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Original Article

Detection Ability of Quality of Life Changes and Responsiveness of the KOQUSS-40 and the EORTC QLQ-C30/STO22 in Patients Who Underwent Gastrectomy: A Prospective Comparative Study

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Purpose The aim of this study is to compare the detection ability of quality of life (QoL) changes and responsiveness of the KOrean QUality of life in Stomach cancer patients Study group (KOQUSS)-40 and European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ).

Materials and Methods A multicenter prospective observational study was conducted to evaluate QoL changes after various gastrectomies between January 2021 and April 2022. Participants were instructed to complete the KOQUSS-40 and EORTC QLQ-C30/STO22 preoperatively and at 1, 3, 6, and 12 months postoperatively. QoL changes over time and QoL responsiveness were assessed for each questionnaire.

Results Data from 491 patients who underwent curative gastrectomy for gastric cancer at 22 institutions were analyzed. The summary scores of the KOQUSS-40 and EORTC QLQ-STO22 showed significant differences between the total and proximal gastrectomy groups (p=0.044 and p=0.038, respectively), but no difference was observed for the EORTC QLQ-C30. Dysphagia on the KOQUSS-40 was significantly different between the total and proximal gastrectomy groups (p=0.031); however, dysphagia on the EORTC QLQ-STO22 did not differ. The responsiveness of the KOQUSS-40 was similar to that of the EORTC QLQ in patients who experienced ≥ 10% body weight loss, but approximately 10% less in patients receiving adjuvant chemotherapy than the EORTC QLQ.

Conclusion KOQUSS-40 has several advantages over EORTC QLQ-C30/STO22 when comparing QoL between the total and proximal gastrectomy groups. The findings provide information for researchers investigating the QoL of patients who have undergone curative gastrectomy for gastric cancer.

Key words Stomach neoplasms, Gastrectomy, Quality of life, Surveys and Questionnaires

Introduction

In recent years, the prognosis of patients with gastric cancer has improved owing to the early detection of gastric cancer, standardized surgical techniques, and the development of new targeted drugs [1-4]. In particular, early detection through screening endoscopy leads to an increase in curability, and most patients return to their routine lives after curative treatment for gastric cancer. With improved survival, interest in the postoperative quality of life (QoL) has increased. QoL is one of the most important outcomes in studies on new surgical approaches or methods, even in clinical trials of new drugs [5-7].

Many instruments have been used to assess QoL in patients with gastric cancer, and the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ) and the Functional Assessment of Cancer Therapy-gastric (FACT-Ga) are the most representative instruments worldwide [8-10]. These instruments have been translated into various languages, including Korean, and have been applied in many clinical trials and retrospective studies [5,11-13].

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However, existing gastric cancer-specific questionnaires, such as the EORTC QLQ-STO22 and FACT-Ga, focus on general gastrointestinal symptoms, and there is no scale assessing the symptoms experienced after gastrectomy, such as dumping syndrome. Thus, the Korean QUality of life in Stomach cancer patients Study group (KOQUSS) recently developed a postgastrectomy symptom-focused QoL questionnaire (KOQUSS-40) for patients who underwent gastrectomy for gastric cancer [14]. The KOQUSS-40 showed a good model fit and was correlated with clinical factors, such as body weight loss and the extent of gastrectomy, in the validation study. Currently, the KOQUSS-40 has been applied in several clinical trials and prospective observational studies in Korea [15].

In this study, we aimed to determine the strengths and differences of the KOQUSS-40 compared with that of the EORTC QLQ. Postoperative QoL changes were assessed using both the KOQUSS-40 and EORTC QLQ-C30/STO22 in patients who underwent curative gastrectomy. As the scales of each instrument did not match completely, the scores of several similar scales were compared. The responsiveness of the two instruments was analyzed according to key clinical factors.

Materials and Methods

1. KOrean QUality of life in Stomach cancer patients Study group PRO study

KOQUSS-PRO is a multicenter, prospective, observational study that evaluates patient QoL after curative gastrectomy for gastric cancer using the KOQUSS-40. Patients were recruited from 22 hospitals, including 19 tertiary and three general hospitals in the Republic of Korea, from January 2021 to April 2022. Patients aged ≥ 19 years and scheduled to undergo curative gastrectomy for gastric cancer were eligible. The exclusion criteria were synchronous cancer, previous abdominal surgery, regular postoperative follow-up unavailability because of residence issues, insufficient capacity of understanding, and pregnancy. This study was approved by the institutional review board of each hospital, and written informed consent was obtained from all the participants before enrollment.

2. Treatment

In this study, surgical procedures adhered to radical gastrectomy with lymph node dissection according to gastric cancer treatment guidelines [16,17]. Distal, total, pylorus-preserving, or proximal gastrectomy was performed according to the tumor location and clinical stage. After distal gastrectomy, Billroth I, Billroth II, or Roux-en-Y anastomosis was performed, and esophagogastrostomy or double tract reconstruction was performed after proximal gastrectomy, according to the tumor extent and the surgeon's preference. All surgical approaches, including open, laparoscopic, and robotic, were accepted.

Adjuvant chemotherapy was recommended for patients diagnosed with pathological stage II or III disease according to gastric cancer treatment guidelines [17].

3. Clinical data collection

Patient demographics, physical status, preoperative laboratory findings, and surgical methods were collected from medical charts. Pathological stage was classified according to the eighth edition of the American Joint Committee on Cancer tumor-node-metastasis classification [18].

Nutritional parameters, including body weight and laboratory findings, were assessed at 3, 6, and 12 months postoperatively. Endoscopic examination was performed to evaluate food stasis and reflux esophagitis at 12 months postoperatively. Reflux esophagitis was classified as absent or present based on the Los Angeles classification [19].

