

Comparison of Outcomes Between Subtotal Fenestrating Cholecystectomy and Open Conversion Cholecystectomy in Cases of Frozen Calot's Triangle; A Single Centre Experience

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ABSTRACT

Objective: To compare the outcomes of laparoscopic subtotal fenestrating cholecystectomy (LSFC) and open conversion cholecystectomy (OCC) performed for difficult gallbladder surgery with frozen calot's triangle (FCT).

Study Design: Prospective comparative study.

Place and Duration of Study: Department of General Surgery, Pak-Emirates Military Hospital Rawalpindi, Pakistan from Jan 2023 to Jan 2024.

Methodology: The study population included adult patients who underwent laparoscopic cholecystectomy for gallbladder pathology. The study included a total of eighty-six (n=86) patients. 43 patients underwent LSFC and 43 patients underwent OCC because of FCT. Both groups were compared in terms of Operation time, intra-operative complications, postoperative outcomes, and length of stay (LOS) in the hospital.

Results: The mean age of eighty-six (n=86) patients was 47.70±0.67 years, including 60(69.8%) males and 26(30.2%) females. Patients who underwent LSFC had operation time 91.90±10.32 minutes, length of stay in hospital 4.86±0.70 days, and biliary fistula was formed in 8(18.60%) patients. Patients who underwent OCC had operation time 112.34±12.45 minutes, length of stay in hospital 7.67±0.96 days, bile duct injury in 2(4.65%) patients and formation of biliary fistula in 1(2.32%) patients.

Conclusion: LSFC is associated with reduced operation time, decrease LOS in hospital and lesser incidence of bile duct injury as compared to OCC. However, the incidence of formation of biliary fistula was more with LSFC.

Keywords: Frozen calot's triangle, Laparoscopic subtotal fenestrating cholecystectomy, length of stay, Open conversion cholecystectomy.

How to Cite This Article: Bukhari ST, Wattoo NM, Khan WA, Badar M, Javed R, Zahid S. Comparison of Outcomes Between Subtotal Fenestrating Cholecystectomy and Open Conversion Cholecystectomy in Cases of Frozen Calot's Triangle; A Single Centre Experience. Pak Armed Forces Med J 2025; 76(Suppl-2): S377-S382. DOI: <https://doi.org/10.51253/pafmj.v76iSUPPL-2.12370>

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INTRODUCTION

Cholecystectomy is a surgical procedure in which the gallbladder is removed from the body. Removal of the gallbladder is indicated for various pathologies including symptomatic cholelithiasis, acute/chronic cholecystitis, choledocholithiasis, biliary pancreatitis, and gallbladder malignancy.^{1,2} Over the period of time, a steady increase in the number of gallbladder and biliary pathologies has been reported in multiple studies available in the literature.^{3,4} Cholecystectomy is therefore one of the procedures that General and Hepatobiliary surgeons perform very frequently. In the United States, more than 1.2 million cholecystectomies are performed per year.⁵ In the initial days, surgeons used to perform open cholecystectomy (OC) for the removal of the gallbladder. However, in the early 1990s, the traditional open approach was largely replaced by laparoscopic cholecystectomy (LC) which offered a

minimally invasive surgical approach with enhanced recovery after surgery.⁶ In the present era, LC is considered as the gold standard treatment for gall bladder pathologies.

Despite significant advancements in laparoscopic skills, safe completion of conventional LC could become very challenging for a surgeon. This difficulty faced during the surgery is because of altered anatomy, dense adhesions, and loss of normal tissue planes. Various operative difficulty scoring systems have already been studied and are used in various hospitals as per local guidelines.^{7,8} "Frozen Calot's triangle" (FCT) is a term used for the loss of normal planes of dissection in hepatocystic triangle due to dense adhesions and inflammation. A multicenter prospective observational study conducted in India documented that FCT was encountered in 11.2% of the patients undergoing LC.⁹ Encountering such operative difficulty during the surgery significantly increases the risks of surgical complications including unexpected bleeding, gallbladder perforation, and bile duct injury.¹⁰ To avoid such troublesome operative

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Received: 20 Jun 2024; revision received: 06 Oct 2024; accepted: 07 Oct 2024

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complications from happening, surgeons look for certain bail-out procedures that may include performing laparoscopic subtotal cholecystectomy or open conversion cholecystectomy (OCC).

In our country, LSFC and OCC are the two commonly performed bail-out procedures during a difficult gallbladder surgery. Surgeons adopt these techniques as per their personal preferences or local departmental policies. Yet, no study has been conducted in our country to compare the outcomes of these two procedures. Moreover, limited international data is available in the literature in this regard. Therefore, it is difficult to establish the superiority of one procedure over another at present. A study hence needed to be conducted to compare the outcomes of LSFC and OCC with special emphasis on our local population.

