Original article

Comparison of outcomes after laparoscopy-assisted and open total gastrectomy for early gastric cancer

J. H. Lee[1], B.-H. Nam[2], K. W. Ryu[3], S. Y. Ryu[4], Y. K. Park[4], S. Kim[1] and Y. W. Kim[2]

[1]Department of Surgery, Sungkyunkwan University School of Medicine, Seoul, [2]Department of Cancer Control and Policy, Graduate School of Cancer Science and Policy and [3]Centre for Gastric Cancer, National Cancer Centre, Goyang-si, Gyeonggi-do, and [4]Department of Surgery, Chunnam National University Whasoon Hospital, Seoul, Korea

Correspondence to: Dr Y. W. Kim, Department of Cancer Control and Policy, Graduate School of Cancer Science and Policy, National Cancer Centre, 323 ilsan-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, 410-769, Korea (e-mail: gskim@ncc.re.kr)

Background: **The aim of this study was to compare the results of laparoscopy-assisted total gastrectomy with those of open total gastrectomy for early gastric cancer.**

Methods: **Patients with gastric cancer who underwent total gastrectomy with curative intent in three Korean tertiary hospitals between January 2003 and December 2010 were included in this multicentre, retrospective, propensity score-matched cohort study. Cox proportional hazards regression models were used to evaluate the association between operation method and survival.**

Results: **A total of 753 patients with early gastric cancer were included in the study. There were no significant differences in the matched cohort for overall survival (hazard ratio (HR) for laparoscopy-assisted *versus* open total gastrectomy 0·96, 95 per cent c.i. 0·57 to 1·65) or recurrence-free survival (HR 2·20, 0·51 to 9·52). The patterns of recurrence were no different between the two groups. The severity of complications, according to the Clavien–Dindo classification, was similar in both groups. The most common complications were anastomosis-related in the laparoscopy-assisted group (8·0 per cent *versus* 4·2 per cent in the open group; $P = 0·015$) and wound-related in the open group (1·6 *versus* 5·6 per cent respectively; $P = 0·003$). Postoperative death was more common in the laparoscopy-assisted group (1·6 *versus* 0·2 per cent; $P = 0·045$).**

Conclusion: **Laparoscopy-assisted total gastrectomy for early gastric cancer is feasible in terms of long-term results, including survival and recurrence. However, a higher postoperative mortality rate and an increased risk of anastomotic leakage after laparoscopic-assisted total gastrectomy are of concern.**

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Introduction

Laparoscopy-assisted distal gastrectomy is considered safe and the patients' quality of life has been reported to be superior to that of patients who undergo open distal gastrectomy[1–3]. With the development of better laparoscopic instruments and accumulated experience of laparoscopic surgery, laparoscopy-assisted distal gastrectomy has become a widely used treatment worldwide for patients with early gastric cancer[3,4]. Recent data have shown that long-term outcomes of laparoscopy-assisted distal gastrectomy are comparable to those of open distal gastrectomy[5].

In contrast to laparoscopy-assisted distal gastrectomy, laparoscopy-assisted total gastrectomy is not popular because of its technical complexity[6]. The main obstacle is the difficult reconstruction. Some investigators[7,8] have reported that laparoscopy-assisted total gastrectomy is feasible in terms of safety and survival, but the sample sizes in these studies were so small that the results were not conclusive. Recent meta-analyses[9,10] of laparoscopy-assisted total gastrectomy have shown similar results, but there have been no high-quality controlled clinical trials and the existing studies have limitations of potential bias and heterogeneity[1].

It would be difficult to recruit patients for a high-quality controlled clinical trial comparing laparoscopy-assisted with open total gastrectomy. Moreover, there is a high possibility of selection bias because of the technical complexity of laparoscopy-assisted total gastrectomy. The propensity score matching method might be an alternative approach to obtain matched results[11]. This study used the propensity score matching method to compare survival of patients

with gastric cancer who underwent laparoscopy-assisted total gastrectomy with that of patients who had open total gastrectomy.

Methods

A retrospective review of prospectively maintained gastric cancer databases was carried out. The study cohort included patients with early gastric cancer who were treated by open or laparoscopic total gastrectomy between January 2003 and December 2010 at one of three institutions in Korea: Chunnam Whasoon Hospital, National Cancer Centre and Samsung Medical Centre. Patients who had a histologically confirmed gastric adenocarcinoma, a mucosal or submucosal tumour, and newly diagnosed cancer without previous treatments were included in the analysis. All information was obtained with appropriate institutional review board waivers and data were collected without revealing any personal information.

