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# Does Timing of ERCP Matter? – A Prospective Single-Center Study

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## ABSTRACT

**Background:** *Acute cholangitis is a potentially fatal infection resulting from biliary obstruction. Early endoscopic retrograde cholangiopancreatography (ERCP) has been proposed to improve outcomes, but the optimal timing and its impact across different severity grades remain uncertain, particularly in resource-limited settings.* **Objective:** *To evaluate the effect of ERCP timing on clinical outcomes in patients with acute cholangitis stratified by Tokyo Guidelines 2018 (TG18) severity grades.* **Methods:** *This prospective observational cohort study enrolled 158 patients diagnosed with acute cholangitis at Dr. Ruth K. M. Pfau Civil Hospital Karachi. Participants were categorized as early ( $\leq 48$  hours;  $n=79$ ) or late ( $>48$  hours;  $n=79$ ) ERCP groups. Primary outcome was length of hospital stay; secondary outcomes included 30-day and in-hospital mortality, ICU admission, organ failure, and ERCP-related complications. Statistical analysis used t-tests, Chi-square, and multivariate logistic regression with  $p<0.05$  considered significant.* **Results:** *Early ERCP significantly reduced 30-day mortality (5.1% vs 15.2%,  $p=0.035$ ), hospital stay ( $5.9\pm2.1$  vs  $9.5\pm3.2$  days,  $p<0.001$ ), ICU admission (8.9% vs 22.8%,  $p=0.015$ ), and multiorgan dysfunction (12.7% vs 27.8%,  $p=0.019$ ). The mortality benefit was confined to severe TG18 grade (8.3% vs 41.7%,  $p=0.008$ ).* **Conclusion:** *ERCP within 48 hours confers substantial survival and recovery benefits, especially in severe cholangitis, supporting early biliary decompression as a critical management priority.*

## Keywords

*Acute cholangitis, ERCP timing, biliary obstruction, TG18 severity, mortality, prospective cohort study.*

## INTRODUCTION

Acute cholangitis is a life-threatening infection of the biliary tree that arises when biliary obstruction and bacterial contamination lead to ascending infection and systemic inflammatory response (1). Since Jean-Martin Charcot first described the triad of fever, right upper-quadrant pain, and jaundice in 1877, endoscopic retrograde cholangiopancreatography (ERCP) has evolved into the mainstay of both diagnosis and therapy for biliary decompression (2). Despite major advances in antibiotic therapy and critical-care support, the mortality of untreated or delayed-treated acute cholangitis can exceed 50 %, primarily because persistent obstruction precipitates sepsis and multiple-organ failure (3). Biliary drainage can be achieved endoscopically, percutaneously, or surgically, but ERCP remains the least invasive and most effective method when performed by skilled endoscopists (4). Earlier diagnostic reliance on Charcot's triad provided excellent specificity but poor sensitivity—approximately 26 %—often delaying recognition of the disease (2). To standardize assessment, an expert consensus developed the Tokyo Guidelines 2007, later updated as the Tokyo Guidelines 2018 (TG18), which introduced validated diagnostic criteria and severity grading into mild, moderate, and severe categories based on systemic inflammation, cholestasis, and imaging evidence (5). TG18 also recommends that biliary drainage be performed as soon as feasible after hemodynamic stabilization; however, it does not specify an exact time threshold, leaving clinical teams to determine “early” versus “late” intervention according to institutional capacity.

Several observational studies and meta-analyses have examined the relationship between ERCP timing and clinical outcomes, yet findings remain heterogeneous. Kiriyma et al. demonstrated that urgent or early drainage significantly improved survival among patients with moderate acute cholangitis (6). Hou et al. later reported that benefits were most pronounced when ERCP was performed within 48 hours in severe disease but diminished in milder grades (7). More recent multicenter data suggested that ERCP beyond 48 hours is associated with prolonged hospitalization, increased organ failure, and higher 30-day mortality (8, 9). Conversely, a few reports observed no difference when procedures were delayed in hemodynamically stable, mild cases, reflecting ongoing uncertainty about the threshold at which timing alters prognosis (10).

