

# Strategies and Techniques for the Treatment of Concomitant Gallbladder and Common Bile Duct Stones: An Economic Dilemma Only?

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## ABSTRACT

**Background:** Single stage laparoendoscopic rendez-vous (LERV), single-stage laparoscopic common bile duct exploration – cholecystectomy (LCBDE), and two-stage endolaparoscopic (LC-ERCP) management of cholecystocholedocholithiasis can be performed with similar short and long-term outcomes. This multicentric study retrospectively examined the outcome and hospital costs of one-stage vs. sequential two-stage strategies of treatment.

**Methods:** From January 2013 to December 2016, all the patients affected by cholecystocholedocholithiasis and treated at 2 different medical centers (General surgery and senology Unit - Policlinico Vittorio Emanuele Hospital and G.B. Morgagni Hospital, Catania - Italy) were enrolled in a retrospective study. Measures of outcome were hospital costs, postoperative morbidity and length of hospital stay. The 3 different approaches to cholecystocholedocholithiasis were retrospectively compared: two-stage endolaparoscopic (LC-ERCP) (Group A), laparoendoscopic rendez-vous (LERV) (Group B), and laparoscopic common bile duct exploration (LCBDE) (Group C) that includes laparoscopic trans-cystic common bile duct exploration (LTC-CBDE) and laparoscopic direct common bile duct exploration (LD-CBDE).

**Results:** A total of 204 patients met the study criteria. One-stage laparoscopic management using a direct common bile duct exploration approach (LD-CBDE) was the least expensive option when compared to LTC-CBDE (LTC-CBDE 1480 € versus LD-CBDE 1264 €,  $p < 0.001$ ). However, two-stage LC-ERCP appears to be, according to our experience, the least expensive of all (998 €). The rendezvous technique group demonstrated a better overall efficacy with a complete clearance of the bile duct in 100% of the cases, as compared to the 80% of the LC-ERCP group and 72% of the LCBDE. Postoperative morbidity was 5% in the LC-ERCP group versus 9.75% in the LERV group, and 3.12% in the LCBDE group, respectively. The average length of hospital stay was 7.7 days and 17, and 11.8 days in the LERV, LCBDE, and LC-ERCP, respectively.

**Conclusions:** According to our experience, the Rendezvous technique provides the best strategy for the treatment of cholecystocholedocholithiasis in terms of clearance of the biliary duct, hospital stay, morbidity and costs. Randomized trials should be designed to confirm these findings.

**Key words:** laparoscopy, choledocholithiasis, rendezvous, choledocotomy, sequential technique, one-stage technique, cost-analysis

## Abbreviations:

CBD - Common Bile Duct;  
ERCP - Endoscopic Retrograde  
Cholangiopancreatography;  
EUS - Endoscopic Ultrasound;  
LC - Laparoscopic Cholecystectomy;  
LCBDE - Laparoscopic Common Bile  
Duct Exploration;  
LERV - Laparoendoscopic Rendez-Vous;  
MRC - Magnetic Resonance  
Cholangiography;

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## BACKGROUND

Nowadays laparoscopic cholecystectomy (LC) represents the gold standard procedure for symptomatic cholecystolithiasis, despite the advent of newer minimally invasive approaches, such as robotic or natural transluminal endoscopic surgery. However, the management of patients with concomitant gallbladder and common bile duct (CBD) stones remains a challenge, as there are many available options for treating this condition. All of these are effective but none of them is clearly superior to the others (1-4).

The sequential endolaparoscopic approach (two stage technique) (LC-ERCP) was considered for a long time a better choice. It combines endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (ES), before or after laparoscopic cholecystectomy.

Successful stone clearance rates for preoperative ERCP range from 87% to 97%, although up to 25% of patients require two or more ERCP procedures (4).

The associated morbidity and mortality rates reported in the literature are 5-11% and 0.7-1.2%, respectively (5-6). Complications of ERCP may include several conditions, such as bleeding, duodenal perforation, cholangitis, pancreatitis and bile duct injury (7).

Nowadays, as a result of the economic sustainability era, it is of fundamental importance to include the economic outcomes in the decision making process. One stage techniques LCBDE and LERV have progressively gained some consensus as cost effective and efficient minimally invasive methods for treating cholecystocholedocholithiasis (8-12).

