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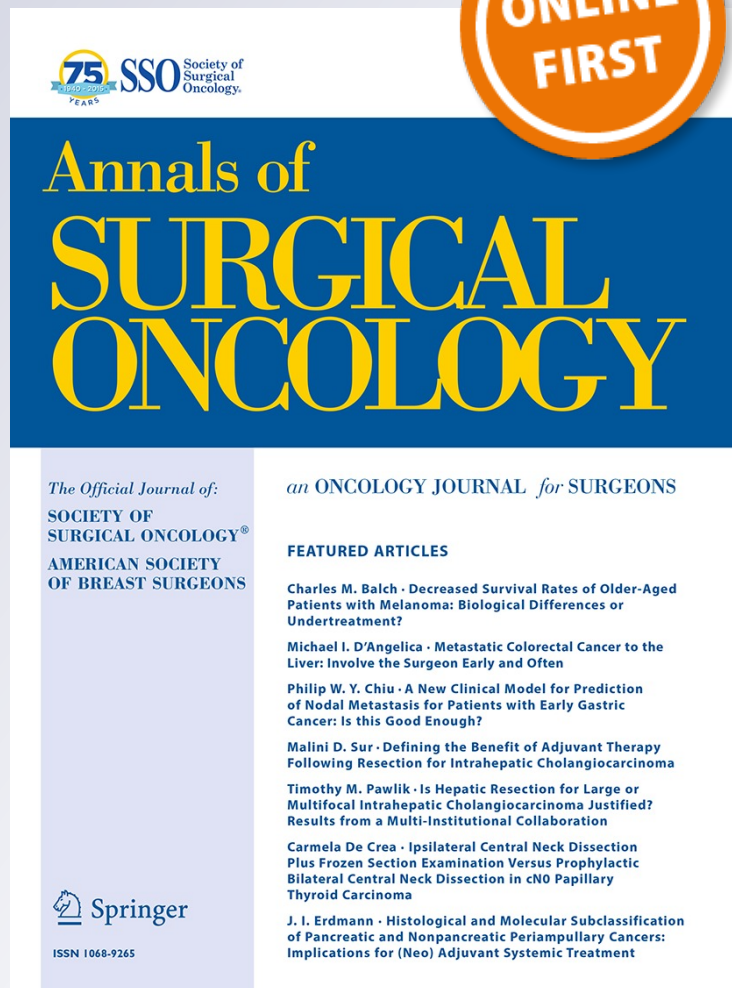
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Development and Validation of a Disease-Specific Instrument to Measure Diet-Targeted Quality of Life for Postoperative Patients with Esophagogastric Cancer

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ABSTRACT

Background. Patients who have undergone esophagectomy or gastrectomy have certain dietary limitations because of changes to the alimentary tract. This study attempted to develop a psychometric scale, named "Esophago-Gastric surgery and Quality of Dietary life (EGQ-D)," for assessment of impact of upper gastrointestinal surgery on diet-targeted quality of life.

Methods. Using qualitative methods, the study team interviewed both patients and surgeons involved in esophagogastric cancer surgery, and we prepared an item pool and a draft scale. To evaluate the scale's psychometric reliability and validity, a survey involving a large number of patients was conducted. Items for the final scale were selected by factor analysis and item response theory. Cronbach's alpha was used for assessment of reliability, and correlations with the short form (SF)-12, esophagus and stomach surgery symptom scale (ES[4]), and nutritional indicators were analyzed to assess the criterion-related validity.

Results. Through multifaceted discussion and the pilot study, a draft questionnaire comprising 14 items was prepared, and a total of 316 patients were enrolled. On the basis of factor analysis and item response theory, six items were excluded, and the remaining eight items demonstrated strong unidimensionality for the final scale. Cronbach's alpha was 0.895. There were significant associations with all the subscale scores for SF-12, ES[4], and nutritional indicators.

Conclusions. The EGQ-D scale has good contents and psychometric validity and can be used to evaluate disease-specific instrument to measure diet-targeted quality of life for postoperative patients with esophagogastric cancer.

In recent years, there have been many advances in the treatment of esophagogastric cancer, including the establishment of surgical techniques for tumor resection and lymph node dissection, together with progress in chemotherapy, radiotherapy or molecular-targeted therapy, and prolongation of patient survival.[1,2] Apart from survival rate, clinical studies focusing on treatment-related symptoms or deterioration in the quality of life have been increasing.[3–8] The introduction of less invasive surgery, function-preserving procedures, improvements in surgical techniques for reconstruction, and innovations in perioperative nutritional care are all promising interventions that

have improved conditions for patients after surgery for esophagogastric cancer.[3,9–16] As a consequence, the importance of patient-reported outcome data has been recognized.

