INTRODUCTION

In addition to standard outcome measures, such as morbidity, mortality, and survival rates, quality of life (QOL) measurements specific to gastrointestinal disease have become increasingly important for assessing the efficacy of gastrointestinal surgery. To achieve a standard QOL measurement that allows global, cross-study comparisons, it is necessary to adopt a disease-specific questionnaire that is validated in the perioperative phase.

The Gastrointestinal Quality of Life Index (GIQLI) is a commonly used questionnaire that was first developed and validated in German, then subsequently translated into English. The survey includes 36 items divided into five domains: symptoms, physical dysfunction, emotional dysfunction, social dysfunction, and effect of medical treatment.

Validating the Japanese version of the Gastrointestinal Quality of Life Index (GIQLI) questionnaire

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Abstract
Aim: To validate a Japanese version of the Gastrointestinal Quality of Life Index (GIQLI) in patients with symptomatic gallstone disease.

Methods: We investigated responsiveness, reliability, and convergent validity of the translated GIQLI in patients who underwent elective laparoscopic cholecystectomy. Questionnaire scores were compared with the Gastrointestinal Symptom Rating Scale (GSRS) to verify convergent validity.

Results: There were 120 patients originally enrolled in the study; three were excluded after their surgery as they no longer met the inclusion criteria. Questionnaires were collected from the remaining 117 patients (100% response rate). At 2 weeks postsurgery, total GIQLI score increased significantly from pre-surgery levels, suggesting high responsiveness. Cronbach’s alpha ranged from 0.901 to 0.934 for the total score, while a comparison of scores at 2 vs 6 weeks post-surgery yielded an intra-class correlation coefficient of 0.843; thus, the Japanese version of the questionnaire was reliable. Correlations with GSRS ranged between −0.459 and −0.679, indicating fair to good convergent validity.

Conclusion: The Japanese GIQLI had high responsiveness and reliability to assess how surgery for symptomatic gallstone disease influenced patient quality of life.

KEYWORDS
Gallstone disease, gastrointestinal surgery, quality of life, reliability, responsiveness
Each domain includes 4-19 items except for the last one, which contains only a single item. Items are scored on a 5-point scale (most desirable option: 4 points, least desirable option: 0 points), where the total score is the sum of item points and ranges from 0 to 144, with higher scores indicating better QOL. The responsiveness and internal consistency of the GIQLI was first assessed in patients undergoing laparoscopic cholecystectomy. Next, it was applied to patients subjected to other gastrointestinal surgeries, such as Nissen fundoplication, sigmoid resection, and restorative proctocolectomy with ileal pouch anal anastomosis. However, the GIQLI is not available in other languages, including Japanese. Another option already translated into Japanese is the Gastrointestinal Symptom Rating Scale (GSRS). However, this scale was specifically designed to evaluate gastrointestinal reflux disease and is heavily focused on the severity of gastrointestinal symptoms. Moreover, it has not been validated in the perioperative phase.

With the goal of using an internationally comparable tool to investigate post-surgery QOL in Japan, we translated the GIQLI into Japanese and validated the Japanese-language GIQLI with patients who underwent laparoscopic cholecystectomy.

2 | MATERIALS AND METHODS

2.1 | Japanese version of the GIQLI (JGIQLI)

Two of the authors (YW and HO) with fluent knowledge of gastrointestinal disease translated the English GIQLI into Japanese. The translation did not exhibit major deviations from the original version in terms of linguistic, social, and religious differences between the West and Japan. Permission to conduct this validation was obtained from Dr Eypasch, the first author of the original GIQLI. The JGIQLI and original GIQLI are provided in Appendices S1 and S2, respectively.

2.2 | Patients

Questionnaire validity was verified prospectively with patients who underwent elective laparoscopic cholecystectomy for symptomatic gallstone disease. All patients were 20 years or older and native Japanese speakers. Surgery was performed at Hiroshima University Hospital or Hiroshima Memorial Hospital. Patients were excluded if they had advanced dementia, severe comorbidities, neoplastic lesions, or abdominal lesion-related pain (excluding gallstones). Following the original procedure, patients were asked to complete the JGIQLI immediately before surgery, as well as at 2 and 6 weeks post-surgery. Patients were also asked to complete the GIQLI to enable a results comparison for validation. The sample size was calculated as 101 patients with a confidence coefficient of 0.95. This calculation was based on the original survey’s “Responsiveness” findings that had a standard deviation of 17.52 and 95% confidence interval (101.06 – 107.91) at 2 weeks post-surgery. The target number of cases was 120 patients assuming a dropout rate of 15%. Our Institutional Review Board approved a gift card with a value equivalent to 1000 yen to be sent to patients as a reward for each completed questionnaire.