We present a retrospective review of two centres on the management of cholecystocholedocholithiasis, using the different popular minimally invasive approaches.

## MATERIALS AND METHODS

Between January 2013 and December 2016 all the patients affected by cholecystocholedocholithiasis treated at two medical centers (General Surgery and Senology Unit - Policlinico Vittorio Emanuele Hospital, and G.B. Morgagni Hospital, Catania – Italy) were retrospectively reviewed. A total of 204 patients met the study inclusion criteria.

All patients underwent a first step of diagnosis which included clinical symptoms, blood test analysis and abdominal ultrasound.

Patients with symptomatic cholelithiasis were stratified according to the American Society for Gastrointestinal Endoscopy (ASGE) clinical score system

into 3 different categories: low (< 10%), intermediate (10% - 50%) and high (> 50%) risk for concomitant choledocholithiasis.

Patients with intermediate risk underwent additional biliary imaging, such as magnetic resonance cholangiography (MRC) or endoscopic ultrasound (EUS).

### *Population characteristics*

Our retrospective study included 204 patients (86 males and 118 females) admitted for suspected choledocholithiasis from January 2013 to December 2016.

The mean age was 62 years (range: 30 - 85). 97 (97/204; 47,5%) patients had a recent history of mild acute pancreatitis or abnormal increase of amylase or lipase levels associated with biliary pain.

Sixty-five patients presented jaundice (65/204; 31.9%), twenty-two patients had subclinical jaundice (22/204 10.8%), while twenty-six of them displayed clinical symptoms of cholangitis at presentation (26/204; 12.7%).

All patients underwent routine chemical blood tests (bilirubin levels, liver function indices,  $\gamma$ -GT and alkaline phosphatase, as well as pancreatic function tests, amylase and lipase) and abdominal ultrasonography (with an evaluation of common bile duct size).

Based on the analytical evaluation of these factors, we divided the patients into the various classes of predictive risk of choledocholithiasis: 35 patients (17%) presented high risk, 139 patients (66.2%) intermediate risk, while 30 patients (14,7%) had low risk.

In 199 patients a second level diagnostic imaging was also performed: cholangio-magnetic resonance in 109 patients (53.4%) and computed tomography in 90 patients (44%), respectively.

The 204 patients with preoperative diagnosis of CBD stones were subdivided into 3 groups according to the therapeutic action:

- Patients treated with two-stage technique, combining ERCP with ES before LC (Group A: 131).
- Patients treated with the LERV technique (Group B: 41).
- Patients treated with the LCBDE technique (Group C: 32), further divided into LDCBDE (28) and LTCBDE (4).

### *Different strategies of treatment*

The LC-ERCP technique is performed in two stages. A duodenoscope is inserted into the second part of the duodenum. Once the papilla is recognized, the CBD is cannulated through the papilla of Vater, and cholangiography is performed. This is followed by a sphincterotomy and stone extraction using a wire

basket. After biliary tract irrigation, a second cholangiography is performed to confirm complete clearance of the CBD.

LC is subsequently performed, normally 48 to 72 hours later, using a standard four-port technique.

The LERV technique is performed in one stage. During LC, a guide wire is inserted through the cystic duct into the CBD, advanced into the duodenum where it is endoscopically gripped with a snare or a polypectomy loop, pulled through the working channel of the duodenoscope and retrieved through the mouth. The sphincterotome is inserted over the wire and selective CBD cannulation is obtained to be followed by sphincterotomy and CBD clearance intra-operatively.

The LDCBDE technique involves the insertion of 5 trocars. After dissection of the Calot triangle, cystic duct is clipped in order to prevent spillage of stones into the common bile duct. The choledochotomy is made vertically in the supra duodenal portion of the CBD with a retractable blade. Choledochoscopy is performed using a flexible choledochoscope. Stones are extracted after flushing with saline with a Dormia basket or Fogarty catheter. Stones are removed through the trocar in the epigastric port. After all stones are extracted, a check cholangioscopy of hepatic ducts and CBD is performed to ensure clearance of the biliary system. The CBD is therefore closed and the LC is performed. There are two types of common bile duct closure after choledochotomy: primary closure or T-tube drainage.

