의학석사 학위논문

근위부 조기 위암에서 복강경 이중 통로 문합 근위부 위 절제술과 복강경 위 전절제술의 비교

Comparison between laparoscopic proximal gastrectomy with double tract reconstruction and Laparoscopic total gastrectomy for proximal early gastric cancer

울산대학교 대학원

의 학 과

최 민 하

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지 도 교 수 김 범 수

이 논문을 의학석사 학위 논문으로 제출함

2022 년 2 월

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최민하의 의학석사 학위 논문을 인준함

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ABSTRACT

Purpose: The actual benefits of laparoscopic proximal gastrectomy with double-tract reconstruction (LPG) in terms of nutrition remain uncertain.

Materials and Methods: We performed 35 LPGs and 98 laparoscopic total gastrectomies (LTG) for early gastric cancer located in the upper third of the stomach between December 2013 and December 2018 at Asan Medical Center. We analyzed and compared the nutritional and hematologic outcomes between LPG and LTG.

Results: The mean operation time was significantly longer in the LPG group than in the LTG group (176.74 ± 34.26 min vs. 148.61 ± 32.39 min; $p < 0.001$). The retrieved lymph nodes were significantly fewer in the LPG group than in the LTG group (28.83 ± 13.05 vs. 39.67 ± 16.84; $p = 0.039$). The other surgical outcomes, such as the time to the first flatus, postoperative transfusion, hospital stay, and postoperative complications, were not significantly different between the groups. No significant difference in the 5-year overall survival was found between them. The mean body weights at 6, 12, and 24 months were higher in the LPG group than in the LTG group, but with no significant differences. There were also no significant differences in the patterns of changes in the serum hemoglobin, cholesterol, and albumin levels between them.

Conclusions: LPG yielded similar nutritional and hematologic outcomes with LTG. Thus, the findings do not support the benefits of LPG for early gastric cancer located in the upper third of the stomach.

Keywords: Laparoscopic surgery; Gastrectomy; Anastomosis; Stomach neoplasms

INTRODUCTION

According to a worldwide survey, gastric cancer is the third most common cause of death and the fifth most common malignancy worldwide (1, 2). In South Korea, the incidence of early gastric cancer has increased from 28.6% in 1995 to 63.6% in 2019 with advancements in screening methods, such as gastric endoscopy. Moreover, the incidence of gastric cancer located in the upper third of the stomach has constantly increased over the past decade (3, 4).

Total gastrectomy (TG) has been considered as a standard treatment for upper-third gastric cancer according to Korean gastric cancer treatment guidelines. Because TG basically involves the removal of the entire stomach, it can lead to serious hematologic and nutritional problems. Specifically, patients experience considerable weight loss and skeletal muscle reduction after TG; most patients also inevitably develop iron and vitamin B12 deficiencies. (5, 6) These fundamental disadvantages of TG have been attempted to be addressed by introducing proximal gastrectomy with double-tract reconstruction (PG-DTR), which helps preserve the stomach (7, 8). Theoretically, owing to the preservation of the distal stomach, PG-DTR saves the gastric reservoir function and extent of parietal cells related to vitamin B12 metabolism. In addition, it maintains the passage to the duodenum, contributing to better iron absorption.(7, 9)

Previous studies have reported that PG-DTR yielded several benefits. For instance, the change in the hemoglobin level was significantly smaller, and the increasing percentages of the serum albumin and protein levels were significantly higher after PG-DTR than after TG (9-11). Conversely, Cho et al. demonstrated that PG-DTR had no hematologic and nutritional advantages compared with TG (12). Therefore, whether PG-DTR has superior practical benefits over TG remains uncertain. In this study, we aimed to compare the surgical and nutritional outcomes of PG-DTR with those of TG in patients with early gastric cancer located in the upper third of the stomach.

MATERIALS AND METHODS

Patients

This study was conducted in accordance with the principles of the Declaration of Helsinki and approved by the institutional review board of Asan Medical Center (approval no. 2019-0702). Data on patients who underwent laparoscopic proximal gastrectomy with double-tract reconstruction (LPG) or laparoscopic total gastrectomy (LTG) between December 2013 and December 2018 at Asan Medical Center (Seoul, South Korea) were collected using electronic medical records. The inclusion criteria were upper-third early gastric cancer invading no more deeply than the submucosa with no lymph node metastasis. The exclusion criteria were possible confounding factors, such as adjuvant chemotherapy or combination with major surgery.

Surgical procedures

We performed LPG and LTG as described in our recent studies.

