



Actual compliance rate of Enhanced Recovery After Surgery protocol in laparoscopic distal gastrectomy

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Purpose: The Enhanced Recovery After Surgery (ERAS) protocol enhances recovery rate after laparoscopic distal gastrectomy (LDG). An ERAS protocol has been applied to most patients who underwent LDG at our center. In this study, we determined the actual compliance rate of the ERAS protocol and analyzed the risk factors for noncompliance.

Methods: Medical records of 1,013 patients who underwent LDG from March 2016 to December 2017 were reviewed retrospectively. The compliance group (A) included 327 patients who were discharged within four days postoperatively. The noncompliance group (B) comprised 686 patients who were not discharged within four days postoperatively.

Results: The compliance rate of the ERAS protocol was 32.3%. Potential compliance rate was 53.2%. Most common reasons for noncompliance were fever ($n = 115$) and ileus ($n = 111$). The 30-day emergency room visit rate was significantly lower in group A than that in group B ($p = 0.006$). Median age, American Society of Anesthesiologists (ASA) physical status classification, operation time, and pathologic stage were significantly higher in group B than those in group A ($p < 0.001$, $p < 0.001$, $p = 0.005$, and $p < 0.001$, respectively). Risk factors for noncompliance were ASA classification of $\geq III$ (odds ratio [OR], 2.251; $p = 0.007$), age of ≥ 70 years (OR, 1.572; $p = 0.004$), operation time of ≥ 180 minutes (OR, 1.475; $p = 0.003$), and pathologic stage of $\geq III$ (OR, 2.224; $p < 0.001$).

Conclusion: The current ERAS protocols should be applied to patients without risk factors.

Keywords: Laparoscopy, Stomach neoplasms, Gastrectomy, Enhanced Recovery After Surgery, Compliance

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INTRODUCTION

According to several studies, laparoscopic gastric cancer surgery and open surgery are equally safe and effective; however, laparoscopic gastric cancer surgery has many advantages such as low operative pain, small blood loss, and short postoperative hospital stay over open surgery [1–3]. Therefore, laparoscopic gastrectomy

has largely replaced open surgery for the treatment of gastric cancer. In order to maximize the advantages of laparoscopic gastrectomy, the application of Enhanced Recovery After Surgery (ERAS) protocols after gastric cancer surgery is increasing [4–7].

ERAS protocol is a multidisciplinary perioperative care offered for minimizing postoperative stress and accelerating recovery [8]. It includes minimal preoperative fasting, early oral intake, and

early ambulation. ERAS protocols reportedly improve postoperative recovery in many abdominal surgeries, especially in colorectal surgery [9,10].

However, not enough studies have assessed the application of the ERAS protocols for gastric cancer. Therefore, our institute performed a prospective randomized control trial and reported that the ERAS protocol significantly improves recovery time in laparoscopic distal gastrectomy (LDG) patients without significantly affecting complications, readmission, and mortality [11].

Based on the previous results, our center has applied ERAS protocol to the most LDG patients since March 2016. In this study, we aimed to determine the actual compliance rate of the ERAS protocol and identify the risk factors for noncompliance with the ERAS protocol.

MATERIALS AND METHODS

Patient selection

Gastric cancer patients who underwent LDG from March 2016 to December 2017 in single center (Seoul National University Bundang Hospital) were included. Cases of synchronous malignancy and cases of conversion to open or combined resection of other organs were excluded. A total of 1,013 patients were included in this study.

Surgical procedures

Surgeries were performed by four surgeons in a single center. Totally LDG with D1+ or D2 lymph node dissection was performed. Billroth I, Billroth II, and Roux en Y reconstructions were performed in 72 (7.1%), 378 (37.3%), and 563 cases (55.6%), respectively.

ERAS protocol in our institute

The ERAS protocol used in this study is almost similar to the one used by Kang et al. [11], except that our protocol routinely uses intravenous (IV) patient-controlled analgesia (PCA) instead of epidural PCA (Table 1). Before admission, operative risk was assessed, and patients received preoperative education. After admission, oral carbohydrate solution intake was allowed until 2 hours before surgery. Bowel preparation was not carried out. Patients started taking sips of water on postoperative day (POD) 1. If tolerated, the diet was progressed in the order; semifluid diet, followed by semi-blended diet each day. The IV PCA was removed on POD 2. Patients who met the discharge criteria on POD 4 were discharged. The discharge criteria were as follows: (1) tolerance to soft blended diet for 24 hours, (2) safe ambulation of 600 m without assistance, (3) no requirement for additional oral

