

Is early laparoscopic cholecystectomy after clearance of common bile duct stones by endoscopic retrograde cholangiopancreatography superior?

A systematic review and meta-analysis of randomized controlled trials

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Abstract

Background: With medical advancement, common bile duct stones were treated by endoscopic retrograde cholangiopancreatography (ERCP), considered the standard treatment. However, ERCP might induce complications including pancreatitis and cholecystitis that could affect a subsequent laparoscopic cholecystectomy (LC), leading to conversion to open cholecystectomy perioperative complications. It is not yet known whether or not the time interval between ERCP and LC plays a role in increasing conversion rate and complications. Bides, in the traditional sense, after ERCP, for avoiding edema performing LC was several weeks later. Even no one study could definite whether early laparoscopic cholecystectomy after ERCP affected the prognosis or not clearly.

Objective: Comparing some different surgical timings of LC after ERCP.

Method: Searching databases consist of all kinds of searching tools, such as Medline, Cochrane Library, Embase, PubMed, etc. All the included studies should meet the demands of this meta-analysis. In all interest outcomes below, we took full advantage of RevMan5 and WinBUGS to assess; the main measure was odds ratio (OR) with 95% confidence. Moreover, considering the inconsistency of the specific time points in different studies, we set a subgroup to analyze the timing of LC after ERCP. For this part, Bayesian network meta-analysis was done with WinBUGS.

Result: In the pool of conversion rate, the result suggested that the early LC group was equal compared with late LC (OR = 0.68, $I^2 = 0\%$, $P = .23$). Besides, regarding morbidity, there was no significant difference between the 2 groups (OR = 0.74, $I^2 = 0\%$, $P = .26$). However, early LC, especially for laparoscopic-endoscopic rendezvous that belonged to performing LC within 24 hours could reduce the post-ERCP pancreatitis (OR = 0.16, $I^2 = 29\%$, $P = .0003$). Considering early LC included a wide time and was not precise enough, we set a subgroup by Bayesian network, and the result suggested that performing LC during 24 to 72 hours was the lowest conversion rate (rank 1: 0%).

Conclusion: In the present study, LC within 24 to 72 hours conferred advantages in terms of the conversion rate, with no recurrence of acute cholecystitis episodes.

Abbreviations: CBD = common bile duct, ERCP = endoscopic retrograde cholangiopancreatography, ES = endoscopic sphincterotomy, IL = interleukin, LC = laparoscopic cholecystectomy, MeSH = Medical Subject Heading, OR = odds ratio, RCT = randomized controlled trial.

Keywords: common bile duct, endoscopic retrograde cholangiopancreatography, laparoscopic cholecystectomy

1. Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) was regarded as a standard treatment for patients with common bile duct (CBD)^[1] stone, and success was accomplished in more

than 90%^[2] patients. Meanwhile, approximately a few patients with gallstones might result in CBD stones or have coexisting CBD stones. Therefore, performing laparoscopic cholecystectomy (LC) was necessary. However, the timing interval between ERCP and LC was an issue of debate that might vary

