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Laparoscopic common bile duct exploration plus cholecystectomy versus endoscopic retrograde cholangiopancreatography plus laparoscopic cholecystectomy for cholecystocholedocholithiasis: a meta-analysis

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Abstract

Background The purpose of the study was to compare the safety and effectiveness of laparoscopic common bile duct exploration plus laparoscopic cholecystectomy (LCBDE+LC) with preoperative endoscopic retrograde cholangiopancreatography plus laparoscopic cholecystectomy (pre-ERCP+LC) for cholecystocholedocholithiasis.

Methods An electronic search was performed using the following databases: PubMed, Embase, Web of Science, the Cochrane Central Register of Controlled Trials, and ClinicalTrials.gov until 1 July 2018. Randomized controlled trials (RCTs) comparing LCBDE+LC versus pre-ERCP+LC were included. The common bile duct (CBD) stone clearance rate, postoperative bile leakage, postoperative pancreatitis, morbidity, mortality, and overall hospital stay were analyzed.

Results Twelve RCTs involving 1545 patients were included in this meta-analysis. Of the 12 RCTs, seven confirmed and five did not confirm CBD stones preoperatively. The meta-analysis showed a significantly higher CBD stone clearance rate for pre-ERCP+LC than LCBDE+LC. A similar result was found in the subgroup analysis of patients with confirmed CBD stones. A significantly lower postoperative bile leakage rate was found for pre-ERCP+LC than LCBDE+LC in all 12 RCTs and in the subgroup of patients with confirmed CBD stones. However, a significantly higher rate of pancreatitis was found in pre-ERCP+LC and in the subgroup of patients with confirmed CBD stones. LCBDE+LC was superior to pre-ERCP+LC in terms of the overall hospital stay. No significant differences were found in morbidity or mortality.

Conclusions Pre-ERCP+LC is associated with a higher CBD stone clearance rate, lower postoperative bile leakage rate, and higher rate of pancreatitis. LCBDE+LC might help to shorten the hospital stay. Further studies on this topic are recommended.

Keywords Common bile duct stones · Laparoscopic common bile duct exploration · Laparoscopic cholecystectomy · Endoscopic retrograde cholangiopancreatography · Meta-analysis · Systematic review

The presence of common bile duct (CBD) stones combined with gallstones, also known as cholecystocholedocholithiasis (CCL), is one of the most common clinical diseases and accounts for 8–20% of patients with gallstones [1–4]. With the development of laparoscopic and endoscopic techniques, minimally invasive treatment has become a trend in the management of CBD stones combined with gallstones [4, 5]. At present, the minimally invasive treatment technique for CCL is mainly laparoscopic CBD exploration (LCBDE) plus laparoscopic cholecystectomy (LCBDE+LC) or endoscopic retrograde cholangiopancreatography (ERCP) plus laparoscopic cholecystectomy (ERCP+LC) [6, 7]. The preferred laparoendoscopic procedure is preoperative ERCP+LC (pre-ERCP+LC), which is recommended by the European Association for the Study of the Liver [3]; however, no robust statements have been published regarding the best

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treatment for CCL. Notably, ERCP may cause destruction of the sphincter of Oddi, potentially resulting in reflux of duodenal juice, which may in turn lead to recurrence of CBD stones, recurrent episodes of cholangitis, and even biliary malignancies [8–10]. ERCP is also associated with a series of complications such as pancreatitis, bleeding, and perforation [11–14]. The other drawback of any two-stage procedure is that the patient undergoes two different uncomfortable anesthesiologic sessions. As a one-stage treatment for CCL, LCBDE+LC, with the advantage of preserving the function of the sphincter of Oddi, can reduce the overall hospital stay and cost [6, 15]. However, this highly technical procedure has a long learning curve, especially when a T-tube is used, which increases patient discomfort [16]. The optimal strategies for the management of CCL remain controversial. However, previous meta-analyses have compared the two procedures [6, 17–19]. Because of various limitations such as small sample sizes and bias, these studies have failed to demonstrate a reliable conclusion. Additionally, two randomized controlled trials (RCTs) have been published recently [20, 21]. Therefore, we conducted the present up-to-date meta-analysis to compare the efficacy and safety between the two above-mentioned minimally invasive procedures in the treatment of patients with CCL.

Methods

Search strategy

Two authors (Cheng YX and Ting L) independently conducted a thorough electronic search of the PubMed, Embase, Web of Science, Cochrane Central Register of Controlled Trials (CENTRAL), and ClinicalTrials.gov databases until 1 July 2018 to identify original studies comparing LCBDE+LC and pre-ERCP+LC for treatment of CCL. English search terms included but were not limited to the following: "gallstones," "cholecystolithiasis," "choledocholithiasis," "laparoscopic common bile duct exploration," "endoscopic retrograde cholangiopancreatography," and "laparoscopic cholecystectomy." The search was restricted to human subjects and English-language articles. The references of the articles identified after the initial search were also manually reviewed. Institutional review board approval of our hospital was obtained for this study.

Inclusion and exclusion criteria

The following two inclusion criteria were applied: the RCT must compare LCBDE+LC versus pre-ERCP+LC for patients with proven or suspected CBD stones, and the original article must have been published in English with full text. The exclusion criteria were non-RCTs, retrospective studies, review articles, case reports, abstracts, editorials, and letters to the editor; repeated publication by the same author or agency; and insufficient data on outcome measures.

Outcome measures

The primary outcome of this study was the CBD stone clearance rate. The secondary outcomes were wound infection, the overall hospital stay, postoperative bile leakage, postoperative pancreatitis, morbidity, and mortality.

Subgroup analysis

The included studies were divided into two subgroups: preoperative confirmation of CBD stones and lack of preoperative confirmation of CBD stones.