4. QoL instruments and scoring

The participants were instructed to complete both the KOQUSS-40 and EORTC C30/STO22 preoperatively and at 1, 3, 6, and 12 months postoperatively.

The KOQUSS-40 comprise eight scales (indigestion, dysphagia, reflux, dumping syndrome, bowel habit change, constipation, psychological factors) of 32 items addressing postgastrectomy symptoms and eight items providing important information based on expert consensus [14]. The EORTC core questionnaire (EORTC QLQ-C30) consists of five functional scales (physical, role, social, emotional, and cognitive functioning) and nine symptom scales (fatigue, nausea and vomiting, pain, dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties). The EORTC stomach module (EORTC QLQ-STO22) for patients with gastric cancer comprises five scales (dysphagia, pain, reflux symptoms, eating restrictions, and anxiety) and four single items (dry mouth, taste, body image, and hair loss).

The scoring system of the KOQUSS-40 was generated based on methods for the EORTC QLQ-C30/STO22, in which raw scores (the average of the items that contribute to the scale) were divided by ranges and converted to a 0-100 score [20]. We also adopted the principle of summary scoring of the EORTC QLQ-C30 for that of the KOQUSS-40 [21]. The summary score of the KOQUSS-40 was defined as the mean of eight postgastrectomy symptom scales included in the exploratory factor analysis. A high score indicated a high QoL or few post-gastrectomy symptoms.

For the EORTC QLQ-C30/STO22, a high score repre-

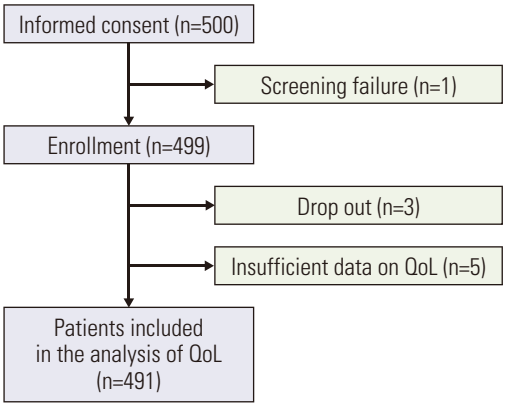

Fig. 1. Consort diagram.

sents high functioning or good QoL for functional scales or global health status and a severe symptomatic problem for symptom scales/items. In this study, symptom scores were reversed (100–scores) to obtain a uniform direction. Thus, a high score indicates a high QoL or fewer symptoms on the EORTC QLQ-C30/STO22. The summary score of the EORTC QLQ-C30 is defined as the mean of 13 scales of the 15 QLQ-C30 scales, excluding financial difficulties and global health status [21]. We adopted this summary scoring system for the EORTC QLQ-STO22 and defined the summary score of the EORTC QLQ-STO22 as the mean of all nine scales/items.

5. Statistical analysis

Descriptive statistics are presented as means with standard deviations for continuous variables and numbers with percentages for categorical variables. Statistical differences between the two groups were determined using Student's t test or Wilcoxon rank-sum test for continuous variables and the chi-squared or Fisher's exact test for categorical variables, as appropriate.

Linear mixed models with a compound symmetry covariance structure were used to compare QoL changes over time according to the extent of surgery for summary score, indigestion, dysphagia, and reflux. The extent of surgery was compared only when the interaction between time and extent of gastrectomy was not statistically significant.

The standardized response mean (SRM) and effect size were calculated to evaluate the responsiveness of the KOQUSS-40 and EORTC QLQ-C30. The SRM is calculated as the mean change in scores between baseline and follow-up divided by the standard deviation of this change [22]. The effect size is calculated as the mean change in scores between baseline and follow-up divided by the standard deviation of the baseline score, which interpret changes in health-related QoL following treatment [23]. An effect size of 0.2-0.5, 0.5-0.8, and ≥ 0.8 is typically considered small, moderate, and large changes, respectively [24]. We used the same threshold levels for SRM. The SRM is sensitive to within-subject variability, whereas the effect size is sensitive to between-subject variability. A bootstrap method was used to estimate the 95% confidence intervals for the SRM and effect size [25].

Statistical analyses were performed using the R software ver. 4.3.0 (R project for Statistical Computing). All tests were two-sided, and p-values < 0.05 were considered statistically significant.

Results

1. Baseline characteristics of the patients

Of the 499 patients enrolled in the KOQUSS-PRO study, 491 were included in the QoL analysis (Fig. 1). The clinicopathological characteristics of the patients are summarized in Table 1. The mean age was 59.7 years, and 58.7% of the patients were male. The proportions of distal, total, pylorus-preserving, and proximal gastrectomies were 71.3%, 13.7%, 5.1%, and 10.0%, respectively. In total, 370 patients (75.4%) were diagnosed with early gastric cancer, and 93 (19.5%) received adjuvant chemotherapy for pathological stage II or III gastric cancer.

2. QoL changes according to the extent of gastrectomy

The changes in summary scores are shown in Fig. 2. All three questionnaires identified significant differences in the changes in summary scores between the distal and total gastrectomy groups and the distal and proximal gastrectomy groups. However, the summary scores were significantly different between the total and proximal gastrectomy groups for the KOQUSS-40 and EORTC QLQ-STO22 (p=0.044 and p=0.038, respectively), and no significant differences were observed for the EORTC QLQ-C30 (p=0.603).

