

were evaluated by these instruments after gastrectomy remain sparse. In the current study, the EORTC QLQ-C30 and QLQ-STO22 were applied to Japanese patients who underwent potentially curative gastric cancer surgery for robust longitudinal HRQOL assessment to compare the patient-reported outcomes among the three frequently performed surgical procedures.

Materials and methods

Patients

The questionnaires were sent to 110 consecutive gastric cancer patients who underwent potentially curative gastrectomy between May 2005 and November 2007 at the Department of Surgery II, Nagoya University Graduate School of Medicine. Among these patients, those who had distant metastases or recurrences were excluded; the remaining patients who had been disease-free at 1 year after surgery were evaluated. The patients were treated by open total gastrectomy (TG) ($n = 8$), open distal gastrectomy (DG) ($n = 24$), or laparoscopy-assisted distal gastrectomy (LADG) ($n = 44$). Patient demographics are summarized in Table 1.

Treatment details

Details of surgical procedure and postoperative course that may influence HRQOL data are summarized in Table 2. TG was performed for cancer located partially or completely in the upper third of the stomach. D2 dissection with splenectomy was routinely performed for patients with advanced cancer who underwent TG. All patients who underwent TG had reconstruction by Roux-Y anastomosis. DG was performed for more advanced cancer with the preoperative diagnosis of stage II, III, or IV. Almost all patients underwent D2 dissection and reconstruction by Roux-Y anastomosis. LADG was performed in patients with a preoperative diagnosis of up to stage IB (T1N1 or T2N0) according to the Japanese Guidelines for Gastric Cancer. Either D2 dissection or D1 with additional resection of some second-tier lymph nodes (the nodes around the left gastric artery, common hepatic artery, celiac axis, and splenic artery) was performed with LADG. Most patients who underwent LADG had Billroth type I reconstruction, whereas a small fraction of patients with small gastric remnants or preoperative diagnosis of reflux disease had Roux-Y reconstruction. Cholecystectomy was simultaneously performed in patients who were found to have gallbladder stones during any of the procedures. D3 dissection (dissection of the paraaortic lymph nodes) was performed in patients who were diagnosed as N3 preoperatively.

Table 1 Characteristics of patients who underwent TG, DG, or LADG

Characteristic	TG ($n = 8$)	DG ($n = 24$)	LADG ($n = 44$)
Sex (M/F)	8/0	15/9	32/12
Age (years), median	69.0	61.5	59.5
Macroscopic type			
0	3	5	43
1	0	1	0
2	2	11	1
3	2	5	0
4	0	1	0
5	1	1	0
Depth of invasion			
T1	3	8	38
T2	5	9	6
T3	0	7	0
T4	0	0	0
Lymph node metastasis			
N0	4	10	37
N1	3	10	3
N2	1	2	4
N3	0	2	0
Stage			
I	4	11	39
II	3	7	3
III	1	4	2
IV	0	2	0
Curability			
A	6	17	41
B	2	7	3
C	0	0	0
Pathological type ^a			
Differentiated	3	9	17
Undifferentiated	5	14	26
Others	0	1	1

Clinical findings and staging classification are described according to the Japanese Classification of Gastric Carcinoma

TG total gastrectomy, DG distal gastrectomy, LADG laparoscopy-assisted distal gastrectomy

^a Lauren classification

Vagal nerve preservation was not undertaken for any of the procedures with the exception of the hepatic branch, which was preserved in the LADG cases.

We performed adjuvant chemotherapy for essentially all of the patients with a final diagnosis of stage II or III disease. The only exceptions were patients who did not give consent for the treatment. S-1, an oral derivative of tegafur, was adopted for most of the patients who underwent adjuvant chemotherapy.

Table 2 Background of patients who underwent TG, DG, or LADG

Parameter	TG (n = 8)	DG (n = 24)	LADG (n = 44)
Lymph node dissection			
D1 + β	4	2	19
D2	3	21	25
D3	1	1	0
Combined resection			
Gallbladder	2	12	3
Spleen	4	0	0
Reconstruction procedure			
Billroth I	–	4	36
Roux-Y	8	20	8
Operative morbidity (%)	25.0	12.5	15.9
Late complication			
Ileus	0	0	0
Cholecystitis	0	1	0
Adjuvant chemotherapy	3	11	1
Duration of adjuvant chemotherapy (months), median	12	12	6

D1+ β : D1 with additional resection of some second-tier lymph nodes (nodes around the left gastric artery, common hepatic artery, celiac axis, and splenic artery)

Assessment of the HRQOL

The fully validated Japanese version of the EORTC QLQ-C30 (version 3.0) and QLQ-STO22 were mailed to the patients for self-completion at the baseline (before surgery) and at 1, 3, 6, and 12 months after surgery. Missing values were handled according to the recommendations in the EORTC QLQ-C30 scoring manual [16]. Time windows of ± 2 weeks were applied for each postoperative assessment.

The EORTC QLQ-C30 consists of a 30-item cancer-specific integrated system for assessing key functional aspects of HRQOL, the global quality of life (QOL), and symptoms that commonly occur in cancer patients. The items are grouped into five function scales (physical, role, cognitive, emotional, social), three symptom scales (fatigue, pain, nausea and vomiting), a global health status and QOL scale, and single items (dyspnea, insomnia, appetite loss, constipation, diarrhea, financial difficulties). Of the 30 items, 28 are scored on four-point Likert scales and the remaining 2 items for the global health status scale on modified seven-point linear analog scales. All scales were linearly transformed to a 0 to 100 score, with 100 representing the best global health status or functional status or the worst symptom status.

The EORTC QLQ-STO22, a stomach cancer-specific questionnaire, consists of 22 items. It includes five scales (dysphagia, chest and abdominal pain, reflux, eating restrictions, anxieties) and four single items (dry mouth, body image, taste problems, hair loss) reflecting disease symptoms, treatment side effects, and emotional issues specific to gastric cancer, with high scores indicating worse symptomatic problems [16, 17].

The mean scores of the global health status and functional scales were compared between TG and DG and between DG and LADG at various time intervals after surgery. As for the symptom scales and single items, the proportion of patients with symptoms were compared among the surgical procedures as described by Avery et al.: Patients with symptoms were defined as responding, “a little,” “quite a bit,” or “very much” to symptom items and scales, whereas patients responding “not at all” were classified as asymptomatic [10].

The StatView 5.0 program was used for the statistical analyses. Variables were analyzed using Mann-Whitney’s U-test. A value of $p < 0.05$ was considered statistically significant.