Data extraction

The standardized selection form included the first author, year of publication, type of study, country in which the study took place, sample size, and CBD stone status. Conflicts in data abstraction were resolved by consensus and by referring to the original article. EndNote version X8 (Thomson Reuters, Toronto, Ontario, Canada) was used to remove duplicate studies.

Risk of bias assessment

The quality of the literature was assessed in accordance with the Cochrane Collaboration Handbook [22]. The scoring system included the following criteria: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of the results assessment, incomplete results data, selective reporting, and other sources of bias.

Statistical analysis

All statistical analyses were performed using Review Manager (RevMan) version 5.3 software (Cochrane Informatics and Knowledge Management Department, Nordic Cochrane Centre, Copenhagen, Denmark). Odds ratios (ORs) with 95% confidence intervals (CIs) were used for dichotomous outcomes. Publication bias was evaluated by the χ^2 test and funnel plots. Heterogeneity among studies was evaluated by the χ^2 test. A two-tailed p value of <0.05 was considered statistically significant. We also assessed the potential for publication bias through a visual inspection of funnel plot asymmetry. The meta-analysis was conducted according to the PRISMA statement.

Results

Study selection and trial characteristics

Following the search strategy, we identified 265 papers from the online database; of these, 120 duplicate articles were excluded. The remaining 145 studies were retrieved based on their titles and abstracts. Additional 133 citations were excluded for various reasons. Finally, 12 RCTs involving 1545 participants were included in the current meta-analysis [20, 23–33]. A flowchart of the literature search process is shown in Fig. 1.

The characteristics and quality evaluation of the included citations are shown in Table 1. The LCBDE+LC group comprised 771 patients, and the pre-ERCP+LC group comprised 774 patients. The sample sizes among the studies ranged from 53 to 296 patients, and the year of publication ranged from 1999 to 2016. CBD stones were confirmed preoperatively in seven studies [20, 24–26, 28–30] and unconfirmed in five studies [23, 27, 31].

Figure 2 shows an overview of the methodological quality of the studies included in the meta-analysis using the Cochrane Collaboration tool for assessing the risk of bias.

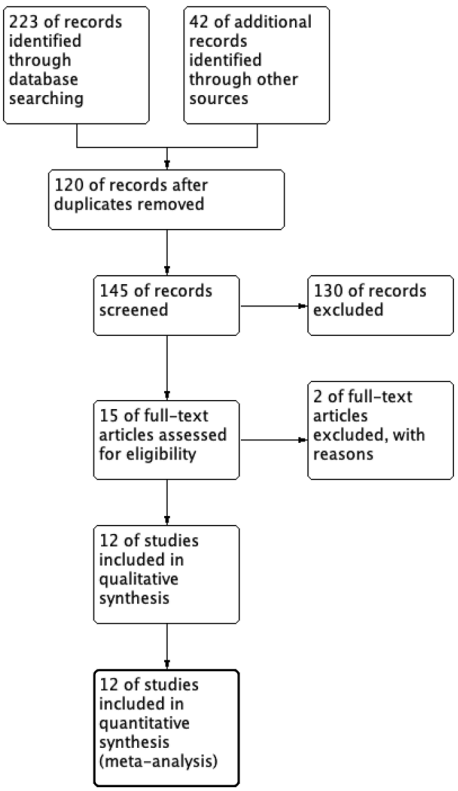

Fig. 1 Flow diagram of the published articles evaluated for inclusion in this meta-analysis

Outcome measures

CBD stone clearance rate

All 12 studies involving 1262 patients reported the CBD stone clearance rate, which was considered a major parameter of treatment efficacy for CCL. The pre-ERCP+LC group had a higher CBD stone clearance rate than the LCBDE+LC group (OR 1.63; 95% CI 1.16–2.28; $p=0.005$) (Fig. 3A). The subgroup analysis of the patients with confirmed CBD stones also showed that the pre-ERCP+LC group had a higher CBD stone clearance rate than the LCBDE+LC group (OR 1.92; 95% CI 122–3.14; $p=0.005$) (Fig. 3A). There were no significant differences in the CBD stone-unconfirmed subgroup (OR 1.32; 95% CI 0.81–2.16; $p=0.27$) (Fig. 3B).

Postoperative bile leakage

Eleven trials reported the postoperative bile leakage rate. The pre-ERCP+LC had a lower postoperative bile leakage rate than the LCBDE+LC group (OR 4.08; 95% CI 2.08–7.98; $p<0.0001$) (Fig. 4A). A similar result was obtained in the subgroup analysis of the patients with confirmed CBD stones (OR 6.5; 95% CI 2.49–16.99; $p=0.0001$) (Fig. 3B). In the CBD stone-unconfirmed subgroup, the difference was not significant (OR 2.19; 95% CI 0.82–5.87; $p=0.12$) (Fig. 4B).

Postoperative pancreatitis

Ten trials reported the rate of postoperative pancreatitis. There was a significant difference in the rate of postoperative pancreatitis between the two groups (OR 0.23; 95% CI 0.11–0.50; $p=0.0002$) (Fig. 5A). The subgroup analysis of patients with confirmed CBD stones showed that the rate of postoperative pancreatitis was significantly higher in the pre-ERCP+LC than LCBDE+LC group (OR 0.18; 95% CI 0.06–0.50; $p=0.001$) (Fig. 5B). However, there were no significant differences in the CBD stone-unconfirmed subgroup (OR 0.34; 95% CI 0.11–1.08; $p=0.07$) (Fig. 5B).