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

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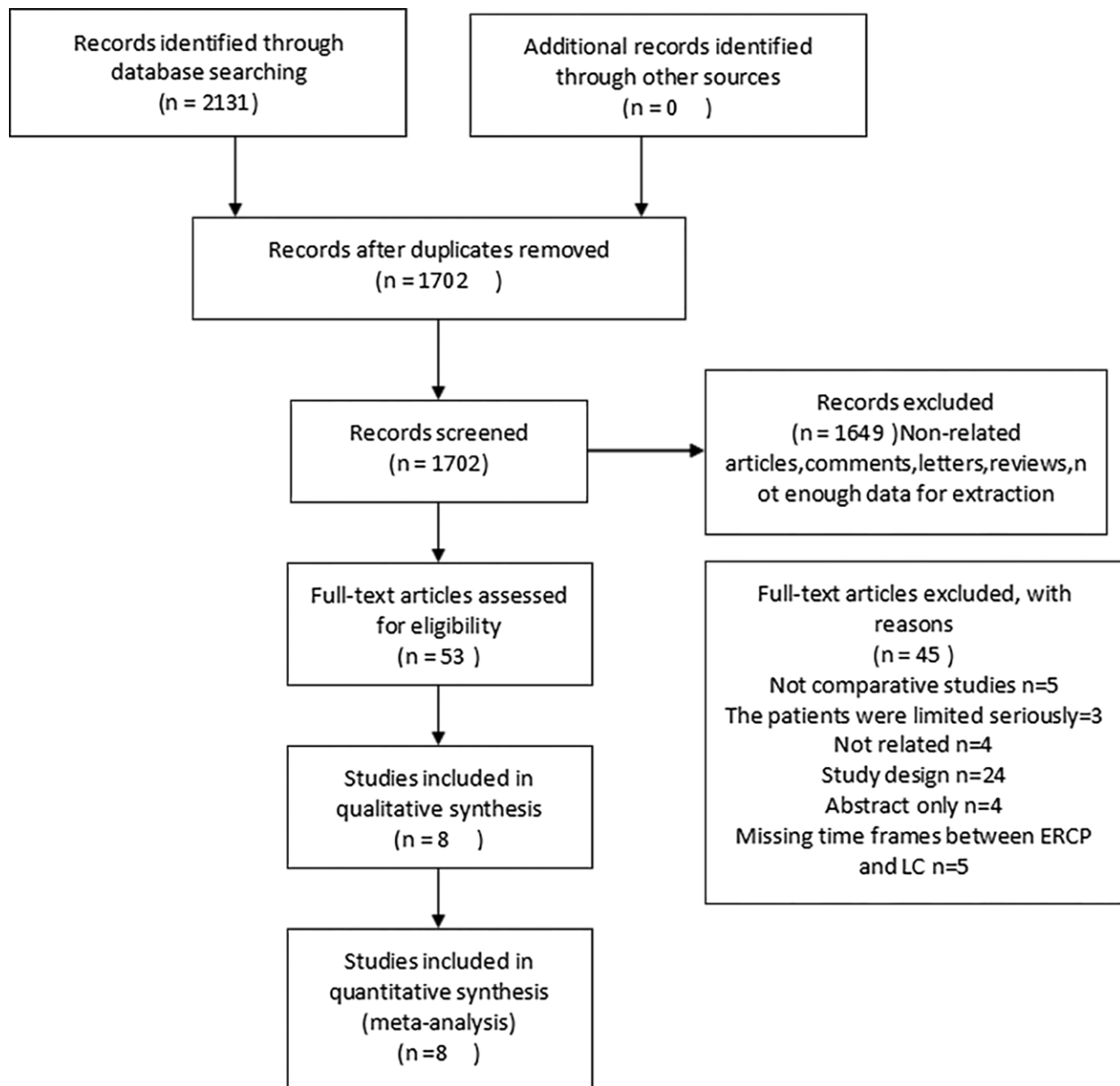


Figure 1. Flow diagram showing the selection of randomized controlled trials.

from days to months. Some retrospective and other prospective studies had investigated this issue without sharpness or definite conclusion.^[3-6]

In the era of an open cholecystectomy, intraoperative cholangiography was routinely done, and detection of CBD stones resulted in the exploration of the CBD and placement of T-tube.^[7] With the advent of laparoscopy and endoscopy, followed by standardization of LC as the gold standard in the management of symptomatic gallstone disease, there was a move away from the surgical management of CBD stones towards endoscopy.^[8] Algorithms were developed to predict the presence of CBD stones preoperatively and to select the best treatment for the patient.^[9-11] Preoperative ERCP and LC were most often preferred.^[12,13] The time interval between ERCP and LC was usually a few days, depending on the surgeon's availability.^[14] Even patients who underwent delayed LC after ERCP that was a practice common in many countries. In their opinion, ERCP could induce complications, including pancreatitis and cholecystitis.^[1,15,16] These complications might affect a subsequent LC, leading to conversion to

open cholecystectomy, preoperative complications, and longer operating times.^[3,17-19] As they had mentioned above, LC after ERCP showed a superior outcome compared with a wait-and-see policy^[3,17] up to 47% of patients in the wait-and-see group developed recurrent biliary events, necessitating a subsequent LC in most cases. Management options were primarily LC after ERCP, which led to a specific concern in the timing of the LC in conjunction with surgery, as this was done as a 2-stage procedure.^[20]

Considering LC was performed extensively and progress was improved in medical technology, given the truth that patients with acute cholecystitis could be handled laparoscope, delay LC had become controversial. In the current study, our purpose was to investigate whether ERCP followed by early LC affected the prognosis or not.

