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Validation Assessment of the Chinese (Taiwan) Version of the Gastrointestinal Quality of Life Index for Patients with Symptomatic Gallstone Disease

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ABSTRACT

***Background*: Symptomatic gallstone is one of the most common diseases in Taiwan. The aim of this study was to develop a Mandarin Chinese outcomes measure for the assessment on quality of life among gallstone patients.**

***Materials and Methods*: The Gastrointestinal Quality of Life Index (GIQLI) is a valid, disease-specific measure for the evaluation of health status and treatment effectiveness for adults with chronic gastrointestinal condition. The GIQLI was translated into Mandarin Chinese using a parallel model. The Chinese (Taiwan) version of the GIQLI (CGIQLI) was administered to 102 patients with symptomatic gallstone disease in a prospective manner; the CGIQLI then was validated according to established criteria for reliability, validity, and longitudinal sensitivity.**

***Results*: The CGIQLI demonstrates good test-retest reliability ($r = 0.92$, $P < 0.001$) and internal consistency (Cronbach's $\alpha = 0.92$). The CGIQLI significantly correlates with the Mandarin Chinese (Taiwan) version of the generic 36-Item Short-Form Health Survey (SF-36). The standardized response mean for the CGIQLI total score is 0.96, indicating excellent sensitivity to clinical change in the study group.**

***Conclusion*: This validation study demonstrated that the performance characteristics of the CGIQLI are equivalent to the English version, the GIQLI. This study demonstrates that the CGIQLI is a valid tool to evaluate adults with chronic gastrointestinal problems among the Chinese-speaking population.**

INTRODUCTION

Symptomatic gallstone is one of the most common diseases in the world; laparoscopic cholecystectomy (LC) is currently the standardized management for the treatment gallstone.[1–5] Since the 1990s, several articles have been published regarding the severity of symptoms, nature of gallstones, and benefits and risk of LC, based on the information obtained from some 5500 LC surgeries performed in the Cathay General Hospital (Taipei, Taiwan).[6–11] It is obvious that LC indeed benefits patients, especially for those with severe symptoms. Unfortunately, limited studies have focused on the quality of life among patients with gallstone; and the health-related quality-of-life status following LC remains unknown among the Chinese-speaking population, which is

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in need of a patient-centered outcomes measure to gain a more comprehensive insight of gallstone patients' well-being.

The Gastrointestinal Quality of Life Index (GIQLI) is a validated outcomes measure designed to evaluate health impact and treatment effectiveness for adults with chronic gastrointestinal conditions. The GIQLI has been used to identify quality-of-life consequences of chronic gastrointestinal conditions, such as physical symptoms, mental problems, digestion, and defecation associated with gastrointestinal diseases. Whereas treatment effectiveness in chronic gastrointestinal conditions have been established through conventional studies, the patient-based GIQLI enables physicians to understand the effects of gastrointestinal diseases and its intervention on the functioning and well-being of patients from their point of view.[12–14]

The need for quality-of-life instruments is global; ideally, similar instruments will be used in different cultures to allow for comparison and collaboration. However, because different cultures adopt different values and norms, a linguistic translated instrument must also be appropriately adapted and evaluated in culture.

There is currently no validated Chinese-language quality-of-life instrument to evaluate patients with chronic gastrointestinal disease. Rather than design a new instrument, it is believed that having a common tool available in both English and Chinese will make it possible to combine data from various centers worldwide for analysis. A uniform gastrointestinal outcomes measure will provide cross-cultural quality-of-life information and provide a way to compare treatment effectiveness under different health care systems. The aims of this study were to translate and validate a Chinese (Taiwan) version of the GQLI (CGIQLI), and to compare the performance characteristics between the CGIQLI and the original GIQLI. The performance characteristics of a quality-of-life measure include its validity, reliability, and responsiveness to clinical change.

MATERIALS AND METHODS

The GQOLI

The GIQLI was originally developed by Eypasch et al.[12] The GIQLI is a 36-item survey that evaluates the physical and mental problems associated with chronic gastrointestinal disease on a Likert scale; each survey question has five response options (0–4, worst to best condition). The GIQLI generates a total score and four subscale scores (physical well-being 0–40, mental well-being 0–20, gastrointestinal digestion 0–40, and gastrointestinal defecation 0–24). The physical well-being subscale reflects the limitations in physical or social activities directly related to chronic gastrointestinal conditions. The three remaining subscales are reflective of a patient's mental, digestive, and defecation problems. Survey total and subscale scores are normalized on a 0 ("worst") to 144 ("best") scale based on published algorithms. The GIQLI was designed to evaluate adult patients with chronic gastrointestinal diseases.