In South-Asian tertiary centers, logistical barriers such as limited endoscopy suite availability, referral delays, and late presentation frequently push interventions beyond the 48-hour window. Although one local audit documented over 5700 ERCPs in seven years at a major public hospital, no prospective Pakistani study has systematically correlated ERCP timing with outcomes stratified by TG18 severity (11). Consequently, the optimal intervention window in this setting remains undefined. This study was therefore designed to prospectively evaluate whether performing ERCP within 48 hours of emergency-department presentation confers measurable advantages in mortality, morbidity, and length of stay compared with delayed procedures among adults diagnosed with acute cholangitis. The central hypothesis posits that early ERCP is associated with lower 30-day mortality and shorter hospitalization, particularly in patients classified as having severe disease under TG18 criteria.

## MATERIAL AND METHODS

This investigation was designed as a prospective observational cohort study conducted in the Endoscopy Suite of Dr. Ruth K. M. Pfau Civil Hospital Karachi, a tertiary-care teaching hospital serving a large urban population. Data were collected over an eight-month period following institutional review board approval. The study included consecutive adult patients aged 18 to 80 years who presented to the emergency department

with clinical suspicion of acute cholangitis and subsequently underwent ERCP. Diagnosis and severity classification were established according to the Tokyo Guidelines 2018 (TG18) diagnostic framework, requiring one or more findings from each of the following domains: systemic inflammation, cholestasis, and imaging confirmation of biliary obstruction (12). Patients who underwent ERCP more than seven days after emergency presentation or whose data were incomplete were excluded to reduce bias from unrelated delays in care.

Eligible patients were approached upon admission, and informed written consent was obtained before enrollment. Recruitment followed a consecutive non-probability technique to reflect real-world case flow. For each participant, baseline demographic and clinical data—including age, sex, comorbidities, known malignancy, and prior upper-gastrointestinal or biliary interventions—were recorded at presentation. Vital signs were documented, and venous blood samples were collected for complete blood count, liver function tests, coagulation profile, C-reactive protein, serum albumin, creatinine, and electrolytes. Radiologic assessment using abdominal ultrasonography or cross-sectional imaging (CT or MRCP) identified biliary dilation, level of obstruction, and underlying etiology. Disease severity was graded as mild, moderate, or severe in accordance with TG18 parameters. To minimize misclassification bias, two experienced gastroenterologists independently assigned severity grades, resolving discrepancies by consensus.

ERCP was performed under conscious sedation using nalbuphine and midazolam, with propofol added if required under anesthetist supervision. Olympus therapeutic duodenoscopes were employed for all procedures. Cannulation of the ampulla of Vater was achieved using guidewire technique, followed by cholangiography with water-soluble contrast (diatrizoate). Once obstruction was visualized, sphincterotomy and balloon sweep were performed for choledocholithiasis, while stent placement was undertaken for strictures or malignant causes according to the endoscopist's discretion. The interval between emergency-department triage and initial cannulation attempt defined the "time to ERCP." Patients undergoing the procedure within 48 hours were categorized as the early group, and those treated after 48 hours constituted the late group. Standard antimicrobial therapy was initiated at diagnosis and continued post-procedure following institutional protocol.

The primary outcome was length of hospital stay, while secondary outcomes included in-hospital and 30-day mortality, intensive-care-unit admission, need for mechanical ventilation, occurrence of multiple-organ dysfunction syndrome, procedural success, and ERCP-related complications. All patients were followed until discharge, and survival status at 30 days was verified via inpatient records or telephonic followup. The required sample size was estimated using ClinCalc based on mean hospital stay from a previous national cohort, assuming means of  $6.9 \pm 3.1$  days and  $4.5 \pm 2.0$  days in late and early groups respectively,  $\alpha = 0.05$ , and power = 80 %, yielding 158 participants (79 per group) (13). Data integrity was ensured through double entry and periodic audit of 10 % of records.

