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REVIEW

Systematic review with meta-analysis of studies comparing primary duct closure and T-tube drainage after laparoscopic common bile duct exploration for choledocholithiasis

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Abstract
Background With advances in laparoscopic instrumentation and acquisition of advanced laparoscopic skills, laparoscopic common bile duct exploration (LCBDE) is technically feasible and increasingly practiced by surgeons worldwide. Traditional practice of suturing the dochotomy with T-tube drainage may be associated with T-tube-related complications. Primary duct closure (PDC) without a T-tube has been proposed as an alternative to T-tube placement (TTD) after LCBDE. The aim of this meta-analysis was to evaluate the safety and effectiveness of PDC when compared to TTD after LCBDE for choledocholithiasis.
Methods A systematic literature search was performed using PubMed, EMBASE, MEDLINE, Google Scholar, and the Cochrane Central Register of Controlled Trials databases for studies comparing primary duct closure and T-tube drainage. Studies were reviewed for the primary outcome measures: overall postoperative complications, postoperative biliary-specific complications, re-interventions, and postoperative hospital stay. Secondary outcomes assessed were: operating time, median hospital expenses, and general complications.
Results Sixteen studies comparing PDC and TTD qualified for inclusion in our meta-analysis, with a total of 1770 patients. PDC showed significantly better results when compared to TTD in terms of postoperative biliary peritonitis (OR 0.22, 95 % CI 0.06–0.76, $P = 0.02$), operating time (WMD, −22.27, 95 % CI −33.26 to −11.28, $P < 0.00001$), postoperative hospital stay (WMD, −3.22; 95 % CI −4.52 to −1.92, $P < 0.00001$), and median hospital expenses (SMD, −1.37, 95 % CI −1.96 to −0.77, $P < 0.00001$). Postoperative hospital stay was significantly decreased in the primary duct closure with internal biliary drainage (PDC + BD) group when compared to TTD group (WMD, −2.68; 95 % CI −3.23 to −2.13, $P < 0.00001$).
Conclusions This comprehensive meta-analysis demonstrates that PDC after LCBDE is feasible and associated with fewer complications than TTD. Based on these results, primary duct closure may be considered as the optimal procedure for dochotomy closure after LCBDE.

Keywords Cholelithiasis · Choledochotomy · Common bile duct exploration · Laparoscopy · Primary duct closure · T-tube

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Common bile duct stones are the second most frequent complication of cholecystolithiasis, occurring in approximately 5 % of asymptomatic patients with a normal diameter bile duct on trans-abdominal ultrasound scan at the time of cholecystectomy, and in 10–20 % of patients with symptomatic gallstones [1, 2]. Treatment is advisable to prevent further complications, such as obstructive jaundice, acute cholangitis, and pancreatitis [3]. The optimal treatment for common bile duct stones is still unclear, and the options available include open common bile duct exploration (CBDE), laparoscopic common bile duct exploration (LCBDE), and pre-, intra- or postoperative endoscopic retrograde cholangiopancreatography with sphincterotomy (ERCP and ES) combined with laparoscopic cholecystectomy [2].

In the era of open cholecystectomy, CBDE was the gold-standard procedure for CBD stones, but nowadays, with advances in laparoscopic instrumentation and acquisition of advanced laparoscopic skills, LCBDE for choledocholithiasis is increasing in popularity among surgeons worldwide [4, 5]. There is evidence in the literature to suggest that LCBDE for choledocholithiasis is of equal efficacy, is associated with equal morbidity rate, and is more cost-effective than ERCP followed by laparoscopic cholecystectomy [6–8].

LCBDE may be performed trans-cystic or by direct choledochotomy, and this is determined by stone size, load and distribution, and also the diameter of the cystic duct [9, 10]. When there is an indication for direct bile duct dochotomy to clear the stone burden, this is subsequently managed by primary duct closure (PDC) or closure with T-tube drainage (TTD). TTD was common practice in open CBD exploration and has been common practice after LCBDE to achieve postoperative decompression of the common bile duct and visualization of the biliary system through cholangiography to check for residual stones [11, 12]. However, this practice is associated with significant T-tube-related complications that include drain site pain, biliary leak, CBD obstruction due to accidental tube dislodgement, persistent biliary fistula, and biliary peritonitis due to tube dislodgement or after T-tube removal. These complications are reported to occur in approximately 15 % of patients with TTD [13, 14]. Furthermore, T-tube insertion after laparoscopic or open CBDE is associated with prolonged hospital stay, longer operating time, and higher hospital expenses [6, 15–19].

Consequently, some surgeons have recommended primary closure of the common bile duct immediately after dochotomy to reduce the risk of T-tube-related complications, and also to facilitate early discharge, early return to normal activity, and less hospital expenses [15, 20, 21].

Various internal and external biliary drainage methods have been analyzed in the literature in order to decompress the biliary tree after LCBDE and primary duct closure + biliary drain (PDC + BD), with ante-grade biliary stents, modified biliary stents, modified intra-cystic biliary catheters, and J-tubes which are all described [22–26]. These authors showed that internal biliary stenting following LCBDE is an effective and safe technique that prevents T-tube-related morbidity and results in a shorter postoperative hospital stay and an earlier return to work, when compared to TTD [27, 28].

To date four meta-analyses have been performed to compare the results of PDC with those of TTD [21, 29–31]. The most complete pooled analysis, performed by Yin et al. [31], enrolled twelve studies (three randomized controlled trials and nine retrospective cohort studies) comparing PDC, with or without BD insertion, and TTD.

This review has included two new randomized controlled trials comparing PDC versus TTD, and PDC + BD insertion versus TTD [18, 28]. Moreover, this review has included five retrospective cohort studies in the pooled analysis that have not been included previously [4, 17, 27, 32, 33]. Therefore, this meta-analysis reports on the largest number of patients from all randomized controlled trials and retrospective cohort studies in the literature to assess and validate the safety, feasibility, and potential benefits or limitations of PDC when compared to TTD after LCBDE.

Materials and methods

Search methods for identification of studies

A systematic literature search was performed using PubMed, EMBASE, MEDLINE, Google Scholar, and the Cochrane Central Register of Controlled Trials databases for studies comparing PDC and TTD. We combined database-specific search terms for primary closure (*primary duct closure or primary closure or primary suture or PDC*), T-tube (*T-tube or T-tube drainage*), and LCBDE (*laparoscopic common bile duct exploration, laparoscopic choledochotomy*). The search was then extended to related articles suggested by the databases and supplemented with manual searches for reference lists of all relevant articles. When the results of a single study were reported in more than one publication, only the most recent and complete data were included in the meta-analysis. Literature search was completed in September 2014.

Selection of studies

This systematic review and meta-analysis included randomized controlled trials (RCTs) and retrospective cohort studies (RCSs), in which different techniques of PDC and TTD after LCBDE were compared, *irrespective of language*, *blinding*, *or publication status*. To be included in the analysis, studies had to meet the following inclusion criteria:

a. Patients did not have any contraindication for laparoscopic surgery.
b. Patients did not have acute biliary pancreatitis, ampullary stenosis with multiple intrahepatic stones,

severe acute cholangitis, suspected biliary neoplasia, hemorrhagic tendency due to any reason, known cirrhosis of the liver.

c. The included studies were required to report at least one of the following outcomes measures of the different techniques used for treatment: postoperative overall morbidity, postoperative biliary-specific complications, re-intervention rate, operating time, postoperative hospital stay, or median hospital expenses.

The exclusion criteria were: articles not reporting data on the outcomes of interest or articles in which the outcomes of interest were impossible to calculate, non-human studies, review articles, editorials, letters and case reports.

Types of outcome measures

Primary outcomes assessed were: overall postoperative complications, postoperative biliary-specific complications (biliary peritonitis, biliary leak, retained stones and postoperative common bile duct obstruction), re-intervention (radiology/endoscopy), re-intervention (surgery) and postoperative hospital stay.

Secondary outcomes assessed were: operating time, median hospital expenses, and other general complications not directly related to the techniques of bile duct closure (wound infection, pneumonia, deep vein thrombosis, internal hemorrhage).

