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Single-stage intraoperative ERCP combined with laparoscopic cholecystectomy versus preoperative ERCP Followed by laparoscopic cholecystectomy in the management of cholecystocholedocholithiasis

A meta-analysis of randomized trials

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Abstract

Objectives The optimal treatment strategy for cholecystocholedocholithiasis is still controversial. We conducted an up-to-date meta-analysis to compare the efficacy and safety of the intra- endoscopic retrograde cholangiopancreatography (ERCP) + LC procedure with the traditional pre-ERCP + laparoscopic cholecystectomy (LC) procedure in the management of cholecystocholedocholithiasis.

Methods We searched the PubMed, Embase, Cochrane Library, and Web of Science databases up to September 2020. Published randomized controlled trials comparing intra-ERCP + LC and pre-ERCP + LC were considered. This meta-analysis was performed by Review Manager Version 5.3, and outcomes were documented by pooled risk ratio (RR) and mean difference (MD) with 95% confidence intervals.

Results Eight studies with a total of 977 patients were included in this meta-analysis. There was no significant difference between the two groups regarding CBD stone clearance (RR = 1.03, $P = .27$), postoperative papilla bleeding (RR = 0.41, $P = .13$), postoperative cholangitis (RR = 0.87, $P = .79$), and operation conversion rate (RR = 0.71, $P = .26$). The length of hospital stay was shorter in the intra-ERCP + LC group (MD = −2.75, $P < .05$), and intra-ERCP + LC was associated with lower overall morbidity (RR = 0.54, $P < .05$), postoperative pancreatitis (RR = 0.29, $P < .05$) and cannulation failure rate (RR = 0.22, $P < .05$).

Conclusions Intra-ERCP + LC was a safer approach for patients with cholecystocholedocholithiasis. It could facilitate intubation, shorten hospital stay, and lower postoperative complications, especially postoperative pancreatitis, and reduce stone residue and reduce the possibility of reoperation for stone removal.

Abbreviations: ERCP = endoscopic retrograde cholangiopancreatography, LC = laparoscopic cholecystectomy, LERV = laparoendoscopic rendezvous, MD = mean difference, PEP = post-endoscopic retrograde cholangiopancreatography pancreatitis, RCT= randomized controlled trial, RR = risk ratio, CBD = common bile duct.

Keywords: endoscopic retrograde cholangiopancreatography, laparoendoscopic rendezvous, laparoscopic cholecystectomy

1. Introduction

Gallstones are a common digestive system disease affecting approximately 15% of all Americans, 5.9% to 21.9% of Europeans, and 4.6% to 11.64% of Han Chinese.[1–4] Choledocholithiasis were found simultaneously in 11% patients undergoing cholecystectomy.[5] Although partial choledocholithiasis could eliminated spontaneously; choledocholithiasis can

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YL, QC, and XZ have contributed equally to this work.

The authors report no conflicts of interest.

The datasets generated during and/or analyzed during the present study are publicly available.

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cause severe cholangitis and pancreatitis. Therefore, choledocholithiasis needs timely surgical intervention.[1,6]

There are several surgical approaches in managing cholecystocholedocholithiasis, including laparoscopic cholecystectomy combined with intraoperative endoscopic sphincterotomy; laparoscopic common bile duct exploration; preoperative endoscopic sphincterotomy plus laparoscopic cholecystectomy. Nowadays, preoperative ERCP plus LC has become the preferred option in most centers and was recommended by the European Association for the Study of the Liver.[7] Recently, a meta-analysis[8] compared the efficacy between pre-ERCP + LC and LCBDE + LC, demonstrating the former had a higher choledocholithiasis clearance rate, nevertheless with the disadvantage of a higher rate of pancreatitis. The most challenging maneuver of ERCP was duodenal papilla cannulation, and the rate of successful cannulation was ranging from 89.2% to 92.4%.[9,10] Another attractive technique was the intraoperative ERCP combined with LC, in which partial patients were treated with Laparoendoscopic rendezvous (LERV) technique .[11] LERV was a concomitant procedure: the gallbladder was removed laparoscopically. While the surgeon placed a wire through the cystic duct into the duodenum, and transcystic cholangiography was performed, which could facilitate the process of biliary catheterisation.[12] However, no robust consensus has been reached regarding the preferable therapeutic strategy between LERV and pre-ERCP + LC in the management of choledocholithiasis. The aim of present the up-to-date meta-analysis was to evaluate the efficacy and safety of intraoperative ERCP combined with LC in treating cholecystocholedocholithiasis.

2. Methods

2.1. Search strategy

PubMed, Embase, Cochrane Library, and Web of Science databases had been searched up to September 2020. the keywords and search strategy were: ((((((LC) OR (laparoscopic cholecystectomy)) OR (celioscopic cholecystectomy)) AND ((((ERCP) OR (endoscopic retrograde cholangiopancreatography)) OR (endoscopic sphincterotomy)) OR (EST))) OR (((laparoendoscopic rendezvous) OR (LERV))))) AND ((((RCT) OR (randomized controlled trial)) OR (randomized controlled clinical trial)) OR (randomized experiment)). The search is restricted in studies published in the English language. Ethical approval was not necessary for this study. All the data used in this study were from the original article, and all the original articles had previously undergone ethical approval.

