SF-36 general health), indicating significantly improved health status after cholecystectomy. The MCID observed in this study was higher than that reported in previous studies of cholecystectomy patients,[7,23] which may be attributable to differing medical treatment or disease severity.

Importantly, although the improvements were in different subscales of the GIQLI and the SF-36, the estimated effectiveness of the GIQLI generally was greater than that of the SF-36. However, such effectiveness estimates in previous studies[4,5] were made using a small sample size or lacked comparative statistical data before and after interventions. Thus, the bootstrap method employed in this study generated a 95% confidence interval. Although the two measures significantly differed in responsiveness, each exhibited superior responsiveness in different subscales. The GIQLI exhibited superior responsiveness in emotional and physical function subscales, whereas the SF-36 had better responsiveness in social function. This difference may have been due to the additional SF-36 subscales for vitality, mental health, and general health, which had low responsiveness.

An acknowledged limitation of this study is the small sample size, which restricts the extent to which the findings can be generalized to larger populations. Future studies are needed to examine outcomes, patient attributes, hospital attributes, quality of care, preoperative functional status, and related factors in a larger population. Further, the patient outcome may be highly dependent on variables such as operator proficiency, advancing technology, and available facilities.[24,25] However, all procedures evaluated in this study were performed by surgeons with the most experience in cholecystectomy procedures in each of two different institutions, and the potential confounding factors in both effectiveness and MCID were controlled simultaneously. Given this design, the surgical outcomes in this study were more representative than those of a single-surgeon study.

Table 5 presents a cross-sectional comparison to confirm the data regarding the effectiveness of the GIQLI and the SF-36. Data from this and four other similar studies performed in the United States and Europe were comparatively analyzed.[5,26–28] All four studies were comparable to the current study in sample size, performance of both preoperative and postoperative surveys, and application of both disease-specific and generic HRQoL instruments. While several other studies in orthopedic surgery and medicine have used MCID to compare HRQoL instruments,[6,7] no investigators have applied MCID calculations to the GIQLI. The current finding of greater responsiveness of the disease-specific measure in comparison with the generic measure was consistent with all comparable studies examined. Specifically, the increased responsiveness of the disease-specific measure suggests that symptoms and related functions improve more rapidly and more completely than overall quality of life in patients who undergo cholecystectomy.

In conclusion, the comparative results of this prospective cohort study provide comprehensive and systematic information regarding the expected responsiveness and MCID in patients undergoing cholecystectomy. The GIQLI exhibited

responsiveness superior to that of the SF-36 between the preoperative and 3-month surveys. Therefore, clinicians and health researchers may consider weighting the disease-specific measure more heavily than the generic measure to determine treatment effectiveness. Further study may also examine the extent to which the HRQoL instrument is applicable to other forms of gastrointestinal surgery.

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