2. Materials and methods

Ethical approval or patient consent was not required since the present study was a review of previously published literature.

Table 1
The characteristics of including studies.

| Author | Year | Country | Design | Group | Number of patients (n) | Time intervals between ERCP and LC |
|----------|------|-------------|--------|-------|------------------------|------------------------------------|
| El akeeb | 2016 | Egypt | RCT | Early | 55 | <3 d |
| | | | | Late | 55 | 4 wk |
| Reinders | 2010 | Netherlands | RCT | Early | 47 | <72 h |
| | | | | Late | 47 | 6–8 wk |
| Aalman | 2009 | Turkey | RCT | Early | 39 | <72 h |
| | | | | Late | 40 | 3–7 d |
| Rıbbago | 2006 | Spain | RCT | Early | 59 | 0 d |
| | | | | Late | 64 | <8 wk |
| Lella | 2006 | <2 d | RCT | Early | 59 | 0 d (ERCP during LC) |
| | | | | Late | 58 | Within 24–72 h |
| Sahoo | 2014 | India | RCT | Early | 41 | 0 d (ERCP during LC) |
| | | | | Late | 42 | <2 d |
| Tzovaras | 2012 | Greece | RCT | Early | 50 | 0 d (ERCP during LC) |
| | | | | Late | 49 | <2 d |
| Morino | 2006 | Italy | RCT | Early | 46 | 0 d (ERCP during LC) |
| | | | | Late | 45 | <8 wk |

ERCP = endoscopic retrograde cholangiopancreatography, LC = laparoscopic cholecystectomy, RCT = randomized controlled trial.

2.1. Searching strategy

The following method was employed to perform a thorough literature search that included PubMed, EMBASE, Cochrane Library, Scopus, and Web of Science. In addition to using keywords like “endoscopic retrograde cholangiopancreatography,” we also used medical subject headings (MeSH), endoscopic retrograde cholangiopancreatography [Title/Abstract], ERCP [Title/Abstract], laparoscopic cholecystectomy [Title/Abstract], LC [Title/Abstract], laparoscopic cholecystectomy [Mesh] and Endoscopic retrograde cholangiopancreatography [Mesh]. What’s more, we used similar words about the optimal time of ERCP followed by LC, such as single-stage ERCP that belonged to the same meaning with different description types (Fig. 1).

2.2. Study selection

Two people (KX and JX) screened the searching studies. If they had divergences, an additional author (KW) reassessed the study. All the eligible studies should comply with the following: Studies were a comparison between early LC and delay or traditional LC after ERCP; For the definition of the “Early,” it meant no more than 72 hours; Maybe in some literature, they did not use early or late LC after ERCP, but the meaning and comparison were the same. We also included; All the studies included were randomized controlled trials (RCTs).

2.3. Exclusion criteria

We would be excluded from the current meta-analysis if any of the following circumstances actually happened. Studies did not have enough data. The article was not published as rich text.

2.4. Data extraction

Data extraction, which was based on a standardized collection, was reviewed on 2 authors (LH and LX) and cross-checks. The following data were our collection: the 7 trials characteristics, which mainly contain the year of publication, the authors, the design of research, the number of patients in each control, study country, and the time intervals between ERCP and LC were included (Table 1).

2.5. Evaluation of quality

The current meta-analysis included 8 RCTs,^[18,21–27] their evaluation of quality were assessed by the Cochrane Handbook, which

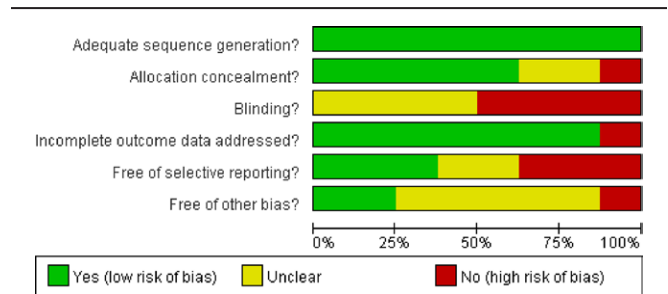


Figure 2. Risk bias of graph. Each risk of bias item presented as percentages across all of the included trials, which indicated the proportion of different level risk of bias for each item.

