

**Outcomes of clinical pathway in laparoscopic and
open surgical treatments for
gastric cancer patients:**

**Patients selection for fast-track program through
retrospective analysis**

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Major in Medicine

Department of Medical Sciences

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**A Dissertation Submitted to The Graduate School of
Ajou University in Partial Fulfillment of the Requirements
for the Degree of Master Science in Medicine**

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February, 2015**

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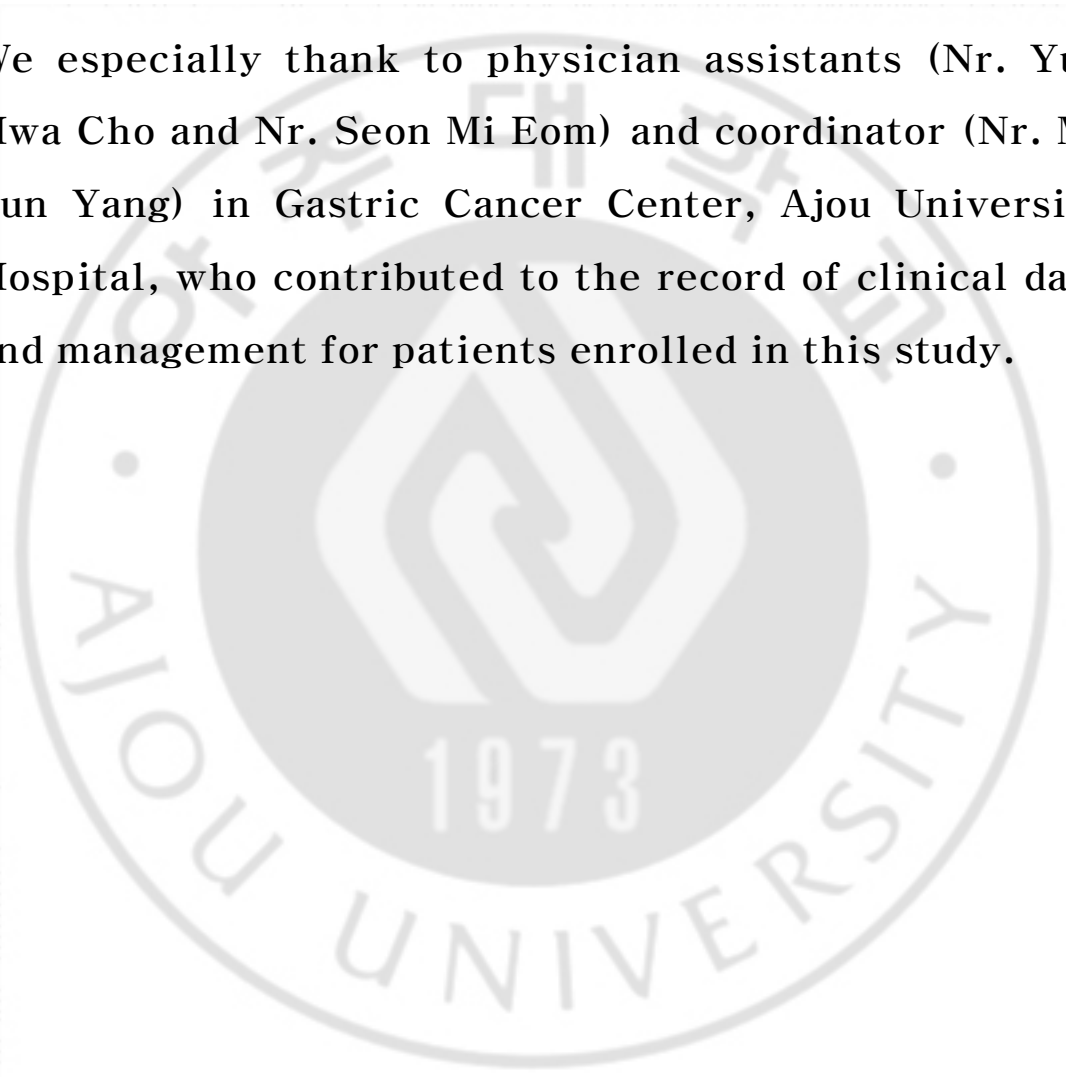
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December, 19th, 2014**

ACKNOWLEDGEMENT

We especially thank to physician assistants (Nr. Yun Hwa Cho and Nr. Seon Mi Eom) and coordinator (Nr. Mi Sun Yang) in Gastric Cancer Center, Ajou University Hospital, who contributed to the record of clinical data and management for patients enrolled in this study.



