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Open Surgery versus Endoscopic Intervention in the Management of Bile Duct Stones

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ABSTRACT

Background: Choledocholithiasis or the presence of common bile duct stones (CBDS) is one of the medical conditions that requires surgical intervention. The management of choledocholithiasis has evolved from open common bile duct exploration (OCBDE) to therapeutic endoscopic retrograde cholangiopancreatography (ERCP) to laparoscopic common bile duct exploration (LCBDE). Each entails a degree of difficulty. In this review we aim to assess and compare the benefits and pitfalls of open surgery (OCBDE) versus endoscopic retrograde cholangiopancreatography (ERCP) in management of common bile duct stones.

Methods: A systematic review of the electronically searched publications of the scientific literature. We searched the Cochrane HepatoBiliary Group Controlled Trials Register, Cochrane Central Register of Controlled Trials in The Cochrane Library, MEDLINE (1946 to 2016), EMBASE (1974 to 2016), and Science Citation Index Expanded (1900 to 2016). Initially all randomized clinical trials which compared the results from open surgery versus endoscopic clearance for common bile duct stones were included, articles were selectively screened according to the eligibility criteria.

Results: eight publications were selectively included with 761 participants compared to open surgical clearance with ERCP. All trials had a high risk of bias. There was no significant difference in the mortality between open surgery versus ERCP clearance (eight trials; 733 participants; 5/371 (1%) versus 10/358 (3%) OR 0.51;95% CI 0.18 to 1.44). Neither was there a significant difference in the morbidity between open surgery versus ERCP clearance (eight trials; 733 participants; 76/371 (20%) versus 67/358 (19%) OR 1.12; 95% CI 0.77 to 1.62). Participants in the open surgery group had significantly fewer retained stones compared with the ERCP group (seven trials; 609 participants; 20/313 (6%) versus 47/296 (16%) OR 0.36; 95% CI 0.21 to 0.62), P = 0.0002. Meta-analysis of the outcomes duration of hospital stay, quality of life, and cost of the procedures could not be performed due to lack of data.

Conclusion: open surgery intervention in order to remove the gallbladder and trapped gallstones appears to be as safe as endoscopy and further suggested to be more successful than the endoscopic technique in clearing the duct stones.

Keywords: CBDS , bile duct stones, gallstones, choledocholithiasis, cholecystectomy , ERCP.

INTRODUCTION

The prevalence of gall bladder stones in adults is approximately 15% [1]. Most patients will be unaware of their presence, but over a 10-year period, 15-26% of initially asymptomatic individuals develop biliary colic [2] .This is important because in most cases, biliary colic heralds the beginning of recurrent problems. The natural history of stones in the bile duct is not well understood. Some pass spontaneously into the duodenum, but others will cause full or partial obstruction of the bile and/or pancreatic duct. The consequences can include pain, jaundice, sepsis (cholangitis), acute pancreatitis

and, if left untreated, liver cirrhosis. In studies looking at patients who have asymptomatic gall stones at enrolment, the risk of such complications occurring over the following decade is approximately 2% [3].

Common bile duct (CBD) stones are seen in approximately 7%-12% of patients who undergo cholecystectomy for symptomatic cholelithiasis and are a common indication for referral to a

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biliary endoscopist[4] .They vary in size ranging from rather small (approximately 1-2 mm) to very large (> 3 cm). Endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (ES) and basket or balloon extraction are well established therapeutic procedures for the management of CBD stones. It is estimated that nearly 85%-95% of all CBD stones can be managed effectively by these conventional endoscopic methods[5].Failure to clear the bile duct renders the patient vulnerable to biliary obstruction, cholangitis and pancreatitis, thereby increasing the morbidity[6] .The occurrence of acute cholangitis is associated with significant mortality, especially in the elderly, underscoring the need for early intervention to clear the bile duct stones and to relieve the obstruction to achieve adequate biliary drainage. Extraction of CBD stones is one of the most commonly performed procedures by therapeutic endoscopists[7] .

Multiple factors have been postulated to govern the success or failure of endoscopic extraction of CBD stones. In approximately 10%-15% of patients, managing biliary stones becomes formidable primarily due to difficulties in accessing the bile duct (periampullary diverticulum, sigmoid shaped CBD, post-gastrectomy Billroth type II anatomy, Roux-en-Y-gastrojejunostomy), large number of stones (greater than 10), large size of stones (stones with a diameter > 15 mm which cannot be grasped with a basket), unusually shaped stones (barrel-shaped) or location of the stones (intra hepatic, cystic duct, proximal to strictures)[8]. In addition, endoscopic management becomes challenging in Mirizzi syndrome, in which stones in the cystic duct cause obstruction of the main bile duct[9] .

