Cost analysis of laparoendoscopic rendezvous versus preoperative ERCP and laparoscopic cholecystectomy in the management of cholecystocholedocholithiasis

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Abstract

Background

Evidence from controlled trials and meta-analyses suggests that laparoendoscopic rendezvous (LERV) is preferable to sequential treatment in the management of common bile duct stones.

Materials and methods

With this retrospective analysis of a prospective database that included consecutive patients treated for cholecystocholedocholithiasis at our institution between January 2007 and July 2015, we compared LERV with sequential treatment. The primary endpoint was global cost, defined as the cost/patient/hospital stay, and the secondary end points were efficacy and morbidity. Fisher's exact test or Mann–Whitney test was used.

Results

Of a total of 249 consecutive patients, 143 underwent LERV (group A) and 106 a two-stage procedure (group B). Based on an average cost of €613 for 1 day of hospital stay in the General Surgery Department, the overall median cost of treatment was €6403 for group A and €8194 for group B ($p < 0.001$). Operative time was significantly shorter ($p < 0.001$), and length of hospital stay was significantly longer for group B ($p < 0.001$). No mortality in either group was observed. The postoperative complications rate was significantly higher in group B than in group A (24.5 vs. 10.5%; $p = 0.003$). No significant difference in the postoperative pancreatitis rate or the number of patients with increased serum amylase at 24 h was observed in either group.

Conclusion

Our study suggests that LERV is preferable to sequential treatment not only in terms of less morbidity, but also of lower costs accrued by a shorter hospital stay. However, the longer operative time raises multiple organizational issues in the coordination of surgery and endoscopy services.

Keywords

Common bile duct stones ERCP Laparoscopic cholecystectomy Rendezvous technique

Background

Choledocholithiasis is associated with symptomatic gallstones in 11–20% of cases reported in Western countries [1, 2]. While laparoscopic cholecystectomy is considered gold standard treatment for cholelithiasis [3, 4], the management of common bile duct (CBD) stones remains controversial [5, 6]. Several approaches to the management of this situation have been described: cholecystectomy and laparoscopic surgical treatment of the bile duct, preoperative endoscopic retrograde cholangiopancreatography (ERCP) followed by cholecystectomy, cholecystectomy followed by postoperative ERCP [7], or combined laparoscopic cholecystectomy and ERCP (rendezvous technique) [8]. The final choice among these therapeutic strategies usually depends on local availability, expertise, and experience [9]. Controlled trials [10, 11, 12] and meta-analyses [13, 14] comparing endolaparoscopic rendezvous with sequential treatment have suggested that, because the rendezvous technique is associated with higher success rates, fewer complications (especially pancreatic), shorter hospitalizations, and lower costs, it is preferable over other treatment options. The main potential advantage of the rendezvous technique is that intraoperative ERCP can be performed with endoscopic sphincterotomy along a guide wire inserted through the cystic duct and retrieved in the duodenum, thus minimizing iatrogenic injury to the papilla [15, 16, 17]. In practice, however, the rendezvous technique is not universally accepted because it creates organizational difficulties that introduce additional complexities to structuring the duties of surgeons and endoscopists [18, 19].

With this retrospective case–control study, we compared the rendezvous technique with the sequential treatment (ERCP followed by laparoscopic cholecystectomy) in the management of cholelithiasis with CBD stones in a tertiary university hospital. The end points were costs, efficacy, and morbidity.

Materials and methods

A prospectively collected database was queried for all consecutive patients with cholecystocholedocholithiasis (CCL) referred to our institution between January 2007 and July 2015. Diagnosis was confirmed by imaging with ultrasonography (US), magnetic resonance imaging (MRI), or computed tomography (CT) scans. Patients who underwent laparoscopic cholecystectomy and ERCP were included. Two groups were defined and compared: one was composed of patients who underwent simultaneous ERCP and cholecystectomy (rendezvous approach), the other included patients who underwent ERCP followed by laparoscopic cholecystectomy within 45 days (sequential approach). In the rendezvous approach, a flexible 0.0125–0.03-mm/400-cm Radifocus guide wire (Terumo Corporation, Tokyo) or, more recently, a 0.035-mm/450-cm Jagwire (Microvasive Endoscopy, Boston Scientific, Natick, MA, USA) was inserted through the cholangiogram catheter into the CBD according to the Hunter technique [20]. The duodenoscope, positioned on the left side of the patient’s head, was passed into the duodenum

