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Very urgent endoscopic retrograde cholangiopancreatography is associated with early discharge in patients with non-severe acute cholangitis

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Abbreviations: AC: acute cholangitis; ERCP: endoscopic retrograde cholangiopancreatography; HR: hazard ratio; LOS: length of hospital stay; T-BIL: total bilirubin; TG18: 2018 Tokyo guidelines; WBC: white blood cell.

Disclosures: the authors declare no conflicts of interest.

Ethics approval and consent to participate: the study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki (2013 revision) as reflected in a priori approval by the study institution's Human Research Committee. The Institutional Review Board of Hakodate Municipal Hospital approved this study (2020-54). Informed consent to participate in the study was obtained from the patients or their families using an opt-out form.

REVISTA ESPAÑOLA DE
ENFERMEDADES DIGESTIVAS
The Spanish Journal of Gastroenterology

Authors' contributions: RS designed and performed the study and wrote the manuscript; HN, YY, KH, KK, SA, SM, KS, MH and RK collected and analyzed the data; NS interpreted the data and contributed writing the manuscript; all authors approved the final manuscript.

ABSTRACT

Background: endoscopic retrograde cholangiopancreatography (ERCP) is a first-line procedure for biliary drainage in patients with acute cholangitis, and there are no studies focused on very urgent ERCP within several hours of hospital arrival. This study aimed to elucidate the use of very urgent ERCP for non-severe acute cholangitis.

Methods: this retrospective observational study included patients with non-severe acute cholangitis who underwent ERCP between April 2011 and June 2020 in our institution. Patients were stratified into three groups based on time to ERCP after hospital arrival: very urgent (≤ 3 hours), urgent (3-24 hours) and elective (> 24 hours). The primary outcome was length of hospital stay (LOS).

Results: the study cohort included 291 patients, 168 males (57.7 %), with a median age of 76 (interquartile range, 70-83) years. In all, 47, 196 and 48 patients underwent very urgent, urgent and elective ERCP, respectively. Median LOS in the very urgent, urgent, and elective groups was 12, 14, and 15 days, respectively (Kaplan-Meier method). A shorter LOS was associated with earlier ERCP (log-rank trend test, $p = 0.04$). The rates of readmission within 30 days of discharge and of adverse events were not significantly different among the three groups. By multivariate analysis, very urgent ERCP was associated with a significantly earlier discharge than urgent and elective ERCP (HR, 0.71, $p = 0.04$ and HR, 0.47, $p < 0.01$, respectively). In addition, age ≥ 75 years, pancreatitis, albumin ≤ 2.8 g/dL and two or more ERCP procedures were associated with a significantly longer LOS (HRs < 1, $p < 0.05$).

Conclusions: very urgent ERCP for non-severe acute cholangitis was associated with early discharge.

Keywords: Acute cholangitis. Endoscopic retrograde cholangiopancreatography.

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Length of stay. Non-severe cholangitis. Urgent procedure.

INTRODUCTION

Acute cholangitis (AC) is an acute-onset bacterial infection of the biliary tract arising from bile duct obstruction. Patients without emergency drainage occasionally have septicemia and organ failure (1,2). Currently, endoscopic retrograde cholangiopancreatography (ERCP) is performed as a first-line procedure for biliary drainage in patients with AC (3). The 2018 Tokyo guidelines (TG18) recommend stratification of patients into three grades (mild, moderate and severe) based on the presence of specific criteria for severity (4). The guidelines also recommend urgent biliary drainage for patients with severe AC (5). However, the use and efficacy of urgent biliary drainage in patients with non-severe AC remains to be determined.

Few studies have focused on urgent ERCP performed within 12-48 hours after hospital arrival in patients with non-severe AC (6-9). However, very urgent ERCP performed within several hours following hospital arrival is also considered in clinical practice, and no study has investigated the use of very urgent ERCP in patients with non-severe AC.