Overall morbidity

Twelve trials reported overall morbidity. There were no significant differences between the two groups (OR 0.91; 95% CI 0.66–1.24; $p=0.54$) (Fig. 6A). The subgroup analysis also showed that overall morbidity was not significantly different between the CBD stone-confirmed and -unconfirmed subgroups ($p=0.10$ and $p=0.51$, respectively) (Fig. 6B).

Table 1 Characteristics of the 20 included studies

Study	Country	Study period	Sample size (L+L/E+L)	Sex (F/M) (L+L/E+L)	Age (year) (L+L/E+L)	CBD stones	Jadad score
Nakeeb et al. 2016 [20]	Egypt	April 2012–March 2014	50 50	31/19 32/18	45(16–63) 42(23–73)	Confirmed	5
Bansal et al. 2010 [24]	India	July 2007–April 2008	15 15	11/4 10/5	47.1(34–72) 39.07(23–64)	Confirmed	4
Bansal et al. 2014 [25]	India	February 2009–October 2012	84 84	61/23 50/34	45.1 ± 15.1 43 ± 13.7	Confirmed	5
Cuschieri et al. 1999 [27]	Scotland	1994–1997	149 147	90/59 108/39	19–88 18–89	Unconfirmed	5
Ding et al. 2014 [28]	China	January 2002–December 2005	110 111	57/53 58/23	58.42 ± 7.21 57.53 ± 6.31	Confirmed	4
Ferulano 2011 [23]	Italy	January 1996–June 2010	45 39	NA	NA	Unconfirmed	4
González et al. 2016 [26]	Cuba	November 2007–November 2011	100 101	NA	56.3 (22–87) 57.7 (20–84)	Confirmed	5
Koc et al. 2013 [29]	Turkey	January 2008–September 2010	54 54	37/20 36/18	51.5 6 16.6 54.9 6 17.9	Confirmed	2
Lv et al. 2016 [30]	China	February 2014–April 2015	29 24	9/15 9/20	63.5 ± 12.4 61.3 ± 14.5	Confirmed	4
Nobel et al. 2009 [31]	United Kingdom	2000–2006	44 47	28/16 25/22	75.9 (70.0–80.8) 74.3 (70.0–78.9)	Unconfirmed	4
Rogers et al. 2010 [32]	United Kingdom	September 1997–June 2003	57 55	37/20 36/18	39.9 ± 1.9 44.6 ± 1.9	Unconfirmed	6
Sgourakis et al. 2002 [33]	Greece	April 1997–August 2000	36 42	21/15 25/17	15(43–88) 17(46–89)	Unconfirmed	4

L+L laparoscopic bile duct exploration+laparoscopic cholecystectomy, *E+L* pre-endoscopic retrograde cholangiopancreatography+laparoscopic cholecystectomy, *NA* not applicable

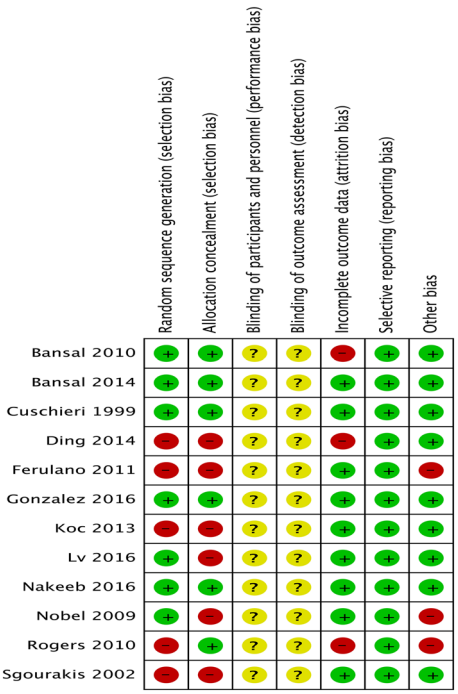

Fig. 2 Consensus risk of bias assessment of the included studies. Green, low risk; yellow, unclear; red, high risk. (Color figure online)

Overall mortality

The present analysis showed no significant difference in overall mortality between the two groups (OR 0.36; 95% CI 0.08–1.58; $p = 0.18$) (Fig. 7A). The subgroup analysis also indicated no significant differences between the CBD stone-confirmed and -unconfirmed subgroups ($p = 0.19$ and $p = 0.60$, respectively) (Fig. 7B).

Overall hospital stay

Only four trials reported the overall hospital stay. The overall hospital stay was significantly shorter in the LCBDE+LC group (mean difference [MD], − 2.46 days; 95% CI − 3.67 to − 1.24; $p < 0.0001$) (Fig. 8A). A similar result was obtained in the subgroup of patients with unconfirmed CBD stones (MD, − 2.28 days; 95% CI, − 3.93 to − 0.64; $p < 0.0001$) (Fig. 8B). The subgroup analysis showed that the differences were not significant in the CBD stone-confirmed subgroup (MD, − 2.28 days; 95% CI − 3.93 to − 0.64; $p = 0.15$) (Fig. 8B).