Results

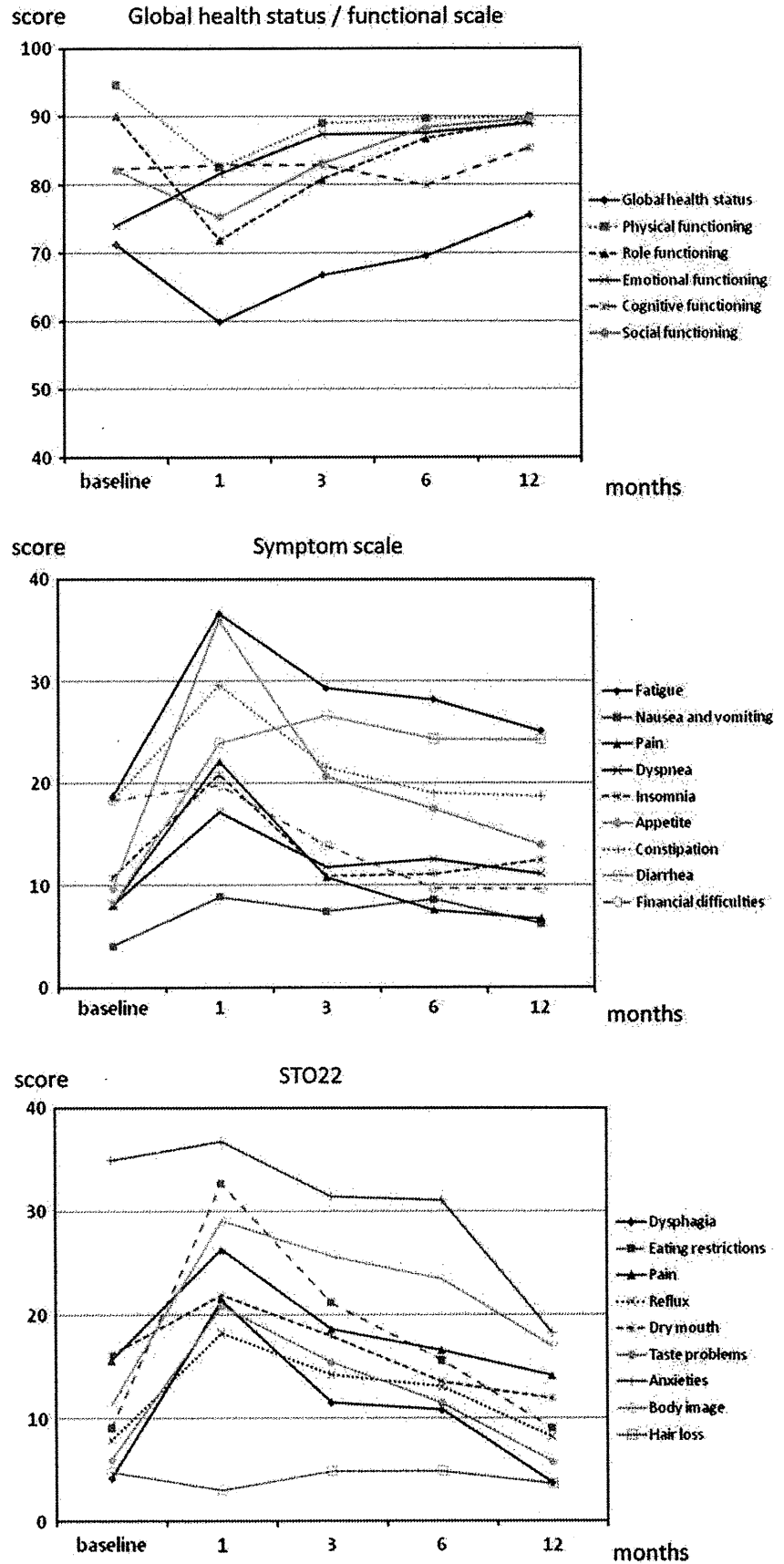
Questionnaire, compliance, missing data

Before treatment, 81.6% of patients returned questionnaires. Overall compliance during the follow-up was 85.0%. The rate of missing values was 0.8%.

Time course of patient-reported outcomes

The mean scores for all surgical procedures—TG, DG, LADG—were calculated in a longitudinal fashion during the first postoperative year (Fig. 1). For most of the functional scales, the mean score was worst 1 month after surgery and generally improved during the course of the follow-up. The exception was the score for the emotional

Fig. 1 Mean scores of all patients treated by gastrectomy for gastric cancer were calculated at each time point (baseline and 1, 3, 6, and 12 months after surgery) during the first postoperative year. For most of the functional scales (*top*) and symptom scales in the QLQ-C30 (*middle*) and QLQ-STO22 (*bottom*), the mean score was worst at 1 month after surgery (a higher score denotes better quality of life in the functional scales, whereas a higher score represents stronger symptoms in the symptom scales) and generally improved during the course of follow-up



functioning scale, which was worst at baseline and improved constantly after surgery.

For almost all of the symptoms scales and EORTC QLQ-C30 items, the mean scores were worst 1 month after surgery and generally improved thereafter. Particularly large fluctuations were observed in appetite loss, fatigue, and diarrhea. Of note, the scores for more than half of all the symptom scales and items did not return to the baseline level during the year after surgery. Similarly, for almost all components of the STO22 symptom scales, the mean score was the worst 1 month after surgery. The largest fluctuation was observed in the eating restrictions. Body image was the only item that did not return to the baseline level 1 year after surgery.

Global health status and functioning scores for patients undergoing different surgical procedures and approaches

The mean score for global health status after LADG was superior to that after DG at 1 month after surgery. The

differences in the physical functioning scores were more prominent, and the superiorities of LADG over DG and DG over TG were significant 12 months postoperatively. The role functioning scores recovered to the baseline level 12 months after LADG and DG but not after TG. For cognitive functioning, the scores for TG were consistently low, and the scores for DG and LADG were similar (Fig. 2).

Percentage of symptomatic patients in EORTC QLQ-C30 and QLQ-STO22 for different surgical procedures

In the fatigue scale, the percentage of patients with symptoms was lower after LADG when compared to TG and DG. However, recovery was not evident during the first year of follow-up for any of the procedures. In the pain scale, the percentage of symptomatic patients recovered to the baseline level at the 6th postoperative month. The open surgery group generally suffered from a higher percentage with symptoms than those in the laparoscopic approach group throughout the postoperative period. In the nausea and vomiting scale, the scores were inconsistent and

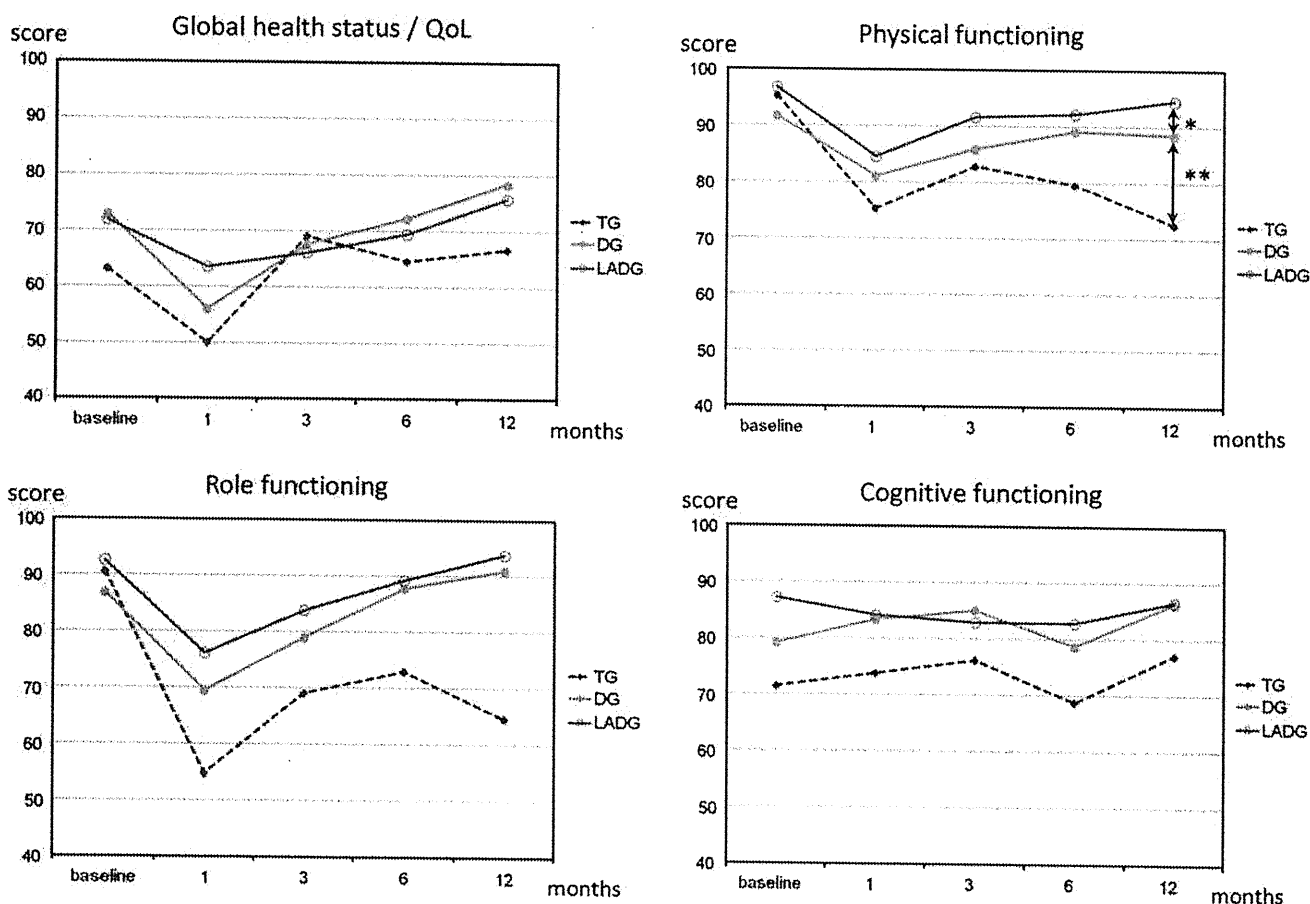


Fig. 2 Global health status and functioning scores for patients who underwent total gastrectomy (TG), open distal gastrectomy (DG), or laparoscopy-assisted distal gastrectomy (LADG). For the physical

functioning scale, the score after LADG was superior to that after DG at the 12th postoperative month (*p = 0.0269). Similarly, the score after DG was superior to that after TG at 12 months (**p = 0.0190)

tendency could not be defined. In the dyspnea scale, the percentage of symptomatic patients tended to be higher after DG than after LADG throughout the postoperative period. The appetite loss scale indicated that the percentage of symptomatic patients after DG and LADG almost recovered to the baseline level 6 months after surgery, whereas that after TG remained higher than baseline throughout the first year of follow-up (Fig. 3).