as done in conventional ERCP. When the transcystic flexible guide wire reached the duodenum, it was caught by an endoscopic loop inserted through the duodenoscope. The guide wire was used to cannulate the Vater papilla with a conventional papillotome inserted into the working channel over the guide wire. Endoscopic sphincterotomy was performed and the CBD explored with a Dormia basket and an 8-mm Fogarty angioplasty catheter to complete CBD clearance. Clearance was confirmed by endoscopic cholangiography. At the end of the endoscopic procedure, a biliary stent was left in place in case of biliary leak, sphincter bleeding, CBD <6 mm, or incomplete CBD clearance. Laparoscopic cholecystectomy was then completed. Neither the supine position of the patient nor the image intensifier used for cholangiography was changed during the procedure [21]. No patient selection criteria were applied. Instead, we took into account the availability of the operating room (OR) for a longer procedure and of the endoscopic team to perform a laparoendoscopic rendezvous (LERV) procedure. Age at diagnosis, sex, height, weight, comorbidities, American Society of Anesthesiology (ASA) score, antiplatelet and anticoagulant therapy, preoperative serum bilirubin, GGT, and amylase levels were compared to test homogeneity between the two groups.

The primary end point was the global cost, defined as the cost/patient/hospital stay. In a further analysis, the two groups were compared in relation to morbidity, mortality, length of hospital stay, success rate of the procedure, conversion to open surgery, operative time, need for reintervention, use of biliary stents, and postoperative serum amylase at 24 h.

Categorical variables were tested using Fisher's exact test and continuous variables using the Mann–Whitney test. All results for the continuous variables are expressed as the median (range); all reported *p* values are two-sided at the conventional 5% significance level. Data were analyzed by means of the R freeware program (http://www.cran.r-project.org) [22].

Results

Between January 2007 and July 2015, 343 patients affected by CCL were referred to our institution: 26 were considered unfit for surgery, 17 underwent ERCP alone, and 9 were not treated. ERCP was not feasible because of a Roux-en Y reconstruction of the digestive tract in 21 patients (after gastric by-pass for obesity in 13 and after gastric resection for cancer in 8). Cholecystectomy and conventional surgical CBD cleaning via choledochotomy was performed in these patients. Forty-seven patients were lost to follow up (Fig. 1). A total of 249 patients were included in the final analysis: 143/249 (57.4%) underwent a laparoendoscopic rendezvous procedure (group A) and 106/249 (42.6%) a two-stage procedure (group B). The median interval time between the two procedures was 4 days (range 1–42) in group B. There were no significant differences except for older age in group B. Table 1 presents the patients' characteristics.

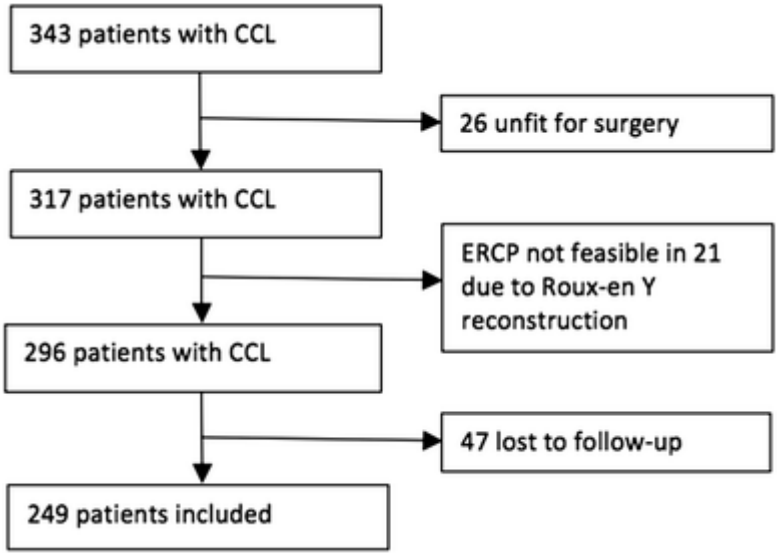

Fig. 1

Algorithm of patient selection. ERCP denotes endoscopic retrograde cholangiopancreatography