2.2. Selection criteria

The inclusion criteria were: study design (randomized controlled trials were included); interventions (studies compared intra-ERCP + LC with preoperative ERCP followed by LC); participants (patients with both cholecystolithiasis and choledocholithiasis); documentation of at least one type of primary clinical outcome of interest such as successful CBD stone clearance, overall postoperative morbidity, postoperative pancreatitis, and length of hospital stay; type of article (only published literature with full text available). The exclusion criteria were: observational study; case reports, case series, letters, and reviews; studies published as conference documents and abstracts.

2.3. Data extraction and quality assessment

The two researchers (YL and QCC) independently extracted the corresponding data and evaluated the study qualifications. The extraction table was designed in advance to standardize the data extraction process, including the following relevant items: first author, year of publication, country, intervention method, sample size, essential characteristics of patients, postoperative complications, and other outcomes. The third researcher (XZZ) arbitrated when there was a discrepancy. The Cochrane risk of bias tool was used to evaluate the methodological quality and risk of bias of all included studies.

2.4. Statistical analysis and publication bias

All statistical synthesis was performed by Review Manager Software Version 5.3 for Windows (Cochrane Collaboration, Oxford, UK). Statistical heterogeneity was evaluated with a forest plot and χ^2 test. Heterogeneity was quantified using the I^2 statistic. If the heterogeneity among studies were remarkable ($I^2 > 50\%$), a random-effects model would be utilized. Otherwise, a fixed-effects model would be employed. Weighted mean difference (WMD) and risk ratio (RR) were used to calculate continuous and dichotomous variables with a 95% confidence interval (CI); $P < .05$ indicated a statistically significant difference.

When the mean and standard deviation (SD) were not reported, median and range values were used to estimate the mean and SD with the formulas reported by Wan et al[13] and Luo et al.[14] Sensitivity analysis was performed by removing the included studies sequentially to observe the stability of the synthesized outcomes. A funnel plot was used to explore the publication bias, Egger tests were used to quantify publication bias further (Stata version 12.0, College Station, TX).

3. Results

3.1. Study selection and quality assessment

A process of literature retrieval and selection was presented in (Fig. 1). The search initially identified a total of 430 references. A total of 151 repetitive articles were excluded. According to titles and abstracts, 245 studies were excluded. The full texts of the remaining 25 articles were carefully distinguished, 3 studies failed to extract significant data, 4 were excluded because their full text could not be acquired. Five studies were excluded because their intervention criteria were not met. Five were not included because their operation methods were not ERCP + LC. Finally, 8 RCTs[11,12,15–20] were propitious to our analysis. Eight articles included 977 patients. The general characteristics of the 8 RCTs were summarized in Table 1.

According to the Cochrane Collaboration's tool for assessing the risk of bias for RCTs, evaluation of literature quality was reported in (Fig. 2). Double-blind techniques could not implement effectively because of the specified and transparent surgical procedures. We believed that blinding of participants and personnel had a high risk of bias. Data were analyzed on an intention-to-treat basis.

3.2. Stones clearance rate

All studies[11,12,15–20] documented data in the rate of CBD stones clearance. The overall clearance rates were 93.3% and 89.4% in