In the dysphagia scale, the percentage of symptomatic patients was higher after TG than after DG and after DG than after LADG throughout most of the follow-up. In the eating restrictions scale, the percentage of symptomatic patients after TG was higher than the others throughout the first year, whereas the difference between DG and LADG was negligible (Fig. 4).

Discussion

In the current study, EORTC QLQ-C30 and QLQ-STO22 were used primarily to detect any differences in the postoperative patient-reported outcome between laparoscopic

and open gastrectomy. The differences between total and distal gastrectomy were also explored as a reference. Our ultimate aim was to use these instruments to compare HRQOL between the laparoscopic and open approach for early-stage gastric cancer on a multiinstitutional basis, and we were particularly interested on when and in which item the differences between the two approaches were most prominent.

First, we looked at chronological changes in the HRQOL after gastrectomy. Gastrectomized patients generally suffer more from postgastrectomy symptoms during the first few months. In the current analysis, the worst values were clearly observed at the first postoperative month across almost all dimensions. Interestingly, scores of the several function scales recovered to the baseline level after 1 year, as was reported from another longitudinal study, suggesting that the patients more or less live an ordinary life by that time [9, 18]. On the other hand, scores of symptom scales such as fatigue, appetite loss, dysphagia, eating restrictions, body image, and diarrhea remained short of the baseline level after 1 year, indicating the detrimental adverse effect of gastrectomy.

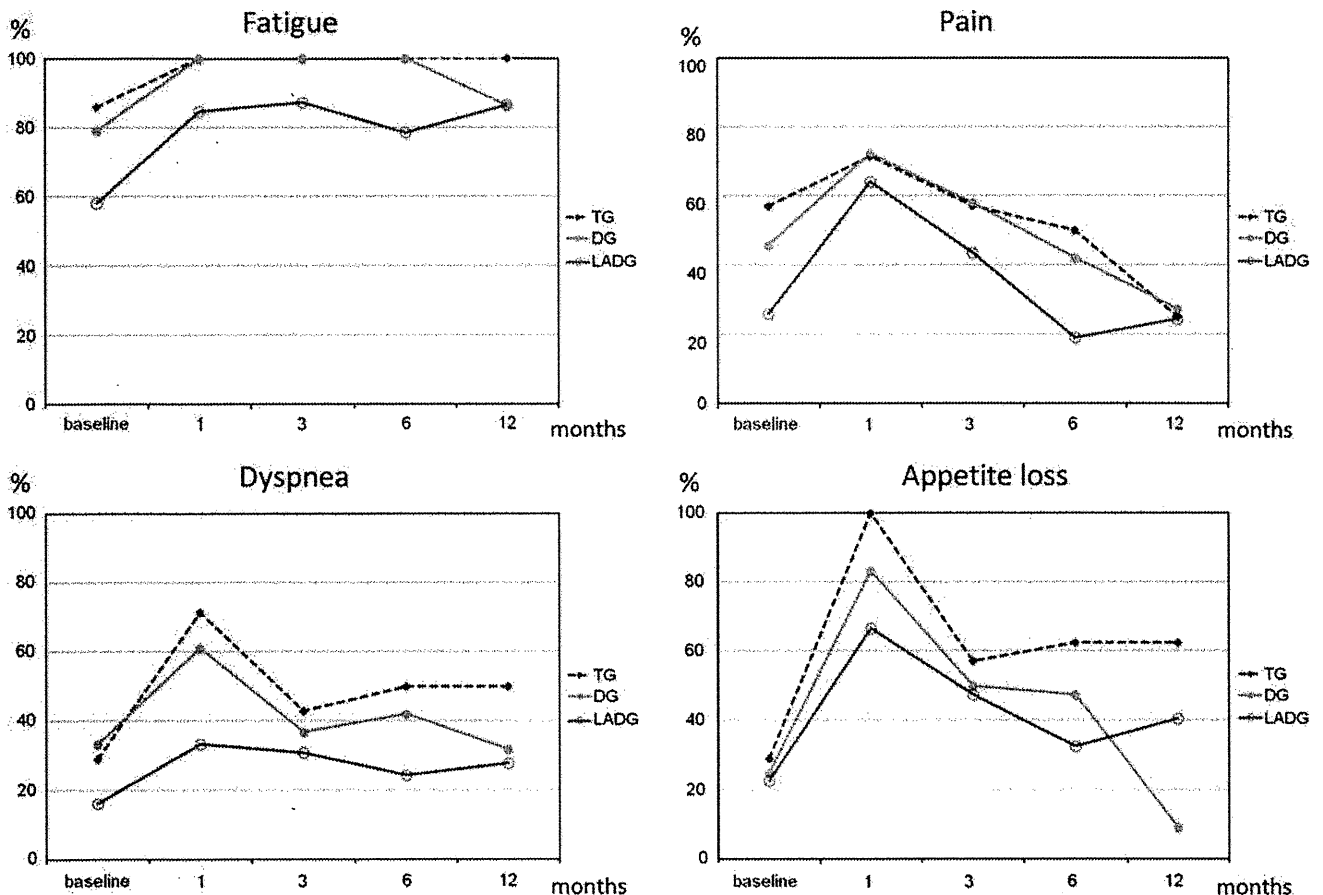


Fig. 3 Percentage of symptomatic patients evaluated by the EORTC QLQ-C30: comparison between TG, DG, and LADG. In the fatigue scale, although the percentage of symptomatic patients was lower

after LADG than after TG or DG, none of the scores in any of the treatment groups recovered to the baseline level

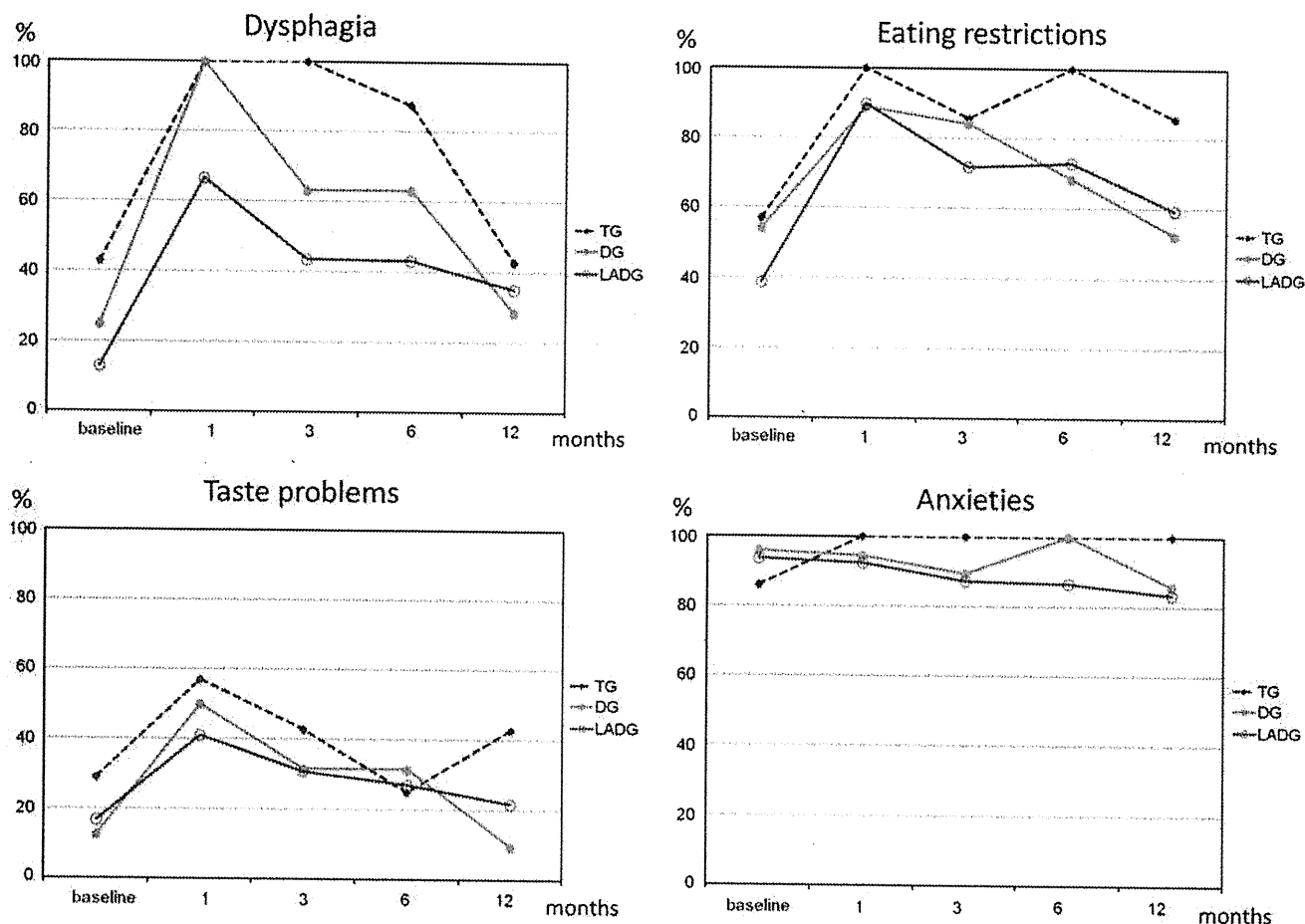


Fig. 4 Percentage of symptomatic patients in the EORTC QLQ-STO22: comparison between TG, DG, and LADG. There were longitudinal changes in the proportion of symptomatic patients in regard to dysphagia, eating restrictions, taste problems, and anxieties

