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ORIGINAL ARTICLE

#### **Retrospective Study**

# Use of a clinical pathway in laparoscopic gastrectomy for gastric cancer

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# Abstract

**AIM:** To evaluate the implementation of a clinical pathway and identify clinical factors affecting the clinical pathway for laparoscopic gastrectomy.

**METHODS:** A standardized clinical pathway for gastric cancer (GC) patients was developed in 2001 by the GC surgery team at the Asan Medical Center. We reviewed the collected data of 4800 consecutive patients treated using the clinical pathway following laparoscopic gastrectomy with lymph node dissection for GC involving intracorporeal and extracorporeal anastomosis. The patients were treated between August 2004 and October 2013 in a single institution. To evaluate the rate of completion and risk factors affecting dropout from the clinical pathway, we used a multivariate logistic regression analysis.

**RESULTS:** The overall completion rate of the clinical pathway for laparoscopic gastrectomy was 84.1% (n = 4038). In the comparison between groups of intracorporeal anastomosis and extracorporeal anastomosis patients, the completion rates were 83.88% (n = 1740) and 84.36% (n = 2071), respectively, showing no statistically significant difference. The main reasons for dropping out were postoperative complications (n = 463, 9.7%) and the need for patient observation (n = 299, 6.2%). Among the discharged patients treated using the clinical pathway, the number of patients who were readmitted



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within 30 d due to postoperative complications was 54 (1.1%). In a multivariate analysis, the intraoperative events (OR = 2.558) were the most predictable risk factors for dropping out of the clinical pathway. Additionally, being male (OR = 1.459), advanced age (OR = 1.727), total gastrectomy (OR = 2.444), combined operation (OR = 1.731), and ASA score (OR = 1.889) were significant risk factors affecting the dropout rate from the clinical pathway.

**CONCLUSION:** Laparoscopic gastrectomy appears to be a good indication for the application of a clinical pathway. For successful application, patients with risk factors should be managed carefully.

Key words: Clinical pathway; Laparoscopic gastrectomy; Gastric cancer; Extracorporeal anastomosis; Intracorporeal anastomosis

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**Core tip:** Laparoscopic gastrectomy has been proven to enhance postoperative recovery compared to open gastrectomy for gastric cancer (GC) patients. Therefore, laparoscopic gastrectomy is thought to be a suitable procedure for a clinical pathway. In this study, we retrospectively analyzed the outcomes of a clinical pathway application for laparoscopic gastrectomy and tried to investigate the clinical factors that may influence a clinical pathway in a high-volume center. Laparoscopic gastrectomy for GC appears to be a good indicator for the application of a clinical pathway. For successful application, patients with risk factors (male, advanced age, total gastrectomy, combined operation, intraoperative events, American Society of Anesthesiologists score) should be managed carefully.

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# INTRODUCTION

A clinical pathway (CP) is a comprehensive, systematized plan that details the essential steps in patient care in a given process, including any time-dependent clinical decisions<sup>[1,2]</sup>. The purpose of the CP is to minimize the hospital stay and to provide resources to achieve the best results and increase postoperative quality of life<sup>[3]</sup>. Therefore, CPs for multidisciplinary processes have been used to provide a coordinated program after various surgical procedures<sup>[4]</sup>.

Gastric cancer (GC) is the most prevalent malignancy in South Korea and remains the second most common cause of cancer-related deaths in the world<sup>[5-7]</sup>. The proportion of early gastric cancers (EGCs) has increased to over 50% in South Korea and Japan as a result of early detection through mass screening<sup>[8,9]</sup>. GC detected at an early stage can be cured by surgical treatment, and the subsequent prognosis is excellent<sup>[10]</sup>. However, CP has rarely been suggested for conventional open gastrectomy (OG) in GC patients due to the complexity of the procedure, which involves postoperative hemodynamic changes, compared with the procedures for patients with benign diseases<sup>[11,12]</sup>. Recently, laparoscopic gastrectomy (LG) has been established as an alternative modality for the treatment of EGC patients, and it has better surgical outcomes. LG causes less postoperative pain, enhances postoperative recovery, reduces the length of hospital stay, and increases post-operative quality of life compared to open surgery<sup>[13-16]</sup>. It seems that LG improves outcomes because the less-invasive procedure decreases surgical trauma. It has been proposed that minimally invasive surgery might be a good candidate for a CP<sup>[1,12,17]</sup>. Therefore, LG may be suitable for the use of a CP that provides a timebased schedule for patients. Despite the usefulness of CPs in surgical settings, the use of a CP for LG for GC has not been adequately investigated. LG has become a primary minimally invasive operation for GC in the Asan Medical Center, especially for EGC patients. Since 2004, our institute has used a CP for large numbers of GC patients undergoing LG performed by experienced surgeons.

In this study, we retrospectively analyzed the outcomes of the CP for LG and investigated the clinical factors that influence the dropout rate from the CP.