If a T-tube drainage is used, a verification cholangiography is performed on postoperative day 7. In case of no residual stones, the T-tube is removed on the 10-15th postoperative day. In case of residual stones, distal obstruction or continuous bile leak patients undergo ERCP with sphincterotomy. Patients with primary closure of the common bile duct are discharged on postoperative day 3-7.

The LTCCBDE technique differs from LDCBDE in regards to the use of a transcystic balloon dilatator. Choledochoscopy is performed using a transcystic flexible choledochoscopy. Stones are extracted through the cystic duct, after flushing with saline, with a Dormia basket.

### *Statistical analysis*

The categories were examined as raw numbers and as percent of the group and factors studied were analyzed as univariate independent factors. The Statistical analysis was conducted using  $\chi^2$ -test for categorical data by MedCalc software, version 16.4.3.

## **RESULTS**

### *Group A*

In group A 131 patients underwent the sequential technique (ERCP + ES) followed by LC. A total of 105 patients (80.15%) had successful CBD stone extraction, while in 26 cases (19.85%) it was unsuccessful. Twenty-one (80.7%) of the 26 failed cases had a successful CBD extraction with a second ERCP 8-10 days later. The remaining 5 (19.2%) unsuccessful cases were treated either by the RendezVous technique (3) or by a traditional surgical approach (2).

The intraprocedural difficulties presented in 3.8% of the cases are represented by:

- stenotic papilla (2% of the cases);
- juxtapapillary diverticula (1% of the cases);
- papillary edema (1 % of the cases).

The main procedural complications were moderate pancreatitis in 6 cases (4.6%), and haemorrhage in a single case (0.76%). No perforation occurred. This group had an average hospital stay of 11.8 days (range 3-32 days).

### *Group B*

Group B, consisting of 41 patients who underwent the Rendez-Vous technique, presented complete CBD stone extraction in 100% of cases without intra-procedural difficulties. Procedural complications occurred in 4 cases (9.75%), of which 3 cases (7.31%); of mild pancreatitis, and a single case (2.43%) of fever. In this group the average hospital stay was 7.7 days (range 3-14 days).

### *Group C*

In group C 32 patients underwent laparoscopic common bile duct exploration. 28 patients had LD-CBDE, while 4 patients underwent LTC-CBDE.

A total of 23 patients (71.87%) were successfully treated, while incomplete stone clearance occurred in 9 cases (28.13%). The intraprocedural difficulties responsible for the latter were: acute cholecystitis (3.12%), impacted stones (6.25%) and cholecysto-duodenal fistula (3.12%), respectively. All 9 patients were successfully treated with postoperative ERCP. One (4.34%) patient developed a superficial wound infection, successfully treated with antibiotics. In this group the average hospital stay was 17 days (range 8-22 days).

The analysis of Study Population is summarized in *table 1*.

Table 1 - Study Population

Total no patients	Value (n/tot) (%)
Age	62 (range: 30-85)
Sex	
Female	118
Male	86
Symptoms	
Biliary colic	154
Jaundice or sub-jaundice	87
Cholangitis	26
ASGE risk score for choledocholithiasis	
High	35 (17.1%)
Intermediate	139 (68.1%)
Low	30 (14.5%)
Imaging	
Ultrasound	204 (100%)
Abdominal computed tomography (CT)	90 (44%)
Abdominal cholangio-magnetic resonance (RM)	109 (53.4%)

According to our experience, the best therapeutic result was obtained in group B, as we have obtained a complete clearance of the bile duct in 100 % of the cases against the in comparison to 80% of the in group A and 72% in group C ( $p < 0.05$ ).

The remaining 20% of group A underwent either successful repeat ERCP (80,7 %) after a few days, or Rendezvous technique/full surgical approach (5 patients).

The remaining unsuccessful cohort (28%) of group C, was treated with ERCP, thus obtaining complete stone extraction.

The causes of failures in group A are to be found in the alteration of the papilla (stenosis) or in the presence of papillary edema (linked to trauma due to the same method) or finally in the presence of juxtapapillary diverticula.

The causes of failures in group C are different from the ones in group A, and consist of impacted stones, cholecystitis and colecysto-duodenal fistula (table 3).