Second, we made comparisons between the three commonly performed surgical procedures from a perspective of perioperative HRQOL. Although the extent to which the different types of resection or approach affect HRQOL remains poorly defined, it has been well documented that DG is superior to TG [18–21] and that laparoscopic surgery shows an advantage over open surgery for a few weeks after surgery [22–25]. The results obtained in the current study were in line with these observations and fulfilled our expectations. The difference between TG and DG was substantial in the physical functioning, role functioning, appetite loss, and eating restrictions scales. It is of note that the sample size of the TG group was too small for any meaningful comparison with other procedures. In addition, marked differences in the background (e.g., sex, age, incidence of combined resection) were observed between TG and the other procedures. Comparison between TG and other procedures must therefore be considered at best as referential data.

LADG was superior to DG in most of the items for up to 3 months after surgery, but the difference was not

long-lasting with the exception of physical functioning. This comparison is heavily biased by the fact that LADG was performed in patients with a preoperative diagnosis of early-stage cancer, whereas patients undergoing DG suffered from more advanced disease. In addition to the difference in the extent of nodal dissection, a large proportion of patients with stage II–III cancer were given postoperative adjuvant chemotherapy. This is a weakness inherent to and inevitable in a single-institution study by investigators conducting exemplary clinical practice in Japan because a laparoscopy-assisted approach has been approved only for stage IA and IB gastric cancer in the Japanese Guidelines for Treatment of Gastric Cancer; in contrast, phase III evidence exists for delivering postoperative chemotherapy to patients with stage II–III disease. We noted with interest, however, that despite the large difference in the background in favor of laparoscopic surgery the difference between the approaches reconciled in the long term and remained noticeable only in physical functioning and fatigue. It remains compelling, therefore, to make a comparison between LADG and DG among patients of a

similar clinical stage. Kim et al. measured HRQOL using EORTC QLQ-C30 and STO22 in their randomized trial comparing the two approaches, and reported on the significant superiority in several of the scales during an observation period of up to 3 months after surgery [26]. An important issue is whether such differences in HRQOL continue in the long term. The current study suggests that the marked differences between the two approaches are unlikely to persist at 12 months postoperatively.

Conclusions

We have concluded that the EORTC QLQ-C30 and QLQ-STO22 suggested some differences in HRQOL among surgical procedures for gastric cancer. Our main goal in this study was to fathom how useful these questionnaires are and whether the HRQOL thus measured could be used as endpoints in our future studies. As this goal was fulfilled, a nonrandomized prospective study to compare HRQOL between the laparoscopic and open approach for early-stage gastric cancer is currently ongoing. Our future goal in this series of studies is primarily to evaluate the benefit of the laparoscopic approach from the viewpoint of HRQOL.

Conflict of interest None.

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Nutritional recovery after open and laparoscopic gastrectomies

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Abstract

Background The aim of this study was to evaluate longitudinal changes in body composition after laparoscopic and open gastrectomies for gastric cancer.

Methods Body mass, arm muscle mass, leg muscle mass, and fat mass were measured by performing a bioelectrical impedance analysis using a “BodyScan” body composition analyzer (HXE19-JA; Konami, Tokyo, Japan) in 41 patients who had undergone gastrectomy: 14 patients underwent open distal gastrectomy, 8 patients underwent open total gastrectomy, and 19 patients underwent laparoscopy-assisted distal gastrectomy. All measurements were obtained preoperatively and at 1, 3, and 6 months after the operation.

Results Fat mass decreased significantly throughout the 6-month period after distal gastrectomy and until 3 months after the laparoscopic surgery, while similar reductions in the total muscle mass and limb muscle mass were observed only in the first month after operation for all three groups. Patients with the laparoscopic approach had completely regained muscle mass at 6 months postoperatively.

Conclusion Both fat and muscle mass reductions were responsible for the body weight loss during the first postoperative month, whereas loss of fat mass contributed to further weight loss after that period. Enhanced recovery of

muscle mass at 6 months after laparoscopic surgery suggests the benefit of this surgery, among other factors.

Keywords Body composition · Gastric cancer · Laparoscopic gastrectomy

Introduction

Body composition is substantially affected by gastrointestinal surgery, and a certain period of time is needed for recovery. Significant changes in nutritional status shortly after distal gastrectomy have been demonstrated by Katsube et al. [1]. The laparoscopic approach is considered to be minimally invasive, is considered to result in better short-term outcome [2–5], and is hoped to be oncologically feasible even for advanced gastric cancers [6]. One of the advantages of laparoscopic gastrectomy was reported to be the prevention of overt weight loss, which had generally been explained in terms of decrease in protein mass rather than fat mass [7]. Another study has demonstrated selective loss of fat mass during the first 6 months after open gastrectomy, with a minor decrease of arm circumference [8]. There have been no other longitudinal studies evaluating changes in the composition of the body and extremities after gastrectomy.

The main goal of this study was to observe the trends in muscle and fat masses during the first 6 months after various types of gastrectomies.

Methods

Patients

Forty-one patients with resectable gastric cancer who underwent gastrectomy and were followed for 6 months

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were analyzed. Twenty-two patients whose cancer was diagnosed to have penetrated as far as the subserosa or deeper were operated by conventional open surgery with D2 lymph node dissection; total gastrectomy (TG) was performed in eight patients and distal gastrectomy (DG) in 14. Roux-en-Y reconstruction was used routinely for this population. Twenty-four patients with the preoperative diagnosis of up to T2 stage gastric cancer underwent laparoscopy-assisted distal gastrectomy (LADG) with D1–D2 lymph node dissection. Billroth I reconstruction was selected for 19 patients. Five patients with preoperative reflux symptoms or extraordinarily small residual stomach underwent Roux-en-Y reconstruction, were considered as atypical cases, and were excluded from this study. Details of the surgical procedures have been reported previously [9–11]. Postoperative adjuvant chemotherapy with S-1 [12] was delivered to 10 patients treated by DG, 3 patients treated by TG, and one patient treated by LADG. Another 3 patients in the TG group received postoperative chemotherapy with S-1/cisplatin (CDDP) and another patient was treated with chemoradiation. Parenteral nutrition was not introduced after surgery in any of the patients.

Measurements of body composition

Measurements of body composition were performed at the baseline (preoperatively) and at 1, 3, and 6 months after the surgery. Body weight, muscle mass (total mass and upper and lower limb mass), and fat mass (total mass and upper and lower limb mass) were measured using segmental multifrequency bioelectrical impedance analysis performed with the “BodyScan” HXE19-JA analyzer (Konami, Tokyo, Japan) after obtaining written informed consent from the patients. The height and the waist circumference of each patient were measured before each measurement as parameters that are mandatory for calculating body composition data. Patients with installed pacemakers and those with severe cardiac arrhythmia were not eligible for the study.

Statistical analysis

General linear models of repeated measures were used for longitudinal analysis. Results are presented in delta values with 95% confidence intervals (CIs) between two time points. A *p* value of <0.05 was considered to be statistically significant. Statistical analysis was carried out using an SPSS software package (version 15; SPSS, Chicago, IL, USA).

Results

Patient demographics and tumor stages are presented in Table 1. As has been recommended in the Japanese

treatment guidelines for gastric cancer, laparoscopic surgery was indicated for patients with early-stage cancer. The oncological background of patients who underwent LADG and those treated by open surgery was, therefore, completely different, along with the method of reconstruction.