assessed 7 different domains in each study, which were consisted of random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other sources of bias (Figs. 2 and 3). In each domain, a “low,” “high,” or “unclear” could be applied to assess the quality of each study—low risk of bias: sequence generation using computer-generated random numbers or a random number table. Drawing lots, tossing a coin, shuffling cards, and throwing dice is adequate if performed by an independent person not otherwise involved in the trial. Unclear risk of bias: method of sequence generation not specified. High risk of bias: the investigators described a nonrandom component in the sequence generation process, such as odd or even date of birth; date (or day) of admission; hospital or clinic record number; alternation; judgment of the clinician; results of a laboratory test or a series of tests; availability of the intervention (Figs. 2 and 3).

2.6. Data synthesis and statistical analysis

We did the traditional pair-wise meta-analysis with Review Manager 5 software. In the outcomes of interests, only the hospital stay was a continuous variable which was described as mean difference with 95% confidence interval; the others belonged to dichotomous variables, which were described as odds ratios (ORs) with 95% confidence interval. To test heterogeneity, 2 researchers (WX and KW) independently affiliated the data into RevMan. When the value I^2 is beyond 50%, it means a high heterogeneity.^[28] What’s more, we excluded the including literature in sequence or changed model or OR to check the result. Moreover, considering the inconsistency of the specific

time points in different studies, we set a subgroup to analyze the timing of LC after ERCP. For this part, Bayesian network meta-analysis was done with WinBUGS. We used 4 different sets of starting values to fix the model, yielding 50,000 iterations (20,000 per chain) to obtain posterior distributions of model parameters.

2.7. Outcomes of interest

Two thousand one hundred thirty-one publications were searched from the literature. Meanwhile, 1702 studies were screened on title and abstract after duplicates were removed. Consequently, 53 potentially relevant studies were applied for further assessment, which revealed 8 studies eligible for current meta-analysis.

Almost 796 participants were included in present meta-analysis of the literature. The characteristics of each study were depicted in Table 1, which also included the timing between ERCP and LC. The primary outcome was the conversion rate. The forest plot of outcome was presented followed each result, which was just based on different definitions or restrictions.

2.8. Conversion rate

The conversion rate was the primary outcome and was reported in 7 studies. In this pool, compared with early LC, delay LC did not increase the conversion rate (OR = 0.68, $I^2 = 0\%$, $P = .23$). Notably, I^2 was fairly low. Additionally, the result was stable despite modifying the OR or fixed model (Fig. 4). Considering different definitions of early LC, we did a Bayesian network meta-analysis in the subgroup. There was a certain possibility that when performing LC within 24 to 72 hours, the conversion rate was the lowest (3%) while performing LC within 72 hours to 7 days conversion rate was the highest (17.5%) (Table 2) due to the fact that there was no significant difference concerning the results from the individual studies (Table 3). The heterogeneity was low, and the result was stable. (Using 4 different sets of starting values to fix the model, simulation iterations 50,000 (20,000 per chain) to obtain the potential scale reduction factor of model parameters: 1.01–1.03)

2.9. Morbidity

Morbidity was an outcome after investigation in 5 studies. In this pool, the result indicated that there was no significant difference in morbidity when LC performed in the early group as compared to a delay between ERCP and LC. At the same time, there was a fairly low heterogeneity (OR = 0.74, $I^2 = 0\%$, $P = .26$). After removing each study or changing the OR or fixed model, the result did not change at all, indicating the result was stable (Fig. 5). Given the variety of definitions for early LC, we developed another group in which early LC was performed within 24 hours, and there was no difference (OR = 0.48, $I^2 = 0\%$, $P = .06$).