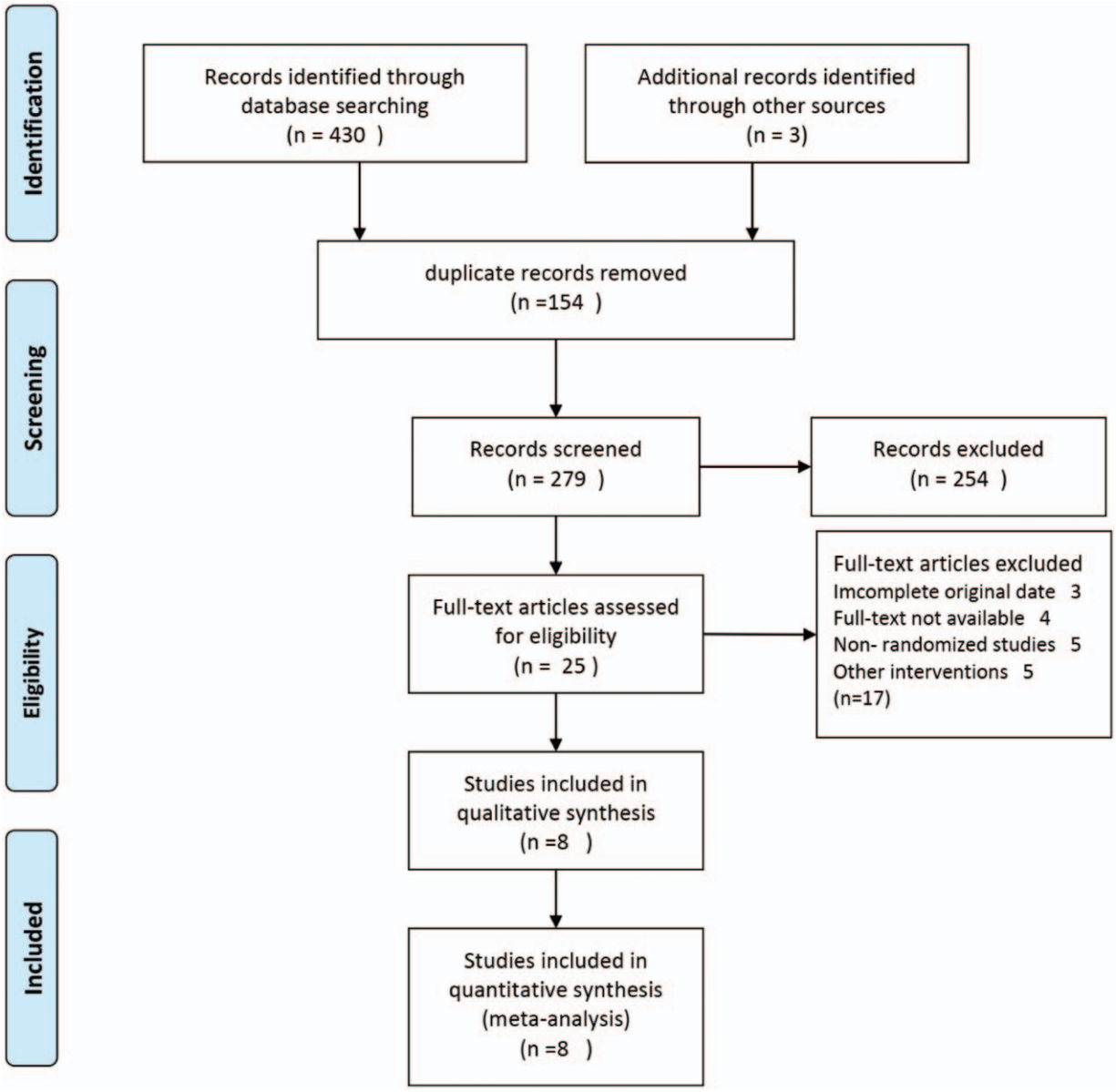

Figure 1. Study selection flow diagram.

LERV and pre-ERCP + LC arms, respectively. No statistically significant difference was found (RR 1.03, 95% CI [0.98–1.09], $P = .27$, Fig. 3A) with significant heterogeneity ($\chi^2 = 15.35$, $P = .03$, $I^2 = 54\%$). We did not detect the origin of heterogeneity through sensitivity analysis.

3.3. Morbidity

Seven studies[11,12,15–17,19,20] provided data the overall morbidity rates. The overall morbidity rates were 9.7% and 17.7% in LERV and pre-ERCP + LC arms, respectively. There was a significantly lower overall morbidity rate in the LERV procedure (RR 0.54, 95% CI [0.39–0.76], $P < .05$, Fig. 3B) without significant heterogeneity ($\chi^2 = 6.95$, $P = .33$, $I^2 = 14\%$).

All studies[11,12,15–20] documented data in postoperative pancreatitis. The LERV group had obvious advantages in reducing postoperative pancreatitis (RR 0.29, 95% CI [0.13–0.68], $P < .05$, Fig. 3C) without significant heterogeneity ($\chi^2 = 7.41$, $P = .19$, $I^2 = 33\%$).

Postoperative cholangitis was observed in 4 of the studies.[11,15,17,19] There was no significant statistically difference between the 2 groups (RR 0.41, 95% CI [0.13–1.28], $P = .13$, Fig. 3D) without significant heterogeneity ($\chi^2 = 3.41$, $P = .33$, $I^2 = 12\%$)

Postoperative papilla bleeding was recorded in 5 studies.[11,12,15–17] No statistically significant difference was found (RR 0.87, 95% CI [0.30–2.54], $P = .79$, Fig. 3E). There was no heterogeneity among the studies ($\chi^2 = 2.58$, $P = .63$, $I^2 = 0\%$)

3.4. Operation procedures conversion rate

Five studies[11,12,15–17] documented operation procedures conversion in detail. The outcome demonstrated no statistically significant difference between the 2 arms (RR 0.71, 95% CI

Table 1

Characteristic of studies included in the meta-analysis.