Statistical analyses were performed using SPSS version 20. Continuous variables were tested for normality using the Shapiro–Wilk test. Normally distributed data were expressed as mean  $\pm$  standard deviation and compared using independent-sample t-tests; non-normal variables were reported as median with interquartile range and analyzed by the Mann–Whitney U test. Categorical variables were summarized as frequencies and percentages and assessed by Chi-square or Fisher's exact test where appropriate. Logistic regression was applied to identify independent predictors of 30-day mortality. Covariates included ERCP timing, TG18 severity grade, age  $\geq 75$  years, presence of malignancy, renal dysfunction, vasoactive drug requirement, and incomplete biliary drainage. Model diagnostics were assessed by Hosmer–Lemeshow goodness-of-fit and area under the receiver-operating-characteristic curve. A p-value  $< 0.05$  was considered statistically significant at 95 % confidence interval.

Ethical approval was obtained from the Institutional Review Board of Dr. Ruth K. M. Pfau Civil Hospital Karachi. All procedures conformed to the Declaration of Helsinki principles. Participant confidentiality was preserved by de-identifying datasets and restricting access to authorized investigators only.

## RESULTS

A total of 158 patients fulfilling TG18 diagnostic criteria for acute cholangitis were prospectively enrolled, with 79 undergoing ERCP within 48 hours (early group) and 79 after 48 hours (late group). The mean age of participants was  $65.3 \pm 11.1$  years, and 81 (51.3%) were female. The two groups were comparable in gender distribution ( $p = 0.620$ ), though patients in the late group were significantly older ( $68.1 \pm 10.5$  vs  $62.5 \pm 11.2$  years,  $p = 0.003$ ) and had a higher proportion of individuals aged  $\geq 75$  years (27.8% vs 12.7%,  $p = 0.019$ ). Malignancy was more prevalent among late ERCP cases (24.1% vs 10.1%,  $p = 0.021$ ). Laboratory findings demonstrated significantly higher total bilirubin levels in the late group (median 8.9 [IQR 4.5–15.2] mg/dL) compared with the early group (4.8 [IQR 2.1–8.5] mg/dL,  $p = 0.001$ ). Hypoalbuminemia ( $\leq 2.5$  g/dL) was also more frequent in the late cohort (51.9% vs 31.6%,  $p = 0.010$ ). Severe (Grade III) acute cholangitis occurred in 24 patients (30.4%) undergoing delayed ERCP compared with 12 (15.2%) in the early group ( $p = 0.027$ ). Etiologic analysis revealed choledocholithiasis in 69.6% of early cases versus 50.6% of late cases ( $p = 0.015$ ), while malignant obstruction was significantly higher among delayed procedures (24.1% vs 10.1%,  $p = 0.021$ ). These baseline and diagnostic characteristics are summarized in Table 1.

**Table 1. Baseline Characteristics and Diagnosis Comparison (Early vs. Late ERCP)**

Variable	Early ERCP ( $\leq 48$ h) (n=79)	Late ERCP ( $>48$ h) (n=79)	p-value
<b>Age (years), Mean <math>\pm</math> SD</b>	$62.5 \pm 11.2$	$68.1 \pm 10.5$	0.003
<b>Female Gender, n (%)</b>	39 (49.4)	42 (53.2)	0.620
<b>Age <math>\geq 75</math> years, n (%)</b>	10 (12.7)	22 (27.8)	0.019
<b>Known Malignancy, n (%)</b>	8 (10.1)	19 (24.1)	0.021
<b>Previous ERCP, n (%)</b>	15 (19.0)	18 (22.8)	0.575
<b>Grade III (Severe) AC, n (%)</b>	12 (15.2)	24 (30.4)	0.027
<b>Total Bilirubin (mg/dL), Median (IQR)</b>	4.8 (2.1–8.5)	8.9 (4.5–15.2)	0.001
<b>WBC Count (/mm<sup>3</sup>), Mean <math>\pm</math> SD</b>	$13.5 \pm 3.1$	$12.8 \pm 4.2$	0.210
<b>Hypoalbuminemia (<math>\leq 2.5</math> g/dL), n (%)</b>	25 (31.6)	41 (51.9)	0.010
<b>Choledocholithiasis, n (%)</b>	55 (69.6)	40 (50.6)	0.015
<b>Malignant Obstruction, n (%)</b>	8 (10.1)	19 (24.1)	0.021