Many patients who undergo upper gastrointestinal surgery have limitations to their daily eating habits due to certain sequelae, such as reflux, diarrhea, or dumping symptoms.[17–20] Therefore, details of the degree to which their daily dietary intake is impaired are important for evaluation of their health-related quality of life (HRQOL). Although several clinical studies have assessed the HRQOL of postoperative patients using questionnaires that were developed using psychological methods, these scales are fundamentally limited, because they include few items that inquire about daily diet. For example, the short form (SF)-36 questionnaire, which is the most major comprehensive HRQOL scale, lacks any items inquiring about the quality of dietary life.[21] The European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 questionnaire, which is the one used most often for patients with cancer, includes only one item related to appetite, and even some scales designed specifically for assessment of gastrointestinal diseases, such as the GSRS, GIQLI, or DAUGS, have only 0–2 items.[22–25] Therefore, it is possible that the importance of HRQOL in patients after surgery for esophagogastric cancer may have been overlooked. On the other hand, some questionnaires have been designed to evaluate dietary life in healthy individuals, but these scales obviously lack validity for patients after gastrointestinal surgery.[26,27] In order to assess postoperative HRQOL in clinical studies of new surgical procedures or interventions, surgeons need a disease-specific scale that can evaluate dietary life after upper gastrointestinal surgery.

The present study was performed to develop a new scale, the "Esophago-Gastric surgery and Quality of Dietary life" scale (EGQ-D), which allows psychometrically appropriate evaluation of patients after esophagogastric surgery, with a focus on their dietary life.

METHODS

This study consisted of two parts. An item pool and a draft questionnaire were prepared through a pilot survey in part I. This was followed by a quantitative survey of a large number of patients who underwent esophagogastric surgery to establish the final scale and investigate its reliability and validity. The study team consisted of six experts (two gastrointestinal surgeons, one gastroenterologist, one psychometrician, and two clinical epidemiologists). The survey was performed at six hospitals during the period from November 2011 to January 2013, after approval had been obtained from the institutional review board in each hospital.

PART I. PREPARATION OF THE DRAFT QUESTIONNAIRE

Through expert discussions and reference to previous articles, the study team prepared 35 items as an item pool that was assumed to evaluate the quality of patients' dietary life or limitations that were intrinsically diet-related. Then, to confirm the content validity of the items, semistructured interviews of patients were performed in a qualitative survey. The subjects for this survey were 12 patients, including seven males and five females, aged 34–71 years. Four of the patients underwent esophagectomy, five underwent total gastrectomy, and three underwent distal gastrectomy. The findings from the interviews were discussed again by the study team to make any appropriate additions and to revise the expression of any items. Finally, a new item pool (prototype scale) composed of 40 items was obtained. Thereafter, a pilot survey was performed involving 20 patients, including 7 who had undergone esophagectomy, five who had undergone total gastrectomy, and eight who had undergone distal gastrectomy. Patients were asked to answer the questions contained in the prototype scale to evaluate whether or not the contents and language of the questions were appropriate and easy to understand. The items also were examined by descriptive statistics (means and standard deviations) and item-total correlations. On the basis of the pilot survey results, inappropriate questions were deleted and the answer format was adjusted. Finally, 14 questions were selected for the draft scale. For each question, the patients were asked to answer using a five-grade scale: 0 (strongly disagree), 1 (somewhat disagree), 2 (neither agree nor disagree), 3 (somewhat agree), 4 (strongly agree).

PART II. INVESTIGATION OF RELIABILITY AND VALIDITY

Subjects

For assessment of psychometric reliability and validity, a survey involving a large number of patients was conducted using the draft questionnaire. Patients were considered to be eligible if they had undergone surgery for malignant disease of the esophagus or stomach. A total of 360 patients were randomly recruited from participated hospitals. All patients were at least 20 years old, and the time after surgery ranged from 6 months to 5 years. Patients were required to have an Eastern Cooperative Oncology Group performance status of 0 or 1. The exclusion criteria for the patients were: inability to take any food orally at all; having undergone chemotherapy or radiotherapy in the previous 3 months; having suffered

recurrence or other malignant disease; pregnancy; and currently taking antipsychotic, antidepressant, or antianxiety medication.

