

COMPARATIVE STUDY BETWEEN LAPAROSCOPIC COMMON BILE DUCT EXPLORATION PLUS CHOLECYSTECTOMY VERSUS ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY PLUS CHOLECYSTECTOMY FOR CHOLECYSTO-CHOLEDOCHOLITHIASIS

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ABSTRACT

Introduction

The management of concomitant gallbladder and common bile duct stones have been debated between both endoscopic and laparoscopic techniques. This study aimed to compare the efficacy, safety, cost and surgical outcomes of laparoscopic common bile duct exploration plus cholecystectomy and endoscopic retrograde cholangiopancreatography plus cholecystectomy.

Methodology

This is a comparative interventional study carried out among 62 patients with concomitant gallstones and common bile duct stones. The study population was divided into two groups by simple randomized sampling technique (lottery technique). Group A underwent laparoscopic common bile duct exploration followed by laparoscopic cholecystectomy in one stage (single-staged management). Group B underwent endoscopic retrograde cholangiopancreatography followed by laparoscopic cholecystectomy in second hospital visit (two-staged management).

Result

Complete clearance of the stone with a single attempt was achieved in Group A compared to Group B as 8 patients had gone for a second attempt in group B. Post operative pancreatitis was higher i.e. 7(22.58%) in Group B with statically significance (p value <0.005). Other complications like bleeding i.e. 2(6.4% in A and 5(16.12%) in B group, perforation was also noted during the study period that includes 2(6.45%) in B group. The mean operative time was longer in Group A i.e. 130.2 ± 41.5 minutes while in Group B was 78.5 ± 10.2 minutes which was statistically significant (p <0.001). The cost of procedure was higher for patients undergoing two-staged management.

Conclusion

The complete clearance of the stone with a single attempt was achieved in Group A compared to Group B where 8 patients had a second attempt. Also incidence of pancreatitis was higher in Group B and statically significant. Other complications like bleeding & perforation were also noted during the study period in B group. The mean operative time was longer in Group A which was statistically significant. However, for those patients with concomitant gallbladder and common bile duct stones, single-staged management consisting of laparoscopic common bile duct exploration and laparoscopic cholecystectomy could be the preferred method of treatment where the expertise and facilities are available.

KEYWORD

Common bile duct stone, Endoscopic retrograde cholangiopancreatography, Laparoscopic cholecystectomy.



INTRODUCTION

The common bile duct stones is seen in almost 10-15 % of cases of cholelithiasis.¹ Despite advancements in endoscopic and laparoscopic techniques, there still exists controversies regarding the proper management approach of the concomitant gallbladder and common bile duct stones (CBD stones).² Laparoscopic cholecystectomy (LC) has remained the standard of care for gallbladder stones³. With the emergence of endoscopic retrograde cholangiopancreatography (ERCP), prior endoscopic removal of stones followed by LC six weeks later (a two-staged management approach) became the procedure of choice for many surgeons in patients with concomitant gallbladder and CBD stones.⁴ Single staged management consisting of Laparoscopic CBD Exploration (LCBDE) followed by LC for concomitant gallbladder and common bile duct stones is now gaining popularity because of its low associated morbidity, length of hospital stay (LOS) and the possibility of complete management of the disease within a single setup where the facilities exist.^{2,7} In our study, we compare two management options for patients with concomitant gallbladder and common bile duct stones and try to identify the better treatment option for patients in centers having technical expertise.

METHODOLOGY

This comparative interventional study was carried out at Nobel Medical College Teaching Hospital from November 2019 up to February 2021. Patients who had proven concomitant gallbladder and common bile duct stones by transabdominal ultrasonography (USG) and/or magnetic resonance cholangiopancreatography (MRCP) were included in the study. The indication of MRCP were for the patients having dilated common bile duct, clinical evidence of cholangitis and serum bilirubin more than 1.7 mg/dl. Patients who had acute cholangitis, common bile duct diameter less than 10 mm, history of hepatobiliary surgery, ASA class 4, 5 diseases, and who did not give consent for the study were not included in the study.

Demographic data at the time of diagnosis was taken. Detailed history and physical examination were performed. Pertinent laboratory parameters like complete blood count (CBC), and liver function test (LFT) were obtained. The study population was then divided into 2 groups (Group A and Group B). Patients who were in Group A underwent laparoscopic CBD exploration followed by LC on the same day. Patients who were in Group B underwent ERCP followed by LC six weeks later. Patients were explained about the course of treatment throughout the operative period.

Group division was done randomly by the lottery method. A convenient sampling technique was used. Study patients were divided equally into two groups and compared.