Table 1. Enhanced Recovery After Surgery protocol used in our institute

Time	Protocols
Days before admission	Preoperative education (including videos on smartphones) Operative risk assessment
Preoperative days	Counseling for patient and family Written informed consent No bowel preparation Oral carbohydrate solution intake up to 2 hr before surgery
Day of surgery	Insertion of a Foley catheter No Nasogastric tube insertion IV PCA Routine use of closed drain O ₂ inhalation (3 L/min)
POD 1	Use of routine antiemetics Sips of water, if tolerated IV PCA Removal of Foley catheter in the morning O ₂ inhalation (3 L/min) Encouragement of ambulation
POD 2	Semifluid diet, if tolerated Removal of IV PCA and use of oral analgesics Laboratory blood test Drain removal
POD 3	Soft blended diet, if tolerated
POD 4	Discharge, if the patient met the discharge criteria ^{a)}

IV, intravenous; PCA, patient-controlled analgesia; POD, postoperative day.

^{a)}Discharge criteria: (1) tolerance to soft blended diet for 24 hours, (2) safe ambulation of 600 m without assistance, (3) no requirement for additional oral or IV analgesics after cessation of PCA, and (4) afebrile status (an axillary temperature of less than 37.2°C) without major complications.

or IV analgesics after cessation of PCA, and (4) afebrile status (an axillary temperature of less than 37.2°C) without major complications [11].

Study design

Patients who were discharged within 4 days after surgery were defined as the compliance group (group A), and patients who were not discharged within 4 days after surgery for any reason were defined as the noncompliance group (group B).

The primary endpoint of this study was the rate of compliance group among all patients (compliance rate). The secondary endpoints of this study were 30-day readmission rate and emergency room (ER) visit rate in each group. Additionally, the risk factors for noncompliance with the ERAS protocol were analyzed.

Data collection and analysis

Data were collected in our electronic medical record database and reviewed retrospectively. Statistical analyses were performed using IBM SPSS version 22.0 (IBM Corp., Armonk, NY, USA). The chi-square test and *t* test were conducted to analyze categorical variables and continuous variables, respectively. Logistic regression analysis was performed for multivariate analysis.

RESULTS

Patients' characteristics

The median age was 58.70 years in group A and 62.27 years in group B. The mean age was significantly lower in group A than that in group B ($p < 0.001$). Group A showed significantly shorter operation time than group B (164.61 minutes vs. 174.13 minutes, $p = 0.005$). The proportion of patients with an American Society of Anesthesiologists (ASA) physical status (PS) classification of III

Table 2. Patients' characteristics

Characteristic	Group A	Group B	<i>p</i> value
No. of patients	327	686	
Age (yr)	58.70 ± 11.51	62.27 ± 12.06	<0.001
Sex			0.349
Male	213 (65.1)	426 (62.1)	
Female	114 (34.9)	260 (37.9)	
Body mass index (kg/m ²)	23.84 ± 3.02	24.15 ± 3.27	0.167
Previous abdominal surgery	69 (21.1)	124 (18.1)	0.252
Operation time (min)	164.61 ± 50.90	174.13 ± 50.65	0.005
ASA PS classification			<0.001
I	151 (46.2)	246 (35.9)	
II	168 (51.4)	383 (55.8)	
III	8 (2.4)	55 (8.0)	
IV	0 (0)	2 (0.3)	
Early complications	9 (2.8)	50 (7.3)	0.004
Blood loss (ml)	31.42 ± 49.288	36.48 ± 61.987	0.162
Extent of LND			0.602
D1+	212 (64.8)	430 (62.7)	
D2	115 (35.2)	256 (37.3)	
cT staging			<0.001
cTx	129 (39.5)	272 (39.7)	
cT1	118 (36.1)	162 (23.6)	
cT2	33 (10.1)	67 (9.8)	
cT3	37 (11.3)	113 (16.5)	
cT4	7 (2.1)	52 (7.6)	
cN staging			0.003
cN0	307 (93.9)	590 (86.0)	
cN1	14 (4.3)	38 (5.5)	
cN2	1 (0.3)	18 (2.6)	
cN3	2 (0.6)	20 (2.9)	

Table 2. Continued

Characteristic	Group A	Group B	<i>p</i> value
Postoperative TNM staging			<0.001
IA	212 (64.8)	390 (56.9)	
IB	44 (13.5)	71 (10.3)	
IIA	18 (5.5)	45 (6.6)	
IIB	17 (5.2)	37 (5.4)	
IIIA	9 (2.8)	39 (5.7)	
IIIB	7 (2.1)	32 (4.7)	
IIIC	3 (0.9)	31 (4.5)	
IV	0 (0)	9 (1.3)	
No residual tumor (after ESD)	17 (5.2)	31 (4.5)	

Values are presented as mean ± standard deviation or number (%).

ASA, American Society of Anesthesiologists; PS, physical status; LND, lymph node dissection; c, clinical; ESD, endoscopic submucosal dissection.