The primary and secondary outcome measures are presented in Table 2. Early ERCP was associated with a markedly shorter mean hospital stay ( $5.9 \pm 2.1$  vs  $9.5 \pm 3.2$  days;  $p < 0.001$ ) and lower 30-day mortality (5.1% vs 15.2%;  $p = 0.035$ ). In-hospital mortality also favored the early group

(3.8% vs 12.7%;  $p = 0.048$ ). Rates of intensive-care-unit admission (8.9% vs 22.8%;  $p = 0.015$ ) and multiple-organ dysfunction syndrome (12.7% vs 27.8%;  $p = 0.019$ ) were significantly higher in delayed procedures. Although mechanical ventilation tended to be more frequent in the late group (13.9% vs 5.1%), this difference did not reach statistical significance ( $p = 0.080$ ). ERCP procedural success remained high and comparable between groups (97.5% vs 93.7%,  $p = 0.200$ ), with no increase in procedure-related complications (7.6% vs 10.1%,  $p = 0.600$ ).

**Table 2. Comparison of Primary and Secondary Outcomes (Early vs. Late ERCP)**

Outcome Measure	Early ERCP ( $\leq 48$ h) (n=79)	Late ERCP ( $>48$ h) (n=79)	p-value
<b>30-day Mortality, n (%)</b>	4 (5.1)	12 (15.2)	0.035
<b>Length of Stay (days), Mean <math>\pm</math> SD</b>	$5.9 \pm 2.1$	$9.5 \pm 3.2$	<0.001
<b>In-hospital Mortality, n (%)</b>	3 (3.8)	10 (12.7)	0.048
<b>ICU Admission, n (%)</b>	7 (8.9)	18 (22.8)	0.015
<b>Mechanical Ventilation, n (%)</b>	4 (5.1)	11 (13.9)	0.080
<b>Organ Failure (MODS), n (%)</b>	10 (12.7)	22 (27.8)	0.019
<b>ERCP Success Rate, n (%)</b>	77 (97.5)	74 (93.7)	0.200
<b>ERCP-related Complications, n (%)</b>	6 (7.6)	8 (10.1)	0.600

Subgroup analysis according to TG18 severity is shown in Table 3. Among patients with mild or moderate cholangitis (n = 122), 30-day mortality did not differ significantly between early and late ERCP (2.5% vs 1.6%,  $p = 0.720$ ). In contrast, among those with severe (Grade III) cholangitis (n = 36), early ERCP was strongly associated with improved survival, with mortality of 8.3% compared to 41.7% when delayed ( $p = 0.008$ ).

**Table 3. Stratified 30-Day Mortality by AC Severity and ERCP Timing**

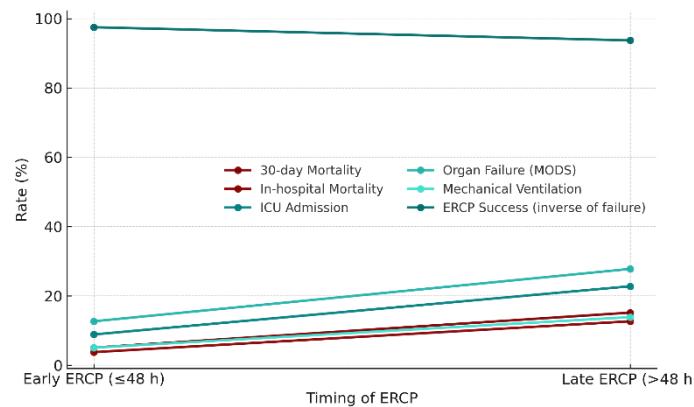
AC Severity (TG18)	Early ERCP ( $\leq 48$ h)	Late ERCP ( $>48$ h)	p-value
<b>Grade I/II (Mild/Moderate, n=122)</b>	3 deaths (2.5%)	2 deaths (1.6%)	0.720
<b>Grade III (Severe, n=36)</b>	1 death (8.3%)	10 deaths (41.7%)	0.008