Outcomes of clinical pathway in laparoscopic and open surgical treatments for gastric cancer patients: Patients selection for fast-track program through retrospective analysis

Background. The aim of this study is to investigate the clinical factors affecting on the complete rate from the clinical pathway in minimally invasive and open surgery for gastric cancer, and to establish a subgroup of patients who can be applied by the early recovery after surgery program through this retrospective analysis.

Methods. In this retrospective study, we analyzed 425 patients who underwent gastric cancer surgery from January 2011 to December 2011 and were managed with conventional clinical pathway. This clinical pathway was made as the patients in minimally invasive surgery group start the diet and discharge from hospital one day faster than them in open surgery group.

Results. The completion rate of the clinical pathway was 62.4%. Despite the different applications of clinical pathway, completion rate in minimally invasive surgery group was significantly higher than it in open group ($P < .001$). In multivariate analysis, the surgical procedure of minimally invasive surgery (Odd ratio = 4.281) was most predictable factor to complete clinical pathway. Additionally, younger patients (Odd ratio = 1.933) who underwent distal gastrectomy (Odd ratio = 1.999) without combined resection (Odd ratio = 3.069) were predicted to accomplish the clinical pathway without modifications.

Conclusion. We concluded that high efficacy of the clinical pathway for gastric cancer surgery was expected to selected patients through retrospective analysis (Expected complete rate = 85.4%). In addition, these patients would become enrolled criteria for early recovery program in gastric cancer surgery.

Keyword: Stomach neoplasm, Clinical pathways, Gastrectomy, Minimally invasive

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I . INTRODUCTION

Although the incidence of gastric cancer has been increased world wide, it is still one of the most common solid tumors in Asian countries like Korea and Japan.(Shin et al., 2011)The standard treatment to be able to improve the survival of the patients diagnosed with the gastric cancer without distant metastasis is surgical resection.(Kim, 2002)Therefore, most of patients who have been diagnosed with gastric cancers in Asian countries require the surgical resection for their treatments, and then gastric cancer surgery has become the most of popular surgical procedures.(Kim, 2002)

The clinical pathway (CP) for surgical patients is a standardized plan including preoperative preparation and postoperative managements. For the popularly performed surgery, the standardization of patients care is one of the ways to improve surgical outcomes, reduce the postoperative length of stay and hospital cost.(Bradshaw et al., 1998; Uchiyama et al., 2002; Kulkarni et al., 2011; Lin et al., 2011)Regarding with gastric cancer surgery, CP has been rarely suggested due to complicated procedures performed in gastric cancer surgery. However, recent development in gastric cancer surgery has been made the surgical outcome to be improved, and the possibility of application of the CP for perioperative care has been increased.

In particular, minimally invasive surgery (MIS) for early gastric cancer showed the improved surgical outcomes like enhanced postoperative recovery and reduced the length of stay.(Kitano et al., 2002; Hayashi et al., 2005; Kim et al., 2008)Based on these clinical studies, we established different CP according to laparoscopic and open surgeries. The CP was planned as the patients in MIS group start the diet one day faster than them in open group. To date, there had been no report to evaluate the different efficacy about the application of CP according to approach methods in gastric cancer surgery. In this study, we reviewed the results of application of the CP to investigate the clinical factors affecting on the drop from the CP in MIS and open surgery.

After the analysis of this retrospective study, we will progress more advanced CP in which the perioperative care programs for early recovery after surgery (ERAS), so called fast-track CP, like early oral feeding were included. Several results in colon surgery have been reported that it

could enhance the recovery of patients, and reduced the length of hospital stay. However, it is not established that ERAS program is acceptance in gastric surgery. Therefore, it is impossible to apply the ERAS program on all patients who underwent gastric cancer surgery. Here, we want to investigate a subgroup of patients who can be applied by the ERAS program through this retrospective analysis for the patients managed with conventional CP.



II. MATERIALS AND METHODS

Our clinical study for early recovery after surgery (ERAS) program in gastric cancer surgery was approved by the Institutional Review Board at the Ajou University Hospital, Suwon, Korea (AJIRB-MED-OBS-11-420). Approved clinical study included the retrospective review about the results from patients managed under conventional CP and prospective clinical trial for ERAS. Here, we reported the results from retrospective study.