Data collection

Data on patient demographics and baseline characteristics were collected. The patients' general condition was assessed using the American Society of Anesthesiologists (ASA) Physical Status Classification System. Pathologic data were evaluated using the classification guideline presented in the eighth edition of the American Joint Committee on Cancer Staging Manual (13). We also evaluated the complications that occurred within 30 days after surgery using the Clavien–Dindo classification (14). Further, survival and recurrence data were gathered. Overall survival was defined as the time between the date of surgery and death from any cause. Disease-free survival was defined as the time between the date of surgery and recurrence. The postoperative nutritional and hematologic outcomes were assessed via regular follow-up. The patients regularly visited the outpatient clinic at postoperative 3, 6, 12, 18, and 24 months. Nutritional data and hematologic parameters, including body weight, albumin level, cholesterol level, hemoglobin level, and vitamin B12 and iron profiles

(e.g., iron and ferritin levels and total iron binding capacity [TIBC]) were collected until 24 months after surgery.

Statistical analysis

Statistical analysis was conducted using the IBM SPSS software for Windows, version 23.0 program (Armonk, NY: IBM corp.). For the baseline characteristics of the study population, categorical variables were analyzed using the chi-square test or Fisher's exact test and continuous variables using a t-test. For the surgical and pathologic outcomes, categorical variables were analyzed using the chi-square test or Fisher's exact test and continuous variables, using the Wilcoxon rank sum test. Linear mixed-effect models were used to analyze the nutritional and hematologic changes.

RESULTS

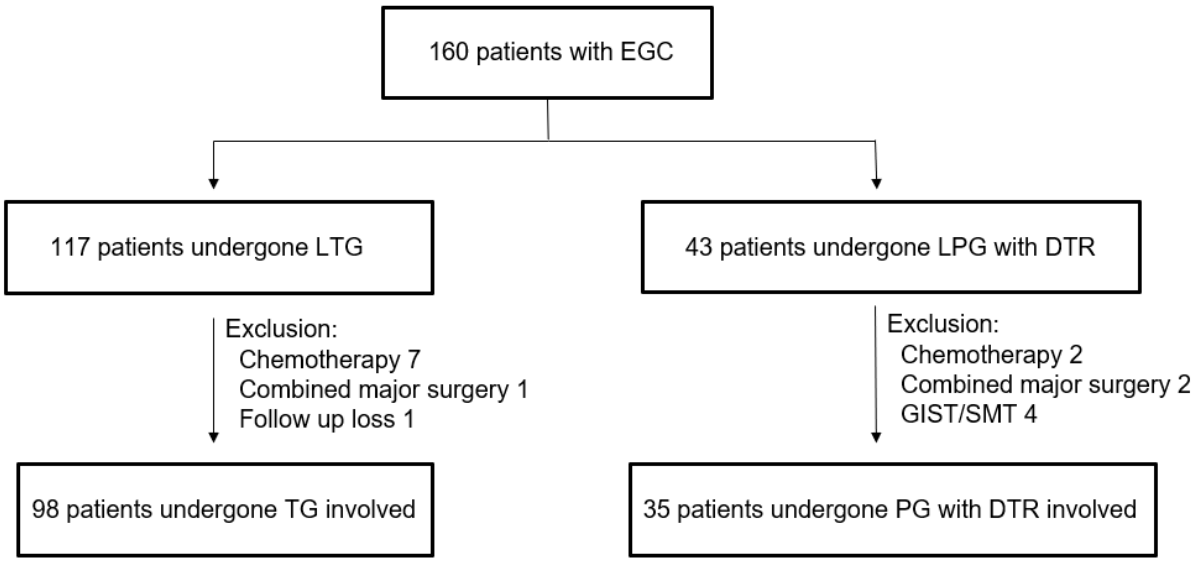

Fig. 1 The flowchart of patient enrollment

Fig. 1 demonstrates the flowchart of patient enrollment. Based on data from the electronic medical records at Asan Medical Center, a total of 160 patients (43 patients who underwent LPG- DTR and

117 patients who underwent LTG) were included in this study. We excluded eight patients who underwent LPG and nine patients who underwent LTG. Finally, 35 patients who underwent LPG and 98 patients who underwent LTG were selected and included in the analysis.

The baseline characteristics of the study population are shown in **Table 1**. These characteristics showed no significant differences between the two groups. However, the ASA score and percentage of the presence of comorbidities tended to be lower in the LPG group than in the LTG group ($p = 0.085$).