Changes in the common symptom scales of the KOQUSS-40 and EORTC QLQ are shown in Fig. 3. In the KOQUSS-40, indigestion was significantly different between the distal and total gastrectomy groups and the distal and proximal gastrectomy groups (p=0.021 and p < 0.001, respectively), and there was a trend toward a significant difference between the total and proximal gastrectomy groups (p=0.088). Similar results were observed for eating restrictions on the EORTC QLQ-STO22 among the three operation types (p=0.050, p < 0.001, and p=0.057, respectively). Dysphagia was significantly different between the distal and total gastrectomy groups and the distal and proximal gastrectomy groups in both KOQUSS-40 and EORTC QLQ-STO22 (both p < 0.001). However, a significant difference in dysphagia between the total and proximal gastrectomy groups was observed only

Table 1. Patient demographics and clinicopathological characteristics

Factor	No. (%)
Age (yr), mean±SD	59.7±10.9
Sex	
Male	288 (58.7)
Female	203 (41.3)
BMI (kg/m²), mean±SD	24.1±3.3
Surgical approach	
Open	44 (9.0)
Laparoscopy	403 (82.1)
Robot	44 (9.0)
Extent of gastrectomy	
Distal	350 (71.3)
Total	67 (13.7)
Proximal	49 (10.0)
Pylorus-preserving	25 (5.1)
Reconstruction method	
Billroth I	90 (18.3)
Billroth II	179 (36.5)
Roux-en-Y gastrojejunostomy	81 (16.5)
Roux-en-Y esophagojejunostomy	67 (13.7)
Esophagogastrostomy	18 (3.7)
Double tract reconstruction	31 (6.3)
Gastrogastrostomy	25 (5.1)
T classification	
T1	370 (75.4)
T2	45 (9.2)
T3	50 (10.2)
T4	26 (5.3)
N classification	
N0	378 (77.0)
N1	57 (11.6)
N2	31 (6.3)
N3	25 (5.1)
Adjuvant chemotherapy	
Not done	384 (78.2)
Done	94 (19.1)
Unknown	13 (2.6)

BMI, body mass index; SD, standard deviation.

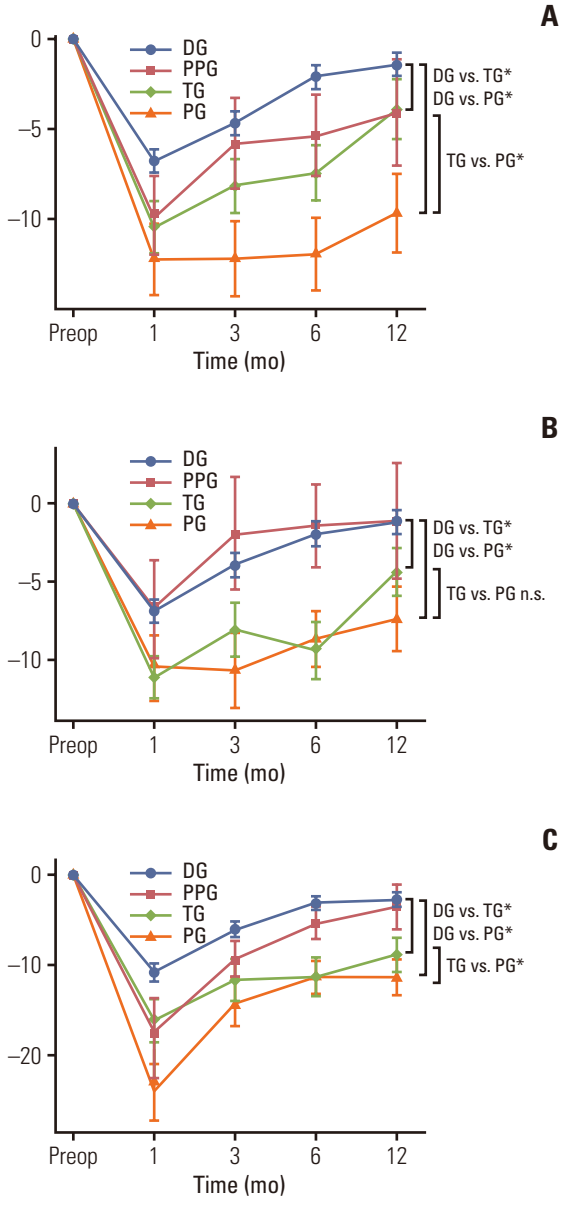

Fig. 2. Postoperative changes of summary scores of the KOQUSS-40 (A), EORTC QLQ-C30 (B), and EORTC QLQ-STO22 (C). DG, distal gastrectomy; EORTC QLQ, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; KOQUSS, KOrean QUality of life in Stomach cancer patients Study group; n.s., not significant; PG, proximal gastrectomy; PPG, pylorus-preserving gastrectomy; TG, total gastrectomy. *$p < 0.05$.

in the KOQUSS-40 (p=0.031), but not in the EORTC QLQ-STO22 (p=0.168). Regarding reflux in the KOQUSS-40, a trend toward significance was observed between the total and proximal gastrectomy groups (p=0.055), but not in the EORTC QLQ-STO22 (p=0.114).

Bowel habit changes in the KOQUSS-40 corresponded to diarrhea in the EORTC QLQ-C30, and there was no significant difference between the two questionnaires. Constipation from the KOQUSS-40 and EORTC QLQ-C30 also showed similar patterns—no significant difference among all types of gastrectomy group (data not shown).