Table 1

Demographics and clinical characteristics of patients undergoing laparoendoscopic rendezvous (LERV) or sequential (two-stage) treatment for common bile duct stones

	LERV—Group A	**Two-stage—Group B**	
			***p* value**
	***N* = 143 (%)**	***N* = 106 (%)**	
Sex (M/F)	64/79	57/46	0.073
Mean age (range)	59 (16–88)	68 (23–88)	**<0.001**
Age >60	66 (46)	72 (67.9)	**0.001**
Height in cm (range)	165 (157–185)	167 (150–190)	0.238
Weight in kg (range)	70 (40–160)	70 (43–110)	0.801
Preoperative serum level			
Bilirubin in mg/dL (range)	1.1 (0.2–32.2)	1.4 (0.2–32.5)	0.214
GGT in UI/L (range)	207 (8–1393)	229 (12–1243)	0.167
Amylase in UI/L (range)	30 (10–2312)	31 (2–1251)	0.381
Comorbidity	117 (81.8)	93 (87.7)	0.222
ASA score III–IV	17 (11.9)	16 (15.1)	0.571
Antiplatelet therapy	17 (11.9)	16 (15.1)	0.571
Anticoagulant therapy	6 (4.2)	5 (4.7)	1.0

p values < 0.05 are in bold

According to the data provided by our hospital administration, the average cost for 1 day of hospital stay in the General Surgery Department was €613.00 and the average cost for 1 h of OR time, excluding personnel costs, was €233.00. The estimated average OR staff costs were €3 per minute. The average flat rate cost of an ERCP was estimated at €351.00 per procedure. The average cost of the extra endoscopic session for stent removal was €219.00. The costs related to OR use, including

or not OR staff costs, were significantly higher for group A ($p < 0.001$), whereas the costs related to hospital stay were significantly higher for group B. The overall mean cost of treatment, including personnel costs and stent removal, was significantly lower for group A ($p < 0.001$ (Table 2). Operative time was significantly shorter ($p < 0.001$), and length of hospital stay was significantly longer for group B ($p < 0.001$).
Table 2

Comparison of costs of laparoendoscopic rendezvous (LERV) and sequential treatment (two-stage) for common bile duct stones

	Group A	**Group B**	
	LERV (*N* = 143)	**Two-stage (*N* = 106)**	***p* value**
Surgery costs in € (range)	1480 (516–3187)	998 (207–2732)	**<0.001**
Hospital stay costs in € (range)	4291 (1226–36,780)	6743 (1839–24,520)	**<0.001**
Total costs in € (range)	6403 (2472–40,138)	8194 (3235–26,054)	**<0.001**

p values < 0.05 are in bold

No mortality was observed. Postoperative complications are reported in Table 3. The postoperative complications rate was significantly higher for group B than group A (24.5 vs. 10.5%; $p = 0.039$). The incidence of abdominal intrahepatic collections detected at US examination was significantly higher for group B. Conservative treatment (antibiotic therapy and pain medication) was successful in all but 1 group A patient who required laparoscopic drainage. Late bleeding after endoscopic sphincterotomy occurred in both groups and was treated with adrenaline injection in 2/3 cases in group A and in 3/5 cases in group B. No significant difference in the postoperative biliary fistula rate was observed; all cases of biliary leak were treated by biliary stent positioning, except for 1 group A patient in which surgical suture of the cystic duct was performed. In another patient, a LERV procedure was not possible because the guide wire could not be advanced to the duodenum. An ERCP procedure was performed but was subsequently complicated by acute pancreatitis. The postoperative pancreatitis rate was similar for both groups; conservative management based on fasting and pain medication was successful in all cases. The median serum amylase levels at 24 h post-procedure were significantly higher in group A in relation to cutoff values of 53 UI/L (laboratory cutoff) and 200 UI/L. The difference was not statistically significant on subanalysis of only those patients with a normal serum amylase level before surgery (Table 3).
Table 3