In high risk patients, the risks and benefits of alternative techniques for removal of bile duct stones not amenable to conventional endoscopic techniques must be carefully balanced against each other and with surgery. The individual decision concerning the appropriate therapy is also influenced by the local expertise and the availability of the technical equipment [7].
CBD stones up to 1.5 cm in diameter can be extracted intact after endoscopic sphincterotomy. The rate of successful retrieval progressively declines with increasing size of the stone [10] .Larger stones especially those with a diameter ≥ 2cm may need fragmentation before removal to reduce the risk of stone impaction.

The management of concomitant gall bladder and common bile duct (CBD) stones has evolved significantly over the past 20 to 30 years. In the era of open surgery, open common bile duct exploration (OCBDE) would be performed if any common bile duct (CBD) stones were identified at cholangiography. Following the introduction and rapid uptake of endoscopic retrograde cholangiopancreatography (ERCP), OCBDE was reserved for patients who failed ERCP[11].

One of the main factors in the management is initially the detection of CBDS, before, during, or after cholecystectomy. The main options for treatment are pre- or postoperative ERCP with endoscopic biliary sphincterotomy (EST), laparoscopic or open surgical bile duct clearance. There are other options for the treatment of CBDS such as electrohydraulic lithotripsy (EHL), extracorporeal shockwave lithotripsy (ESWL), dissolving solutions, and laser lithotripsy. It is unlikely that one option will be appropriate for all clinical circumstances in all centers. Variables such as disease status, patient demographics, availability of endoscopic, radiological and surgical expertise, and healthcare economics will all have significant influence on practice [12]. The aim of this study was to review the overall results of the surgical management of CBD stones.

MATERIALS AND METHODS

Data Source

Literature electronic search of Cochrane HepatoBiliary Group Controlled Trials Register, Cochrane Central Register of Controlled Trials in The Cochrane Library, MEDLINE (1946 to 2016), EMBASE (1974 to 2016), and Science Citation Index Expanded (1900 to 2016). Initially all randomized clinical trials which compared the results from open surgery versus endoscopic clearance for common bile duct stones were included then articles were then selectively screened according to the eligibility criteria**.**

The search terms (Bile stones , CBDS, stones , ERCP , gallstones) were used in combinations and together with the Boolean operators OR and AND. 412 articles initially matched the stipulated criteria and were included in the current review.

Study Selection and Criteria

Search results were screened by scanning abstracts for the following inclusion and exclusion criteria's.

Inclusion Criteria:

1- All randomized clinical trials which compared surgical (open or laparoscopic) versus ERCP treatment for common bile duct stones.
2- Adults (over 21 years) with suspected or proven common bile duct stones prior to open or laparoscopic cholecystectomy.
3- Intervention type: Open surgery versus ERCP.

Exclusion Criteria:

1- Trials that compared the role of pre-operative ERCP + LC versus postoperative ERCP + LC as these trials do not compare the surgical and endoscopic procedures as two different arms.
2- Retrospective case series of pre-operative ERCP/ES + LC.

Allocation sequence generation

- Low risk of bias: sequence generation was achieved using computer random number generation or a random number table. Drawing lots, tossing a coin, shuffling cards, and throwing dice were adequate if performed by an independent person not otherwise involved in the trial.
- Uncertain risk of bias: the method of sequence generation was not specified.
- High risk of bias: the sequence generation method was not random.

Allocation concealment

- Low risk of bias: the participant allocations could not have been foreseen in advance of, or during, enrolment. Allocation was controlled by a central and independent randomisation unit. The allocation sequence was unknown to the investigators (for example, if the allocation sequence was hidden in sequentially numbered, opaque, and sealed envelopes).
- Uncertain risk of bias: the method used to conceal the allocation was not described so that intervention allocations may have been foreseen in advance of, or during enrolment.
- High risk of bias: the allocation sequence was likely to be known to the investigators who assigned the participants.

RESULTS

Description of studies

The initial search was broad, accepting any article related to CBDS formation and all treatment surgical interventions available to ensure a comprehensive view of available work, and generated 412 articles.

Preliminary application of study criteria identified 182 potential studies for inclusion that met one or more criteria. Further screening resulted in the exclusion of 33 papers full text that could not be retrieved and another 112 papers with the same cohort or were not identified as randomized trails. There were also 29 papers excluded because they did not meet the endpoint of the study. Finally the review yielded **8 RCTs** that fully met all inclusion criteria. No individual authors were contacted for information. No further review of methodological quality of the studies was conducted beyond that it appeared in a peer review journal and comprised an RCT. The 50 eligible articles were again closely examined. Comparison among provider type was computation of differences between percent of successful program to number attempted. No further statistical analyses were employed.