# **MATERIALS AND METHODS**

### Patients and methods

A standardized CP for GC patients was developed in 2001 by a committee consisting of gastric surgeons, nurses, nutritionists, and members of the clinical support services in the Asan Medical Center. In 2004, we started LG in our gastric division, and a revised version of the CP was created for patients who underwent LG.

We reviewed the collected data of 4800 consecutive patients treated by the CP following LG for GC involving both extracorporeal and intracorporeal anastomoses at the Asan Medical Center between August 2004 and October 2013. Preoperative clinical staging was based on the depth of invasion using esophagogastroduodenoscopy and endoscopic ultrasound (EUS) and on nodal status by computed tomography (CT) scan. The absolute indications for LG were EGC, cT1N0-1, and serosa-negative cases without distant lymph node metastasis, while cT2-3N1-2 was a relative indication in our division according to the preoperative clinical staging. The contraindication was serosa-positive (cT4) advanced GC (AGC) or AGC with cN3 at preoperative evaluation for LG. All



patients underwent a standardized laparoscopic radical gastrectomy with D1 +  $\beta$  or D2 lymph node dissection according to the Japanese classification of gastric carcinoma<sup>[18]</sup>. Nine experienced gastric surgeons participated, all of whom had performed more than 150 conventional OGs and over 50 LGs for GC. Patients undergoing emergency surgery or palliative surgery or having concomitant malignancies and neo-adjuvant chemotherapy were excluded from application of the CP.

The contents of the CP for LG are composed of three components for preoperative, perioperative and postoperative care, which are listed in Table 1.

### Summary of the clinical pathway

All preoperative examinations were performed on an outpatient basis, and the patients were admitted one day before the operation. Patients and their families were given preoperative information and education regarding the schedule of the CP by members of our stomach surgery team. Information consisted of the following categories: nursing care, activity, diet, treatment procedures, medication, laboratory tests, and education. In most cases, no nasogastric tube was used before surgery. Patients were permitted sips of water 24 h after surgery. Laboratory examinations were performed on postoperative days 1, 3 and 5. A liquid diet (LD) was given three days after surgery regardless of passing flatus, and a soft diet (SD) was given after passing flatus. If there was no issue with the SD, the patient's intra-abdominal drain was removed. Patients were well educated about diet, and nutrition information was provided by a nutritionist and a clinical nurse specialist. After consuming a SD three times and showing no postoperative complications, patients were discharged on the 5<sup>th</sup> or 6<sup>th</sup> postoperative day. Information about the postoperative follow-up schedule was given in the outpatient clinic before discharge.

# Surgical procedure

**Extracorporeal anastomosis:** After dissection of all the lymph nodes, a 6-9 cm mini-laparotomy incision was made in the epigastric area in the form of midline incision, and a wound protector was applied. All anastomoses were performed in the same way as in conventional OG.

**Intracorporeal anastomosis:** After dissection of all of the lymph nodes, the stomach was resected into the abdominal cavity using endoscopic linear staplers and then removed through the umbilical port site by extending the incision by 2-3 cm. For reconstruction of the intracorporeal anastomosis, a double staple was inserted with a linear stapler. For a distal gastrectomy, a gastroduodenostomy was performed *via* a deltashaped anastomosis, and a gastrojejunostomy was mainly performed *via* antecolic Roux-En-Y type

anastomoses. For a total gastrectomy, functional-type esophagojejunostomies were mainly performed<sup>[19-22]</sup>.

## Criteria for completion of the CP

The CP was considered to be completed if the patient was discharged within 8 d after surgery without any complications, and the patients were divided into two categories. In the first category, the patient was discharged 5 to 6 d after surgery without any complications (planned), and in the second category, the patient voluntarily decided to stay longer for personal reasons and was discharged 7 to 8 d after surgery (wanted). A patient was considered to have dropped out of the CP if the surgeon decided to change the schedule because of a patient's postoperative condition or complication. Early postoperative complications occurred within 30 d after surgery and were classified according to the Clavien-Dindo classification system<sup>[23]</sup>. Readmission within 30 d after discharge was included in the category of complications because all readmissions were due to complications. The following clinical features were analyzed: patient characteristics and data from hospital records [sex, age, body mass index (BMI), American Society of Anesthesiologists (ASA) score, history of previous abdominal operations, and TNM stage]; operative methods (method of anastomosis, percent of the resection); and postoperative outcomes (early postoperative complications, postoperative hospital stay). The study was reviewed and approved by the Ethics Committee of the Asan Medical Center, Ulsan University, Seoul, South Korea.

# Statistical analysis

Statistical analysis was performed by the Statistical Package for Social Sciences (SPSS) version 21.0 J for Windows (SPSS, Inc., Chicago, IL, United States). Patient characteristics were expressed as number and percent (%) for categorical variables, and mean  $\pm$  SD for continuous variables. Chi-square tests were used to compare the anastomosis groups, and binary logistic regression was used to evaluate risk factors for dropping out of the CP. Multiple regressions were constructed by backward elimination, and the anastomosis groups were further adjusted in the final model. All tests were two sided, and a *P* value of less than 0.05 was considered statistically significant.