Group A, compliance group; Group B, noncompliance group.

or IV was significantly greater in group B than that in group A ($p < 0.001$). Moreover, clinical (c) stage and postoperative pathologic stage were significantly higher in group B than those in group A (cT, $p < 0.001$; cN, $p = 0.003$; postoperative pathologic stage, $p < 0.001$). Sex, body mass index, history of previous abdominal operation, estimated blood loss, and extent of lymph node dissection showed no significant differences between the groups (Table 2).

Compliance rate

Group A included 327 patients. Therefore, the actual compliance rate of the ERAS protocol in patients who underwent LDG was 32.3% (327 of 1,013). Potential compliance rate, including 212 patients without postoperative medical problems in group B, was 53.2% (539 of 1,013).

There was no significant difference in 30-day readmission rate between groups A and B (3.7% vs. 5.1%). Group A showed significantly lower 30-day ER visit (without readmission) rate than group B (1.2% vs. 4.7%, $p = 0.006$).

Reasons for delayed discharge

In 686 patients, discharge was delayed. Among them, 212 patients had no medical reasons for delayed discharge. The most common medical reason for delayed discharge was fever without a focus of infection ($n = 115$, 11.4%), followed by ileus ($n = 111$, 11.0%), intraoperative events ($n = 38$, 3.8%), underlying diseases ($n = 31$, 3.1%), postprandial discomfort ($n = 28$, 2.8%), and others (Table 3).

Table 3. Causes for noncompliance with the Enhanced Recovery After Surgery protocol

Cause	Data
Unknown (without medical problem)	109 (10.8)
Patient's demand (without medical problem)	103 (10.2)
Fever (without a focus of infection)	115 (11.4)
Ileus	111 (11.0)
Intraoperative event/findings	38 (3.8)
Underlying diseases	31 (3.1)
Postprandial discomfort (no ileus or delayed gastric emptying)	28 (2.8)
Atelectasis	19 (1.9)
Pneumonia	17 (1.7)
Drain related problems ^{a)}	16 (1.6)
Lab abnormalities	15 (1.5)
Postoperative pain	15 (1.5)
Postoperative bleeding	11 (1.1)
Delayed gastric emptying	8 (0.8)
Fluid collection	7 (0.7)
Anastomosis or duodenal stump leakage	4 (0.4)
Others	39 (3.9)

Values are presented as number (%).

^{a)}Chylous drainage, excessive ascites drainage, tractitis, etc.

Risk factor analysis

In univariate analysis, hypertension (odds ratio [OR], 1.493; $p =$

Table 4. Analysis of the risk factors for noncompliance with the Enhanced Recovery After Surgery protocol

Risk factor	Univariate analysis		Multivariate analysis	
	OR (95% CI)	<i>p</i> value	OR (95% CI)	<i>p</i> value
Underlying disease				
Hypertension	1.493 (1.106–2.014)	0.009	1.140 (0.852–1.525)	0.378
Diabetes mellitus	1.680 (1.128–2.503)	0.010	1.245 (0.857–1.809)	0.250
Cardiac	2.218 (1.072–4.590)	0.028	1.583 (0.794–3.156)	0.192
Cerebral	2.105 (0.757–5.849)	0.145	1.125 (0.472–2.682)	0.790
Pulmonary	0.985 (0.553–1.752)	0.958	0.953 (0.553–1.643)	0.863
Renal	1.402 (0.709–2.770)	0.329	0.403 (0.040–4.038)	0.440
Hepatic	1.765 (0.863–3.727)	0.132	5.662 (0.515–62.233)	0.156
Age, ≥70 yr	1.823 (1.325–2.510)	<0.001	1.572 (1.158–2.135)	0.004
ASA PS classification, ≥III	4.286 (1.995–9.207)	<0.001	2.251 (1.245–4.070)	0.007
Operation time, ≥180 min	1.494 (1.165–1.916)	0.002	1.475 (1.137–1.914)	0.003
Postoperative stage, ≥3	2.595 (1.759–3.828)	<0.001	2.224 (1.488–3.324)	<0.001

ASA, American Society of Anesthesiologists; PS, physical status.

0.009), diabetes (OR, 1.680; $p = 0.010$), cardiac disease (OR, 2.218; $p = 0.028$), old age (OR, 1.831; $p < 0.001$), high ASA PS classification (OR, 4.286; $p < 0.001$), long operation time (OR, 1.494; $p = 0.003$), and advanced postoperative pathologic stage (OR, 2.595; $p < 0.001$) showed significantly higher odds ratio (Table 4). However, in multivariate analysis, old age (OR, 1.572; $p = 0.004$), high ASA PS classification (OR, 2.251; $p = 0.007$), long operation time (OR, 1.475; $p = 0.003$), and advanced postoperative pathologic stage (OR, 2.224; $p < 0.001$) showed significantly higher odds ratio (Table 4).