Study	Country +year	Age	Sample size (P/C)	Hospital stay (d)	Overall morbidity (n)	CBD clearance rate (n)
Rabago et al[15]	Spain	NR	59/64	P 5±3	P 5	P 52/59
	2006			C 8±5	C 15	C 62/64
Morino et al[16]	Italy	P 56.6 (22–82)	46/45	P 4.3±3.1	P 3	P 44/46
	2006	C 63.1 (25–83)		C 8.0±5.5	C 4	C 36/45
Lella et al[11]	Italy	54.2 (22–60)	60/60	P 3 (2-4)	P 2	P 58/60
	2006			C 6 (5-11)	C 8	C 58/60
ElGeidie et al[12]	Egypt	P 31.2 (20–67)	98/100	P 1.3 (1–4)	P 4	P 89/98
	2011	C 27.5 (19–64)		C 3 (2–11)	C 6	C 88/100
Tzovaras et al[17]	Greece	P 66 (22–87)	50/49	P 4 (2–19)	P 7	P 47/50
	2012	C 69 (25–85)		C 5.5 (3–22)	C 6	C 44/49
Sahoo et al[18]	India	NR	42/41	P 6.8	NR	P 38/42
	2014			C 10.9		C 29/41
Gonzalez et al[19]	Cuba	P 58.4 (23 -87)	99/101	NR	P 0	P 45/46
	2016	C 57.7 (20 -84)			C 6	C 42/45
Liu et al[20]	China	P 42±5.2	32/31	P 7.5±1.7	P 17	P 31/32
	2017	C 40±6.1		C10.6±2.5	C 25	C 30/31

Study	Major inclusion criteria	Major exclusion criteria	CBD diameter (P/C, mm)	Position of ERCP
Rabago et al[15]	US/CT/MRCP diagnosis of CBDS elevated serum enzymes, CBD >8 mm, with cholangitis	Age <18 or >80 y, no contraindication to laparoscopy, no previous upper abdominal surgery, no chronic pancreatitis	NR	Supine
Morino et al[16]	Elevation of serum enzymes + US diagnosis of CBDS or CBD >8-10 mm, no cholangitis and necrotizing pancreatitis	Age <18 y, ASA IV and V, CBD malignancy, previous cholecystectomy, contraindications to MRCP and ERCP, contraindications to laparoscopic surgery	CBD >10 mm60.8% 64.4%	NR
Lella et al[11]	US and MRI Diagnosis of CBD stone	Age <18 y, pregnancy, previous sphincterotomy, chronic pancreatitis, allergy to propofol and/or fentanyl	NR	Prone
ElGeidie et al[12]	Clinical assessment + US diagnosis of CBDS or CBD >8 mm + liver chemistry, MRI diagnosis of CBDS, no cholangitis and pancreatitis	Age <18 or >80 y, ASA IV and V, CBD malignancy, pregnancy, previous cholecystectomy, contraindications to MRCP and ERCP, contraindications to laparoscopic surgery, previous upper abdominal surgery, marked liver cirrhosis	9.6 (8–18) 9.2 (7–20)	Supine or prone
Tzovaras et al[17]	US/MRCP diagnosis of CBDS	Age <18 or >80 y, ASA IV and V, BMI >35, previous upper abdominal surgery, pregnancy	9 (4–20) 9 (4–21)	Supine
Sahoo et al[18]	Diagnosis of gallstone and CBDS	CBDS >12 mm	12.6	NR
Gonzalez et al[19]	Clinical features + US diagnosis of CBDS or CBD >8 mm + liver function tests, ASA I–III	Age <18, ASA IV and V, previous upper abdominal surgery, previous ERCP, contraindications to ERCP, contraindications to laparoscopic surgery	8.2 (4–20) 8.4 (5–12)	Supine OR prone
Liu et al[20]	US/CT/MRCP diagnosis of CBDS Age ≤75 y, CBDS > 0.2 and <1.5 cm, no upper abdominal surgery, no pancreatitis	Contraindications to ERCP, iodine allergy	NR	NR

BMI = body mass index; C = pre-ERCP+LC; CBDS = common bile duct stones; CT = computed tomography; MRCP = magnetic resonance cholangiopancreatography; MRI = magnetic resonance imaging; NR = Not reported; P = intra-ERCP + LC group; US = ultrasound.

[0.39–3.10], $P=.26$, Fig. 4F) with moderate heterogeneity ($\chi^2=5.84$, $P=.21$, $I^2=32\%$)

3.5. Cannulation failure rate

Seven studies[11,12,15–19] documented details in biliary catheterization. LERV could facilitate the achievement of biliary catheterization (RR 0.22, 95% CI [0.10–0.50], $P<.05$, Fig. 4G) without heterogeneity ($\chi^2 = 3.84$, $P=.57$, $I^2=0\%$).