Patients demonstrated a significant body weight loss of 5.55 kg (95% CI 3.81–7.30 kg) during the first month after DG, due to decreases in both the fat (2.08 kg, 95% CI 0.70–3.45 kg) and muscle masses (2.18 kg, 95% CI 0.77–3.59 kg) (Table 2; Figs. 1, 2, 3). The muscle masses of the upper and lower extremities also decreased by significant margins [0.37 kg (95% CI 0.07–0.67 kg) and 1.13 kg (95% CI 0.33–1.94 kg)] (Table 2; Figs. 4, 5). After this period, the body weight loss mostly reflected a consistent decrease in the fat mass, while the muscle mass stabilized and even showed a tendency to recover. In the patients with TG, significant losses in the body fat component and the muscle masses of the total body and the upper and lower extremities were observed during the first month [2.40 kg (95% CI 0.59–4.21 kg), 2.30 kg (95% CI 0.27–4.33 kg), 0.29 kg (95% CI 0.16–0.41 kg), and 1.38 kg (95% CI 0.26–2.51 kg), respectively]. The trend of losing the fat mass went on for 6 months and the trend of losing muscle mass lasted for 3 months, although the differences in fat mass between 3 and 6 months postoperatively and in the muscle between 1 and 3 months were not significant, probably due to the small sample size. In the first month after the LADG, the extent of reduction in the fat mass was 1.87 kg (95% CI 1.02–2.73 kg), along with a less prominent loss of muscle mass of 1.11 kg (95% CI 0.60–1.61 kg). During this period, the leg muscle mass decreased by 0.57 kg (95% CI 0.13–1.01), while the decrease in the arm muscle mass was insignificant. Most notably, the patients started to regain body muscle mass after the first month, and an increase of 0.43 kg (95% CI 0.03–0.82) was observed by the third month. The total increase from the first to the 6 months postoperatively turned out to be significant, at 0.63 kg (95% CI 0.25–1.27 kg). Corresponding recovery was also observed in the lower limb muscle mass (0.44 kg, 95% CI 0.04–0.83 kg).

At 6 months postoperatively, the total postoperative changes in body composition after the DG and LADG consisted of fat mass reduction by 5.83 kg (95% CI 3.86–7.79 kg) and 5.40 kg (95% CI 3.56–7.24 kg), respectively. In addition, total muscle mass after the DG decreased by 1.59 kg (95% CI 0.51–2.67 kg), while no significant reduction in the muscle-related parameters at that time point were observed for the LADG group, due to the aforementioned recovery. After the TG, body weight reduction of 9.94 kg (95% CI 4.91–14.97 kg) was observed at the 6th postoperative month.

Table 1 Medical and demographic characteristics of patients

Characteristics	DG (N = 14)	TG (N = 8)	LADG (N = 19)
Age, years (\pm SD)	67.2 \pm 10.1	58.13 \pm 18.0	62.0 \pm 10.9
Male	13 (92.9%)	6 (80.0%)	13 (68.5%)
Initial weight (kg \pm SD)	63.38 \pm 11.63	60.16 \pm 13.06	58.75 \pm 10.39
Initial fat mass (kg \pm SD)	15.51 \pm 3.39	12.11 \pm 2.33	14.09 \pm 3.37
Initial total muscle mass (kg \pm SD)	20.04 \pm 4.14	19.96 \pm 3.71	18.52 \pm 3.85
Initial arm muscle mass (kg \pm SD)	2.80 \pm 0.69	2.91 \pm 0.55	2.78 \pm 0.86
Initial leg muscle mass (kg \pm SD)	8.83 \pm 2.00	8.67 \pm 1.84	7.93 \pm 2.26
BMI			
Underweight <18	1 (7.1%)	0 (0.0%)	2 (10.5%)
Normal 18–24.9	8 (57.2%)	7 (87.5%)	15 (79.0%)
Overweight >25	5 (35.7%)	1 (12.5%)	2 (10.5%)
Tumor characteristics			
Tumor depth			
T1a/T1b	1/1	0	17/1
T2	4	0	1
T3	3	3	0
T4a/T4b	4/1	4/1	0
N factor			
N0	3	2	19
N1N2	11	6	0
Stage			
IA/IB	1/3	0	18/1
IIA/IIB	0/2	0/3	0
IIIA/IIIB/IIIC	0/4/1	1/1/0	0
IV	3	3	
Distant metastasis			
M0	0	6	19
M1	1	2	0
Maximal size (mm \pm SD)	46.1 \pm 25.2	59.4 \pm 35.8	28.1 \pm 17.2
Number of removed lymph nodes (\pm SD)	36.4 \pm 14.2	46.0 \pm 21.7	27.3 \pm 11.2
Number of positive lymph nodes (\pm SD)	3.6 \pm 1.1	8.4 \pm 1.6	0

SD standard deviation, *DG* distal gastrectomy, *TG* total gastrectomy, *LADG* laparoscopy-assisted distal gastrectomy, *BMI* body mass index

Discussion

This study is the first report of muscle dynamics after gastrectomy. Our goal was not to make comparisons, between different surgical procedures, of various parameters related to the body composition at each time point, but to observe trends in the nutritional status of the patients after each procedure. Through longitudinal measurements after surgery, interesting data were obtained to speculate on and discuss the process of recovery after major surgery. The total body weight changes observed in our study were due mainly to the change in fat mass, regardless of the type of surgery. In patients with DG and LADG, the loss in fat mass even exceeded the body weight loss at 1–3 months postoperatively, due at least partly to the recovery of muscle mass.

The two prominent mechanisms of fat metabolism, increased consumption and reduced restoring, lead to a

profound decrease in fat mass. It is considered that a small gastric remnant (or total resection of the stomach), poor oral food intake, and impaired carbohydrate digestion after gastrectomy lead to insufficient glucose intake, with subsequent depletion of glycogen storage, resulting in loss of body fat mass. In addition, fat malabsorption following gastrectomy is well established to be due to a relative pancreatic insufficiency with low lipase secretion, due to rapid intestinal transit and vagotomic effects [13–15]. The anabolic phase after gastrectomy starts with adequate carbohydrate intake and digestion which initially lead to fat mass stabilization. There was at least a sign of stabilization after the third month for our LADG group, whereas loss of fat mass continued consistently throughout the 6 months of observation for the DG group (Fig. 2). Postoperative chemotherapy given almost exclusively to the DG and TG groups may also have been the cause of reduced food

Table 2 Body composition parameters (all in kg) after open and laparoscopic gastrectomies

	0–1 Month [95% CI]	1–3 Months [95% CI]	3–6 Months [95% CI]	0–6 Months [95% CI]
DG				
Body weight	5.55 [3.81; 7.30]	1.48 [0.44; 2.51]	1.16 [−0.06; 2.38]	8.02 [6.04; 9.99]
Fat	2.08 [0.70; 3.45]	1.91 [0.48; 3.34]	1.53 [0.42; 2.65]	5.83 [3.86; 7.79]
Muscle	2.18 [0.77; 3.59]	−0.23 [−0.86; 0.40]	−0.21 [−1.18; 1.61]	1.59 [0.51; 2.67]
Arm muscles	0.37 [0.07; 0.67]	−0.02 [−0.11; 0.06]	0.02 [−0.25; 0.29]	0.25 [0.02; 0.47]
Leg muscles	1.13 [0.33; 1.94]	−0.10 [−0.37; 0.16]	0.20 [−0.59; 1.00]	0.89 [0.27; 1.52]
TG				
Body weight	6.41 [4.12; 8.71]	2.86 [−0.87; 6.59]	0.47 [−3.84; 4.77]	9.94 [4.91; 14.97]
Fat	2.40 [0.59; 4.21]	2.63 [−0.73; 5.99]	0.80 [−2.51; 4.11]	4.70 [−2.49; 11.88]
Muscle	2.30 [0.27; 4.33]	0.19 [−1.47; 1.85]	−1.07 [−3.75; 1.61]	2.28 [−3.93; 8.49]
Arm muscles	0.29 [0.16; 0.41]	−0.09 [−0.34; 0.16]	−0.12 [−0.78; 0.53]	0.24 [−0.17; 0.65]
Leg muscles	1.38 [0.26; 2.51]	0.12 [−1.21; 1.45]	−0.29 [−1.06; 0.47]	1.63 [−1.41; 4.67]
LADG				
Body weight	3.75 [2.81; 4.70]	1.64 [0.18; 3.09]	0.17 [−1.01; 1.34]	6.10 [3.83; 8.37]
Fat	1.87 [1.02; 2.73]	2.74 [1.41; 4.08]	0.30 [−0.66; 1.26]	5.40 [3.56; 7.24]
Muscle	1.11 [0.60; 1.61]	−0.43 [−0.82; −0.03]	−0.17 [−0.53; 0.19]	0.58 [−0.22; 1.38]
Arm muscles	0.10 [−0.24; 0.44]	−0.13 [−0.47; 0.22]	0.06 [−0.10; 0.22]	0.36 [−0.02; 0.74]
Leg muscles	0.57 [0.13; 1.01]	−0.07 [−0.24; 0.10]	−0.17 [−0.52; 0.17]	0.18 [−0.44; 0.81]