Table 1. Baseline characteristics of the study population

	Level	LPG (n = 35)	LTG (n = 98)	*p*
Age (year)		62.29 ± 9.60	61.12 ± 10.46	0.565
Sex (%)	Male	24 (68.6)	63 (64.3)	0.647
	Female	11 (31.4)	35 (35.7)	
BMI		24.77 ± 3.12	24.65 ± 3.29	0.847
ASA score (%)	1	4 (11.4)	22 (22.4)	0.061
	2	31 (88.6)	68 (69.4)	
	3	0 (0.0)	8 (8.2)	
Number of comorbidities (%)	0	13 (37.1)	53 (54.1)	0.335
	1	15 (42.9)	28 (28.6)	
	2	6 (17.1)	11 (11.2)	
	3	1 (2.9)	5 (5.1)	
	7	0 (0.0)	1 (1.0)	
Presence of comorbidities (%)	None	13 (37.1)	53 (54.1)	0.085
	Yes	22 (62.9)	45 (45.9)	
History of abdominal surgery (%)	None	31 (88.6)	76 (77.6)	0.216

	Yes	4 (11.4)	22 (22.4)	
Combined surgery (%)	None	33 (94.3)	88 (89.8)	0.731
	Minor or major	2 (5.7)	10 (10.2)	

ASA = American Society of Anesthesiologists; BMI = body mass index; LPG = laparoscopic proximal gastrectomy with double-tract reconstruction; LTG = laparoscopic total gastrectomy; SD = standard deviation.
For the categorical variables, the chi-square test or Fisher's exact test was used, and data are presented as n (%).
For the continuous variables, a t-test was used, and data are presented as means (SDs).

Table 2 presents the surgical and pathologic outcomes in the two groups. The mean operation time was significantly longer in the LPG group than in the LTG group (176.74 ± 34.26 min vs. 148.61 ± 32.39 min; $p < 0.001$). The retrieved lymph nodes were significantly fewer in the LPG group than in the LTG group (28.83 ± 13.05 vs. 39.67 ± 16.84; $p = 0.039$). The other surgical and pathologic outcomes, such as the time to the first flatus, postoperative transfusion, hospital stay, and postoperative complications, were not significantly different between them.

The follow-up rate in the LPG group was 46.1%, and the median follow-up duration was 55.17 months.

Table 2. Surgical and pathologic outcomes

	Level	LPG (n = 35)	LTG (n = 98)	*p*
Operation time (min)		172.00 ± 34.26	144.00 ± 34.39	<0.001
Time to the first flatus (days)		3.54 ± 1.04	3.82 ± 1.01	0.158
Postoperative transfusion (%)	none	33 (94.3)	96 (98.0)	0.283

	yes	2 (5.7)	2 (2.0)	
Hospital stay duration (days)		8.49 ± 4.17	9.09 ± 6.12	0.436
Early postoperative complications (%)	None	27 (77.1)	78 (79.6)	0.76
	Yes	8 (22.9)	20 (20.4)	
Early CDC3 (%)	< 3	35 (100.0)	89 (90.8)	0.111
	≥ 3	0 (0.0)	9 (9.2)	
Late postoperative complications (%)	None	33 (94.3)	91 (92.9)	1
	Yes	2 (5.7)	7 (7.1)	
Late CDC3 (%)	< 3	34 (97.1)	94 (95.9)	1
	≥ 3	1 (2.9)	4 (4.1)	
Retrieved LN (mean [SD])		28.83 ± 13.05	39.67 ± 16.84	<0.001
PRM (mean [SD])		17.83 ± 12.82	27.19 ± 25.17	0.094
DRM (mean [SD])		43.80 ± 31.73	125.00 ± 40.88	<0.001

IQR = interquartile range; LN = lymph node; LPG = laparoscopic proximal gastrectomy with double-tract reconstruction; LTG = laparoscopic total gastrectomy; SD = standard deviation.
For the categorical variables, the chi-square test or Fisher's exact test was used, and data are reported as n (%).
For the continuous variables, the Wilcoxon rank sum test was used, and data are reported as means (SDs) or medians (IQRs).