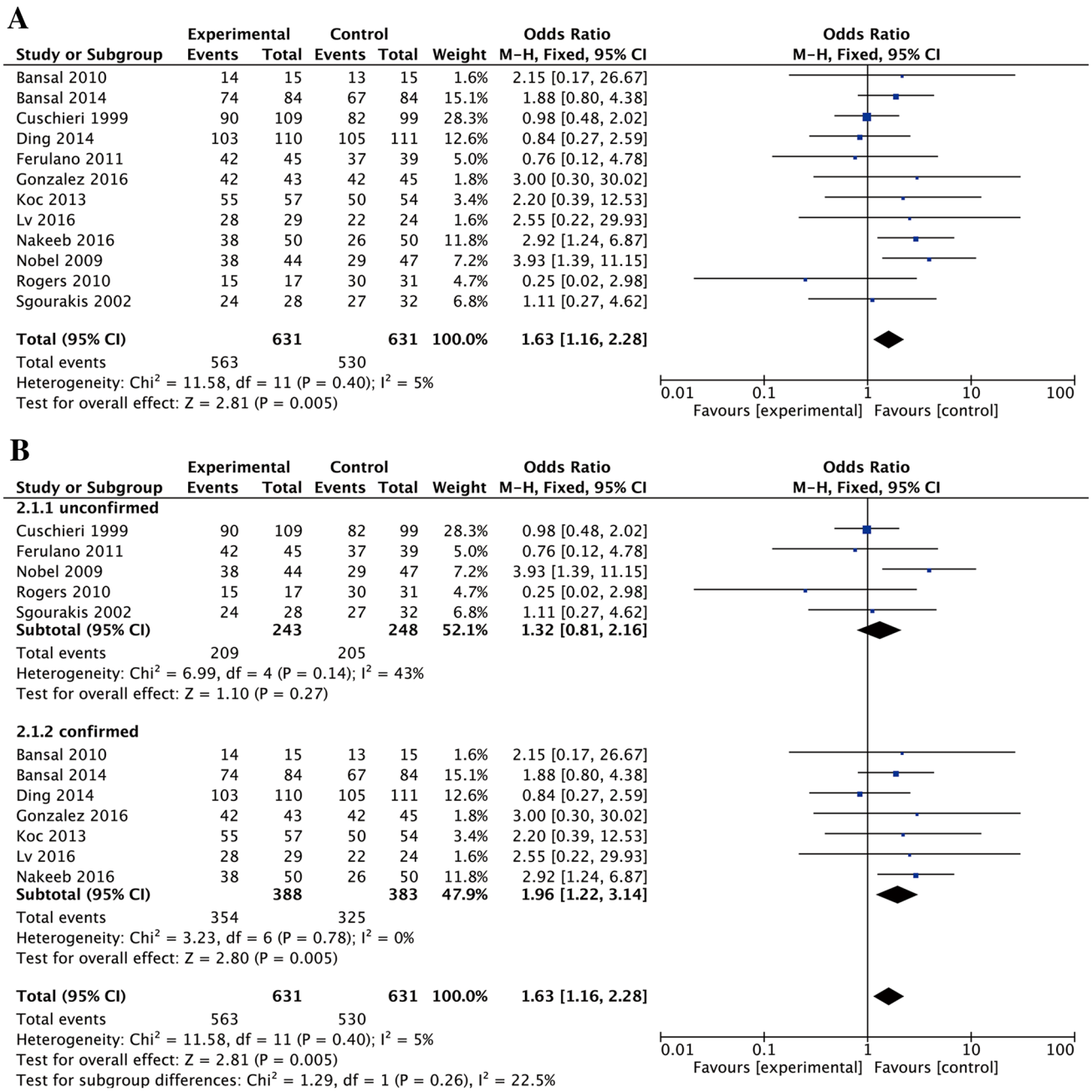

Fig. 3 Forest plot of the meta-analysis comparing LCBDE+LC and pre-ERCP+LC regarding the CBD stone clearance rate (**A**) total studies (**B**) subgroup analysis

Sensitivity analysis

The influence of a single study on the overall meta-analysis estimate was investigated by omitting one study at a time. The omission of any study resulted in no significant difference, indicating that our results were statistically reliable.

Publication bias

Most graphical funnel plots of the parameters were symmetrical. Egger's test revealed no significant publication bias.