The aim of the present study was to elucidate the use of very urgent ERCP as performed within ≤ 3 hours after hospital arrival for non-severe AC, by comparing with ERCP as performed > 3 hours after hospital arrival.

PATIENTS AND METHODS

In this retrospective, observational cohort study performed at the Hakodate Municipal Hospital in Hokkaido, Japan, the hospital database was searched to identify consecutive patients who underwent ERCP for a diagnosis of AC between April 2011 and June 2020. In the present study, only the first hospital admission and ERCP procedure were included for patients readmitted with AC during the study period.

The exclusion criteria were the following: 1) transfer from/to a different hospital; 2) percutaneous transhepatic biliary/gallbladder drainage tube left in situ; 3) failure of endoscopic biliary drainage during the initial ERCP; 4) subsequent procedures such as

surgery or chemotherapy; 5) subsequent treatment for other diseases such as cardiopulmonary disease or neurological disease; 6) severe AC according to the TG18 (4); and 7) refusal to enroll in the study by the patient or their family.

The Institutional Review Board approved this study (2020-54). Informed consent to participate in the study was obtained from the patients or their families using an opt-out form.

Endoscopic procedures

ERCP was performed under conscious sedation with a therapeutic duodenoscope (TJF-240, JF-260V or TJF-290V; Olympus Medical Systems, Tokyo, Japan). A balloon-assisted endoscope (EC-450BI5 or EI-580BT; FUJIFILM Medical, Tokyo, Japan) was used in patients with a surgically altered upper gastrointestinal anatomy. After bile duct cannulation, bile was obtained for culture and a cholangiogram was performed through a catheter. A 5-Fr, 6-Fr, or7-Fr nasobiliary drainage tube, or a 7-Fr or 8.5-Fr plastic stent was placed at the endoscopist's discretion. In patients with AC, single-stage stone removal could be selected due to choledocholithiasis (10).

Antimicrobial therapies

Patients were treated with intravenous antimicrobial treatment during 7 days based on guideline recommendations (11-13), regardless of a positive bile or blood culture. Antimicrobial agents were selected referencing the antibiogram in the institution and previous guidelines (12,13) and was changed to a new appropriate one according to the antibiotic sensitivity if the bile or blood culture was positive.

Definitions

Time to ERCP was defined as the time from patient arrival at the hospital to initiation of ERCP. The study cohort was stratified into three groups based on the time to ERCP: very urgent (≤ 3 hours), urgent (3-24 hours) and elective (> 24 hours).

AC was diagnosed and graded according to the TG18 (4) at the time of arrival. Only patients fulfilling either the definite diagnostic criteria or the suspicious diagnostic criteria were included in the analysis. Leukopenia due to chemotherapy or underlying

diseases such as leukemia or liver cirrhosis, renal dysfunction due to chronic renal failure, and prolonged prothrombin time due to liver cirrhosis or anticoagulation therapy were excluded from the criteria used to assess the severity of AC.

Adverse events following the initial ERCP were assessed according to the severity grading system of the American Society for Gastrointestinal Endoscopy lexicon (14). The present study included the analysis of adverse events until 14 days after the initial ERCP or until additional ERCP, whichever occurred first.

Outcome measures

The primary outcome was length of hospital stay (LOS). The secondary outcomes were in-hospital mortality, admission to intensive care unit, readmission within 30 days of discharge, number of ERCP procedures, and adverse events following the initial ERCP. The predictive factors for LOS were also evaluated by multivariate analysis.

Statistical analysis

Statistical analyses were performed using the free statistical software EZR (15). Data were presented as the median (interquartile range) for nonparametric variables and as percentages for categorical variables. LOS was estimated using the Kaplan-Meier method. The log-rank trend test was performed to examine changes in LOS in relation to the time to ERCP. Categorical variables were compared using Fisher's exact test. The Kruskal-Wallis test was used to compare median values among groups. Predictive factors for LOS were analyzed using a Cox proportional hazards model. Factors with a p-value of < 0.20 in the univariate analysis were included in the multivariate analysis. A Hazard Ratio (HR) < 1 suggested a decreased risk of discharge, which in turn implied a longer LOS. Differences with a p-value < 0.05 were considered statistically significant.