Instrument translation

The production of the Chinese (Taiwan) version of the GIQLI followed the standard forward, backward, and pretest steps for instrument translation. Authorization to translate was secured in advance. The GIQLI was first translated into Mandarin Chinese and then back into English iteratively by two bilingual physicians, until the two versions were considered completely interchangeable. A bilingual lay panel consisting of three heterogeneous individuals was then used to measure comprehensibility, test translation alternatives, highlight unexpected errors, and reveal inappropriate survey items.

Study population

One hundred and two (102) consecutive adult patients with a diagnosis of symptomatic gallstone disease were prospectively enrolled. Diagnosis was made based on symptoms consistent with cholecystitis (i.e, right-upper quadrant abdominal pain with or without back or shoulder radiation, fat meal intolerance, nausea and vomiting, etc.) and the sonographic presence of gallstones. Diagnoses for all patients were later histopathologically confirmed after surgery.

Survey forms

Upon entry into this study, all patients received the self-administered CGIQLI and the research-validated Mandarin Chinese (Taiwan) version Medical Outcome Study 36-Item Short-Form Health Survey (SF-36).[15–17] Permission to use the SF-36 was obtained from the Medical Outcomes Trust of Boston. The SF-36 is a widely used, generic quality-of-life measure with eight domains of general health, including: physical function (PF), role functioning-physical problems (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role functioning-emotional problems (RE), and mental health (MH). Scores are tabulated according to published algorithms from 0 ("worst") to 100 ("best").[18–20]

Reliability of the CGIQLI

Fifty-six (56) patients with symptomatic gallstone disease awaiting surgical scheduling and without known interval clinical change from treatment were retested with the CGIQLI after a 2- to 4-week interval. The Spearman

rank-order correlation coefficients were used to determine the test-retest reliability for subscales, as well as for total survey scores; the item-total, subscale-subscale, and subscale-total correlations were also calculated by using the same statistical method. Cronbach's α correlation coefficients were used to calculate the internal consistency of the CGIQLI.

Validity of the CGIQLI

The CGIQLI was assessed for convergent and divergence validity through correlations to validated SF-36. A total of 102 complete sets of the CGIQLI and SF-36 were obtained.

Responsiveness of the CGIQLI

All 102 patients participating in the validity test were again tested with the CGIQLI 2 months after standard LC surgery. The conditions of these patients were determined by their physicians to have had clinical recovery based on standard criteria at the 2-month postoperative evaluation. Longitudinal sensitivity to clinical change was calculated as the standardized response mean (SRM = response mean/response standard deviation), according to methodology described by Liang et al.[21]

Statistical analysis

All data were stored in Access 7.0 database (Microsoft; Redmond, Seattle). Analyses were conducted using STATA software package (STATA Corp; College Station, TX).

RESULTS

Study population

The mean age for these 102 patients was 49.7 ± 13.6 years (range, 23–75); 69 of the patients (67.7%) were female and 33 (32.3%) were male. Fifty-six (56) patients (54.9%) participated in the retest.

Reliability of the CGIQLI

Internal consistency. Cronbach's α correlation coefficients for internal consistency was 0.80 for the physical well-being subscale, 0.88 for the mental well-being subscale, 0.84 for the gastrointestinal digestion subscale, 0.57 for the gastrointestinal defecation subscale, and 0.92 for the total survey. The comparisons of internal consistency between the GIQLI and CGIQLI are shown in Table 1. T1

Intrasurvey reliability. The item-total, intersubscale, and subscale-total correlation coefficients are tabulated in Tables 2 and 3. Overall, the individual items correlated well with the total score ($P < 0.001$). The item-total correlation coefficients varied from 0.50 (item 8) to 0.89 (item 11). The intersubscale correlations vary from 0.49 (mental well-being with gastrointestinal defecation) to 0.69 (gastrointestinal defecation with gastrointestinal digestion) ($P < 0.05$). The subscale scores all correlated well with the total survey score ($P < 0.001$). The subscale-total correlation coefficients ranged from 0.77 (gastrointestinal defecation) to 0.86 (physical well-being and gastrointestinal digestion). T2 T3

Test-retest reliability. The test-retest reliability of individual subscales and total score are high; the correlation coefficients for physical well-being, mental well-being, gastrointestinal digestion, gastrointestinal defecation subscores, and total score were 0.93, 0.95, 0.90, 0.86, and 0.92, respectively ($P < 0.001$) (Table 4). T4

Validity of the CGIQLI

The correlations between CGIQLI and the eight subscale scores of the SF-36 are shown in Table 5. Overall, the CGIQLI physical well-being, mental well-being, gastrointestinal digestion, and gastrointestinal defecation T5