METHODOLOGY

This prospective comparative study took place at General Surgery Department of Pakistan Emirates Military Hospital Rawalpindi, Pakistan from January 2023 to January 2024 after obtaining approval from the Ethical Review Committee (Serial no# A/28/ER/59/24). For calculating sample size, the WHO Sample Size Calculator was used, using the following parameters: 80% power of the test, 10% level of significance, ileus with LSFC 9.2% and ileus with OCC 1.8%.¹¹ Based on these, the total sample size of 91 patients was computed. Out of these, 5 patients were lost to follow-up and hence removed from the study, making the final sample size of 86 patients, which were divided into two groups.

Inclusion Criteria: We included patients of either gender with ages ranging from 16-60 years, who underwent emergency or elective laparoscopic cholecystectomy for gallstones and FCT was encountered.

Exclusion Criteria: We excluded patients with no or mild/moderate adhesions and normal planes of dissection at the calot's triangle. Moreover, patients with Mirizzi syndrome and those with suspected gallbladder mass/neoplasm were also removed from the study. Patients with liver cirrhosis, compromised immunity, known malignancy, chronic renal disorder and getting radiotherapy/chemotherapy were also excluded. Those patients who did not provide consent to be included in the study were removed from the study.

Patients reported to the hospital's outpatient department (OPD) or emergency department with gallbladder disease that required cholecystectomy performed in either emergency or elective settings. Patients were selected through "non-probability consecutive sampling" after getting informed written consent. Pre-operative risk factors predicting the difficulty of operation were evaluated in detail in all patients. These risk factors included previous episodes of acute cholecystitis or acute biliary pancreatitis, a history of previous hospital admissions for gallbladder pathology, prior abdominal surgery, obesity, clinically palpable gallbladder, multiple large stones, thick wall gallbladder with pericholecystic fluid, previous endoscopic retrograde cholangiopancreatography.^{12,13} Based on these risk factors, patients were counseled regarding the possibility of LSFC or OCC, and informed written consent was obtained.

All surgeries were performed by the same laparoscopic and hepatobiliary surgeon. At the time of induction of anesthesia, an intravenous broad-spectrum antibiotic was administered to all patients. LC was performed using the standard four-port technique. Careful dissection was performed at the calot's triangle avoiding any injury to the viscera, vessel, or bile duct. The decision to abort a conventional LC and choose a bail-out procedure was taken by the operating surgeon based on the increased risk of intra-operative complications for attempting conventional LC due to FCT which was defined as loss of planes of dissection due to fibrosis and adhesions. Operating surgeon decided to either perform a LSFC or OCC taking into consideration the safety of the procedure. During LSFC, the remnant gallbladder was left open but an attempt was made to close the cystic duct from the internal side to prevent post-operative bile leak and formation of biliary fistula. Biliary fistula was defined as abnormal channel bringing out the bile from biliary tree to the abdominal wall. A sub-hepatic drain was placed in all patients after LSFC. In patients who underwent OCC, the right subcostal (Kocher) incision was made. Careful dissection was done at the calot's triangle and open total cholecystectomy was completed. A sub-hepatic drain was placed in all patients. Histopathological analysis of the gallbladder was obtained in all patients. During the surgery operation time, bile duct injury and intraoperative bleeding were assessed and documented. Reduced operative time and decrease blood loss lowers peri-operative complications, quickens recovery time and reduces hospital stay. Moreover, reduced operative

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time decreases burden of operation room resources and potentially reduces health care cost. After surgery, patients were shifted to the ward or high dependency unit (HDU) as per the advice of the surgeon or anesthetist. Enhanced recovery after surgery (ERAS) protocol was followed for all patients with the involvement of a dedicated multidisciplinary team, including surgeons, anesthesiologists, nurses, and physiotherapists.¹⁵ Patients were educated about the ERAS protocol before surgery, ensuring their active participation. Post-operative key parameters including pain management, early mobilization and nutrition were monitored and documented to ensure compliance with ERAS guideline. All patients were prescribed intravenous broad-spectrum antibiotics (Sulzone 2 gm twice daily). The duty nurse and the doctor did constant surveillance of patients. Drain output was monitored for any abdominal bleeding and bile leak. Liver function tests of patients were advised if required. Abdominal ultrasound was used to look for any sub-hepatic collection. Length of stay (LOS) in hospital was recorded before discharging the patients. After discharge, oral broad-spectrum antibiotics (cefixime 400mg once daily) were prescribed to all patients for 05 days. Weekly follow-up visits were planned till 30 days post-surgery. All patients were assessed for wound infection and bile leak. A 30-days mortality after surgery was also documented. Follow-up period was kept for 30 days and not beyond as post-surgery outcome parameters which were included in our study could be assessed within 30 days after surgery. Collected data was endorsed in a pre-designed proforma.

