

## OUTCOME OF EARLY VS DELAYED CHOLECYSTECTOMY AMONG PATIENTS PRESENTED WITH MILD ACUTE BILIARY PANCREATITIS IN A TERTIARY CARE HOSPITAL

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### Abstract

**Background and Objective:** The optimal timing for cholecystectomy in mild acute biliary pancreatitis (ABP) remains debated. This study aimed to compare the outcomes of early cholecystectomy (within 7 days of presentation) versus delayed cholecystectomy (at 4 weeks) in terms of recurrent biliary events and persistent choledocholithiasis.

**Methods:** This randomized clinical trial was conducted at the Department of General Surgery, Fauji Foundation Hospital, Rawalpindi. A total of 170 patients with mild ABP were randomized into an early group (n=85) or a delayed group (n=85). The primary outcomes measured were the recurrence of biliary events and the incidence of choledocholithiasis. Data were analyzed using SPSS v25.0. Outcome were compared using chi-square tests, considering a p-value  $\leq 0.05$  as significant.

**Results:** The recurrence of biliary events was higher in the delayed group (12.9%) compared to the early group (4.7%), though this difference was not statistically significant ( $p=0.058$ ). However, the incidence of choledocholithiasis was significantly higher in the delayed group (17.6%) than in the early group (5.9%) ( $p=0.017$ ). Stratification analysis revealed that males and overweight patients in the delayed group were at a significantly higher risk of developing choledocholithiasis.

**Conclusion:** Early cholecystectomy within one week of presentation for mild ABP is associated with a significantly lower risk of persistent choledocholithiasis compared to a delayed approach. While not statistically significant, a strong trend towards reduced recurrent biliary events was also observed with early intervention. These findings advocate for early surgical management to prevent serious complications, particularly in high-risk subgroups.

## INTRODUCTION

Acute biliary pancreatitis (ABP) represents a severe and potentially life-threatening complication arising from gallstone disease, accounting for a substantial burden of morbidity and mortality [1]. Globally, it is implicated in 30-50% of all acute pancreatitis cases [2], with its prevalence being particularly pronounced in Pakistan, where gallstones are identified as the primary etiological agent in 70-80% of patients [3]. The disease pathogenesis is primarily driven by a persistent obstruction of the biliopancreatic duct, triggering a cascade of progressive pancreatic inflammation. Following an initial episode of ABP, patients remain at high risk for recurrent complications, including further attacks of pancreatitis, common bile duct obstruction, acute cholangitis, or biliary colic [4]. Consequently, for patients who survive an initial episode, cholecystectomy is considered the definitive and essential intervention to prevent disease recurrence. Without this curative surgery, the risk of subsequent, potentially more severe, attacks remains significantly high [5,6].

While early intervention carries risks such as extended operative times, perioperative bleeding, a longer postoperative hospital stay, and potential recurrence of pancreatitis [7], a strategy of delayed cholecystectomy introduces its own significant drawbacks. Principally, it elevates the risk of recurrent gallstone-related complications including pancreatitis, cholecystitis, and cholangitis within the critical 30-day period following discharge. These recurrent events often lead to hospital readmission, thereby escalating the overall economic burden of treatment. Conversely, an argument for delay posits that it allows for a more thorough diagnostic workup, facilitates the identification of the underlying cause, helps avoid unnecessary biliary exploration, and provides a critical window for the initial pancreatic inflammation to subside, potentially reducing the risk of operating on a friable, inflamed field. [8,9]. In a recent randomized clinical trial, Facundo HG and colleagues reported that persistent choledocholithiasis was higher 9% in early group as compared to another comparative study from Algeria conducted by Khiali R et al, in which persistent choledocholithiasis was 0% in delayed group and readmission rates due to biliary