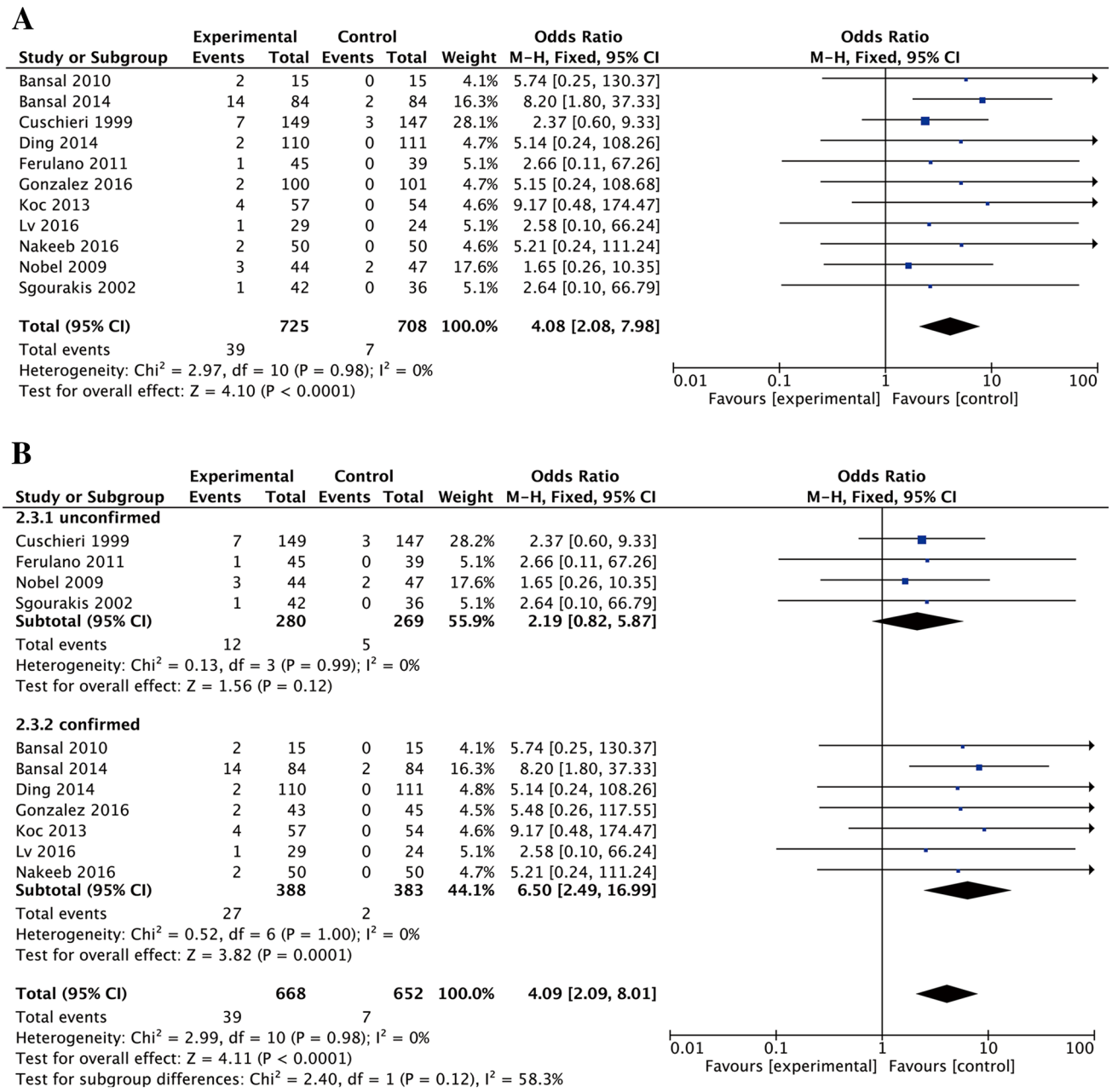

Fig. 4 Forest plot of the meta-analysis comparing ELC and DLC regarding the postoperative bile leakage (**A**) total studies (**B**) subgroup analysis

Discussion

This current meta-analysis compared pre-ERCP+LC with LCBDE+LC in terms of their safety and effectiveness for patients with CCL. This study showed that pre-ERCP+LC had a higher CBD stone clearance rate and lower postoperative bile leakage rate. However, pre-ERCP was associated with more pancreatitis and longer hospital stays. Pre-ERCP+LC and LCBDE+LC had similar morbidity and mortality rates.

An important indicator in the treatment evaluation for CBD stones combined with gallstones is the clearance rate of CBD stones [34]. In the present study, the clearance rate of CBD stones in the LCBDE+LC group and pre-ERCP+LC group was 88.98% and 84.27%, respectively. This is consistent with previous research reports [6, 7, 34]. To date, little agreement has been reached on the rate of CBD stone clearance. One meta-analysis of eight RCTs showed that LCBDE+LC was associated with a higher rate of CBD stone clearance than pre-ERCP+LC (90.17% vs. 85.71%, respectively; $p = 0.03$) [6]. A similar result was shown in another