Italicized values are statistically significant ($p < 0.05$), negative values denote increase in the body composition parameters
CI confidence interval, *DG* distal gastrectomy, *TG* total gastrectomy, *LADG* laparoscopy-assisted distal gastrectomy

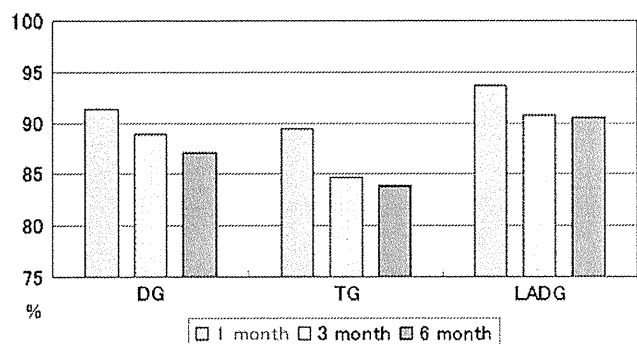


Fig. 1 Body weight expressed as a percentage of the preoperative value at 1, 3, and 6 months after surgery. *DG* Distal gastrectomy, *TG* total gastrectomy, *LADG* laparoscopy-assisted distal gastrectomy

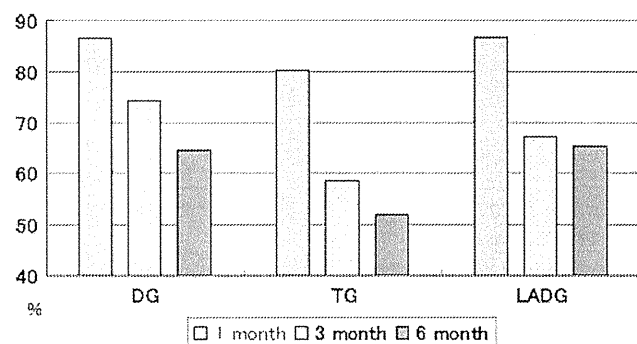


Fig. 2 Total fat mass expressed as a percentage of the preoperative value at 1, 3, and 6 months after surgery. *DG* Distal gastrectomy, *TG* total gastrectomy, *LADG* laparoscopy-assisted distal gastrectomy

intake, through loss of appetite. It is not possible at this time to analyze how each of these factors independently affected the outcome.

Low gastric enzyme levels and intestinal bacterial overgrowth are implicated in protein maldigestion [16–18], along with the altered ratio of serum concentrations of essential and branched-chain amino acids reported after gastrectomy which may predispose to muscle atrophy [19]. In addition, muscle mass after surgical intervention could also be affected by the patient’s physical activity. The perioperative loss in total muscle mass may have reflected both poor nutritional status and lack of physical activity, and the condition was quite similar for all groups in our

study. The leg muscle mass reduction was also significant in all groups and may have reflected patients’ postoperative in-bed immobility. However, both the total muscle mass and leg muscle mass showed remarkable recovery 3 months after the operation in the LADG group. Given that nutritional recovery in terms of fat mass had not been achieved at 6 months postoperatively even for the LADG group, the recovery of the muscle mass may have been due exclusively to near-complete recovery in terms of physical activity.

There is no doubt that factors such as the type of reconstruction, extent of lymph node dissection, and postoperative adjuvant chemotherapy affect outcomes after

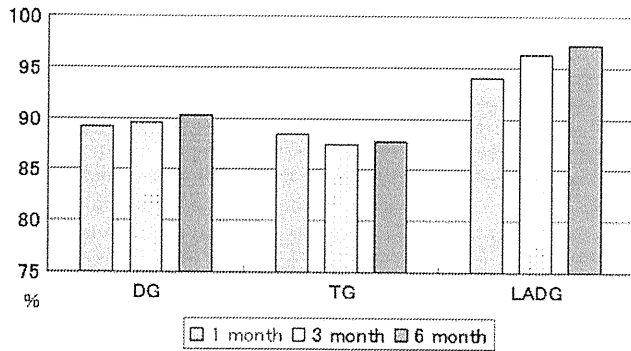


Fig. 3 Total muscle mass expressed as a percentage of the preoperative value at 1, 3, and 6 months after surgery. *DG* Distal gastrectomy, *TG* total gastrectomy, *LADG* laparoscopy-assisted distal gastrectomy

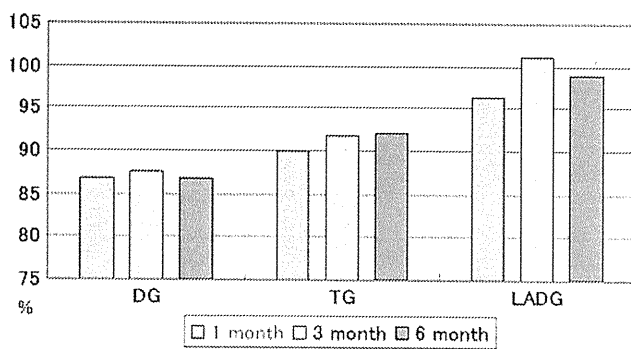


Fig. 4 Arm muscle mass expressed as a percentage of the preoperative value at 1, 3, and 6 months after surgery. *DG* Distal gastrectomy, *TG* total gastrectomy, *LADG* laparoscopy-assisted distal gastrectomy

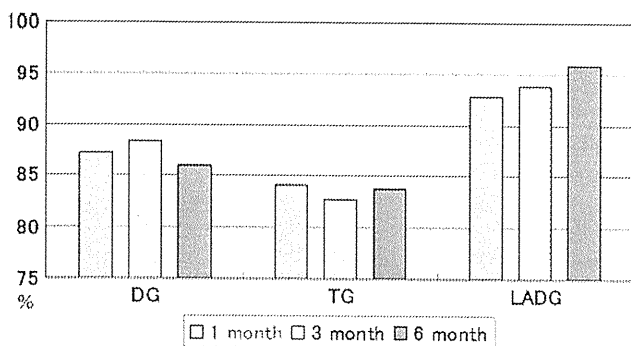


Fig. 5 Leg muscle mass expressed as a percentage of the preoperative value at 1, 3, and 6 months after surgery. *DG* Distal gastrectomy, *TG* total gastrectomy, *LADG* laparoscopy-assisted distal gastrectomy

surgery. Earlier resumption of food intake with preserved duodenal transit after LADG may have contributed to early nutritional recovery in our patients who had this procedure [20, 21]. More extended lymph node dissection performed for the DG and TG groups, with greater damage to the celiac nerve plexus, might have affected the postoperative digestive function more seriously. Perioperative

chemotherapy, also given almost exclusively to the TG and DG groups, is expected to have had adverse effects on the nutritional status. Thus, the differences observed between the groups in the present study cannot be attributed solely to the operative approach. We were unable to analyze the effect of each of these factors, due to the retrospective and non-randomized nature of the study and the limited number of patients. Evaluation of a greater number of patients with similar backgrounds treated by different approaches is needed to confirm the speculations arising from this study.

In conclusion, after gastrectomy, all patients demonstrated loss of fat and muscle masses during the first postoperative month, regardless of the type of gastric resection or the operative approach. After DG, patients showed a continuous reduction of fat mass during the 6 months of follow-up, whereas recovery was observed 3 months after LADG. In addition, the recovery of muscle mass at 3 months after LADG was remarkable. While more vigorous programs for nutritional support may be warranted after gastric cancer surgery, minimally invasive surgery may facilitate recovery in terms of physical activities.

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Conflict of interest The authors declare that there is no conflict interest.

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Measurement of Inserting Motion of Bladeless Trocar at Real Surgery for Development of a Virtual Training System for Initial Trocar Placement in Laparoscopic Surgery

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KEY WORDS:

Optical view method; Trocar inserting motion; Training system; Virtual reality

ABBREVIATIONS:

U.S. Food and Drug Administration (FDA); Laparoscopic Pylorus Preserving Gastrectomy (LAPPG); Laparoscopic Distal Gastrectomy (LADG); Laparoscopic Total Colectomy (LATC); Laparoscopic Local Gastric Wedge Resection (LWR); Around the Navel (AN); Right Lower Quadrant of the Abdomen (RLQ); Left Side of the Abdomen (LS); Right Side of the Abdomen (RS); Left Lower Quadrant of the Abdomen (LLQ)

ABSTRACT

Background/Aims: The optical view method is an alternative to the open method as a laparoscopic entry technique, but it calls for a certain experience. Therefore we undertook the development of a training system for optical view method in initial trocar placement. For this purpose, kinetic data concerning insertion of a trocar were measured by means of non-invasive monitoring during actual surgery.