Data extraction and management and assessment of risk of bias in included studies

Two reviewers (M.P and I.S.T) independently considered the eligibility of potential titles and extracted data. Discrepancies were resolved by mutual discussion. Inclusion and exclusion criteria, country and year of publication, study type, number of patients operated on with each technique, and the general characteristics of patients (age, gender, perioperative outcome, postoperative results) were extracted. The risk of bias for the trials enrolled in the meta-analysis were evaluated according to the Cochrane Handbook for Systematic Reviews of Interventions, while the quality of non-randomized studies was assessed using the criteria suggested by the Newcastle–Ottawa quality assessment tool [34, 35]. According to this scale, the maximum score could be nine points, representing the highest methodological quality.

Data synthesis

Systematic review with meta-analysis was performed in accordance with the recommendations from the preferred items for systematic reviews and meta-analyses statement (PRISMA) [36]. The effect sizes were calculated by odds ratio (OR) for dichotomous variables and weighted mean differences (WMD) for continuous outcome measures with 95 % confidence intervals (CIs). The point estimate of the OR value was considered statistically significant at P level of less than 0.05 if the 95 % CI did not cross the value 1. The point estimate of the WMD value was considered statistically significant at P level of less than 0.05 if the 95 % CI did not cross the value 0. Heterogeneity of the results across studies was assessed using the Higgins' I^2 and Chi-square tests.

A P value of Chi-square test less than 0.10 with an I^2 value of greater than 50 % were considered as indicative of substantial heterogeneity [34]. Fixed-effects model was applied if statistically significant heterogeneity was absent; otherwise, a random-effects model was used for meta-analysis if statistically significant heterogeneity was found, according to the method of DerSimonian and Laird [37]. Statistical analysis was performed using Review Manager software [38].

Results

Description of studies

A total of 315 references were identified through electronic database searches. 290 searches were excluded based on titles and abstract reviews because they did not match the inclusion criteria of the meta-analysis or they reported data from open choledochotomy. The remaining 25 publications underwent full article review. A further eight publications were excluded because they did not focus on the subject. One prospective randomized trial [39] was excluded because it showed the preliminary data of another study [18]. A total of sixteen studies comparing PDC and TTD qualified for inclusion in this review and meta-analysis. Four were randomized controlled trials [15, 18, 19, 28] and twelve were retrospective cohort studies [4, 16, 17, 22–27, 32, 33, 40], with a total of 1770 patients: 1012 in the subgroup analysis PDC versus TTD and 758 patients in the subgroup analysis PDC + BD insertion versus TTD (Fig. 1). The meta-analysis performed by Yin et al. [31] included 956 patients. However, this pooled analysis contained the patients enrolled from the study by Fujimura et al. [41] which included open procedures during his early experience. Therefore, this study was excluded, and the patients analyzed by Martin et al. [4] Morcillo et al. [33], Cai et al. [32], Zhang et al. [17] and Martinez-Baena et al. [27] were included. Two new randomized controlled trials which were not analyzed in previous meta-analyses were: the RCT performed by Zhang HW et al. which compared PDC and TTD and the RCT published by Mangla et al. which reported a comparison between PDC + BD insertion and TTD [17, 28].

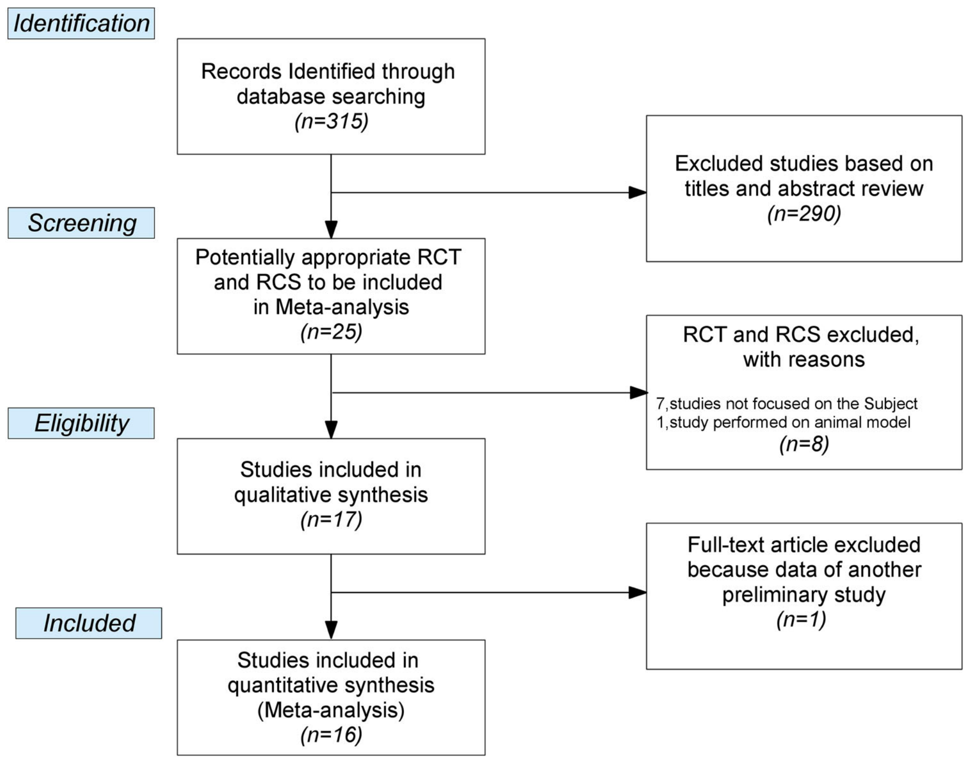

Fig. 1 The PRISMA flow chart for systematic search and selection of articles for review and meta-analysis

Table 1 shows the characteristics of the included studies and the demographic details regarding the enrolled patients. The sixteen articles involved in the quantitative synthesis were published between 1998 and 2014.

Table 2 lists the methods for PDC, PDC + BD, and TTD. Suture techniques of primary closure included running absorbable sutures or interrupted absorbable sutures. Studies also described the T-tube type. Normally, a latex rubber T-tube (14–20 Fr) was used, and the choledochotomy around the tube was closed both through running and interrupted absorbable sutures. T-tube removal times varied depending on the surgeons' experience from 8 days minimum [40] to 12 weeks maximum [32]. Various techniques have been described for PDC + BD. Ante-grade biliary stent insertions under direct vision of choledochoscopy are described in six studies [4, 23, 25, 27, 28, 33], modified biliary stents were inserted in one study [22], modified trans-cystic biliary catheter in one study [24], J-tube drainage in one study [26], and preoperative percutaneous transhepatic cholangiographic drainage (PTCD) in another study [40]. All authors reported the use of abdominal drain.

Risk of bias in included randomized controlled trials

The risk of bias in the four randomized controlled trials [15, 18, 19, 28] was assessed through the Cochrane Collaboration Risk of Bias Tool. Results are shown in Table 3. Allocation sequence generation was clearly described by authors in two studies [15, 28], while concealment and blinding of the patient, personnel, and observer were clearly reported in the study by El-Geidie [19]. Adequate assessment of each outcome and selective outcome reporting were determined for all trials, but authors did not report intention-to-treat analysis for outcomes. Power analysis calculation for minimum sample size has not been provided by any author and handling of missing data remained unclear. For the 12 RCSs, risk of bias was evaluated by the Newcastle–Ottawa scale. Two studies achieved five stars, and seven studies achieved four stars. Outcomes may have been influenced by allocation bias in all RCSs for patients who underwent PDC or TTD. Furthermore, the follow-up length was unclear in most of the RCSs.

Effects of interventions

Primary outcome measures

All outcome measures have been evaluated in order to assess the safety and feasibility of PDC, PDC + BD, and TTD. For all the primary outcomes, the detailed results are reported in Table 4 and Fig. 2.