# RESULTS

Patient characteristics are listed in Table 2. Of a total of 4800 patients, 2920 (60.8%) were men and 1880 (39.2%) were women. The mean age was  $56.7 \pm 11.7$  years and the mean BMI was  $23.71 \pm 3.0$ . Intracorporeal and extracorporeal anastomoses were performed in 2345 patients (48.9%) and 2455 patients (51.1%), respectively. Distal gastrectomy was performed in 4218 (87.9%) patients, and total



Activities date	1 d before OP (Admission)	Pre-OP (the day of OP)	Operation (the day of OP)	Post-OP (the day of OP)	POD 1	POD 2	POD 3	POD 4	POD 5 and 6 (D/C)
Nursing care	Admission to room: (1-3 pm) Fluid balance Surveillance V/S Weight measurement	Room nurse: Fluid balance, Check V/S	Surgical nurse: OP preparation	Room nurse: Fluid balance Check V/S, drainage	Room nurse: Fluid balance Check V/S, drainage	Room nurse: Fluid balance Check V/S, drainage	Room nurse: Fluid balance, Check V/S, Drainage	Room nurse: Check V/S	Room nurse: Check V/S
	Check (Surgeon/ anesthesiologist): Preoperative study Written consent Protocol for OP preparation						Remove peripheral line after start of 2 <sup>rd</sup> SD		
Activity Treatment	Usual Skin nrenaration	Bed rest	Bed rest Survical murse	Bed rest Breathinσ	Ambulation Ambulation Breathing exercises Breathing exercises	Ambulation 3reathing exercises	Ambulation Breathing exercises	Ambulation	Ambulation Surgeon:
procedure	No Levin tube		Foley catheter	exercises	: use of IS	: use of IS			Wound S/O
	Breathing exercises use of 15 Bowel preparation: Magcorol solution, 250 mL: Dulcolax supplement, 2 sup		Insertion	: use of IS			remove JP		Evaluation on D/C criteria
			Surgeons: OP	Anesthesiologist: PCA (Fentanyl 3000 mg)					
Medication		Prophylaxis: TE	Prophylaxis: TE Prophylaxis: ATB	Prophylaxis: ATB Mucolytic agent	Prophylaxis: TE				
				Anesthesiologist: PCA	PCA	PCA			
Medication on demand				Pain killer: (IV) Demerol NSAIDs Antiemetics	Pain killer: (IV) Demerol NSAIDs Antiemetics	Pain killer: (IV) Demerol NSAIDs Antiemetics	Pain killer: (IV) Demerol NSAIDs Antiemetics	Pain killer: (Oral) NSAIDs	Pain killer: (Oral) NSAIDs
Laboratory test				Laboratory teet	Laboratory test		Laboratory test		Laboratory test
Diet	Usual diet at breakfast NPO after breakfast	NPO	ONPO	OGN	SOW: post 24 h OP		LD at breakfast SD after G/O	SD	SD
Education and information	Information on CP Permission		Information on leaving OP room				Education: diet for patient and/or relative	Education: diet for patient and/or relative	Information on D/C

Kim HS et al. Clinical pathway for laparoscopic gastrectomy

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Table 2 Demographic d	ata for the enroll	ed patients <i>n</i> (%)
Variables		No. of patients $(total n = 4800)$
Sex	Male:Female	2920:1880
		(60.8:39.2)
Age (yr)	mean ± SD	$56.7 \pm 11.7$
BMI $(kg/m^2)$	mean ± SD	$23.71 \pm 3.0$
Anastomosis method	Intra:Extra	2345:2455
		(48.9:51.1)
Resection	Distal:Total	4218:582
		(87.9:12.1)
Combined OP	None:Yes	4531:269
		(94.4:5.6)
Event during OP	None:Yes	4723:77
		(98.4:1.6)
Number of comorbidities	0:1:2 and more	3196:1137:467
		(66.6:23.7:9.7)
ASA	1:2:3	3025:1549:226
		(63.0:32.3:4.7)
Previous Abd. OP history	N:Y	4057:743
		(84.5:15.5)
TNM stage	1:2:3	4380:314:106
		(91.3:6.5:2.2)
-		

SD: Standard deviation; BMI: Body mass index; Intra: Intracorporeal anastomosis; Extra: Extracorporeal anastomosis; OP: Operation; ASA: American Society of Anesthesiologists; Abd: Abdominal.