2.3 | Validation methods

Responsiveness, reliability, and convergent validity of the JGIQLI were determined. Analyses were conducted for the total score and sub-scores of the five domains.

2.4 | Responsiveness

To assess sensitivity in detecting postoperative QOL changes, we evaluated the JGIQLI responsiveness by comparing preoperative JGIQLI scores with scores at 2 weeks post-surgery, as well as with the original outcomes.

2.5 | Reliability

Questionnaire reliability was evaluated through internal consistency and reproducibility measurements. Cronbach’s alpha was calculated for the total JGIQLI score, with a high positive value (≥0.70) indicating consistency. Next, a test-retest study using intraclass correlations was conducted to compare the JGIQLI scores at 2 and 6 weeks post-surgery. A highly positive correlation coefficient (≥0.70) indicated reproducibility.

2.6 | Validity

Postoperative JGIQLI symptom domain scores were compared with individual postoperative GSRS subscales using Fisher’s z-transformation. A fair to good relationship was suggested with correlation coefficients ranging from −0.4 to −0.7.

2.7 | Statistical analysis

Continuous data were expressed as means ± SD. Statistical analyses were performed in SAS 9.4 (SAS Institute Japan Inc, Tokyo, Japan). Cronbach’s alpha, correlations, and paired t-tests were conducted as appropriate. Significance was set at P < 0.05.

3 | RESULTS

Between June 2016 and November 2017, 120 patients were enrolled in the study. Out of them, three patients were excluded after their surgery because their laparoscopic cholecystectomy was converted to open abdominal surgery and their final pathological diagnosis was not gallstone but neoplasia. Consequently, the questionnaire was
administered to the 117 patients, and we obtained responses from all of the 117 patients (100% response rate) averaging 59.7 ± 13.0 years of age at the time of surgery (see Table 1 for patient details). Missing data, which were excluded from the analysis, were 0.43%, 1.33%, and 2.61% for pre-surgery, 2 weeks post-surgery, and 6 weeks post-surgery, respectively. At 2 and 6 weeks post-surgery, QOL improved from pre-surgery scores in all five domains of the JGIQLI except the social dysfunction domain (Table 2), leading to an increase in the total score. Comparable with previous research,2 the outcome indicated preoperative total scores of 87.27 ± 17.25 to postoperative scores of 104.49 ± 17.52 and 111.71 ± 14.42 at 2 and 6 weeks, respectively.

Paired t-tests revealed that pre-surgery total and domain scores differed significantly from the scores at 2 weeks post-surgery, except for “social dysfunction” (Table 3). These results are in line with the original GIQLI responsiveness assessment.2 Cronbach’s alpha was >0.9 for the JGIQLI total score (Table 4), indicating that the survey is internally consistent for all measurements. Additionally, the intraclass correlation coefficient from the test-retest analysis was 0.843, indicating a strong relationship between the total scores from 2 and 6 weeks post-surgery (Table 5).

The JGIQLI symptom domain scores were strongly associated (Fisher z-transformation: −0.459 to −0.679) with each GSRS subscale score (Table 6).

4 | DISCUSSION

In this study, we successfully validated the Japanese version of the GIQLI, a gastrointestinal-disease-specific QOL assessment tool. The JGIQLI will facilitate comparing QOL data from Japanese patients to international data for the first time. The good response rate to the questionnaire may be due to our follow-up approach and partially because of the gift card; although, most of the patients initially refrained from accepting a gift card.

We confirmed that the JGIQLI had high responsiveness, with a significant increase in scores between pre-surgery and 2 weeks post-surgery. Significant responsiveness was demonstrated in the total score and all domains except “social dysfunction.” We speculated that perioperative social function might not be influenced in general by the severity of the disease or the surgical invasiveness of laparoscopic cholecystectomy. Following analysis of the original survey,2 we examined reproducibility at 2 and 6 weeks post-surgery. This duration