Table 1 Characteristics of the included studies and demographic characteristics of the patients (PDC vs. TTD and PDC + BD vs. TTD)

References	Country	Study type	No. of patients		Age		Sex M/F	
			PDC	TTD	PDC	TTD	PDC	TTD
Leida et al. [15]	China	RCT	40	40	52.0 ± 14.0 (12–76)	45.0 ± 12.0 (14–73)	17/23	18/22
El-Geidie [19]	Egypt	RCT	61	61	43.0 (20–67)	39.0 (20–71)	22/39	16/45
Dong et al. [18]	China	RCT	101	93	57.6 ± 4.2 (23–76)	58.3 ± 4.4 (26–78)	43/58	40/53
Martin et al. [4]	Australia	RCS	41	61	52 (24–83)	56 (19–94)	NA	NA
Ha et al. [16]	China	RCS	12	26	58.0 ± 15.0	67.0 ± 15.0	5/7	12/14
Cai et al. [32]	China	RCS	137	102	64.6 (23–78)	66.9 (26–83)	59/78	41/61
Morcillo et al. [33]	Spain	RCS	16	36	58 (31–91)	60.7 (24–80)	5/11	12/24
Zhang et al. [17]	China	RCS	93	92	55.40 ± 10.48	53.08 ± 9.00	47/53	45/47
Total			501	511				
References	Country	Study type	No. of patients		Age		Sex M/F	
			PDC+	TTD	PDC+	TTD	PDC+	TTD
Mangla et al. [28]	India	RCT	31	29	46.80 ± 14.80	47.17 ± 12.30	9/22	5/24
Martin et al. [4]	Australia	RCS	14	61	52 (24.0–83.0)	56 (19.0–94.0)	NA	NA
Kim and Lee [22]	S. Korea	RCS	50	36	63.7 ± 11.6	61.0 ± 13.1	NA	NA
Wei et al. [24]	China	RCS	30	52	28–77	26–82	12/18	17/35
Griniatsos et al. [23]	United Kingdom	RCS	21	32	53 (45.0–64.0)	69.5 (51.0–75.2)	5/16	9/23
Tang et al. [25]	China	RCS	35	28	60.2 ± 17.2	65.6 ± 13.6	19/16	11/17
Kanamaru et al. [26]	Japan	RCS	30	15	NA	NA	NA	NA
Huang et al. [40]	China	RCS	10	40	67.1 ± 40.8	66.0 ± 20.7	4/6	32/8
Martinez-Baena et al. [27]	Spain	RCS	28	47	61.96 ± 15.22	61.17 ± 16.93	9/19	24/23
Morcillo et al. [33]	Spain	RCS	133	36	55.6 (13.0–87.0)	58.0 (31.0–91.0)	43/90	12/24
Total			382	376				

PDC primary duct closure, *BD* biliary drainage, *PDC+* primary duct closure + biliary drainage, *TTD* T-tube drainage, *RCT* randomized controlled trial; *RCS* retrospective cohort study, *NA* not available

Postoperative overall morbidity

Complications were reported for 36 patients (7.4 %) in the PDC group and for 55 patients (11.6 %) in the TTD group. The overall morbidity rate was slightly lower in the PDC group than in the TTD group, but this difference is not statistically significant (OR 0.64, 95 % CI 0.41–1.00, $P = 0.05$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.83$).

In the subgroup analysis of PDC + BD versus TTD, complications were reported for 33 patients (13.2 %) in the PDC + BD group and for 55 patients in the TTD group (16.2 %). The overall morbidity rate appeared slightly lower in the PDC + BD group than in the TTD group, but this was not a significant difference (OR 0.77, 95 % CI 0.47–1.25, $P = 0.29$; no heterogeneity was found for $I^2 = 16$ %; $P = 0.30$) (Table 4; Fig. 2).

Postoperative biliary-specific complications

In the overall meta-analysis of RCTs and RCSs comparing all biliary-specific complications after PDC and TTD, there was no significant difference in biliary-specific complications. Complications were reported in 28 patients (5.8 %) in the PDC group and in 40 patients (8.4 %) in the TTD group (OR 0.69, 95 % CI 0.42–1.16, $P = 0.16$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.86$).

When comparing the PDC + BD group and the TTD group, biliary-specific complications were again similar (21 cases, 8.4 % versus 40 cases, 11.8 %. OR 0.69, 95 % CI 0.39–1.24, $P = 0.22$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.56$) (Table 4; Fig. 2). However, when the biliary-specific complications are analyzed individually, differences are apparent between the different techniques for dochotomy closure.

Table 2 Methods for primary duct closure and for T-tube drainage (PDC vs. TTD and PDC + BD vs. TTD)

References	Abdominal drain		Suture techniques of primary closure	T-tube type	T-tube removal
	PDC	TTD			
Leida et al. [15]	40 A subhepatic drain	40	40 PDC running absorbable suture (4-0 Vicryl. Ethicon, NJ)	40 TTD latex rubber T-tube 14–20 Fr. Interrupted sutures (4-0 Vicryl. Ethicon, NJ)	3–4 weeks after the operation
El-Geidie [19]	61 A subhepatic drain	61	61 PDC interrupted intracorporeal knotting, absorbable suture (4-0 Vicryl. Ethicon, NJ)	61 TTD latex rubber 14–16 Fr. Continuous sutures (4-0 Vicryl. Ethicon, NJ)	10 days after surgery. After cholangiogram
Dong et al. [18]	101 A single infrahepatic suction drain	93	101 PDC. Interrupted Vicryl 4-0 sutures (Ethicon, NJ)	93 TTD latex rubber T-tube 14–20 Fr. Interrupted Vicryl 4-0 sutures (Ethicon, NJ)	3–4 weeks after surgery
Martin et al. [4]	41 Small suction drain placed routinely in the subhepatic space	61	41 PDC. Continuous or interrupted 4-0 PDS sutures	NA	T-tube was clamped at 7 days and cholangiography was performed at 21 days, before tube removal
Ha et al. [16]	12 Kind of drainage not specified.	26	12 PDC. 3-0 monocryl (Johnson & Johnson, Brussels, Belgium) interrupted sutures	NA	14 days after surgery
Cai et al. [32]	137 A non-suction drain placed in the gallbladder bed	102	137 PDC. Interrupted 3-0 Vicryl sutures (Johnson & Johnson, Brunswick, NJ, USA)	102 TTD latex rubber T-tube. Interrupted 3-0 Vicryl sutures (Johnson & Johnson, Brunswick, NJ, USA)	12 weeks after the operation after routine tubogram and choledoschopy
Morcillo et al. [33]	16 Robinson drain, removed after 24 h	36	16 PDC. Continuous suture (Vicryl 5-0, Ethicon, Johnson & Johnson Company, Edinburgh, United Kingdom)	NA	T-tube was removed after 4 weeks. After cholangiography
Zhang et al. [17]	93 Sub-hepatic drain, removed on the second or third day after surgery	92	93 PDC. Continuous 5-0 polydioxanone (PDS) suture	92 T-tube. Continuous 5-0 PDS sutures	T-tube removed on day 14 postoperatively, after cholangiogram

References	Abdominal drain		Suture techniques of primary closure	T-tube type	T-tube removal
	PDC+	TTD			
Mangla et al. [28]	31 Sub-hepatic drain was placed in all the patients	29	31 PDC+. Either a 7- or a 10-Fr. 10-cm straight flap biliary stent (Devon, Agra, India). The choledochotomy was then closed with interrupted or continuous 4-0 Vicryl sutures (Ethicon, Johnson & Johnson, Somerville, NJ)	29 T-tube. Not specified	T-tube clamped on the day 10 or later and removed the next day
Martin et al. [4]	14 Small suction drain placed routinely in the subhepatic space	61	14 PDC+. Continuous or Interrupted 4-0 PDS sutures. Ante-grade stents were inserted in cases of cholangitis or when more than five stones were found in the duct	NA	T-tube clamped at 7 days and removed at 21 days

