

# Early Vs Delayed Laparoscopic Cholecystectomy after Management of Choledocholithiasis with ERCP: A Comparative Institutional Experience

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## Abstract

In the current age and day of expertise the widespread cross-section of clinicians, an encounter with choledocholithiasis is usually dealt with in the following 2-step process. The patient is subjected to an ERCP which includes a sphincteromy followed by one of many methods of extracting gall stones from the CBD. In this study, we have compared the timing of cholecystectomy following ERCP in many aspects Such as, duration of surgery, chances of conversion to open surgery, subtotal cholecystectomy, and duration of hospital stay, postoperative morbidity and mortality. Performing laparoscopic cholecystectomy within index admission is beneficial to the surgeon in terms of operation time, chances of encountering adhesions, and chances of conversion to open cholecystectomy.

**Keywords:** Endoscopic retrograde cholangio pancreatography; Early *vs* delayed laparoscopic cholecystectomy; Choledocholithiasis; Cholangitis.

## Introduction

When encountered with concomitant calculi in the gall bladder along with biliary tree, most clinicians in the current Indian scenario resort to the rather safe approach of Common Bile Duct clearance by ERCP followed by a Laparoscopic Cholecystectomy

to eliminate the so-called factory of gallstones.<sup>1</sup> Attempting to treat any pathology detected in one clinical visit is crucial in a scenario where patient follow-up is not as strong as the Western set-up, even if the chances of complications are a number not strong enough to warrant aggressive intervention in other set-ups. The wait-and-watch policy for asymptomatic CBD stones is slowly diminishing due to the easy accessibility of modalities like ERCP and the rapid increase in spread of technical knowledge of Laparoscopic CBD exploration. This is in addition to the decades old practices of Open CBD exploration.

Hence, ERCP followed by laparoscopic cholecystectomy remains the cornerstone of treatment worldwide for coexisting CBD and gall bladder calculi.<sup>2</sup> According to recent studies, the overall outcome is better if Laparoscopic Cholecystectomy is performed early (< 72 hours).<sup>3,4</sup> There was a significant rate of conversion to open cholecystectomy in cases performed after 6 weeks, than within the first week after ERCP.<sup>5</sup>

However, some studies claim that there is benefit to be sought by allowing the gall bladder to recover<sup>6,7</sup> from the acute inflammatory changes.<sup>8</sup> But the major drawback of delaying surgery is the high incidence (~ 20%) of biliary complication.<sup>9</sup> On the other hand, Donkervoort et al. reported that the interval between the two procedures did not affect the outcome of surgery.<sup>10</sup> As there is a variety of evidence suggesting results contradictory to one another and some even equivocal in nature, this study has sought to analyze the effects of interval between ERCP and surgery based on certain vantage points. We look at the advantages and

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disadvantages of each school of thought, from the point of view of surgeon as well as the patient.

## Materials and Methods

Ours is single institutional observational study for duration of five years conducted in Kasturba Hospital Manipal. All the patients with choledocholithiasis who underwent Endoscopic retrograde cholangio pancreatography (ERCP) followed by cholecystectomy in the same admission or elective surgery at the later date were included in the study. All patients were had documented USG findings of Choledocholithiasis. Patients with previous abdominal surgeries and Final HPE showing Carcinoma of gall bladder were excluded from the study. Outcome measures such as Duration of surgery, Rate of conversion to Open, Duration of Hospital Stay, Postop stay, Encounter with intraop challenges like adhesions, Frozen Calot's triangle, Postop Complications and Wound infection were analyzed. Total of 86 patients were included in the study, out of which 43 underwent early laparoscopic/open cholecystectomy and another 43 patients in delayed group. All these patients were followed up in Department of General Surgery and the data collected from the case files.

## Statistical Methods

Results were analyzed using SPSS software version SPSS 20.0. Continuous variables to be expressed as mean. Comparison of continuous variables done by independent sample *t* - test. Categorical data compared by either Chi-square or Fisher's exact test, *p* - value of < 0.05 is considered statistically significant.

## Results

After applying the necessary inclusion/exclusion criteria, 86 patients were tracked from their admission for ERCP till their discharge after laparoscopic cholecystectomy. 43 had index admission surgery after ERCP (Group 1) while 43 (Group 2) had surgery in the next sitting. 42 patients had their surgery within 72 hours while one patient had to wait 7 days due to logistical issues. Jaundice was noted in 19 patients. Findings of the Classical Charcot's triad for cholangitis was noted in only 3 patients. However, 16 patients were diagnosed to have cholangitis by laboratory and ERCP findings. Overall spectrum of presentation in (Table 1).

**Table 1:** Spectrum of presentations

Type of Symptom	n	% (Out of 86)
Pain only	38	44.2%
Pain, Fever	5	5.8%
Pain, Fever, Jaundice	3	3.5%
Pain, Fever, Vomiting	7	8.1%
Pain, Fever, Vomiting, Jaundice	3	3.5%
Pain, Jaundice	9	10.5%
Pain, Vomiting	19	22.1%
Pain, Vomiting, Jaundice	2	2.3%
Total (N)	86	100.0%

There is no statistical difference between the Two Groups related to age, sex, body mass index, co-morbidities, initial leucocyte count, initial total and direct bilirubin, initial CBD size and Initial alkaline phosphatase level. 16 out of 43 patients in the Early Group were stented whereas 27 out of 43 patients were stented in the Delayed Group. Even though there are more number of patients with CBD stent in the Delayed Group, there was no statistically significant difference between the Two Groups (*p* - 0.083). All the above patient characteristics in (Table 2).

