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Present and Future Status of Gastric Cancer Surgery

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The type of surgery and the role of adjuvant therapies in the treatment of gastric cancer have changed in recent times. The treatment of gastric cancer with curative intent is moving away from standard D2 or more extensive surgery to a tailored approach depending on the stage of the disease. Data collected from extensive lymphadenectomy for all stages of gastric cancer have confirmed that some subsets of early gastric cancer are very low risk for nodal metastasis. This group of patients may benefit from resection by endoscopic or laparoscopic techniques and may also be suitable for function-preserving procedures. The extent of resection for gastric cancer has always excited debate. D2 gastrectomy was criticized for its higher mortality in the early European Phase III trials, but recent studies from Taiwan and Italy have shown that the procedure is safe when performed by experienced surgeons and has a survival benefit over D1 gastrectomy. The role of para-aortic lymph node dissection for nodes without apparent metastasis in advanced gastric cancer was assessed by a Phase III Japanese trial and showed no additional benefit over D2 resection. Radical gastric resections, involving resection of adjacent organs for direct tumor invasion result in higher rates of complications, and the role of multi-visceral resections has also been reevaluated. Effective adjuvant therapies for gastric cancer have been reported since the early part of 2000. Development of more effective adjuvant therapy combined with D2 resection should continue to improve survival in the future.

Key words: gastric cancer – surgery – function-preserving gastrectomy – laparoscopic gastrectomy – adjuvant therapy

INTRODUCTION

Chemotherapy helps to prolong survival in cases of advanced disease, but surgery is still the mainstay of curative treatment for gastric cancer. From uniform use of D2 or more extensive surgery, surgical treatment has evolved to become more tailor-made depending on the stage of the disease.

Extensive operations have been reevaluated for advanced gastric cancer and the role of effective adjuvant therapies in this setting has expanded. More radical operations than D2 for gastric cancer have often been carried out without clear evidence until clinical trials have failed to show the survival benefit of these procedures over D2. For early gastric cancer,

less extensive resections and minimally invasive techniques have been developed, such as function-preserving procedures and laparoscopic surgery.

D2 LYMPHADENECTOMY

Total or subtotal gastrectomy with D2 lymphadenectomy is the gold standard surgical treatment for gastric cancer in eastern Asia. The procedure initially developed in Japan, has been safely performed and provided good survival outcomes for patients with gastric cancer regardless of disease stage (1,2). The use of this technique has been challenged by Western clinical trials since the 1990s.

RESULTS OF EARLY EUROPEAN TRIALS

Phase III trials on D2 dissection for curable gastric cancer were carried out by the Medical Research Council and the Dutch Gastric Cancer Group in the early 1990s (3,4). These trials failed to show a survival benefit for D2 over D1 dissection.

The British and Dutch trials demonstrated extremely high hospital mortality after D2, reaching 10 and 13%, respectively. In the British trial, the survival curve of D2 was never better than that of D1 until the end of the trial. In the Dutch trial, the survival curve of D2 caught up with that of D1 after 4 years and remained superior, but the difference between D1 and D2 survival never reached statistical significance.

DISCUSSION OF THE EARLY TRIALS

The lack of surgical training in the technique of D2 gastrectomy and sub-optimal quality control may explain the inferior outcomes of D2 versus D1 gastrectomy in these early trials. Both trials were carried out without pre-trial training or preliminary studies to confirm the safety of the procedure, and were concluded before many surgeons would have reached the plateau of their learning curve. The 80 hospitals contributing data to the Dutch trial were all relatively low volume units, with most performing only a few gastric resections per year. With such limited experience, it is almost impossible to maintain the quality of the technique and gain adequate experience in managing major complications such as anastomotic leakage, pancreatic fistula or intra-abdominal abscess, all of which can lead to an increase in morbidity and mortality.

Routine resection of the tail of the pancreas in total gastrectomy has been credited with disappointing results. Detailed analysis of the Dutch and British studies showed that splenectomy and distal pancreatectomy were more significant causes of morbidity and mortality than D2 itself (5). In the D2 arm of these trials, splenectomy and distal pancreatectomy were mandatory during total gastrectomy. Resection of the distal pancreas and spleen is no longer deemed a necessary component of modern D2.

Fifteen-year follow-up results of the Dutch trial were recently reported in 2010 (6). The authors reported that D2 was associated with lower loco-regional recurrence and gastric cancer-related death rates than D1. They concluded that D2 is the recommended surgical approach for patients with resectable gastric cancer.

RECENT TRIALS ON D2 DISSECTION

The Italian Gastric Cancer Study Group (IGCSG) started a prospective one-arm Phase II study in 1994 to confirm the safety and efficacy in increasing survival, using the D2 gastrectomy (7). Following concerns about the high mortality observed in the Dutch and British trials, with total

gastrectomy, they utilized the pancreas-preserving procedure according to the Maruyama technique instead of employing routine distal pancreatectomy (8). Furthermore, they implemented a strict quality control component consisting of pre-trial surgical training at a specialized center in Japan and intra-operative supervision by experienced surgeons. As a result, the Italian trial, including nine hospitals with a total of 191 patients, demonstrated 3% mortality. The survival results of this Phase II study were much better than that of the D2 arms in the Dutch and British trials (9).

Following the favorable results of the Phase II trial, the IGCSG conducted a Phase III trial comparing D1 ($n = 133$) with D2 ($n = 134$), including five specialized hospitals with a total of 267 patients. The post-operative 30-day mortality was 3% for D1 and 2.2% for D2 (10). The safety of D2 performed by experienced surgeons at specialized centers was confirmed in the Phase III study. The survival data from this study is eagerly awaited.

The results of a Phase III trial from Taiwan, comparing D1 ($n = 110$) with D3 ($n = 111$), were reported in 2006 (11). Their D3, according to the old Japanese Classification, in addition to D2, included lymph nodes within the hepato-duodenal ligament, on the superior mesenteric vein, behind the common hepatic artery and on the posterior pancreatic surface but not the para-aortic lymph nodes. This trial was conducted by three experienced surgeons at a single institution and showed statistically significant improvement in survival of D3 compared with D1, demonstrating 5-year survival rates of 59.5 and 53.6%, respectively ($P = 0.04$). This is the first Phase III trial in the world showing survival benefit of radical lymphadenectomy compared with the limited lymphadenectomy. However, this study cannot be considered as solid evidence for the superiority of D3 over D1 because of the rather small sample size and modest survival benefit.

IS SPLENECTOMY ESSENTIAL TO D2 TOTAL GASTRECTOMY?