RESULTS

During the study period, 291 patients who fulfilled the study criteria were included in the final analyses (Fig. 1). Of the 291 patients, ERCP was performed within three hours after hospital arrival in 47 patients (very urgent group), 3-24 hours after hospital arrival in 196 patients (urgent group), and more than 24 hours after hospital arrival in 48

patients (elective group).

Baseline characteristics

The baseline characteristics of the patients are shown in table 1. Patients with right hypochondriac pain, higher body temperature, faster heart rate, higher white blood cell (WBC) count, higher total bilirubin (T-BIL) level, and lower creatinine level were more likely to undergo ERCP in the early phase. Conversely, patients who were admitted to hospital during the daytime were likely to undergo elective ERCP. Most patients with a surgically altered upper gastrointestinal anatomy underwent elective ERCP.

Primary outcome

The median LOS of the entire cohort was 13 days (95 % confidence interval, 12-14 days). The median LOS in the very urgent, urgent and elective groups was 12, 14 and 15 days, respectively (Fig. 2). The LOS was shorter in patients who underwent ERCP earlier following arrival at the hospital (log-rank trend test, $p = 0.04$).

Secondary outcomes

Clinical outcomes

There were no in-hospital deaths and no patient was admitted to the intensive care unit (Table 2). The readmission rates within 30 days of discharge and the adverse event rates following the initial ERCP were not significantly different among the three groups ($p > 0.05$). The very urgent, urgent and elective groups underwent a median of 2, 2 and 1 ERCP procedures, respectively, which was significantly different among the three groups ($p < 0.01$).

Bile duct stone caused the majority of AC (n = 217, 74.6 %). Of these, the execution rates of single-stage stone removal in the very urgent, urgent and elective groups were 21.1 % (8/38), 31.1 % (46/148) and 51.6 % (16/31), respectively, which was significantly different among the three groups ($p = 0.03$).

Bile culture was obtained in 244 patients (83.8 %). Of these, 187 patients (76.6 %) had a positive bile culture. In addition, a blood culture was obtained for 119 patients

(40.9 %). Of these, 45 patients (37.8 %) had a positive blood culture.

Predictive factors for LOS

The univariate analysis of patient characteristics and clinical outcomes to evaluate predictive factors for LOS showed that age, acute pancreatitis, chemotherapy and number of ERCP were significant predictive factors for LOS ($p < 0.05$). In addition, acute cholecystitis, time to ERCP, gastrointestinal tract reconstruction, antibiotic use, C-reactive protein, T-BIL, and albumin were potential predictive factors for LOS ($p < 0.20$). The multivariate analysis (Table 3) showed that, compared with the very urgent group, the HRs were significantly lower in the urgent (HR, 0.71, $p = 0.04$) and elective (HR, 0.47, $p < 0.01$) groups, indicating that the patients who underwent very urgent ERCP were discharged significantly earlier than those who underwent urgent or elective ERCP. In addition, the multivariate analysis indicated that age ≥ 75 years, acute pancreatitis, serum albumin ≤ 2.8 g/dL, and two or more ERCP procedures were associated with significantly longer LOS (HRs < 1, $p < 0.05$).

DISCUSSION

The results of the present study showed that the LOS was shorter in patients with non-severe AC who underwent ERCP earlier. Although most patients with non-severe AC might be controlled with antibiotics, early biliary decompression is effective in improving AC in the early stage. A shorter LOS is associated with lower medical costs and prevention of a decline in activities of daily living, especially in elderly patients. If specialized staff and the examination room are secured, very urgent ERCP should be considered, particularly during the daytime on weekdays.