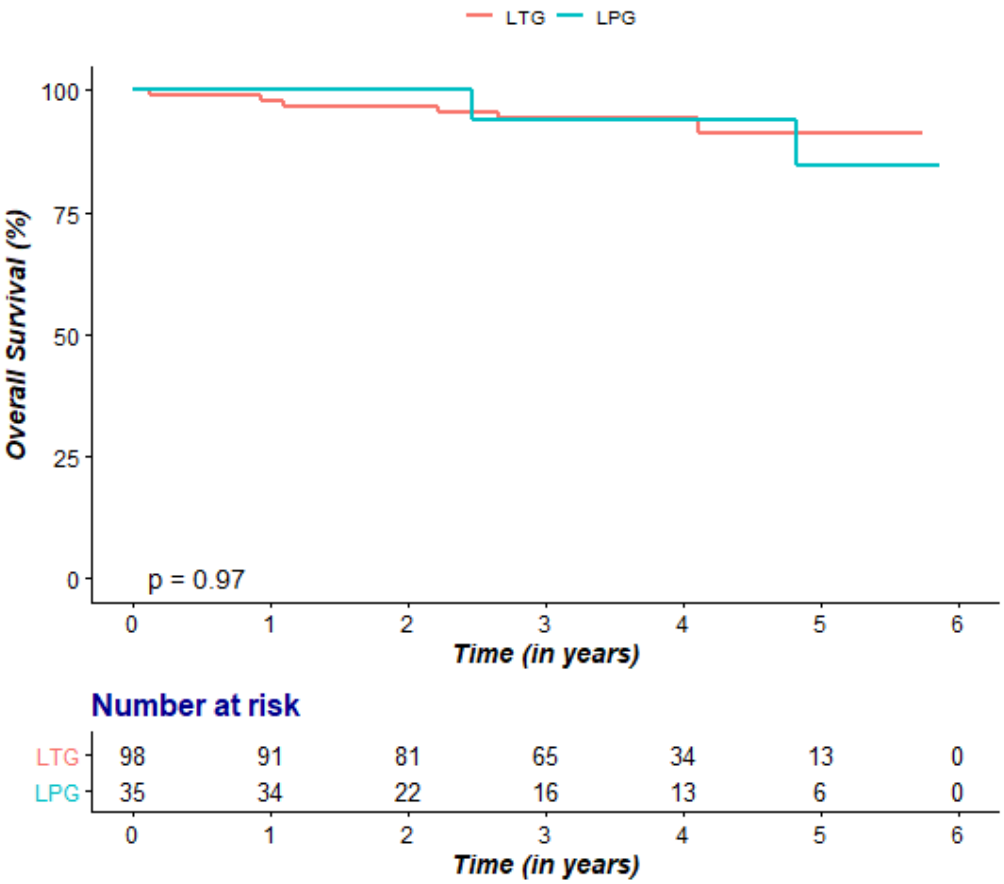

Fig. 2 Overall survival of the two group

Fig. 2 shows the overall survival of the two groups. The overall survival rate was 84.7% and 91.3% in the LPG and LTG groups, respectively, with no significant difference between them.