Table 1. Internal Consistency (Cronbach's Alpha) of the CGIQLI

	GIQLI (n = 125)		*CGIQLI (n = 102)*	
	Mean ± SD	*α*	*Mean ± SD*	*α*
Subscale				
Physical well-being	25 ± 9	0.91	23.9 ± 6.8	0.80
Mental well-being	14 ± 4	0.87	12.7 ± 4.2	0.88
Gastrointestinal digestion	32 ± 6	0.83	26.4 ± 7.3	0.84
Gastrointestinal defecation	21 ± 3	0.75	19 ± 3.5	0.57
Total scores	107 ± 20	0.93	95 ± 20.5	0.92

GIQLI, Gastrointestinal Quality of Life Index; CGIQLI, Chinese (Taiwan) version of the GIQLI.

TABLE 2. ITEM-TOTAL (IT) CORRELATIONS OF THE CGIQLI

	CGIQLI			
	No.	*Mean ± SD*	*IT correlate*	P[a]
Physical well-being				
Item 8	102	2.01 ± 1.22	0.50	<0.001
Item 15	102	2.23 ± 1.09	0.58	<0.001
Item 16	102	2.30 ± 1.08	0.68	<0.001
Item 18	102	3.03 ± 1.00	0.56	<0.001
Item 19	102	2.28 ± 1.08	0.79	<0.001
Item 20	102	2.32 ± 1.05	0.75	<0.001
Item 21	102	1.71 ± 1.24	0.57	<0.001
Item 22	100	2.64 ± 1.37	0.50	<0.001
Item 23	102	2.18 ± 1.21	0.58	<0.001
Item 33	102	3.25 ± 0.98	0.52	<0.001
Mental well-being				
Item 10	102	2.31 ± 0.88	0.77	<0.001
Item 11	102	2.77 ± 0.95	0.89	<0.001
Item 12	102	2.48 ± 1.06	0.87	<0.001
Item 13	102	2.12 ± 1.13	0.80	<0.001
Item 14	102	3.03 ± 1.02	0.81	<0.001
Gastrointestinal digestion				
Item 1	102	2.31 ± 1.26	0.76	<0.001
Item 2	102	2.02 ± 1.27	0.76	<0.001
Item 3	102	2.14 ± 1.23	0.81	<0.001
Item 4	102	2.23 ± 1.00	0.55	<0.001
Item 5	102	2.75 ± 1.13	0.66	<0.001
Item 6	102	2.75 ± 1.00	0.67	<0.001
Item 27	100	3.21 ± 1.06	0.49	<0.001
Item 28	102	2.67 ± 1.27	0.58	<0.001
Item 32	102	3.15 ± 1.12	0.43	<0.001
Item 35	102	3.16 ± 1.05	0.66	<0.001
Gastrointestinal defecation				
Item 7	102	2.84 ± 1.08	0.67	<0.001
Item 26	102	2.94 ± 1.02	0.42	<0.001
Item 30	102	2.96 ± 1.16	0.58	<0.001
Item 31	102	3.31 ± 0.97	0.70	<0.001
Item 34	102	3.78 ± 0.65	0.43	<0.001
Item 36	102	3.16 ± 1.18	0.58	<0.001

CGIQLI, Chinese (Taiwan) version of the Gastrointestinal Quality of Life Index.
[a]Pearson's correlation coefficient.

subscale scores demonstrated significant correlations with most of the SF-36 subscale scores, except for the poorer correlation between the SF-36 MH and CGIQLI gastrointestinal defecation subscales ($r = 0.14$). The CGIQLI total score correlated well with all the SF-36 subscale scores; the correlation coefficients varied from 0.29 to 0.62.

Responsiveness of the CGIOLI

Of the 102 patients who underwent clinically successful LC, the SRM for the CGIQLI total score was 0.967, indicating an excellent responsiveness or sensitivity to clinical change. The SRM for physical well-being, mental well-being, gastrointestinal digestion, and gastroin-

TABLE 3. INTERSCALES AND SUBSCALE-TOTAL CORRELATIONS OF THE CGIQLI

	Physical well-being	*Mental well-being*	*Gastrointestinal digestion*	*Gastrointestinal defecation*
Mental well-being	0.62[a]			
Gastrointestinal digestion	0.63[a]	0.52[a]		
Gastrointestinal defecation	0.54[a]	0.49[a]	0.69[a]	
Total scores	0.86[a]	0.79[a]	0.86[a]	0.77[a]

CGIQLI, Chinese (Taiwan) version of the Gastrointestinal Quality of Life Index.
[a]Pearson's correlation coefficient ($P < 0.05$).