No study has focused on very urgent ERCP for AC regardless of its severity, and few studies have focused on urgent ERCP for non-severe AC (6-9). A previous study showed that the average LOS was significantly shorter in patients undergoing urgent ERCP (≤ 24 hours) than in those undergoing elective ERCP (> 24 hours) (6.8 vs. 9.2 days, $p < 0.01$) (6). In contrast, another study failed to show the advantage of urgent ERCP (≤ 12 hours) for non-severe AC in shortening LOS (7). However, the number of ERCP procedures was not included as a factor in the study analysis, which might explain the

different findings between the studies, because we demonstrated the significant association between the number of ERCP and LOS in the present study. Meanwhile, a systematic review, meta-analysis and nationwide analysis revealed that the mortality rates were lower in patients with non-severe AC who underwent ERCP within 48 hours compared to those who underwent ERCP beyond the first 48 hours (8,9). In the present study, there was no in-hospital death which might be associated with early ERCP performed within 24 hours in most patients (n = 243, 83.5 %). Therefore, the results of the present study, together with previous studies, indicated that early ERCP within the first 24 hours, in particular for very urgent ERCP, should be considered for the management of patients with non-severe AC.

In the present study, patients in the very urgent and urgent groups underwent more ERCP procedures than those in the elective group. The first reason for this could be due to difference in rates of single-stage stone removal among the groups. In addition, the present study also included patients taking antithrombotic drugs and these patients had to undergo biliary drainage alone in the initial ERCP, especially in very urgent and urgent ERCP due to drug holiday. Meanwhile, there was a possibility that an earlier ERCP procedure caused longer LOS due to multiple ERCP procedures. However, as a result, earlier ERCP was associated with earlier discharge. Although various factors affected LOS, the results of the present study indicated that time to ERCP would have more influence on LOS than the number of the ERCP procedures.

LOS in the preset study was longer than a previous study (mean LOS, 6.8-9.2 days) (6). The difference might be caused by the difference in baseline characteristics. The previous study included only patients with AC due to choledocholithiasis and relatively young patients (mean age, 64.6-66.3 years). On the other hand, LOS of other previous studies (median LOS, 11 days (7) and mean LOS, 10.8-12.3 days (16)), which included patients with non-severe AC due to various etiologies and relatively elderly patients, were similar to our study.

In the present study, we evaluated the criteria for moderate AC according to the TG18 (WBC count > 12,000 cells/μL; body temperature ≥ 39.0 °C; age ≥ 75 years; T-BIL ≥ 5 mg/dL; albumin ≤ 2.8 g/dL) (4) and found that age ≥ 75 years and serum albumin ≤ 2.8 g/dL were independent predictive factors for LOS. One study previously showed that a

WBC count > 20,000 cells/µL and serum T-BIL ≥ 10 mg/dL were independent prognostic factors for death or organ failure (17). However, our univariate analysis indicated that a WBC count > 20,000 cells/µL and serum T-BIL ≥ 10 mg/dL were not predictive factors for LOS (HR, 0.79, p = 0.44 and HR, 0.69, p = 0.30, respectively) (data not shown). The parameters included in the analyses of the present study were limited to those obtained after the arrival of the patients at the hospital. However, the patient parameters occasionally fluctuate after the initial diagnosis. Further studies are warranted to evaluate predictive factors for LOS, including patient parameters after hospital admission.

Previous studies for non-severe AC showed that the adverse event rates did not differ between the urgent and elective groups (14.6 % and 9.8 %, respectively, p = 0.40 (6) and 8.5 % and 7.1 %, respectively, p = 0.82 (7)) and the rates of adverse events in the present study groups were similar to these reported rates. Altogether, these results indicated that very urgent ERCP was a safe procedure, similar to urgent and elective ERCP.

There are several limitations in the present study. First, this was a single-center retrospective study with a relatively small sample size. Additionally, the ERCP method and patient management during hospitalization were based on the discretion of the endoscopist performing the procedure. In conclusion, very urgent ERCP for non-severe AC is a safe procedure, similar to urgent and elective ERCP and is associated with early discharge.

