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Evaluation of the Critical Pathway for Laparoscopic Cholecystectomy from the Perspective of Pain Course

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Purpose: The critical pathway is a standardized practice guideline for providing quality healthcare. It improves patient outcomes by providing comprehensive treatment. Although many studies have explored the effectiveness of the critical pathway in laparoscopic cholecystectomy, no study has reported how it affects pain levels during a patient's hospital stay. This study aimed to evaluate the effectiveness of the critical pathway in reducing pain severity.

Methods: Between January 2022 and December 2023, 723 patients underwent laparoscopic cholecystectomy. The patients were categorized into two groups: 407 patients in the critical pathway group and 316 in the non-critical pathway group. Patient outcomes, namely the length of hospital stay, postoperative hospital stay, total healthcare cost, unplanned emergency room visits within 30 days, pain score, and number of analgesics administered, were analyzed and compared between the groups.

Results: The length of hospital stay was 3.43 ± 1.02 and 3.73 ± 1.78 days for the critical pathway and non-critical pathway groups, respectively (p=.007). The total healthcare cost was 3981.77 ± 747.02 US$ and 4929.10 ± 1710.33 US$ for the critical pathway and non-critical pathway, respectively (p<.001). No significant difference was observed in unplanned 30-day emergency room visits between the two groups. The average pain during the hospital stay was 3.17 ± 0.68 and 3.29 ± 0.75 points in the critical pathway and non-critical pathway groups, respectively (p=.023).

Conclusion: The critical pathway is an effective protocol for achieving rapid postoperative recovery. The results showed that reduced pain and faster discharge are possible through the critical pathway. In addition, despite the shorter hospitalization period in the critical pathway group, no significant difference was observed in unplanned 30-day emergency room visits between the two groups. This is a promising outcome for the widespread application of the critical pathway in laparoscopic cholecystectomy.

Keywords: Critical pathway, Laparoscopic cholecystectomy, Pain

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Ⅰ. Introduction

Many hospitals are implementing the critical pathway (CP) to improve the quality of medical care and provide patient safety [1]. The CP is a standardised treatment process that determines the treatment order and treatment time for a specific disease [2]. It sets goals for patients and outlines the ideal sequence and timing for staff actions to efficiently achieve these goals. The purpose of CP is to maximise the quality of medical care with limited medical service resources [2], and it has been validated in several previous studies [1].

Recently, with the increasing number of individuals with obesity due to changes in eating habits and lifestyles, the incidence of gallbladder disease has also increased [3]. Laparoscopic cholecystectomy (LC) is widely used as the standard treatment for cholecystitis caused by gallbladder disease [4-7]. Laparoscopic cholecystectomy is a common surgery performed in Korea, which has an increased prevalence of gallbladder disease [8,9].

Many hospitals are adopting a CP for laparoscopic cholecystectomy to enhance patient's understanding of the surgery and provide high-quality care. Chang et al. [10]'s study, the mean length of hospital stay decreased significantly after implementation of CP and there was no difference in the postoperative morbidity and number of hospital visits. Holderried et al. [11]'s study, the mean total healthcare costs and length of hospital stay were significantly reduced by the integrated clinical pathway. Further, the variation of costs per case and variation of length of hospital stay were significantly smaller with integrated clinical pathway [11]. In addition, several other papers that applied CP in Laparoscopic cholecystectomy also presented effects including a short hospital stay and fewer complications [12-16].

However, few studies have analysed the effect of the critical pathway in terms of pain course and analgesic use. Ko-iam et al. [17]'s study found that high pain score and with an oral analgesia requirement more than 2 doses were a factor in increasing the length of hospital stay in patients with laparoscopic cholecystectomy. So we compared the effects of CP application on pain scores and length of hospital stay, which are the critical issues for patients undergoing surgery.

Some hospitals and doctors still do not use the CP because of a lack of awareness or environmental factors [18]. The barriers of critical pathway were 4 factors included clinician knowledge, familiarity, attitude, workload factors [19]. Another study analyzed the reasons for the low CP adoption rate and divided them into the following five groups: limited applicability, lack of flexibility to accommodate atypical clinical presentations, perception of insufficient evidence to support recommendations, local organizational barriers, and need for local adaptation [20]. Therefore, the purpose of this study was to reaffirm the usefulness of CP, including pain and length of hospital stay management, for medical professionals who are hesitant about applying CP.