Statistical Package for the Social Sciences version 23 software was used for data interpretation. Quantitative variables (age, operation time, LOS in hospital) were represented using Mean±SD. Categorical variables (gender, obesity, bile duct injury, blood loss, biliary fistula, wound infection, mortality) were represented using frequency/percentage. We utilized the Chi-Square test to compare categorical variables and the Independent Samples t-test for quantitative variables. Shapiro-Wilk test was used for assessing the normal distribution of data (LOS in hospital), which was not normally distributed. Median and Interquartile range (IQR) of LOS in hospital was calculated. The *p*-value of ≤0.05 was considered significant.

RESULTS

Eighty six Eighty-six patients were included in the study. 43 patients underwent LSFC and 43 patients underwent OCC. Mean age of the participants was 47.70±0.67 years, including 60(69.8%) males and 26(30.2%) females. Obesity (BMI ≥30) was found in 13(15.1%) patients. The comparison of baseline characters between the two groups is tabulated in Table-I.

Table-I: Comparison of Baseline Characteristics (n =86)

Characteristics	Laparoscopic Subtotal Fenestrating Cholecystectomy (n=43)		Open Conversion Cholecystectomy (n = 43)	<i>p</i> -value
	Male	Female		
Gender	28(65.11%)	15(34.88%)	32(74.41%) 11(25.58%)	0.34
Mean age, years	47.51±5.93		47.90±6.60	0.77
Obesity (BMI ≥ 30 kg/m ²)	6 (13.95%)		7(16.27%)	0.76

*LSFC: Laparoscopic subtotal fenestrating cholecystectomy, OCC= open conversion cholecystectomy

Operation timing in LSFC was 91.90±10.32 minutes while in OCC it was 112.34±12.45 minutes (*p*-value <0.001). No Bile duct injury occurred in LSFC. However, in OCC bile duct injury occurred in 2(4.65%) patients (*p*-value 0.15, odds ratio 2.04, 95% Confidence Interval 1.64 - 2.55). More than 100ml blood loss occurred in 3(6.97%) patients during LSFC and in 39(90.67%) patients during OCC (*p*-value <0.001). A subhepatic drain was placed in all patients from either group. This comparison of operative findings/parameters is displaced in Table-II.

Table-II: Comparison of operative Findings Between Study Groups (n=83)

Operative Findings/ Parameters	Laparoscopic Subtotal Fenestrating Cholecystectomy (n = 43)	Open Conversion Cholecystectomy (n=43)	<i>p</i> -value
Operation time (Mean±SD), Minutes	91.90±10.32	112.34±12.45	<0.001
Bile Duct Injury	0	2(4.65%)	0.15
Blood loss (>100ml)	3(6.97%)	39(90.67%)	<0.001
Drain	43(100.00%)	43(100.00%)	-

LOS in the hospital after LSFC was 4.86±0.70 days and after OCC it was 7.67±0.96 days (*p*-value<0.001). Biliary fistula was formed in 8(18.60%) patients after LSFC and in 1(2.32%) patient after OCC (*p*-value 0.01). Wound infection happened in 1(2.32%) patient after LSFC and in 3(6.97%) patients after OCC (*p*-value 0.30). No mortality occurred within 30 days

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post-surgery in any patient. This comparison is tabulated in Table-III.

Table-III: Comparison of Postoperative Outcomes (n = 83)

Post-operative outcome	Laparoscopic Subtotal Fenestrating Cholecystectomy (n = 43)	Open Conversion Cholecystectomy (n = 43)	p-value
Length of Stay in hospital, days (median, IRQ)	5.00(IQR:1.00)	8.00(IQR:1.00)	<0.001
Biliary Fistula	8(18.60%)	1(2.32%)	0.01
Wound Infection	1(2.32%)	3(6.97%)	0.30

DISCUSSION

Laparoscopic subtotal fenestrating cholecystectomy (LSFC) is a commonly performed bail-out procedure in cases of difficult gallbladder surgery. During LSFC, the remnant part of the gall bladder is not closed however cystic duct may be sutured internally. A recent study conducted in Turkey emphasized the importance of LSFC in preventing major bile duct injuries during difficult LC.¹¹ In another retrospective study conducted in Chandigarh, India concluded that FCT was the most common case of OCC, and timely conversion to open procedure prevented major operative complications.¹² Top of FormLC is one of the most common surgeries performed in routine by General Surgeons all around the world. It is now considered a gold standard technique for treating symptomatic gallstones. With improvement in laparoscopic surgical skills and the availability of advanced laparoscopic equipment, the surgical outcome has been improved significantly.^{13,14} Despite all these facts, in some cases, surgeons have to face great difficulty in successfully removing the gallbladder without causing any surgical complication. The presence of dense adhesions and loss of normal tissue planes for dissection make it extremely difficult to identify important anatomical structures and achieve a critical view of safety.^{15,16} Top of FormPresence of FCT, significantly increases the risk of operative injury to the viscus, named vessels or bile duct. Surgical complications not only result in severe and detrimental outcomes for the patient but also have the potential to expose the surgeon to medicolegal repercussions.