Characteristics, methods, intervention and key outcome measures are interpreted in Table 1, Table 2 , Table 3 and Table 4.

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TABLE 1: characteristics , intervention and Key Outcome measures reported by Study 1 and Study 2.

Authors	**Suc *et al.*** [13]	**Targarona *et al.*** [14]
Year of Study	1998	
Study Type	RCT	RCT
Method	Open cholecystectomy +/- ECD versus ERCP/ES. Cholecystectomy not necessarily per-formed in ERCP group	high-risk surgical pts suspected of having CBDS to eitherOC +/- CBDE alone or ERCP/ES and stone extraction alone
	Multicentre.	Single Center
Participants (n)	220	109
Intervention	Open cholecystectomy +/- ECD versus ERCP/ES. Cholecystectomy not necessarily per-formed in ERCP group	If the allocated therapy could not be performed within 30 days post-randomisation, it was classed as a primary failure of that therapy Group 1: (surgery)OC performed post-randomisation. IOC performed in all and CBDE as required. Group 2: (endoscopy)ERCP performed post-randomisation.ES performed regardless of presence of stones on cholangiogram
Outcome	Retained stones, additional procedures, mortality, morbidity, total duration of hospital stay	Primary duct clearance rate, total morbidity, mortality, total hospital stay, recurrent biliary symptoms, readmissions due to recurrent symptoms.
Follow-up duration ERCP Surgery	not stated	mean (sd): 15 (11) months mean (sd): 18 (10) months

TABLE 2: characteristics , intervention and Key Outcome measures reported by Study 3 and Study 4.

Authors	**Stiegmann *et al.*** [15]	**Neoptolemos *et al.*** [16]
Year of Study	1992	1987
Study Type	RCT	RCT
Method	Open cholecystectomy, IOC +/- bile duct exploration vs pre-operative ERCP/ES followed by OC	ERCP, USS, or PTC to have CBDS, with intact gallbladder and fit for surgery; randomized to either ES and endoscopic extraction followed by OC or OC + CBDE.
	Single Center	Single Center
Participants (n)	34	120
Intervention	Endoscopic/Operative group: ERCP/ES followed by OC plus IO C (usually the following day).Operative only group:OC + IOC +/- CBDE Essential investigations: Serum bilirubin, ALP, amylase, USS.IOC in all pts. Choledochoscopy in some of the surgical group.ERCP/ES in the endoscopic group. T-tube cholangiography in the surgical group at 10 days postoperatively. Costing retrieved from hospital finance office.	Group 1: ES and clearance performed at same time as diagnostic ERCP (if performed), or else on next available list. OC performed on next available operating list. Group 2: OC performed on next available operating list. Both ES and OC covered with prophylactic antibiotic cefazolin 1 g IV/IM unless cholangitic, in which case penicillin/gentamycin/metronidazole given.
Outcome	Mortality, morbidity, stone clearance rates, hospital stay, procedure time, cost.	Mortality, morbidity, endoscopic clearance rates, retained stones, median total hospital stay.
Follow-up duration ERCP Surgery	not stated	minimum of 6 months minimum of 6 months

TABLE 3: characteristics , intervention and Key Outcome measures reported by Study 5 and Study 6.

Authors	**Bornman *et al.* [17]**	**Hammarstrom *et al.* [18]**
Year of Study	1992	1995
Study Type	RCT	RCT
Method	Group 1: 62 pts. Pre-operative ERCP/ES and open surgery including subtotal cholecystectomy with or without cholangiogram and bile duct surgery where necessary. Group 2: 58 pts. Open cholecystectomy and cholangiogram with or without CBD exploration. Bile duct surgery in Group 2 also included: choledocho-duodenostomies in 5 and transduodenal sphincteroplasty in 2.	Comparing ERCP/ES and stone removal versus open surgery alone for pts found to have CBDS proven on ERCP, intravenous cholangiogram, or USS, with an intact gallbladder.
	Single Center	Single Center
Participants (n)	110	83
Intervention	Group 1: 62 pts.Pre-operative ERCP/ES and open surgery including subtotal ch olecystectomy with or without cholangiogram and bile duct surgery where necessary Group 2: 58 pts. Open cholecystectomy and cholangiogram with or without CBD exploration. Bile duct surgery in Group 2 also included: choledocho-duodenostomies in 5 and trans-duodenal sphincteroplasty in 2	Group 1 (ERCP/ES): Proceeded to ES and stone extraction by a variety of means (basket, balloon, mechanical lithotriptor). Subsequent surgery only if ongoing biliary symptoms. Group 2 (Surgery): Open cholecystectomy and ECBD on next available list. T-tube always used. Choledochoscopy optional.
Outcome	Successful clearance, bile leak, postoperative death , morbidity, duration of procedure, post-procedural hospital stay	Successful stone clearance, additional endoscopic procedures, median hospital stay, complications - bile leak, gastric retention, duodenal injury after surgery, biliary colic (no surgery), pancreatitis (no surgery), re-operation for bleeding, bile duct injuries, late complications: incisional hernia, retained stone.
Follow-up duration **ERCP** **Surgery**	not stated	median: 92 months median: 82 months

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TABLE 4: characteristics , intervention and Key Outcome measures reported by Study 7 and Study 8.