3.6. Postoperative second ERCP

Postoperative second ERCP was recorded in three studies,[12,16,19] LERV group had obvious advantages in reducing

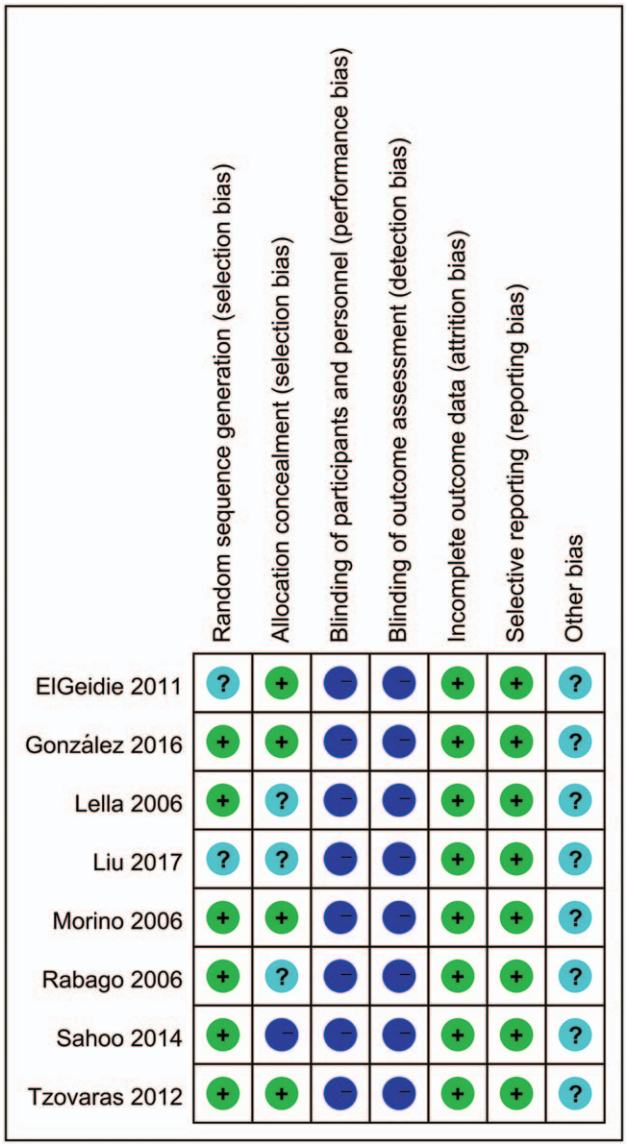

Figure 2. Risk of bias summary: review of authors' judgements about each risk of bias item.

postoperative second ERCP (RR 0.13, 95% CI [0.03–0.57], $P < .05$, Fig. 4H) without heterogeneity ($\chi^2 = 0.29$, $P = .87$, $I^2 = 0\%$).

3.7. The length of hospital stay

All studies[11,12,15–20] reported the duration of hospital stay. However, only 6 studies[11,12,15–17,19,20] provided data regarding hospital stay, which could be used for further analysis. The study by Sahoo et al[18] only provided the mean without standard deviation. Three studies[11,12,17] only provided the median and range. Consequently, data conversion was performed during the data analysis process. Overall, there was a significantly shorter hospital stay in the LERV group (MD −2.75, 95% CI [−3.51 to −2.00], $P < .05$, Fig. 4I) with significant heterogeneity ($\chi^2 = 28.94$; $I^2 = 83\%$). Heterogeneity mainly originated from the study by ElGeidie et al,[12] authenticated by the sensitivity analysis. And it did not alter the corresponding pooled results (MD −3.22, 95% CI [−3.51 to −2.91], $P < .05$, Fig. 4J).

3.8. Publication bias

A funnel plot was generated by the overall morbidity (Table 2) and the funnel plot was symmetrical with a visual inspection. It was further verified using Egger regression test and found no statistical significance (Fig. 5).

4. Discussion

Choledocholithiasis commonly derived from the descending of gallstones through the cystic duct,[21] the consensus was that symptomatic choledocholithiasis should be treated positively.[22] A study suggested that the cumulative incidence of complications in patients diagnosed with asymptomatic common bile duct stones was 17% at 5 years.[23] Many endoscopic experts believed that asymptomatic choledocholithiasis needs timely intervention to avoid complications, although asymptomatic CBDS possessed a high risk of ERCP-related complications up to 26.9% and an incidence rate of post-ERCP pancreatitis (PEP) up to 14.6%.[24,25] Moreover, it is generally accepted that cholecystectomy should be implemented early after preoperative ERCP + EST.[6] One study[26] showed that both pre-ERCP + LC and LC + LCBDE were highly efficacious in eliminating CBD stones and were equivalent in cost. Nevertheless, diagnostic capability and endoscopic techniques have rapid progress in recent years. The pre-ERCP + LC group had a higher stone clearance rate in patients with definite choledocholithiasis.[8] In most centers, ERCP + LC is still the dominant therapeutic strategy for treating cholecystocholedocholithiasis. However, ERCP had inherent shortcomings; the most typical complication of ERCP was post-ERCP pancreatitis (PEP), the incidence of PEP could up to 9.7%.[27] Laparoendoscopic rendezvous or intraoperative ERCP combined with Laparoscopic cholecystectomy, a novel and feasible one-stage technique, has been introduced to obtain selective biliary catheterization and ease the risk of post-ERCP pancreatitis. Laparoscopic intraoperative cholangiography via the cystic duct was implemented to confirm the existence of choledocholithiasis concurrently. Moreover, in some patients, a soft-tipped guidewire was passed through the cystic duct, common bile duct, and papilla into the duodenum, and this manipulation assisted endoscopists in identifying the duodenal papilla and facilitating selective CBD cannulation, and reduce PEP.[11,28]