More attention has to be paid to the postoperative period. According to the literature, our study has shown that the sequential method (Group A) can be associated

Table 2 - Collected data

Rescue ERCP	30
Average hospital stay	
Group A	11.8 (range: 3-32)
Group B	7.7 (range: 3-14)
Group C	17 (range: 8-22)
Cost analysis	
Group A	998 €
Group B	1480 €
Group C	1264 €
Complication of sequential techniques	
Pancreatitis	6 (4.6%)
Haemorrhage	1 (0.8%)
Complication of LEVS	
Pancreatitis	3 (7.31%)
Fever	1 (2.43%)

with complications as well. Morbidity in Group A occurred in 5% of the cases, and consisted of mild to moderate pancreatitis in 4.6% of cases and intraoperative haemorrhage in 0.7% of cases.

Complications also occurred in Group B in 9.75% of cases: 7% of cases were mild pancreatitis and 2% of cases a modest fever.

Finally, in Group C, there was a single case of post-operative minor wound infection (table 4).

The length of hospital stay, according to the literature, shows how the Rendezvous technique is the preferable approach to this pathology compared to the others. In fact, in our analysis there was a lower average hospitalization in group B, with a value of 7.7, an average hospital stay of 11.8 days in Group A, and one of 17 days in Group C (table 5).

One-stage laparoscopic management using the transductal approach was less expensive compared to laparoscopic transcystic one-stage approach (TC 1480 € versus TD 1264 €,  $p < 0.001$ ). Nevertheless, two-stage management is the least costly of all (998 €) (table 6).

Costs of disposable equipment were significantly higher in the LERV group compared to the LC-CBDE group due to an higher price of ERCP disposables.

Table 3 - Causes of failure

	N° patients	Causes of failures (Hypothesized)	Causes of failures (real)	Chi squared	P value
Group A	131	5.78	5	0.11	
Group B	41	1.81	0	1.81	
Group C	32	1.41	4	4.75	
tot	204		9	6.66	The P-Value is 0.035793. The result is significant at $p < 0.05$ .

Table 4 - Complications

	N° patients	Complications (Hypothesized)	Complications (real)	Chi squared	P value
Group A	131	8.99	7	0.44	
Group B	41	2.81	6	3.61	
Group C	32	2.20	1	0.65	
tot	204		14	4.7	P-Value 0.095369. The result is not significant at $p < 0.05$ .

Table 5 - Length of hospital stay

	N° patients	length of hospital stay (Hypothesized)	length of hospital stay (real)	Chi squared	P value
Group A	131	11.79	11.8	0.00	
Group B	41	11.79	7.7	1.42	
Group C	32	11.79	17	2.30	
TOT	204		36.5	3.72	The p-Value is 0.155673. The result is not significant at $p < 0.05$ .

Table 6 - Costs

	N° patients	Costs (Hypothesized)	Costs (real)	Chi squared	P value
Group A	131	1136.60	998	16.9	
Group B	41	1136.60	1480	103.75	
Group C	32	1136.60	1264	14.28	
tot	204			134.93	The P-Value is $< 0.00001$ . The result is significant at $p < 0.05$ .

## DISCUSSION

Cholelithiasis is associated with CBD stones in approximately 20% of the cases. This association should not be underestimated because it could result in morbid complications such as jaundice, cholangitis, and pancreatitis. Therefore it is paramount to diagnose CBD stones promptly in order to apply the proper treatment strategy. Furthermore, an accurate differential diagnosis should be mandatory in order to exclude a concomitant neoplastic pathology (13-20).

Several options are available for the treatment of patients with concomitant gallbladder stones and CBDS. However, the ideal management protocol remains controversial.

LCBDE for CBD stones was first described in 1991 by Petelin et al [1]. Since then, several studies have been performed by either the laparoscopic transcystic (LTC-CBDE) or by the direct common bile duct exploration

(choledochotomy) route. Significant advancements in laparoscopic techniques have made LCBDE a feasible and effective option for the treatment of patients with CBDS.

Successful stone clearance rates for LCBDE range from 85% to 95%, with a risk of incomplete stone clearance rate of 8% to 13.8%. The morbidity rate is 4-16% (complications include bile leak and CBD stricture) and the mortality rate is 0-2% (7-8).