Methodology: We slotted force and motion sensors into an adapted trocar and measured the kinetic aspects of trocar insertion in terms of force and torque. The measurement was carried out at the time of the second and third trocar insertion by a single experienced surgeon.

Results: The measurement was carried out at 11 sites in 6 patients. We measured position, insert-

ing force and inserting torque of the measuring trocar continuously. Mean maximum inserting force was 71.4N (range: 63.9-75.5N) at the perinavel port and 65.3N (range: 31.8-83.8N) at other sites. Mean maximum torque was 0.19Nm (range: 0.18-0.21Nm) at the perinavel port, and 0.23Nm (0.15-0.35Nm) at other sites. The number of rotations needed to penetrate the abdominal wall differed considerably among the patients.

Conclusion: In the measurement by an experienced operator, inserting force and torque data were consistent and generally did not depend on the patient characteristics or the site of puncture. Difficulty in penetration according to the physical characteristics of the patients was adjusted by differences in the number of rotations applied to the trocar.

INTRODUCTION

In recent years, laparoscopic surgery has been performed as a most popular version of minimally invasive surgery, and the number of cases of oncological surgery performed in Japan has increased exponentially. Laparoscopic surgery is considered to be beneficial to the patients, particularly regarding the short-term outcome, but can only be performed after the surgeons have received adequate education and training.

Initial trocar placement is the first challenging step in laparoscopic surgery that can lead to serious consequences, and is performed by various methods including Veress needle method (blind entrance), Hasson's open method and optical view method. In Japan, the open method has been most commonly performed since it does not need special training for those who have already established themselves as surgeons. However, skin incision tends to be longer than the diameter of the trocar, causing continuous leakage of carbon dioxide while the pneumoperito-

neum is being maintained. This is often irritating for the surgeons and could prolong the operating time. In addition, the open method can be technically cumbersome, especially in obese patients.

In the optical view method, a bladeless trocar with a handle and blunt tip made of transparent plastic material is used. The laparoscope is inserted into the trocar which a surgeon holds by the handle and inserts directly into the peritoneal cavity by applying a constant axial penetration force accompanied with rotations. The insertion is performed after making a small skin incision and while the abdominal wall is lifted upwards by the surgeons. During insertion, the blunt tip will progress by pushing the blood vessels aside rather than cutting into them, resulting in minimal hemorrhage from the abdominal wall. Since the tip is transparent, surgeons will be able to identify the abdominal wall layers as the laparoscope-containing trocar progresses through the wall. The penetrated structures such as rectal sheath are visualized as multi-layers of a ring that starts from the tip center and becomes enlarged before disap-

pearing outside of the trocar. When the last ring known as the white ring enlarges and disappears, that ring represents the peritoneum and the surgeon will notice that the insertion is complete. When the surgeon becomes accustomed to the procedure and the direct visual identification of the abdominal wall layers, this method could be considered as a safe and time-sparing method for initial trocar placement (1). On the other hand, according to the database of the U.S. Food and Drug Administration (FDA), fatalities occur even when laparoscopists used optical trocars. Although designed to help avoid injury, these designs are not a substitute for adequate training or for the use of proper technique (2). A teaching leaflet has been created to facilitate surgeons in identifying the layers as the laparoscope-containing trocar penetrates through the abdominal wall. Currently, however, the only method to train a surgeon to insert the trocar with adequate force remains to be the hands-on training.

This situation prompted us to create a virtual reality simulator for trocar insertion using the optical view method. The training using virtual reality technology is different from training using animals or dummy models and has many advantages such as allowance for repeated usage and failed attempts (3-5). For this purpose, some basic data regarding the number of rotations and axial force needed to drive the bladeless trocar was necessary. However, little data measuring the entry force of trocar in animals or dummy models is available (6-9). In the current study, original data needed for development of the virtual abdominal wall model were accumulated using non-invasive monitoring of trocar insertion during actual laparoscopic surgery.

METHODOLOGY

System for measurement of kinetic data for trocar insertion

At first, we developed a non-invasive measuring system for trocar insertion at Nagoya Institute of Technology (Figure 1). We modified a 12mm disposable Optiview trocar (Ethicon Endo-surgery Cincinnati, OH, USA), and constructed a measuring trocar of 340mm length, containing the 6DOF force sensor (NANO sensor 5/4, BL Autotech, Ltd.) and receiver of the three dimensional motion tracking system (FASTRAK, Polhemus) (Figure 2). Through insertion of this trocar, the position of the trocar tip can be continuously tracked and recorded by the FASTRAK and kinetic data (force and torque) can be measured by the NANO sensor 5/4. Because the FASTRAK uses a magnetic field, the transmitter was placed as far from the surgical bed as possible.

Acquisition of kinetic data for trocar insertion during actual laparoscopic surgery

Since the measuring trocar cannot accommodate the laparoscope, insertion of a camera port was needed before insertion of the measuring tro-

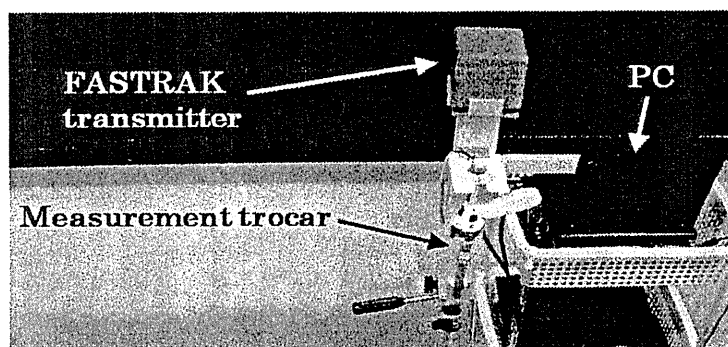


FIGURE 1 The inserting motion measurement system

car to ensure its safe placement under the laparoscopy. The measuring trocar was accordingly inserted as a second or third trocar. One experienced laparoscopic surgeon (M.F.) with experience of optical view method in more than 1,000 patients inserted the measuring trocar for all cases. This was because data had to be compared between patients with different body contour and between different sites of trocar insertion, and difference owing to the technique of the surgeon had to be minimized. This study was approved by the ethics committee of Nagoya University and written informed consent was obtained from all patients.

RESULTS

Evaluation was performed at 11 sites in 6 patients. Figure 3 shows an example of the pressure applied upon insertion of the trocar as monitored by NANO sensor 5/4. Figure 4 shows an example of torque applied upon insertion as monitor by the same device. In this particular case, the maximum force was about 61N and maximum torque was about 0.26Nm. The time needed for insertion time was about 13 seconds.

Table 1 shows the summary of all cases. At the perinavel site, the mean maximum inserting force (N) was 71.4N (range: 63.9-75.5N) at the perinavel site and 65.3N (range: 31.8-83.8N) at the other port sites, with no significant difference between the two sites. No difference was observed between the individuals. The mean maximum torque (Nm) was 0.19Nm (range: 0.18-0.21Nm) at the perinavel site and 0.23Nm (range: 0.15-0.35Nm) at other sites, again, with no significant difference. Total number of rotations (twisting motion as the trocar penetrates through the abdominal wall) ranged from 11 to 33 and was variable among the individuals.

DISCUSSION

The authors have utilized optical view method for the laparoscopic entry in 1,300 cases of laparoscopic surgery since 1998. This method has its own training process and learning curve (10). Although this procedure is safe and practical, there are some pitfalls. One potential hazard is derived from inability to identify the position of the trocar tip through the simultaneously obtained endoscopic vision. In this case, the surgeon could keep driving

the trocar when the tip is already in the abdominal cavity, causing visceral and vascular injuries. To avoid this serious problem, training to identify the abdominal wall layers, particularly the aforementioned white ring that represents the peritoneum, is mandatory. In addition, inadequate force to drive the trocar could lead either to an abrupt and unexpected penetration into the abdominal cavity and beyond, or to the inability to penetrate through either of the anatomical layers that constitute the abdominal wall. When the trocar is inappropriately guided, the trocar tip could slide on the surface of the fascia without penetrating through it. For these problems, training to exert adequate pressure to

drive the trocar through each of the anatomical layers is necessary.

Abdominal wall dummy model does not imitate the layered structure of the abdominal wall with sufficient authenticity and is not suited for training optical view method where the inserting procedures should coordinate with the laparoscopic findings of the penetrating abdominal wall. Training using the animals is unsuitable due to the anatomical difference in which the swine, typically used for training, has smaller amount of subcutaneous fat and tough and thickened peritoneum that do not resemble the human abdominal wall. Thus, the authors opted for training by virtual reality simulators.