Table 2 continued

References	Abdominal drain		Suture techniques of primary closure	T-tube type	T-tube removal
	PDC+	TTD			
Kim and Lee [22]	50 Closed suction drain was inserted at the end of the procedure	36	50 PDC+. Modified biliary stent made from a Percuflex Biliary Drainage Stent; (Microinvasive, Boston Scientific Corporation, Watertown, MA, USA). Bile duct closed in an interrupted fashion using SutureLoop; Sejong Medical, Paju, Korea	36 rubber T-tube	T-tubes were removed on an outpatient basis an average of 32.0 ± 7.5 days, after postoperative cholangiogram
Wei et al. [24]	30 A no. 10 Jackson-Pratt drain tube was placed in the sub-hepatic space	52	30 PDC+. Modified transcystic biliary decompression (mTCBD). Primary closure with a running suture (3-0 Vicryl). The catheter was fixed to the cystic duct by a 12-mm absorbable Lapro-Clip	52 T-tube. Latex rubber (12–16 Fr). After proper positioning, the choledochotomy was closed using interrupted sutures (3-0 Vicryl)	T-tube clamping 7–10 days postoperatively. Removal at 3–4 weeks after surgery
Griniatsos et al. [23]	21 NA	32 NA	21 PDC+. Biliary endoprosthesis and primary closure of the CBD for biliary decompression	32 T-tube. Not specified	16 days after surgery
Tang et al. [25]	35 Yes (not specified)	28	35 PDC+. Ante-grade biliary stenting, a 10-Fr Cotton-Leung biliary stent. Interrupted single-layered closure of the common bile duct	35 T-tube. 16-Fr latex T-tube	2 weeks after the operation, if the cholangiogram did not reveal any abnormality
Kanamaru et al. [26]	30 Sub-hepatic drainage is routinely positioned through the lateral subcostal port in all cases	15	30 PDC+. The choledochotomy was closed with bile drainage through a J-Tube (Hakko Medical, Nagano, Japan). The common bile duct was closed by interrupted stitching with absorbable 4-0 polyglycolic acid suture	15 T-tube. Choledochotomy was closed around the T-tube with interrupted 4-0 sutures	3–4 weeks after the operation, after postoperative cholangiography
Huang et al. [40]	10 10 mm Jackson-Pratt drain in Morrison's pouch	40	10 PDC+. Combined with percutaneous trans-hepatic cholangiographic drainage (PTCD) inserted preoperatively. Primary closure with 4-0 interrupted Vicryl sutures	40 TTD latex rubber T-tube 16–20 Fr	8 days after surgery
Martinez-Baena et al. [27]	28 Sub-hepatic aspirative drain was left in all the cases	47	28 PDC+. Ante-grade trans-papillary biliary stent: Flexima from Boston Scientific Corporation, MA, USA (7–8.5 Fr; 5–7 cm). Choledochorraphy performed with interrupted suture of Vicryl 4-0, and then with a running suture	47 T-tube. Latex Kehr tube (8–14 Fr depending on the diameter of the bile duct)	T-tube cholangiography, and removal after 30 days after surgery
Morcillo et al. [33] Spain	133 Placement of a Robinson drain, removed 24 h after surgery	36	133 PDC+. Ante-grade biliary stent (10 Fr × 7 cm, Amsterdam Type Stent). Primary common bile duct closure. Continuous suture (Vicryl 5-0, Ethicon, Johnson & Johnson Company, Edinburgh, UK)	36 T-tube (not specified)	T-tube was removed after 4 weeks. After cholangiography

PDC primary duct closure, *BD* biliary drainage, *PDC+* primary duct closure + biliary drainage, *TTD* T-tube drainage, *NA* not available

Table 3 Risk of bias in the published randomized controlled trials (by the Cochrane Risk of Bias Tool) and in the retrospective cohort studies (by the Newcastle–Ottawa quality assessment tool)

References	Random sequence generation	Allocation concealment	Blinding of outcome assessment			Adequate assessment of each outcome	Selective outcome reporting avoided	Other potential bias	Handling of missing data	Final judgment
			Patient	Personnel	Assessor					
Leida et al. [15]	YES	NO	NO	NO	NO	YES	YES	Not powered. No intention-to-treat analysis	Unclear	Unclear risk
El-Geidie [19]	NO	YES	YES	YES	YES	YES	YES	Not powered. No intention-to-treat analysis	Unclear	Unclear risk
Mangla et al. [28]	YES	NO	YES	NO	NO	YES	YES	Not powered. No intention-to-treat analysis	Unclear	Unclear risk
Dong et al. [18]	NO	NO	YES	NO	NO	YES	YES	Not powered. No intention-to-treat analysis	Unclear	Unclear risk

	Representative cohort/control group	Exposure Ascertainment	Comparability of cohorts on the basis of design or analysis	Outcome Assessment	Duration of F-U and methods	Selection bias	Handling of missing data
Martin et al. [4]	Yes/same patient base	Surgical records	No restriction or matching	Record linkage	Not adequate	Possible allocation bias in PDC group and TTD group	Unclear****
Kim and Lee [22]	Unclear/same patient base	Unclear	No restriction or matching	Record linkage	Adequate, but six patients lost to FU	Possible allocation bias in PDC group and TTD group	Unclear***
Ha et al. [16]	Yes/same patient base	Surgical records	No restriction. Matching on diameters of the CBD and CBD stones in order to allocate patients in different groups	Record linkage	Adequate	Possible allocation bias in PDC group and TTD group	Unclear*****
Wei et al. [24]	Yes/same patient base	Surgical records	Restriction to ASA I and II patients	Record linkage	Adequate, but unclear methods	Possible allocation bias in PDC group and TTD group	Unclear****
Griniatsos et al. [23]	Unclear/same patient base	Unclear	No restriction or matching	Unclear	Adequate	Possible allocation bias in PDC group and TTD group	Unclear**
Tang et al. [25]	Yes/same patient base	Surgical records	No restriction or matching	Record linkage	Adequate, but unclear methods	Possible allocation bias in PDC group and TTD group	Unclear****
Kanamaru et al. [26]	Yes/same patient base	Surgical records	Unclear, details not provided	Record linkage	Adequate, but unclear methods	Possible allocation bias in PDC group and TTD group	Unclear***

Table 3 continued

	Representative cohort/control group	Exposure Ascertainment	Comparability of cohorts on the basis of design or analysis	Outcome Assessment	Duration of F-U and methods	Selection bias	Handling of missing data
Huang et al. [40]	Yes/same patient base	Surgical records	Sources of patients/experience of surgeons	Record linkage	Adequate, but unclear methods	Protocol for PDC group	Unclear****
Cai et al. [32]	Yes/same patient base	Surgical records	No restriction or matching	Record linkage	Adequate in times and methods	Possible allocation bias in PDC group and TTD group	Unclear*****
Martinez-Baena et al. [27]	Yes/same patient base	Surgical records	No restriction or matching	Record linkage	Unclear. No details in time and methods provided	Possible allocation bias in PDC group and TTD group	Unclear****
Morcillo et al. [33]	Yes/same patient base	Surgical records	No restriction. Matching on diameters of the CBD and CBD stones in order to allocate patients in different groups	Record linkage	Unclear. No details in time and methods provided	Low risk of allocation bias	Unclear****
Zhang et al. [17]	Yes/same patient base	Surgical records	No restriction or matching	Record linkage	Adequate, but unclear methods	Possible allocation bias in PDC group and TTD group	Unclear****

1. Biliary peritonitis

Eight studies comparing PDC with TTD provided data on postoperative biliary peritonitis. No events were reported in the PDC group, while 12 events (2.3 %) were reported in the TTD group. So, primary closure showed a lower rate of postoperative biliary peritonitis, with a statistically significant difference (OR 0.22, 95 % CI 0.06–0.76, $P = 0.02$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.99$). There was no statistically significant difference between the PDC + BD group and the TTD group for this outcome of interest. However, the result tended to favor the PDC + BD group (0.3 vs. 3.8 %, OR 0.35, 95 % CI 0.12–1.06, $P = 0.06$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.88$) (Table 5; Fig. 3).

2. Biliary leak

No statistically significant difference was found regarding postoperative biliary leak in the meta-analysis of studies comparing PDC and TTD. Nineteen cases (3.9 %) were reported in the PDC group, and 17 cases (3.6 %) were reported in the TTD group (OR 1.13, 95 % CI 0.58 to 2.21, $P = 0.71$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.94$).

When comparing PDC + BD and TTD, no statistically significant difference for this outcome was found between the techniques (17 cases, 6.8 % vs. 19 cases, 5.6 %. OR 1.05, 95 % CI 0.53–2.06, $P = 0.89$; no heterogeneity was found for $I^2 =$ %; $P = 0.43$) (Table 5; Fig. 3).

3. Retained stones and postoperative common bile duct obstruction

No significant difference was found in the meta-analysis of studies comparing PDC and TTD for *retained stones* (1.3 vs. 1.4 %, OR 0.95, 95 % CI 0.32–2.87, $P = 0.93$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.77$) or *postoperative common bile duct obstruction* (0.4 vs. 0.6 %, OR 0.81, 95 % CI 0.16–4.12, $P = 0.80$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.77$).