Predictors of 30-day mortality were analyzed using univariate and multivariate logistic regression (Table 4). On univariate analysis, delayed ERCP ( $>48$  h) increased odds of mortality 3.33-fold (95% CI 1.05–10.58,  $p = 0.041$ ). After multivariate adjustment for potential confounders, late ERCP remained an independent predictor (OR 2.55, 95% CI 1.10–5.91,  $p = 0.030$ ), together with TG18 Grade III disease (OR 8.80, 95% CI 2.75–28.10,  $p < 0.001$ ) and requirement for vasoactive drugs (OR 3.50, 95% CI 1.25–9.80,  $p = 0.017$ ). Advanced age and malignancy, although significant in univariate models, lost significance after adjustment. Renal dysfunction and incomplete biliary drainage trended toward higher mortality but were not statistically significant in multivariate analysis.

**Table 4. Univariate and Multivariate Logistic Regression for Predictors of 30-Day Mortality**

Variable	Univariate OR (95% CI)	p-value	Multivariate OR (95% CI)	p-value
<b>Late vs. Early ERCP</b>	3.33 (1.05–10.58)	0.041	2.55 (1.10–5.91)	0.030
<b>Grade III vs. Grade I/II AC</b>	19.40 (6.35–59.20)	<0.001	8.80 (2.75–28.10)	<0.001
<b>Age <math>\geq 75</math> years</b>	2.60 (1.15–5.88)	0.021	1.20 (0.45–3.20)	0.720
<b>Known Malignancy</b>	2.44 (1.00–5.95)	0.049	1.15 (0.40–3.30)	0.790
<b>Need for Vasoactive Drugs</b>	6.90 (2.50–19.00)	<0.001	3.50 (1.25–9.80)	0.017
<b>Renal Dysfunction (<math>\uparrow</math>Creatinine)</b>	4.20 (1.80–9.80)	0.001	1.85 (0.70–4.90)	0.210
<b>Incomplete Biliary Drainage</b>	5.50 (1.50–20.10)	0.010	3.10 (0.80–12.00)	0.100

Collectively, these findings indicate that early ERCP within 48 hours is associated with significantly improved short-term outcomes in acute cholangitis, particularly in patients with severe disease. Delayed procedures were linked with prolonged hospitalization, higher risk of multiorgan dysfunction, and increased mortality even after adjustment for confounding clinical factors.



**Figure 1 Overlapping Outcomes Curves by ERCP Timing**

Mortality lines (maroon) rise steeply with delay—30-day mortality increases from 5.1% → 15.2% and in-hospital mortality from 3.8% → 12.7%. Teal covariate curves show parallel adverse shifts with late ERCP: ICU admission 8.9% → 22.8%, MODS 12.7% → 27.8%, and mechanical

ventilation 5.1% → 13.9%. The deep-teal success line moves modestly downward 97.5% → 93.7%, indicating procedure efficacy remains high but overall clinical outcomes worsen when ERCP is delayed.

## DISCUSSION

The present prospective cohort study demonstrates that the timing of ERCP plays a decisive role in determining short-term outcomes among patients admitted with acute cholangitis. The data show that performing ERCP within 48 hours of emergency department presentation significantly reduced both 30-day and in-hospital mortality, shortened hospital stay, and lowered rates of ICU admission and multiorgan dysfunction compared with delayed intervention. Importantly, the survival benefit of early biliary drainage was most pronounced in patients classified as having severe cholangitis under TG18, while the mortality difference in mild or moderate cases remained nonsignificant. These findings suggest that the prognostic influence of ERCP timing is not uniform across disease severity but interacts strongly with the systemic burden of infection and organ dysfunction.