2.10. Post-ERCP pancreatitis

Five studies were included, the outcome of post-ERCP pancreatitis for early LC was at 3 out of 254 patients (2.2%) compared to delay LC with 25 out of 256 (9.8%). Notably, there was a substantial distinction between the groups (OR = 0.16,

| | Adequate sequence generation? | Allocation concealment? | Blinding? | Incomplete outcome data addressed? | Free of selective reporting? | Free of other bias? |
|----------------|-------------------------------|-------------------------|-----------|------------------------------------|------------------------------|---------------------|
| El Nakeeb 2016 | + | + | ? | + | + | ? |
| Iella 2006 | + | ? | - | - | ? | ? |
| Morino 2006 | + | + | - | + | ? | - |
| reinders2010 | + | + | ? | + | + | ? |
| Rubago 2006 | + | ? | ? | + | - | ? |
| sahoo 2014 | + | + | - | + | - | + |
| Salman 2009 | + | - | ? | + | - | ? |
| tzovaras 2012 | + | + | - | + | + | + |

Figure 3. Risk bias of summary. Judgments about each risk of bias item for each included trials. Green indicates low risk of bias. Yellow indicates unclear risk of bias. Red indicates high risk of bias.

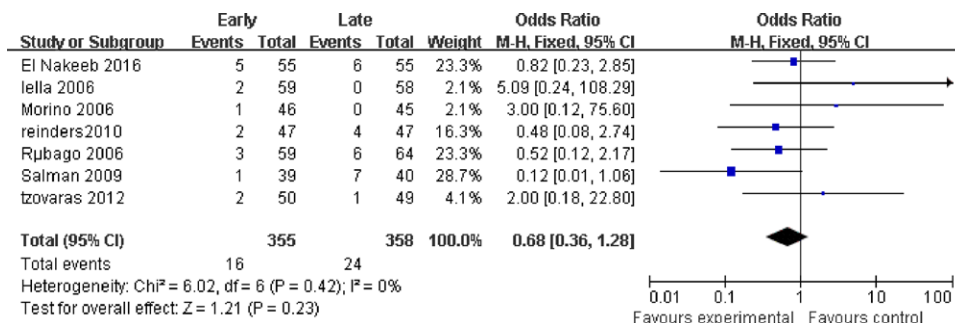


Figure 4. Forest plots of conversion rate in patients with early LC versus those late LC after ERCP. ERCP = endoscopic retrograde cholangiopancreatography, LC = laparoscopic cholecystectomy.

$I^2 = 29\%$, $P = .0003$). There was no serious concern regarding the possibility of bias or heterogeneity ($I^2 = 29\%$). Likewise, there was no indirectness, imprecision, or detected publication bias (Fig. 6). Furthermore, considering the different definitions of “early,” we found the result was stable after eliminating study Rinder^[18] (OR = 0.09, $I^2 = 0\%$, $P = .0003$), even the I^2 declined, and heterogeneity was low.

3. Discussion

Eight randomized clinical trials (796 participants) were included from the 2131 records identified through database searches and other sources in our qualitative and quantitative analysis. Clinical heterogeneity across the 8 trials was low. There was insufficient

evidence to determine the effects of overall mortality (low-quality evidence). Notwithstanding, there was only one case out of the 796 participants included in the analysis. It was demonstrated that the overall morbidity appeared equal after early LC and after the late LC technique. Nonetheless, it was found that early LC, which was especially for LC during ERCP, might be associated with a slightly lower incidence of clinical postoperative pancreatitis. The differences were noteworthy when the fixed-effects model was applied, but not when the random-effects model was utilized. For the primary outcome, there was exceptionally low-quality evidence that the conversion rate was lowest when LC was performed within 24 to 72 hours, but there was no statistically significant difference when 7 studies were analyzed.

Approaches varied with experience and expertise, which included several methods: laparoscopic CBD exploration, conversion to open CBD exploration, and various sequences of LC and ERCP sequential. Some randomized trials have compared the different therapeutic strategies: ERCP and LC versus single-stage laparoscopy,^[29] postoperative ERCP versus LC,^[12] preoperative versus postoperative ERCP,^[30] Laparoendoscopic rendezvous versus preoperative ERCP, and laparoscopic^[26] cholecystectomy. In general, preoperative ERCP and LC constituted the majority of procedures. Nevertheless, the time interval between ERCP and LC was a subject of debate.^[15,16] Considering that it was highly probable that the timing of ERCP after LC affected the complexity of the operation and that previous studies lacked evidence for determining the optimal timing of LC after ERCP and endoscopic sphincterotomy (ES), we compared early LC with late LC in the present study and attempted to determine the optimal timing of LC after ERCP.