gastrectomy was performed in 583 patients (12.1%). Additional operations on other organs were performed in 269 cases (5.6%). The most frequent additional operation was a laparoscopic cholecystectomy (208 cases); there were also 24 cases of gynecological surgery, such as laparoscopic salpingo-oophorectomy, laparoscopic ovarian cysterectomy, laparoscopic myomectomy, and laparoscopic total hysterectomy. Other additional operations included laparoscopic herniorrhaphy, video-assisted thoracoscopic surgery, laparoscopic distal pancreatectomy, laparoscopic nephrectomy, laparoscopic appendectomy, laparoscopic adrenalectomy, and laparoscopic colectomy. Intraoperative events occurred in a total of 77 cases (1.6%) (Table 3). Among them, there were 31 intraoperative events during anastomosis, and almost all of them developed during esophagojejunostomies after total gastrectomy. Organ injuries occurred in 30 cases during lymph node dissection, mostly due to spleen injury. Vessel injuries occurred in 12 cases, and spleen artery injuries mainly occurred during the dissection of lymph node number 11 or retraction of the stomach. Seven of the 30 instances of organ injury involved severe adhesions due to previous abdominal operations, and these patients had a history of upper gastrointestinal surgery. Four of the remaining intraoperative events were subcutaneous emphysemas. One or more comorbidities were identified in 1604 patients (34.4%), including diabetes mellitus, hypertension, coronary artery disease, and asthma. The majority of patients were classified as ASA grade [ (3025 patients) or [] (1549 patients). A total of 743 patients (15.5%) had histories of

#### Kim HS et al. Clinical pathway for laparoscopic gastrectomy

Table 3	Eventer	LINING OF	a wati a w
Table 5	Events a	iiiring o	

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	Intra ( $n = 25$ )	Extra ( $n = 52$ )
Anastomosis failure ( $n = 31$ )	8	23
Esophagojejunostomy failure	7	9
Gastroduodenostomy failure	1	14
Organ injury ( $n = 30$ )	10	20
Spleen injury	6	10
Duodenum	0	5
Small bowel injury	1	1
Colon injury	1	2
Pancreas injury	1	1
Liver injury	1	1
Vessel injury $(n = 12)$	4	8
Splenic artery injury	2	6
Splenic vein injury	0	1
Common hepatic artery injury	1	1
Proper hepatic artery injury	1	0
Emphysema ( $n = 4$ )	3	1

Intra: Intracorporeal anastomosis; Extra: Extracorporeal anastomosis.

previous abdominal surgery. Most were gynecologic surgery (351 cases) followed by appendectomy (281 cases) and cholecystectomy (51 cases). The others were bowel surgery, pancreatectomy, and incisional herniorraphy. Most of the patients were at stage I according to the American Joint Committee on Cancer - International Union for Cancer Control 7<sup>th</sup> edition<sup>[24]</sup>. There was no case converted to a laparotomy. However, six cases of intracorporeal anastomosis were converted to extracorporeal anastomosis due to intraoperative events, such as anastomosis failure and bleeding.

Comparisons between the intracorporeal and extracorporeal anastomosis groups are shown in Table 4. There were no statistically significant differences in terms of sex, age, combined operations, or history of previous abdominal operations. However, BMI, extent of resection, ASA classification system score, and TNM stage were significantly higher in the intracorporeal anastomosis group, and the number of intraoperative events was higher in the extracorporeal anastomosis group (P < 0.005).

The overall completion rate of the CP was 84.1%; it was 83.9% in the intracorporeal anastomosis group and 84.4% in the extracorporeal anastomosis group (Table 5). Of the 4038 patients who completed the CP, 3781 patients (78.8%) were planned, and 257 (5.3%) patients were wanted. The main reasons for dropping out were postoperative complications and need for additional patient observation. Early postoperative complications occurred within 30 d of surgery, and they were classified according to the Clavien-Dindo classification system<sup>[23]</sup>. Complications higher than grade I were considered clinically significant, such as anastomosis stenosis, leakage, fluid collection, and bleeding (Table 6). The most common complications were fluid collection in the intracorporeal anastomosis group and wound infection in the extracorporeal anastomosis group. There were two cases of mortality.



### Kim HS et al. Clinical pathway for laparoscopic gastrectomy

Table 4 Clinicopathological characteristics of patients who underwent total laparoscopic gastrectomy (intracorporeal anastomosis) and laparoscopic assisted gastrectomy (extracorporeal anastomosis) n (%)

Variables	Intra ( $n = 2345$ )	Extra ( $n = 2455$ )	<b>P</b> value <sup>1</sup>
Sex			0.118
Male	1453 (61.96)	1467 (59.76)	
Female	892 (38.04)	988 (40.24)	
Age (yr)			0.110
≤ 65	1716 (73.18)	1846 (75.19)	
> 65	629 (26.82)	609 (24.81)	
BMI $(kg/m^2)$			< 0.001
≤ 25	1490 (63.54)	1835 (74.75)	
> 25	855 (36.46)	620 (25.25)	
Resection			< 0.001
Distal	2018 (86.06)	2200 (89.61)	
Total	327 (13.94)	255 (10.39)	
Combined OP			0.958
None	2214 (94.41)	2317 (94.38)	
Yes	131 (5.59)	138 (5.62)	
Event during OP			0.002
None	2321 (98.98)	2402 (97.84)	
Yes	24 (1.02)	53 (2.16)	
Number of			< 0.001
comorbidities			
0	1477 (62.99)	1719 (70.02)	
1	588 (25.07)	549 (22.36)	
2 and more	280 (11.94)	187 (7.62)	
ASA			< 0.001
1	1404 (59.87)	1621 (66.03)	
2	822 (35.05)	727 (29.61)	
3	119 (5.07)	107 (4.36)	
Abd OP history			0.008
None	1949 (83.11)	2108 (85.87)	
Yes	396 (16.89)	347 (14.13)	
TNM stage			< 0.001
Ι	2066 (88.10)	2314 (94.26)	
Ш	197 (8.40)	117 (4.77)	
Ш	82 (3.50)	24 (0.98)	

 ${}^1\chi^2$  test. Intra: Intracorporeal anastomosis; Extra: Extracorporeal anastomosis; BMI: Body mass index; OP: Operation; ASA: American Society of Anesthesiologists; Abd: Abdominal.

