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Original Article

Morbidity and Mortality After Laparoscopy-Assisted Distal Gastrectomy and Totally Laparoscopic Distal Gastrectomy to Treat Gastric Cancer: An Interim Report: A Phase III Multicenter, Prospective, Randomized Trial (The KLASS-07 Trial)

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ABSTRACT

Purpose: We conducted a randomized prospective trial (KLASS-07 trial) to compare laparoscopy-assisted distal gastrectomy (LADG) and totally laparoscopic distal gastrectomy (TLDG) for gastric cancer. In this interim report, we describe short-term results in terms of morbidity and mortality.
Methods and Methods: The sample size was 442 participants. At the time of the interim analysis, 314 patients were enrolled and randomized. After excluding patients who did not undergo planned surgeries, we performed a modified per-protocol analysis of 151 and 145 patients in the LADG and TLDG groups, respectively.
Results: The baseline characteristics, including comorbidity status, did not differ between the LADG and TLDG groups. Blood loss was somewhat higher in the LADG group, but

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Conflict of Interest
No potential conflict of interest relevant to this article was reported.

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statistical significance was not attained (76.76±72.63 vs. 62.91±65.68 mL; P=0.087). Neither the required transfusion level nor the operation or reconstruction time differed between the 2 groups. The mini-laparotomy incision in the LADG group was significantly longer than the extended umbilical incision required for specimen removal in the TLDG group (4.79±0.82 vs. 3.89±0.83 cm; P<0.001). There were no between-group differences in the time to solid food intake, hospital stay, pain score, or complications within 30 days postoperatively. No mortality was observed in either group.
Conclusions: Short-term morbidity and mortality rates did not differ between the LADG and TLDG groups. The KLASS-07 trial is currently underway.

Trial Registration: ClinicalTrials.gov Identifier: NCT03393182

Keywords: Gastrectomy; Laparoscopy; Morbidity; Mortality; Stomach neoplasms

INTRODUCTION

Laparoscopy is commonly used to treat early-stage gastric cancer [1-4]. The approach to reconstruction after resection (extracorporeal vs. intracorporeal) is usually determined by the surgeon's preference or the type of planned anastomosis. The extracorporeal approach was developed prior to the intracorporeal method, and a mini-laparotomic extracorporeal approach is used for both the extraction of the gastric specimen and anastomosis [5]. In the extracorporeal approach, mini-laparotomy features a vertical incision of the upper midline, or a transverse incision of the right upper quadrant, depending on the type of anastomosis [6]. Both hand-sewn suturing and several types of stapling are used to perform anastomoses under such extracorporeal conditions. When using the intracorporeal approach, surgeons must employ a linear stapler for anastomosis and an extended umbilical port is usually employed to remove the resected stomach [7].

The operative method that uses mini-laparotomy for anastomosis is termed laparoscopy-assisted distal gastrectomy (LADG), whereas totally laparoscopic distal gastrectomy (TLDG) refers to intracorporeal anastomosis without mini-laparotomy [8,9]. To date, no prospective multicenter randomized controlled trial (RCT) has compared the operative outcomes of LADG and TLDG treatments for gastric cancer. Therefore, we (the Korean Laparoendoscopic Gastrointestinal Surgery Study [KLASS] group) are conducting a multi-institutional RCT (KLASS-07) to assess postoperative outcomes including quality of life (QoL) after LADG and TLDG [10]. The purpose of this interim report is to compare the morbidity and mortality associated with LADG and TLDG.

MATERIALS AND METHODS

Study design

KLASS-07 is an investigator-initiated, multi-institutional, parallel-assigned RCT that is a superiority trial of TLDG over LADG for distal third clinical stage I gastric cancer (cT1N0-1M0 and cT2N0M0) (ClinicalTrial.gov, NCT03393182). This study was approved by the Institutional Review Board (IRB) of the Korea University Medical Centre (approval No. 2017AN0328) and the IRBs of all investigators. This study adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all patients before

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enrolment. This RCT was monitored by an independent data and safety monitoring committee of Anam Korea University Hospital.