Retrospective Japanese studies revealed that 20–30% of patients with advanced gastric cancer in the proximal stomach had nodal metastasis in the splenic hilum (12) and therefore pancreas-preserving splenectomy is part of the standard D2 total gastrectomy (8). After the British and Dutch trials on D2 showed that splenectomy was an important risk factor for post-operative morbidity and mortality, the Japan Clinical Oncology Group (JCOG) conducted a Phase III trial to evaluate the role of splenectomy in total gastrectomy (13). A total of 505 patients with advanced gastric cancer in the upper third of the stomach, without involvement of the greater curvature were randomly assigned to total gastrectomy with ($n = 254$) or without splenectomy ($n = 251$). Recruitment has been completed and final results are awaited. The trial is powered to evaluate the impact on overall survival. If the survival is approximately equivalent, splenic preservation will be the preferred treatment for patients with such tumors.

ADJUVANT THERAPY

A Phase III study comparing surgery alone to surgery plus post-operative adjuvant chemoradiotherapy (CRT), the INT0116/SWOG9008, showed a large survival benefit of the latter (14). The CRT arm included curative surgery and radiation therapy of 45 Gy with combination chemotherapy using fluorouracil and leucovorin. A total of 556 patients were randomly assigned to surgery alone ($n = 275$) or surgery plus CRT ($n = 281$). The median survival time of surgery alone and surgery plus CRT was 27 and 36 months, respectively ($P = 0.005$). In this trial, 90% of the patients underwent less extensive D0 or D1 surgery while only 10% underwent D2. Although the extent of lymphadenectomy failed to significantly correlate with survival due to the small patient population of D2, detailed analysis showed that inadequate surgery negatively affected survival (15). Sasako et al. (16) noted that the patient population in the CRT arm of this trial was quite similar to the population in a Japanese clinical trial comparing surgery alone to surgery plus adjuvant chemotherapy (17). Most of the prognostic factors, i.e. histological type, tumor location, age, tumor size, and, tumor depth were reasonably comparable between the groups. Nevertheless, the 5-year overall survival of the CRT arm of the INT0116 and the surgery alone arm of the Japanese trial were 42 and 61%, respectively. Sasako et al. strongly suggested that D2 surgery alone might produce better survival than D0/D1 surgery followed by CRT and that the effect of adjuvant CRT may not be so significant if D2 gastrectomy was performed as the standard operation.

The MAGIC trial, a Phase III trial comparing surgery alone to surgery plus peri-operative adjuvant chemotherapy, is the first study demonstrating a clear benefit of neoadjuvant chemotherapy (combined with post-operative chemotherapy) over surgery alone (18). The chemotherapy protocol consisted of three pre-operative and three post-operative cycles of intravenous epirubicin, cisplatin and fluorouracil. A total of 503 patients were randomly assigned to surgery alone ($n = 253$) or surgery plus peri-operative chemotherapy ($n = 250$). The 5-year survival rate of surgery alone and peri-operative chemotherapy group were 23 and 36%, respectively ($P = 0.009$). There was no hazard ratio analysis for the extent of surgery and therefore the benefit of peri-operative adjuvant chemotherapy in addition to D2 surgery remains unclear.

The results of the Adjuvant Chemotherapy Trial of TS-1 for Gastric Cancer (ACTS-GC trial) comparing surgery alone to surgery plus adjuvant S-1 was reported in 2007 (19). Administration of S-1 was started within 6 weeks after curative D2 surgery and continued for 1 year. Patients treated with adjuvant S-1 ($n = 529$) demonstrated a significantly better 3-year survival than those who underwent surgery alone ($n = 530$) (80.5 versus 70.1%, $P = 0.003$). In Japan, adjuvant S-1 therapy has become the standard treatment of choice for Stages II and III gastric cancer patients after curative D2.

MORE EXTENSIVE SURGERY THAN D2

More extensive surgery than D2 was often carried out in the 1980s and the early 1990s, without any high-level evidence favoring these more extensive procedures. Japanese clinical trials of para-aortic lymph node dissection (PAND) for advanced tumor without apparent metastasis to the nodes and left thoraco-abdominal approach (LTA) for cardiac tumors have shown no survival benefit for patients who underwent such extensive procedures (20,21).

PARA-AORTIC LYMPH NODE DISSECTION

In advanced gastric cancer, the incidence of microscopic metastases in the para-aortic lymph nodes had been reported from 10 to 30% (22–24). Because the 5-year overall survival rate of patients with para-aortic nodal metastases could be as high as 20% after systematic dissection, PAND had been performed in Japan since the 1980s (25). JCOG conducted a Phase III trial at 24 hospitals in Japan comparing D2 alone ($n = 263$) to D2 plus PAND ($n = 260$) in the late 1990s (JCOG9501) (20). The 5-year overall survival rate was 69.2% for D2 alone and 70.3% for D2 plus PAND. The median operation time was 63 min longer and the median blood loss was 230 ml greater in the group assigned to D2 plus PAND. Treatment with D2 plus PAND did not significantly improve the survival rate in curable gastric cancer when compared with D2. The results may have been disappointing due to the low incidence of para-aortic node metastasis (8%) in this patient population. However, PAND is no longer routinely applied in patients without apparent para-aortic nodal metastases.

Along with para-aortic node metastasis, bulky nodal metastases surrounding the celiac artery and its branches usually suggest poor prognosis. A Phase II trial was carried out by JCOG to evaluate the efficacy and safety of pre-operative chemotherapy followed by D2 plus PAND for locally advanced gastric cancer with bulky celiac nodes and/or para-aortic node metastasis (JCOG0001) (26). The neoadjuvant chemotherapy consisted of irinotecan and cisplatin. This trial was terminated after 55 patients were enrolled because of three treatment-related deaths. The survival outcomes in these patients were promising, with the median survival time of 14.6 months and the 3-year survival rate of 27%.

Following the reasonable results of JCOG0001, JCOG conducted a Phase II trial of pre-operative S-1 plus cisplatin followed by D2 plus PAND for the same patient population as JCOG0001 (JCOG0405) (27). S-1 plus cisplatin is the Japanese standard chemotherapy regimen for unresectable or recurrent gastric cancer. Of 53 enrolled patients, 51 patients were eligible and resection rate and R0 rate were 92 and 82%, respectively. No treatment-related death was observed. Improvement in survival outcome is highly anticipated. The PAND procedure in this scenario is evaluated in combination with neoadjuvant chemotherapy for patients with apparent para-aortic node metastasis.