One was caused by esophagojejunal leakage in extracorporeal anastomosis and the other by duodenal stump leakage in intracorporeal anastomosis. Reasons for readmissions were intra-abdominal fluid collection (23 patients), ileus (19 patients), anastomosis stenosis (5 patients), internal herniation (3 patients), duodenal stump leakage (2 patients), and wound infection (2 patients). There were eight (14.9%) reoperations from the readmission cases. Patients who needed additional observation without definite postoperative complications were classified as observation cases (Table 7). The causes of observation were laboratory test abnormality, underlying disease, turbid drainage, and need for an upper gastrointestinal (UGI) series for cases of anastomotic site problems or ileus.

Table 8 shows the result of an analysis of the risk factors for dropping out of the CP. Male (OR = 1.459), advanced age (OR = 1.727), total gastrectomy (OR = 2.444), combined operation (OR = 1.731), intraoperative event (OR = 2.558), and ASA score

Table 5 Results of the clinical pathway n (%)					
Results	Total ( <i>n</i> = 4800)	Intra ( <i>n</i> = 2345)	Extra ( <i>n</i> = 2455)	<i>P</i> value <sup>1</sup>	
Complete	4038 (84.1)	1967 (83.9)	2071 (84.4)	0.651	
Planned	3781 (78.8)	1740 (74.2)	2041 (83.2)		
Wanted	257 (5.3)	227 (9.7)	30 (1.2)		
Drop	762 (15.9)	378 (16.1)	384 (15.6)		
Complication	463 (9.7)	230 (9.8)	233 (9.5)		
(readmission)	(54) [(1.1)]	(29) [(1.2)]	(25) [(1.0)]		
Observation	299 (6.2)	148 (6.3)	151 (6.1)		

 ${}^{1}\chi^{2}$  test comparing proportions of dropouts. Intra: Intracorporeal anastomosis; Extra: Extracorporeal anastomosis.

# Table 6 Reasons for dropping out: Early postoperative complications n (%)

	Total ( <i>n</i> = 4800)	Intra ( <i>n</i> = 2345)	Extra ( <i>n</i> = 2455)
Complications	463 (9.7)	230 (9.8)	233 (9.5)
Wound infection	127 (2.6)	41 (1.7)	86 (3.5)
Fluid collection	77 (1.6)	49 (2.1)	28 (1.1)
Anastomosis leakage	57 (1.2)	31 (1.3)	26 (1.1)
Anastomosis stenosis	16 (0.3)	11 (0.5)	5 (0.2)
Luminal bleeding	58 (1.2)	25 (1.1)	33 (1.3)
Extraluminal bleeding	19 (0.4)	10 (0.4)	9 (0.4)
Passage disturbance	20 (0.4)	8 (0.3)	12 (0.5)
Paralytic ileus	24 (0.5)	13 (0.6)	11(0.5)
Mechanical ileus	7 (0.2)	2 (0.1)	5 (0.2)
Medical problem	41 (0.9)	26 (1.1)	15 (0.6)
Internal herniation	5 (0.1)	5 (0.2)	0 (0.0)
Others	12 (0.3)	9 (0.4)	3 (0.1)

Intra: Intracorporeal anastomosis; Extra: Extracorporeal anastomosis.

(OR = 1.889) were all risk factors in the multivariate analysis.

# DISCUSSION

The use of CP for patients undergoing surgical procedures can help with postoperative care and reduce the cost and the length of hospital stays<sup>[25,26]</sup>. Several researchers have reported that the CP was effective for gastrectomy for stomach cancer<sup>[4,27,28]</sup>. On the other hand, some studies have shown relatively low CP completion rates of 19%<sup>[11]</sup> and 40.6%<sup>[12]</sup>. These reports suggest that the CP is not suitable for patients undergoing gastrectomy for GC because it is frequently associated with postoperative hemodynamic changes that are risk factors for morbidity and mortality. Advanced age, combined disease, and poor nutrition are common in GC patients, and these factors may increase the risk of postoperative complications<sup>[4,29]</sup>. The long upper abdominal incisions needed for OG can cause significant postoperative pain and lead to lung problems, such as atelectasis, because patients do not care for their lungs appropriately because of the pain<sup>[30]</sup>. Recently, LG has been performed as the standard treatment for EGC, whereas OG is usually done for AGC. Severe AGC has a higher possibility of intraoperative