Eligibility criteria

The inclusion criteria were age 20–80 years, histologically proven gastric adenocarcinoma, Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, and clinical stage IA (T1N0M0) or IB (T1N1M0/T2N0M0) according to the American Joint Committee on Cancer/Union for International Cancer Control seventh edition. All the patients underwent preoperative gastroscopy and abdominal computed tomography. These findings revealed that the tumors could be resected via distal gastrectomy with curative intent, and all patients provided written informed consent [11,12]. Patients with a history of gastric surgery, including gastrojejunostomy; intra-abdominal adhesions attributable to intraperitoneal surgery; gastric cancer treatment via chemotherapy, radiotherapy, or resection; or any malignancy within the past 5 years were excluded.

Quality control and randomization

Each surgeon who participated in the trial performed a minimum of 50 gastrectomies and continued to perform more than 30 gastrectomies annually. Randomization was conducted before surgery to assign patients to different treatment groups. Eligible patients were enrolled in the trial by submitting their screening data to an electronic clinical record form. After the data were entered into a central data registry server, randomization was coordinated by the data center. The patients were assigned to either the TLDG or LADG group in a 1:1 ratio, and stratified by the surgeon.

Surgical procedures

Using a laparoscopic approach, standard distal gastrectomy combined with D1+ or D2 lymph node dissection was performed in both the LADG and TLDG groups as dictated by the Japanese Gastric Cancer Treatment Guideline 2010 (ver. 3) [13]. In the LADG group, reconstruction was performed extracorporeally via a mini-laparotomy, which commenced near the epigastrium. All TLDG steps were intracorporeal, including reconstruction, which employed the Billroth II, Roux-en-Y, or uncut Roux-en-Y procedures as chosen by the surgeon.

Postoperative care and follow-up

Based on the standards of the participating institutions, the diet consisted of sips of water, as dictated by individual patient conditions. If a soft diet was tolerated for 2 to 3 days without complications, the surgeon considered discharge. All patients were followed up at 25±7 days and at 3, 6, and 12 months after surgery. Blood tests, including assays of markers of nutritional status (total protein and albumin), were performed at 25±7 days and 6 and 12 months. Endoscopy was performed at 6 and 12 months, and QoL questionnaires were completed at 3, 6, and 12 months after surgery.

Final endpoints and short-term outcome measures

The primary endpoint of this trial was early postoperative morbidity within 30 days after surgery. The secondary endpoint was the questionnaire score for QoL, which was assessed using the Korean version of the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 (version 3.0) and STO22 questionnaires. This interim analysis reports the short-term morbidity and mortality observed during this trial. Short-term morbidity for interim analysis was defined as any surgery-related complication within 30 days postoperatively. Morbidities were categorized as local or systemic, and severities were graded

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using the Clavien-Dindo system [14]. Other short-term clinical outcomes included operative details, Wong-Baker Faces pain score rating, time to a soft diet, and length of hospital stay. Mortality was defined as death during the hospital stay or death from complications within 30 days of surgery.

Statistical analysis

The sample size calculation based on short-term complications after TLDG and LADG for the treatment of clinical stage I gastric cancer is described in the study protocol. This interim analysis considered the per-protocol population; no patient was reassigned to an alternative surgical treatment (LADG to TLDG or vice versa) after randomization (**Fig. 1**). Chi-squared and Fisher's exact tests were used to compare categorical variables, and the Student's t-test or the Mann-Whitney U test was used to compare continuous variables. P-values less than 0.05 were considered significant. All statistical analyses were performed using the IBM SPSS Statistics version 25 (IBM Corp., Armonk, NY, USA).