Item Analysis, Factor Analysis, Item Selection, and Reliability

First, the descriptive statistics for each item were evaluated; the mean value, standard deviation, and distribution of all items were confirmed. Second, to confirm the one factor structure and to investigate the factor loading of each item, exploratory factor analysis (principal factor method) was performed. In addition, analysis employing item response theory (IRT), which has commonly been used to select questions for an achievement test, was performed to determine the item characteristic curve for each item.[28] The generalized partial credit model was used as an IRT model. This model estimated two parameters: location and slope. The location represented the severity of the patients' burden for eating (difficulty). The slope represented the ability of an item to discriminate between a better or worse quality of dietary life (discrimination ability). Through multifaceted discussion of these results, the study team selected items that had high discrimination and appropriate difficulty as the final items for the EGQ-D scale. Furthermore, the test information function was calculated to examine the precision of measurement of the final scale. Third, the distribution of the total score was confirmed. The total score was calculated from the average of the final items and then converted to fall within a range of 0–100 points. A higher score indicated a higher QOL, using the following conversion equation: Total EGQ-D score = 100 − "average score for each item" × 25. Finally, Cronbach's alpha was estimated as the reliability coefficient.

External Validity

To assess the criterion-related validity, the subjects were asked to answer the SF-12 (a comprehensive QOL scale) and ES[4] (esophagus and stomach surgery symptom scale) survey form.[17,29] The correlations of the total EGQ-D score with the subscale score of the ES[4] and SF-12 were analyzed. The ES[4] includes four subscales: CTS (cervicothoracic symptoms), AHS (abdominal hypersensitivity symptoms), ADS (abdominal distension symptoms), and DIS (diet-induced systemic symptoms). The SF-12 includes eight subscale scores: Physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH).[29]

Furthermore, to assess the known-groups validity, nutritional indicators including meal quantity and body weight loss at the time of the survey were compared. The

meal quantity (%) was defined as the percentage of the quantity of food ingested daily at the time of the survey relative to the quantity before surgery (self-reported by individual patients). The proportion of body weight loss (%) was calculated using the equation: (present body weight) − (body weight before surgery)/(body weight before surgery) × 100. The individual patients were divided into one of three categories using a cutoff level of mean ± ½ SD, and the mean values of these indicators were compared. The level of significance was set at $p < 0.05$, and the Tukey method was used for adjustment in multiple comparisons.

RESULTS

The investigation was conducted using 360 patients, of whom 339 (94.2 %) returned answers, 28 (8.3 %) cases with missing data were excluded, and 316 valid respondents (87.8 %) were finally included in the analysis. The patients' characteristics are shown in Table 1.

Item Analysis, Factor Analysis, and Item Response Theory (IRT)

The mean values and standard deviations of the results of the exploratory factor analysis of 14 items and IRT are shown in Table 2. The factor loading implied a structure of one factor (Table 2). All items were plotted as coordinates

TABLE 1 Patient characteristics

Total number of patients	316	
Male/female ratio	223/93	
Median age (range)	65	(32–82)
Body mass index (range, SD)	19.3 kg/m^2	(12.7–33.1, 2.69)
Postoperative period (range, SD)	2.54 year	(0.5–5.0, 2.22)
Disease		
Gastric cancer (%)	208	65.8 %
(Stage I/II/III)[a]	(135/50/23)	
Esophageal cancer (%)	98	31.0 %
(Stage I/II/III)[a]	(32/31/35)	
Others (GIST or lymphoma) (%)	10	3.2 %
Procedure		
Esophagectomy	104	32.9 %
Total gastrectomy	80	25.3 %
Distal gastrectomy	101	32.0 %
Proximal gastrectomy	19	6.0 %
Pylorus preserving gastrectomy	12	3.8 %
Laparoscopic surgery	147	46.5 %

SD standard deviation, *GIST* gastrointestinal stromal tumor

[a] Stage conformed to the International Union Against Cancer (UICC), TNM Classification 7th edition