This pattern aligns with prior international literature emphasizing the critical role of early biliary decompression. A meta-analysis by Iqbal *et al.* reported that emergent ERCP performed within 48 hours was associated with lower in-hospital mortality and reduced organ failure compared with later procedures (14). Similarly, Mulki *et al.* analyzed a large national dataset and found that ERCP beyond 48 hours was independently linked to higher mortality and prolonged hospitalization (15). Hou *et al.* highlighted that the advantage of early ERCP was most evident among patients with grade III disease, a trend precisely mirrored in the current cohort (16). Huang *et al.* further confirmed that in severe cholangitis, early intervention significantly improved survival, whereas in milder grades, the timing exerted minimal impact (17). Together, these data consolidate the clinical recommendation that early endoscopic drainage within 24–48 hours should be prioritized, particularly in patients with severe presentation.

The pathophysiological explanation for these outcomes lies in the interplay between biliary obstruction and systemic inflammation. Prolonged obstruction facilitates continuous bacterial translocation and cytokine release, perpetuating a cycle of cholestasis-induced sepsis that rapidly evolves into multiple-organ failure. Early ERCP interrupts this cascade by decompressing the biliary system, thereby reducing biliary pressure, restoring bile flow, and enabling rapid infection control. The finding that mortality did not differ significantly between early and late ERCP in mild or moderate cases likely reflects their better physiological reserve, more localized infection, and responsiveness to antibiotic therapy before decompression.

In contrast, the subgroup of patients with severe cholangitis represents a distinct clinical trajectory where delays beyond 48 hours allow irreversible organ dysfunction to progress despite antimicrobial therapy. The adjusted analysis in the present study revealed that late ERCP increased the odds of 30-day mortality more than twofold even after controlling for confounders, emphasizing that timely biliary drainage is an independent determinant of survival. The persistence of disease severity and vasoactive drug use as independent predictors further underscores that hemodynamic instability and systemic compromise magnify the mortality risk of procedural delay.

An additional noteworthy observation is that procedural success and complication rates did not differ significantly between early and late groups, supporting the procedural safety of early intervention. These findings are consistent with previous multicenter evidence indicating that urgent ERCP, when performed by experienced teams, does not increase the risk of post-ERCP pancreatitis or bleeding but markedly improves overall clinical recovery (18). From a systems perspective, this reinforces the importance of allocating resources to ensure around-the-clock endoscopic coverage in tertiary centers.

Despite these strengths, the study's observational nature warrants cautious interpretation. While the timing of ERCP was associated with outcomes, causal inference remains limited by potential confounding due to case selection and hemodynamic stability at presentation. Patients receiving delayed ERCP were older and more likely to have malignancy or advanced cholangitis, factors that may partly explain their worse prognosis. Nevertheless, the robustness of the multivariate model and consistency with international evidence strengthen the reliability of these conclusions. In a resource-constrained healthcare environment, these results have direct implications for policy and clinical prioritization. Establishing structured triage pathways guided by TG18 grading could ensure early referral of severe cases for prompt ERCP. The evidence from this cohort suggests that achieving ERCP within 48 hours should be considered a critical quality indicator for the management of acute cholangitis in tertiary hospitals. Future multicenter randomized or quasi-experimental studies could further delineate the causal relationship between procedural timing, severity stratification, and long-term outcomes.

## CONCLUSION

The findings of this prospective cohort study establish that the timing of ERCP is a key determinant of clinical outcomes in acute cholangitis. Early ERCP performed within 48 hours of presentation was associated with significantly lower mortality, reduced ICU admission, decreased multiorgan dysfunction, and shorter hospitalization compared with delayed procedures, with the greatest survival advantage observed in patients with severe disease according to TG18 criteria. These results corroborate international evidence underscoring the importance of timely biliary decompression in optimizing prognosis while confirming the safety and feasibility of early intervention in a tertiary-care setting. Incorporating structured triage systems to expedite ERCP for high-severity cases could meaningfully improve patient outcomes and serve as a benchmark for quality of care in biliary sepsis management.

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