Patient characteristics and clinical data

Characteristics of patients were obtained from a review of medical records. Demographic data included age, sex and body mass index. Clinicopathological characteristics included tumour location, tumour size, differentiation, gross type, depth of invasion, lymphatic invasion, lymph node metastasis, stage at diagnosis and operation method. Stage at diagnosis was determined according to the sixth edition of the International Union Against Cancer (UICC)/American Joint Committee on Cancer (AJCC) classification system[12]. In patients with multiple synchronous gastric cancers, the lesion with the deepest infiltration of the gastric wall was considered to be the main lesion and any others were regarded as accessory lesions. The clinicopathological characteristics of the main lesion were used in the analysis.

Operative procedures and adjuvant treatment

A total of 12 gastric cancer surgeons were involved in the study; all staff surgeons had previously conducted more than 200 open gastric cancer operations. Gastrectomy was performed with a tumour-free margin of 2 cm. The extent of lymph node dissection was determined using the recommendations of the Japanese Research Society for Gastric Carcinoma[13]. After laparotomy or laparoscopy, surgeons examined the intra-abdominal cavities, and inspected the peritoneum, diaphragm, liver capsule and pelvic cavity. All patients enrolled in the present study underwent gastrectomy with D1 + β or more lymph node dissection.

Roux-en-Y oesophagojejunostomy was performed using a 25-mm circular stapler after open total gastrectomy. Extracorporeal Roux-en-Y oesophagojejunostomy using a 25-mm circular stapler or intracorporeal Roux-en-Y oesophagojejunostomy using an OrVil™ device (Covidien, Mansfield, Massachusetts, USA) was carried out after laparoscopy-assisted total gastrectomy. An extracorporeal Roux-en-Y oesophagojejunostomy was made using a circular stapler in the same manner as for open total gastrectomy, after creating a 5–6-cm minilaparotomy on the epigastrium[5]. A jejunojejunostomy was prepared manually through the minilaparotomy wound. Intracorporeal Roux-en-Y oesophagojejunostomy using the OrVil™ stapler was done as described previously[14]. The OrVil™ anvil was passed transorally by the anaesthetist through the larynx to the stapled oesophageal stump. A small hole was created in the corresponding position in the stapled oesophageal stump, and the tube was pulled through the hole into the abdominal cavity until the white plastic ring was fully revealed. The connecting thread was cut and the orogastric tube was disconnected from the anvil; then the spike was connected to the oesophageal anvil to create an oesophagojejunal anastomosis. A 3-cm longitudinal minilaparotomy incision was then made at the midline of the epigastric region. After a wound protector had been placed, the stomach was delivered through the incision for pathological examination. The jejunum was cut off at 15 cm from the ligament of Treitz and the stump of proximal jejunum was sutured. A 25-mm circular stapler was inserted into the distal limb of the jejunum and introduced into the abdominal cavity after a second pneumoperitoneum had been created. The anvil and circular stapler were connected and an end-to-side oesophageal jejunostomy anastomosis was fashioned under direct laparoscopic view. After restoring the continuity of the oesophagus and jejunum, the Peterson defect was closed.

Because all patients included in this study were diagnosed with early gastric cancer, no patient was received adjuvant chemotherapy.

Follow-up schedule

Follow-up was conducted according to accepted clinical practice at each institution. In general, follow-up consisted of abdominopelvic CT every 6 months for 5 years after surgery and oesophagogastroduodenoscopy annually for 5 years. Cancer recurrence was diagnosed when there was positive radiological evidence. Patients were followed until death or until the cut-off date of 31 December 2013. Those lost to follow-up and operative deaths were treated as censored.