3. Correlation between QoL scores and endoscopic findings

Based on the endoscopic findings at 1 year postoperatively, the patients were divided into two groups: reflux

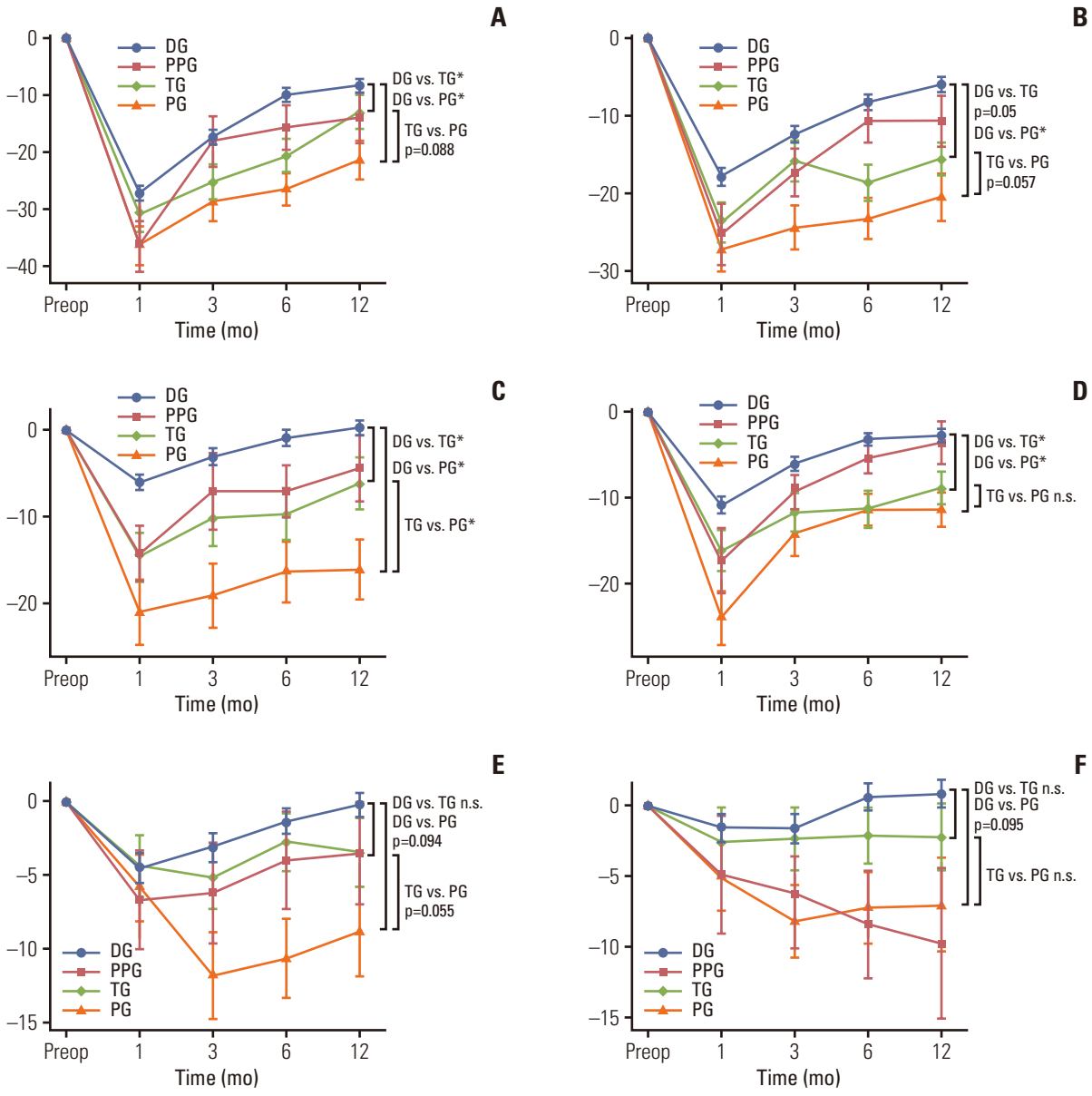

Fig. 3. Postoperative changes of common symptoms. (A) Indigestion of the KOQUSS-40. (B) Eating restriction of the EORTC QLQ-STO22. (C) Dysphagia of the KOQUSS-40. (D) Dysphagia of the EORTC QLQ-STO22. (E) Reflux of the KOQUSS-40. (F) Reflux of the EORTC QLQ-STO22. DG, distal gastrectomy; EORTC QLQ, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; KOQUSS, KOrean QUality of life in Stomach cancer patients Study group; n.s., not significant; PG, proximal gastrectomy; PPG, pylorus-preserving gastrectomy; TG, total gastrectomy. *p < 0.05.

esophagitis (n=31) and no reflux esophagitis (n=419). The mean changes of reflux score of the KOQUSS-40 from baseline were –6.8±19.6 and –1.3±15.5 in the reflux and no reflux groups, respectively (p=0.064). For the same reflux scale of the EORTC QLQ-STO22, the mean changes were 0±20.8 and –1.1±18.2 in the two groups, respectively (p=0.76).

The patients were also divided into two groups according to food stasis: presence of food stasis (n=48) and no food stasis (n=393). On all scales of the KOQUSS-40 and EORTC QLQ C30/STO22, there were no significant differences between the food stasis and no food stasis groups (S1 Table).

