Development and Validation of a Symptom Scale to Evaluate Postoperative Patients with Esophagogastric Cancer

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BACKGROUND: Postgastrectomy or esophagectomy symptoms can be a significant burden for patients. However, no standard scale for evaluating these symptoms has been established. We recently developed a postoperative symptom-specific scale.

STUDY DESIGN: After a draft scale was prepared based on a pilot study, psychometric methods were used to assess its reliability and validity. This study involved specialized and multifaceted discussions by a team consisting of gastrointestinal surgeons, gastroenterologists, psychologists, and epidemiologic researchers. The draft questionnaire included 40 questions and 3 domains. A factor analysis was carried out to refine the items and subscale design. To assess the reliability, Cronbach's alpha and score distributions were estimated. To assess the criterion-related validity, the correlations with the Short Form (SF)-12, Gastrointestinal Symptom Rating Scale (GSRS), endoscopic findings, and nutritional indicators were analyzed.

RESULTS: A total of 344 patients were enrolled in this study. In an exploratory factor analysis (principal factor method), the eigenvalue attenuation data showed 4 domains. The final scale, named the Esophagus and Stomach Surgery Symptom Scale (ES^4), included 23 items and 4 domains; 7 items for cervico-thoracic symptoms, 6 for abdominal hypersensitivity symptoms, 4 for abdominal distention symptoms, and 6 items for systemic symptoms. Cronbach's alphas for these domains were 0.82, 0.81, 0.79, and 0.74, respectively. The scale scores were normally distributed, and there were significant associations with the endoscopic findings, nutritional indicators, the summary score of the SF-12, and the GSRS.

CONCLUSIONS: The ES^4 scale has high psychometric validity and can evaluate the profiles and severity of postoperative symptoms. This scale is applicable as an outcomes measure for various interventional studies on esophagogastric surgery aimed at alleviating postoperative symptoms. (J Am Coll Surg 2014;219:895–903. © 2014 by the American College of Surgeons)

Treatment of esophagogastric cancer has made progress in recent years. The development of new surgical techniques (including techniques for lymph node dissection), improvements in perioperative intensive care and nutritional management, and advances in multidisciplinary therapy have all enhanced the safety and curability of the treatments.[1,2] On the other hand, diverse symptoms can develop after operations for gastric or esophageal cancer,

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Abbreviations and Acronyms

ADS = abdominal distension symptoms
AHS = abdominal hypersensitivity symptoms
CTS = cervico-thoracic symptoms
DIS = diet-induced systemic symptoms
ES[4] = Esophagus and Stomach Surgery Symptom Scale
GSRS = Gastrointestinal Symptom Rating Scale
MCS = mental component score
PCS = physical component score
QOL = quality of life
RCS = social role/function component score
SF = Short Form

primarily related to intense reflux, a small stomach, or dumping syndrome.[3-6] These symptoms can cause a significant burden for the patients. Preventing these postoperative disorders is an important issue, and various attempts have been made to modify the procedure used for reconstruction or to perform less invasive surgery.[7-13]

However, a major problem in evaluating the effectiveness of these interventions is the lack of an established and validated scale applicable to these symptoms. As scales of quality of life (QOL), the gastric cancer module STO-22,[14,15] esophageal cancer module OES-18[16] of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ C-30),[17] the Functional Assessment of Cancer Therapy (FACT-G),[18] the Gastrointestinal Quality of Life Index (GIQLI),[19] or the Gastrointestinal Symptom Rating Scale (GSRS)[20] have previously been used in published articles. However, they are focused on QOL, and the evaluation of surgery-specific and detailed symptoms, such as those related to a small stomach or dumping symptoms, were not included. A postoperative scale named the DAUGS (dysfunction after upper gastrointestinal surgery) has been developed in Japan.[4,21] This focused on the postoperative dysfunction, including QOL, and the concept that these scales attempted to measure was unclear for gastrointestinal surgeons. The QOL should be distinguished from the symptom scale[22,23]; the QOL is associated with the daily burden caused by symptoms, but the severity of postoperative symptoms cannot be evaluated using these tools. None of these scales can be considered to provide adequate validity for the evaluation of postoperative symptoms. Because upper gastrointestinal surgery can cause specific gastrointestinal or systemic symptoms depending on the surgical technique and procedure, there is a particularly strong need for a scale that is appropriate for the assessment of these postoperative symptoms.

Gastrointestinal surgeons need a scale that would enable evaluation of the advantages and shortcomings of individual surgical procedures. The desirable features of such a scale would include the ability to clarify the profile and severity of symptoms appearing after the operation, and the possibility for use as a comparable outcomes measure in the development of new surgical procedures, or in clinical studies aimed at evaluating the efficacy of such interventions.

This study was undertaken to develop a new scale (the Esophagus and Stomach Surgery Symptom Scale; ES[4]), which enables the psychometrically appropriate evaluation of patients after upper gastrointestinal surgery, with a focus on physical symptoms.

METHODS

The study team consisted of 6 members (2 gastrointestinal surgeons, 1 gastroenterologist, 1 psychometrician, and 2 clinical epidemiologists). The study was carried out at 6 hospitals during the period from November 2011 to January 2013, after approval was obtained from the Institutional Review Board. The ES[4] was developed in accordance with established psychometric procedures for the development of a psychological scale, and the outline of this study is shown in Figure 1. A draft scale was first prepared from the results of qualitative research and a pilot survey. Next, the reliability and validity of the scale was investigated in a larger number of patients.

Preparation of draft questionnaire

The questions considered for inclusion in the scale for the evaluation of the postoperative upper gastrointestinal disorders were identified during discussions by experts and by referring to published articles, to yield a pool of items. The study team prepared 48 items that were assumed to fall into 3 domains for the questionnaire; thoracic, abdominal, and systemic symptoms. Then, to confirm the content validity of the item pool, a qualitative survey was carried out in clinical cases. The qualitative survey covered 12 patients (7 men and 5 women, aged 34 to 71 years, including 4 patients who underwent esophagectomy, 5 who underwent total gastrectomy, and 3 who underwent distal gastrectomy). Two members of the study team conducted semi-structured interviews of the patients and investigated their physical symptoms. The findings from the interviews were discussed again by the study team in order to make any appropriate additions and corrections to the items. The pooled items were corrected and supplemented on the basis of the results. Finally, a new item pool (prototype scale), composed of 52 items, was made.

Thereafter, a pilot survey was carried out involving 22 patients (7 after esophagectomy, 5 after total gastrectomy, and 10 after distal gastrectomy). Patients were asked to