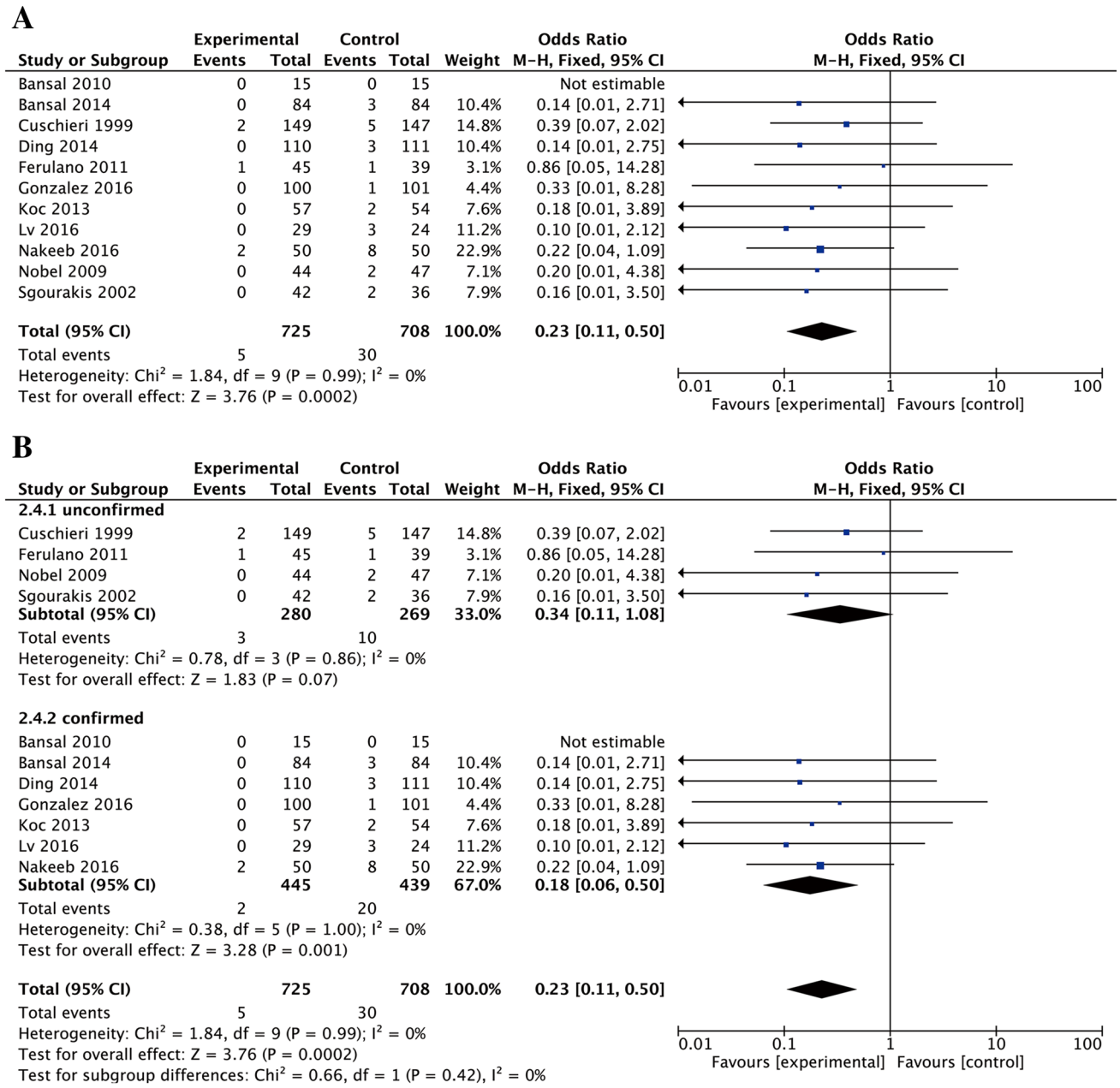

Fig. 5 Forest plot of the meta-analysis comparing ELC and DLC regarding the postoperative pancreatitis (**A**) total studies (**B**) subgroup analysis

recent meta-analysis [35]. However, a study conducted by Elgeidie et al. showed that pre-ERCP+LC was associated with a higher success rate of CBD stone clearance [36]. One of the strengths of this study is that a subgroup analysis was performed according to the preoperative status of CBD stones. In the subgroup analysis of the group of patients with confirmed CBD stones before surgery, we found that the pre-ERCP group had a higher rate of CBD stones. However, there was no significant difference in the subgroup of patients with unconfirmed CBD stones. We believe that these differences may be related to the research period. The studies in the subgroup of patients with unconfirmed choledocholithiasis were performed before 2011. Endoscopic techniques have developed rapidly in recent years, potentially resulting in an increased clearance rate of CBD stones. Another strength of this study is the inclusion of several recent RCTs. However, these two recent studies showed that pre-ERCP+LC was associated with an equal clearance rate [26, 30]. Additional studies with larger sample sizes and high-quality evaluation methods are required.

There was no significant difference in overall morbidity and mortality between the two groups. The main

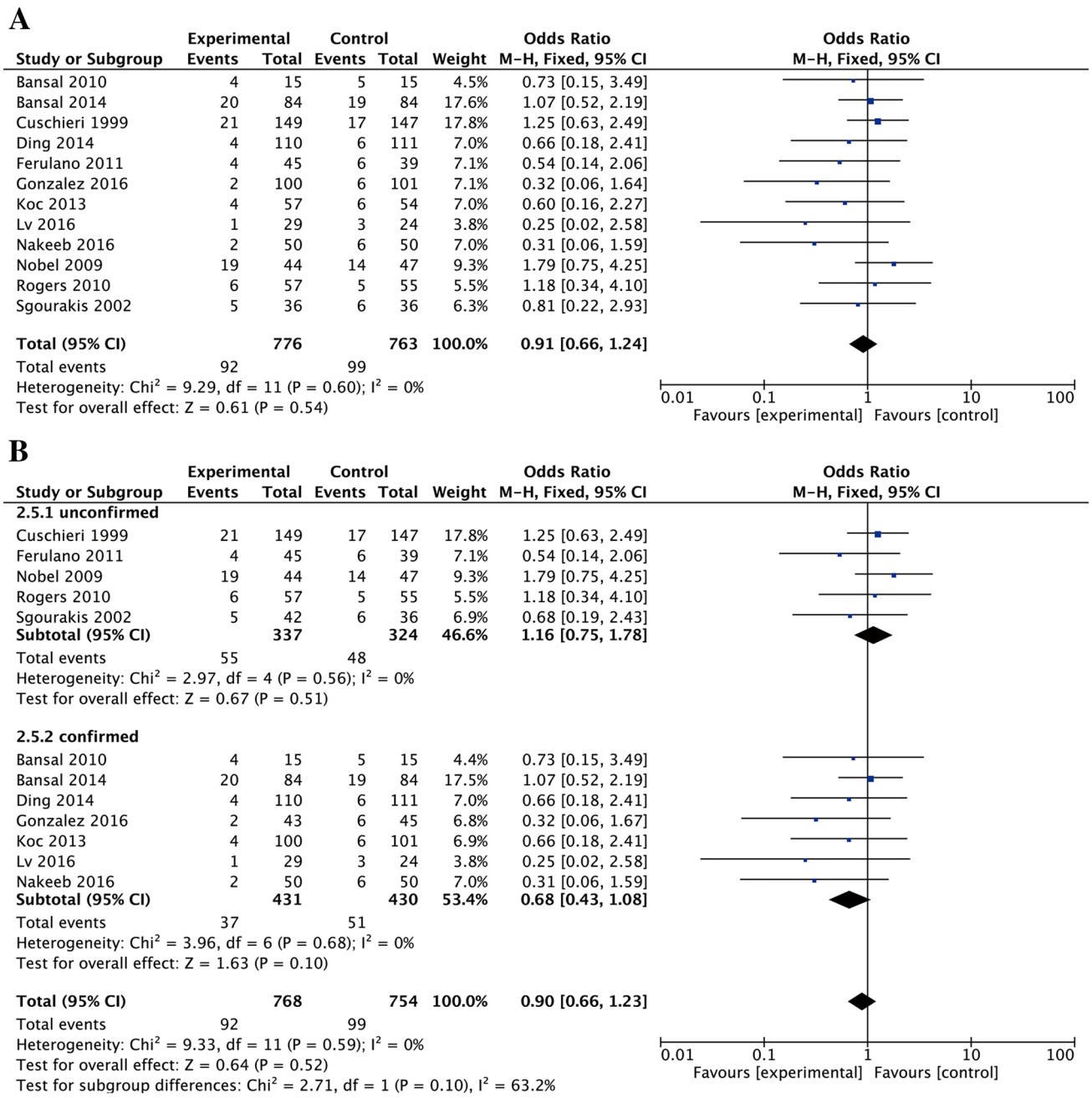

Fig. 6 Forest plot of the meta-analysis comparing ELC and DLC regarding the overall morbidity (**A**) total studies (**B**) subgroup analysis