Fig. 3 Nutritional and hematologic changes of two group

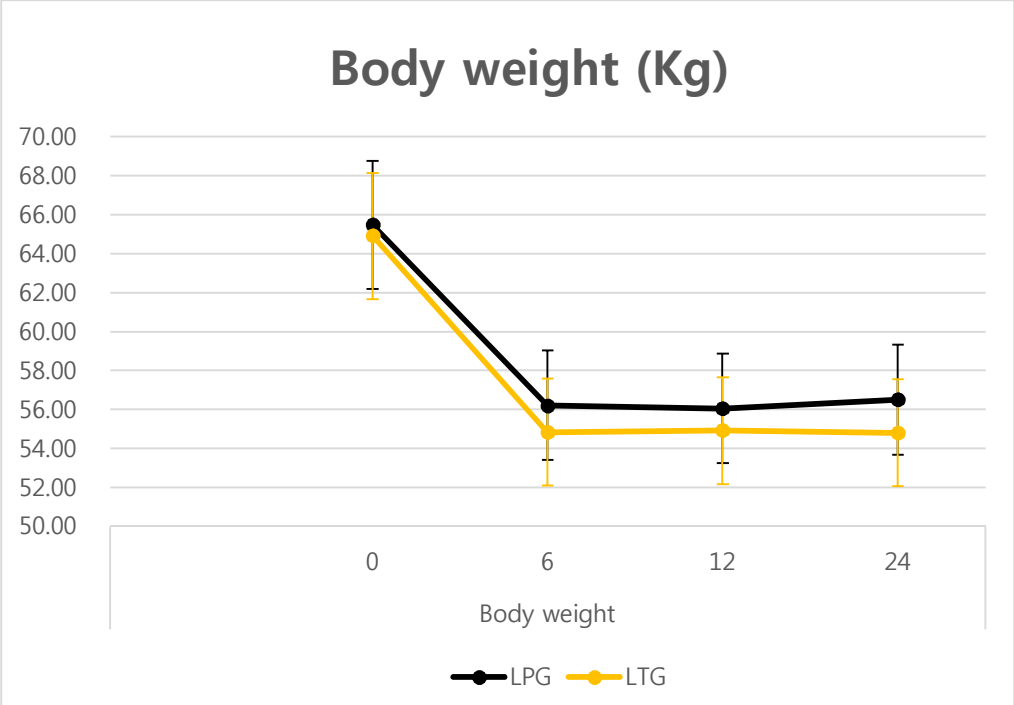

FIg. 3A Body weight changes of two group after gastrectomy

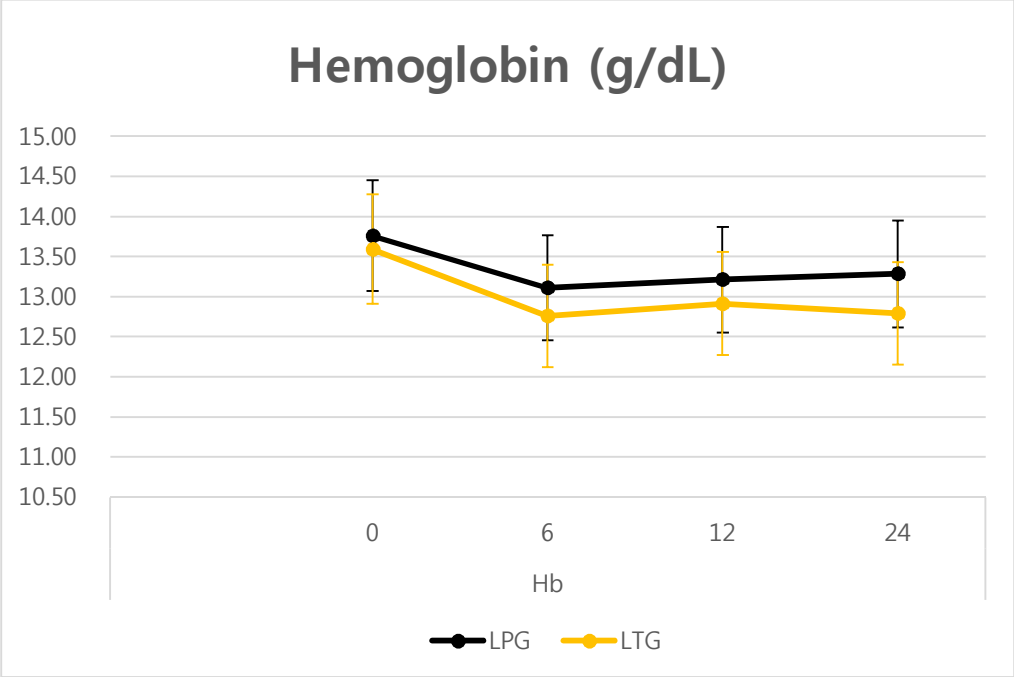

FIg. 3 B Hemoglobin changes of two group after gastretomy

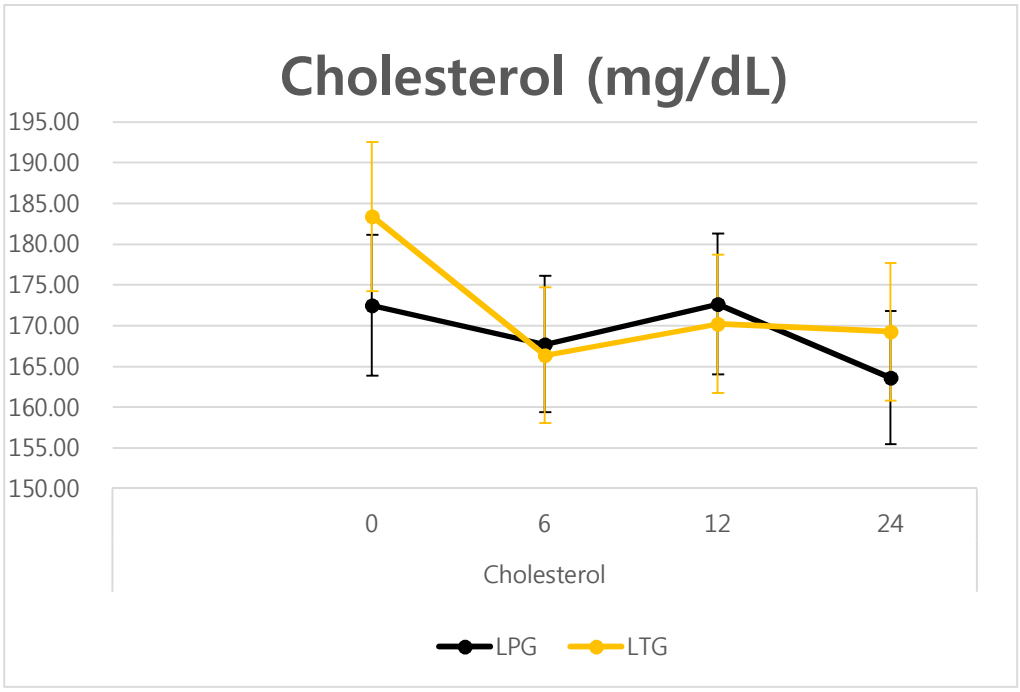

FIg. 3C Cholesterol changes of two group after gastrectomy

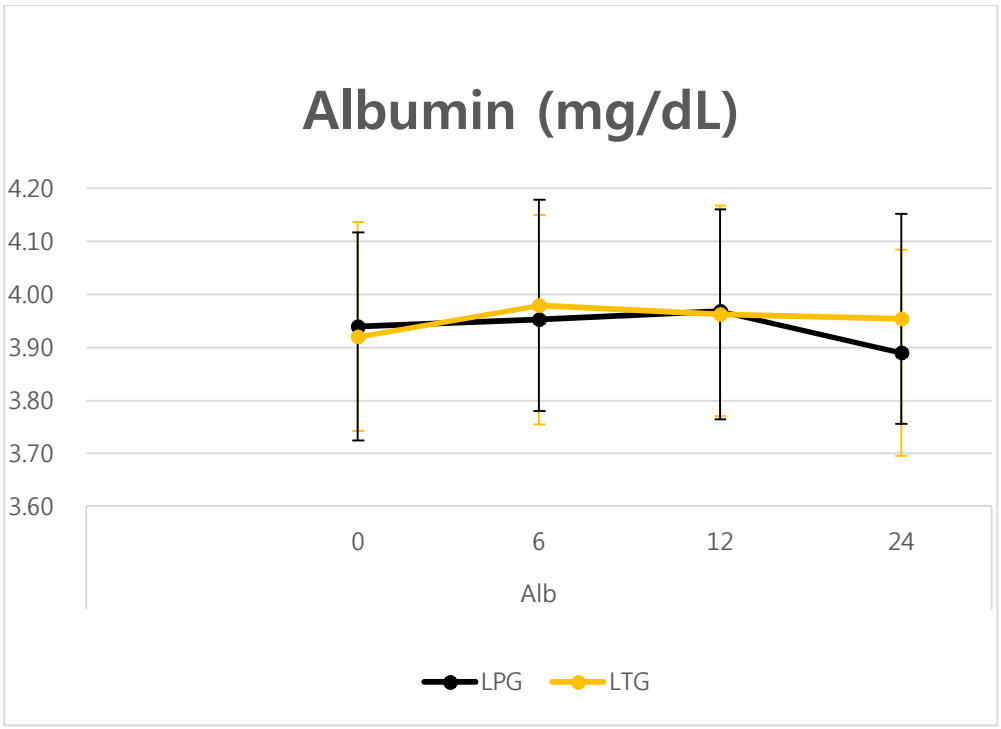

FIg. 3D Albumin changes of two group after gastrectomy

The changes in the nutritional status were also analyzed between the two groups (**Table. 3**). **Fig. 3** presents the nutritional and hematological changes after surgery. The baseline body weight of the

patients was not significantly different between the groups (**Fig. 3A**). The body weight rapidly decreased until 6 months postoperatively. Thereafter, it was slightly restored over time in both groups. The mean body weights at 6, 12, and 24 months were higher in the LPG group than in the LTG group, but with no significant differences. There were also no significant differences in the patterns of changes in body weight after surgery between them.

The hemoglobin level decreased until 6 months after surgery and then slightly recovered over time in both groups (**Fig. 3B**). The changes in the cholesterol and albumin levels are described in **Figs. 3C** and **3D**. There were no significant differences in the patterns of changes in the cholesterol and albumin levels between the groups.

Because data on the preoperative iron level and TIBC were not available, we analyzed these parameters until 12 months postoperatively. The iron level and TIBC gradually increased until 12 months after surgery. However, no significant differences were observed at 6 and 12 months after surgery between the two groups.