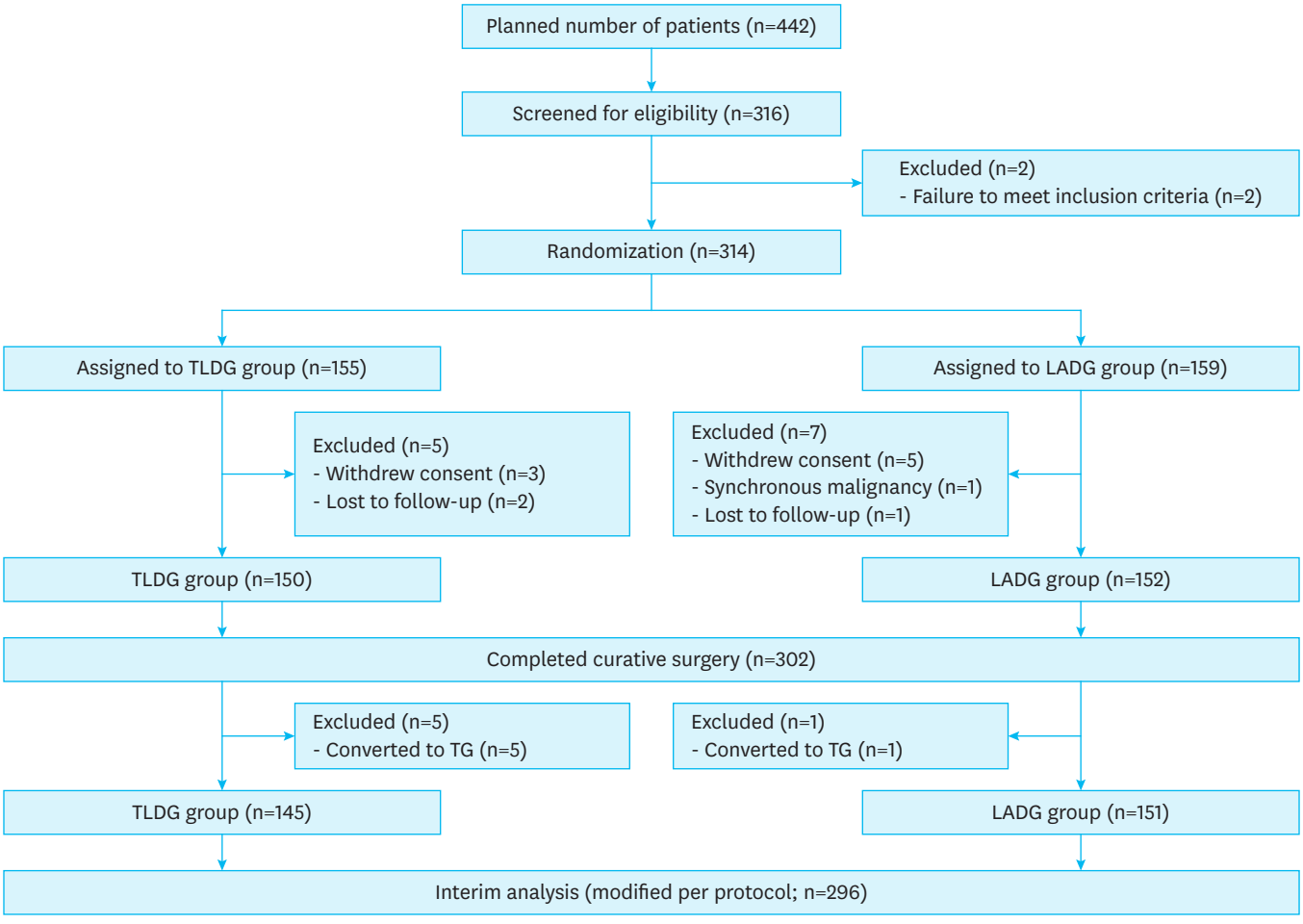

Fig. 1. Consort diagram.
LADG = laparoscopy-assisted distal gastrectomy; TLDG = totally laparoscopic distal gastrectomy; TG = total gastrectomy.

