



“A RANDOMIZED CONTROLLED COMPARATIVE STUDY OF LAPAROSCOPIC CBC EXPLORATION AND CHOLECYSTECTOMY WITH ENDOSCOPIC STONE EXTRACTION AND CHOLECYSTECTOMY FOR CHOLEDOCHOLITHIASIS”

Surgery

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ABSTRACT

Background and study aims: Overall, 5 % to 15 % of patients undergoing cholecystectomy for cholelithiasis have concomitant bile duct stones, and the incidence of choledocholithiasis increases with age. There is no clear consensus on the best therapeutic approach (endoscopic versus surgical).

Patients and methods: A prospective randomized controlled clinical trial was performed to compare three treatment options for patients with choledocholithiasis at Gandhi Hospital, Secunderabad from October 2012 to October 2015. The patients were randomized in three groups. Group I: patients who underwent intraoperative cholangiography (IOC) to confirm the choledocholithiasis followed by laparoscopic cholecystectomy (LC) associated with intraoperative endoscopic retrograde cholangiopancreatography (ERCP), group II: patients who underwent preoperative ERCP, ES and stone clearance followed by LC during the same hospital admission and group III: patients who underwent IOC to confirm the choledocholithiasis followed by LC associated with laparoscopic common bile duct exploration (LCBDE).

Results: A total of 100 patients with suspected choledocholithiasis were included in the trial and were randomized. As a result, a total of 45 patients were diagnosed with the presence of choledocholithiasis and treated during the study period. There were no significant differences in success rates of ductal stone clearance, but retained stone, postoperative complications and length of hospital stay were better in group I.

Conclusions: Intraoperative ERCP/ES shows a higher rate of common bile duct stones clearance, a shorter hospital stay, and lower morbidity, but further research with a larger study population is necessary to determine the additional benefits of this procedure. The results to date suggests that in appropriate patients, single-stage treatments are the best options.

KEYWORDS

INTRODUCTION

Overall, 5% to 15 % of patients undergoing cholecystectomy for cholelithiasis have concomitant bile duct stones, and a small percentage of patients will develop common duct stones after cholecystectomy. Incidence of choledocholithiasis increases with age. About 20 % to 25 % of patients older than age 60 with symptomatic gallstones have stones in the common bile duct and in the gallbladder [1, 2].

Thus, bile duct stones and their management constitute an important clinical problem. The primary goal in management of choledocholithiasis is to obtain complete clearance of the common bile duct and cholecystectomy, when indicated [1, 2].

Options for management of common bile duct stones (CBDS) are increasing with development of new technologies for diagnosis and treatment. There is no clear consensus on the best therapeutic approach (endoscopic versus surgical) [3, 4, 5, 6, 7].

Preoperative endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic sphincterotomy (ES) are safe and effective options for removing CBDS in most cases, but even when clinical, biochemical, and ultrasound criteria are used, only 10 % to 60 % of patients will have stones on ERCP. As a result, far too many unnecessary ERCP are being performed [8]. In fact, one of the best preventive measures to reduce ERCP complications is not to perform it if it is unnecessary.

Laparoscopic surgery of CBDS was introduced over 15 years ago and various surgical groups have shown that it has a high success rate [9, 10] and is just as efficient and safe as preoperative or postoperative ERCP associated with laparoscopic cholecystectomy (LC), thereby avoiding the need to perform additional procedures [11]. Nevertheless, its technical difficulties, long and difficult learning curve and the need for the allocation of technical resources (high-quality fluoroscopy and choledochoscopes), which are not available at many operating theaters, has curtailed its expansion [10].

Use of intraoperative ERCP has slowly increased among various endoscopic groups, because the transition of ERCP from the endoscopy unit to the operating room has a short learning curve (endoscopic groups with expertise in preoperative and postoperative ERCP) without the high technical requirements needed by

laparoscopic management of the bile duct [12, 13, 14].

The aim of this prospective, randomized controlled trial was to compare the efficacy, safety, and surgical outcomes of the intraoperative ERCP plus LC (ERCP + LC), preoperative ERCP + LC and laparoscopic common bile duct exploration (LCBDE) plus LC (LCBDE + LC), and determine the most appropriate approach for patients with choledocholithiasis.