Ⅱ. Methods

1. Patients and Settings

We retrospectively investigated patients who underwent laparoscopic cholecystectomy for gallbladder disease between January 2022 and Decem-

ber 2023. A total of 723 patients were included, excluding those with missing patient information and treatment records and those who underwent emergency surgery. Patients who were transferred to other departments were also excluded. The included patients were categorized into two groups, including 407 patients in the CP group and 316 patients in the non-CP group. In this retrospective review, patient outcomes were analysed and compared between the groups.

Data collected for analysis included sex, age, American Society of Anaesthesiologists (ASA) classification, comorbidity (hypertension, diabetes, tuberculosis, hepatitis), diagnosis, length of hospital stay, postoperative hospital stay, total healthcare cost, unplanned emergency room (ER) visits within 30 days, pain score, and number of analgesics administered.

The length of hospital stay was calculated as the number of days from hospitalization to discharge, and the postoperative hospital stay was calculated as the number of days from surgery to discharge, excluding the surgery date. Because the length of hospital stay increases depending on postoperative pain [17], the length of postoperative hospital stay was classified separately.

Total healthcare costs was the sum of patient and insurance costs, and include surgery costs, hospital room costs, examination costs, medication costs, and treatment costs.

Unplanned ER visits within 30 days referred to revisiting the same medical institution within 30 days after discharge; patient's visits for symptoms unrelated to cholecystectomy surgery or receiving treatment at another department were excluded.

This study was approved by the Institutional Review Board of Gangnam Severance Hospital (IRB 3-2024-0158), and data were collected using a medical record system.

2. Pain score assessment

Pain scores were assessed using the Numeric Pain Intensity Scale (NPIS). For each patient, routine pain scores were recorded every 8 hours by a nurse before and after surgery in the supine resting position at certain times during the hospitalisation. Additional pain scores were recorded in patients who expressed pain or received pain-related interventions.

Pain scores were collected from the inpatient ward and analysed by dividing them into maximum pain during hospitalisation, average pain during hospitalisation, pain at the time of admission and pain at the time of discharge. Pain at the time of admission was measured to determine the homogeneity of the CP group and the non-CP group. Appropriate pain control at the right time is an important factor for rapid discharge and early recovery to daily life [17]. Accordingly, referring to previous studies [21], it was divided into maximum pain during hospitalisation, average pain during hospitalisation and pain at the time of discharge.

The number of analgesics administered was analysed, including the use of additional analgesics (pro re nata [PRN], as needed) based on the pain experienced by the patient. According to the hospital regulations, tramadol hydrochloride (50 mg) and pethidine hydrochloride (25 mg) were used as PRN analgesics. If the NPIS score was 4 or higher, PRN analgesics were administered.

3. Components of the CP

The purpose of the CP is to ensure that patients receive necessary care at the optimal time and are discharged safely. The CP for laparoscopic cholecystectomy that we developed is presented in Figure 1. This CP was newly developed in 2022 to activate application.

Patients are admitted a day before surgery; their vital signs, pain, and weight are measured; and prophylactic antibiotics are administered before surgery. The patients fast from midnight. The doctor explains the surgery to the patient and obtains consent from the patient.

Vital signs and pain are assessed on the day of surgery. Antibiotics, liver function supplements, and routine analgesics are provided, and additional analgesics are administered if the patient complains of persistent pain. After fully awakening from the surgery, the patient can drink a little water and eat a low-fat dinner.

If no surgical complications occur, the patient discharges the day after surgery. Vital signs and pain are assessed on the day of discharge. Analgesics and liver function supplements are prescribed, and blood tests are performed. The patient consumes a low-fat breakfast. The discharge education provides to patients included information on outpatient schedules, blood tests, discharge medications intake, and necessary precautions.