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Table 1. Baseline characteristics

	Very urgent (n = 47)	**Urgent (n = 196)**	**Elective (n = 48)**	**p-value**
Age, median (IQR), years				
74 (67-84)	77 (71–83)	75 (66-82)	0.38	
Male gender, n (%)	25 (53.2)	112 (57.1)	31 (64.6)	0.51
American Society of Anesthesiologists score, n (%)				0.67
1	5 (10.6)	22 (11.2)	3 (6.3)	
2	35 (74.5)	137 (69.9)	39 (81.2)	
3	7 (14.9)	37 (18.9)	6 (12.5)	
Charlson comorbidity index score, n (%)				0.29

0	11 (23.4)	66 (33.7)	14 (29.2)	
1	14 (29.8)	39 (19.9)	15 (31.2)	
≥ 2	22 (46.8)	91 (51.2)	19 (39.6)	
Concomitant disease, n (%)				
Acute pancreatitis	6 (12.8)	36 (18.4)	4 (8.3)	0.21
Acute cholecystitis	5 (10.6)	16 (8.2)	4 (8.3)	0.82
Liver abscess	0	8 (4.1)	1 (2.1)	0.59
Time of admission, n (%)				0.03
Daytime	23 (48.9)	114 (58.2)	36 (75.0)	
Nighttime	24 (51.1)	82 (41.8)	12 (25.0)	
Type of admission day, n (%)				0.76
Weekday	33 (70.2)	147 (75.0)	35 (72.9)	
Weekend	14 (29.8)	49 (25.0)	13 (27.1)	
Etiology, n (%)				0.07
Bile duct stone	38 (80.9)	148 (75.5)	31 (64.6)	
Stent occlusion	5 (10.6)	34 (17.4)	7 (14.6)	
Others	4 (8.5)	14 (7.1)	10 (20.8)	
History of gastrointestinal tract reconstruction, n (%)				
	0	3 (1.5)	4 (8.3)	0.03
Presence of malignant biliary obstruction, n (%)				
	9 (19.1)	38 (19.4)	10 (20.8)	0.98
Chemotherapy, n (%)	3 (6.4)	20 (10.2)	7 (14.6)	0.43
Antibiotics, n (%)	44 (93.6)	191 (97.4)	46 (95.8)	0.26
Severity of acute cholangitis, n (%)				0.05
Mild	27 (57.4)	110 (56.1)	36 (75.0)	
Moderate	20 (42.6)	86 (43.9)	12 (25.0)	
Presence of right hypochondriac pain, n (%)				
	25 (53.2)	113 (57.7)	18 (37.5)	0.04
Vital parameters, median (IQR)				
Body temperature, °C	37.5 (36.6-38.5)	37.4 (36.6-38.2)	36.8 (36.3-37.5)	< 0.01
Systolic BP, mmHg	142 (115-166)	132 (119-154)	130 (116-146)	0.28
Heart rate, bpm	88 (74-102)	85 (73-98)	78 (67-92)	0.02
Saturation, %	96 (95-98)	97 (95-98)	97 (96-98)	0.07
Laboratory data, median (IQR)				
WBC, $10^4/\mu L$	10.9 (8.2-14.5)	11.0 (8.5-4.2)	8.6 (5.5-12.2)	< 0.01
C-reactive protein, mg/dL	5.73 (1.11-9.30)	4.96 (1.13-10.3)	5.72(1.78-9.32)	0.99
Total bilirubin, mg/dL	3.4 (2.4-4.6)	2.5 (1.6-4.3)	2.4 (1.2-3.5)	0.01
Albumin, g/dL	3.5 (3.1-3.9)	3.7 (3.3-4.0)	3.7 (3.3-4.1)	0.29
Creatinine, mg/dL		0.66(0.51-0.87)	0.79 (0.62-1.00)	0.80 (0.67-1.00) 0.04

Table 2. Clinical outcomes

REVISTA ESPAÑOLA DE
ENFERMEDADES DIGESTIVAS
The Spanish Journal of Gastroenterology