Table 7 Reasons for dropout: Observation cases $n$ (%)					
	Total $(n = 4800)$	Intra $(n = 2345)$	Extra ( <i>n</i> = 2455)		
Observation cases	299 (6.2)	148 (6.3)	151 (6.1)		
Laboratory test abnormality	220 (4.6)	107 (4.6)	113 (4.6)		
Underlying disease	20 (0.4)	14 (0.6)	6 (0.2)		
JP turbid	5 (0.1)	4 (0.2)	2 (0.1)		
Due to UGI series	29 (0.6)	10 (0.4)	19 (0.8)		
Others	25 (0.5)	13 (0.5)	11 (0.4)		

Intra: Intracorporeal anastomosis; Extra: Extracorporeal anastomosis; JP: Jackson-Pratt; UGI: Upper Gastrointestinal.

events and complications due to difficult node dissection and extended surgery. Some studies have suggested that the CP is more effective in patients with benign diseases or those receiving minimally invasive surgery than in those undergoing conventional OG<sup>[12,17]</sup>. The most common causes of dropout from the CP were postoperative complications that needed additional medical treatment. Postoperative complications, such as leakage, stricture, and bleeding, occurred more often in gastrointestinal cancer surgery than in benign or other types of cancer surgery. In this study, the CP completion rate was 84.13%, which was higher than in other  $reports^{[4,11,12,31]}$ . One of the most important factors that can influence early surgical outcomes and CP dropout is the surgeon's experience. However, surgeons who participated in this study were highly experienced gastric surgeons working in a high-volume center, where more than 2000 gastrectomies for GC are performed each year.

Many surgeons still advocate the slow and careful introduction of oral intake after a gastrectomy because of concerns over the functioning of the remnant stomach and the risk of disrupting the anastomosis or of postoperative paralytic ileus. These factors may make surgeons hesitant to apply the planned dietary schedule to patients undergoing a gastrectomy.

Since LG was first described by Kitano et al<sup>[32]</sup> in 1994, it has become well established as a minimally invasive operation for GC. Its benefits include the need for a small incision, reduced postoperative pain, fewer postoperative adhesions, earlier recovery of bowel movement because of reduced trauma compared to open surgery, and a shorter postoperative hospital stay<sup>[13-15]</sup>. LG is thought to be suitable for the application of a CP because it reduces the incidence of postoperative complications and provides a more rapid recovery and earlier hospital discharge due to its low invasiveness<sup>[33-35]</sup>. Recently, LG's effectiveness in enhancing recovery after surgery has been reported<sup>[15,36,37]</sup>. Furthermore, LG has a predictable clinical course, which facilitates the use of a CP in GC surgery<sup>[17]</sup>. Choi *et al*<sup>[12]</sup> reported that the completion rate of a CP in LG for GC was 76.2%, and the expected completion rate in selected patients with no risk factors was 85.4%, which was similar to that of this study.

These results support the belief that it is possible to develop and apply a CP for LG in GC patients.

In LG for GC, there are two methods of reconstruction after a gastrectomy. The intracorporeal anastomosis method is not yet performed as frequently as the extracorporeal anastomosis method because of its greater technical difficulty. Despite the complexity of intracorporeal anastomosis, our studies have shown that it is feasible and safe when performed by experienced gastric surgeons<sup>[14,19-22,38]</sup>. In the present study, the completion rates of the CP in both the intracorporeal and the extracorporeal anastomosis groups were considerably higher than those in other reports<sup>[39]</sup>. Intracorporeal anastomosis could improve early surgical outcomes because it can provide a wide operating view with direct sight, which can make anastomosis safer, and an endoscopic linear stapler provides greater tensile strength than a circular stapler<sup>[19,20,40]</sup>. The most common reason for complications in this study was wound infection in extracorporeal anastomosis due to an additional mini-laparotomy. The second most frequent cause of termination of the CP was the need for additional patient observation and further laboratory tests or a UGI series, which led the surgeon to change the schedule. The laboratory tests were required to identify abnormalities, such as leukocytosis or aberrant artery ligation, during the gastrectomy. For patients who experienced intraoperative events during anastomosis, dietary intake was postponed until after the UGI series confirmed that there was no leakage or stricture, and the CP was terminated. The other reason for dropout was postoperative aggravation of an underlying disease, independent of surgical complications.

There is a striking difference of the numbers of "wanted completion CPs" between the intracorporeal anastomosis and the extracorporeal anastomosis groups. We believe that the reason can be explained as follows: Starting in 2004, the LG was performed by extracorporeal anastomosis, and starting in approximately 2008, it gradually converted to intracorporeal anastomosis. Since 2010, intracorporeal anastomosis procedures outnumbered extracorporeal anastomosis procedures. Over the last ten years, there have been many changes in the healthcare and reimbursement system in South Korea, and the national health insurance allows cancer patients to stay in the hospital longer for treatment at reduced costs. These changes seem to influence the patient's desire to stay in the hospital.