The Gastric Cancer Center, Ajou University Hospital introduced a standard CP in order to guide perioperative care of the patients who underwent gastric cancer surgery from 2008. Revised version of CP was established to differently manage the patients who underwent MIS including laparoscopic and robotic procedures from 2010, since several prospective researches has been reported that laparoscopic surgery for gastric cancer has been improved the recovery after surgery.(Kitano et al., 2002; Hayashi et al., 2005; Lee and Han, 2005)

We operated consecutive 441 patients diagnosed with gastric adenocarcinoma at the Gastric Cancer Center, Ajou University Hospital from January 2011 to December 2011. They did not receive neoadjuvant treatment for gastric cancer diagnosed at this time. Sixteen patients who could not undergo tumor resection for severe advanced disease were excluded. Finally, we analyzed 425 patients in this retrospective study.

Three surgeons (Cho YK, Han SU and Hur H) who had more than 50 gastric cancer surgeries per year were participated in this study. Preoperative gastrofiberscope and computed tomography were performed to exclude the patients with metastatic lesions and to plan the operation including the range of resection, the extent of lymphadenectomy and combined resection. Before surgery, we discussed with patients about the surgical procedures and possibility of postoperative complication. We explained the plan for management after surgery, and obtained informed consents from all patients enrolled in this study. We applied MIS for patients relatively less advanced disease (clinical stage I and stage IIA, AJCC 7th edition), but robotic surgery were selected by patients themselves because of the higher cost of it. We have been managed two kinds of CP for gastric cancer surgery in our institution according the

approach methods (MIS vs. open surgery). Different and common points of these two pathways were listed in Table 1.

These pathways included preoperative bowel preparation by enema, non-per oral diet at one day before surgery in common. Surgical procedures including the resection of primary tumor and lymphadenectomy were performed according to the guideline suggested by Japanese Gastric Cancer Association.(Japanese Gastric Cancer Association, 2011)We planed that the soft diet start at postoperative 5 days for patients underwent MIS and six day for open conventional surgery. All patients were recommended the discharge from a hospital when the patients exhibited tolerability three times of soft diet without complaint and had normal physical condition. As results, there was a difference of one day at the time of discharge from the hospital between two procedures.

Table 1. Clinical pathway for gastrectomy with lymphadenectomy in gastric cancer patients at Ajou University Hospital, 2011

Clinical pathway		
	MIS	Open
Admission	2 days before operation	
Preparation	<ul style="list-style-type: none"> • Non per oral 1 day before • Enema for bowel preparation • No nasogastric tube • No subclavian line 	
Fluid	3000 cc/day (60kg)	
Pain control	PCA (Fentanyl)	
Sips of water	POD 2	POD 3
Liquid diet	POD 3	POD 4

Soft diet	POD 5	POD 6
Discharge	POD 6	POD 7

MIS, minimally invasive surgery; *PCA*, patients controlled anesthesia;
POD, postoperative day.

The “Complete” of clinical pathway was defined when it was progressed favorably without schedule change, and the patients discharged or recommended at planned schedule. The “Drop” was defined when that surgeon intentionally changed the schedule because of the preoperative or postoperative observation of the patients’ condition and the postoperative complication, or patients were readmitted for various reasons.

Statistical analyses were performed using Statistical Package for Social Science ver. 18.0 (IBM Corp. NY, USA). Chi-square tests were adopted to analyze the difference of distribution among the categorized data. We performed the binary logistic regression test for multivariate analysis to predict the drop from clinical pathway. A *P* value was of 0.05 or less was considered statistically significant.

III. RESULTS

Comparison between MIS and open groups. During 12 months, we performed MIS for 260 and open surgery for 165 patients. MIS was including 222 patients who operated by laparoscopic surgery and 38 patients by robotic surgery. Although there was no difference in clinical features like age, gender and so on, the rate of palliative resection ($P < .001$), total gastrectomy ($P = .003$) and combined resection ($P = .004$) in MIS group were significantly lower than those in open group (Table 2). In pathologic finding, the proportion of early gastric cancer in the patients who underwent MIS was significantly higher than that in open surgery ($P = .001$).