	Very urgent (n = 47)	Urgent (n = 196)	Elective (n = 48)	p-value
In-hospital mortality, n	0	0	0	Not available
Admission to ICU, n	0	0	0	Not available
Readmission within 30 days of discharge, n (%)	3 (6.4)	5 (2.6)	1 (2.1)	0.30
Adverse events following the initial ERCP, n (%)	4 (8.5)	11 (5.6)	2 (4.2)	0.66
Pancreatitis	3 (6.4)	11 (5.6)	2 (4.2)	0.86
Acute cholecystitis	1 (2.1)	0	0	0.16
Number of ERCP, median(interquartile range), n	2 (1-2)	2 (1-2)	1 (1-2)	< 0.01

REVISTA ESPAÑOLA DE
ENFERMEDADES DIGESTIVAS
The Spanish Journal of Gastroenterology

Table 3. Multivariate analysis of predictive factors for length of hospital stay

	Univariate analysis		Multivariate analysis	
	p-value	HR	95 % CI	p-value
Age	< 0.01			
< 75years	1			
≥ 75years	0.76		0.59-0.99	0.04
Acute pancreatitis	< 0.01			
Absence	1			
Presence	0.51		0.37-0.72	< 0.01
Acute cholecystitis	0.06			
Absence	1			
Presence	0.69		0.45-1.05	0.08
Time to ERCP	0.08			
Very urgent (≤ 3 hours)	1			
Urgent (3-24 hours)	0.71		0.51-0.99	0.04
Elective (> 24 hours)	0.47		0.31-0.73	< 0.01
Gastrointestinal tract reconstruction	0.11			
Absence	1			
Presence	0.52		0.24-1.16	0.11
Chemotherapy	< 0.01			
Absence	1			
Presence	1.39		0.93-2.09	0.11
Antibiotics	0.12			
Non-use	1			
Use	0.83		0.43-1.59	0.58
C-reactive protein	0.19			
< 5 mg/dL	1			
≥ 5 mg/dL	0.97		0.76-1.24	0.81
Total bilirubin	0.18			
< 5.0 mg/dL	1			
≥ 5.0 mg/dL	1.23		0.90-1.69	0.20
Albumin	0.18			
> 2.8 g/dL	1			
≤ 2.8 g/dL	0.47		0.30-0.75	< 0.01
Number of ERCP	< 0.01			
1	1			
2 or 3	0.50		0.39-0.65	< 0.01

REVISTA ESPAÑOLA DE
ENFERMEDADES DIGESTIVAS
The Spanish Journal of Gastroenterology