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RESULTS

Of the planned 442 patients, 314 met the inclusion criteria and were randomized and subjected to this interim analysis. A total of 159 and 155 patients were assigned to the LADG and TLDG groups, respectively. In these groups, 8 and ten patients were excluded during surgery because of conversion to total gastrectomy, withdrawal of consent, or loss to follow-up. Thus, we analyzed 296 patients: 151 in the LADG group and 145 in the TLDG group (**Fig. 1**). The sex ratios and mean ages of the 2 groups were similar. The mean body mass indices of both groups were similar (approximately 24 kg/m^2). No significant differences in ECOG performance status or American Society of Anesthesiologists (ASA) classification were noted. Particularly, the number of patients with ASA III was identical between the 2 groups. The preoperative comorbidity status and the proportion of patients with a history of abdominal surgery did not differ between the 2 groups (**Table 1**).

The operative details are presented in **Table 2**. The reconstruction method did not differ between the 2 groups. Billroth II reconstruction with Braun anastomosis was preferred (both the groups). There was no between-group difference in either operation or reconstruction time. Blood loss in the LADG group was somewhat higher than that in the TLDG group; however, the difference was not statistically significant, and the transfusion level did not differ between the 2 groups. The mini-laparotomy incision length in the LADG group was significantly greater than that of the extended umbilical incision for tumor removal in the TLDG group.

Table 1. Patients' demographics

Variables	TLDG group (n=145)	LADG group (n=151)	P-value
Age (yr)	61.1±10.7	60.5±10.1	0.647
Sex			0.528
Male	104 (71.7)	103 (68.2)	
Female	41 (28.3)	48 (31.8)	
BMI (kg/m^2)	24.0±3.1	24.0±2.8	0.898
ECOG			0.866
0	126 (86.9)	130 (86.1)	
1	19 (13.1)	21 (13.9)	
ASA classification			0.965
I	72 (49.7)	73 (48.3)	
II	65 (44.8)	70 (46.4)	
III	8 (5.5)	8 (5.3)	
Comorbidity			
Overall	59 (40.7)	56 (37.1)	0.552
Hypertension	33 (22.8)	37 (24.5)	0.785
Cardiovascular	15 (10.3)	13 (8.6)	0.693
Pulmonary	5 (3.4)	5 (3.3)	0.948
Neurologic	5 (3.4)	3 (2.0)	0.494
Diabetes mellitus	10 (6.9)	18 (11.9)	0.166
Hepatic disease	3 (2.1)	1 (0.7)	0.363
Renal	0 (0)	3 (2.0)	0.248
Others	14 (9.7)	13 (8.6)	0.841
History of previous operation			0.876
Yes	23 (15.9)	26 (17.2)	
None	122 (84.1)	125 (82.8)	

Values in parentheses are percentages unless indicated otherwise. Or values are presented as mean ± standard deviation.
TLDG = totally laparoscopic distal gastrectomy; LADG = laparoscopy-assisted distal gastrectomy; BMI = body mass index; ECOG = Eastern Cooperative Oncology Group; ASA = American Society of Anesthesiologists.

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Table 2. Operative details

Variables	TLDG group (n=145)	LADG group (n=151)	P-value
Type of reconstruction			0.750
Billroth II	59 (40.7)	53 (35.1)	
Billroth II with Braun	69 (47.6)	80 (53.0)	
Roux-en-Y	15 (10.3)	15 (9.9)	
Uncut Roux-en-Y	2 (1.4)	3 (2.0)	
Combined operation			0.545
Cholecystectomy	5 (3.4)	4 (2.6)	
Others	1 (0.7)	0 (0)	
None	139 (95.9)	147 (97.4)	
Operation time (min)	177.6±44.8	173.6±39.65	0.422
Reconstruction time (min)	28.0±14.8	27.1±11.1	0.537
Transfusion (cases)	1 (0.7)	1 (0.7)	0.977
Transfusion (cc)	2.2±26.6	2.3±28.5	0.972
Blood loss (cc)	62.9±65.7	76.8±72.6	0.087
Length of mini-laparotomy (cm)	3.9±0.8	4.8±0.8	<0.001

Values in parentheses are percentages unless indicated otherwise. Or values are presented as mean ± standard deviation.
TLDG = totally laparoscopic distal gastrectomy; LADG = laparoscopy-assisted distal gastrectomy.