Table 2. Clinicopathologic characteristics of enrolled patients in this study

<i>Variables</i>	<i>Total</i>	<i>MIS</i> (n=260)	<i>Open</i> (n=165)	<i>P</i> <i>value</i>
Age (year old)				
≤ 65	289	178 (68.5)	111 (67.3)	0.798
> 65	136	82 (31.5)	54 (32.7)	
Gender				
Male	279	167 (64.2)	112 (67.9)	0.440
Female	146	93 (35.8)	53 (32.1)	
Comorbid				
None	203	124 (47.7)	79 (47.9)	0.847
One	171	103 (39.6)	68 (41.2)	
Two and more	51	33 (12.7)	18 (10.9)	
BMI (kg/m ²)				
≤ 25	312	191 (73.5)	121 (73.3)	0.977
> 25	113	69 (26.5)	44 (26.7)	
Curability				
Curative	413	259 (99.6)	154 (93.3)	< 0.001
Palliative	12	1 (0.4)	11 (6.7)	

Resection					
	Total	99	48 (18.5)	51 (30.9)	0.003
	Distal	326	212 (81.5)	114 (69.1)	
Lymphadenectomy					
	D1/D1+a	151	101 (38.8)	50 (30.3)	0.073
	D1+b/D2/D2+	274	159 (61.2)	115 (69.7)	
Combined Resection					
	Yes	22	7 (2.7)	15 (9.1)	0.004
	None	403	253 (97.3)	150 (90.0)	
Depth of Invasion					
	Early(T1)	244	200 (76.9)	44 (26.7)	<0.001
	Advanced(T2~T4)	181	60 (23.1)	121 (73.3)	
Location					
	Upper	44	19 (7.3)	25 (15.2)	0.001
	Middle	187	131 (50.4)	56 (33.9)	
	Lower	194	110 (42.3)	84 (50.9)	

Values are presented as number (%). MIS = minimally invasive surgery; BMI = body mass index.

There was significant difference in the complete rate of CP between two procedures ($P < .001$). Of 260 patients who underwent MIS for gastric cancer, 198 patients (76.2%) showed the scheduled postoperative recovery without any complaint, and were recommended discharge from hospital. On the other hand, only 67 patients (40.6%) of 165 in open group completed the CP. Common cause of drop from in MIS group was to take care of postoperative complication. However, it was most common cause of drop in open group that surgeons adjusted the planned schedule of CP to observe the patients without postoperative complication. This category included to improve preoperative condition using nutritional support or to manage patients' comorbidity before surgery or to delay discharge due to perioperative non-specific symptom

without any complication. This group is called ‘desired delay and no readmission group’(Table 3).

Table 3. Results of clinical pathway in the patients enrolled in this study

Results after clinical pathway	Total	MIS (n=260)	Open (n=165)	P value*
Complete	265	198 (76.2)	67 (40.6)	< 0.001
• Planned discharge and no readmission		95	37	
• Wanted delay and no readmission		103	30	
Drop	160	62 (23.8)	98 (59.4)	
• Change of schedule due to complication		35	40	
• Change of schedule due to surgeons’ observation		26	55	
• Readmission		1	3	

Values are presented as number (%). MIS = minimally invasive surgery.

*P value was analyzed by Chi-square test the proportion of the drop between MIS and open groups.

Factors affecting on the drop from CP. Besides open conventional surgery, the rate of drop from CP was significantly increased in old age ($P = .011$) and patients who underwent palliative surgery ($P = .007$), total gastrectomy($P = .001$) or combined resection ($P = .002$) (Table 4). Palliative resection, total gastrectomy and patients’ age were predicting factors for the drop from CP in multivariate analysis (Table 5). However, open surgery showed the most obvious factor to predict it (Odd ratio = 4.281, $2.771 < 95$ percent c.i. < 6.613).

Table 4. Clinicopathologic factors which effected on the drop from clinical pathway

Variables	Total	Drop	P value
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Age (year old)				
	≤65	289	97 (33.6)	0.011
	>65	136	63 (46.3)	
Gender				
	Male	279	105 (37.6)	0.994
	Female	146	55 (37.7)	
Comorbid				
	None	203	67 (33.0)	0.145
	One	171	70 (40.9)	
	Two and more	51	23 (45.1)	
BMI (kg/m²)				
	≤25	312	114 (36.2)	0.422
	>25	113	46 (40.5)	
Invasiveness				
	MIS	260	62 (23.8)	<0.001
	Open	165	98 (59.4)	
Curability				
	Curative	413	151 (36.6)	0.007
	Palliative	12	9 (75.0)	
Resection				
	Total	99	51 (51.5)	0.001
	Partial	326	109 (33.4)	
Lymphadenectomy				
	D1/D1+a	151	64 (42.4)	0.135
	D1+b/D2/D2+	274	96 (35.0)	
Combined Resection				
	Yes	22	15 (68.2)	0.002
	None	403	145 (36.0)	

Values are presented as number (%).