PATIENTS AND METHODS

A prospective, randomized controlled clinical trial was performed to compare 3 treatment options for patients with choledocholithiasis. The study was conducted at Gandhi Hospital, Secunderabad from October 2012 to October 2015. This is a tertiary referral university-affiliated center specializing in endoscopic and laparoscopic surgery (Multidisciplinary work group). Informed consent was obtained from patients before study participation. The sample size calculation is as follows: With 3 groups and a binary endpoint (success-failure), we constructed a 3×2 contingency table. We used the Grizzle, Starmer, and Koch method [15].

The primary endpoint was the rate of success in clearing ductal stones. Suspected CBDS admitted to the hospital were evaluated prospectively for study eligibility. The intake was restricted to appropriate patients [American Society of Anesthesiologists (ASA) I, II and III] in whom choledocholithiasis was suspected on the basis of clinical features (biliary colic with jaundice and recent acute pancreatitis), liver function tests (elevated bilirubin, alkaline phosphatase, gamma-glutamyltranspeptidase), and external ultrasound findings (showing possible CBDS or a dilated common bile duct > 8 mm).

Further exclusion criteria included cholangitis or pancreatitis, age < 18 years, ASA IV and V, suspected common bile duct (CBD) malignancy, previous cholecystectomy, previous ERCP and/or ES, and contraindications to ERCP or laparoscopic surgery. Moreover, patients treated with total or partial gastric resection were excluded.

After obtaining consent, eligible patients were randomized in 3 treatment groups using computer-generated random number sequences in concealed envelopes with block randomization design.

Group I patients underwent intraoperative cholangiography (IOC) to confirm choledocholithiasis followed by LC associated with

intraoperative ERCP, ES and endoscopic stone extraction (ESE). All patients were placed in the usual supine position for LC. LC with IOC was always attempted and images were obtained during this step. ERCP and ES were performed during LC. The surgeon carried out LC without completely dissecting the gallbladder from its bed. This maneuver facilitated ending LC after ERCP, because bowel distention during this procedure limits gallbladder dissection. Besides, in case of ERCP failure, traction of the vesicular bottom facilitated CBD visualization.

We performed a "rendevous" technique only in those patients, in which endoscopic cannulation of the papilla was difficult (when the papilla is hidden within a diverticulum). We used a guided wire through the cystic duct into the CBD to facilitate bile duct cannulation at subsequent endoscopy.

Group II patients underwent preoperative ERCP, ES with ESE followed by LC (24 to 48 hours later). All patients were placed in prone position.

Group III underwent IOC to confirm the choledocholithiasis followed by LC associated with LCBDE and laparoscopic stone extraction. We performed LCBDE via transcystic, choledochotomy and a few patients underwent flexible choledochoscopy. First, we performed transcystic common bile duct exploration but if a patient had an anomalous anatomy, proximal stones and large or numerous stones, we used choledochotomy for common bile duct exploration. LCBDE via choledochotomy required placement of a T-tube and drain.

The following criteria were recorded: success rates (ERCP cannulation rate and surgical success rate), success rates of ductal stone clearance, conversion rates, morbidity (complications were defined as any intraoperative or postoperative (30 days) event that altered the clinical course such as complications of ERCP including pancreatitis, perforation and bleeding), CBD retained stones, mortality (postoperative mortality was defined as death within 30 days of surgery), total operative time in minutes, and length of hospital stay.

The level of power for the study was set at 80 % with a 5 % significance level. Categorical variables were compared by X² test, with Yates correction and the Fisher exact test (two-tailed) when necessary. Continuous variables were compared by the Student t-test or HSD Tukey, depending on distribution. All P values were two-sided. P < 0.05 indicated a statistically significant difference. Data were analyzed on an intention-to-treat basis. All calculations were performed by using SPSS_ version 21.0.

RESULTS

A total of 135 patients with suspected choledocholithiasis were admitted to Gandhi Hospital, Hyderabad from October 2012 to October 2015. After excluding 35 ineligible cases (acute cholecystitis, cholangitis, pancreatitis and suspected CBD malignancy), 100 patients were included in the trial and randomized to either group I (Intraoperative ERCP/ES) (n = 33), group II (Preoperative ERCP/ES) (n = 34, or group III (LCBDE) (n = 33). 2 patients had protocol violations (management different from that dictated by random allocation) and 1 had anesthesia complications. As a result, a total of 45 patients were diagnosed with presence of choledocholithiasis and treated during the study period.