4. QoL changes and responsiveness according to ≥ 10% body weight loss

We evaluated the changes in QoL according to postoperative body weight loss. The patients were divided into

Table 2. QoL changes according to the 10% body weight loss at postoperative 3 months

Scale	Weight loss of less than 10% (n=283)	Weight loss of 10% or more (n=181)	p-value	SRM of weight loss of 10% or more (95% CI)	Effect size of weight loss of 10% or more (95% CI)
KOQUSS-40					
General QoL	2.4±24.6	–5.4±27.6	0.002[a]	–0.19 (–0.34 to –0.06)	–0.25 (–0.44 to –0.06)
Indigestion	–17.2±21.9	–23.6±24.3	0.003[a]	–0.97[a] (–1.17 to –0.77)	–1.24[a] (–1.49 to –0.99)
Dysphagia	–3.7±18.0	–9.4±23.1	0.005[a]	–0.41 (–0.55 to –0.26)	–0.54[a] (–0.75 to –0.33)
Reflux	–2.9±16.4	–7.0±20.3	0.024[a]	–0.35 (–0.48 to –0.21)	–0.47 (–0.68 to –0.26)
Dumping syndrome	–4.2±13.1	–7.6±15.2	0.015[a]	–0.50[a] (–0.65 to –0.34)	–0.66[a] (–0.88 to –0.45)
Bowel habit change	–9.0±17.9	–9.8±17.9	0.604	–0.55[a] (–0.72 to –0.36)	–0.69[a] (–0.89 to –0.48)
Constipation	0.2±23.5	–7.6±26.0	0.694	–0.03 (–0.18 to 0.12)	–0.04 (–0.22 to 0.15)
Psychological factors	–1.0±17.9	–6.5±19.7	0.002[a]	–0.33 (–0.48 to –0.17)	–0.38 (–0.55 to –0.20)
Worry about cancer	3.3±23.5	–0.0±26.2	0.163	0.00 (–0.15 to 0.15)	0.00 (–0.19 to 0.18)
Scar problem	3.9±18.6	8.1±18.5	0.453	0.44 (0.11 to 0.74)	0.56[a] (–0.07 to 1.18)
Financial problem	2.7±24.6	5.2±19.6	0.636	0.27 (–0.07 to 0.60)	0.27 (–0.10 to 0.63)
EORTC QLQ-C30					
Global health status	–1.7±25.4	–7.3±27.9	0.029[a]	–0.26 (–0.41 to –0.11)	–0.32 (–0.50 to –0.13)
Physical functioning	–3.0±17.7	–8.6±18.4	0.001[a]	–0.46 (–0.63 to –0.28)	–0.56[a] (–0.74 to –0.37)
Role functioning	–7.6±20.0	–13.1±25.3	0.016[a]	–0.52[a] (–0.67 to –0.35)	–0.64[a] (–0.84 to –0.44)
Emotional functioning	0.7±19.5	0±21.1	0.693	0.00 (–0.15 to 0.14)	0.00 (–0.16 to 0.16)
Cognitive functioning	–0.7±18.6	–4.4±18.4	0.041[a]	–0.24 (–0.38 to –0.09)	–0.28 (–0.45 to –0.10)
Social functioning	–3.4±25.3	–3.3±25.7	0.968	–0.13 (–0.27 to 0.02)	–0.15 (–0.33 to 0.03)
Fatigue	–6.0±22.8	–14.4±25.7	< 0.001[a]	–0.56[a] (–0.71 to –0.40)	–0.69[a] (–0.89 to –0.49)
Nausea and vomiting	–5.2±17.1	–11.5±23.4	0.002[a]	–0.49 (–0.62 to –0.35)	–0.65[a] (–0.87 to –0.44)
Pain	–0.8±19.9	–4.3±23.7	0.109	–0.18 (–0.32 to –0.03)	–0.24 (–0.44 to –0.04)
Dyspnea	–1.4±22.6	–2.4±24.9	0.665	–0.10 (–0.25 to 0.06)	–0.12 (–0.30 to 0.06)
Insomnia	1.9±30.7	–0.4±28.0	0.420	–0.01 (–0.16 to 0.13)	–0.02 (–0.19 to 0.16)
Appetite loss	–9.2±30.7	–19.8±36.6	0.001[a]	–0.54[a] (–0.69 to –0.39)	–0.74[a] (–0.97 to –0.51)
Constipation	0.5±27.7	–3.0±31.8	0.235	–0.09 (–0.24 to 0.05)	–0.12 (–0.30 to 0.07)
Diarrhea	–11.1±31.7	–16.2±32.8	0.099	–0.49 (–0.65 to –0.33)	–0.65[a] (–0.87 to –0.44)
Financial difficulties	–1.6±25.6	1.1±23.7	0.263	0.05 (–0.10 to 0.19)	0.05 (–0.11 to 0.22)
EORTC QLQ-STO22					
Dysphagia	–5.7±13.2	–11.1±18.9	0.001[a]	–0.59[a] (–0.73 to –0.44)	–0.78[a] (–1.00 to –0.56)
Pain	–4.7±18.7	–9.7±19.8	0.007[a]	–0.49 (–0.64 to –0.34)	–0.63[a] (–0.83 to –0.42)
Reflux	–1.7±18.5	–4.5±18.9	0.126	–0.24 (–0.38 to –0.09)	–0.28 (–0.46 to –0.10)
Eating restriction	–11.4±18.0	–19.2±21.1	< 0.001[a]	–0.91[a] (–1.06 to –0.75)	–1.24[a] (–1.51 to –0.98)
Anxiety	–9.2±24.4	–13.7±25.2	0.061	–0.54[a] (–0.68 to –0.39)	–0.63[a] (–0.81 to –0.44)
Having a dry mouth	–4.2±29.3	–6.3±32.0	0.467	–0.20 (–0.35 to –0.05)	–0.24 (–0.43 to –0.06)
Taste	–7.5±26.0	–16.0±30.5	0.002[a]	–0.53[a] (–0.65 to –0.40)	–0.71[a] (–0.93 to –0.49)
Body image	–9.8±28.8	–11.2±32.4	0.632	–0.35 (–0.49 to –0.20)	–0.42 (–0.61 to –0.23)
Hair loss	0.1±13.0	1.4±14.7	0.326	0.10 (–0.06 to 0.24)	0.13 (–0.07 to 0.34)

Values are presented as mean±standard deviation or median (95% CI). CI, confidence interval; EORTC QLQ, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; KOQUSS, KOrean QUality of life in Stomach cancer patients Study group; SRM, standardized response mean. [a]p-values < 0.05 or moderate/high ability for SRM and effect size.