**Table 2:** Summary of patient characteristics

Parameter	Early ( <i>n</i> = 43)	Delayed ( <i>n</i> - 43)	<i>p</i> - value
Age (in years)	53.56	53.26	0.707
Sex	Male-18 Female-25	Male-26 Female-17	0.130
BMI (in kg/m <sup>2</sup> )	24.607	25.042	0.402
Comorbidities	Present-19 Absent-24	Present-22 Absent- 21	0.667
Initial TLC (per mm <sup>3</sup> )	9676.74	11683.72	0.077
Initial ALP (IU/L)	223.47	221.30	0.378
Initial Total Bilirubin (mg/dL)	2.304	3.063	0.103
Initial Direct Bilirubin (mg/dL)	1.629	2.286	0.080
ERCP stent in situ	16	27	0.083

Mean operating time in Early Group is 98.45 minutes while it is 127.07 in Delayed Group which is statistically significant with *p*-value of 0.015. 5(11%) out of 43 cases in the Early Group started off as Laparoscopic cholecystectomy but were converted to open cholecystectomy due to various reasons. 13 (31%) out of 43 were converted in the Delayed Group. This difference is statistically significant (*p* = 0.0399).

Dense adhesions within the Calot's triangle and adhesions between different parts of the gall bladder to the surrounding viscera or the peritoneal wall, are known to increase the difficulty of the surgery. This both increases the duration of

laparoscopically managed cholecystectomies and the rate of conversion to open cholecystectomy.

In Table 3 below shows the incidence of these findings. It is evident that there is a statistically significant difference in the rate of encountering these two findings. 3 cases in early and 6 in Delayed Group underwent subtotal cholecystectomy with *p* - value of 0.148 showing no statistical significance. 7 (16%) cases in early and 16 (37%) in delayed required drain placement which is statistically significant with *p* - value of 0.0320. Six (14%) cases in early and 13 (31%) in delayed had bile spill during the surgery with no statistical significance (*p* - values of 0.0746).

**Table 3:** Comparison of major intraoperative findings (*n* = 86)

Findings/Events	Early (n = 43)	Delayed (n = 43)	Odds Ratio	<i>p</i> - value
Frozen Calot's	7 (16%)	17 (40%)	0.2974	0.0191
Intraabdominal adhesions	18 (42%)	30 (69%)	0.3120	0.0102

The incidence of postoperative fever, vomiting and wound infections can lead to added morbidity and prolonged hospital stay for the patient. Although there was no significant difference in the number of patients treated for nausea with vomiting, 3 in early and 11 in delayed had fever and 1 in early and 9 in delayed had surgical site infection. *P* - value of 0.04 and 0.02 was found for postoperative fever and surgical site infections respectively.

A significant difference in total days of in-patient stay as well as the number of postoperative days (Table 4). This is one of the prime factors from the patient point of view as it is directly linked with costs incurred and amounts to an absent period from financial productivity for patient and by-standers.

**Table 4:** Duration of stay in Early and Delayed Group (*n* = 86)

Parameter	Mean in Early Group	Mean in Late Group	<i>p</i> - value
Total duration of stay (days)	9.60	16.32	< 0.001
Postop duration (days)	4.58	6.07	0.005

An attempt was made to analyze whether the time elapsed between the first attack of cholecystitis and the surgery had a bearing on the primary outcomes of operative time and rate of conversion. On applying the Kruskal Wallis test, a *p* - value of 0.318 was obtained (not significant). Hence, it can be noted that the interval between first onset of symptoms and the surgery had no bearing on the outcome of mean operating time.

Rate of conversion to open surgery based on interval between first symptom and surgery was found out by applying Fischer's exact test, *p* - value was found to be not significant of 0.6 in early and 0.691 in Delayed Group. On studying and interval between ERCP and surgery, and applying Kruskal Wallis test and Fischer's exact test, there was no bearing on either duration of surgery or rate of conversion respectively.

## Discussion

There is no clear set guidelines for how to approach the timing of cholecystectomy after ERCP. Most clinicians practice operating on the gall bladder within 72 hours as a means of fast-tracked management of the entire spectrum of gall stone disease affecting the patient. However, there is a significant chunk of surgeons who believe that handling a biliary system that has been subjected to an insult and a breach of sterility is better at a delayed stage after the inflammation settles.<sup>7,8</sup> There is a debate as to whether the handling of acutely inflamed gall bladder and duct is worth the heroics and whether it is easier to just handle the adhesions that are encountered in interval surgery.

The answer to this debate will require to view the problem from different vantage points. As far as the surgeon goes, the main concern is operating time, intraoperative complications like bile leak, excessive hemorrhage, rate of conversion to open cholecystectomy, postoperative morbidities. When we look at it from the patient's point of view, the duration of stay becomes a prime factor.