### TABLE 1 Patient characteristics (n = 117)

| Category            | Number of patients | %  |
|---------------------|--------------------|----|
| Sex                 |                    |    |
| Male                | 57                 | 48.7|
| Female              | 60                 | 51.3|
| Comorbidities       |                    |    |
| Yes                 | 56                 | 47.9|
| No                  | 61                 | 52.1|
| Diagnosis           |                    |    |
| Cholelithiasis      | 42                 | 35.9|
| Cholecystitis       | 75                 | 64.1|
| Institution         |                    |    |
| Hiroshima University Hospital | 30 | 25.6|
| Hiroshima Memorial Hospital | 87 | 74.4|

### TABLE 2 Patients’ JGIQLI (n = 117)

| Measurement point | Mean   | SD    | 95% confidence interval |
|-------------------|--------|-------|-------------------------|
| Total score       |        |       |                         |
| Before            | 112.4  | 19.2  | 108.9-116.0              |
| 2 wk              | 120.1  | 16.8  | 116.9-123.3              |
| 6 wk              | 121.8  | 17.0  | 118.5-125.0              |
| Symptoms domain   |        |       |                         |
| Before            | 62.2   | 10.9  | 60.2-64.2                |
| 2 wk              | 65.9   | 8.6   | 64.3-67.4                |
| 6 wk              | 67.4   | 7.5   | 66.0-68.8                |
| Emotional dysfunction domain |       |       |                         |
| Before            | 13.5   | 4.1   | 12.7-14.2                |
| 2 wk              | 16.0   | 3.0   | 15.5-16.6                |
| 6 wk              | 15.9   | 3.3   | 15.3-16.5                |
| Physical dysfunction domain |       |       |                         |
| Before            | 19.4   | 6.9   | 18.2-20.7                |
| 2 wk              | 20.9   | 6.2   | 19.7-22.0                |
| 6 wk              | 20.7   | 6.1   | 19.6-21.8                |
| Social dysfunction domain |       |       |                         |
| Before            | 13.2   | 2.8   | 12.7-13.7                |
| 2 wk              | 13.1   | 2.8   | 12.6-13.6                |
| 6 wk              | 13.5   | 2.6   | 13.0-13.9                |
| Effect of medical treatment |       |       |                         |
| Before            | 3.0    | 1.2   | 2.8-3.3                  |
| 2 wk              | 3.4    | 1.1   | 3.2-3.6                  |
| 6 wk              | 3.6    | 0.9   | 3.4-3.7                  |
is more reflective of actual clinical practice than a shorter interval (e.g. 7-10 days). Additionally, a shorter interval could overestimate test-retest reliability because patients may recall their answers to the first test when responding to the second.⁸ Although both Cronbach’s alpha and intraclass correlation coefficients for the total JGIQLI were high, their relatively weak relationship failed to reach 0.7 for “emotional dysfunction,” “social dysfunction,” and “effect of medical treatment” between 2 and 6 weeks post-surgery. A possible reason for this result is that the patients in this study were not in the same or similar conditions between 2 and 6 weeks after surgery on these three domains. We have to bear in mind that the questionnaire at 2 weeks post-surgery is asking about conditions during the unstable 2-week period from immediately after the surgery while still in hospital and 2 weeks post-surgery at home, while the questionnaire at 6 weeks post-surgery is asking about conditions during the stable period between 4 and 6 weeks post-surgery, usually at home and sometimes at work. Therefore, after cholecystectomy some patients might stay at home or at least would not go out drinking at 2 weeks post-surgery, but might attend a party at 6 weeks post-surgery, which could affect “social dysfunction” domain scores. They might recover emotionally from perioperative stress at 2 weeks post-surgery, and would further recover emotionally at 6 weeks, which would influence the “emotional dysfunction” domain scores. Therefore, it is not surprising that the intraclass correlation coefficient was low (0.516) for “effect of medical treatment,” because the responses would differ at 2 weeks post-surgery, which includes the period when patients are still in hospital receiving medical treatment, compared to 6 weeks post-surgery when patients have fully recovered and no longer require medical treatment.

Currently, a gold-standard, gastrointestinal-disease-specific QOL questionnaire comparable to the GIQLI does not exist in Japanese. Previous research⁹ has reported significant but relatively low (0.29-0.62) correlations between the GIQLI and the SF-36 questionnaire.¹⁰ The lack of a convincingly strong correlation is not surprising, because the SF-36 is not specific to gastrointestinal disorders.⁸