In a multivariate analysis, being male (OR = 1.459), advanced age (OR = 1.727), total gastrectomy (OR = 2.444), combined operation (OR = 1.731), intraoperative event (OR = 2.558), and ASA score (OR = 1.889) were risk factors for dropout. A large amount of intra-abdominal fat deposition or intra-abdominal adhesions from previous operations can make the surgery more difficult, resulting in intraoperative

### Kim HS et al. Clinical pathway for laparoscopic gastrectomy

	Total	Drop	Univariate		Multivariab	le¹
			OR (95%CI)	<b>P</b> value	OR (95%CI)	P value
Sex				< 0.001		< 0.001
Male	2920	534 (18.29)	1.622 (1.372-1.917)		1.459 (1.228 -1.734)	
Female	1880	228 (12.13)	1		1	
Age (yr)						
≤ 65	3562	462 (12.97)	1		1	
> 65	1238	300 (24.23)	2.146 (1.824 -2.525)	< 0.001	1.727 (1.448-2.059)	< 0.001
BMI $(kg/m^2)$		· · · ·	× ,		· · · · · ·	
≤ 25	3325	496 (14.92)	1			
> 25	1475	266 (18.03)	1.255 (1.066-1.478)	0.006		
Anastomosis method		· · · ·	· · · · · ·			
Intra	2345	378 (16.12)	1		1	
Extra	2455	384 (15.64)	0.965 (0.826-1.126)	0.651	1.057 (0.900-1.242)	0.499
Resection					(	
Distal	4218	593 (14.06)	1		1	
Total	582	169 (29.04)	2.501 (2.050-3.052)	< 0.001	2.444 (1.988-3.005)	< 0.001
Resection group	562	107 (27.04)	2.501 (2.050-5.052)	\$ 0.001	2.111 (1.900-9.009)	× 0.001
I -distal	2018	285 (14.12)	1	< 0.001		
I -total	327	93 (28.44)	2.417 (1.843 -3.169)	< 0.001		
E-distal	2200	308 (14.00)	0.990 (0.832 -1.178)	0.909		
E-total	2200	· · · ·	2.582 (1.920-3.472)	< 0.001		
Combined OP	255	76 (29.80)	2.382 (1.920-3.472)	< 0.001		
	4501	(04 (15 00)	1		1	
None	4531	694 (15.32)	1		1	
Yes	269	68 (25.28)	1.870 (1.404-2.491)	< 0.001	1.731 (1.284-2.334)	< 0.001
OP event						
None	4723	732 (15.50)	1		1	
Yes	77	30 (38.96)	3.480 (2.187-5.539)	< 0.001	2.558 (1.554-4.212)	< 0.001
Number of comorbidities						
0	3196	411 (12.86)	1	< 0.001	1	0.031
1	1137	221 (19.44)	1.635 (1.366 -1.957)	< 0.001	1.179 (0.882 -1.576)	0.266
2 and more	467	130 (27.84)	2.614 (2.082-3.281)	< 0.001	1.564 (1.110-2.204)	0.011
ASA score						
1	3025	382 (12.63)	1	< 0.001	1	0.006
2	1549	305 (19.69)	1.696 (1.438-2.000)	< 0.001	1.182 (0.893-1.565)	0.242
3	226	75 (33.19)	3.437 (2.554-4.625)	< 0.001	1.889 (1.271-2.808)	0.002
Abdominal OP history						
None	4057	661 (16.29)	1			
Yes	743	101 (13.59)	0.808 (0.645-1.013)	0.065		
TNM stage		· /				
I	4380	688 (15.71)	1	0.274		
П	314	51 (16.24)	1.041 (0.763-1.420)	0.802		
Ш	106	23 (21.70)	1.487 (0.930-2.377)	0.097		

<sup>1</sup>Backward elimination. Logistic regression to predict dropout (= 762/4800). OR: Odd ratio; BMI: Body mass index; Intra/I: Intracorporeal anastomosis; Extra/E: Extracorporeal anastomosis; OP: Operation; ASA: American Society of Anesthesiologists.

events such as bleeding<sup>[41]</sup>. Intraoperative events (OR = 2.558) were the most significant risk factors for dropout because they are related to a longer operation time and more postoperative complications. Many researchers have reported that advanced age, type of reconstruction, combined operation, and ASA score contribute to postoperative morbidities in  $\mathsf{GC}^{\scriptscriptstyle[42\text{-}44]}.$  We found that being male was a risk factor for dropout even though there was no difference in the BMI between male and female patients. This suggests that men have a larger proportion of visceral adipose tissue than women  $^{\left[ 45-47\right] }$  , which might increase postoperative complications. Women generally have a higher amount of body fat in subcutaneous areas, whereas men have more body fat in the abdominal (visceral) region<sup>[48]</sup>. However, BMI does not accurately reflect the extent of

a patient's visceral fat because the distribution of fat varies with gender, and the visceral fat area is a more accurate risk factor for postoperative complications than BMI in LG for GC<sup>[41,49]</sup>.