LTA APPROACH FOR CARDIAC TUMOR

The incidence of lower mediastinal lymph node metastasis from cardiac tumors is reported from 10 to 40% (28–32). Because of the inaccessibility of the mediastinal nodes, the LTA had often been used to treat gastric cancer in the cardia (28,29). A randomized Phase III trial was carried out by JCOG to compare the LTA to the abdominal–transhiatal (TH) approach in the treatment of gastric cancer of the cardia with esophageal invasion of <3 cm (JCOG9502) (21). A total of 167 patients were enrolled and randomly assigned to TH ($n = 82$) or the LTA ($n = 85$). At the first interim analysis, 5-year overall survival rate was 52.3% in the TH group and 37.9% in the LTA group. Mortality and morbidity were worse after the LTA (mortality 4%, morbidity 49%) compared with the TH group (0, 34%). The predicted probability of the LTA having a significantly better overall survival than TH group at the final analysis was only 3.65%, and the trial was closed before achieving the projected sample size ($n = 302$). These results do not support routine use of the LTA in treating such tumors.

MULTI-VISCERAL RESECTIONS FOR GASTRIC CANCER

For locally advanced gastric cancer with invasion of the head of the pancreas or duodenum, pancreato-duodenectomy may be required. This procedure was rarely performed due to the substantial associated morbidity and mortality until some favorable results were recently reported with a 5-year survival rate of 16–34% (33–36). Although the rate of morbidity after pancreato-duodenectomy is high, this procedure can be attempted by experienced surgeons at specialized hospitals in order to achieve an R0 resection. This may be attempted with the caveat that survival benefit is only likely for patients with a low burden of lymphatic disease (35,37).

For linitis plastica type gastric cancer, which is diffusely infiltrative and often incurable, wide resection such as the left upper abdominal evisceration with or without Appleby's procedure was sometimes attempted (38,39). However, many of these tumors were eventually incurable, and some curable tumors showed a very poor prognosis even after extensive surgery. Surgery alone is currently thought to be inadequate, and the addition of neoadjuvant chemotherapy has demonstrated interesting results for marginally resectable tumors (40).

LESS EXTENSIVE SURGERY FOR EARLY GASTRIC CANCER

Examination of lymph node status from extensive lymphadenectomy performed in all stages of gastric cancer has resulted in a vast amount of knowledge concerning the extent and pattern of nodal metastasis. We accordingly know that certain subsets of early gastric cancer have a rare chance of nodal metastasis and in this group extensive lymphadenectomy is unnecessary (41–44).

FUNCTION-PRESERVING GASTRECTOMY

Early gastric cancer has an excellent prognosis after surgical treatment, with 5-year survival rates of more than 90%. Since the early 1990s, function-preserving surgery has been introduced in the treatment of early gastric cancer to minimize post-gastrectomy syndromes with the intention of creating a better quality-of-life, while maintaining a high level of radicality (45–47).

PYLORUS-PRESERVING GASTRECTOMY

Pylorus-preserving gastrectomy (PPG) is a function-preserving procedure initially described for treatment of peptic ulcer disease by Maki et al. in 1967 (48). Early gastric cancer in the gastric body rarely spreads to the suprapyloric nodes, with an incidence of <1% (49). The pyloric branch of the vagal nerve running alongside the right gastric artery can be preserved by omitting the removal of the suprapyloric nodes so as to maintain the function of the pylorus. As a result, PPG is currently indicated for such tumors. A pyloric cuff of ~2–5 cm in length is preserved to prevent rapid gastric emptying and consequent dumping syndrome. Infrapyloric vessels are preserved to maintain the blood supply of the pyloric cuff. It has been reported that the incidence of the post-prandial dumping syndrome, biliary reflux and gallstone formation is decreased, and body weight recovery is as good as compared with Billroth I reconstruction (47,50–53). Survival outcome after PPG is comparable to that after conventional gastrectomy (49).

PROXIMAL GASTRECTOMY

Early gastric cancer located in the proximal third of the stomach rarely spreads to the distal peri-gastric lymph nodes (54). Proximal gastrectomy has been applied to these patients so as to maintain a gastric reservoir. Pylorus function is preserved with this method by preserving vagal nerves in a way similar to PPG. This procedure has clear advantages over total gastrectomy regarding short-term side effects and long-term survival (54,55). Reflux esophagitis is a common complication after proximal gastrectomy (56–58), and an anti-reflux procedure is usually combined with proximal gastrectomy (54,59).

LAPAROSCOPIC GASTRECTOMY

Since the early 1990s, laparoscopic surgery has been adopted as minimally invasive treatment for early gastric cancer. Laparoscopic wedge resection with a lesion-lifting method and intra-gastric mucosal resection were initially developed for the treatment of early gastric cancer without the risk of lymph node metastasis (60,61). Since Kitano et al. (62) first reported laparoscopic-assisted distal gastrectomy (LADG) with lymph node dissection, this procedure has been widely applied worldwide for early gastric cancer with a low risk of lymph node metastasis.

There have been four small randomized controlled trials, which reported that LADG has several advantages over open surgery, including early recovery, less pain and less impaired pulmonary function. At the same time, there appears to be no difference in morbidity and mortality when compared with open distal gastrectomy (ODG) (63–66). A recent multi-center retrospective study with 1294 patients conducted by the Japanese Laparoscopic Surgery Study Group reported morbidity and mortality rates after laparoscopic gastrectomy to be 14.8 and 0%, respectively, and showed a comparably good survival outcome to open gastrectomy (67).

A Phase II study estimating the feasibility of LADG in the treatment of Stage I gastric cancer patients was carried out by JCOG (JCOG0703). The results demonstrate that LADG can be performed safely with an acceptable morbidity by experienced surgeons (68). Following the result of this Phase II study, JCOG has initiated a large Phase III trial comparing LADG with ODG for Stage I cancer (JCOG0912).

The Korea Laparoscopic Gastrointestinal Surgery Study Group conducted a multi-institutional Phase III trial (KLASS trial) to assess the short- and long-term outcomes of LADG for early gastric cancer (69). A total of 342 patients were randomly assigned to LADG ($n = 179$) or ODG ($n = 161$) and the morbidity rates were 10.5 and 14.7%, respectively ($P = 0.137$). The mortality rates were 1.1 and 0% in the LADG and ODG groups ($P = 0.497$), respectively. Survival outcomes from this trial are still awaited.

CONCLUSION

D2 gastrectomy is still considered the gold standard surgical treatment for advanced gastric cancer but multi-modality treatments combined with surgery may further improve survival. There are now several surgical options for early gastric cancer depending on the risk of nodal metastasis. The efficacy of LADG for early gastric cancer is currently being assessed. If the results are favorable, then LADG may also be appropriate for more advanced disease. These specialist procedures will require good quality control achieved through supervision and training by experienced surgeons in high volume centers.

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Conflict of interest statement

None declared.