The Ethical clearance was taken from the institutional

review committee of Nobel Medical College (Ref:IRC-NMCTH with 323/2019). Collected data were checked thoroughly for completion and error. They were then analyzed using IBM Statistical Package for Social Sciences (SPSS) version 25. Descriptive variables were expressed using number/percentage. Numerical data were compared using a student's t-test and chi-square was used to compare qualitative data. A p-value of <0.05 was considered statistically significant.

Operative technique used for Group A:

a) Creation of pneumoperitoneum and entry port:

At the time of induction of anaesthesia, prophylactic CEFTRIAXONE 1 gram intravenous (IV) was given. 4-port Direct Trocar Insertion (DTI) was used to create pneumoperitoneum. CO₂ was used for pneumoperitoneum. Four ports consisted of a supra-umbilical port, one epigastric port (10 mm) and two 5 mm operating ports (one lateral to rectus muscle at right midclavicular line and another at right anterior axillary line at level of umbilicus).

b) Removal of CBD stone by choledochotomy:

The anterior wall of the CBD was dissected within the porta hepatis. A longitudinal supraduodenal choledochotomy was made using the Endo knife. The stones and debris from the CBD were removed either by thorough flushing with a copious amount of normal saline or by using forceps. Choledochoscopy was performed using a flexible choledochoscope inserted through the epigastric port. Thorough visualization of the upper portion of the CBD, the right and left hepatic ducts, and the secondary and tertiary biliary ducts was performed. The choledochoscope then was directed downward to visualize the lower part of the CBD up to the papilla. Any residual stones were removed using a Dormia basket. A check Choledochoscopy was performed to ensure CBD clearance. The choledochotomy was closed using absorbable suture 3-0 Vicryl (Unisynth) over a biliary stent.

c) Removal of gall bladder:

Cholecystectomy was done by dissecting the gallbladder from its bed using the diathermy hook. Following cholecystectomy, a sub-hepatic drain was placed which was removed on 3rd to 5th postoperative day (when drain volume was <50 ml serosanguinous.)

d) Insertion of biliary stent:

Internal plastic biliary stent was placed intraoperatively in antegrade fashion. Feeling of "give-away" of the sphincter of Oddi during insertion was noted when the stent reached the duodenum. In doubtful cases check choledochoscope was done. No patient had proximal migration of CBD stent.

e) Patients were discharged once they resumed daily ordinary activity and had no significant complaints. The internal plastic biliary stent which was placed intraoperatively was removed after 4-6 weeks. Figures representing the above techniques are shown from 1-2.





Figure 1: Removal of CBD stones using forceps



Figure 2: Insertion of biliary stent

Operative technique used for Group B:

- a) Removal of CBD stones using ERCP: ERCP was performed by a general surgeon in presence of an experienced gastroenterologist. It was performed under intravenous (IV) anaesthesia using a side-viewing duodenoscope (olympus exera II TJF-Q180V video duodenoscope). Selective cannulation of the bile duct was done using a wire-guided sphincterotome and a hydrophilic guidewire (straight tip 0.05 inch). After cannulation, a radiopaque dye (urograffin 76%) was injected into the biliary tree and a cholangiogram was taken intraoperatively. Biliary sphincterotomy was performed using cutting and coagulation currents. CBD stones were extracted using an extraction balloon. A final check-cholangiogram was performed to confirm the complete clearance of stones from CBD. Biliary stent was placed. The patients were kept in the post-operative ward after the procedure and discharged the next day uneventfully.
- b) **Removal of the gallbladder:** Cholecystectomy was done after six weeks in another session. The following reasons were responsible for delayed cholecystectomy in our study.
1. Different operative days for ERCP and laparoscopic cholecystectomy in our center.
 2. For prevention of chemical cholecystitis.

Figures representing above techniques are shown in figure 3-4



Figure 3: A Cholangiogram

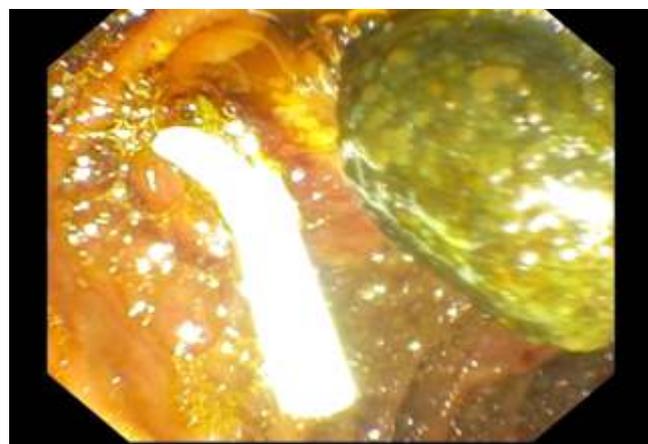


Figure 4: Picture showing extracted CBD stone and biliary stent

Follow-up and assessment: Patients from both the study groups were followed up in the first week, after six weeks and three months from the day of Laparoscopic common bile duct exploration (LCBDE) (in Group A) or ERCP (in Group B). Symptoms like abdominal pain and bleeding were considered during the follow-up period. Liver function test, pancreatic function test, and transabdominal USG were also obtained during the follow-up period.