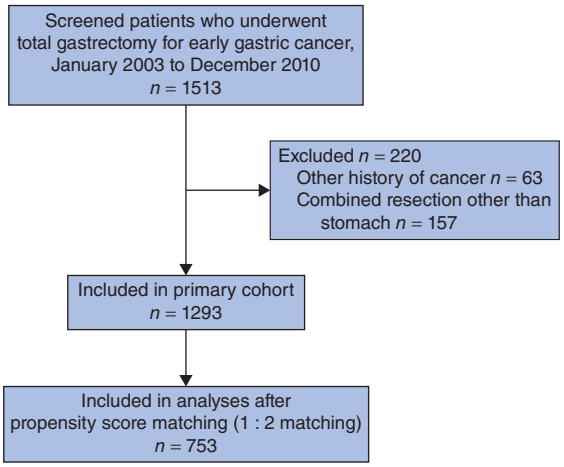

Fig. 1 Study flow chart

Outcome data

The primary endpoints of the study were death and tumour recurrence. Deaths from any cause and disease-related deaths (defined as death from recurrence) were analysed. Peritoneal recurrences were defined as carcinomatosis or ovarian metastasis. All recurrences were documented pathologically and/or by radiological imaging. Morbidity was defined as complications that required an extended hospital stay or readmission, and was graded according to the Clavien–Dindo classification[15]. Overall survival was calculated from the time of surgery to death from any cause. Recurrence-free survival (RFS) was calculated from the time of surgery to tumour recurrence or death with evidence of recurrence. For RFS, patients who died without known tumour recurrence were censored at the last documented evaluation.

Statistical analysis

Continuous variables were compared using the *t* test or Mann–Whitney *U* test, and categorical variables were analysed using the χ^2 test. To make this study as close as possible to a randomized clinical trial setting, propensity score matching was employed[11]. To generate the propensity score, a multiple logistic regression model was used. The dependent variable was the treatment received, and variables included in the multivariable model were: age, sex, tumour differentiation, depth of tumour invasion, tumour size and presence of lymphatic invasion. Using the SAS® Greedy 5 → 1 digit match macro (SAS Institute, Cary, North Carolina, USA), propensity score-matched pairs were created without replacement (1 : 2 match for laparoscopic : open).

A mixed-effect model was used, where matched-pair effects were considered as random. Statistical significance and the effect of treatment on outcomes were estimated using appropriate statistical methods for matched data. In the propensity score-matched cohort, continuous variables were compared using the mixed linear model and categorical variables by conditional logistic regression. The risks of death, recurrence and metachronous gastric cancer were compared using Cox proportional hazards regression models with robust standard errors that accounted for the clustering of matched pairs. The proportional hazards assumption was confirmed by examination of log (–log [survival]) curves; no relevant violations were found. Survival curves were generated by the Kaplan–Meier method and analysed using the log rank test. Statistical significance was set at $P < 0{\cdot}050$.

Results

From January 2003 to December 2010, 1513 patients with early gastric cancer underwent total gastrectomy at one of three institutions. Of these, patients who had another cancer (63) or needed combined resection other than stomach (157) were excluded; the final study population comprised 1293 patients (*Fig. 1*). After propensity score matching, a total of 753 patients were included in this study. Clinical and pathological characteristics of the tumours are shown in *Table 1*. Median age was 59 (range 23–84) years and 479 patients (63·6 per cent) were men. All tumours were located in the upper or middle third of the stomach. Sixty-two tumours (8·2 per cent) had metastasized to lymph nodes. There was no significant difference in baseline characteristics other than tumour size between the open and laparoscopy-assisted total gastrectomy groups.

Effect of operation method on short-term outcomes

The mean number of dissected lymph nodes was lower and the mean duration of operation was longer in the laparoscopy-assisted group (*Table 2*).

The overall morbidity rate was 18·9 per cent. The most common type of morbidity was wound-related complications, including infection (23 patients, 3·1 per cent), dehiscence (6 patients, 0·8 per cent) and hernia (3 patients, 0·4 per cent), followed by anastomosis-related complications, including stricture (22 patients, 2·9 per cent), leakage (11 patients, 1·5 per cent) and bleeding of the oesophagojejunostomy (8 patients, 1·1 per cent). Patterns of complications were different in the two groups. The most common complication in the open group was

Table 1 Baseline characteristics of propensity score-matched patients who underwent open or laparoscopy-assisted total gastrectomy