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Construct validity of the LapVR virtual-reality surgical simulator

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Abstract

Background Laparoscopic surgery requires fundamental skills peculiar to endoscopic procedures such as eye–hand coordination. Acquisition of such skills prior to performing actual surgery is highly desirable for favorable outcome. Virtual-reality simulators have been developed for both surgical training and assessment of performance. The aim of the current study is to show construct validity of a novel simulator, LapVR (Immersion Medical, San Jose, CA, USA), for Japanese surgeons and surgical residents.

Methods Forty-four subjects were divided into the following three groups according to their experience in laparoscopic surgery: 14 residents (RE) with no experience in laparoscopic surgery, 14 junior surgeons (JR) with little experience, and 16 experienced surgeons (EX). All subjects executed “essential task 1” programmed in the LapVR, which consists of six tasks, resulting in automatic measurement of 100 parameters indicating various aspects of laparoscopic skills.

Results Time required for each task tended to be inversely correlated with experience in laparoscopic surgery. For the peg transfer skill, statistically significant differences were observed between EX and RE in three parameters, including total time and average time taken to complete the procedure and path length for the nondominant hand. For the cutting skill, similar differences were observed between EX and RE in total time, number of unsuccessful cutting attempts, and path length for the

nondominant hand. According to the programmed comprehensive evaluation, performance in terms of successful completion of the task and actual experience of the participants in laparoscopic surgery correlated significantly for the peg transfer ($P = 0.007$) and cutting skills ($P = 0.026$).

Conclusions The peg transfer and cutting skills could best distinguish between EX and RE. This study is the first to provide evidence that LapVR has construct validity to discriminate between novice and experienced laparoscopic surgeons.

Keywords Laparoscopic surgery · Virtual reality · Simulation training · Assessment

The most apparent benefit of laparoscopic surgery is faster recovery through attenuated postoperative pain. Tireless efforts of surgeons and the invention and distribution of novel techniques and devices have enabled expansion of the indications for this approach to include complex oncological surgery. In addition to knowledge of anatomy and general surgical technique, acquisition of skills peculiar to the laparoscopic approach is essential for conducting these demanding procedures safely and accurately. These include eye–hand coordination, depth perception, and translation of a two-dimensional video image into a three-dimensional working field. Several virtual-reality (VR) simulators have been proposed as devices both for surgical training to improve performance and for measurement of various laparoscopic skills [1–3]. As new and more refined simulators continue to emerge, assessment of validity is indispensable to justify their introduction into the educational curriculum of laparoscopic surgery [1, 4–6]. The aim of the current study is to evaluate construct validity for a

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new VR simulator, LapVR, to distinguish between expert and novice laparoscopic surgeons.

Subjects

Forty-four participants were divided into three groups according to their experience of laparoscopic surgery. Those without any hands-on laparoscopic surgery experience were classified into a novice resident (RE) group ($n = 14$, 11 males and 3 females). Those who had performed 1–100 laparoscopic procedures were defined as junior surgeons (JR) ($n = 14$, 10 males and 4 females). Those who had performed >100 laparoscopic procedures were defined as experienced surgeons (EX) ($n = 16$, 14 males and 2 females). None of the subjects had any prior encounter with the LapVR.

Equipment and methods

The LapVR (Immersion Inc., San Jose, CA, USA) is a personal-computer-based VR system. It consists of a 20-inch flat liquid-crystal digital display, two laparoscopic instrument handles, a camera device, and two foot pedals (Fig. 1). The software consists of four modules: essential skill, procedural skill, obstetrics/gynecology module, and general surgery procedures module, and contains an original haptic feedback system.

The “essential skill” module contains six tasks: camera navigation, clipping, cutting, peg transfer, knot tying, and needle driving (Fig. 2) at three different levels (levels 1, 2, and 3 representing beginner, intermediate, and advanced levels, respectively), and default settings at each level are defined arbitrarily. The LapVR automatically evaluates each performance by summing a total score of 100 parameters which include factors such as the time taken to complete the task, the number of errors (e.g., the extent of tissue damage, the number of wrongly placed clips, the time needed for grasping a needle tip, the estimated amount of blood loss, etc.), and path lengths of the instruments. At the end of each task, a participant receives a printout revealing details of the performance in the form of a comprehensive evaluation which assesses all parameters and determines whether he or she completed the task successfully.

One instructor (N.I.) provided all subjects with a tutorial concerning the rules of each task and the way to handle the instruments, and supervised the test without active help or advice. After an initial familiarization with the simulator, all subjects attempted “essential skill 1,” namely all six tasks at the beginner’s level. Differences between each group of participants in scores of all of the 100 parameters