two groups: < 10% (n=283) and ≥ 10% (n=181) weight loss at 3 months postoperatively. The ≥ 10% weight loss group experienced significantly worse QoL changes in six of the 11 scales of the KOQUSS-40 (general QoL, indigestion, dysphagia, reflux, dumping syndrome, and psychological factors; p=0.002, p=0.003, p=0.005, p=0.024, p=0.015, and p=0.002, respectively) than the < 10% weight loss group (Table 2). In the EORTC QLQ-C30, significant differences were noted in seven of the 15 scales between the two groups (global health status; physical, role, and cognitive functioning; fatigue;

Table 3. QoL changes according to receiving adjuvant chemotherapy at postoperative 3 months

Scale	No adjuvant chemotherapy (%) (n=384)	Adjuvant chemotherapy (%) (n=94)	p-value	SRM of adjuvant chemotherapy (95% CI)	Effect size of adjuvant chemotherapy (95% CI)
KOQUSS-40					
General QoL	1.5±26.0	–9.0±25.6	0.001[a)]	–0.35 (–0.56 to –0.13)	–0.40 (–0.65 to –0.15)
Indigestion	–18.6±22.9	–23.7±23.1	0.063	–1.03[a)] (–1.28 to –0.75)	–1.21[a)] (–1.54 to –0.88)
Dysphagia	–5.2±19.7	–9.4±21.9	0.080	–0.43 (–0.63 to –0.21)	–0.54[a)] (–0.84 to –0.25)
Reflux	–4.9±17.6	–2.8±20.0	0.335	–0.14 (–0.34 to 0.06)	–0.19 (–0.48 to 0.10)
Dumping syndrome	–5.4±13.5	–5.9±15.9	0.776	–0.37 (–0.57 to –0.16)	–0.50[a)] (–0.81 to –0.20)
Bowel habit change	–8.4±17.8	–12.4±18.1	0.064	–0.69[a)] (–0.90 to –0.45)	–0.86[a)] (–1.17 to –0.55)
Constipation	–0.1±23.7	–0.2±28.2	0.983	–0.01 (–0.23 to 0.20)	–0.01 (–0.27 to 0.25)
Psychological factors	–3.1±18.1	–3.3±21.1	0.924	–0.16 (–0.37 to 0.07)	–0.17 (–0.41 to 0.06)
Worry about cancer	2.3±24.2	0.9±25.9	0.651	0.04 (–0.17 to 0.25)	0.04 (–0.22 to 0.30)
Scar problem	5.3±19.4	5.6±15.5	0.963	0.36 (–0.25 to 0.97)	0.43 (–0.36 to 1.22)
Financial problem	5.5±22.3	–4.6±21.3	0.090	–0.22 (–0.87 to 0.70)	–0.22 (–0.70 to 0.26)
EORTC QLQ-C30					
Global health status	–2.2±26.2	–9.8±27.9	0.017[a)]	–0.35 (–0.57 to –0.12)	–0.40 (–0.65 to –0.15)
Physical functioning	–4.2±17.4	–8.6±20.7	0.065	–0.42 (–0.65 to –0.16)	–0.53[a)] (–0.81 to –0.24)
Role functioning	–8.0±20.7	–16.3±28.2	0.012[a)]	–0.58[a)] (–0.75 to –0.39)	–0.65[a)] (–0.92 to –0.39)
Emotional functioning	0.9±20.0	–1.1±20.6	0.408	–0.05 (–0.27 to 0.16)	–0.05 (–0.26 to 0.016)
Cognitive functioning	–1.4±18.3	–4.7±19.2	0.143	–0.24 (–0.45 to –0.03)	–0.31 (–0.60 to –0.03)
Social functioning	–2.2±24.7	–7.4±28.3	0.088	–0.26 (–0.48 to –0.03)	–0.31 (–0.56 to –0.05)
Fatigue	–7.9±24.1	–13.6±25.0	0.053	–0.54[a)] (–0.74 to –0.33)	–0.65[a)] (–0.94 to –0.37)
Nausea and vomiting	–6.4±18.1	–12.4±26.3	0.048[a)]	–0.47 (–0.67 to –0.26)	–0.67[a)] (–1.01 to –0.34)
Pain	–2.2±20.1	–1.4±26.7	0.784	–0.05 (–0.27 to 0.16)	–0.07 (–0.36 to 0.22)
Dyspnea	–1.8±23.1	–1.9±25.2	0.949	–0.08 (–0.29 to 0.15)	–0.09 (–0.33 to 0.16)
Insomnia	0.7±29.6	2.7±29.5	0.570	0.09 (–0.13 to 0.31)	0.11 (–0.14 to 0.35)
Appetite loss	–11.6±31.8	–21.3±38.6	0.033[a)]	–0.55[a)] (–0.77 to –0.32)	–0.76[a)] (–1.09 to –0.43)
Constipation	–0.3±28.2	–1.9±34.8	0.678	–0.06 (–0.27 to 0.15)	–0.07 (–0.35 to 0.21)
Diarrhea	–12.3±31.3	–16.3±36.1	0.307	–0.45 (–0.66 to –0.23)	–0.62[a)] (–0.94 to –0.30)
Financial difficulties	–0.9±25.1	1.9±25.7	0.350	0.08 (–0.14 to 0.28)	0.08 (–0.15 to 0.32)
EORTC QLQ-STO22					
Dysphagia	–6.9±15.3	–11.7±17.5	0.010[a)]	–0.67[a)] (–0.85 to –0.47)	–0.87[a)] (–1.20 to –0.55)
Pain	–6.5±18.6	–7.3±21.6	0.743	–0.34 (–0.56 to –0.11)	–0.43 (–0.72 to –0.15)
Reflux	–2.6±18.6	–2.8±19.1	0.903	–0.15 (–0.35 to 0.05)	–0.18 (–0.43 to 0.08)
Eating restriction	–13.9±19.0	–16.1±22.1	0.355	–0.73[a)] (–0.91 to –0.52)	–0.96[a)] (–1.30 to –0.62)
Anxiety	–10.3±24.7	–13.2±25.4	0.325	–0.52[a)] (–0.72 to –0.32)	–0.58[a)] (–0.84 to –0.32)
Having a dry mouth	–3.5±30.5	–10.9±29.1	0.044[a)]	–0.37 (–0.56 to –0.18)	–0.44 (–0.70 to –0.18)
Taste	–8.5±25.6	–19.8±35.9	0.007[a)]	–0.55[a)] (–0.73 to –0.36)	–0.79[a)] (–1.14 to –0.44)
Body image	–8.6±29.1	–16.3±33.8	0.034[a)]	–0.48 (–0.68 to –0.27)	–0.62[a)] (–0.93 to –0.32)
Hair loss	0.2±13.7	2.8±13.6	0.110	0.21 (0.01 to 0.41)	0.26 (–0.02 to 0.54)