Primary outcome: The success of the intervention (defined as the removal of CBD stone and laparoscopic cholecystectomy) by the intended approach was considered a primary outcome. Unable to do so was considered a failure.

In Group A, all stones were removed in single setting. A maximum of 2 attempts were made to remove the CBD stone using ERCP in different settings in Group B. This was because of the absence of a cholangioscope at our center. In cases where there was failure to remove stones in the first setting, biliary stent was placed. After 6 weeks of first attempt, second attempt was made using CRE balloon dilatation and basketing. Failed patients even after 2 ERCP attempts underwent laparoscopic CBD exploration and LC 6 weeks later.

Secondary outcome: The following variables were considered as secondary outcomes during our study:

1. Operative time (Total operative time for Group A, Cumulative time taken for ERCP and Laparoscopic cholecystectomy for Group B)
2. Duration of hospital stay (For both groups)
3. Cost of the procedure (Operative and procedure charge only for both groups)
4. Complications during and after the procedure (For both groups)

RESULT

During the study period, 62 patients with concomitant gall bladder and CBD stones were studied. The mean age of patients in either group was (52 years in Group A and 51 years in Group B). Both groups had more female patients than the male which had no statistical significance ($p=0.155$). Table 1

Table 1: Socio-demographic detail of both group

Characteristics	Categories	Group A	Group B	p-value
Gender	Male	6 (9.6 %)	11 (17.7 %)	0.155
	Female	25 (40.3%)	20 (32.2%)	

All patients who were on Group A underwent successful laparoscopic CBD clearance and laparoscopic cholecystectomy. None of the patients on Group A required conversion into open cholecystectomy. In Group B 28 patients underwent successful ERCP. Among the patients who had successful stone removal using ERCP, the stone was removed in a single attempt in 20 patients. In eight patients, two intraoperative attempts were made to remove the stone successfully. Three patients in whom despite two attempts the stone could not be removed were considered a failure. The failed cases underwent laparoscopic CBD exploration followed by laparoscopic cholecystectomy six weeks later. The difference in the number of attempts to clear the stone was statistically significant ($p=0.002$). The number of CBD stones (solitary vs multiple stones) had no statistical significance. A 100% primary outcome was achieved in Group A while in Group B it was 90.3%. Which was not statistically significant ($p=0.076$). Table 2.

Table 2: Comparison of outcomes between the two groups

Parameters	Group A n=31	Group B n=31	p-value
Success rate	31 (100%)	28 (90.3%)	0.076
Choledocholithiasis			
Single	18 (58.06%)	16 (51.61%)	0.206
Multiple	13 (41.93%)	12(38.70%)	
Number of attempts			
2 or less	31 (100%)	28 (90.32%)	0.002*
More than 2	0	3 (9.67 %)	

Mean operative time in Group A was 130.2 ± 41.5 minutes while in Group B was 78.5 ± 10.2 minutes which was statistically significant ($p < 0.001$). The mean duration of hospital stay postoperatively was 6.7 ± 2.3 days in Group A and 7.42 ± 1.6 days in Group B (total of both admission). The

mean duration of hospital stay postoperatively was quite long in this study as both the group were compared however, duration of postoperative hospital stay was not significant. The cost of the procedure was higher in Group B (Nepalese rupee= 58000) compared to Group A (Nepalese rupee= 45000).

Post-procedure bleeding occurred more in patients in Group B (16.12%, $p= 0.229$). Patients who had minor bleeding episodes were managed with intravenous tranexamic acid 500mg. One patient in Group B required two units of blood transfusion. The incidence of complications like perforation and pancreatitis were higher in Group B compared to Group A (6.4 and 22.5% respectively). The postprocedure pancreatitis was managed in Group B were managed conservatively. Perforations that occurred were ERCP induced Type II periampullary leaks which were managed conservatively. Pancreatitis was mild and did not complicate any morbidity and mortality. The incidence of pancreatitis was statistically significant ($p= 0.05\%$). Table 3. All patients had follow-up on a predefined period. No significant postoperative complications were noted on follow-up.