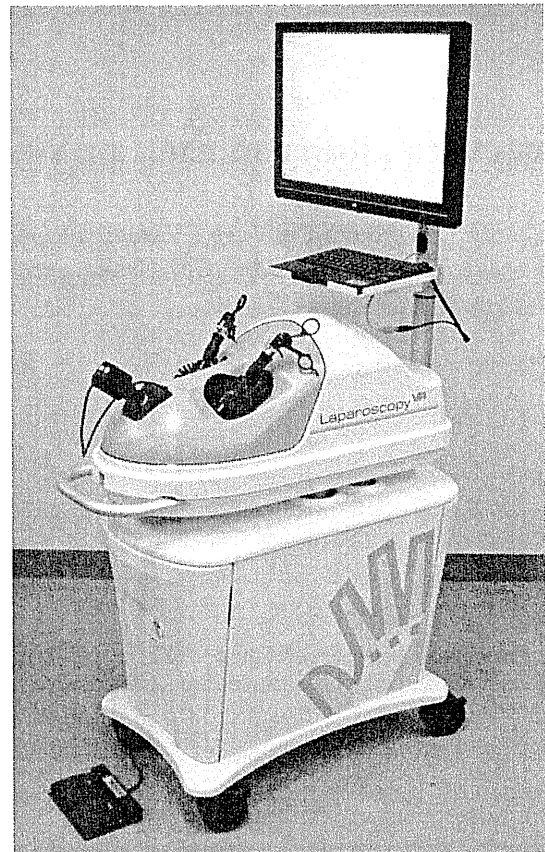


Fig. 1 The LapVR virtual-reality surgical simulator

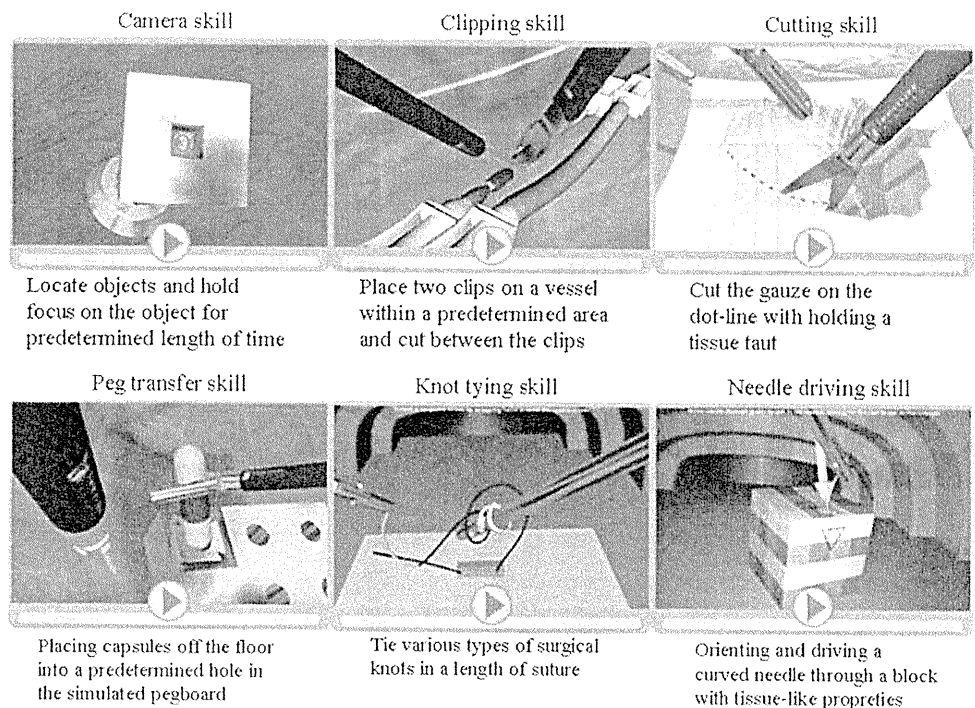
and results of comprehensive evaluation for each of the six tasks between each group of participants were statistically evaluated.

Statistical analysis

Categorical variables were compared by χ^2 test or Fisher’s exact test, and differences were considered significant at $P < 0.05$. Significance of differences between two groups was determined by Mann–Whitney U test with Bonferroni correction, and differences were considered significant at $P < 0.017$. All statistical analyses were performed using SPSS 17.0 software (SPSS, Chicago, IL, USA).

Results

Statistically significant differences were observed for 16 of the 100 parameters. EX completed three tasks faster than JR and five tasks faster than RE. JR completed the knot tying task faster than RE (Table 1). Regarding the number of subjects who could complete each task within the time limit, statistical significance between the groups was observed for the cutting ($P = 0.003$) and the knot tying

Fig. 2 Pictures and brief explanation of the tasks**Table 1** Total time to complete tasks

Task	Time, median (range) (s)					P value		
	EX	JR	RE	EX vs. RE	EX vs. JR	JR vs. RE		
Camera	52 (39–67)	58 (41–98)	53 (40–138)	0.394	0.252	0.765		
Clipping	87 (59–141)	103 (68–197)	117 (74–181)	0.010*	0.429	0.260		
Cutting	188 (129–374)	311 (138–530)	384 (196–732)	<0.001*	0.002*	0.168		
Peg transfer	122 (98–204)	164 (97–266)	207 (107–766)	0.002*	0.015*	0.190		
Knot tying	201 (124–409)	284 (123–937)	416 (228–757)	<0.001*	0.044	0.012*		
Needle driving	269 (193–561)	421 (220–1015)	615 (280–1699)	<0.001*	0.016*	0.103		

PL path length, TT total time

* Statistically significance

($P < 0.001$) tasks, that is to say, a greater proportion of the EX participants completed the task within the time limit. In the camera navigation, clipping, and peg transfer tasks, the number of participants who could not complete the task within the time limit was small (0, 2, and 2 of 44, respectively). In the needle driving task, however, as many as 12 RE, 11 JR, and 9 EX participants, adding up to more than half of all participants, failed to complete the task within the time limit.

Discrepancies in the trend of scores between the dominant and nondominant hands among experienced and nonexperienced participants also provided useful information. In the cutting task, the difference between EX and RE was statistically significant in terms of path length for the nondominant hand ($P = 0.014$) and the number of unsuccessful cutting attempts ($P = 0.005$), although no difference

was detected in terms of path length for the dominant hand ($P = 0.109$). In the peg transfer task, the difference between EX and RE was statistically significant in terms of path length ($P < 0.001$) and average time ($P = 0.004$) for the nondominant hand. However, no significant difference was observed in terms of path length ($P = 0.032$) and average time ($P = 0.026$) for the dominant hand. In the knot tying task, there was a statistically significant difference between EX and RE in terms of path length for the dominant hand ($P = 0.008$) rather than in terms of path length for the nondominant hand ($P = 0.046$). In the needle driving task, significant differences between EX and RE were seen in terms of path length for both dominant ($P = 0.016$) and nondominant hands ($P = 0.004$) (Table 2).

Finally, the comprehensive evaluation taking into account the scores of all relevant parameters reached the

Table 2 Comparison of *P* value between dominant and nondominant hand

Task	<i>P</i> value (dominant hand)			<i>P</i> value (nondominant hand)		
	EX vs. RE	EX vs. JR	JR vs. RE	EX vs. RE	EX vs. JR	JR vs. RE
Clipping						
PL	0.967	0.575	0.460	0.383	0.787	0.748
Cutting						
PL	0.109	0.124	0.713	0.014*	0.092	0.535
Peg transfer						
PL	0.032	0.662	0.520	<0.001*	0.546	0.002*
TT	0.026	0.139	0.421	0.004*	0.058	0.214
Knot tying						
PL	0.008*	0.170	0.077	0.046	0.053	0.581
Needle driving						
PL	0.016*	0.025	0.581	0.004*	0.020	0.505

* Statistically significance

Table 3 Result of comprehensive evaluation

Task	<i>P</i> value	Successful completion	<i>N</i>		
			EX (<i>n</i> = 16)	JR (<i>n</i> = 14)	RE (<i>n</i> = 14)
Camera	0.073	Yes	8	4	10
		No	8	10	4
Clipping	1.000	Yes	6	6	6
		No	10	8	8
Cutting	0.026*	Yes	12	5	4
		No	4	9	10
Peg transfer	0.007*	Yes	13	5	4
		No	3	9	10
Knot tying	0.102	Yes	4	6	1
		No	12	8	13
Needle driving	0.335	Yes	5	3	1
		No	11	11	13

*Statistically significance

conclusion that the peg transfer task ($P = 0.007$) and cutting task ($P = 0.026$) were the two tasks for which experienced participants had significantly higher incidence of completing the task successfully when compared with inexperienced participants (Table 3).