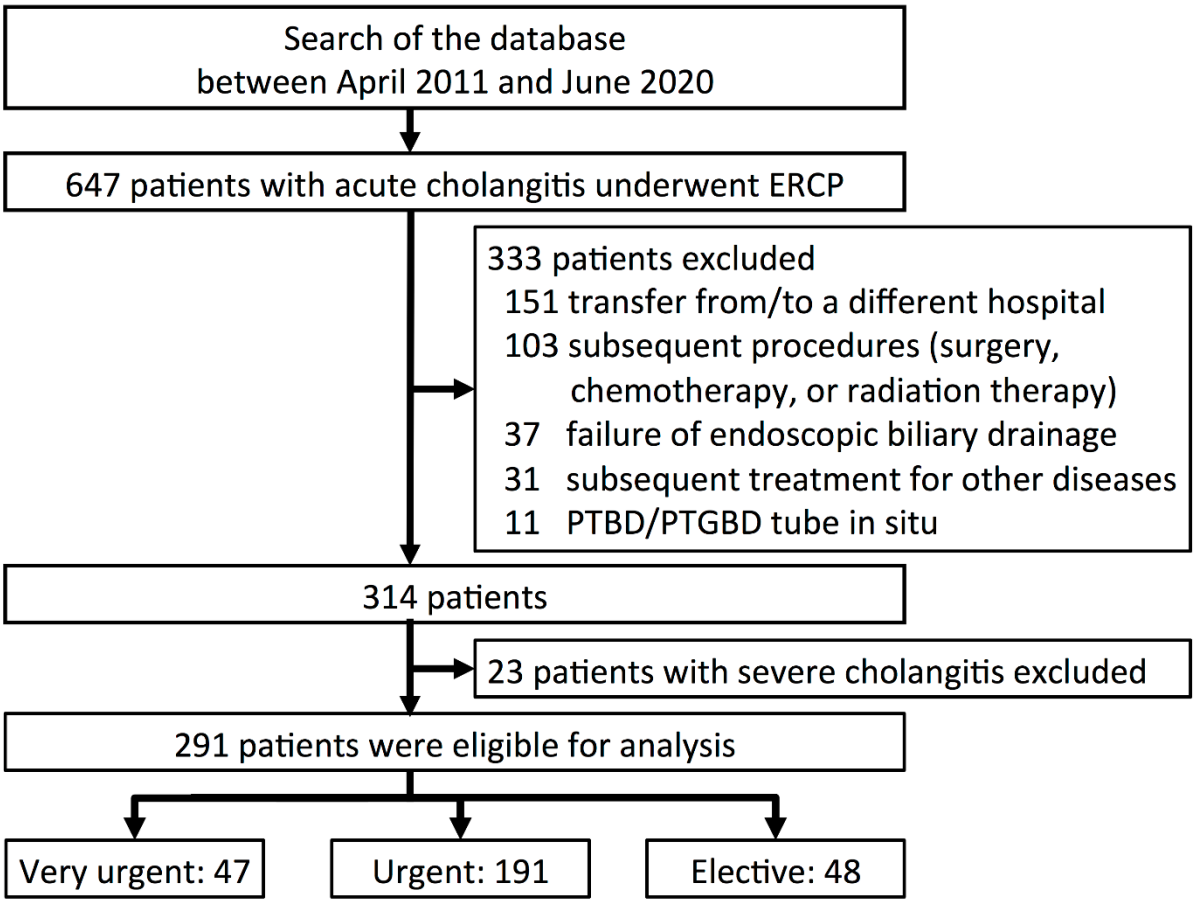
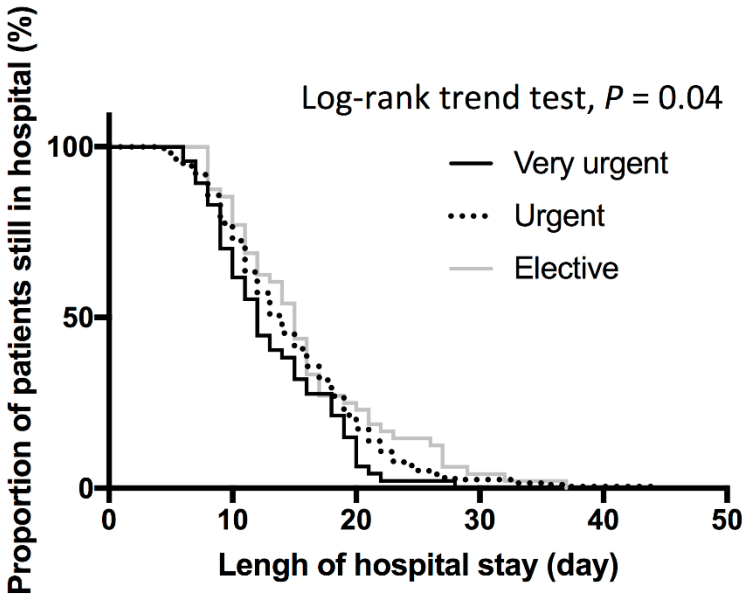


Fig. 1. Flow chart.



Number at risk					
Very urgent	47	33	7	0	0
Urgent	196	152	42	5	1
Elective	48	41	12	2	0

Fig. 2. Length of hospital stay according to the time to endoscopic retrograde cholangiopancreatography.