Table 3: Comparison of complications between two groups

Nature of complication		Group A (n=31)	Group B (n=31)	p-value
Post procedure bleeding	No	29 (93.54%)	26 (83.87%)	0.229
	Yes	2(6.4%)	5 (16.12%)	
Pancreatitis	No	31 (0%)	24 (77.41%)	0.005*
	Yes	0	7 (22.58%)	
Perforation	No	31 (0%)	29 (93.54%)	0.151
	Yes	0	2 (6.45 %)	

DISCUSSION

From the advancement of laparoscopic surgery, single-stage management (LCBDE followed by LC) is currently replacing the two-staged management (ERCP followed by LC). LCBDE is now being viewed as a better procedure compared to endoscopic extraction of stones due to its low morbidity, mortality and shorter hospital stay.⁸ The main objective of the treatment of concomitant CBD and gall bladder stones is an accomplishment of complete ductal clearance independent of the number of stones. Although endoscopic removal is still an effective and safe management technique, the need for multiple intra-operative attempts for stone extraction, post-procedural pancreatitis, recurrent stone formation, ampullary perforations remains well-recognized complications.⁹⁻¹³ The need for second-time anesthesia during two-staged management is also present. Studies have shown that one staged management has benefits as compared to two-staged management.² In one study, morbidity, after one staged management, was almost two times lower.⁴ No study has compared single staged and two-staged management techniques in Nepal. In our study, we have made an effort to compare either procedure at our center.



Studies show a success rate of one staged management to vary largely from 80%-98.5%,⁶⁻⁸ and two-staged management to vary from 79%-92%.⁹⁻¹¹ In our study, we had a 100% success rate for one-staged in first attempt in Group A and a 90% success rate for two-staged management in Group B. The reasons for the low success rate in Group B may be due to the presence of impacted stones, difficulty in cannulation, lack of cholangioscope at our center and lower threshold for multiple ERCP attempts before converting into LCBDE.

Factors like operative time, duration of hospital stay, the overall cost of the procedure are often used as deciding parameters for the procedure of choice by patients as well as health care providers. In studies conducted by Topal et al.¹² Urbach et al.¹³ the mean average costs for single staged approach/management were significantly lower than two-staged management. Our study also shows that the overall cost of the procedure is lower in a single staged approach.

In studies by Martin et al.¹⁴ Rogers et al.⁸ and Cuschieri et al.⁶ the mean duration of hospital stay shorter¹⁴, shorter for LC +LCBDE with mean[SD] 55[45]hours vs 98[83]hours $p < 0.001$ ⁸ and 3 days⁶ and significantly lower in two-staged approach compared to single staged management respectively in each study. This is in contrast to the study done by Bansal et al.² who found mean hospital stay to be lower in patients in the LCBDE group compared to those undergoing ERCP followed by laparoscopic cholecystectomy. Our study results are along with the findings of Bansal et al.

Published literature shows no or very less significant complication rates between either approach.^{2,11,15} In our study, there is a statistically significant difference between patients who suffered pancreatitis. Higher incidence of pancreatitis in our study may be because of small sample size. All pancreatitis that occurred were of mild severity. A large percentage of complications occurred in patients undergoing ERCP followed by LC. Although the nature of complications that occurred did not require surgical intervention, two-staged procedures had a higher incidence of complications compared to single staged management. As this study is the first of its kind in our region, study results may not be generalizable to other centers. We have found that although both the techniques help achieve the desired management objective i.e. CBD clearance, single-stage management may be better in terms of cost of operation, duration of hospital stay and complications encountered compared to two-staged management.

Various studies and meta-analyses have suggested one-session and two-session treatments for patients with concomitant gallbladder and CBD stones were effective.¹⁶

but one-session treatment is characterized by a shorter hospital stay and more cost benefits.¹⁷ The generalization of the study findings need to be put cautiously because of availability of local resources and expertise.¹⁸

CONCLUSION

From our study, we conclude complete clearance of the stone with a single attempt was achieved in Group A compared to Group B where 8 patients had second attempt. Also incidence of pancreatitis was higher in Group B and statically significant. Other complications like bleeding & perforation were also noted during the study period in B group. So in centers where expertise and resources are available, a one-staged approach may be favorable in terms of cost of operation, duration of hospital stay and lower incidence of complications.

RECOMMENDATIONS

From this study we recommend there should be multicentric study with large sample size on this topic as we found single-stage management (LCBDE) is better for low socio-economic countries like ours, which will help us to implement this type of technique in the local setting of our country. So, I would also encourage availability of expertise in most of the centers, not only at tertiary health care, so that this technique can be used by many more people.

LIMITATION OF THE STUDY

Because of the limited study population, the results of the study may not be generalizable. A multicentric study with a larger sample size is required.

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CONFLICTS OF INTEREST

None

FINANCIAL DISCLOSURE

The study total cost financed by the principal authors for all the requirements which includes for the print of the questionnaire or any paper or articles required for the study and internet services etc. It cost around 1 lakh total for this study. Regarding the payment structure of patients for the treatment were also considered for which certain amount of incentives were given.



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