Discussion

VR surgical simulators have been developed for the purpose of saving time and cost when training surgeons and to enhance patient safety [7]. VR simulators are regarded as effective devices both for surgical training and to evaluate surgical skills of trainees [1–3] and have potential to enhance surgical-team training [8]. Use of a proficiency-based training simulator has been proposed as a paradigm shift in surgical skill training [9]. Recent studies have

demonstrated significant correlation between actual operative performance and psychomotor performance in the virtual environment [10], and have shown simulator-based training to translate into improvement in actual surgical performance [11–14]. Before implementation of a new simulator to the surgical curriculum, systematic objective validation is required [1, 4–6]. An assessment should be able to demonstrate several forms of validity. The degree to which the assessment can discriminate between individuals at different technical levels is related to construct validity [6, 15], for which evidence has been reported for simulators such as Xitact LS 5000 [15], LapSim [2, 3, 16–18], LapMentor [1, 4], and ProMIS [19]. The current study aimed to establish construct validity of the newly developed surgical simulator, LapVR. One of the notable new features of LapVR is that haptic feedback can be modified to suit the preference of the user. In addition, the

acceptance threshold for various parameters is user-configurable, and various tasks at different technical levels and requirements can be combined to tailor the curriculum according to the level and goal of the users.

In the current study, performance for the camera navigation task was shown not to reflect laparoscopic experience: none of the parameters related to this task revealed statistical significance between groups with different surgical experience. A similar result had been reported with LapMentor [5]. The explanation for this could simply be that the “camera navigation 1” task, adjusted to the beginner’s level, is too easy to complete even for RE. The clipping task could be characterized as a procedure that could be accomplished by a single hand, not calling for coordination of both hands, which is essential for more complex procedures. Accordingly, a statistical significance was observed in only one parameter, namely total time needed for completion of the task, and this task can be considered not to be a strong discriminator.

On the contrary, the cutting task requires coordination of both hands. The forceps must be controlled by the non-dominant hand to apply appropriate traction while the dominant hand needs to use the scissors to cut at an appropriate angle. This is in line with the actual task often encountered in the operating theater. It is difficult for the inexperienced RE to move their nondominant hand skillfully, leading to prolonged time taken to complete the task. This is evidenced by the result that only the nondominant hand parameter showed statistical significance. Depth perception was another factor influencing the result of this task. Several residents actually manipulated scissors in irrelevant space due to lack of depth perception, frequently resulting in tissue damage and time loss. The difference in the number of unsuccessful cutting attempts could also be attributed to differences in dexterity between the two hands. The importance of the nondominant hand was also highlighted in the peg transfer task, as seen from the result that statistically significant differences were observed in terms of average time and path length for the nondominant hand, although dominant hand parameters did not show any difference. These results suggest that development of dexterity of the nondominant hand could be key to improving laparoscopic skills [4].

Although statistically significant differences were also detected in two parameters related to the knot tying task, all 16 EX left comments that the image of thread was not realistic. Because a formal questionnaire survey was not performed in the current study, assessment of face validity, in which a defined group of subjects are asked to judge the degree of resemblance of the system to reality, is limited [2, 6]. Even with this limitation, face validity in this task seems rather questionable. In fact, Dongen et al. [2] excluded the knot tying task and Woodrum et al. [17] the

suturing task from their study, because they alleged that each of the tasks did not represent the actual procedure. In the needle driving task, three parameters revealed statistically significant differences between the groups of experienced and novice surgeons. However, the result that more than half of the participants failed to complete the task in the predetermined time limit of 5 min indicates that this task in the current form also is unsuitable as an indicator of laparoscopic skill.

Several studies have used some form of original composite score to evaluate construct validity [2, 18]. The authors had considered these original composite scores as impractical, because it was cumbersome for a trainee or instructor to calculate by hand a score based on the outcome of several parameters. Through automatic calculation, LapVR enabled trainees to receive the result of comprehensive evaluation immediately after completion of the tasks. The authors attempted to verify whether the result of comprehensive evaluation given after finishing each task actually reflects experience as a laparoscopic surgeon, finding that the peg transfer and cutting tasks were the two strongest discriminators, aptly reflecting laparoscopic skills of the participants.

The authors regard a task as a more useful discriminator when it contains a greater number of parameters that significantly differ between experienced and inexperienced surgeons. Only 16 of 100 parameters showed statistically significant differences between different groups of surgeons, and four tasks (cutting, peg transfer, knot tying, and needle driving) contained two or more such parameters. Although the knot tying and needle driving tasks reflected laparoscopic experience by revealing differences in multiple parameters, these two tasks did not seem to be best suited as optimal discriminators of surgical experience, because of the weaknesses in face validity and difficulty of the task such that even experienced surgeons often failed to complete the task within the allocated time. The cutting and peg transfer tasks, on the contrary, showed differences between EX and RE in three parameters as well as in the comprehensive evaluation, despite the fact that these tasks were relatively simple to perform.

The next step in evaluating the LapVR as a training tool is to demonstrate that training with the simulator actually translates into performance improvement in the operating room. This requires a randomized trial comparing operating-room performance by participants with or without intensive training using the simulator, as has been conducted to evaluate other simulators [11, 13, 20] and may be warranted for LapVR in the near future.

To summarize, statistically significant differences according to surgical experience were shown in three parameters and in comprehensive evaluation for the cutting and peg transfer tasks, and these were found to be strong

discriminators of laparoscopic experience. The current study is among the first to demonstrate construct validity of the LapVR.

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Assessment of Quality of Life After Gastrectomy Using EORTC QLQ-C30 and STO22

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Abstract

Background The European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire–Cancer (QLQ-C30) and the site-specific module for gastric cancer (QLQ-STO22) have seldom been used to measure the postoperative health-related quality of life (HRQOL) in Japanese gastric cancer patients. The aim of this study was to evaluate the HRQOL after gastrectomy using these instruments and to compare various aspects of HRQOL among surgical procedures.

Methods A total of 98 patients who underwent gastrectomy and had no recurrence were evaluated. Among them, we compared the differences between major surgical procedures consisting of open total gastrectomy (TG, $n = 8$), open distal gastrectomy (DG, $n = 24$), and laparoscopy-assisted distal gastrectomy (LADG, $n = 44$). Questionnaires were completed at baseline and at 1, 3, 6 and 12 months postoperatively.

Results The worst scores for most of the items were observed at 1 month after surgery and usually improved thereafter. Scores after TG were the worst of all surgical procedures across all dimensions throughout the period. Scores after LADG were generally superior to those after DG at 1 and 3 months postoperatively but not at 12 months.

Conclusions EORTC QLQ-C30 and STO22 detected differences in several aspects of HRQOL among patients treated by the three surgical procedures. The laparoscopic approach resulted in superior short-term outcomes,

whereas TG continued to affect the HRQOL in several items 12 months after surgery.