	HOD#1 (Pre-OP[1] day)	HOD#2 (OP day)	HOD#3 (Post OP day)
Assessment	□ Blood Pressure check BID[2] □ Vital Sign check BID □ Body Weight check □ Pain assessment	□ Blood Pressure check TID[3] □ Vital Sign check TID □ Pain assessment	□ Blood Pressure check BID □ Vital Sign check BID □ Pain assessment
Lab Test (serum)			□ CBC[4]/ WBC[5]/ PLT[6] □ Routine chemistry □ Electrolyte □ Amylase/Lipase/CRP[7]
Diet	□ Dinner: General Food □ Midnight NPO[8]	□ NPO (before surgery) □ SOW[9] (after full awakening) □ Dinner: Low fat diet	□ Breakfast: Low fat diet
Medication	□ IV[10] Fluid (Hartmann solution) □ Antibiotics; Cefazedone sodium	□ IV Fluid (Hartmann solution) □ Antibiotics; Cefazedone sodium □ Analgesics; Ibuprofen, PRN[11] (Tramadol hydrochloride, Pethidine hydrochloride) □ Oral medication; Aceclofenac, Ursodeoxycholic acid, Rowachol	□ Oral medication; Aceclofenac, Ursodeoxycholic acid, Rowachol □ Analgesics; PRN (Tramadol hydrochloride, Pethidine hydrochloride) □ Discharge medication; Aceclofenac, Ursodeoxycholic acid, Rowachol, Citrulline malate
Permission & Education	□ Get operative permission □ Hospitalized life education □ Precautions about surgery		□ Discharge education - Outpatient schedule information after 2 weeks (include blood test f/u) - How to take discharge medication

Figure 1. Laparoscopic cholecystectomy using the critical pathway (CP).

[1] OP=Operation; [2] BID=Bis in die(twice a day); [3] TID=Ter in die (thrice a day); [4] CBC=Complete blood count; [5] WBC=White blood cell; [6] PLT=Platelet; [7] CRP=C-Reactive Protein; [8] NPO=Nothing per oral; [9] SOW=Sips of water; [10] IV=Intravenous; [11] PRN= Pro re nata(when necessary).

4. Statistical analyses

The general and clinical characteristics of the CP and non-CP groups were analysed using descriptive statistics. A homogeneity test between the CP and non-CP groups was performed using the Chi-squared test and Welch's t-test. Continuous variables, including length of hospital stay, postoperative hospital stay, total healthcare cost, pain scores, and analgesic administration, are presented as mean ± standard deviation and were compared using the Student's t-test and Welch's t-test. Categorical variables, including unplanned 30-day ER visits, are expressed as counts and percentages. If the minimum expected frequency was 5 or less, Fisher's exact test was used. All statistical analyses were performed using the R software (version 4.4.0). Statistical significance was set at $p<.05$.

Ⅲ. Results

1. Clinical characteristics of the CP and non-CP group

Table 1 summarizes patients' sex, age, ASA classification, comorbidities (hypertension, diabetes, tuberculosis, and hepatitis), diagnoses and pain score at admission in the CP and non-CP groups.

Table 1. Clinical characteristics of patients in the CP and non-CP groups.

		CP group (n=407) n (%)	Non-CP group (n=316) n (%)	x^2/t	*p*
Sex	Male	170 (41.8)	154 (48.7)		
	Female	237 (58.2)	162 (51.3)	3.21	.073
Age (years)	≤39	80 (19.7)	49 (15.5)		
	40 - 49	95 (23.3)	79 (25.0)		
	50 - 59	99 (24.3)	77 (24.4)		
	60 - 69	87 (21.4)	69 (21.8)		
	70≤	46 (11.3)	42 (13.3)		
	Mean ± SD	52.42±13.77	53.70 ± 13.80	2.52	.642
ASA class	1	59 (14.5)	47 (14.9)		
	2	236 (58.0)	171 (54.1)		
	3	110 (27.0)	97 (30.7)		
	4	2 (0.5)	1 (0.3)	1.46	.688[1)]
Comorbidity	Yes	152 (37.3)	130 (41.1)		
	No	255 (62.7)	186 (58.9)	0.92	.337
Diagnosis	Gallbladder stone	314 (77.1)	226 (71.5)		
	Gallbladder polyp	68 (16.7)	73 (23.1)		
	Chronic cholecystitis	20 (4.9)	11 (3.5)		
	Acute cholecystitis	5 (1.2)	6 (1.9)	5.86	.119[1)]
Pain score (Admission)	Mean ± SD	0.49 ± 1.09	0.45 ± 1.24	0.48	.628[2)]