complications of pre-ERCP+LC are postoperative pancreatitis, hemorrhage, and perforation. In the current study, pre-ERCP+LC showed a higher rate of postoperative pancreatitis. Notably, however, the diagnostic criteria and severity of pancreatitis were not described in detail in the included studies. The severity of postoperative pancreatitis varied from mild to life-threatening [37]. In this study, the incidence of postoperative bile leakage was lower in the pre-ERCP+LC group. This is consistent with some previous studies [6, 20, 29]. Postoperative bile leakage can lead to a prolonged hospital stay and patient dissatisfaction. Although recent studies have shown that primary sutures have the same safety and effectiveness as T-tube drainage [38, 39], this is still controversial. The studies included in the present meta-analysis included T-tube drainage and primary suturing. The existence of this heterogeneity may have had an impact on the outcome. More detailed and higher-quality research on postoperative pancreatitis and bile leakage is necessary in the future.

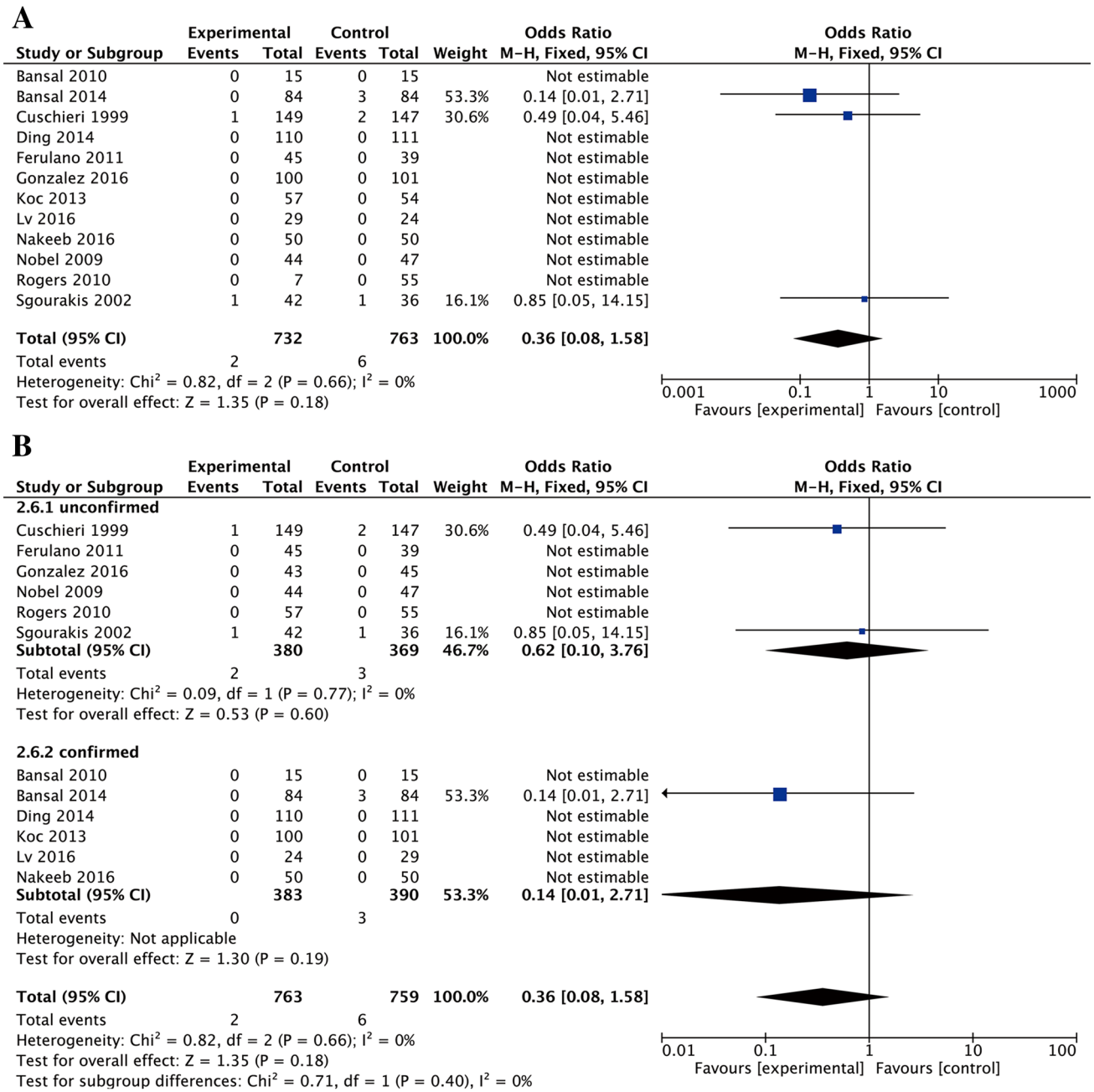

Fig. 7 Forest plot of the meta-analysis comparing ELC and DLC regarding the overall mortality (**A**) total studies (**B**) subgroup analysis

Of the 12 studies included in this meta-analysis, only four provided detailed data on the overall hospital stay. In our meta-analysis of all studies, the LCBDE+LC group had shorter hospital stays. However, this finding needs to be interpreted with caution. Interestingly, there was no significant difference in terms of the overall hospital stay in the subgroup of patients with preoperatively confirmed CBD stones. One explanation may be that LCBDE+LC, performed as a single procedure, may prolong the hospital stay because of postoperative bile leakage and the presence of an indwelling T-tube. Conversely, the interval of time between ERCP and LC differed among the included studies. In a comparative study of postoperative hospital stays, Noble et al. found no statistically significant difference between the two groups [31]. Further research on the overall hospital stay is necessary in the future.