Values are presented as mean±standard deviation or median (95% CI). CI, confidence interval; EORTC QLQ, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; KOQUSS, KOrean QUality of life in Stomach cancer patients Study group; SRM, standardized response mean. [a)]p-values < 0.05 or moderate/high ability for SRM and effect size.

nausea and vomiting; and appetite loss; p=0.029, p=0.001, p=0.016, p=0.041, p < 0.001, p=0.002, and p=0.001, respectively). In the EORTC QLQ-STO22, there were significant differences in four of the nine scales (dysphagia, pain, eating restriction, and taste; p=0.001, p=0.007, p < 0.001, and p=0.002, respectively).

The indicators of responsiveness, including SRM and effect size, were also calculated for patients who experienced ≥ 10% body weight loss. Indigestion, dumping syndrome, and bowel habit changes of the KOQUSS-40 appeared to be

responsive, with ≥ 0.5, reflecting a moderate or high ability to detect the effect of body weight loss. Moderate or high responsiveness was observed in three of 11 (27.3%) scales of the KOQUSS-40 based on SRM and five of 11 (45.4%) scales based on effect size. Regarding the EORTC QLQ, role functioning, fatigue, appetite loss of C30, dysphagia, eating restriction, anxiety, and taste of STO22 were moderately or highly responsive. Moderate or high responsiveness was identified in seven of 24 (29.2%) scales of the EORTC QLQ-C30/STO22 based on SRM and in 11 of 24 (45.8%) scales based on effect size.

5. QoL changes and responsiveness according to adjuvant chemotherapy

A total of 94 patients were treated with adjuvant chemotherapy at 3 months postoperatively. In the KOQUSS-40, a significant difference was noted only in the general QoL scale between the chemotherapy and no chemotherapy groups (p=0.001) (Table 3). In contrast, there were significant differences in four of 15 scales (global health status, role functioning, nausea and vomiting, and appetite loss; p=0.017, p=0.012, p=0.048, and p=0.033, respectively) of the EORTC QLQ-C30 and in 4 of 9 scales (dysphagia, dry mouth, taste, and body image; p=0.010, p=0.044, p=0.007, and p=0.034, respectively) of the EORTC QLQ-STO22.

Regarding responsiveness, indigestion and bowel habit changes of the KOQUSS-40 were responsive, with a moderate or high ability to detect the effect of adjuvant chemotherapy. Moderate or high responsiveness was observed in two of 11 (18.2%) scales of the KOQUSS-40 based on SRM and four of 11 (36.3%) scales based on effect size. In the EORTC QLQ, role functioning, fatigue, appetite loss of the C30, dysphagia, eating restriction, anxiety, and taste of the STO22 were moderately or highly responsive. In seven of 24 (29.2%) scales of the EORTC QLQ-C30/STO22 and 11 of 24 (45.8%) scales, moderate or high responsiveness was shown based on SRM and effect size, respectively.

Discussion

In this study, we assessed changes in QoL in patients who underwent gastrectomy for gastric cancer using both the KOQUSS-40 and EORTC QLQ-C30/STO22 and attempted to identify any advantages or differences of the KOQUSS-40 over the EORTC QLQ. The KOQUSS-40 showed a significant difference in dysphagia between the total and proximal gastrectomy groups, and the reflux scale showed a trend toward significance in correlation with endoscopic reflux esophagitis, which was not observed in the EORTC QLQ-STO22. The responsiveness of the KOQUSS-40 was similar to that of the EORTC QLQ-C30/STO22 in detecting the effect of ≥ 10% body weight loss. However, the KOQUSS-40 was less responsive in patients who received adjuvant chemotherapy than that in the EORTC QLQ C30/STO22.

When designing a study, researchers select appropriate instruments that can effectively derive study outcomes. However, there is no standard assessment tool recommended with high-level evidence for QoL studies, and well-known questionnaires, such as the EORTC QLQ and FACT, have usually been selected. As each questionnaire has different domains and scoring systems, it is difficult to directly compare the two questionnaires. In previous studies comparing two QoL questionnaires, the structure of each tool were summarized and the development process, characteristics, validity, and reliability of the tools were listed up [26-28]. In one study, health-related QoL instruments were rated on nine measurement properties (internal consistency, reliability, measurement error, content validity, structural validity, hypothesis testing, cross-cultural validity, criterion validity, and responsiveness), and the number of positive rating of each instrument was demonstrated [28]. Based on the overall rating, a questionnaire with the most positive ratings on measurement properties was recommended in the study.