The stone clearance rate is the main index to evaluate the therapeutic efficacy of choledocholithiasis. In the present meta-analysis, the clearance rate of choledocholithiasis in the intra-ERCP + LC group and pre-ERCP + LC group was 93.3% and 89.4%, respectively, was consistent with previous research outcome.[29] Intra-ERCP + LC was superior to pre-ERCP + LC in reducing the occurrence of overall postoperative morbidity and postoperative pancreatitis in our study. The incidence rate of post-ERCP pancreatitis was 1.0% in the intra-ERCP + LC group and 4.4% in the pre-ERCP + LC group. The independent pathogenic factors related to post-ERCP pancreatitis were considered to be associated with the difficult cannulation, precut sphincterotomy, main pancreatic duct contrast agent injection, and sphincter of Oddi dysfunction.[30,31] Intra-ERCP + LC effectively reduced the number of catheterization and the probability of precut sphincterotomy and prevented inadvertent

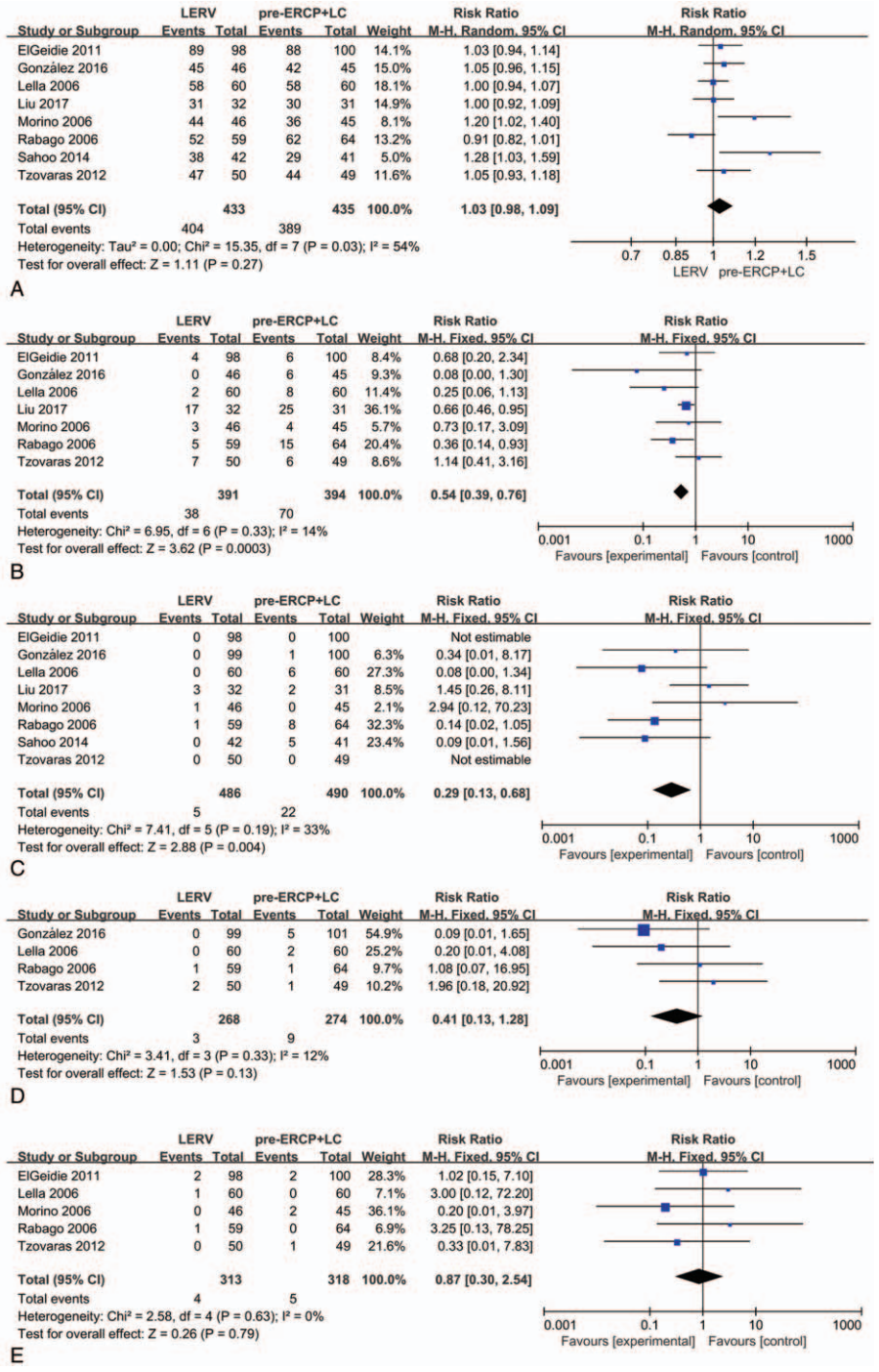

Figure 3. Forest plot of outcome. (A) Success CBD clearance. (B) Overall morbidity. (C) Postoperative pancreatitis. (D) Postoperative cholangitis. (E) Postoperative papilla bleeding.