Table 3. Pathological characteristics

Variables	TLDG group (n=145)	LADG group (n=151)	P-value
Tumor size (cm)	2.9±2.1	2.8±2.0	0.583
No. of retrieved nodes	41.2±16.2	41.3±17.4	0.952
Proximal resection margin (cm)	5.4±3.1	5.2±3.0	0.597
Distal resection margin (cm)	6.0±2.9	6.1±3.2	0.770
Histology			0.613
Differentiated	66 (45.5)	66 (43.7)	
Undifferentiated	78 (53.8)	82 (54.3)	
Others	1 (0.7)	3 (2.0)	
pT stage			0.276
T1	135 (93.1)	138 (91.4)	
T2	8 (5.5)	6 (4.0)	
T3	2 (1.4)	4 (2.6)	
T4	0 (0)	3 (1.0)	
pN stage			0.026
N0	136 (93.8)	129 (85.4)	
N1	4 (2.8)	17 (11.3)	
N2	5 (3.4)	4 (2.6)	
N3	0 (0)	1 (0.7)	
Pathological stage (8th AJCC)			0.251
I	138 (95.2)	138 (91.4)	
II	7 (4.8)	11 (7.3)	
III	0 (0)	2 (1.3)	

Values in parentheses are percentages unless indicated otherwise. Or values are presented as mean ± standard deviation.
TLDG = totally laparoscopic distal gastrectomy; LADG = laparoscopy-assisted distal gastrectomy; AJCC = American Joint Committee of Cancer.

No pathological characteristics, including tumor size, resection margin status, histological type, or number of retrieved lymph nodes, differed between the 2 groups. Although the nodal stage of the LADG group was significantly higher than that of the TLDG group, there were no between-group differences in terms of either the T stage or the final pathological stage of the Eighth American Joint Committee on Cancer TNM Criteria (**Table 3**).

Neither the time to a solid diet nor the duration of hospital stay differed between groups. The postoperative pain scores were similar. The early complication rates (local and systemic)

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Table 4. Postoperative outcomes

Variables	TLDG group (n=145)	LADG group (n=151)	P-value
Start of diet (days)	3.2±2.4	3.2±1.2	0.822
Hospital stays (days)	8.8±4.5	9.2±5.5	0.501
Faces pain rating scale	2.8±1.0	3.0±1.0	0.171
Faces pain rating scale ≥4			0.359
Yes	35 (24.1)	44 (29.1)	
No	110 (75.9)	107 (70.9)	
Early complications			
Overall	18 (12.4)	25 (16.6)	0.327
Localized	15 (10.3)	23 (15.2)	0.228
Wound	2 (1.4)	3 (2.0)	0.685
Fluid collection	5 (3.4)	4 (2.6)	0.746
Intra-abdominal bleeding	1 (0.7)	3 (2.0)	0.623
Intra-luminal bleeding	1 (0.7)	3 (2.0)	0.623
Postoperative ileus	2 (1.4)	7 (4.6)	0.174
Delayed gastric emptying	3 (2.1)	3 (2.0)	0.960
Stenosis	0 (0)	1 (0.7)	0.326
Leakage	1 (0.7)	1 (0.7)	0.977
Fistula	0 (0)	0 (0)	N/A
Systemic	2 (1.4)	5 (3.3)	0.448
Pulmonary	1 (0.7)	5 (3.3)	0.215
Hepatic	1 (0.7)	0 (0)	0.490
Others	1 (0.7)	1 (0.7)	0.977
Clavien-Dindo complication grade			
I	4 (2.8)	10 (6.6)	0.170
II	9 (6.2)	11 (7.3)	0.818
IIIa	5 (3.4)	5 (3.3)	0.948
IIIb	0 (0)	2 (1.3)	0.499
IVa	0 (0)	2 (1.3)	0.499
IVb	0	0	N/A
V	0	0	N/A
Mortality	0	0	N/A

Values in parentheses are percentages unless indicated otherwise. Or values are presented as mean ± standard deviation.
TLDG = totally laparoscopic distal gastrectomy; LADG = laparoscopy-assisted distal gastrectomy; N/A = not available.

within 30 postoperative days and the Clavien-Dindo complication classifications did not differ between the groups. No mortality was observed in either group (**Table 4**).