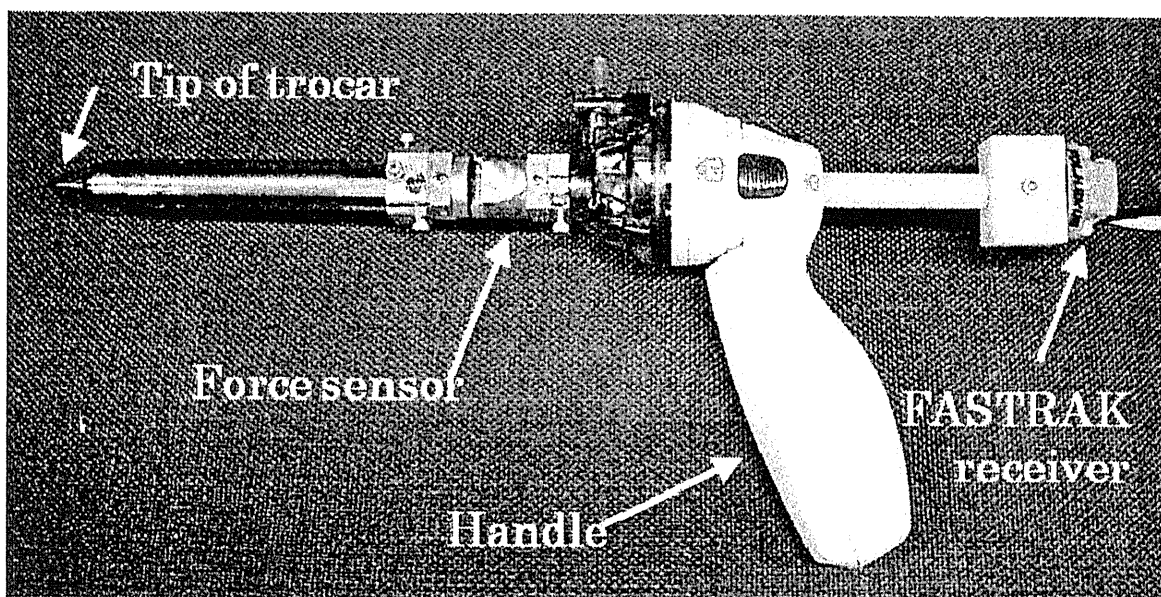


FIGURE 2 The reconstructed measuring trocar

TABLE 1 Summary of All Cases

	Case 1	Case 2	Case 3	Case 4	Case 5	Case 5
age/gender	71M	63M	54M	67M	38F	69M
disease	Gastric cancer	Gastric cancer	Gastric cancer	Ulcerative colitis	Gastric GIST	Gastric cancer
operation	LAPPG	LADG	LAPPG	LATC	LWR	LADG
BMI	27.0	18.9	21.0	19.6	27.6	24.7
The first measurement site	AN	AN	AN	RLQ	AN	LS
Puncture time (S)		13	10	10	20	13
maximum force (N)	Record failure	75.54	72.54	83.02	73.59	61.27
maximum torque (Nm)		0.19	0.18	0.32	0.21	0.26
Total rotation		19	14	14	30	22
The second measurement site	RS	LS	LS	LLQ	LS	AN
Puncture time (S)	26	14	18	7	18	25
maximum force (N)	54.10	62.04	80.76	31.82	83.84	63.85
maximum torque (Nm)	0.15	0.15	0.35	0.09	0.30	0.18
Total rotation	26	23	24	11	31	33

LAPPG, Laparoscopic pylorus preserving gastrectomy; LADG, Laparoscopic distal gastrectomy; LATC, Laparoscopic total colectomy; LWR, Laparoscopic local gastric wedge resection; AN, Around the navel; RLQ, Right lower quadrant of the abdomen; LS, Left side of the abdomen; RS, Right side of the abdomen; LLQ, Left lower quadrant of the abdomen;

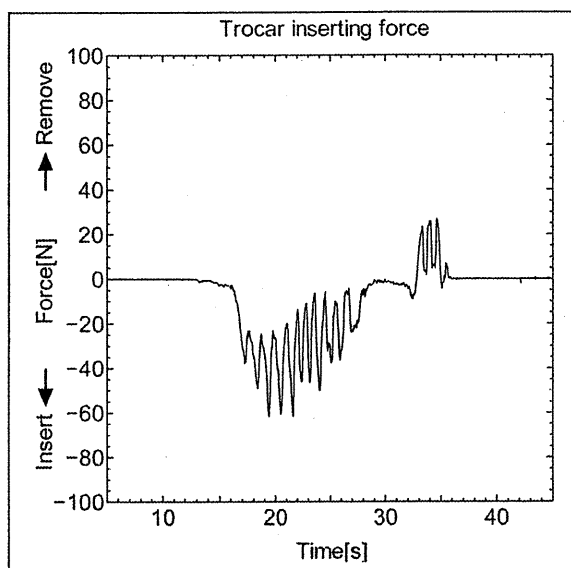


FIGURE 3 Inserting force data of trocar (Case 6)

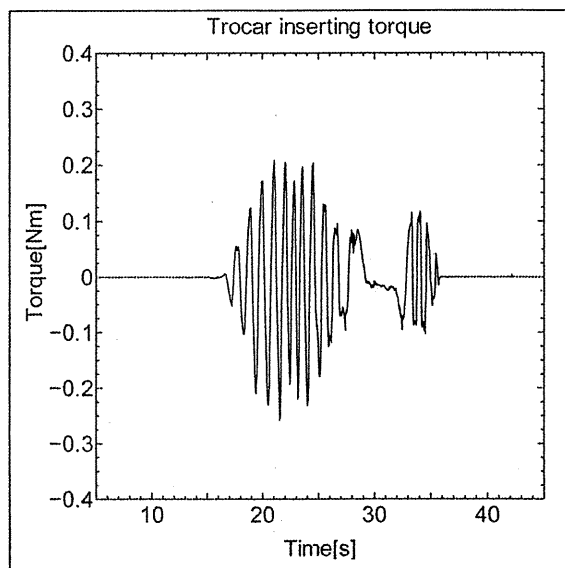


FIGURE 4 Inserting torque data of trocar (Case 6)

The most important data needed to create an original virtual training system were the kinetic profile of trocar insertion obtained from actual patients. Although similar data had been available, these originated from measurements using animals and dummy models. Data from humans have never been reported.

Through the current study, we have shown that the force needed to penetrate through the human abdominal wall is 60-70N. In addition, the force and torque needed for penetration did not in general differ significantly from patient to patient or according to the site of puncture. The only exception was a patient who had been under a high dose steroid therapy. The force needed for trocar insertion was outstandingly small at 31.8N. On the other hand, the number of twists needed depended more heavily on the patient and site of puncture. Thus, the amount of total workload needed for penetration of the abdominal wall, which should apparently be different according to the amount of subcutaneous fat, thickness of the muscles and durability of the fasciae that depend on the gender, age and condition of the patients, has been controlled not by force or torque but by the number of rotations a surgeon gives to the trocar.

This is the first data of the kinetic profile obtained from the human subjects and will be a valuable reference for creating a virtual training system. We are currently in the process of creating a new simulator which can be pre-adjusted to various patterns corresponding to patients with varying conditions. The current data also inform the surgeons that when they have difficulty inserting a trocar to a patient with particularly tough abdominal wall, they are advised to penetrate through the abdominal wall not by putting extra strength, but by keeping the rotating motion of the trocar as long as needed with consistent appliance of their usual force.

There were two weaknesses in the current study. Firstly, the insertion procedure we evaluated was not for the initial trocar. Since the measuring trocar we had built for this study could not accommodate a laparoscope (Figure 2), we had to initially insert another trocar as a laparoscope port to observe while the measuring trocar was inserted. It was not ethical to attempt inserting the measuring trocar to a human subjects through blind access entry. The effect of the pneumoperitoneum that had been obtained at insertion of the measuring trocar is currently considered as negligible, since the actual first trocar insertion through the optical view method is performed by lifting the abdominal wall with a considerable strength. However, the first prototype of the simulator will have to be tested by several surgeons and receive their feedbacks for relevant adjustments before the simulator can be validated. Another weakness was that the information obtained through the laparoscope as the trocar penetrates through the abdominal wall was apparently not available to the surgeon who inserted the measuring trocar. Thus, the surgeon had to insert the measuring trocar without the real time knowledge as to which structure he is penetrating.

In conclusion, we obtained original data under the actual laparoscopic surgery for development of the virtual abdominal wall model. In the measurement by an experienced operator, inserting force and torque data were consistent and generally did not depend on the patient characteristics or the site of puncture. Difficulty in penetration according to the physical characteristics of the patients was adjusted by differences in the number of rotations applied to the trocar. Based on these data, we are planning to develop the training system which combines force feedback system with image display.

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