TABLE 2 All items of the draft scale, factor loading, and parameter of IRT

Questions		Descriptive statistics		FA	IRT	
		Mean	SD	Loading	Slope	Location
Q1	I cannot enjoy eating	1.52	1.43	0.849	1.288	−0.534
Q2	I feel worried about eating	1.16	1.27	0.822	1.560	−0.741
Q3	I find it troublesome that I have to eat slowly because of my symptoms	1.73	1.40	0.776	0.925	−0.441
Q4	I don't like eating in public	1.45	1.39	0.753	0.974	−0.762
Q5	I avoid eating with other people	1.24	1.36	0.717	0.805	−0.666
Q6	I find it troublesome that I have to be careful about what I eat	1.36	1.34	0.716	0.773	−0.812
Q7	I have no appetite	1.04	1.24	0.701	0.834	−0.930
Q8	I don't get the feeling of fullness after a meal	1.08	1.26	0.601	0.617	−1.024
Q9	I'm scared to eat	0.72	1.06	0.704	1.107	−1.175
Q10	It upsets me that I cannot eat what I want	1.60	1.50	0.681	0.655	−0.431
Q11	I find it troublesome that it takes me a long time to eat my meals	1.42	1.34	0.633	0.495	−0.704
Q12	It upsets me that I cannot drink what I want	1.03	1.23	0.624	0.764	−0.944
Q13	I always worry about my symptoms getting worse during eating	2.05	1.48	0.551	0.381	−0.087
Q14	I often get the feeling that I'm about to vomit during eating	0.69	1.05	0.494	0.469	−1.727

FA factor analysis; *IRT* item response theory; *SD* standard deviation

that were the set parameters of the IRT: discrimination and difficulty (Fig. 1a). Considering these results, eight items were identified as the final items for this scale: Q1–Q8 were included, and Q9–Q14 were excluded in Table 2. Cronbach's α, a coefficient estimating reliability, was 0.895. The graph of the test information function is shown in Fig. 1b. The amount of the test information exceeded 9 at a location parameter ranging from −1.5 to 0.15 on the 8-item scale; this scale had high precision of measurement in approximately 50 % of the patients.

Score Distribution

Figure 2 illustrates the distribution of the total EGQ-D score. The mean, standard deviation, and minimum and maximum values were 67.4, 25.9, 0.00, and 100.0, respectively.

EXTERNAL VALIDITY

Association with ES[4] and SF-12

The correlation coefficients between EGQ-D and the subscales of the ES[4] were 0.421 in CTS (95 % confidential interval (95 % CI) 0.326–0.508, $p = 0.000$), 0.340 in AHS (95 % CI 0.239–0.434, $p = 0.000$), 0.418 in ADS (95 % CI 0.323–0.505, $p = 0.000$), and 0.395 in DIS (95 % CI 0.298–0.484, $p = 0.000$), respectively. The relationship between the total EGQ-D score and the SF-12 subscales are shown in Fig. 3a. The results demonstrated reasonable and

statistically significant tendencies among all the SF-12 subscales.

Association with Nutritional Indicators

The scores for the individual patients were divided into three categories—low, middle, and high scores—using a cutoff level of mean ± ½ SD. As the score became higher in EGQ-D, both body weight loss and change in meal quantity tended to become lower, and this tendency was statistically significant (Fig. 3b).