Introduction

Although various treatment modalities have been developed to confront gastric cancer, radical surgery remains the only treatment that offers the possibility for cure. Of the numerous surgical procedures that have been developed to dissect gastric cancer, a single procedure needs to be selected for each patient based on location and preoperative staging of the tumor and the general physical status of the patient. In addition to offering the maximum possibility of cure, various function-preserving procedures and approaches have recently been proposed for patients with favorable disease stages [1]. Such limited procedures are commonly performed in Japan owing to the predominance of early-stage cancers, and the proportion of patients who undergo such surgery is expected to increase once the concept of sentinel navigation begins to gain wider recognition.

When evaluating treatment for cancer, health-related quality of life (HRQOL) has been acknowledged as an important endpoint in addition to oncologic outcomes and safety issues [2–6]. Undoubtedly, it is more or less unavoidable for patients who have undergone gastric cancer surgery to suffer from various gastrointestinal symptoms and malfunctions. However, only a few studies have explored this issue scientifically and quantitatively [7–10]. Recently, validation studies for the Japanese-language version of the European Organization for Research and Treatment of Cancer (EORTC) core questionnaire (EORTC QLQ-C30) [11] and the site-specific module for gastric cancer (EORTC QLQ-STO22) [12, 13] have been reported [14, 15], but actual clinical data of patients who

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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 (<i>n</i> = 8)	DG (<i>n</i> = 24)	LADG (<i>n</i> = 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			
Hes	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