events was significantly higher in delayed groups as compared to early group (12.8% VS 0%). Consequently, their research concluded that for patients with mild ABP, performing an early cholecystectomy effectively reduces the risk of recurrent biliary events and does not heighten operative difficulty or perioperative morbidity [10,11]. The central debate surrounding surgical timing hinges on optimizing both patient safety and procedural efficacy. Despite this focus, a clear consensus on the ideal timing remains elusive within the surgical community. This variation in clinical guidelines and adopted practices stems from divergent professional viewpoints and, most significantly, from a historical scarcity of robust evidence from prospective randomized controlled trials specifically designed to evaluate the timing and safety of early operative management [12]. Both early and delayed protocols for cholecystectomy are being practiced among patients with ABP; however, to the best of my knowledge, no study has done on our local population that ruled out the outcome of either protocol in terms of recurrence rate and persistent choledocholithiasis. So, the rationale of my study is to compare the outcome of early versus delayed cholecystectomy for ABP and subsequently to implement the more appropriate technique in our resource constrained setup. Employing the treatment option with better outcome would definitely reduce the overall morbidity associated with the cholecystectomy procedure among patients with ABP.

## MATERIAL AND METHODS

This study was designed as a randomized clinical trial conducted at the Department of General Surgery, Surgical Unit-II, Fauji Foundation Hospital, Rawalpindi. The study was initiated after obtaining formal approval from the Hospital Ethical Committee and was conducted over a minimum period of six months (from November 2024 to April 2025). The study sample was consisted of both male and female patients with age between 18 and 60 years, who presented with a confirmed diagnosis of mild acute biliary pancreatitis (ABP). The diagnosis was established at presentation based on clinical signs including upper abdominal pain, nausea,

vomiting, and epigastric tenderness coupled with an elevated serum amylase level exceedingly twice the upper limit of normal. A biliary etiology was confirmed via ultrasonography demonstrating gallstones and/or sludge. ABP was classified as mild if the patient met any three of the following criteria: a Ranson's score on admission of  $<3$ ; no evidence of pancreatic necrosis or peripancreatic collections on ultrasound; no persistent organ failure beyond 48 hours; clinical stability not requiring intensive care unit (ICU) admission; and the absence of concomitant acute cholangitis, defined by the classic triad of fever, jaundice, and right upper quadrant pain. Patients were excluded from participation if they had an ASA grade of IV or V, severe biliary pancreatitis, associated cholangitis, pancreatic necrosis, peripancreatic inflammation, pleural effusion, uncontrolled diabetes, a history or confirmed diagnosis of persistent choledocholithiasis, or if they were pregnant or lactating.

The sample size was calculated as 170 participants (85 per group) using the WHO sample size calculator for a hypothesis test of two population proportions, with a significance level of 5% and a test power of 80%. This calculation was based on the findings of Facundo HG [10] and Khiali R [11] that were; anticipated proportions of 9% in the early group and 0% in the delayed group for persistent choledocholithiasis respectively. Consecutive eligible patients were recruited via non-probability consecutive sampling and were subsequently randomized into two groups, 'E' (Early) and 'D' (Delayed), using a lottery method.

Patients randomized to the early cholecystectomy group (Group E) underwent the procedure within seven days of their initial presentation. Those in the delayed intervention group (Group D) underwent cholecystectomy four weeks after presentation. All surgical procedures were four-port laparoscopic cholecystectomies performed under general anesthesia by an experienced consultant surgeon, assisted by the researcher. The decision for surgery was based on the patient's clinical history and current physical condition. All patients received standardized pre-operative and post-operative care, including appropriate antibiotics, analgesics, and intravenous fluids. Biliary event recurrence was

assessed from the time of initial admission until the performed cholecystectomy and was defined as a subsequent hospital presentation requiring clinical management for biliary colic, acute cholecystitis, or recurrent ABP. Persistent choledocholithiasis was evaluated three months post-cholecystectomy via Magnetic Resonance Cholangiopancreatography (MRCP), with a positive diagnosis confirmed by the presence of filling defects within the biliary tree on thin cross-sectional T2-weighted imaging.

Data analysis was performed using SPSS Statistics version 25.0. Descriptive statistics (mean, standard deviation, frequencies, and percentages) were used to summarize continuous and categorical variables. The outcomes were compared between the two groups using the chi-square test, with a p-value of  $\leq 0.05$  deemed statistically significant. Potential effect modifiers were controlled through stratification, with a post-stratification chi-square test applied to the data.