DISCUSSION

In this interim study, the operative details and short-term clinical outcomes of LADG were comparable to those of TLDG. The operative and reconstruction times were similar between groups. The selected reconstruction types were nearly identical. Although intraoperative blood loss was greater in the LADG group than in the TLDG group, the difference was not statistically significant. The time to a solid diet and hospital stay were similar. Despite mini-laparotomy during LADG, neither the pain level nor wound-related issues differed between the groups. Thus, the interim results did not indicate that the short-term outcomes of TLDG were better than those of LADG. The evidence to maintain KLASS-07 is strong, and the primary endpoint is 30-day postoperative morbidity.

TLDG without mini-laparotomy is less invasive than LADG for gastric cancer treatment. When performing mini-laparotomy, surgeons access the stomach and small intestine to complete gastrointestinal resection and reconstruction using an extracorporeal hand-sewn

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technique or an open surgery-dedicated stapler [5]. A laparoscopic linear stapler that can be inserted via a trocar is available; this allows surgeons to perform intracorporeal resection and anastomosis [15,16]. As the performance of laparoscopic linear staplers improved, staple-line bleeding and leakage became much less common, reducing the need for mini-laparotomy [17]. However, during TLDG, the extended umbilical incision required to remove the specimen is a form of mini-laparotomy that can trigger an incisional hernia, given the nature of the umbilicus [18]. Although the length of the incision required to remove the resected specimen in the TLDG group was significantly smaller than the mini-laparotomy incision in LADG, the mean difference was less than 1.0 cm.

To date, only one prospective randomized study has compared the early surgical outcomes of LADG and TLDG [19]. This evaluated the intra- and postoperative results and patient QoL. Although there were no between-group differences in inflammatory marker levels, postoperative recovery, or QoL scores, the trial was a single-center study with a small number of patients. In addition, only Billroth II anastomosis was performed. We (the KLASS-07 researchers) previously meta-analyzed the surgical outcomes of LADG and TLDG treatments of gastric cancer [20]. The meta-analysis of 25 studies showed that TLDG resulted in shorter hospital stays and lower analgesic use compared to LADG, but most other outcomes, including the postoperative complications, were similar. The KLASS-07 RCT of LADG and TLDG will ultimately reveal the similarities and differences between them.

Another endpoint of the KLASS-07 RCT was the endoscopic outcome of the selected reconstruction method. Surgeons can choose from the Billroth II, Billroth II with Braun anastomosis, Roux-en-Y, or Uncut Roux-en-Y methods. The interim results showed that the chosen proportions were similar for both groups, and Billroth II reconstruction with Braun anastomosis was preferred. Although anastomosis is used to prevent bile reflux from the afferent loop of Billroth II, whether it has this effect is controversial [21,22]. In addition, uncut Roux-en-Y reconstruction results in better digestive function than the conventional Roux-en-Y method. We aimed to determine whether Braun anastomosis prevents bile reflux, and whether the uncut method promotes bowel motility [23,24].

To our knowledge, this is the first multicenter prospective trial to compare postoperative surgical outcomes between patients who underwent LADG and TLDG. The hypothesis of the KLASS-07 RCT was that TLDG is superior to LADG, and to explore this hypothesis, we defined set endpoints. The primary endpoint was early morbidity within 30 postoperative days, and the secondary endpoint was QoL 1 year after surgery, examined using the Korean version of the EORTC QLQ-C30 (version 3.0) and STO22 questionnaires. The interim results presented herein do not indicate that TLDG is superior in terms of early morbidity. This trial is ongoing and we will report the final morbidity and QoL results.

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