The meta-analysis of the studies comparing PDC + BD and TTD showed no significant difference for *retained stones* (1.7 vs. 3.9 %, OR 0.53, 95 % CI 0.18–1.52, $P = 0.24$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.99$). Two cases of *postoperative CBD obstruction* were reported in each group (0.9 vs. 0.6 %, OR 2.81, 95 % CI 0.58–13.65, $P = 0.20$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.35$) (Table 5; Fig. 3).

Re-intervention: radiology/endoscopy and re-intervention: surgery

The meta-analysis of the data regarding the radiological and/or endoscopic re-interventions showed a

Table 4 Primary outcomes of interest (PDC vs. TTD and PDC + BD vs. TTD)

References	Postoperative mortality		Postoperative complications n (%)		Postoperative biliary-specific complications n (%)		Re-intervention (radiology/endoscopy)		Re-intervention (surgery)		Postoperative hospital stay (days)	
	PDC	TTD	PDC	TTD	PDC	TTD	PDC	TTD	PDC	TTD	PDC	TTD
Leida et al. [15] RCT	0	0	6 (15 %)	11 (27.5 %)	4 (10 %)	8 (20 %)	3 (7.5 %)	3 (7.5 %)	0	3 (7.5 %)	5.28 ± 2.20	8.30 ± 3.60
El-Geidie [19] RCT	0	0	1 (1.6 %)	5 (8.2 %)	1 (1.6 %)	5 (8.2 %)	0	2 (3.3 %)	0	3 (4.9 %)	2.20 ± 1.00	5.50 ± 1.80
Dong et al. [18] RCT	0	0	13 (12.9 %)	15 (16.1 %)	10 (9.9 %)	10 (10.7 %)	6 (5.9 %)	6 (6.4 %)	1 (0.9 %)	1 (1.1 %)	3.20 ± 2.10	4.90 ± 3.20
Martin et al. [4]	0	0	4 (8.8 %)	10 (16.4 %)	4 (8.9 %)	8 (13.1 %)	0	2 (3.3 %)	4 (8.9 %)	3 (4.9 %)	2 (1–8)	4 (1–35)
Ha et al. [16]	0	0	1 (8.3 %)	4 (15.4 %)	1 (8.3 %)	2 (7.7 %)	0	0	0	0	5.0 ± 2.6	8.5 ± 2.4
Cai et al. [32]	0	0	6 (4.4 %)	6 (5.9 %)	6 (4.4 %)	5 (4.9 %)	0	1 (0.9 %)	0	0	3.1 ± 2.4	5.7 ± 4.3
Morcillo et al. [33]	1 (6.2 %)	2 (5.5 %)	NA	NA	NA	NA	NA	NA	NA	NA	3.5 (1–12)	14.3
Zhang et al. [17]	0	0	5 (5.4 %)	4 (4.3 %)	2 (2.1 %)	2 (2.2 %)	2 (2.1 %)	2 (2.2 %)	0	0	6.95 ± 0.73	12.05 ± 1.08
Total	1 0.2 %)	2 (0.4 %)	36/485 (7.4 %)	55/475 (11.6 %)	28/485 (5.8 %)	40/475 (8.4 %)	11/485 (2.3 %)	16/475 (3.4 %)	5/485 (1 %)	10/475 (2.1 %)		

References	Postoperative mortality		Postoperative complications n (%)		Postoperative biliary-specific complications n (%)*		Re-intervention (radiology/endoscopy)		Re-intervention (surgery)		Postoperative hospital stay (days)	
	PDC+	TTD	PDC+	TTD	PDC+	TTD	PDC+	TTD	PDC+	TTD	PDC+	TTD
Mangla et al. [28]	0	0	2 (6.4 %)	5 (17.2 %)	1 (3.2 %)	3 (10.3 %)	0	0	0	0	3.90 ± 2.00	6.41 ± 4.99
Martin et al. [4]	0	0	1 (7.1 %)	10 (16.4 %)	1 (7.1 %)	8 (16.4 %)	0	2 (3.3 %)	1 (7.1 %)	3 (4.9 %)	2 (1–8)	4 (1–35)
Kim and Lee [22]	0	0	7 (14 %)	5 (13.9 %)	3 (6 %)	4 (11.1 %)	0	0	0	3 (8.3 %)	4.8 ± 1.5	7.8 ± 3.3
Wei et al. [24]	0	0	0	6 (11.5 %)	0	6 (11.5 %)	0	2 (3.8 %)	0	1 (1.9 %)	5 (4–6)	4 (4–6)
Griniatsos et al. [23]	0	0	0	6 (18.7 %)	0	4 (12.5 %)	0	1 (3.1 %)	0	2 (6.2 %)	3 ± 0.8	5.5 ± 1.8
Tang et al. [25]	0	0	11 (31.4 %)	4 (14.3 %)	6 (17.1 %)	2 (7.1 %)	NA	NA	NA	NA	8.8 ± 9.3	10 ± 7.4
Kanamaru et al. [26]	0	0	4 (13.3 %)	2 (13.3 %)	4 (13.3 %)	2 (13.3 %)	4 (13.3 %)	2 (13.3 %)	0	0	18 (10–30)	34 (26–57)
Huang et al. [40]	0	0	2 (20 %)	6 (15 %)	1 (10. %)	4 (10 %)	NA	NA	NA	NA	7.0 ± 3.0	10 ± 3.0
Martinez-Baena et al. [27]	0	0	6 (21.4 %)	11 (23.4 %)	5 (17.9 %)	7 (14.9 %)	1 (3.6 %)	2 (4.2 %)	1 (3.6 %)	4 (8.5 %)	5 ± 10.26	12 ± 10.6
Morcillo et al. [33]	0	2 (5.5 %)	NA	NA	NA	NA	NA	NA	NA	NA	6.2 (1–30)	14.3
Total	0/382	2/376 (0.5 %)	33/249 (13.2 %)	55/340 (16.2 %)	21/249 (8.4 %)	40/340 (11.8 %)	5/214 (2.3 %)	9/312 (2.9 %)	2/214 (1 %)	13/312 (4.2 %)		

PDC primary duct closure, *BD* biliary drainage, *PDC+* primary duct closure + biliary drainage, *TTD* T-tube drainage, *NA* not available