## RESULTS

Participants in both groups have no significant difference in mean age and BMI. However, the delayed group showed a slightly longer mean symptom duration. Females predominated overall (71.2%). The early group had a higher female proportion (76.5%) than the delayed group (65.9%). Most patients were  $\leq 35$ , followed by 36–50 years. Overweight was the most frequent category (40.6%), with broadly comparable BMI distributions in both groups. Early group more often presented within  $\leq 5$  days (41.2% vs 32.9%), while the delayed group more frequently fell in the 6–10 days class (43.5% vs 34.1%). Detailed analysis of various quantitative and qualitative variables of over all study population as well as in both groups is described in table 1 and table 2.

Recurrence of biliary events was observed in 12.9% of patients in the delayed group compared to 4.7% in the early group. Although the recurrence rate was higher in the delayed group, the difference did not reach statistical significance ( $p=0.058$ ). Choledocholithiasis occurred significantly more often in the delayed group (17.6%) than in the early group (5.9%) ( $p=0.017$ ). This indicates that delaying cholecystectomy was associated with a higher risk of developing choledocholithiasis (table 3).

Stratification analysis surprisingly reflected that recurrence of biliary events was higher in the delayed group across most subgroups, but none reached statistical significance. On the other hand, among females, recurrence occurred in 14.3% of delayed cases versus 6.2% in early cases (p=0.136). Among males, recurrence was seen in 10.3% of delayed cases, while no recurrence was observed in early cases

(p=0.138). Although differences did not reach statistical significance, recurrence consistently trended higher in the delayed group across both sexes. Those presenting after >10 days (p=0.031) in the delayed group. Older patients (>50 years) also showed a strong trend (33.3% vs 9.5%, p=0.066). Detailed stratification analysis findings are illuminated in table 4 and table 5.

Table 1: Mean ± standard deviations for quantitative variables among patients of both groups

Variable	Delayed (n=85)	Early (n=85)	Total (N=170)
Age (years)	38.79 ± 11.67	37.89 ± 12.05	38.34 ± 11.83
BMI (kg/m <sup>2</sup> )	25.81 ± 3.69	26.01 ± 3.35	25.91 ± 3.52
Duration of symptoms (days)	7.47 ± 3.78	6.93 ± 4.15	7.20 ± 3.97

Table 2: Frequency and percentages for qualitative variables among patients of both groups

Variable		Delayed n (%)	Early n (%)	Total n (%)
Gender	Female	56 (65.9)	65 (76.5)	121 (71.2)
	Male	29 (34.1)	20 (23.5)	49 (28.8)
Age groups	≤35 years	34 (40.0)	38 (44.7)	72 (42.4)
	36–50 years	33 (38.8)	26 (30.6)	59 (34.7)
	>50 years	18 (21.2)	21 (24.7)	39 (22.9)
BMI group	Normal (≤25)	34 (40.0)	33 (38.8)	67 (39.4)
	Overweight (>25–29)	33 (38.8)	36 (42.4)	69 (40.6)
	Obese (>29)	18 (21.2)	16 (18.8)	34 (20.0)
Duration of symptoms	≤5 days	28 (32.9)	35 (41.2)	63 (37.1)
	6–10 days	37 (43.5)	29 (34.1)	66 (38.8)
	>10 days	20 (23.5)	21 (24.7)	41 (24.1)

Table 3: Comparison of main outcomes between both the study groups

Outcome		Delayed (n=85)	Early (n=85)	p-value
Recurrence of biliary events	Negative	74 (87.1%)	81 (95.3%)	0.058
	Positive	11 (12.9%)	4 (4.7%)	
Choledocholithiasis	Negative	70 (82.4%)	80 (94.1%)	0.017
	Positive	15 (17.6%)	5 (5.9%)	

Table 4: Comparison of recurrence of biliary events between both the study groups (stratification analysis on the basis of gender, age, BMI and duration of symptoms)