	Open group ($n = 502$)	Laparoscopy group ($n = 251$)	P*
Demographic characteristics			
Age (years)			
Mean(s.d.)	57·6(11·6)	58·4(12·7)	
Median (range)	57 (23–84)	58 (23–84)	0·392†
Sex ratio (M : F)	319 : 183	160 : 91	0·957
Body mass index (kg/m^2)			
Mean(s.d.)	23·1(11·6)	23·1(3·0)	
Median (range)	23·6 (15–37)	23·6 (15–37)	0·768†
ASA fitness grade			0·480
I	206 (41·0)	92 (36·7)	
II	278 (55·4)	148 (59·0)	
III	18 (3·6)	11 (4·4)	
Tumour characteristics			
Location			0·081
Upper third	371 (73·9)	200 (79·7)	
Middle third	131 (26·1)	51 (20·3)	
Size (cm)			
Mean(s.d.)	3·9(2·6)	3·3(2·4)	
Median (range)	2·4 (0·1–9·0)	2·4 (0·1–16)	0·004†
Histology			0·796
Differentiated	229 (45·6)	112 (44·6)	
Undifferentiated	273 (54·4)	139 (55·4)	
Morphology			0·243
Ulcer	304 (60·6)	163 (64·9)	
No ulcer	198 (39·4)	88 (35·1)	
No lymphovascular invasion	429 (85·5)	219 (87·3)	0·679
Depth of tumour invasion			0·834
Mucosa	208 (41·4)	106 (42·2)	
Submucosa	294 (58·6)	145 (57·8)	
Lymph node metastasis	42 (8·4)	20 (8·0)	0·851

Values in parentheses are percentages unless indicated otherwise. ASA, American Society of Anesthesiologists. *χ^2 test, except †Mann–Whitney U test.

wound infection, whereas stricture of the oesophagojejunostomy was the most common complication after laparoscopy-assisted total gastrectomy (*Table 2*).

Comparison of the severity of complications, according to the Clavien–Dindo classification, revealed no difference between the two groups. There were five operation-related deaths overall (1 in the open group, 4 in the laparoscopy group). Operation-related deaths were significantly more common after laparoscopy-assisted total gastrectomy (1·6 *versus* 0·2 per cent; $P = 0·045$). Two patients died from internal herniation of the small bowel 22 and 27 months after operation. Other causes of death were aspiration pneumonia, luminal bleeding and anastomosis leakage.

Table 2 Short-term surgical outcomes after open and laparoscopic surgery among the propensity score-matched patients

	Open group ($n = 502$)	Laparoscopy group ($n = 251$)	P †
No. of dissected lymph nodes			
Mean(s.d.)	45·7(17·0)	41·8(16·8)	0·003‡
Median (range)	35 (4–103)	35 (3–100)	
Duration of operation (min)			
Mean(s.d.)	185·8(63·0)	237·6(81·4)	< 0·001‡
Median (range)	184 (84–490)	225 (70–555)	
Complications			
Clavien–Dindo classification			0·118
None	414 (82·5)	197 (78·5)	
I	12 (2·4)	12 (4·8)	
II	29 (5·8)	15 (6·0)	
IIIA	37 (7·4)	15 (6·0)	
IIIB	8 (1·6)	7 (2·8)	
IV	1 (0·2)	1 (0·4)	
V	1 (0·2)	4 (1·6)	
Site of complication			0·007
None	414 (82·5)	197 (78·5)	
Anastomosis	21 (4·2)	20 (8·0)	
Wound	28 (5·6)	4 (1·6)	
Intra-abdominal	11 (2·2)	9 (3·6)	
Other	18 (3·6)	15 (6·0)	
Length of hospital stay (days)*	9·4(0·5)	11·2(0·6)	0·001‡
No. receiving ICU care	33 (7·2)	13 (13·1)	0·054
Length of ICU stay (days)*	0·2(1·0)	0·6(3·3)	0·083‡

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.). ICU, intensive care unit. †χ^2 test, except ‡t test.

Effect of operation method on long-term outcomes

Thirty patients (4·0 per cent) were not available at the time of last follow-up. Median (i.q.r.) follow-up was 55 (37–69) and 58 (44–67) months for the open and laparoscopy-assisted groups respectively. During follow-up, 33 patients experienced recurrences (*Table S1*, supporting information). There was no difference between the groups in the rate or patterns of recurrence. Liver metastases were the most common form of recurrence in both groups, followed by distant lymph node metastases in the open group.

The risk of death did not differ significantly between the two groups (hazard ratio (HR) for laparoscopy-assisted *versus* open total gastrectomy 0·96, 95 per cent c.i. 0·57 to 1·65; $P = 0·894$). The 5-year overall survival rate was 99·7 per cent after open and 99·0 per cent after laparoscopy-assisted procedures (*Fig. S1*, supporting information). There was no significant difference in the risk of recurrence during follow-up (HR 2·20, 0·51 to 9·52; $P = 0·291$). The 5-year RFS rate was 96·5 per cent in the open total gastrectomy group and 92·6 per cent in the laparoscopy-assisted group (*Fig. S2*, supporting information).