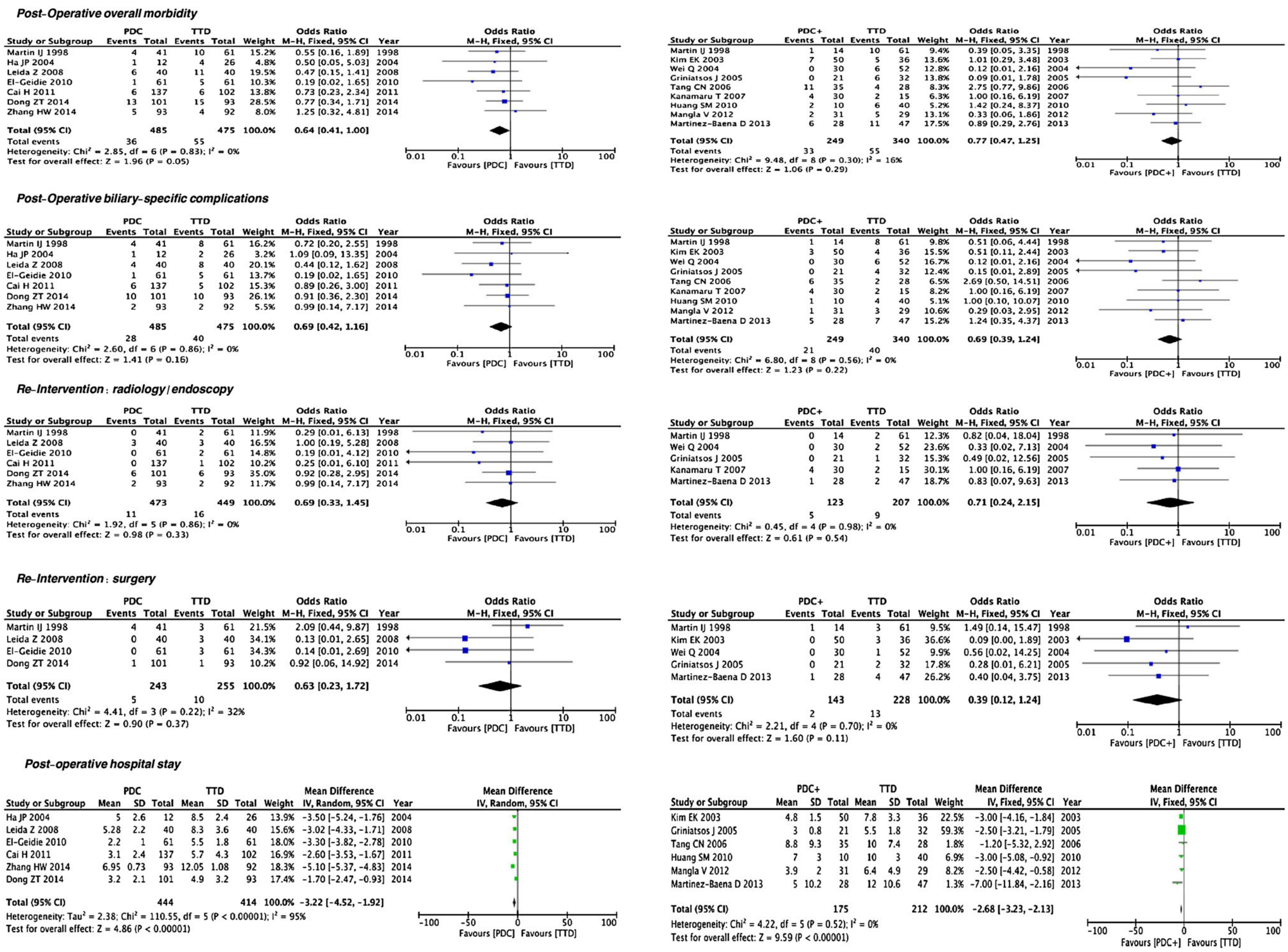

Fig. 2 Meta-analysis of primary outcomes of interest. Primary duct closure (PDC) versus T-tube drainage (TTD) and primary duct closure + biliary drainage (PDC+) versus T-tube drainage (TTD)

similar rate of re-operations in the PDC group and in the TTD group (2.3 vs. 3.4 %, OR 0.69, 95 % CI 0.33–1.45, $P = 0.33$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.86$). PDC + BD showed a similar rate of radiological and/or endoscopic re-intervention when compared to TTD (5 cases, 2.3 vs. 9 cases, 2.9 %, OR 0.71, 95 % CI 0.24–2.15, $P = 0.54$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.98$). (Table 4; Fig. 2).

The surgical re-intervention rate was similar in the PDC group and in the TTD group (1 vs. 2.1 %, OR 0.63, 95 % CI 0.23–1.72, $P = 0.37$; no heterogeneity was found for $I^2 = 32$ %; $P = 0.22$). The meta-analysis of studies comparing PDC + BD and TTD showed a slightly lower rate of surgical re-interventions in the PDC + BD group, but this difference was not statistically significant (1 vs. 4.2 %, OR 0.39, 95 % CI 0.12–1.24, $P = 0.11$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.70$) (Table 4; Fig. 2).

Postoperative hospital stay (days)

PDC was associated with a shorter postoperative hospital stay (WMD, −3.22; 95 % CI −4.52 to −1.92, $P < 0.00001$; heterogeneity was found for $I^2 = 95$ %; $P < 0.00001$). Within the subgroup analysis of studies comparing PDC + BD and TTD, the biliary drain insertion technique showed a shorter postoperative hospital stay (WMD, −2.68; 95 % CI −3.23 to −2.13, $P < 0.00001$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.52$) (Table 4; Fig. 2).

Secondary outcome measures

Other general complications (wound infection, pneumonia, deep vein thrombosis, internal hemorrhage) No significant difference was found for *general complications* when comparing PDC and TTD (1 vs. 2.5 %, OR 0.52, 95 % CI 0.21–1.32, $P = 0.17$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.98$). The meta-analysis of the studies

Table 5 Biliary-specific complications (PDC vs. TTD and PDC + BD vs. TTD)

References	Biliary peritonitis		Biliary leak		Retained stones		Postoperative CBD obstruction	
	PDC	TTD	PDC	TTD	PDC	TTD	PDC	TTD
Leida et al. [15]	0	3* (7.5 %)	2 (5 %)	2 (5 %)	0	0	0	1 (2.5 %)
El-Geidie [19]	0	2 (3.3 %)	1 (1.6 %)	2 (3.3 %)	0	1 (1.6 %)	0	0
Dong et al. [18]	0	2* (2.1 %)	5 (4.9 %)	4 (4.3 %)	4 (3.9 %)	3 (3.2 %)	0	0
Martin et al. [4]	0	3* (4.9 %)	3 (7.3 %)	2 (3.3 %)	NA	NA	1 (2.4 %)	1 (1.6 %)
Ha et al. [16]	0	0	0	2 (46.1 %)	0	0	0	0
Cai et al. [32]	0	1* (0.9 %)	6 (4.4 %)	4 (3.9 %)	0	0	0	0
Morcillo et al. [33]	0	1* (2.7 %)	NA	NA	NA	NA	NA	NA
Zhang et al. [17]	0	0	2 (2.1 %)	1* (1.1 %)	2 (2.1 %)	2 (2.2 %)	1 (1.1 %)	1 (1.1 %)
Total	0/501	12/511 (2.3 %)	19/485 (3.9 %)	17/475 (3.6 %)	6/444 (1.3 %)	6/414 (1.4 %)	2/485 (0.4 %)	3/475 (0.6 %)

References	Biliary peritonitis		Biliary leak		Retained stones		Postoperative CBD obstruction	
	PDC+	TTD	PDC+	TTD	PDC+	TTD	PDC+	TTD
Mangla et al. [28]	0	0	1 (3.2 %)	2 (6.9 %)	0	1 (3.4 %)	0	0
Martin et al. [4]	0	3* (4.9 %)	0	2 (3.3 %)	0	NA	1 (7.1 %)	0
Kim and Lee [22]	0	3* (8.3 %)	2 (4. %)	3 (8.3 %)	1 (2 %)	1 (2.7 %)	0	0
Wei et al. [24]	0	1* (1.9 %)	0	3 (5.8 %)	1 (3.3 %)	2 (3.8 %)	0	1 (1.9 %)
Griniatsos et al. [23]	0	1* (3.1 %)	0	3 (9.4 %)	0	0	0	0
Tang et al. [25]	NA	NA	5 (14.3 %)	1 (3.6 %)	1 (2.8 %)	1 (3.6 %)	NA	NA
Kanamaru et al. [26]	0	0	4 (13.3 %)	2 (13.3 %)	1 (3.3 %)	1 (6.7 %)	0	0
Huang et al. [40]	0	1* (2.5 %)	1 (10 %)	1 (2.5 %)	0	2 (5 %)	1 (10 %)	1 (2.5 %)
Martinez-Baena et al. [27]	1 (3.6 %)	3* (6.4 %)	4 (14.3 %)	2 (4.2 %)	0	3 (6.4 %)	0	0
Morcillo et al. [33]	0	1* (2.8 %)	NA	NA	NA	NA	NA	NA
Total	1/347 (0.3 %)	13/348 (3.8 %)	17/249 (6.8 %)	19/340 (5.6 %)	4/235 (1.7 %)	11/279 (3.9 %)	2/214 (0.9 %)	2/312 (0.6 %)

PDC primary duct closure, *BD* biliary drainage, *PDC+* primary duct closure + biliary drainage, *TTD* T-tube drainage, *NA* not available

* Biliary peritonitis after T-tube removal

comparing PDC + BD and TTD showed no statistically significant difference (3.7 vs. 3.3 %, OR 1.16, 95 % CI 0.44–3.10, $P = 0.76$; no heterogeneity was found for $I^2 = 0$ %; $P = 0.71$) (Table 6; Fig. 4).

Operating time (minutes) Mean operative time was significantly shorter in PDC group than in TTD group (WMD, −22.27, 95 % CI −33.26 to −11.28, $P < 0.00001$; heterogeneity was found for $I^2 = 95$ %; $P < 0.00001$). On the other hand, the pooled analysis of studies comparing PDC + BD and TTD showed no statistically significant difference for this outcome (WMD, −9.96, 95 % CI −22.00 to 2.08, $P = 0.10$; heterogeneity was found for $I^2 = 81$ %; $P = 0.0003$) (Table 6; Fig. 4).