catheterization of the pancreatic duct. However, there was no significant difference in the occurrence of postoperative cholangitis and postoperative papilla bleeding. A study[32] had suggested that age, previous ERCP history, and hilar obstruction were independently associated with post-ERCP cholangitis. Intra-ERCP+LC cannot effectively reduce the corresponding risk factors. Having the opportunity to perform biliary catheterization was another advantage of intra-ERCP+LC. It had been reported that intraoperative cholangiography could exclude patients with negative choledocholithiasis. In some studies, the negative choledocholithiasis rate could reach 6.1%[12] and 2.9%,[33] respectively. Our analysis indicated that postoperative second ERCP rate was significantly higher for pre-ERCP+LC than intra-ERCP+LC; this phenomenon suggested that the pre-ERCP+LC group had a higher choledocholithiasis residual rate or gallbladder stones spontaneously passed through

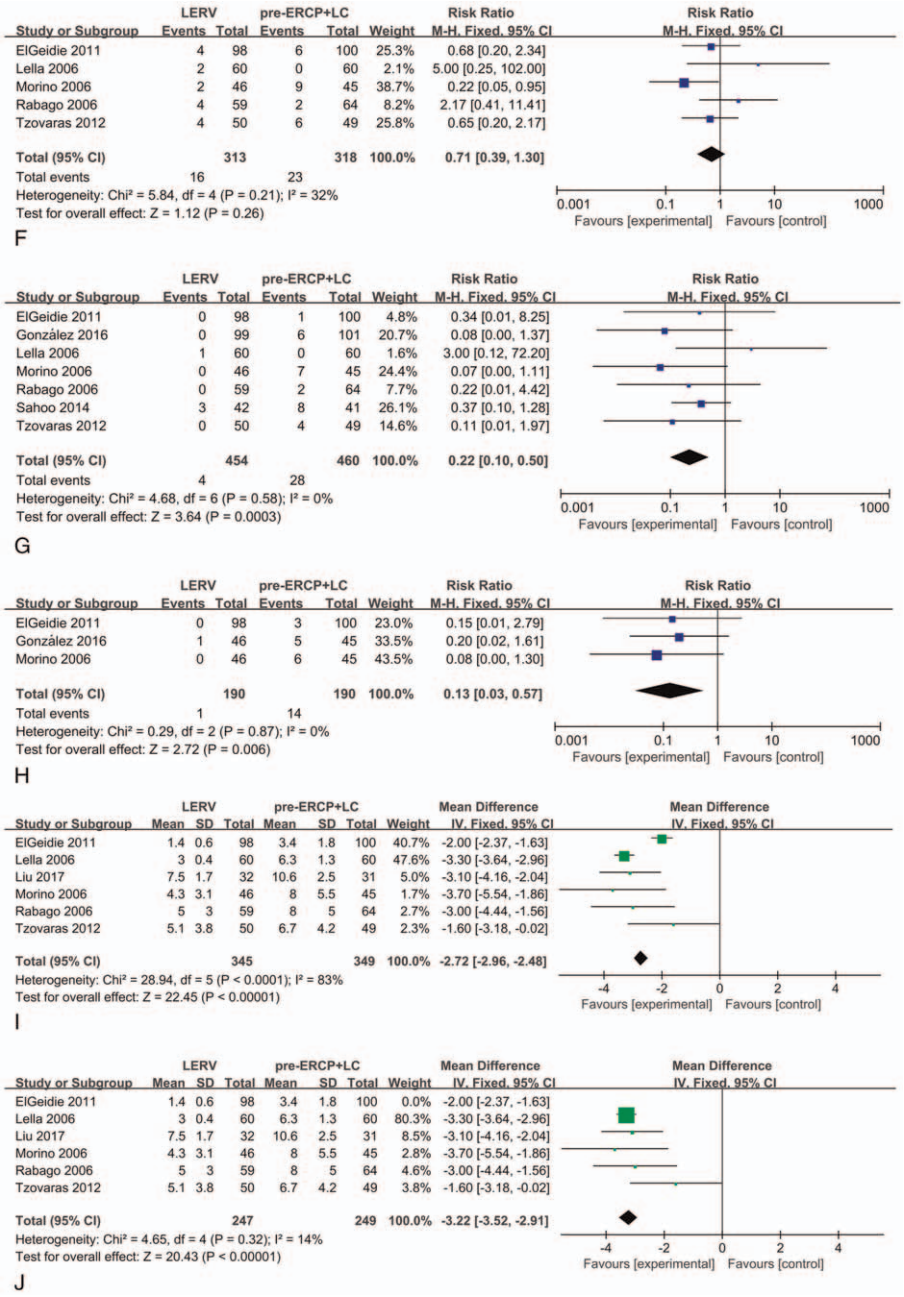

Figure 4. Forest plot of outcome. (F) Operation procedures conversion rate. (G) Cannulation failure rate. (H) Postoperative second ERCP rate. (I) Overall hospital stay. (J) Sensitivity analysis of the overall hospital stay.

the cystic duct into the CBD during the interval between operations. A study demonstrated[34] that the residual stone rate was as high as 11% in patients undergoing pre-ERCP + LC.