A Cochrane meta-analysis (2013) of sixteen randomised clinical trials, with a total of 1758 randomised participants, demonstrated that LCBDE was equivalent to ERCP in terms of bile duct clearance, retained stones, failure rates, morbidity, and mortality (9). Despite having been proven to be one of the best procedures in terms of economical outcomes, compared to the other options, it is slow to become a routine method because it requires uncommon laparoscopic surgical skills. The LERV approach was first



described by Deslandres et al [10]. In 1993 and represents an alternative to sequential or totally laparoscopic approaches. According to the literature the main advantages of LERV compared to the other techniques (LC-ERCP or LCBDE) are the lower morbidity rate (especially pancreatitis), the higher success rate, reduced length of hospital stay, reduced operation time and lower technical difficulties (10-12).

In practice, however, the rendezvous technique is not universally accepted because it creates organizational difficulties and additional complexities in the coordination of surgeons and endoscopists.

Since the introduction of ERCP, a sequential approach is frequently preferred. Although successful stone extraction and low morbidity rates can be achieved with two-stage management, this option is not devoid of drawbacks (21-25).

Recently, Tan C et al (2018) examined the results of 5 randomized controlled trials for a total of 629 patients. According to their study, preoperative ERCP is on par with intraoperative ERCP in terms of CBD clearance. However, it requires two hospital admissions, two anesthetic inductions and demonstrated a higher incidence of post-operative pancreatitis, overall morbidity, and longer hospital stay (26).

Tsiopoulos F et al (2018) compared LERV with classic ERCP in order to evaluate any difference in the success rates of CBD cannulation and clearance. Secondary endpoints were the detection of differences in morbidity (especially post-ERCP pancreatitis [PEP]), and the feasibility of the two approaches. Classic ERCP demonstrated a higher rate of successful CBD cannulation and a similar rate of CBD clearance but also a higher incidence of post procedural pancreatitis (27).

From a health economics point of view, several studies have demonstrated that one-stage techniques are less expensive than two-stage ones in the management of cholecystocholedocholithiasis (28-31).

A meta-analysis of 7 randomized controlled trials (787 patient in total) with the aim to compare one stage vs two stage strategies reported a significantly shorter hospital stay for patients in the one-stage group (28).

Bansal VK et al compared the success and cost effectiveness of single versus two-stage management in a prospective randomized trial of 168 patients. The procedures had similar success and complication rates, but the single-stage strategy was better in terms of shorter hospital stay, need for fewer procedures, and cost effectiveness (30).

Garbarini et al (2017) recently analyzed 249 consecutive patients in a retrospective analysis. The

authors suggest that LERV is preferable to sequential treatment not only in terms of less morbidity, but also of lower costs accrued due to a shorter hospital stay. However, the longer operative time raises the attention on organizational issues in the coordination of surgery and endoscopy services (31).

It is well known that both clinical outcomes and costs of surgery are dependent on surgeon's experience and the quality of treatment. In our experience, the best therapeutic result was in group B, as it achieved a complete clearance of the bile duct in 100 % of the cases compared to 80% in group A and 72% in group C. Our study failed to demonstrate a lower incidence of postprocedural pancreatitis and overall morbidity in the LERV group (group B).

The length of hospital stay, according to the literature, seems to suggest the Rendezvous technique is the preferable approach to this pathology compared to the others. In fact, in our analysis, there was a lower average hospitalization in group B compared to the other two groups.

In our experience one-stage laparoscopic management using the transcholedochal approach was a less expensive option compared to laparoscopic transcystic one-stage approach (TC €1480 versus TD €1264,  $p < 0.001$ ). However, two-stage management is the least costly of all (€998). Costs of disposable equipment were significantly higher in the one-stage LERV group compared to the two-stage LC-ERCP due to a higher price of ERCP disposables.

Limitations and possible biases in this study are the lack of randomization, which may have caused some selection bias, as well as the small number of patients, which renders the detection of small differences between the study groups unreliable. The study design was retrospective.

## CONCLUSION

In conclusion, according to our experience, the Rendezvous technique seems to be the best strategy to clear CBD stones based on shorter hospital stay, low morbidity and overall costs.

However, in centers where the Rendezvous approach cannot be performed, sequential technique and laparoscopic choledochotomy remain effective approaches with satisfying results.

## Authors' contributions

AZ, ACav, MDV ACap conceived the study. AZ, ACav, SC, LF collected the cases. AZ, ACav, LF drafted the

manuscript. AZ and ACap revised the manuscript for important intellectual content. All Authors revised the final manuscript and gave their approval.

### Conflict of interests

The authors declare no conflict of interest.

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