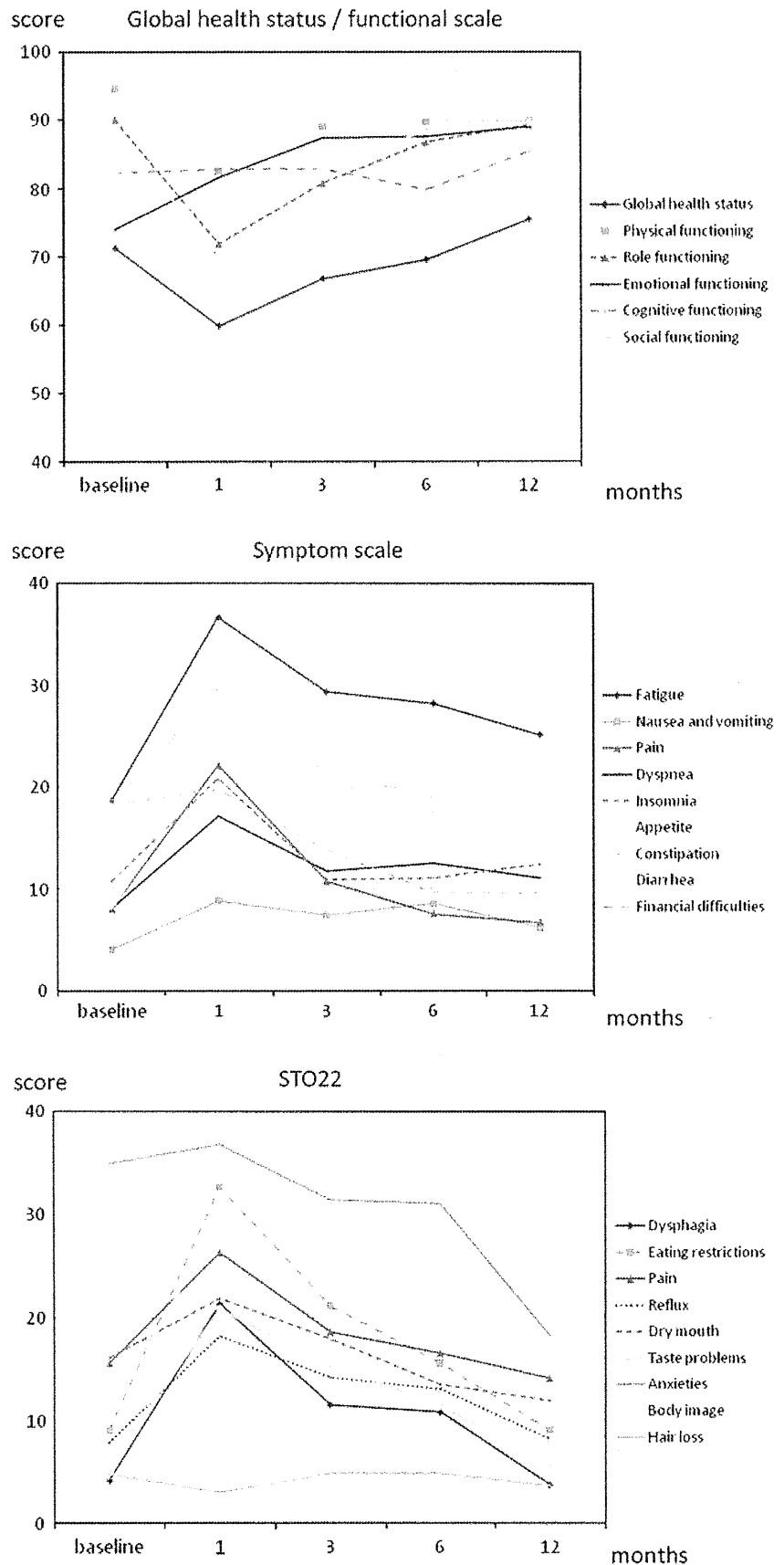
Questionnaire, compliance, missing data

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

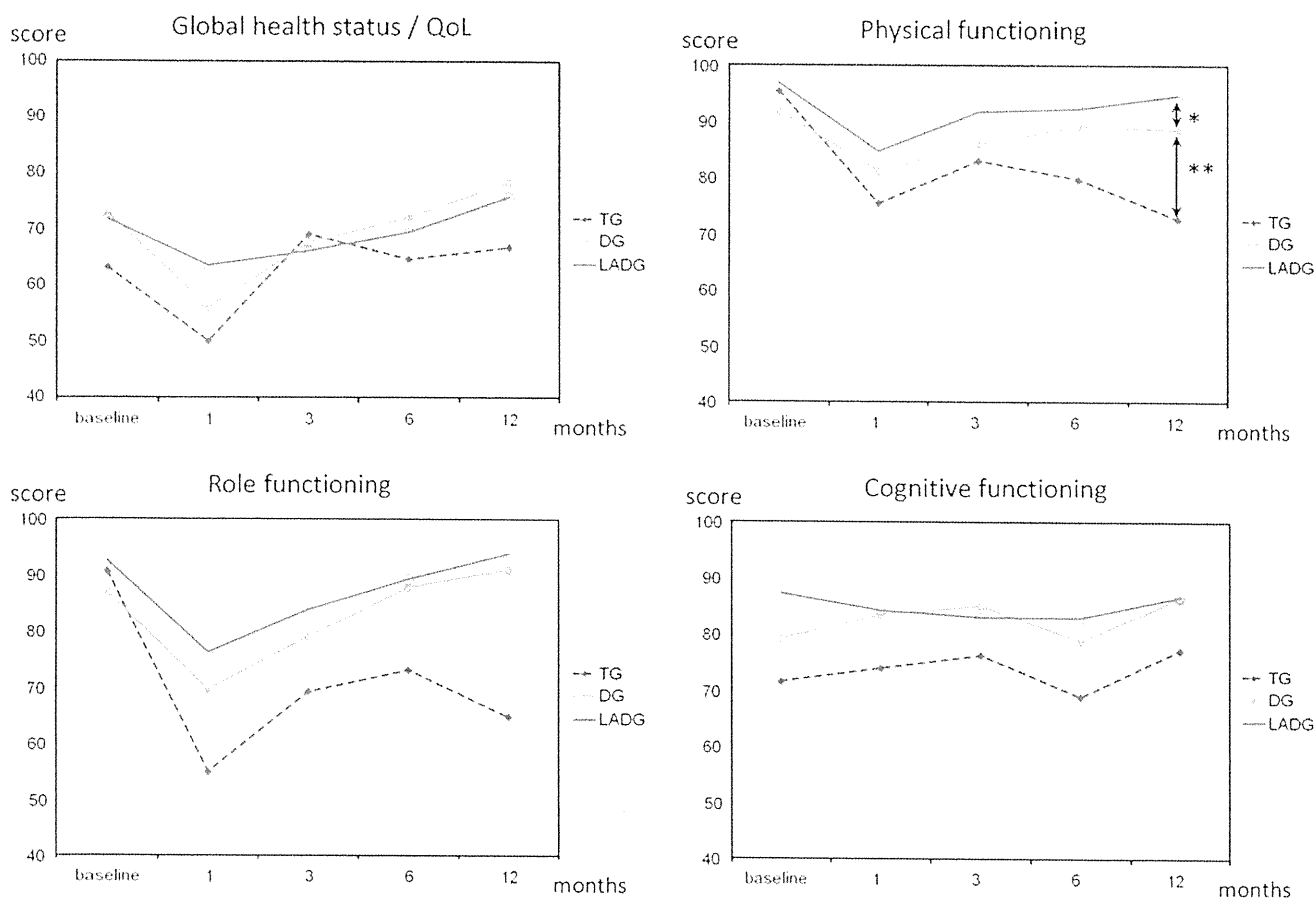


Fig. 2 Global health status and functioning scores for patients who underwent total gastrectomy (TG), open distal gastrectomy (DG), or laparoscopy-assisted distal gastrectomy (LADG). For the physical

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.

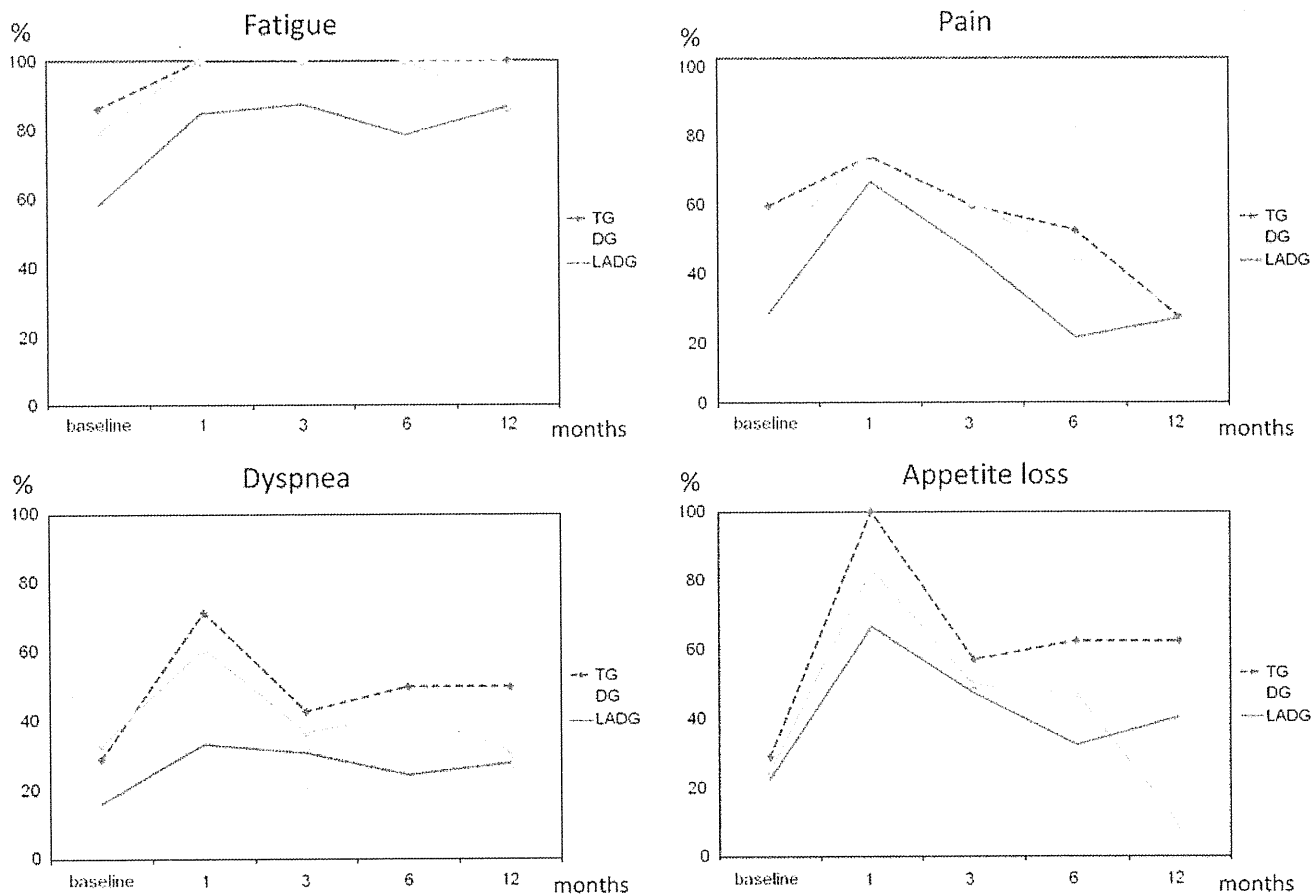


Fig. 3 Percentage of symptomatic patients evaluated by the EORTC QLQ-C30: comparison between TG, DG, and LADG. In the fatigue scale, although the percentage of symptomatic patients was lower

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