CP= Critical Pathway; SD= Standard Deviation; ASA= American Society of Anaesthesiologists
1) Fisher's exact test, 2) Welch's t-test

The mean age of the 723 (399 female and 324 male) patients who underwent cholecystectomy was 52 years. Patients of the attending physician who participated in the development of the CP were assigned to the CP group (n=407), and patients of other attending physicians were assigned to the non-CP group (n=316).

Both the CP and non-CP groups had a higher proportion of female patients; however, no significant difference was observed between the two groups. Additionally, no significant differences in other characteristics, including age, ASA classification, comorbidities, and diagnosis, were observed between the two groups.

In the CP group, 314 patients had gallbladder stones, 68 had gallbladder polyps, 20 had chronic cholecystitis, and 5 had acute cholecystitis. In the non-CP group, 226 patients had gallbladder stones, 73 had gallbladder polyps, 11 had chronic cholecystitis, and 6 had acute cholecystitis. No significant difference in diagnosis was observed between the two groups.

Although the CP group had slightly higher mean pain score at admission than the non-CP group, no significant differences were observed between the two groups (0.49 ± 1.09 points vs. 0.45 ± 1.24 points, p=.628).

2. Postoperative outcomes of the patients

The mean length of hospital stay differed significantly between the CP and non-CP groups (Figure 2). The length of hospital stay was 3.43 ± 1.02 days in the CP group and 3.73 ± 1.78 days in the non-CP group (p=.007). The mean postoperative hospital stay was also significantly different between the two groups (1.34 ± 0.80 days in the CP group and 1.60 ± 1.60 days in the non-CP group; p=.007). Furthermore, the total healthcare cost was 3,981.77 ± 747.02 US$ in the CP group and 4,929.10 ± 1,710.33 US$ in the non-CP group (p<.001).

No significant difference in unplanned ER visits within 30 days was observed between the CP and non-CP groups (2.0% vs. 2.2%, p=.800). None of the patients in either group experienced immediate postoperative complications. The reasons for the unplanned ER visits were fever, abdominal pain, nausea, and wound problems (Table2).

The CP and non-CP groups showed no significant difference in the maximum pain score and pain score at discharge (5.00 ± 1.66 points vs. 5.15 ± 1.63 points, p=.213, and 2.54 ± 1.11 points vs. 2.58 ± 0.94 points, p=.585, respectively). However, a significant difference in the average pain score was observed between the CP and non-CP groups (3.17 ± 0.68 points vs. 3.29 ± 0.75 points, p=.023) (Figure 3).

All patients routinely received analgesics (non-steroidal anti-inflammatory) drugs three times after surgery. Excluding regular analgesic administration, additional analgesic administration was analysed based on the patient's pain complaints.

Regarding the administration of analgesics, the CP group showed a significantly lower number of medications postoperatively than that of the non-CP group (0.61 ± 1.03 times vs. 0.87 ± 1.41 times, p=.006). According to the type of medication, pethidine hydrochloride administration was significantly lower in the CP group than in the non-CP group (0.08 ± 0.38 times vs. 0.17 ± 0.52 times, p=.009). Tramadol hydrochloride administration was also significantly lower in the CP group than in the non-CP group (0.53 ± 0.86 times vs. 0.70 ± 1.13 times, p=.028).