Median hospital expenses Only two randomized controlled trials comparing PDC and TTD reported data on median hospital expenses that were noted to be less with PDC. According to the Cochrane Consumers and Communication Review Group indications, the pooled analysis of data was feasible [42]. The difference was statistically significant (SMD, −1.37, 95 % CI −1.96 to −0.77, $P < 0.00001$; heterogeneity was found for $I^2 = 77$ %; $P = 0.04$) (Table 6; Fig. 4).

Discussion

Management of choledocholithiasis has changed radically in recent years following innovation and developments in minimally invasive surgical techniques. Consensus on the optimal therapy for the management of common bile duct stones remains unclear. Preoperative endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic

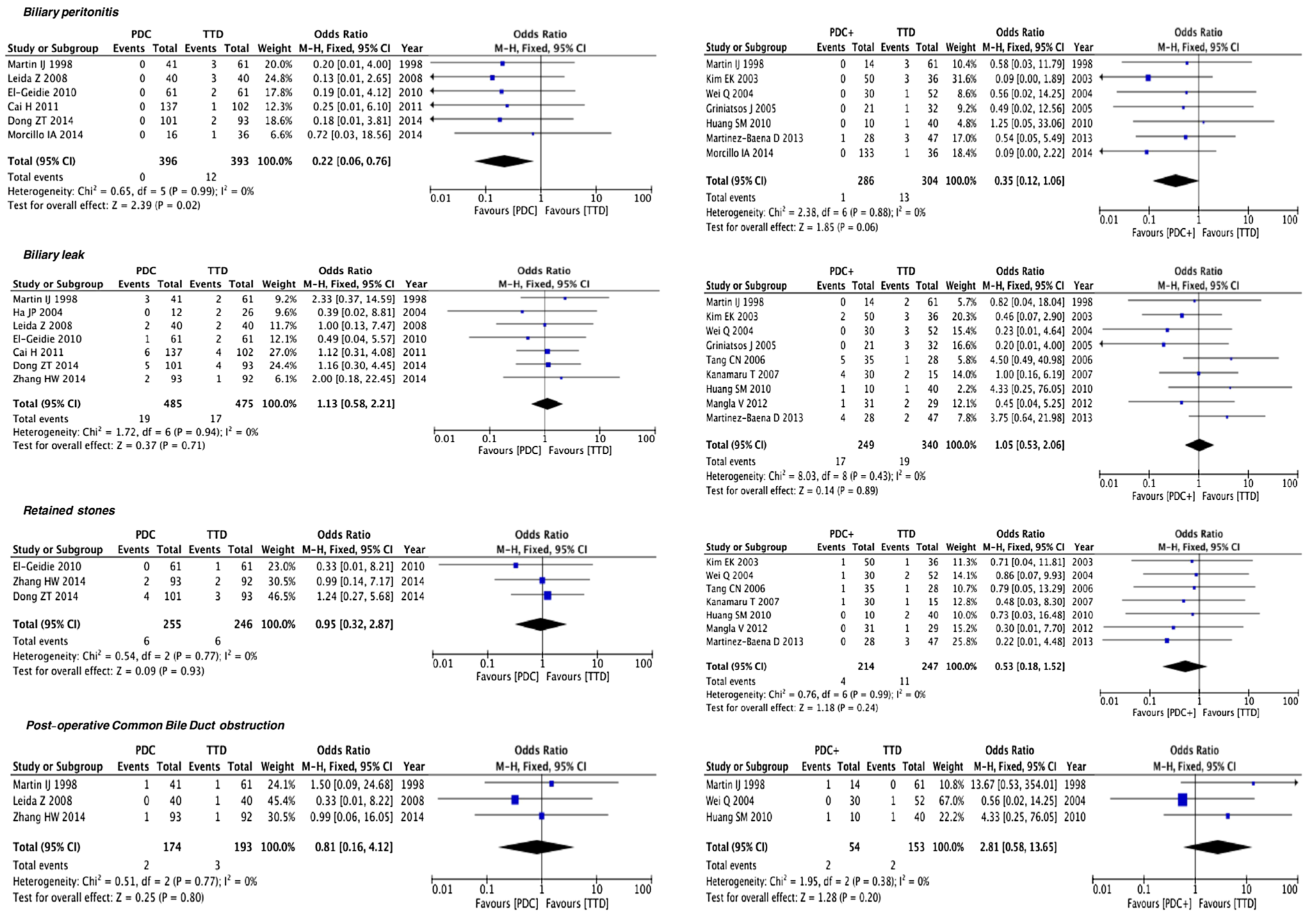

Fig. 3 Meta-analysis of biliary-specific complications. Primary duct closure (PDC) versus T-tube drainage (TTD) and primary duct closure + biliary drainage (PDC+) versus T-tube drainage (TTD)

sphincterotomy (ES) followed by laparoscopic cholecystectomy is a popular option for the treatment of this disease. Nevertheless, ERCP and ES are associated with biliary complications in 8–10 % of patients [43, 53]. Long-term complications of ES were reported in a study of 310 patients with a median follow-up period of 74 months: 7.4 % of patients had recurrent ductal stones, 1.6 % had cholangitis, 0.6 % had stenosis of the papilla, and 0.3 % had biliary pancreatitis [54].

LCBDE for common bile duct stones is cost-effective and has a similar rate of associated morbidity when compared to the two-stage method of ERCP and ES followed by laparoscopic cholecystectomy [44–46]. The large multicenter randomized controlled trial published by Cuschieri et al. [6] indicated that in fit patients (ASA I and II), single-stage laparoscopic treatment is the better option, whereas acute cholangitis, severe biliary pancreatitis, ampullary stone impaction or severe comorbid disease represented relative contraindications for LCBDE and they should be approached preoperatively through ERCP and ES.

LCBDE may be performed either through the cystic duct or through a choledochotomy.

Whenever feasible, the trans-cystic duct approach is the preferred technique, because it is less invasive and has proved to be safe and efficient [47].

The indications for trans-cystic CBDE, however, are limited to stones that are smaller than the size of the cystic duct, to a number of stones, to stones located in the lower CBD and not higher up in the common hepatic duct, and when a favorable anatomy of the cystic duct-CBD junction is present. On the other hand, a choledochotomy is better indicated when the CBD diameter is larger than 8–10 mm and when any of these conditions are detected at the intraoperative cholangiogram: stones considerably larger than the lumen of the cystic duct; more than five CBD stones; low and medial cystic duct-CBD junction; common hepatic duct stones [55].

Historically, exploration of the CBD with both open and laparoscopic surgery was accompanied by the insertion of a T-tube drain in order to minimize the risk of postoperative complications, decompress the biliary tree, and provide easy percutaneous access for cholangiogram and extraction of retained stones. Moreover, T-tube drainage was considered to be necessary to allow the edema and swelling at

Table 6 Secondary outcomes of interest (PDC vs. TTD and PDC + BD vs. TTD)

References	Operating time (min)		Median hospital expenses (RMB)		Other complications	
	PDC	TTD	PDC	TTD	PDC	TTD
Leida et al. [15]	116 ± 54.6	133 ± 58.3	8.638 ± 2.946 RenMinBi	12.531 ± 4.352	2	2
El-Geidie [19]	100.6 ± 7.5	125.1 ± 10.0	NA	NA	0	1
Dong et al. [18]	102.6 ± 15.2	128.6 ± 20.4	11.2789 ± 4791 RenMinBi	12.4367 ± 8793	3	5
Martin et al. [4]	125 (45–250)	130 (45–300)	NA	NA	0	1
Ha et al. [16]	90.0 ± 37.0	120.0 ± 35.2	NA	NA	0	2
Cai et al. [32]	92.4 ± 15.2	125.7 ± 32.6	NA	NA	0	1
Morcillo et al. [33]	NA	NA	NA	NA	NA	NA
Zhang et al. [17]	104.12 ± 10.71	108.92 ± 12.14	NA	NA	0	0
					5/485 (1 %)	12/475 (2.5 %)