**P* value was analyzed by Chi-square test the proportion of the drop according to clinicopathologic factors

BMI= body mass index; *MIS*= minimally invasive surgery.

Table 5. Predicting factors which can predict the drop from clinical pathway in gastric cancer surgery by multivariable analysis

<i>Variables</i>	β	<i>P</i>	<i>Odd ratio</i>	<i>95% C.I.</i>
Invasiveness				
Open vs MIS	1.454	<0.001	4.281	2.771 – 6.613
Combined				
Yes vs None	1.121	0.031	3.069	1.110 – 8.486
Resection				
Total vs Partial	0.692	0.007	1.999	1.212 – 3.295
Age (years old)				
> 65vs≤65	0.659	0.005	1.933	1.223 – 3.057

C.I. = confidence interval; MIS = minimally invasive surgery.

Suggested indications for ERAS in gastric cancer. In our retrospective cohort, 137 patients (32.2%) had the all kinds of factors suggested in multivariate analysis. In these patients, the complete rate of CP was 85.4%, and only 11 patients were dropped due to surgical complication (Fig 1).

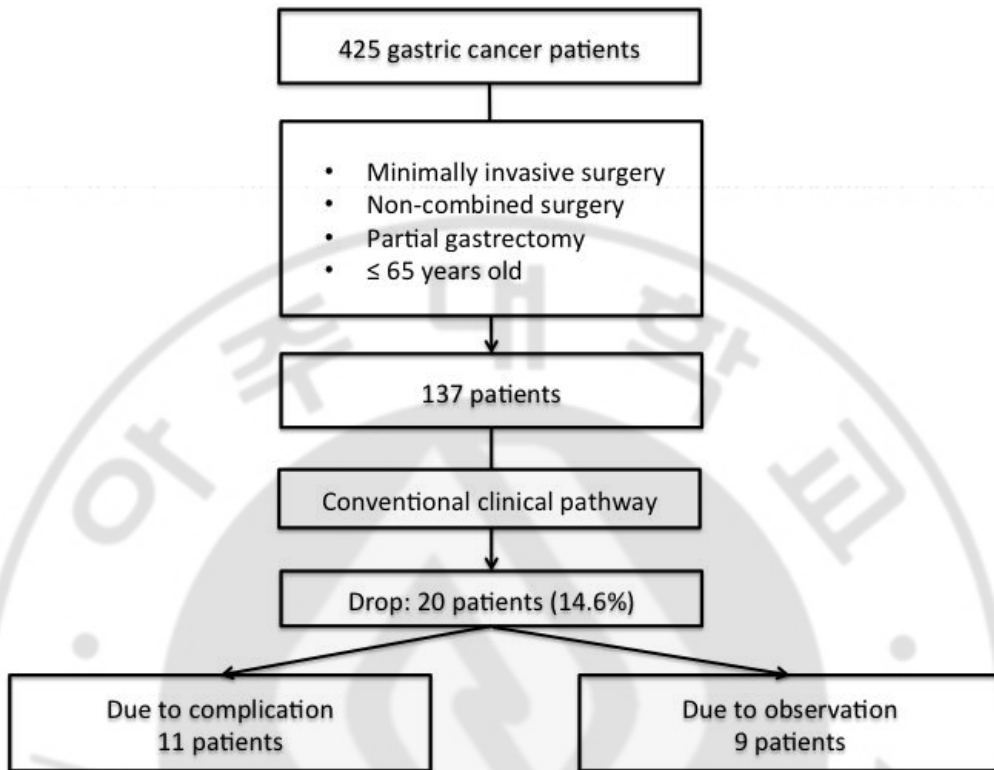


Fig . 1. Outcomes of patients selected by novel criteria for early recovery program in gastric cancer surgery

We compared the surgical outcomes of 137 patients who had those factors with them of other 123 patients who underwent MIS (Table 6). Drop from CP and postoperative complication were significantly less frequent in patients who had four factors ($P < .001$ and $P = .014$). Two case of mortality were occurred only in other group. The postoperative recovery including bowel motility, diet progress and the length of stay of patient who had those factors were faster than those of others.

