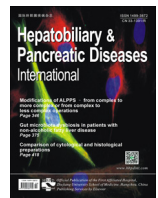




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## Meta-analysis

## Various approaches of laparoscopic common bile duct exploration plus primary duct closure for choledocholithiasis: A systematic review and meta-analysis

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## ABSTRACT

**Background:** Common bile duct (CBD) stones may occur in up to 3%–14.7% of all patients with cholecystectomy. Various approaches of laparoscopic CBD exploration plus primary duct closure (PDC) are the most commonly used and the best methods to treat CBD stone. This systematic review was to compare the effectiveness and safety of the various approaches of laparoscopic CBD exploration plus PDC for choledocholithiasis.

**Data sources:** Randomized controlled trials (RCTs) and non-randomized controlled trials (NRCTs) (case-control studies or cohort studies) were searched from Cochrane library (until Issue 2, 2015), Web of Science (1980–January 2016), PubMed (1966–January 2016), and Baidu search engine. After independent quality assessment and data extraction, meta-analysis was conducted using RevMan 5.1 software.

**Results:** Four RCTs and 18 NRCTs were included. When compared with choledochotomy exploration (CE) plus T-tube drainage (TTD) (CE+TTD), CE plus PDC (CE+PDC) and CE+PDC with biliary drainage (BD) (CE+PDC+BD) had a lower rate of postoperative biliary peritonitis (OR=0.22; 95% CI: 0.06, 0.88;  $P < 0.05$ ; OR=0.27; 95% CI: 0.08, 0.84;  $P < 0.05$ ; respectively) where T-tubes were removed more than 3 weeks. The operative time of CE+PDC was significantly shorter (WMD=−24.82; 95% CI: −27.48, −22.16;  $P < 0.01$ ) than that of CE+TTD in RCTs. Cystic duct exploration (CDE) plus PDC (CDE+PDC) has a lower rate of postoperative complications (OR=0.39; 95% CI: 0.23, 0.67;  $P < 0.01$ ) when compared with CE+PDC. Confluence part micro-incision exploration (CME) plus PDC (CME+PDC) has a lower rate of postoperative bile leakage (OR=0.17; 95% CI: 0.04, 0.74;  $P < 0.05$ ) when compared with CE+PDC.

**Conclusion:** PDC with other various approaches are better than TTD in the treatment of choledocholithiasis.

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## Introduction

Common bile duct (CBD) stones may occur in up to 3%–14.7% of all patients with cholecystectomy [1,2]. The main approaches for treatment of CBD stones are pre- or postoperative endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (EST) and laparoscopic or open surgical bile duct clearance. The others are electrohydraulic lithotripsy (EHL), extracorporeal shock wave lithotripsy (ESWL), dissolving solutions, and laser lithotripsy [2]. ERCP or combined with EST followed by laparoscopic cholecystectomy is a regular choice for the treatment of CBD stones. Nevertheless, CBD stone treatment is associated with

postoperative complications in 8%–10% of patients, including recurrence of stone, pancreatitis, especially iatrogenic injury to the function of the sphincter of Oddi [3]. Laparoscopic CBD exploration (i.e. via the cystic duct, choledochotomy, micro-incision of the cystic duct and its confluence part in CBD) plus primary duct closure (PDC), combination with or without internal or external biliary drainage (BD) and T-tube drainage (TTD) are the most commonly used and the best methods to treat CBD stone [2]. However, cystic duct exploration (CDE) is limited to the size of stones, the number of stones, and CBD diameter [4]. However, traditionally the CBD is closed with TTD which is associated with more complications (e.g., bile leakage and stricture), and inconvenience due to the indwelling of T-tube [5]. Considering that late stricture after surgery of the bile duct and recurrent stones occur in a long-term follow-up, sometimes even 10 years [6], the overall rate of complications were too low to be detected in short-term follow-up. Five

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meta-analyses demonstrated that laparoscopic choledochotomy exploration plus PDC (CE + PDC) was available and associated with lower complications than laparoscopic choledochotomy exploration plus TTD (CE + TTD) [7–11]. However, there is no full evaluation such as the term of follow-up and T-tube removal time.

The present study analyzed whether the outcomes were different in CE + PDC versus CE + TTD according to the long- or short-term follow-up and T-tube removal time. We also compared CDE + PDC with CE + PDC, and confluence part micro-incision exploration plus PDC (CME + PDC) with CE + PDC.

## Methods

### Literature search strategy

A literature search was conducted in Cochrane library (until Issue 2, 2015), Web of Science (1980–January 2016), PubMed (1966–January 2016) and Baidu search engine. The following keywords were used: “laparoscopic” OR “laparoscopy” AND “common bile duct stones” OR “choledocholithiasis” AND “exploration” AND “primary suture” OR “primary duct closure”. Various combinations of the keywords were applied. And a manual search of reference lists from these retrieved publications was performed.