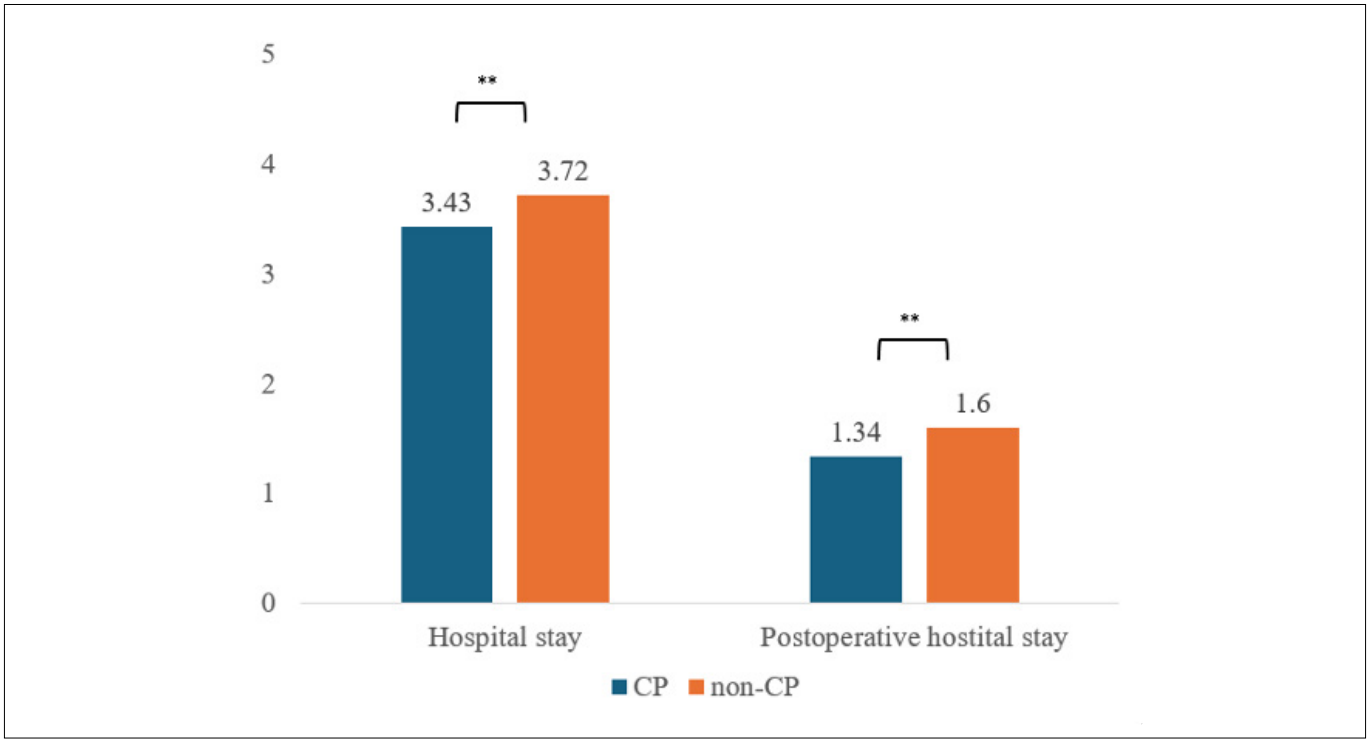

Figure 2. Comparison of outcomes between the CP (critical pathway) and non-CP groups: length of hospital stay and length of postoperative hospital stay.