In cases where there is a high-risk of cholangitis (as assessed by preop and intra ERCP factors), a stent is placed within the CBD and a check cholangiogram is done. Therein lies the divarication of roads for laparoscopic cholecystectomy. It is standard practice to follow up CBD clearance with laparoscopic cholecystectomy<sup>3</sup> but the timing is very clinician oriented. On quizzing the consultants, a variety of factors were put in play. The proponents of early surgery cited decreased hospital stay, decreased patient costs, eradicating the chances of interval biliary episode and a less chance of encountering dense adhesions as factors. The factors pushing the surgeons to operate with an interval were the difficulty in handling acutely inflamed biliary system and the chances of biliary injuries and hemorrhage as a result. The other factors promoting the decision to do interval cholecystectomy are the logistical issues like insurance approvals and operating day schedules that push the interval beyond 72 hours.

Only 1 case in the present study was performed after 72 hours in the index admission and hence, a reasonable justification cannot be given towards relaxing the temporal cut-off of 72 hours. However, there is scope to prospectively analyze the patients who are operated in index admission after 72 hours and to arrive at a statistical significance for the herein studied parameters in the said sub-group.

Putting into play all these factors, we analyzed 86 patients by classifying them as index admission surgeries or delayed surgeries. The study analyzed 86 patients sampled between September 2015 and August 2019. As one of the parameters assessed was the duration of stay, patients were only included if the first ERCP attempt was successful. This also ensured that the interval between the insult to the biliary system with the ERCP, and the surgery was uniformly calculated.

The mean operating time of the study population was 112.76 minutes which is significantly higher than the other studies compared. However, there was a significant difference in the operating time when the patients were sub-divided as well. This is an indirect indicator of the difficulty level of the surgery for the surgeons and hence, can be said to be a strong point tilting the balance in favor of deciding for early surgery.

A similar difference was found in the rate of conversion to open cholecystectomy. Out of the 18 cases which were converted among the 86 samples, 5 were from the early category and 13 in the delayed. This represented a statistical significance which could be attributed to the factors encountered during the surgery. Most of the delayed cases (11 out of 13) and 1 early case were converted due to Frozen Calot's with Intraabdominal adhesions. 1 Early case was converted as the Gall Bladder was contracted and wall was too thickened to grasp laparoscopically. 2 Early cases were converted due to Empyema of Gall Bladder 3 cases were converted due to excessive uncontrolled hemorrhage (1 Early Group & 2 Late group). 5 cases developed Surgical site infection (1 Early vs 4 Delayed -  $p = 0.91$ ). In a surgery where the accepted conversion rates are just 10%<sup>11</sup>, the disproportionate skew of the number of converted cases in the Delayed category is an indicator of how the intraoperative changes encountered by allowing the acute inflammation to settle, are far more nefarious than the challenges posed by acute changes.

There was also an increased occurrence of placing intraoperative drains ( $p = 0.0320$ ). Drains are not routine practice in this surgery and its placement

could be a pointer to the difficulty of the surgery even if performed solely laparoscopically. Drains are a factor for increased hospital stay and surgical site infections and the resultant wound is more often than not, allowed for healing by secondary intention. Another indicator of difficulty of surgery is the incidence of subtotal cholecystectomies. A total of 9 subtotal cholecystectomies were performed, (3 Early and 6 Delayed). Only one of these was performed laparoscopically using Endo-loops. There was also a significant difference in the postoperative stay of the patients in each group. While the postoperative stay was largely disproportionate in the Two Groups ( $p = 0.005$ ), there was also an increased incidence of morbidities like postoperative fever ( $p = 0.04$ ), surgical site infection ( $p = 0.02$ ). There were 16 patients with cholangitis (4 Early vs 12 delayed) and this showed a trend among the surgeons to operate patients with cholangitis in a belated fashion after the ongoing inflammation settled. A difference was also noted in the operative time, postop stay and total in-patient stay. However, the sample couldn't be analyzed due to paucity of cases required to apply regression model.

There were some limitations in our study such as Postoperative pain scale could not be assessed. The experience of the surgeon performing the laparoscopic cholecystectomy could be assessed and matched in a prospective study, giving more weightage to the mean operative time and the rate of conversion.

This was not possible in an observational study as the dynamic experience of the same surgeon over the 5 year study period could not be assessed for each given point of time of surgery. Regression model could not be applied to a statistically significant level so as to assess the role of pancreatitis, cholangitis in affecting the duration of surgery and rate of conversion.

## Conclusion

There is evidence to suggest that performing laparoscopic cholecystectomy within index admission is beneficial to the surgeon in terms of operation time, chances of encountering adhesions, and chances of conversion to open cholecystectomy. The patient is benefitted by completing the entire course of treatment in the same visit and also has a postoperative period that is shorter and less eventful. Thus, it is beneficial to perform Laparoscopic Cholecystectomy within the same admission CBD clearance with ERCP.



*Ethical Clearance:* Ethical clearance taken from the Institutional Ethical Clearance Committee.

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