Table 1 shows the preoperative variables (age, CBD diameter, stone size and stone number) of the three groups.

Preoperative variables of the three groups.

Preoperative variable	Group		
	Group I Intraoperative ERCP ES n= 33	Group II Preoperative ERCP ES n= 34	Group III LCBDE n= 33
Age (years)	58.4 (23-87)	57.7 (20-84)	56.3 (22-87)
CBD diameter (mm)	8.2 (4-20)	8.4 (5-12)	7.7 (4-20)
Stone size (6-10mm)	23 (50.0%)	23 (51.1%)	22 (51.2%)
Stone number (one stone)	24 (52.2%)	29 (64.4%)	31 (72.1%)

ERCP/ES, endoscopic retrograde cholangiopancreatography plus endoscopic sphincterotomy; LCBDE, laparoscopic common bile duct exploration.

Table 1 Preoperative variables of the three groups.

The success rate for ductal stone clearance in each group was approximately the same. The success rate for stone clearance in the Intraoperative ERCP/ES group (97,8 %) was higher than in the preoperative ERCP/ES group (93,3 %) and similar in the LCBDE group (97,7 %). There were no significant differences among the groups (Table 2).

Success rates of ductal stone clearance of the three groups.

	Success rates of ductal stone clearance of the three groups		
	Group I Intraoperative ERCP ES n= 33	Group II Preoperative ERCP ES n= 34	Group III LCBDE n= 33
Positive for Choledocholithiasis	n=16	N=15	N= 14
Success rates of ductal stone clearance	15(93.75%)	14(93.3%)	13 (92.8%)

Table 2 Success rates of ductal stone clearance of the three groups.

Postoperative complications occurred in 6 patients (13,3 %) in the preoperative ERCP/ES group; 5 with cholecystitis and 1 with pancreatitis due to ERCP/ES. In the LCBDE group, postoperative complications occurred in 2 patients (4,7 %); these patients had bile leak from CBD closure and were treated conservatively with broad-spectrum antibiotics. No postoperative complications were reported in the intraoperative ERCP/ES group. Postoperative complications lasted for a significantly shorter time in the intraoperative ERCP/ES group than in the preoperative ERCP/ES group (P < 0.012) (Table 3).

Postoperative complications.

Postoperative complication	Group		
	Group I Intraoperative ERCP/ES n=33	Group II Preoperative ERCP/ES n= 34	Group III LCBDE n= 8
Positive for choledocholithiasis	n=46	n=45	n=43
Postoperative complications	0 (0%)	6 (13.3%)	2 (4.7%)

Comparison of surgical results among the three groups

Groups	RR 1	CI ²	P value
Group I vs. Group II	0.00	0.00-0.86	<0.012
Group I vs. Group III	0.00	0.00-3.84	<0.23
Group III vs. Group II	0.35	0.07-1.63	<0.26

ERCP/ES, endoscopic retrograde cholangiopancreatography plus endoscopic sphincterotomy; LCBDE, laparoscopic common bile duct exploration 'Relative nsk Confidence Intervals

Table 3 Postoperative complications.

Retained stones occurred in 1 patient (2.2 %) in the intraoperative ERCP/ES group and 1 patient (2.3 %) in the LCBDE group and were treated with postoperative ERCP. In the preoperative ERCP/ES group, retained stones occurred in 5 patients (11.1 %) and were treated with postoperative ERCP.

The rate of retained stones was significantly lower in the intraoperative ERCP/ES and LCBDE groups than in the preoperative ERCP/ES group. There were no significant differences among the groups (Table 4).

Retained stones.