Discussion

This study compared short- and long-term results after open and laparoscopy-assisted total gastrectomy for early gastric cancer. A recent large-scale study[5] performed after laparoscopic gastrectomy in Korea showed similar long-term outcomes to open gastrectomy. However, the exact number of patients who underwent laparoscopy-assisted total gastrectomy was not presented and most patients underwent laparoscopy-assisted distal gastrectomy, so interpretation of long-term outcomes after laparoscopy-assisted *versus* open total gastrectomy was difficult.

Favourable long-term outcomes have been reported in the limited number of studies comparing laparoscopy-assisted with open total gastrectomy for early gastric cancer. Five-year overall survival rates following laparoscopy-assisted total gastrectomy were reported to be 98·9 and 91·5 per cent in previous studies[6,16]. Similarly, the 5-year overall survival rate of laparoscopy-assisted total gastrectomy was 99·0 per cent in the present study. However, previous reports[7,8,16] of laparoscopy-assisted total gastrectomy have limited data, with considerable selection bias for long-term outcome.

Although survival after laparoscopy-assisted total gastrectomy was comparable to that following open total gastrectomy and the median number of dissected lymph nodes was similar, the operating time was longer for laparoscopy-assisted total gastrectomy. This might have been due to the more difficult reconstruction and did not appear to increase the risk of complications other than those related to anastomosis. However, anastomotic complications are mostly serious and a frequent cause of delayed discharge or death.

Comparison of complications according to the Clavien–Dindo classification showed that the severity of postoperative complications was similar after laparoscopy-assisted and open total gastrectomy. However, the pattern of complications was different; anastomosis-related complications, including leakage, stenosis and bleeding, were more common in the laparoscopy-assisted group. These complications require a longer hospital stay, explaining why the hospital stay was longer in the laparoscopy-assisted group in this study. These results differ from those of recent meta-analyses[9,10] that showed a reduced risk of postoperative complications after laparoscopy-assisted total gastrectomy compared with open total gastrectomy, similar to the risk after laparoscopy-assisted distal gastrectomy.

Postoperative deaths were more common after laparoscopy-assisted than open total gastrectomy. Four of five postoperative deaths were associated with anastomosis-related complications, including bleeding, leakage, and internal hernia through the afferent limb. Use of effective methods to restore continuity of the oesophagus and jejunum may decrease the postoperative mortality rate after laparoscopy-assisted total gastrectomy. There is currently no standard method for restoration of continuity of the oesophagus and jejunum. Recently reported[17,18] reconstruction methods after laparoscopic surgery might help in reducing such anastomosis-related complications. For example, Okabe and colleagues[17] reported that anastomosis using linear staplers might reduce anastomosis-related complications. It is evident that reconstruction after laparoscopy-assisted total gastrectomy is more difficult than that after open total gastrectomy.

The major limitation of this study is that it is retrospective and as such the treatment strategy was not based on random assignment. As a result, selection bias might have occurred in choosing the treatment modality even though a propensity-matched cohort was studied. Another limitation is that the level of experience in laparoscopy-assisted total gastrectomy was different from that in open total gastrectomy for most surgeons. Data were analysed from the initial experiences of laparoscopy-assisted total gastrectomy and this might have influenced the results. Finally, other important outcomes such as quality of life were not compared in this study. Because survival rates in both groups were similar, other outcomes might more meaningfully inform the decision regarding the method of operation.

Nonetheless, the present data indicate that laparoscopy-assisted total gastrectomy is not inferior to open total gastrectomy in terms of long-term outcomes. However, considering the higher anastomosis-related complication rate, further development of anastomotic methods and technological innovations in laparoscopy-assisted total gastrectomy are needed.

Disclosure

The authors declare no conflict of interest.

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Supporting information

Additional supporting information may be found in the online version of this article:

Table S1 Pattern of recurrence after open and laparoscopy-assisted total gastrectomy among the propensity score-matched groups (Word document)

Fig. S1 Overall survival curves according to treatment method (Word document)

Fig. S2 Recurrence-free survival curves according to treatment method (Word document)