Variable		Delayed		Early		p-value
		Negative	Positive	Negative	Positive	
Gender	Female	48 (85.7)	8 (14.3)	61 (93.8)	4 (6.2)	0.136
	Male	26 (89.7)	3 (10.3)	20 (100.0)	0 (0.0)	0.138
Age group	≤35 yrs	29 (85.3)	5 (14.7)	36 (94.7)	2 (5.3)	0.177
	36–50 yrs	28 (84.8)	5 (15.2)	24 (92.3)	2 (7.7)	0.379
	>50 yrs	17 (94.4)	1 (5.6)	21 (100.0)	0 (0.0)	0.274
BMI group	Normal	27 (79.4)	7 (20.6)	30 (90.9)	3 (9.1)	0.187
	Overweight	31 (93.9)	2 (6.1)	36 (100.0)	0 (0.0)	0.134
	Obese	16 (88.9)	2 (11.1)	15 (93.8)	1 (6.3)	0.618
Duration group	≤5 days	24 (85.7)	4 (14.3)	34 (97.1)	1 (2.9)	0.095
	6–10 days	32 (86.5)	5 (13.5)	27 (93.1)	2 (6.9)	0.386
	>10 days	18 (90.0)	2 (10.0)	20 (95.2)	1 (4.8)	0.520

Table 5: Comparison of choledocholithiasis events between both the study groups (stratification analysis on the basis of gender, age, BMI and duration of symptoms)

Variable		Delayed		Early		p-value
		Negative	Positive	Negative	Positive	
Gender	Female	50 (89.3)	6 (10.7)	61 (93.8)	4 (6.2)	0.364
	Male	20 (69.0)	9 (31.0)	19 (95.0)	1 (5.0)	0.026
Age group	≤35 yrs	29 (85.3)	5 (14.7)	36 (94.7)	2 (5.3)	0.177

Variable		Delayed		Early		p-value
		Negative	Positive	Negative	Positive	
	36–50 yrs	29 (87.9)	4 (12.1)	25 (96.2)	1 (3.8)	0.257
	>50 yrs	12 (66.7)	6 (33.3)	19 (90.5)	2 (9.5)	0.066
BMI group	Normal	29 (85.3)	5 (14.7)	32 (97.0)	1 (3.0)	0.094
	Overweight	26 (78.8)	7 (21.2)	35 (97.2)	1 (2.8)	0.017
	Obese	15 (83.3)	3 (16.7)	13 (81.3)	3 (18.8)	0.874
Duration group	≤5 days	24 (85.7)	4 (14.3)	32 (91.4)	3 (8.6)	0.473
	6–10 days	30 (81.1)	7 (18.9)	27 (93.1)	2 (6.9)	0.158
	>10 days	16 (80.0)	4 (20.0)	21 (100.0)	0 (0.0)	0.031

**DISCUSSION**

Acute biliary pancreatitis (ABP), a serious complication of gallstones, necessitates cholecystectomy to prevent recurrence. However, the optimal timing for this intervention remains contested [13,14]. This randomized trial compared early versus delayed cholecystectomy for mild ABP, focusing on recurrent biliary events and choledocholithiasis, offering valuable insights from our local population.

Our study confirms that the timing of cholecystectomy in mild acute biliary pancreatitis plays a critical role in preventing complications. While the overall recurrence of biliary events was higher in delayed surgery, the difference did not reach significance. Importantly, choledocholithiasis was significantly more frequent in the delayed group, underscoring the risk of stone migration during waiting periods. However, our study findings provide new insights for outcome stratification with respect to gender as females forming the majority (71.2%), recurrence of biliary events was observed more frequently among delayed females, although not statistically significant. This may reflect the higher baseline prevalence of gallstone disease in women due to hormonal and metabolic factors [15]. However, the most striking finding was in males, where delayed cholecystectomy led to a threefold higher incidence of choledocholithiasis. This aligns with literature indicating that men often present

with more severe or complicated biliary disease despite having a lower overall prevalence of gallstones. The pathophysiological explanation may involve differences in stone composition, ductal anatomy, and delayed healthcare-seeking behavior among men [16].