DISCUSSION

The EGQ-D scale developed in this study is the first "dietary life"-specific assessment scale for patients who have undergone gastrointestinal surgery. After upper gastrointestinal surgery, such as esophagectomy or gastrectomy, patients often suffer from several sequelae and cannot enjoy meal intake for a long time after surgery.[11,20,30] Our study team has published previously the "ES[4]" symptom scale to evaluate such sequelae.[10] Aside from symptoms, the degree of dietary impairment also is an important clinical outcome, because patients might mitigate their symptoms through strict restriction of their daily diet; patients who have a better ES[4] score do not necessarily have a better quality of life. Furthermore, marked reduction of daily dietary intake results in weight loss or nutritional disorders, and this may impact the HRQOL. Therefore, for clinical studies focusing on the quality of
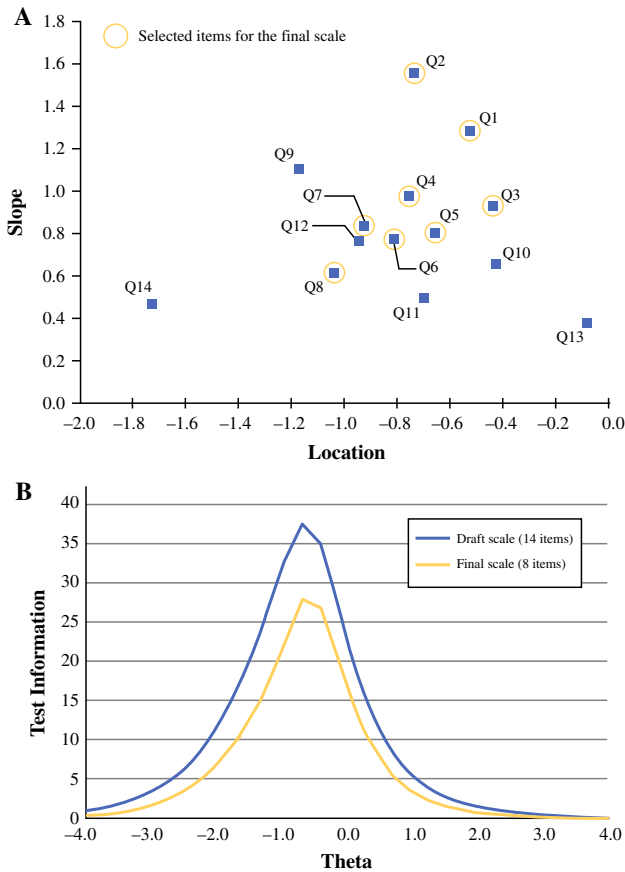
FIG. 1 **a** Plot of the properties for each question item estimated by item response theory. *Horizontal axis* represents the location parameter, indicating the disease severity based on the items that elicited a response. *Vertical axis* represents the slope parameter, indicating the ability of the items to distinguish differences in disease severity among individuals. The number of questions in Table 2 corresponds to "Q1–Q14." The *dotted* circles represent the eight items selected by the study team for the final scale. **b** Amount of test information. *Dotted line* represents the draft scale. *Solid line* represents the final scale, which exceeded 9 at a location parameter (theta) ranging from −1.5 to 0.15 on the 8-item scale
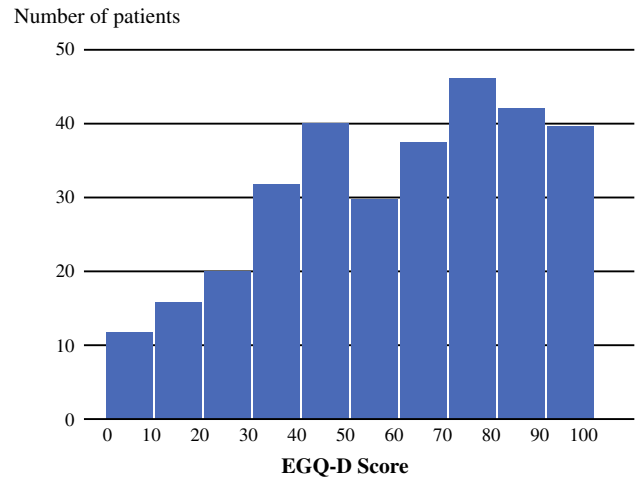

FIG. 2 Score distribution. The histogram of the EGQ-D score showed a normal distribution. The mean scores (standard deviation) was 67.4 (25.9), and the range was 0–100

surgical procedures, one of the most important outcomes is the quality of dietary life after surgery. Many clinical studies have evaluated the HRQOL of postoperative patients, but previous scales for measuring HRQOL have included hardly any items inquiring about the quality of dietary intake.[4,5,7,12] Therefore, there is a strong possibility that gastrointestinal surgeons may have overlooked the importance of the HRQOL in postoperative patients. Accordingly, we developed a new scale to evaluate the dietary quality of patients undergoing esophagogastric surgery.

This scale was developed by a multi-faceted team consisting of not only gastrointestinal surgeons and physicians but also psychologists experienced in the development of psychological scales, as well as epidemiological researchers. The validity and reliability was high for specific

patients who underwent esophagogastric surgery. In addition, the scale was considered to have high generalizability, since its validity was confirmed for outpatients at various institutions nationwide (university hospitals, specialized cancer centers and regional core hospitals). Our results demonstrated a reasonable one-factor structure for assessment of diet quality. Items with higher factor loadings were selected for factor analysis, and items with lower discrimination parameter were excluded, considering the results of IRT. The remaining eight items in the final questionnaire were completely able to cover all aspects of dietary life from the viewpoint of surgeons, and the scale was considered acceptable as one of patient-reported outcomes for clinical studies designed to evaluate surgical procedures. Furthermore, considering the results of IRT and the test information, this scale was better fitted to patients with a relatively poor quality of dietary life.