** $p<.001$

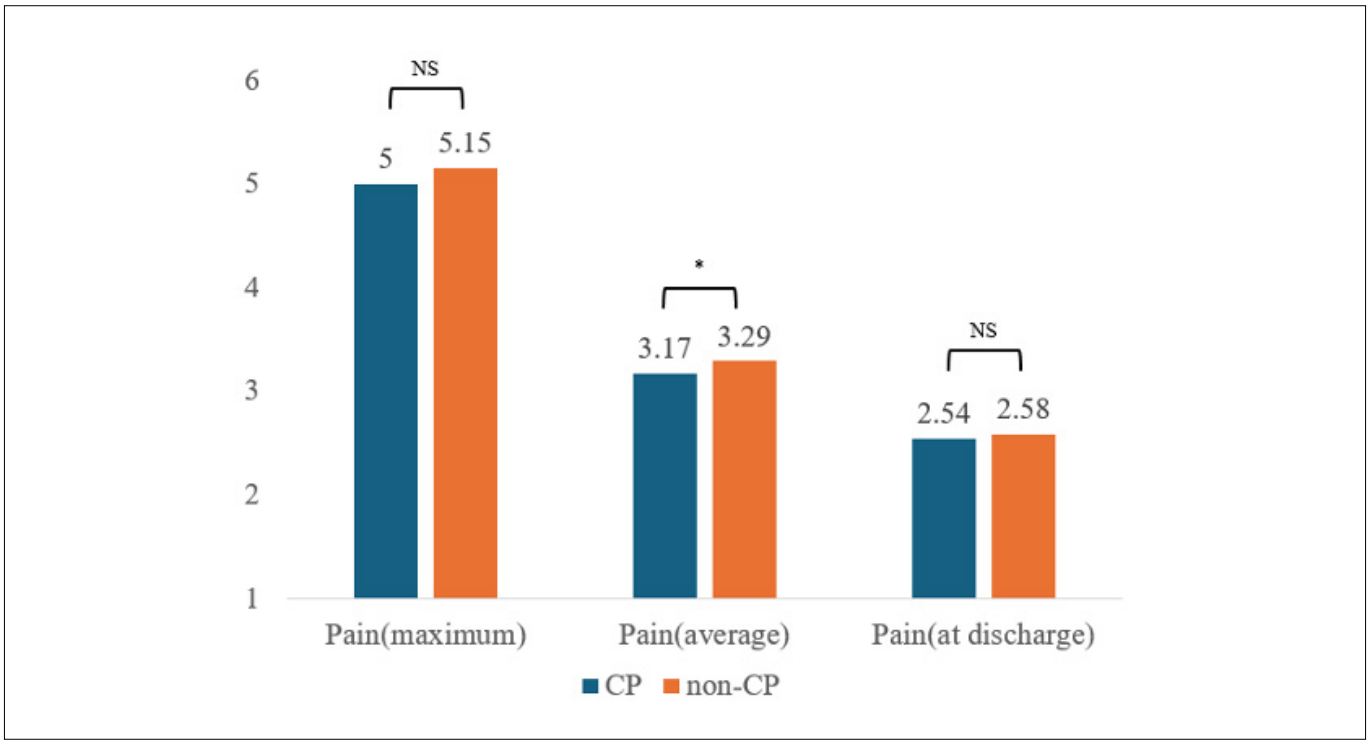

Figure 3. Comparison of outcomes between the CP (critical pathway) and non-CP groups: pain score.

NS= Not significant; * $p<.05$

Table 2. Comparison of outcomes between the CP and non-CP groups.

Clinical outcome	CP group (n=407) Mean ± SD	Non-CP group (n=316) Mean ± SD	t /χ^2	*p*
Total healthcare cost	$3,981.77 ± $747.02	$4,929.10 ± $1,710.33	-9.18	<.001
Unplanned ER visit (Yes)	8 (2.0)	7 (2.2)	<.001	.800[1)]
Unplanned ER visit (NO)	399 (98.0)	309 (97.8)		
Number of analgesic administrations	0.61 ± 1.03	0.87 ± 1.41	-2.77	.006
Pethidine hydrochloride	0.08 ± 0.38	0.17 ± 0.52	-2.63	.009
Tramadol hydrochloride	0.53 ± 0.86	0.70 ± 1.13	-2.28	.028

CP= Critical Pathway; SD= Standard Deviation; ER= Emergency Room
1) Fisher's exact test

Ⅳ. Discussion

The purpose of this study is to analyze the effects of CP on postoperative pain and length of hospital stay in laparoscopic cholecystectomy patients and to reaffirm the usefulness of CP to medical professionals who are hesitant to apply CP.

The length of hospital stay and postoperative hospital stay were statistically significant differences (CP group; 3.43 days vs. non-CP group; 3.73 days, *p*=.007 and CP group; 1.34 days vs. non-CP group; 1.6 days, *p*=.007). Total healthcare cost was 3,981.77 US$ in the CP group and 4,929.1 US$ in the non-CP group, which was statistically significantly lower in the CP group (*p*<.001).