In the LPG group, five patients (14.2%) received iron supplementation (ferritin), and four patients (11.4%) received vitamin B12 supplementation (cobalamin). In the LTG group, 16 patients (16.3%) received iron supplementation, and 25 patients (25.5%) received vitamin B12 supplementation.

DISCUSSION

This study demonstrated that the surgical and nutritional outcomes of LPG are comparable to those of LTG based on oncological safety. Several nutritional parameters evaluated in this study, including body weight, serum cholesterol level, and serum albumin level, were similar until 24 months after surgery in both groups. Furthermore, the hemoglobin level, iron level, and TIBC in relation to anemia were also comparable.

Herein, the operation time of LPG was longer than that of LTG. This difference in the operation time is not consistent with previous retrospective study findings(12, 15-17). The reason for the longer operation time of LPG may be at least partly attributed to the fact that it includes three enteral

anastomoses (esophagojejunostomy, gastrojejunostomy, and jejunojejunostomy). In other words, one more anastomosis (gastrojejunostomy) needed to be performed in LPG compared with LTG. It was assumed that the duration of this anastomosis in LPG was reflected in the total operation time. Another reason was that the gastric cancer surgical team in our center had less experience in performing LPG than in performing LTG. In comparison with performing approximately 200 cases of LTG annually, only 10 cases of LPG had been conducted annually.