The higher frequency of choledocholithiasis in the delayed group in our population resonates with reports from other low- and middle-income countries where delays in surgery often allow for ongoing migration of stones into the common bile duct. In contrast, Facundo et al. [10] suggested that early surgery may occasionally miss residual stones, thereby potentially increasing the immediate risk of choledocholithiasis. However, in our study, the magnitude of choledocholithiasis was much higher in delayed patients, suggesting that postponement of surgery allowed additional gallstone migration to occur [17,18]. Overweight individuals are already known to be at higher risk of complicated gallstone disease due to metabolic predispositions and gallbladder motility disturbances. The strong signal we found in these subgroups highlights the importance of tailored clinical decision-making, whereby early surgery may be especially warranted in such high-risk groups [19,20]. Similarly, patients presenting late (>10 days) had a higher risk of choledocholithiasis if surgery was delayed further, underscoring the compounding effect of prolonged disease duration. Our results echo the prospective

randomized trial by Jee et al., which demonstrated that recurrence of biliary events occurred exclusively in the delayed group (44.1% vs. 0%), with no significant difference in perioperative complications or conversion rates between early and delayed groups [21]. Similarly, Alburakan et al. reported a significant reduction in hospital stay with early cholecystectomy (median 4 vs. 7 days) and no increase in surgical morbidity [22]. Both studies support the concept that early cholecystectomy is not only safe but also prevents recurrent biliary events and avoids unnecessary readmissions, outcomes that align with our observations.

The strong trend towards reduced biliary events, though not statistically significant, is clinically meaningful. The significant reduction in choledocholithiasis with early surgery is paramount. By preventing stones in the common bile duct, early intervention directly avoids subsequent risks of cholangitis, obstructive jaundice, and the need for resource-intensive ERCP, which is a major advantage in low-resource environments [23,24]. The identified high-risk subgroups (males, overweight patients, those with >10-day symptoms) experience a magnified benefit from early surgery. This enables clinicians to prioritize operating room time for these patients when resources are constrained, moving beyond a one-size-fits-all approach.

One of the strengths of this study is its randomized design, which minimizes selection bias and allows for a fair comparison of outcomes between early and delayed cholecystectomy. Another strength is the stratified analysis, which sheds light on subgroups that may be particularly vulnerable to delayed surgery. Additionally, the use of clear operational definitions, standardized surgical technique, and objective outcome measures such as MRCP-confirmed choledocholithiasis enhance the reliability of the findings.

Despite its strengths, several limitations must be acknowledged. First, the study was conducted at a single tertiary care hospital, which may limit generalizability to other healthcare settings, particularly rural or primary care facilities. Second, the follow-up duration for detecting choledocholithiasis was limited to three months, which may underestimate the long-term incidence of biliary complications. Third, although randomization

was performed, the sample size of 170 patients may have been insufficient to detect smaller but clinically relevant differences in recurrence of biliary events. Fourth, patient adherence to follow-up and imaging protocols could influence detection rates, especially in resource-limited contexts. Finally, certain unmeasured variables such as dietary factors, compliance with medical therapy, and genetic predispositions were not accounted for and may have influenced outcomes.

## CONCLUSION

This study provides compelling evidence from our local population to resolve the clinical dilemma regarding the timing of cholecystectomy in mild acute biliary pancreatitis. The significantly higher incidence of persistent choledocholithiasis in the delayed group underscores a critical risk associated with waiting, as the postponement of surgery appears to allow for stone migration and subsequent common bile duct complications. Although the difference in overall biliary event recurrence did not reach statistical significance, the strong clinical trend observed reinforces the benefit of early intervention. The findings of this study strongly suggest that early cholecystectomy, performed within the first week of presentation, is a superior strategy for managing mild ABP. It effectively mitigates the risk of developing choledocholithiasis and shows a strong potential to reduce recurrent painful biliary events. This approach is not only clinically advantageous but is also particularly crucial in resource-limited settings, as it can reduce overall morbidity, prevent readmissions, and optimize the use of healthcare resources. Therefore, early cholecystectomy should be considered the standard of care for patients presenting with mild acute biliary pancreatitis.

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