The correlations with postoperative symptoms were mostly good; correlation coefficients between total EGQ-D score and each of the ES[4] subscale scores ranged from 0.340 to 0.421. The correlation with the CTS score, reflecting reflux, heartburn, or anastomotic stricture was highest. It was thought that these symptoms in particular had a strong influence on eating quality. All of the SF-12 subscale scores were shown to have reasonable correlations; it was suggested that dietary quality had a strong correlation with the comprehensive HRQOL in patients who had undergone upper gastrointestinal surgery. Furthermore, the association with the decline in daily diet or body weight shown in Fig. 3 also provided strong evidence for the clinical validity of this scale.

Because the purpose of this study was merely to develop and validate the "EGQ-D" scale, its clinical utility remains to be established. Also, correlations with quality of life
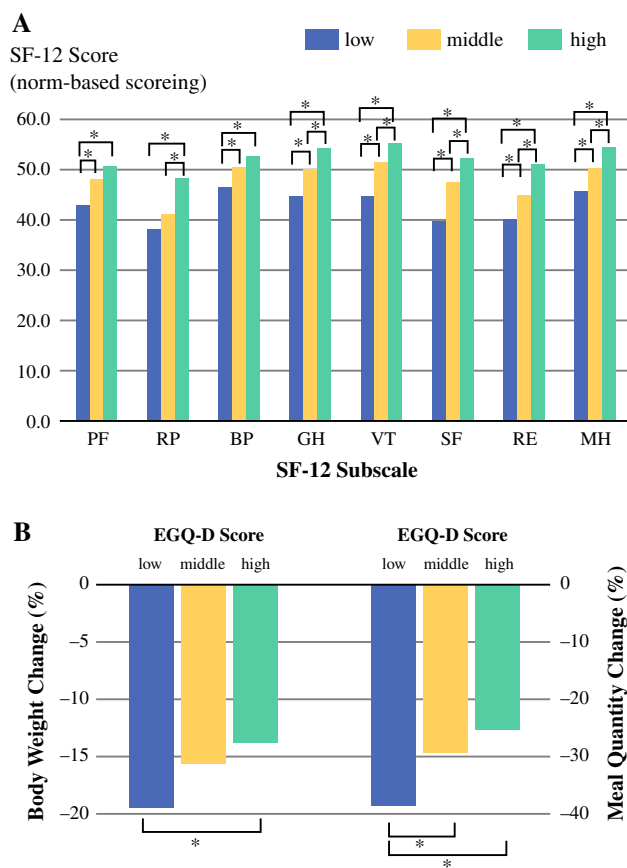
A

SF-12 Score
(norm-based scoring)

B

FIG. 3 EGQ-D scores were divided into three categories using a cutoff level of mean $\pm$ 1/2 SD; the group with a low score (poor quality of dietary life) is colored *black*, the group with an intermediate score (moderate quality) is colored *grey*, and the group with a high score (good quality) is colored *white*. *Significant difference (Tukey's multiple comparison). **a** Concurrent validity of the EGQ-D score compared with the subscale sores of the SF-12. *PF* Physical Functioning; *RP* Role Physical; *BP* Body Pain; *GH* General Health; *VT* Vitality; *SF* Social Functioning; *RE* Role Emotional; *MH* Mental Health. **b** Criterion-related validity of the EGQ-D score compared with changes in body weight and meal quantity (%) before and after surgery

scales other than SF-12, such as the EORTC QLQ C-30 or FACT-G, remain to be clarified. However, we are currently performing some prospective studies on other patients to evaluate the minimally important clinical differences in this scale. Furthermore, practical data for individual surgical procedures will become clearer after publication of this study. In the near future, the scale should allow confident estimation of dietary quality for patients after gastrointestinal surgery.

CONCLUSION

We have developed a new scale named the "Esophago-Gastric surgery and Quality of dietary life" scale (EGQ-D),

which has high psychometric validity and is capable of evaluating the degree of impairment of dietary intake resulting from upper gastrointestinal surgery. This scale should be applicable as an outcome measure for various interventional studies on gastrointestinal surgery designed to alleviate postoperative HRQOL. Furthermore, in clinical studies, we plan to accumulate data on the use of this scale to improve its interpretability.

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