Intra-ERCP + LC was superior to pre-ERCP + LC in decreasing hospital stay. In the pre-ERCP + LC group, the interval time between 2 operations was generally within 24 to 72 hours,[35] which increased hospital stay and reduced patient compliance.[18] Furthermore, in some studies, the intra-ERCP + LC offered advantages of low cost.[16,36] Intraoperative ERCP + LC is more complicated, resulting in a longer operation time.[15] Qian et al[37] reported that the total operative time of the intraoperative ERCP + LC group was longer than that of the preoperative ERCP + LC group (139.8 ± 46.8 minutes vs 107.7 ± 40.6 minutes, $P < .05$). We found an interesting phenomenon that if ERCP and laparoscopic cholecystectomy were performed by a single surgeon or a team, the operation time of the intra-ERCP + LC group would be relatively shorter.[12] This was likely because surgeons no longer have to wait for endoscopists during surgery. In the intra-ERCP + LC group, most patients adopted the supine position, which is different from the routine ERCP operation. It could increase the difficulty of the operation for the endoscopist.[12] A study[37] has shown that prone ERCP has higher feasibility and success rate, slightly shorter operation time, but higher adverse events. Therefore, the supine position may be

Table 2

Egger test of primary indicator.

Item	Egger test	$P>\|t$
CBD stones clearance	0.89	
Overall morbidity	0.39	
Hospital stay	0.34	

CBD = common bile duct.

changed to the prone position, depending on the intraoperative situation.

Although intra-ERCP+LC has broad application prospects, there are some technical restrictions worthy of our attention. First, an abnormal anatomical structure of the cystic duct and impacted ductal stones, it is difficult for the guidewire to pass through the biliary tract to the duodenum; we can choose conventional endoscopic sphincterotomy and biliary catheterization.[17,19] Second, intraoperative endoscopic insufflation leads to intestinal dilatation, which reduces the functional space of laparoscopic cholecystectomy. We can perform most of the laparoscopic procedures before the insertion of the endoscope.[12,17] Third, supine position increases the difficulty of biliary catheterization, we can switch the patient to either the prone position or the post-lateral position.[12] Most of the studies included in this meta-analysis did not attach great importance to long-term follow-up and record the recurrence of choledocholithiasis. Endoscopic sphincterotomy could destroy the physiological barrier provided by the Oddi sphincter, causing the intestinal contents and microflora to flow back to the CBD, which was easy to form recurrent primary CBD stones.[38] One study reported[39] that the incidence of primary choledocholithiasis in patients with sphincterotomy was 8.9%. Interestingly, another study[40] showed that the recurrence rate of choledocholithiasis after LCBDE was as high as 13.5%. A previous meta-analysis[29] compared the 2 methods; however, the study proves a comprehensive conclusion due to the small number of included samples and incomplete indicators. There were still some limitations in our study, there was heterogeneity among the included literature, and some studies did not clearly explain the methodology of randomized controlled trials. The size and quantity of CBD stones were different, the characteristic baseline of included patients was inconsistent.

Intra-ERCP+LC was a safer approach for patients with cholecystocholedocholithiasis. It could facilitate intubation, shorten hospital stay, and lower postoperative complications, especially postoperative pancreatitis, and reduce stone residue and reduce the possibility of reoperation for stone removal.

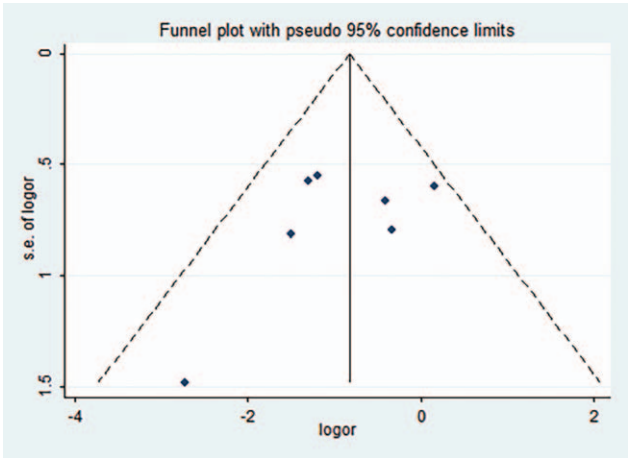

Figure 5. Funnel plot of publication bias with overall morbidity.

Author contributions

Conceptualization: Yang Liao.
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Formal analysis: Yang Liao, Qichen Cai.
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Supervision: Yang Liao, Fugui Li.
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