Postoperative morbidity in patients undergoing laparoendoscopic rendezvous (LERV) or sequential (two-stage) treatment for common bile duct stones

	Group A	**Group B**	
	LERV	**Two-stage**	***p* value**
	***N* = 143 (%)**	***N* = 106 (%)**	
Cumulative morbidity	15 (10.5)	26 (24.5)	**0.039**
Subhepatic collection	7 (4.9)	15 (14.2)	**0.013**
Late bleeding after ERCP	3 (2.1)	5 (4.7)	0.291
Biliary fistula	2 (1.4)	4 (3.8)	0.406

	Group A LERV	Group B Two-stage	*p* value
	***N* = 143 (%)**	***N* = 106 (%)**	
Postoperative acute pancreatitis	3 (2.1)	2 (1.9)	1
Postoperative serum amylase at 24 h	36 (8–3630)	28 (1–336)	**0.002**
>53 UI/L	46 (32.2)	20 (18.9)	0.021
>200 UI/L	18 (12.6)	5 (4.7)	0.045
>53 UI/L at 24 h with normal levels before surgery	23 (16.1)	9 (8.5)	0.087
>200 UI/L at 24 h with normal levels before surgery	11 (7.7)	4 (3.8)	0.283

ERCP denotes endoscopic retrograde cholangiopancreatography

p values < 0.05 are in bold

The conversion to open surgery rate was higher for group B ($p = 0.027$): Conversion was necessary in 14 cases due to adhesions and gallbladder abscess in 1 case. Eight group A patients required conversion to open surgery due to: adhesions in 5, intraoperative bleeding in 1 patient, hydropic cholecystitis in 1, and suspicion of intrahepatic stones on perioperative imaging in 1. A significantly higher number of choledochotomies for CBD cleaning were recorded for group B ($p = 0.032$). The median operative time was 70 min longer for group A ($p < 0.001$). Intraoperative standard ERCP was performed in 8 group A patients because the guide wire could not be passed through the papilla due to stone impaction in 6, the cystic duct could not be isolated in 1 patient, and a CBD fistula was present in 1 patient. In all these cases, ERCP was performed in the OR at the end of laparoscopic cholecystectomy. No significant difference in reintervention rate was observed between the two groups ($p = 0.406$). Reintervention was performed in 2 group A patients because of biliary fistula in 1 patient and bleeding in 1 patient; reintervention was performed in 4 group B patients because of abdominal collection drainage in 1 patient, bleeding in 2 patients, and incomplete cholecystectomy with recurrent gallbladder stones in 1 patient.

Failure of complete CBD cleaning was significantly lower in group A ($p < 0.001$): only 1 patient required a new ERCP 2 months later to complete CBD cleaning, whereas 13 group B patients required subsequent multiple ERCP procedures (Table 4).

Table 4

Comparison of efficacy parameters between laparoendoscopic rendezvous (LERV) and sequential treatment (two-stage) procedures in the management of common bile duct stones

	Group A LERV *N* = 143(%)	Group B two-stage *N* = 106 (%)	*p* value
Conversion to open surgery	8 (5.6)	15 (14.2)	0.027
Choledochotomy	0 (0)	4 (3.8)	0.032
Operative time (min)	215 (75–463)	145 (30–397)	<0.001
Biliary stent placement	117 (81.8)	94 (88.7)	0.156
Reintervention	2 (1.4)	4 (3.8)	0.406
Failure of CBD clearance	1 (0.7)	13 (12.3)	<0.001
Length of hospital stay	7 (2–60)	11 (3–40)	<0.001