Table 6. Surgical outcome in patients who underwent minimally invasive surgery for gastric cancer.

	Indications for ERAS (n=137)	Others (n=123)	<i>P</i>
Drop from CP	20 (14.6%)	42 (34.1%)	< 0.001
Complications	13 (9.5%)*	25 (20.3%)	0.014
Mortality	0 (0.0%)	2 (1.6%)	0.134
Bowel motility	1.98 ± 0.65	2.54 ± 0.86	< 0.001
Water start	2.21 ± 0.47	2.68 ± 0.98	< 0.001
Soft diet	5.39 ± 1.54	6.09 ± 1.63	0.001
The length of hospital stay	7.24 ± 2.33	8.77 ± 6.72	0.013

Values are presented as number (%) or mean±standard deviation. ERAS = early recovery after surgery; CP = clinical pathway. *Non-drop patients were included. †The postoperative day of first flatus.

We investigated the surgical outcomes of complications in patients with indications for ERAS. Except for two patients who diagnosed with wound infection and anastomosis stricture, first symptoms like abdominal pain, fever and abnormality of laboratory were occurred within postoperative four days in most patients. The complications were treated by non-operative managements without mortality (Table 7). Based on those results, we could suggest, 1) minimally invasive surgery 2) no combined resection 3) distal gastrectomy and 4) 65 year old and less, as indications for ERAS in gastric cancer.

Table 7. Clinical outcomes of complications in patients under suggested indication for ERAS

<i>No</i>	<i>Age</i>	<i>Gender</i>	<i>Operation</i>	<i>Complication</i>	<i>Symptom development (POD)</i>	<i>Management</i>
1	32	F	LADG	Cholecystitis	4	Conservative
2	44	F	LADG	Pancreatitis	3	Conservative
3	46	F	TLDG	Fluid collection	4	Percutaneous drainage
4	48	F	TLDG	Atelectasis	2	Conservative
5	48	M	TLDG	Ileus	3	Conservative
6	52	M	LADG	Wound infection	7	Conservative
7	55	M	LADG	Skin burn	1	Conservative
8	56	M	TLDG	Ileus	4	Conservative
9	57	M	LADG	Fluid collection	4	Percutaneous drainage
10	51	M	LAPG	Stricture	10	Endoscopic ballooning
11	63	M	TLDG	Urinary track infection	4	Conservative

ERAS = early recovery after surgery; POD = postoperative days; F = female; M = male; LADG = laparoscopy-assisted distal gastrectomy; TLDG = totally laparoscopy distal gastrectomy; LAPG = laparoscopy-assisted proximal gastrectomy.

IV. DISCUSSION

We found out the several factors to predict the accomplishment of conventional CP in this retrospective study. According to these results, the surgical procedure of MIS was most predictable factor to complete CP, in spite of faster diet and discharge schedule in CP for patients who underwent MIS. In addition, younger patients who underwent distal gastrectomy without combined resection were predicted to accomplish the CP without modification.

In this study, we want to investigate the subclass of patients with reasonable completion rate for the CP in gastric cancer surgery. The CP in surgical procedure was well established that it could reduce the cost and the length of hospital stay.(Pritts et al., 1999; Dy et al., 2005) However, a previous clinical study reported that the CP for gastrectomy in gastric cancer patients is less effective compared with that in patients with other benign disease.(Jeong et al., 2011)The completion rate of the CP was only 19% in that study, on the other hand, 45 to 58 % in mastectomy, thyroidectomy and laparoscopic cholecystectomy.(Jeong et al., 2011) They assumed that this low efficacy of the CP for gastric cancer surgery resulted from serious operative procedures following with requiring additional medical care. Additional care was mainly required when the postoperative complications were occurred, and the complication rate in gastric cancer surgery was generally known as from 17.5% to 20.1% in cohort studies with large-scale series.(Wu et al., 1995; Park et al., 2005; Persiani et al., 2008)Moreover, these studies suggested that age, combined resection, extension of lymphadectomy or the method of reconstruction would be contributing factors for postoperative morbidities.(Park et al., 2005; Persiani et al., 2008)Therefore, we expected that the efficacy of the CP for gastric cancer surgery will be increased if the patients for application of the CP were well selected. In our study, 32.2% of all patients had all kinds of factors, which could predict the completion of the CP. They showed the lower complication rate (8.0%) and available complete rate (85.4%) of CP enough to apply it on them.