The expected benefit of proximal gastrectomy arises from the reduction of the resected stomach, conserving the food storage function; maintenance of parietal cells related to vitamin B12 metabolism; reserved secretin and gastrin release; better digestion of protein and fat; and direct passage to the duodenum in relation to iron absorption (7, 18-20). Preservation of the gastric reservoir and its function is important in nutrition. By allowing food passage to the duodenum, LPG is considered to have advantages in iron metabolism . Several previous retrospective studies have demonstrated that there were nutritional and hematologic benefits of LPG (15-17). In contrast to the expected advantages of LPG, Cho et al. reported similar hematologic and nutritional outcomes after LPG compared with those after LTG (12). In our study, the hematologic and nutritional outcomes also did not significantly differ between the LPG and LTG groups. Because of the incompatible conclusion regarding which procedure is better in terms of nutritional and hematologic outcomes, we are awaiting the results of the KLASS-04 multicenter prospective randomized controlled trial.

Herein, the LPG group had lower iron and vitamin B12 supplementation rates than the LTG group. Because of the oral complementary drug treatment in the LPG group, it is possible that the differences in the hematologic findings between the two groups slightly decreased. Two recent meta-analyses also reported that patients who had undergone LPG required fewer vitamin B12 supplementations than did those who had undergone LTG(12, 16). Vitamin B12 and iron absorption is dependent on gastric acid secretion (21). Decreased gastric acid secretion after surgery has an impact on the efficacy of iron and vitamin B12 absorption. Furthermore, vitamin B12 absorption is mediated by an intrinsic factor derived from gastric parietal cells. Because most parietal cells are located in the gastric body, there are

not enough parietal cells to preserve the vitamin B12 level (22). Therefore, a more preserved gastric volume can affect the hematologic and nutritional outcomes. Most iron absorption occurs in the duodenum and proximal jejunum (23). Because PG-DTR creates two tracks of food passage, only a partial amount of food can pass the duodenum. A recent study introduced PG-DTR, designed to allow more food to flow to the remnant stomach (24). Attempts to increase food passage to the upper intestine can improve hematologic outcomes.

The major concerns on the long-term safety after LPG were marginal ulcer and remnant stomach cancer.(25-27) First, a marginal ulcer at the gastrojejunostomy site could develop theoretically because the antrum of the stomach containing G-cells remains after surgery. However, during follow-up, no patients had a marginal ulcer in the LPG group. Park and Cho et al., who employed a relatively long study duration (more than 24 months), also demonstrated that there was no case of any marginal ulcer after LPG(12, 16). Therefore, LPG could be performed safely in terms of the occurrence of a marginal ulcer.

Second, the development of remnant stomach cancer after LPG is another important issue during long-term management. According to the Korean Gastric Cancer Association-Led Nationwide Survey in 2019, approximately half of total gastric cancer cases were located in the lower third of the stomach(28). It is expected that remnant stomach cancer could develop in the remaining lower third of the stomach over time. However, there were no observed cases of recurrence in the remnant stomach, considering that the mean follow-up period in most previous studies was only less than 24 months. Thus, further studies with long-term follow-up are needed to draw a firm conclusion on this issue.

There are several limitations in this study. First, the sample size of the LPG group was relatively small. Second, the study was a single-center, retrospective cohort study. Third, owing to missing data and loss of follow-up, hematologic parameters, such as vitamin B12 and folate levels, could not be analyzed.

Conclusions

In this study, we found that LPG yielded similar hematologic and nutritional outcomes to those of LTG. Thus, the findings do not support the benefits of LPG for early gastric cancer located in the upper third of the stomach.

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국문요약

연구배경 : 근위부 조기 위암에서, 혈액학적 및 영양학적 결과를 호전시키기 위해 이중통로 문합 근위부 위 절제술이 대체 치료법으로 대두되었다. 하지만, 위 전 절제술과 비교하여 이득은 명확히 밝혀지지 않았다. 이 연구는 후향적 연구로서, 복강경 하 이중통로 문합 근위부 위 절제술과 복강경 하 위 전 절제술의 예후 및 이득에 대해 분석해 보고자 하였다.

연구방법 : 2013 년 12 월부터 2018 년 12 월까지 서울아산병원에서 복강경 하 이중통로 문합 근위부 위 절제술과 복강경 하 위 전 절제술을 시행받은 환자들을 대상으로 하였다. 조기 위암이 아니거나, 수술 후 항암치료나 동반된 수술 등을 시행한 환자는 연구에서 배제하였다. 수술 후 24 개월까지의 영양학적, 혈액학적 지표를 확인하였으며 합병증 등의 수술적 결과를 분석하였다. 전체생존기간은 수술부터 사망까지로 하였으며 무병생존기간은 수술부터 재발까지로 정의하였다.