Table 4. Test-Retest Reliability of CGIQLI

	No.	*Spearman* r	P
Physical well-being	56	0.93	<0.001
Mental well-being	56	0.95	<0.001
Gastrointestinal digestion	56	0.90	<0.001
Gastrointestinal defecation	56	0.86	<0.001
Total scores	56	0.92	<0.001

CGIQLI, Chinese (Taiwan) version of the Gastrointestinal Quality of Life Index.

testinal defecation subscale scores were 0.647, 0.692, 1.08, and 0.493, respectively.

DISCUSSION

Understanding disease-related quality of life and health status is a global issue for practice physicians. Outcomes data collected from various health care systems can enhance our understanding of disease impact and its treatment effectiveness. A significant percentage of the world population reports Chinese as their primary language and this demographic is growing. In the past, there has been no Chinese instrument available to assess quality-of-life outcomes for patients with chronic gastrointestinal diseases. This study demonstrated that the Chinese (Taiwan) version of the GIQLI is a valid, disease-specific health measure that can be used to evaluate adult patients with chronic gastrointestinal problems among the Chinese-speaking population.

The aim for a cross-cultural adaptation of an outcomes measure is to remove the difficulties barring the optimal transfer of informational, emotional, and stylistic content of the original survey. Development of the CGIQLI has followed the standard forward, backward, and pretest steps for instrument translation. The parallel model approach used in this study sought to establish a basis for cross-national comparability in the original validation stages of the GIQLI.

The CGIQLI demonstrates robust test-retest reliability for subscales, as well as for its total score. The test-retest reliability for the physical well-being, mental well-being, gastrointestinal digestion, and gastrointestinal defecation subscale scores, as well as for the total score (correlation coefficients ranged from 0.86 to 0.95) all exceeded the excellent level of statistical association (>0.8). Internal consistency for the CGIQLI total score (Cronbach's α = 0.92) exceeded the recommended level of 0.7 commonly used to establish a reliable measure for population studies[22] and is comparable to the English version of the GIQLI (0.93).[12]

Correlations of the CGIQLI with the SF-36 general health measure are used as a test of convergent validity. The Chinese (Taiwan) version of the SF-36 was validated through standard statistical procedures used previously by other researchers.[16,17] The CGIQLI total survey score shows significant correlations with all eight subscales of the SF-36, including PF, RP, BP, GH, VT, SF, RE, and MH. These significant correlations also imply that symptomatic gallstone disease might have remarkable impact on a patient's general health.

Responsiveness, or sensitivity to longitudinal change, is the ability of a health instrument to detect clinical change over time. The CGIQLI demonstrates a very high standardized response mean (0.967), indicating excellent responsiveness to clinical change (a value of 0.2 or less is poor, 0.5 is moderate, and 0.8 or greater is excellent responsiveness).[22,23] Hence, the CGIQLI meets the criteria for a sensitive instrument that can be used in clinical studies of therapy for chronic gastrointestinal diseases.

CONCLUSIONS

This study demonstrated that the CGIQLI is a valid, reliable, and sensitive tool for outcomes measurement. The validation demonstrates only minor language effects; the statistical properties of CGIQLI are compatible with

Table 5. Correlations Between CGIQLI and SF-36

SF-36	*Physical well-being*	*Mental well-being*	*Gastrointestinal digestion*	*Gastrointestinal defecation*	*Total scores*
PF	0.28[a]	0.22[a]	0.20[a]	0.25[a]	0.29[a]
RP	0.31[a]	0.22[a]	0.19	0.26[a]	0.30[a]
BP	0.60[a]	0.44[a]	0.54[a]	0.46[a]	0.62[a]
VT	0.52[a]	0.56[a]	0.36[a]	0.25[a]	0.52[a]
RE	0.39[a]	0.34[a]	0.24[a]	0.32[a]	0.39[a]
SF	0.51[a]	0.47[a]	0.28[a]	0.33[a]	0.48[a]
GH	0.57[a]	0.54[a]	0.35[a]	0.28[a]	0.53[a]
MH	0.34[a]	0.56[a]	0.22[a]	0.14	0.39[a]

PF, physical functioning; RF, role-functioning-physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role-functioning-emotional; MH, mental health.

CGIQLI, Chinese (Taiwan) version of the Gastrointestinal Quality of Life Index.

[a]Spearman correlations ($P < 0.05$).

the English version of the GIQLI. The CGIQLI is a validated equivalent of the GIQLI that can be used to measure quality-of-life outcomes of chronic gastrointestinal diseases among billions of adults in the Chinese-speaking population. With the validated CGIQLI, clinicians are able to conduct further studies on the quality of life and treatment effectiveness for patients with gallstone.

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