In this study, as both the KOQUSS-40 and EORTC QLQ have already been verified in terms of validity and reliability, we focused on the sensitivity of the instruments to detect differences in QoL according to the surgical method or treatment. Thus, QoL changes according to the surgical method were analyzed, and responsiveness, an important indicator for detecting clinical effects, was compared between the two instruments [29]. Therefore, this study reveals which instrument can effectively show patients' QoL according to clinical factors.

In fact, the KOQUSS-40 was expected to show differences in postgastrectomy symptoms more clearly than the EORTC QLQ-C30/STO22 because it was developed to assess postgastrectomy symptoms in patients who underwent curative gastrectomy. However, the statistical significance of the differences in QoL according to the extent of gastrectomy was similar between the two instruments. The QoL patterns of some common scales, such as indigestion, dysphagia, and reflux, were comparable, and the responsiveness of the two instruments was not significantly different in patients who experienced ≥ 10% body weight loss. Overall, the KOQUSS-40 did not show a significant difference in terms of clinical effectiveness compared with the EORTC QLQ.

One distinct advantage of the KOQUSS-40 is the ability to detect differences in esophagogastric junction-associated scales, such as dysphagia and reflux, between the total and proximal gastrectomy groups. Moreover, the reflux score of the KOQUSS-40 had a trend of correlation with the presence

of reflux esophagitis. These findings were not observed for the EORTC QLQ-STO22. Therefore, the KOQUSS-40 could be more effective in studies comparing QoL between total and proximal gastrectomy groups than the EORTC QLQ-STO22.

In contrast, the KOQUSS-40 was less responsive to adjuvant chemotherapy than the EORTC QLQ-C30/STO22. The KOQUSS-40 consists of postgastrectomy symptoms and other operation-related scales and does not include chemotherapy-related symptom scales, such as fatigue, nausea and vomiting, appetite loss, and taste change. Thus, only one scale of the KOQUSS-40 was significantly different between the no adjuvant chemotherapy and adjuvant chemotherapy groups, and the number of scales with moderate or high responsiveness was lower than that of the EORTC QLQ-C30/STO22. The KOQUSS-40 appears to be less useful than the EORTC QLQ for patients receiving chemotherapy.

This study has some limitations. First, although we tried to compare the responsiveness of the two instruments, differences in the number of scales with statistical significance rather than a statistical comparison were demonstrated. Therefore, the statistical superiority or inferiority of KOQUSS-40 over EORTC QLQ could not be clearly established in this study. Second, esophagogastric junction-related symptoms, such as dysphagia and reflux, can be assessed more effectively using the EORTC QLQ-OG25 (esophagogastric cancer module) than the STO22. Thus, further studies comparing the KOQUSS-40 and EORTC QLQ-OG25 scores in patients who have undergone total or proximal gastrectomy would be helpful in determining the effectiveness of the KOQUSS-40. Third, there were considerable discrepancies in the numbers of patients according to surgical approach, extent of gastrectomy, and pathological stage. More than 70% of the patients who underwent laparoscopic distal gastrectomy, were diagnosed with pT1 and pN0 and did not require adjuvant chemotherapy. These skewed distributions reflecting the clinical characteristics of patients in East Asia can be an obstacle to generalizing the study findings worldwide. Finally, the KOQUSS-40 was developed and validated by Korean patients, and patients from different cultures can respond differently to the KOQUSS-40. Therefore, the results of this study may differ in other cultures, thus it would be desirable to validate them in other cultures as well.

In conclusion, the KOQUSS-40 has some advantages in comparison of QoL between the total and proximal gastrectomy groups. However, the KOQUSS-40 has approximately 10% lower responsiveness in patients who received adjuvant chemotherapy than the EORTC QLQ-C30/STO22. These findings provide information for researchers investigating the QoL of patients who have undergone curative gastrectomies for gastric cancer.

Electronic Supplementary Material

Supplementary materials are available at Cancer Research and Treatment website (https://www.e-crt.org).

Ethical Statement

The study protocol was approved by the institutional review boards of 22 hospitals: National Cancer Center (NCC2021-0105), Samsung Medical Center (SMC 2021-04-084-001), Seoul National University Bundang Hospital (B-2104-676-401), Soonchunhyang University Bucheon Hospital (SCHBC 2021-03-041-001), Yeouido St. Mary's Hospital (SC21QIDI0022), Gyeongsang National University School of Medicine (GNUH 2021-03-018), Ajou University Hospital (AJIRB-MED-SUR-21-063), Pusan National University Yangsan Hospital (05-2021-056), Kyungpook National University Chilgok Hospital (KNUCH 2021-04-002), Yonsei University Severance Hospital (4-2021-1490), Gangnam Severance Hospital (4-2021-1490), Seoul National University Hospital (H-2101-198-1195), Inje University Haeundae Paik Hospital (2021-05-021-002), Gyeongsang National University Changwon Hospital (GNUCH 2021-03-028), Seoul National University Boramae Medical Center (30-2021-82), Kosin University College of Medicine (KUGH 2021-06-002), Soonchunhyang University Cheonan Hospital (SCHCA 2021-03-040), Keimyung University Dongsan Medical Center (DSMC 2021-04-128), Yeungnam University College of Medicine (YUMC 2021-03-035-001), Seoul Medical Center (SEOUL 2021-03-003), Gachon University Gil Medical Center (GAIRB2021-142), and Korea University Guro Hospital (2021GR0143).

Informed consent was obtained from all patients included in the study. All of the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964 and later versions.

Author Contributions

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Conflicts of Interest
Conflict of interest relevant to this article was not reported.

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