### Selection criteria

The inclusion criteria were as follows: (i) study type: randomized (RCTs) and non-randomized controlled trials (NRCTs) (case-control studies or cohort studies); and (ii) laparoscopic CBD exploration may be performed via trans-cystic, micro-incision of the cystic duct and its confluence part in common bile duct or direct choledochotomy, and combined with PDC, such as: CE + PDC versus CE + TTD; CE + PDC + BD versus CE + TTD; CME + PDC versus CE + PDC; and CDE + PDC versus CE + PDC.

The exclusion criteria were as follows: (i) study type: case reports, review articles, non-human studies; (ii) the data of previous meta-analyses have been completed; (iii) unclear and not detailed description of the follow-up length and T-tube removal time (a “T-tuber removal time” or “the indwelling of T-tube” was defined as the time from inserting into the CBD incision or clamping to removing the T-tube); (iv) articles not reporting data on the outcomes of interest or articles in which the outcomes of interest were impossible to calculate; and (v) unclear and not detailed description of baseline clinical variables of patients in two groups.

### Data extraction and critical appraisal

To reduce the bias and improve the reliability, two reviewers (HMY and RWW) checked all relevant studies independently. Data on the following characteristics were also extracted by the reviewer (RWW): the clinical outcomes used to evaluate effectiveness (operative time, postoperative hospital stay, and hospital expenses) and postoperative complications (biliary peritonitis, biliary leakage, retained and recurrent stones, and postoperative CBD obstruction or stricture). The final results were reviewed by all investigators to avoid bias.

The quality of RCTs was assessed by the Cochrane Risk of Bias Tool [12], and the NRCTs was assessed by the Newcastle–Ottawa quality assessment tool [13].

### Statistical analysis

All the statistical analyses were performed using RevMan 5.1 software (The Cochrane Collaboration, Oxford, UK, 2011). We estimated the combined Odds ratio (OR) for experimental groups and control groups, and expressed continuous data as weighted mean

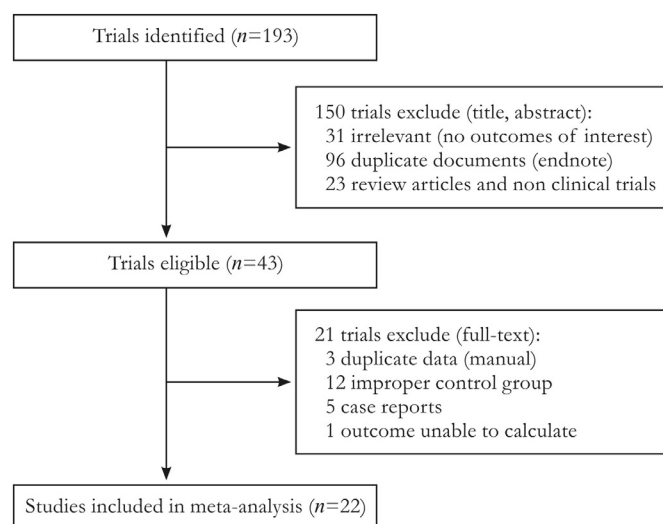


Fig. 1. Flow chart of study selection in the meta-analysis.

differences (WMD) with 95% confidence intervals (CIs) or as standardized weighted mean differences (SMD) if outcomes were conceptually the same but measured in different ways in the different trials. Statistical heterogeneity assumption among studies was checked using the Chi-square-based  $Q$ -test. When  $I^2$  was no more than 50%, pooled outcomes and 95% CIs were calculated using Mantel-Haenszel method with fixed-effect models. Whereas significant heterogeneity ( $P < 0.1$ ,  $I^2 > 50\%$ ) among the studies was detected, a random-effect model (Der Simonian and Laird method) was adopted. If necessary, subgroup analysis was also performed to evaluate the influence of individual studies on the final effect. All  $P$  values were two-sided. A  $P$  value  $< 0.05$  was considered significant.

## Results

### Search results and characteristics

The original search identified 193 studies in electronic databases. We excluded 150 studies after review of the title and abstract, because they were duplicate documents, irrelevant studies or review articles. Forty-three studies were fully evaluated according to the predefined inclusion criteria. The study flow diagram is shown in Fig. 1. Finally, 22 studies [14–35] were eligible for inclusion in the meta-analysis. Two studies from the same group were included because they are not a real duplicated publications [17,35]. Four studies [14–17] were RCTs, and 18 [18–35] were NRCTs. Seventeen studies [14–30] compared CE + PDC or CE + PDC + BD with CE + TTD. Two studies [31,32] compared CME + PDC with CE + PDC. Three studies [33–35] compared CDE + PDC with CE + PDC. The characteristics of eligible 22 studies are summarized in Table 1.

### Quality of trials

Sixteen studies [14–29] reported in previous meta-analysis [11] were not listed in our meta-analysis. The other 6 studies [30–35] were assessed by the Newcastle–Ottawa quality assessment tool and listed in our meta-analysis (Table 2).

### Subgroup analysis of postoperative complications and operative time in the CE + PDC, CE + PDC + BD versus CE + TTD

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