The initial GIQLI study² did not explicitly assess the five domains, despite their presence in the survey. Validation of these domains would allow assessment of specific features associated with disease-related QOL, including social functioning and mental health. Several previous validation studies, which have been translated into Danish,³ Chinese (Hong Kong),¹¹ Chinese (Taiwan),⁷ and

| TABLE 4 | Reliability: Cronbach’s alpha analysis of internal consistency on total JGIQLI scores |
|----------|-----------------------------------------------|
| Measurement point | Cronbach’s alpha |
| Pre-surgery | 0.901 |
| 2 wk post-surgery | 0.907 |
| 6 wk post-surgery | 0.934 |

| TABLE 3 | Responsiveness: results of paired t-test comparing scores pre-surgery and 2 wk post-surgery |
|----------|-----------------------------------------------|
| Measurement point | Pre-surgery | 2 wk post-surgery | Mean change | SD | P |
| Total score | 112.4 | 120.1 | 7.7 | 17.0 | <0.001 |
| Symptoms domain | 62.2 | 65.9 | 3.7 | 9.9 | <0.001 |
| Emotional dysfunction domain | 13.5 | 16.0 | 2.5 | 3.8 | <0.001 |
| Physical dysfunction domain | 19.4 | 20.9 | 1.5 | 6.4 | <0.05 |
| Social dysfunction domain | 13.2 | 13.1 | -0.1 | 2.8 | 0.419 |
| Effect of medical treatment | 3.0 | 3.4 | 0.4 | 1.4 | <0.005 |

| TABLE 5 | Reliability: intraclass correlation analysis by the use of data sets between 2 and 6 wk post-surgery |
|----------|-----------------------------------------------|
| Measurement point | 2 wk post-surgery | 6 wk post-surgery | Intraclass correlation coefficient | 95% confidence interval |
| Total score | 120.1 | 121.8 | 0.843 | 0.778-0.890 |
| Symptoms domain | 65.9 | 67.4 | 0.800 | 0.722-0.858 |
| Emotional dysfunction domain | 16.0 | 15.9 | 0.671 | 0.556-0.761 |
| Physical dysfunction domain | 20.9 | 20.7 | 0.702 | 0.595-0.785 |
| Social dysfunction domain | 13.1 | 13.5 | 0.581 | 0.445-0.691 |
| Effect of medical treatment | 3.4 | 3.6 | 0.516 | 0.366-0.639 |
TABLE 6 Convergent validity: Symptoms domain of the JGIQLI were compared with each subscale of the GSRS using Fisher’s z-transformation

| GRS subscale | Correlation coefficient | 95% confidence interval | P   |
|--------------|-------------------------|-------------------------|-----|
| Indigestion  | -0.679                  | -0.765 to -0.564        | <0.001 |
| Diarrhea     | -0.584                  | -0.692 to -0.447        | <0.001 |
| Abdominal pain | -0.572                | -0.683 to -0.433        | <0.001 |
| Constipation | -0.460                  | -0.592 to -0.300        | <0.001 |
| Reflux       | -0.459                  | -0.591 to -0.300        | <0.001 |

Swedish,12 have used factor analysis to categorize the items across four or five QOL domains. Unfortunately, neither our study nor previous studies used full information for maximum likelihood to assess correlations between the translated GIQLI and the original.2 Therefore, although we can compare international QOL studies using GIQLI, only the total score is currently appropriate for such analyses. The pros and cons of this questionnaire are that gastrointestinal-disease-specific symptom severity and related QOL are measurable as a total score, but the reliability of each domain cannot be verified.

Our study has some important limitations. First, a formal linguistic validation was not performed. The validation process involves using a translation/back-translation method or a linguistic consensus board. Second, to evaluate a questionnaire’s reproducibility with a test-retest method, patients must be stable or at least regarded as stable in terms of the conditions being evaluated, which was not the case in this study. Finally, “uncontrolled stools” in question 36 may mean “fecal incontinence,” but it was not translated as such in this study. Otherwise it showed no statistically significant change between the three points in this study.

5 | CONCLUSIONS

The Japanese version of the GIQLI has high responsiveness and reliability to assess how surgery for symptomatic gallstone disease alters QOL. We therefore recommend that follow-up studies use the JGIQLI to investigate perioperative changes in patients who undergo gastrointestinal surgery.

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DISCLOSURE

Funding: The funding for this study was provided by TSUMURA and Co.

Conflict of Interest: Author H.O received manuscript payments from TSUMURA and Co.

ETHICAL APPROVAL

The study protocol was approved by the institutional review board at Hiroshima University Hospital and Hiroshima Memorial Hospital.

CONCLUSIONS

Written informed consent was obtained from all patients preoperatively (7.1 ± 16.7 days pre-surgery).

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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