Retained stones	Group		
	Group I Intraoperative ERCP/ES n=7	Group II Preoperative ERCP/ES n= 5	Group III LCBDE n= 8

Positive for choledocholithiasis	n=7	n=6	n=7
Retained stones	1 (2.2%)	5 (11.130)	1(2.33)
Comparison of surgical resul			
s among the three groups			
Groups RR			Pratte
Group I vs. Group II	0.20	0.02-1.61	<0.11
Group I vs Group III			
	0.93	0.06-14A8	1.00
Group III vs Group II	10.21	0.03-1.72	<0.20

ERCRES, endoscopic retrograde cholangiopancreatography plus endoscopic sphincterotomy, LCBDE, laparoscopic common bile duct exploration.

'Relative risk

²Confidence Intervals

Table 4 Retained stones.

Mean operative time was 94.2 minutes, 98 minutes and 117 minutes for groups I, II and III respectively. Mean duration of the ERCP/ES procedure for groups I and II was 24.7 minutes and 25 minutes, respectively. These times were significantly shorter than for LCBDE group III (49.7 minutes) ($P < 0.001$).

There were no deaths or cases of conversion to open surgery. Length of hospital stay was significantly shorter in the intraoperative ERCP/ES group (mean 1.2 days) than in the preoperative ERCP/ES group (mean 3.1 days) ($P < 0.0001$) and LCBDE group (mean 2.1 days) ($P < 0.012$).

DISCUSSION

Over the past 20 years, LC has become the gold standard for surgical treatment of symptomatic biliary lithiasis, and its development has favored the appearance of a group of new endoscopic/surgical therapeutic possibilities for patients with choledocholithiasis, namely total laparoscopic treatment of choledocholithiasis versus endoscopic treatment using intraoperative ERCP (both single-stage treatments), or preoperative ERCP and postoperative ERCP with LC (2-stage treatment)⁶.

Very few studies are available comparing single-stage treatments (LCBDE and intraoperative ERCP) and 2-stage treatment (preoperative ERCP)⁶. Since the introduction of laparoscopic cholecystectomy in our institution in 1993, the standard treatment for CBDS had been preoperative ERCP/ES, followed by LC and postoperative ERCP/ES. With the advance in technology and laparoscopic techniques, we started to perform LCBDE (1995) and intraoperative ERCP/ES (2003), and this randomized trial compares the results among the 3 preoperative approaches.

The preoperative and noninvasive tests for predicting CBDS such as clinical examination, history, laboratory tests and ultrasound have a high negative predictive value (92 % - 99 %). However, the positive predictive value is less satisfactory, and in patients with high suspicion of choledocholithiasis, this is only shown in 13 % to 58 % of cases. Application of these criteria reveals a high rate of false-positive diagnoses and many unnecessary ERCPs (40 % - 50 %) 17. Currently MRCP and endoscopic ultrasound are used routinely before ERCP to prevent unnecessary procedures but they are not available in our institution 5 6 7 8 9 10 11 18.

IOC failure occurred at a rate (8 %) which is similar to other publications. The single most frequent reason for failure to complete IOC in our series was an inability to cannulate the cystic duct.

The success of ERCP cannulation in our study is comparable to others reported (over 85 %) 19 20. The success rate for ductal stone clearance in our study is comparable to those in other reported trials 11 21 22 23 24 25 26. No statistically significant differences in success rates were seen for endoscopic versus laparoscopic approaches to choledocholithiasis.

We only used the rendezvous technique in some patients, which allows selective bile duct cannulation and avoids manipulation of the papilla as well as unnecessary injection of contrast material into the pancreatic

duct. Early in our work (first 100 intraoperative ERCP/ES in 2003) we tried to pass a guidewire through the cystic duct into the CBD to facilitate bile duct cannulation at subsequent endoscopy (the endo-laparoscopic "rendezvous" described by Cavina et al) 27 in all cases, but we found it technically difficult and encountered additional difficulties during LC (due to bowel insufflations) and the technique's limitations were related to impacted CBD stones, so we omitted this step in most cases in the clinical trial, as had ElGeidie et al 28, because the endoscopist and team were very experienced with ERCP (more than 10 000 ERCP).