DISCUSSION

The actual compliance rate of the ERAS protocol was 32.3%. However, group B contained many patients without postoperative medical problems ($n = 212$), who could have potentially been in group A. After including these patients, potential compliance rate of the ERAS protocol was 53.2%. In a study of 290 patients with gastric cancer, Gianotti et al. [12] reported that the postoperative compliance of the ERAS protocol was 82.5%, and the median achievement of discharge criteria was 7 days after surgery. The compliance rate in our study was much lower than that reported by Gianotti et al. [12]. However, in our study, all cases that did not be discharged on POD 4 were defined as noncompliance, and more than 80% of all patients satisfied the discharge criteria and were actually discharged within POD 7. Therefore, it cannot be accepted as an inferior result. Nevertheless, setting the discharge date as POD 4 is considered to be rather strict, so we plan to readjust the discharge time of the ERAS protocol.

The proportion of patients with nonmedical reasons for delayed discharge was very high ($n = 212$, 20.9%). It may be due to the low burden of medical expenses for patients as the National Health Insurance of South Korea covers a large portion of medical expenses for cancer patients. Several studies have reported that insurance status actually affects hospital length of stay [13–15].

The most common medical reason for delayed discharge was fever without a focus of infection ($n = 115$, 11.4%). Therefore, if infection is excluded through careful physical examination, laboratory test, and imaging evaluation, patients without significant comorbidity could be discharged with short-term outpatient follow-up care [16,17]. The second most common reason for noncompliance was postoperative ileus ($n = 111$, 11.0%). Liang et al. [18] reported that the proportion of patients with ileus after laparoscopic gastrectomy was 14.14%. Huang et al. [19] reported ileus after laparoscopic gastrectomy in 18.52% of patients. Our study reported a lower rate of postoperative ileus than those studies. Furthermore, both the studies reported that postoperative pathologic stage and age were higher in the postoperative ileus group. These are similar factors of noncompliance group in our study. If the stage is high, the operation is difficult and lengthy, and the time for tissue or intestinal manipulation is long. As a result, it is expected that the inflammatory response or decreased intestinal motility after surgery is more severe. These factors are thought to increase the likelihood of noncompliance [18,19].

Many studies have reported that the compliance with ERAS protocols is poor in elderly patients or patients with comorbidity [20,21]. Similarly, in this study, the compliance with the ERAS

protocol was lower in elderly patients and patients with comorbidity. However, previous studies have recommended the careful application of ERAS protocols even in elderly patients because of the clear benefits of ERAS protocols [20,21]. Therefore, new modified protocols should be applied to these patients. However, since 30-day readmission and ER visit rate were not high in both the groups, the existing protocols could be safely applied to patients without risk factors.

In a previous randomized controlled trial, Kang et al. [11] applied epidural PCA in the ERAS group. However, epidural PCA requires an additional invasive procedure for epidural catheter insertion before surgery, and there were inconveniences such as unexpected removal of the epidural catheter. Therefore, our ERAS protocol uses IV PCA instead of epidural PCA. It seems that IV PCA can replace epidural PCA because the proportion of delayed discharge caused by postoperative pain is quite low ($n = 15$, 1.5%).

We determined the actual compliance rate of the ERAS protocol in a large volume of patients with gastric cancer who underwent LDG and showed that the application of the ERAS protocol should be modified according to patient characteristics. This is an advantage of this study. As this study was retrospective in nature and assessed medical records, there were limitations in interpretation as there were many cases in which delay-causing factors in discharge were omitted or not described in detail. Additionally, this study did not include a new ERAS protocol applicable to patients with risk factors. Therefore, additional research is needed to establish a new ERAS protocol for patients with risk factors.

In conclusion, the compliance rate of the ERAS protocol in LDG patients was lower in patients with old age, high ASA PS classification, and advanced disease. Therefore, the ERAS protocol used in this study can be selectively applied to patients. Further research is needed to develop a modified ERAS protocol for patients with risk factors.

NOTES

Ethical statements

We conducted this study in compliance with the principles of the Declaration of Helsinki. The protocol used in this study was reviewed and approved by the Institutional Review Board of Seoul National University Bundang Hospital (No. B-2109-707-104). Since this study is a retrospective study that reviewed electronic charts, formal consent from the patients was waived.

Authors' contributions

Conceptualization, Formal analysis, Methodology, Visualization:

SHP, SHA

Data curation: SHP, SHK, SJL, YJW

Investigation: All authors

Project administration: SHA, HHK

Writing—original draft: SHP

Writing—review & editing: SHP, SHA, YSS, DJP, HHK

All authors read and approved the final manuscript.

Conflict of interest

All authors have no conflicts of interest to declare.

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