	Group A LERV *N* = 143(%)	Group B two-stage *N* = 106 (%)	*p* value
(days)			

CBD denotes common bile duct

Discussion

There is convincing evidence to support LERV over two-stage treatment for cholelithiasis and CBD stones [13]. The LERV procedure is statistically superior to the two-stage procedure in reducing perioperative complications, which are frequent, prolong hospital stay, and increase the overall cost of the procedure. The correct timing of sphincterotomy for cholelithiasis and CBD stone clearance in patients undergoing cholecystectomy remains debated. Several randomized controlled trials have produced contradictory results, but systematic reviews have reported an association between the LERV technique and lower risk for pancreatitis, higher rate of CBD clearance, and shorter hospital stay.

Moreover, LERV is associated with a higher therapeutic success rate than preoperative sphincterotomy [23], which was corroborated in the present series. A remarkable finding of our study was the significantly higher incidence of failure of the two-stage procedure (12.3% for two-stage vs. 0.7% for LERV; $p < 0.001$), which resulted in multiple ERCP sessions and increased patient discomfort.

Our observation of a significantly lower cumulative morbidity rate in the LERV group is consistent with published data, though only the presence of subhepatic collections was statistically significant on the subgroup analysis. Clinical acute pancreatitis after ERCP was very rare (<2% in both groups). Such a low incidence precludes predicting risk. However, one case of acute pancreatitis in a patient who underwent LERV occurred after conversion to standard ERCP because the guide wire could not be passed through the cystic duct; this cancelled the “protective” effect of the rendezvous technique in identifying the biliary tract and led to excessive manipulation of the papilla of Vater (a known risk factor for post-ERCP pancreatitis [24]).

We found a higher post-procedural increase in serum amylase levels in the patients submitted to LERV. A plausible explanation for this is that these patients had higher preoperative serum amylase levels (i.e., not within the average range albeit not statistically significant) and so may have been selected for LERV because of their higher clinical risk of developing pancreatitis. If this is true, then it constitutes a bias of our study.

What it is still not clear, or not sufficiently supported by prospective randomized studies, is how all this translates into costs. This was, in fact, the main outcome we evaluated in our analysis. The mean length of hospital stay was significantly shorter for the LERV group. Importantly, however, the median of 4 days between the two procedures for the two-stage group was not due to any post-procedural complications requiring prolonged hospitalization. In fact, the length of hospital stay after surgery was similar for both groups. The cost of longer time in the OR for the LERV group was relatively lower as compared with the cost of the endoscopic services. The inhospital stay was shorter after LERV, with a cost reduction of about €2000 per patient.

Despite the advantages of LERV, several limitations of the technique should be mentioned. First, intraoperative endoscopic sphincterectomy during LERV is challenging because it requires addressing the needs of both the surgical and the endoscopic team, including patient position on the

operating table and endoluminal insufflation for endoscopic vision. This entails a longer operative time (about 70 min in our series) than for cholecystectomy alone [21]. Second, patients previously treated with total or partial gastric resection are unlikely to be suitable for a rendezvous procedure. Third, giant impacted stones, Mirizzi syndrome, and periampullary diverticula are other limitations [10, 12, 25]. Finally, LERV requires the availability of an endoscopic team, which, because the team is rarely part of the same surgery unit, raises organization issues. Furthermore, a higher number of subhepatic collections in the sequential two-stage group were recorded, as well as a higher rate of conversion to open surgery. A possible explanation is the difference in surgeons' experience. The higher incidence of choledochotomy might have been due to larger stone diameter or higher rate of stone impaction in the CBD, although no selection was performed.

Future prospective trials are desirable to confirm the advantage of LERV over the two-stage procedure in relation to perioperative complications, costs, and quality of life.

Conclusion

Our study provides further evidence that, because of the lower morbidity associated with the procedure and the lower costs accrued by shorter hospital stay, LERV is preferable to sequential treatment. However, LERV entails longer operative time, which raises multiple organizational issues in the coordination of surgery and endoscopy services.

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