Several studies have also reported the usefulness of CP in relation to length of hospital stay and total healthcare cost. Sung et al. [22] reported that the application of CPs in paediatric patients with supracondylar humeral fractures was useful; the implementation of the developed CP in paediatric patients undergoing closed pinning for supracondylar fractures of the humerus enhanced treatment efficiency by streamlining the treatment process without increase the length of hospital stay or total hospital costs [22]. Additionally, Min et al. [23]'s study, the length of hospital stay (both total and postoperative) was significantly shorter in the post-CP group than in the pre-CP group in patients with acute cholecystitis. Furthermore, the length of hospital stay before surgery was reported to be significantly short after CP implementation, and no significant difference was reported in the number of outpatient clinic revisits for complications or postoperative complications [23].

In this study, the number of unplanned emergency room (ER) visits within 30 days was 8 (2.0%) in the CP group and 7 (2.2%) in the non-CP group, and there was no significant difference between the two groups (*p*=.800). The reasons for the unplanned ER visits were fever, abdominal pain, nausea, and wound problems, and there were no serious complications requiring readmission.

We collected maximum pain score during hospitalisation, average pain score during hospitalisation, pain score at the time of admission and pain score at the time of discharge to analyze the effect of CP on postoperative pain management. Pain score at the time of admission was analyzed for homogeneity between the CP group and non-CP group, and there

was no statistically significant difference (CP group; 0.49 points vs. non-CP group; 0.45 points, p=.628). Maximum pain score and pain score at the time of discharge were no statistically significant differences (CP group; 5 points vs. non-CP group; 5.15 points, p=.213 and CP group; 2.54 points vs. non-CP group; 2.58 points, p=.585). However, the average pain score during hospitalisation and the number of additional analgesic administrations were statistically significant differences (CP group; 3.17 points vs. non-CP group; 3.29 points, p=.023 and CP group; 0.61 times vs. non-CP group; 0.87 times, p=.006).

Jung et al [24] also reported that CP application did not affect pain score at discharge in patients undergoing Laparoscopic Colon Resection. The length of hospital stay was reduced in the CP group, but it did not affect patients' postoperative pain, which is consistent with our study results. Furthermore, in our study, the average pain score during hospitalisation and the number of additional analgesic administrations decreased in the CP group, which was statistically significant, Because application of CP provides consistent prescriptions to patients, it can prevent missing in treatment or procedures in hospital environments where personnel change frequently due to shift work. Therefore, CP application can help early recovery to daily life while maintaining the quality of medical care by reducing postoperative pain management and length of hospital stay.

Although the usefulness of CP has been demonstrated in several studies, some doctors are still reluctant to standardize treatment and promote early discharge. The main factors that make medical staff hesitant to apply CP include physician knowledge (lack of awareness or lack of familiarity), attitudes (lack of agreement, lack of self-efficacy, lack of outcome expectancy, or the inertia of previous practice), or behavior (external barriers) [18]. Based on the usefulness of CP suggested in this study and previous studies, we hope that the problems of lack of awareness and outcome expectations about CP will be solved, and CP development will be activated in more hospitals.

Surely, the CP cannot be applied to all patients. If a complex and difficult disease is selected, there are many differences of opinion on CP development, and it is difficult to apply it due to variation in application [2]. In addition, in the case of rare diseases with a small patient population, CP development is difficult due to difficulties in recruiting research subjects to prove usefulness and limited knowledge about the disease [25].

Therefore, selecting a surgical disease with a clear treatment process and high frequency is easy and suitable for CP development [2]. Its usefulness increases in diseases that require frequent surgery and procedures, predictable treatment process, multidisciplinary approaches, and standardisation. In this regard, this study confirmed the usefulness of the CP in Laparoscopic cholecystectomy, a frequently performed surgery, and demonstrated its substantial benefits in managing pain, which is the most critical concern for patient.

This study evaluated the usefulness of CP in managing pain, but it is limited in that there is no discussion on the types of variations that occur when CP is applied. Therefore, we suggest a follow-up study to identify variations that occur when CP is applied and apply them to CP contents to prevent variations in advance and improve the quality of medical care.

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Supplementary 1. Evaluation of the critical pathway(CP) for laparoscopic cholecystectomy from the perspective of pain course.