Between 8% and 55% of patients who underwent LC and ES had mild gallbladder inflammation^[16] early LC did not reduce the conversion rate (timing was too general), because the patients had an uncomplicated gallbladder. Meanwhile, we set a net analysis and considered there was very low-quality evidence that conversion rate was the lowest when LC was performed within 24 to 72 h. The conversion rate was due to reflux and bacterial colonization of bile after ES leading to inflammation and adhesion in Calot’s triangle and round gallbladder.^[31] This was likely caused by the inflammation that occurred during

Table 2
The rank for time of LC after ERCP.

| Time of LC | Rank 1 | Rank 2 | Rank 3 | Rank 4 |
|------------|--------|--------|--------|--------|
| A | 0.23 | 0.41 | 0.26 | 0.10 |
| B | 0.00 | 0.05 | 0.19 | 0.75 |
| C | 0.59 | 0.19 | 0.18 | 0.05 |
| D | 0.19 | 0.35 | 0.37 | 0.10 |

A = perform LC during ERCP, B = perform LC within 24 to 72 hours after ERCP, C = perform LC within 72 hours to 7 days, D = perform LC over 4 weeks after ERCP.
ERCP = endoscopic retrograde cholangiopancreatography, LC = laparoscopic cholecystectomy.

Table 3
The comparison of different definitions of early LC.

| | | | |
|--------------------|-------------------|--------------------|--------------------|
| A | 0.33 (0.04, 2.08) | 1.58 (0.08, 23.39) | 0.86 (0.11, 6.37) |
| 2.99 (0.48, 26.97) | B | 5.05 (0.67, 39.24) | 2.73 (0.45, 22.89) |
| 0.63 (0.04, 12.61) | 0.20 (0.03, 1.49) | C | 0.49 (0.04, 10.01) |
| 1.16 (0.16, 9.10) | 0.37 (0.04, 2.24) | 2.05 (0.10, 28.53) | D |

A = perform LC during ERCP, B = perform LC within 24 to 72 hours after ERCP, C = perform LC within 72 hours to 7 days, D = perform LC over 4 weeks after ERCP.
ERCP = endoscopic retrograde cholangiopancreatography, LC = laparoscopic cholecystectomy.

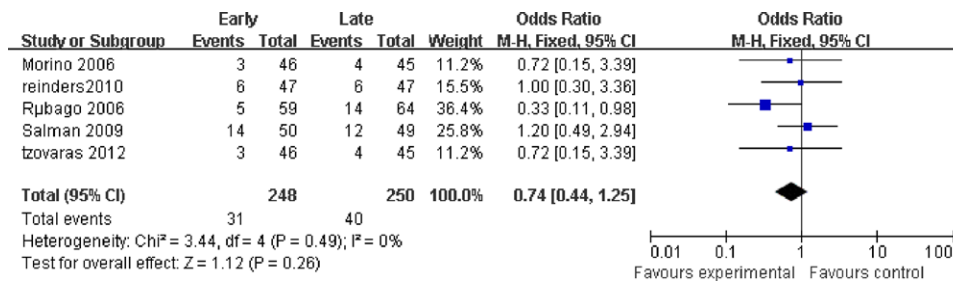


Figure 5. Forest plots of morbidity in patients with early LC versus those late LC after ERCP. ERCP = endoscopic retrograde cholangiopancreatography, LC = laparoscopic cholecystectomy.