Most studies, including the present study, focus on short-term comparisons of the two treatment procedures. A very important prognostic indicator for patients with CBD stones is recurrence of stones. Among the literature included in this

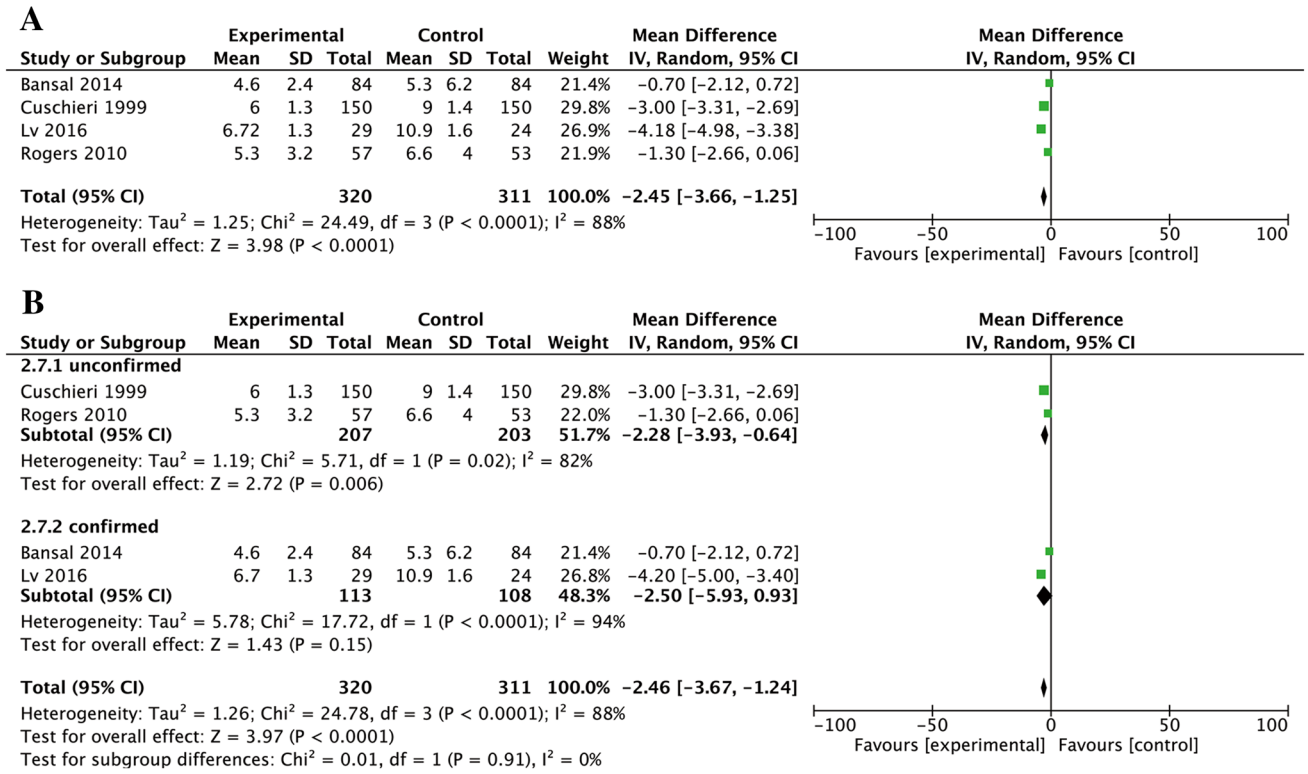

Fig. 8 Forest plot of the meta-analysis comparing ELC and DLC regarding the overall hospital stay (**A**) total studies (**B**) subgroup analysis

study, two RCTs provided data on postoperative calculi recurrence [23, 28]. In the study by Ding et al., the authors reported that LCBDE+LC stones had a lower recurrence rate [28]. In another retrospective study, the authors noted that the rate of postoperative stone recurrence was lower in the LCBDE+LC group [40]. This may be related to the reflux of duodenal juice after incision of the sphincter of Oddi following ERCP. Reflux of duodenal juice is closely associated with the formation of stones. Future studies should focus on the difference in CBD stone recurrence between the two procedures.

Although this study included the latest RCTs, it still had some limitations. First, the quality of the included studies was heterogeneous, and some studies did not clearly explain the methods produced by randomized controls. Second, differences in the number and size of CBD stones, the size of the CBD, and the interval between pre-ERCP and LC among the included studies may have also affected the results. Third, there is still a lack of adequate research on the long-term effects of the two treatments. Therefore, large sample, long-term, high-quality research is still necessary.

Conclusion

Pre-ERCP+LC had a higher CBD stone clearance rate, lower postoperative bile leakage rate, and higher pancreatitis rate. ERCP+LC and LCBDE+LC had similar morbidity, mortality, and overall hospital stays.

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Data Availability All the data used in the study can be obtained from the original articles.

Compliance with ethical standards

Disclosures Yunxiao Lyu, Yunxiao Cheng, Ting Li, Bin Cheng, and in Jin have no conflicts of interest or financial ties to disclose.

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