Single-stage treatments facilitate performance of LC simultaneously. Recurrent biliary complications are more common in patients who do not have elective cholecystectomy after management of choledocholithiasis by ES 28 29. When there is a time lag between ERCP/ES and LC, some patients may develop cholecystitis (5 % - 22 %) 30 31 32. That difference can be partially explained by the length of the interval between the 2 procedures, which is not well defined, as even in the multicenter trial by the European Association for Endoscopic Surgery (EAES) the interval between endoscopic papillosphincterotomy and LC was not specified 33. Patients awaiting LC are known to have a high rate of readmission and complications due to acute cholecystitis, pancreatitis, empyema, and cholangitis; others showed that in case of delayed cholecystectomy, performed over 2 weeks after ES, there is a higher conversion rate, increasing from 4 % when LC was done within 2 weeks, to 31 % between 2 and 6 weeks, and 16 % after 6 weeks 34. Therefore, elective cholecystectomy is indicated 24 to 48 hours after clearance of CBD. Nevertheless, some authors report that it is not possible to know whether the acute inflammation is due to pre-ERCP acute cholecystitis or whether it is induced by ERCP 28.

In our study, a significant amount of local inflammation was found in 5 patients and was associated with pain. We consider that clinically relevant because residual local inflammation in patients after ERCP may negatively affect operative outcomes and necessitate a longer hospital stay. Studies have shown that presence of inflammation as an independent risk factor for bile duct injury during LC 35.

At the time of laparoscopic surgery, bile duct stones can be removed with a straightforward transcystic approach or with technically demanding choledochotomy. LCBDE in all candidates offers advantages over preoperative ERCP/ES: equivalent removal of duct stones with fewer procedures, lower cost, and preservation of the biliary sphincter. When laparoscopic bile duct exploration is used, the operation is longer. Consequently, in elderly patients and those with significant comorbidity who may not tolerate longer procedures, the advantage may be lost 36.

Several trials have compared clinical outcomes with the 2-stage approach to those with a single-stage strategy. Rogers and colleagues 36 randomized 122 patients to LC plus LCBDE or to ERCP/ES plus LC. Although the techniques had equivalent efficacy and safety, length of hospitalization was 2 days shorter for those who underwent the combined laparoscopic procedure.

Recently, Lu and colleagues 38 performed a meta-analysis of 9 randomized trials that compared 2-stage ERCP and LC with combined LC and bile duct exploration. In 787 patients, the approaches were found to have equivalent efficacy and safety. The longer hospital stay seen in the ERCP group in the individual trials was not evident; however, significantly more procedures were required in the ERCP group than in the combined laparoscopic group. The problem with applicability of these data, however, is that most surgeons are not trained to perform LCBDE.

Bin Wang and colleagues 39 concluded that with regard to stone clearance and overall complication rates, preoperative ERCP is equal to intraoperative ERCP in patients with gallbladder and common bile duct stones. However, intraoperative ERCP is associated with a reduced incidence of ERCP-related pancreatitis and results in a shorter hospital stay. The total hospital stay was significantly shorter with intraoperative ERCP than with preoperative ERCP (RR 2.22, 95 % CI 1.98 - 246; $P < 0.01$). A longer hospital stay was required for preoperative ERCP as a result of management of complications and organization of scheduling slots for preoperative ERCP and LC. Also residual local inflammation in patients after ERCP may negatively affect operative outcomes and demand more length of hospital stay.

Use of intraoperative ERCP has slowly increased among various endoscopic groups 1213 14. La Greca et al 14 reviewed all published studies on intraoperative ERCP and found 27 original papers that included between 8 and 96 patients each, thus analyzing a total of 795 patients. The success rate ranged between 69.2 % and 100 % and averaged 92.3 %. The average duration of intraoperative endoscopy was 35 minutes and the average duration of surgery was 104 minutes. The average conversion rate to open surgery was 4.7 % and morbidity was 5.1 % (0 %-19 %). Mortality is extremely rare, and from the 27 publications reviewed, only 3 patient deaths were reported, giving rise to a total mortality rate of 0.37 %.

The 3 types of treatment are effective and the choice of approach depends on a patient's particular circumstances and on the experience of the different endoscopic and surgical teams at each center 10.

CONCLUSIONS

We conclude that intraoperative ERCP/ES for choledocholithiasis results in a higher rate of choledocholithiasis clearance, shorter hospital stay, and lower morbidity, but further research with a larger study population is necessary to determine the procedure's additional benefits. Results to date suggests that in appropriate patients, single-stage treatments are the best options.

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