연구결과 : 수술 시간은 복강경 하 이중통로 문합 근위부 위 절제술 환자에서 유의미하게 길었으며 (176.74 ± 34.26 분 vs. 148.61 ± 32.39 분; $p < 0.001$), 절제된 림프절의 개수는 이중통로 문합 근위부 위 절제술에서 유의미하게 적었다 (28.83 ± 13.05 vs. 39.67 ± 16.84; $p = 0.039$). 첫 방귀, 수술 후 수혈, 입원 기간, 합병증 등의 수술적 결과는 두 군 간에 차이를 보이지 않았다. 두 군간의 5 년 생존률도 차이를 보이지 않았다. 몸무게는 6, 12, 24 개월에서 이중통로 문합 근위부 위 절제술 군이 더 높은 것으로 나타났으나 유의미 하지 않았으며, 혈장 헤모글로빈, 콜레스테롤, 알부민 등의 지표도 두 군간의 차이를 보이지 않았다.

Appendix

Table 3. Nutritional status changes at the 2-year follow-up after surgery

		LPG			LTG			
	Time since surgery (month)	Mean	95% CI		Mean	95% CI		*p* for group difference
Body weight								
	0	65.48	62.08	68.87	64.90	62.87	66.93	0.774
	6	56.21	52.96	59.46	54.84	52.87	56.81	0.477
	12	56.05	52.90	59.20	54.92	53.02	56.82	0.544
	24	56.50	53.17	59.82	54.80	52.87	56.74	0.386
	Change from 0 to 24 months	-8.98	-11.05	-6.91	-10.1	-11.26	-8.94	0.355
Hemoglobin level								
	0	13.76	13.22	14.30	13.59	13.27	13.92	0.602
	6	13.11	12.65	13.58	12.76	12.48	13.04	0.204
	12	13.21	12.78	13.64	12.91	12.66	13.17	0.243
	24	13.28	12.68	13.88	12.79	12.47	13.11	0.154
	Change from 0 to 24 months	-0.48	-1.1	0.14	-0.8	-1.13	-0.47	0.359

Albumin level								
	0	3.94	3.83	4.05	3.92	3.85	3.99	0.773
	6	3.95	3.85	4.06	3.98	3.92	4.04	0.666
	12	3.97	3.85	4.09	3.96	3.89	4.03	0.928
	24	3.89	3.78	4.00	3.95	3.89	4.01	0.312
	Change from 0 to 24 months	-0.04	-0.17	0.072	0.033	-0.035	0.1	0.242
Cholesterol level								
	0	172.51	158.81	186.22	183.41	175.21	191.61	0.180
	6	167.74	156.73	178.76	166.36	159.96	172.76	0.831
	12	172.68	161.26	184.11	170.23	163.56	176.89	0.714
	24	163.60	149.35	177.84	169.25	161.78	176.73	0.489
	Change from 0 to 24 months	-8.91	-24.21	6.38	-14.16	-22.34	-5.97	0.552

CI = confidence interval; LPG = laparoscopic proximal gastrectomy with double-tract reconstruction; LTG = laparoscopic total gastrectomy.

Linear mixed-effect models were used to account for the repeated measures within the patients.

Table 4. Nutritional outcomes at follow-up

	LPG Mean (95% CI)	LTG Mean (95% CI)	Mean difference (95% CI)	p^*
Iron level at 6 months	97.00 (86.45, 107.55)	95.74 (87.09, 104.39)	1.26 (-12.16, 14.68)	0.852
Iron level at 12 months	104.60 (92.78, 116.42)	102.98 (94.73, 111.23)	1.62 (-13.92, 17.16)	0.837
TIBC at 6 months	302.28 (277.44, 327.12)	312.19 (301.59, 322.79)	-9.91 (-33.22, 13.40)	0.401
TIBC at 12 months	326.36 (306.36, 346.36)	325.21 (312.90, 337.53)	1.15 (-23.79, 26.08)	0.927

CI = confidence interval; TIBC = total iron binding capacity.

*Two-sample t-tests were used.

Table 5. Event frequencies and Kaplan–Meier estimates of overall survival

Follow-up time	Overall (n = 133)	LPG (n = 35)	LTG (n = 98)	p^*
3 years	6 (94.4%)	1 (94.1%)	5 (94.2%)	0.715
6 years	8 (89.2%)	2 (84.7%)	6 (91.3%)	0.972

LPG = laparoscopic proximal gastrectomy with double-tract reconstruction; LTG = laparoscopic total gastrectomy.

*Log-rank test was used.