A few years back it was a common practice among surgeons to convert LC into OCC in case of difficult gallbladder surgery. Nevertheless, as time progressed and medical understanding improved, additional bail-out procedures were developed and implemented. LSFC is one of the commonly performed surgeries in cases of FCT in which the remnant gallbladder is left open. It increases the risk of

biliary fistula formation but reduces the risk of bile duct injury and recurrent biliary events. Among OCC and LSFC, the preferred procedure in terms of better outcomes is still a matter of debate among the surgeons. There is a scarcity of national and international data in available literature comparing the outcomes of these two procedures.

In our study, patients were included who were planned to undergo LC. We found a male gender dominance in our participants. Song et al documented in their study that gallstones are more prevalent in the female population which doesn't align with the results of our study.¹⁷ This could be because our study included only those patients with FCT, a condition that is more prevalent in the male population, as also reported by Akcakaya *et al.*¹⁸ Majority of the patients in our study were in their 40s. Joshi *et al.*, reported in their study that gallstone disease was most common in the age group 31-40 years.¹⁹ The disparity may be because, in developing countries like ours where free medical services are not readily available to the common population, people mostly turn up late to get surgical treatment. We found out that operation time and average blood loss were significantly reduced during LSFC as compared to OCC. Moreover, bile duct injury occurred more with OCC as compared to LSFC but the difference was not statistically significant. A similar study was conducted by Grossman *et al.*, and they concluded that OCC is associated with more operative time, more bleeding, and increased risk of bile duct injury as compared to LSFC.¹³ These results aligned with those of our study. Byskosh *et al.*, also mentioned that LSFC is although associated with the complicated post-operative course of events, yet it is a safe alternative to prevent vascular and biliary injury during difficult gallbladder surgery.²⁰ In patients who underwent LSFC, we observed a reduction in LOS in the hospital and an increased rate of biliary fistula formation however there was no significant difference between the incidence of wound infections among the two groups. Biliary fistulas were managed successfully using conservative approach utilizing sub hepatic drains for drainage of bile and using broad spectrum antibiotics to prevent or treat the infection. Moreover, adequate nutritional support was advised for the patients and serial clinical assessments and imaging studies (ultrasound and CT scan) were conducted to assess fistula's status. Yildirim *et al.*, in their study mentioned that LSFC results in an increased incidence of bile leak and subsequent formation of the biliary fistula which

is consistent with the findings of our study.²¹ Gao *et al.*, in their study concluded that the incidence of surgical site infection increases remarkably after conversion from laparoscopic to open cholecystectomy which doesn't align with the results of our study.²²

The current study findings provide support for the idea that in the case of FCT, LSFC is a safe bail-out procedure that is associated with decreased operation time, reduced LOS in the hospital, and lesser incidence of bile duct injury. In order to execute this procedure safely, a surgeon must acquire advance laparoscopic surgery skills and training.

Single center study and limited follow up period were the few limitations of this study. Early postoperative outcomes within the first 30 days after surgery were the main focus of our study because this is a crucial time for spotting early problems and assessing initial healing. Nevertheless, we recognise that long-term monitoring is crucial for a thorough evaluation of complications including late-onset biliary fistulas. This first study lays the groundwork for future investigations that will include longer-term follow-up to give a more comprehensive picture of patient outcomes.

CONCLUSION

LSFC done in the case of FCT is linked with reduced operation time, decreased incidence of bile duct injury, and shortened LOS in the hospital. This procedure results in an increase incidence of biliary fistula formation, most of these can be managed by conservative approach.

ACKNOWLEDGEMENTS

We are thankful to the whole surgical team of the institute as well as the study participants who have helped us in conducting this research.

Conflict of Interest: None.

Funding Source: None.

Authors Contribution

Following authors have made substantial contributions to the manuscript as under:

STB & NMW: Data acquisition, data analysis, drafting the manuscript, critical review, approval of the final version to be published.

WAK & MB: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

RJ & SZ: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity

of any part of the work are appropriately investigated and resolved.

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