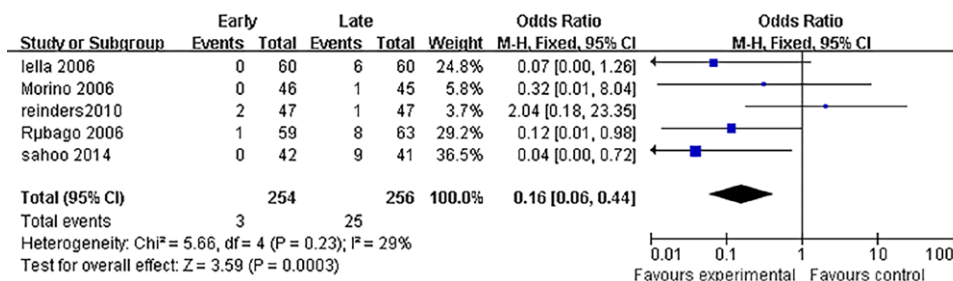


Figure 6. Forest plots of post-ERCP pancreatitis in patients with early LC versus those late LC after ERCP. ERCP = endoscopic retrograde cholangiopancreatography, LC = laparoscopic cholecystectomy.

contrast agent infusion and ES during ERCP. Some other researchers^[32,33] showed there was a near increase in the serum interleukin (IL)-2, IL-4, tumor necrosis factor, and IL-6 levels in the development of post-ERCP pancreatitis or without pancreatitis. Likewise, a number of other studies^[21,22,27] studies discovered no significant difference between the timings. During their operation, it was observed that the duodenum was adherent to the CBD with loose adhesions, implying that an acute inflammatory process had begun early but had no impact on the surgery. Despite this, early LC could be affected before inflammation starts. Accordingly, our meta-analysis confirmed that early LC within 24 to 72 hours was superior due to inflammation that had not yet fully subsided and was unaffected by the ERCP executed just or at the same time. In a recent meta-analysis,^[34] they included multiple types of research, such as RCTs, cohort studies, etc., and discovered that early LC was superior despite a lack of evidence and they did not find a clear time.

Meanwhile, early LC could not reduce the morbidity, though we found that early LC, which was especially for LC during ERCP, might be associated with a slightly lower incidence of clinical postoperative pancreatitis. From the traditional perspective, late LC after ERCP and ES could allow the CBD to cool off and recover their liver status from acute inflammation to undergo LC in an ideal situation. However, this method did not improve the key operative part, such as the Calot triangle. In addition, when performing LC early, the edema had insufficient time to completely appear. Reversely, in late LC, nearly half of the patients developed recurrent biliary symptoms in the intervening period, so far as to rehospitalization.^[35] Notably, several problems arose with the late LC approach. Despite the different predictive models used to stratify patients' risk for CBD stones, patients stratified as high risk even in the presence of clinical, laboratory, and imaging indicators, who underwent ERCP, were found to have CBD stones only 32% of the time.^[36] It makes ERCP diagnostic procedure show a risk of pancreatitis (1–30%), pancreatic necrosis (0.3–0.6%), and mortality (0.4%), which is unacceptable.^[37]

The strength of this review was that it was the first meta-analysis that included RCTs only regarding this subject. More importantly, we found a clear time for LC after ERCP by network. This meta-analysis was aimed at achieving high transparency, as it followed PRISMA guidelines. Furthermore, when compared with the other recent meta-analysis, this was the first time that proved early LC within 24 to 72 hours could reduce the conversion rate by network.

However, it must be noted that several limitations were presented in this meta-analysis. Initially, we lacked information on the long-term benefits or drawbacks of being discharged (e.g., the effect of long-term relapse of biliary stone). In addition, inclusion and exclusion criteria based on the severity of gallbladder disease were not varied across the studies. The level of inflammation did have an impact on the surgical outcomes. Finally, the lack of comparability between the available studies due to their diverse time frames framed a limitation.

4. Conclusion

Due to small sample sizes and heterogeneity among the studies, currently, there were studies advocating that ERCP and cholecystectomy are safe and even more advantageous when performed early. In comparison to ERCP followed by late cholecystectomy, early LC within 24 to 72 hours conferred advantages concerning conversion rate without further recurrence of acute episodes of cholecystitis.

Author contributions

Data curation: Kun Wu.
Formal analysis: LinKing Xiao.
Methodology: LinKing Xiao.

Resources: JiFeng Xiang, Lu Huan, Wei Xie.
Software: Kun Wu, Lu Huan.
Validation: JiFeng Xiang, Lu Huan, Wei Xie.
Visualization: Lu Huan.
Writing – original draft: JiFeng Xiang.
Writing – review & editing: Kun Wu, Wei Xie.

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