Recent trends in gastric cancer surgery, which MIS for early gastric cancer has become a widely acceptable procedure, should be considered in this selection.(Hur et al., 2012)Minimally invasive approach to gastric cancer surgery has showed the several benefits like reducing

postoperative pain and surgical trauma, enhanced recovery and improved quality of life.(Kitano et al., 2002; Kim et al., 2008; Yasunaga et al., 2012) As results, most of clinical studies reported that the length of postoperative ileus and hospital stay after surgery were significantly reduced in the gastric cancer patients who underwent MIS.(Kitano et al., 2002; Lee et al., 2006; Kim et al., 2008) Therefore, we made the different CP between minimally invasive and open surgery for gastric cancer. Based on the results from these previous studies, the diet schedule was delayed one day in the CP for the group of open surgery, and it was planned to stay the postoperative one-day more comparing with it in MIS group. Nevertheless, the complete rate (41.7%) of the CP for open group was significantly lower than it (76.2%) for MIS group. Although there were differences in the distribution of cancer progression, extend of gastric resection and so on, the multivariate analysis showed the MIS was most significant factor for predicting the completion of CP (Odd ration: 4.281). We assumed that increased complication like wound problem and prolonged postoperative ileus, and surgeons' intention of observation in patients who underwent open surgery were contributed to increasing drop rate from the CP.

Besides open surgery, combined resection(Odd ration: 3.069), total gastrectomy(Odd ration: 1.999) and old age (Odd ration: 1.933) were other independent factors which could predict the drop from the CP. Several studies have already reported the morbidity and mortality after gastric cancer surgery were significantly increased in the elderly.(Winslet et al., 1996; Katai et al., 2004; Kunisaki et al., 2006) In addition, other report presented that extent of gastric resection could be significant factors to predict the length of hospital stay.(Bozzetti et al., 1997)Regarding the combined resection, some studies, which evaluated the efficacy of additional splenectomy or pancreatectomy to total gastrectomy in gastric cancer, presented that the combined resection could increase the postoperative complication.(Otsuji et al., 1999; Csendes et al., 2002)Therefore, it is possible that surgeons predict the frequent occurrence of complication and additional medical care in patients with those factors. In addition, most surgeons want to observe more duration the patients who have the risk factors, despite they present mild symptomatic or laboratory change not related to complications. These reasons might affect on increasing the drop rate from the CP.

These retrospective results were analyzed before design for the prospective clinical study about the ERAS program in patients who underwent gastrectomy with lymphadectomy for

gastric cancer (as NCT01642953 registered in www.clinicaltrials.gov). ERAS program in gastric cancer surgery has been unusually applied due to concerning about the early oral feeding after upper gastrointestinal surgery. However, recent prospective clinical trial of single center reported that the early oral feeding after gastric cancer surgery was feasible.(Hur et al., 2011)This trial showed the complication rate of 25% and the length of hospital stay of 7 days in early oral feeding group. In spite of postoperative early oral feeding, these results were not remarkable outcomes compared with recent outcomes of MIS for gastric cancer. Therefore, we tried to make a plan in order to enhance recovery more after gastric cancer surgery. Developed ERAS program for gastric cancer surgery includes the liquid diet without bowel preparation at the preoperative one day, proper pain management combined with non-opioid drug, fluid restriction, early oral feeding and early discharge at postoperative 4th day. However, under the situation as less evidence of fast track-CP, we thought that it is important to select indicated patients who are expected to perform the ERAS program without sever complications. Of enrolled patients in this retrospective study, selected patients showed the lower complication rate and even the most of complications were detected within 4th postoperative day. Although recent several clinical trials about fast-track surgery for gastric cancer were designed as postoperative 4 days stay in hospital,(Wang et al., 2010; Kim et al., 2012) we suggested that the application of this schedule on selected patients with suggested indication would be more effective.

In conclusion, high efficacy of the clinical pathway for gastric cancer surgery was expected to selected patients through retrospective analysis. In addition, these patients would become enrolled criteria for early recovery program in gastric cancer surgery.

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