It was difficult for patients to follow the CP if they did not understand the concept. Most of them were afraid of early food intake and discharge because their food intake had to be strictly limited. Post-gastrectomy symptoms (PSGs), including weight loss, early satiety, eating restriction, appetite loss, dysphagia, reflux, nausea and vomiting are inevitable consequences of gastrectomy, and patients need to receive information about the CP and PSGs in the outpatient clinic. Diet is more challenging after gastrectomy than after other operations. Therefore, it is important that all patients and their family members learn about the

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diet. Most patients without major complications were able to tolerate early oral intake as specified in the CP. All patients were permitted sips of water 24 h after surgery, as well as early oral intake of an LD. To maintain the high quality of the CP, all members of the gastric surgery team, including gastric surgeons, nurses, nutritionists and members of the clinical support services, need to actively participate and cooperate. In our stomach division, a clinical nurse specialist provides patients with detailed information about the CP, including postoperative course, dietary schedule, expected hospital stay, and anticipated return to normal activities. In addition, the surgical team should attempt to reduce the incidence of intraoperative events, which are the most significant risk factor for dropout from the CP. Intraoperative events mainly occurred during the reconstruction of anastomoses, and most involved esophagojejunostomy after total gastrectomy or organ injury during dissection of the lymph nodes. Therefore, LG should be performed by expert surgeons who are experienced in OG and various laparoscopic procedures. Moreover, the surgeons should pay special attention to complex cases with risk factors such as total gastrectomies and combined operations, as well as intraoperative events.

Our findings suggest that LG for GC is a suitable indication for the use of a CP because it can provide better early surgical outcomes due to low invasiveness, and make an early hospital discharge possible. The use of a CP for LG could be helpful in East Asian countries, where the incidence of GC is high, because of the cost benefits and short hospital stays. For successful application of a CP, patients with risk factors should be managed carefully. However, this study was analyzed retrospectively and was not a randomized controlled study, and the groups were not homogeneous, so the results could not be significant. Therefore, a prospective randomized controlled study should be conducted in the near future.

# COMMENTS

### Background

Gastric cancer (GC) is the most prevalent malignancy in South Korea and Japan. The proportion of early gastric cancers (EGC) has increased to over 50% as a result of early detection through mass screening. Recently, laparoscopic gastrectomy (LG) has been established as a standard treatment for the EGC patients, and it has better surgical outcomes than open gastrectomy (OG). LG provides enhanced postoperative recovery compared to OG for GC patients. Therefore, LG is thought to be the one of suitable procedures for a clinical pathway (CP) that provides a time-based schedule for patients. In this study, we developed a standardized CP for GC patients in 2001 by a committee consisting of gastric surgeons, nurses, nutritionists, and members of the clinical support services in the Asan Medical Center. In 2004, our institute implemented a CP for large numbers of GC patients undergoing LG performed by experienced surgeons. In this study, the authors showed the rate of completion of a CP and identified clinical factors affecting the CP for LG.

### **Research frontiers**

Despite the usefulness of a CP in various surgical settings, its use for LG for GC has not been adequately investigated. LG is popular as a minimally

invasive operation for GC in the Asan Medical Center, especially for EGC. Since 2004, the authors' institute has used a CP for large numbers of GC patients undergoing LG performed by experienced surgeons. Their CP will contribute a standard structure for GC patients and provide guidelines for LG.

### Innovations and breakthroughs

This study evaluated the rate of completion of a CP and the clinical factors affecting the CP after laparoscopic gastrectomy for GC patients. The overall completion rate of the CP was 84.1%; it was 83.9% in the intracorporeal anastomosis group and 84.4% in the extracorporeal anastomosis group. In the current study, the completion rates of the CP in both the intracorporeal and the extracorporeal anastomosis groups were considerably higher than in other reports because there was no bias caused by the different technique of each surgeon. Surgeons who participated in this study were all trained in the same surgical technique and had each performed more than 150 conventional OGs as well as more than fifty LGs for GC at a single, high-volume center. A multivariate analysis revealed that being male (OR = 1.459), advanced age (OR = 1.727), total gastrectomy (OR = 2.444), combined operation (OR = 1.731), intraoperative events (OR = 2.558), and ASA score (OR = 1.889) were risk factors for dropping out of the CP. These results can give useful information to the surgeon who is a novice at LG and works in small-volume center. For successful application, patients with risk factors (male, advanced age, total gastrectomy, combined operation, intraoperative events, American Society of Anesthesiologists score) should be managed carefully.

### Applications

LG appears to be a good indication for the application of a CP. The authors' CP can be applied to LG for GC patients.

### Terminology

CP, clinical pathway, is a comprehensive systematized plan that details the essential steps in patient care in a given process, including any time-dependent clinical decisions.

### Peer-review

The authors of this paper evaluated the rate of completion for the CP, identified risk factors for dropping out of the CP, and conclude that those patients who had a risk factor should be managed more carefully. This is an interesting analysis that addresses a clinically relevant question and provides somewhat valuable results due to the large number of patients enrolled in the study.

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