Authors	**Kapoor *et al.*** [19]	**Stain *et al.*** [20]
Year of Study	1996	1991
Study Type	RCT	RCT
Method	CBD stones found at ERCP randomized to either ERCP/ES and extraction followed by open cholecystectomy (ES + S group), or open cholecystectomy and CBDE (Surgery group).	CBDS on ERCP and fit to undergo surgery, randomized to either ERCP/ES + surgery or surgery "alone" .
	Single Center	Single Center
Participants (n)	33	52
Intervention	ES + S group: CBD cleared at time of ERCP by basket or spontaneous passage .Subsequent surgery scheduled within 6 weeks.SA group: Following ERCP, surgery undertaken on next available elective list. Choledochoscopy optional.	**Group 1:** ERCP followed by ES and stone extraction by basket or spontaneous passage. Subsequent OC +/- CBDE in all cases. Surgery scheduled electively. CBDE performed on basis of ERCP findings and IOC. **Group 2:** ERCP followed by OC scheduled electively. CBDE performed as necessary.
Outcome	Mortality, morbidity, clearance rates, hospital stay.	Mortality, morbidity, stone clearance rate, retained stones after surgery, operation time, hospital stay.
Follow-up duration ERCP Surgery	not stated	not stated

TABLE 5: SUMMARY OF Open surgery versus ERCP key Outcome measures

Outcome	**Studies (n)**	**Participants (n)**	**Statistical method**	**Effect size**
Mortality	8	729	Odds Ratio (M-H, Fixed, 95% CI)	0.51 [0.18, 1.44]
Mortality (Sensitivity analysis)	8		Odds Ratio (M-H, Fixed, 95% CI)	0.71 [0.12, 5.27]
Total morbidity	8	729	Odds Ratio (M-H, Fixed, 95% CI)	1.12 [0.77, 1.62]
Morbidity (Sensitivity analysis)	8	737	Odds Ratio (M-H, Fixed, 95% CI)	1.09 [0.76, 1.58]
Retained stones	7	609	Odds Ratio (M-H, Fixed, 95% CI)	0.36 [0.21, 0.62]
Retained stones (Sensitivity analysis)	7	617	Odds Ratio (M-H, Fixed, 95% CI)	0.36 [0.21, 0.62]
Failure of procedure	7	609	Odds Ratio (M-H, Fixed, 95% CI)	0.31 [0.19, 0.51]
Hospital stay			Other data	No numeric data
Cost	1	34	Mean Difference (IV, Fixed, 95% CI)	1102.0 [299.54, 1904.46]

DISCUSSION

In the present study , the data presented by the 8 included publications clearly indicated that open surgery resulted in a significantly reduced number of retained stones, in achieving common bile duct stone clearance and lower rates of failure of planned treatment based on the evidence available from the early endoscopy era . There was no profound difference in the mortality and morbidity between the two groups. However, it is important to remember that these comparative trials are from the early days of endoscopy (1987 to 1998) and might have been influenced by the early experience of the endoscopist as well as the limited technological support.

Duration of surgery and the duration of hospital stay were difficult to assess from the trials included. Evaluation of these two outcomes requires inclusion of the duration of each procedure (endoscopic clearance and surgical removal of gall bladder). There were insufficient data to comment on the effect of the size and number of stones on the outcomes, costs involved, postoperative quality of life and postoperative analgesic requirements. The studies are, however, a little dated and interpretation in the context of modern practice must be guarded. It is entirely possible that the results might have been influenced by the early experience of endoscopists in performing ERCP. It is unlikely that there will be any future trials comparing open surgery with ERCP, and the data from this review represent the best evidence comparing these interventions.

The ideal treatment for common bile duct stones is still controversial. The options are that of surgical treatment alone (open or laparoscopic surgery) or a combination of endoscopy with surgical treatment (pre-, intra- or post laparoscopic cholecystectomy ERCP) to clear the common bile duct stones[21] .

CONCLUSION

There is sufficient evidence in this review proving open bile duct surgery seems superior to ERCP in achieving common bile duct stone clearance based on the evidence available from the early endoscopy times – however , there is evolution in the new era of endoscopic intervention. Hence, more randomized clinical trials without risks of systematic and random errors are necessary to confirm these findings**.**

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