References	Operating time (min)		Median hospital expenses (BPS)		Other complications	
	PDC+	TTD	PDC+	TTD	PDC	TTD
Mangla et al. [28]	139.19 ± 18.26	161.10 ± 19.21	NA	NA	1	0
Martin et al. [4]	125 (45–250)	130 (45–300)	NA	NA	0	1
Kim and Lee [22]	188.3 ± 52.9	166.7 ± 46.2	NA	NA	4	1
Wei et al. [24]	178 ± 34.0	173 ± 45.0	NA	NA	NA	NA
Griniatsos et al. [23]	100 ± 7.5	115 ± 5.0	1620 (1370–2120) British pound sterling	2400 (1650–3650)	0	0
Tang et al. [25]	111.1 ± 33.9	141.4 ± 45.1	NA	NA	0	1
Kanamaru et al. [26]	NA	NA	NA	NA	NA	NA
Huang et al. [40]	138.0 ± 37.0	191.0 ± 75.0	NA	NA	1	2
Martinez-Baena et al. [27]	NA	NA	NA	NA	1	4
Morcillo et al. [33]	NA	NA	NA	NA	NA	NA
					7/189 (3.7 %)	9/273 (3.3 %)

Other complications wound infection, pneumonia, deep vein thrombosis, internal hemorrhage

PDC primary duct closure, *BD* biliary drainage, *PDC+* primary duct closure + biliary drainage *TTD* T-tube drainage, *NA* not available

the Ampulla of Vater time to recover after the trauma of the surgery. However, complications of T-tube insertion have been reported in the literature with a rate of about 10–15 % [13, 39]. Some of these complications, such as biliary peritonitis after T-tube removal or biliary leak due to tube dislodgement, are serious and can lead to a need for further interventions. Furthermore, the presence of T-tube in situ contributes to delayed return to normal activity and work and may cause patients persistent pain and discomfort [15]. Recent randomized controlled trials and retrospective cohort studies with long follow-up periods have shown that PDC with or without BD after LCBDE is a safe alternative to the insertion of a T-tube [15–19].

The Cochrane intervention review published by Gurusamy et al. [21] in 2013 on data from three RCTs concluded that TTD resulted in significantly longer operating time and hospital stay as compared to PDC, without any evidence of advantage. However, the number of patients included in this study was too small to make a firm practice recommendation.

The overall complication rates between LCBDE with choledochotomy and ERCP were comparable in the randomized controlled trial published by Bansal et al. [46] with the total amount of complications reported in the LCBDE group classified as Clavien-Dindo I, and the complications reported in the ERCP and ES group distributed among all classes.

In our systematic review and meta-analysis, the rate of overall morbidity was found to be slightly lower in the PDC (7.4 %) and PDC + BD (13.2 %) groups than in the TTD group (11.6 and 16.2 %), but this difference was not statistically significant.

On the other hand, our meta-analysis showed a significantly ($P = 0.02$) lower rate of biliary peritonitis in the PDC group when compared with the TTD group, with no cases reported after PDC and 12 cases (2.3 %) after TTD.

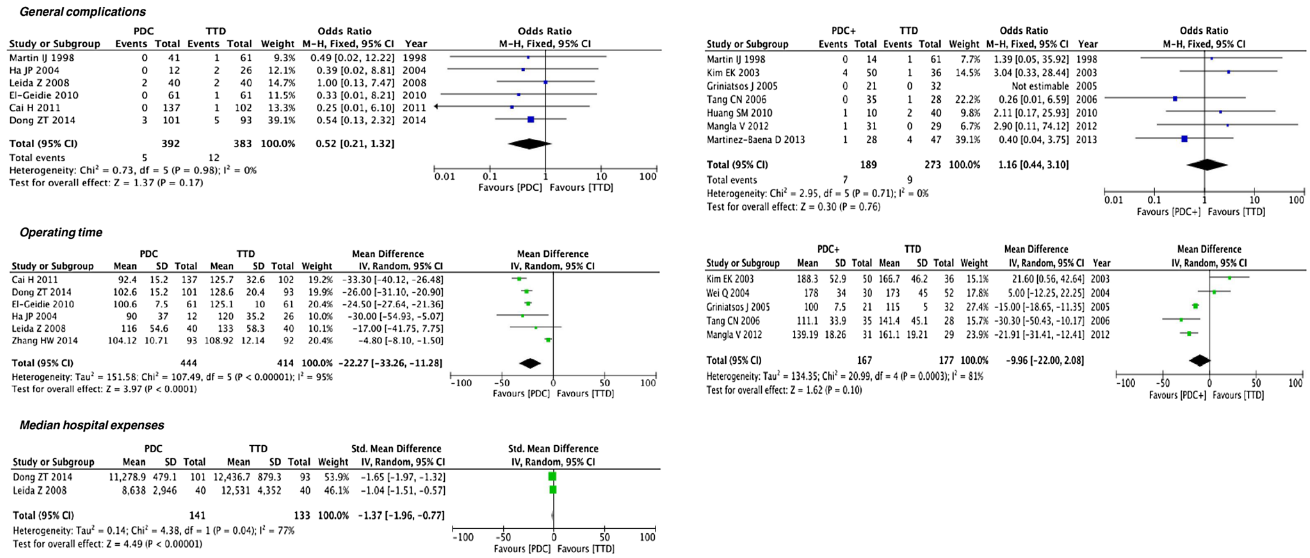

Fig. 4 Meta-analysis of secondary outcomes of interest. Primary duct closure (PDC) versus T-tube drainage (TTD) and primary duct closure + biliary drainage (PDC +) versus T-tube drainage (TTD)

Interestingly, 19/21 cases of biliary peritonitis occurred after T-tube removal, probably due to the insufficient adhesions for T-tube tract formation [18, 19, 22]. Yin et al. in their meta-analysis compared the overall and biliary-specific complications in the studies where T-tubes were removed between 8 and 16 days with the studies where T-tubes were removed after more than 21 days, showing a higher rate of biliary-specific complications occurred when the T-tube was removed earlier [31].

Together with the biliary fistula, CBD stricture is the main complication of LCBDE. PDC of choledochotomy in CBD with diameter <7 mm is related to postoperative stricture and therefore is suggested to be safe only if diameter is >7–9 mm [4, 52].

Decker et al. and Cai et al. reported no biliary strictures in their records of, respectively, 100 and 137 choledochotomies, performed through transverse incision and longitudinal incision, respectively, [32, 50]. In our meta-analysis, postoperative CBD obstruction due to postoperative common bile duct strictures and T-tube twisting was 0.4 % (2 cases) for PDC and 0.6 % (3 cases) for TTD group. Two cases for each group were reported when comparing PDC + BD and TTD.

Although retained bile duct stone after LCBDE with choledochotomy has been reported in up to 4 % of cases in the large study by Khaled et al., this meta-analysis showed high rates of CBD clearance, with no statistically significant difference in the incidence of retained stones when comparing the three techniques for dochotomy closure [48].

In this meta-analysis, we have not found any significant advantage when using biliary stent instead of T-tube positioning, with exception of postoperative hospital stay. The same results were reported in 2007 study by Tailor et al. [49] who did not find any benefit or reduction in rates of biliary leak with use of biliary stents after LCBDE. Other authors recommend selective stent use only when purulent material, sludge, or numerous stones have been extracted from the biliary system.

Length of hospital stay may be influenced by factors that are independent of the patient's postoperative recovery, such as socioeconomic status and local healthcare systems. Nevertheless, patients who underwent PDC had a significantly shorter postoperative hospital stay which is in concordance with many other trials and comparative studies [16, 22, 23, 28, 32, 40]. This meta-analysis also demonstrated a significant reduction in operating time when comparing PDC and TTD.

The longer operating time for the TTD group of patients may have resulted from the complexity of T-tube insertion and subsequent dochotomy closure techniques used. A prolonged operating time and duration of anesthesia are thought to be related to an increased risk of thromboembolic, respiratory, and cardiac complications, as suggested by Wu et al. [30] in their meta-analysis.

An important limitation of this review is the small number of well-designed randomized controlled trails that have reported on this subject to date. Consequently, strong recommendations on the definitive closure technique of a bile duct dochotomy cannot be overly dogmatic until the associations that are described here in this report are validated by further well-constructed and appropriately powered RCTs. Furthermore, missing information regarding randomization methods, allocation sequence generation, and blinding within the RCTs may lead to bias and can possibly distort the conclusions [51]. In our meta-analysis, allocation sequence generation was clearly described by the authors in two studies, while concealment and blinding of the patient, personnel, and observer were clearly reported by only one author. Power analysis calculations for minimum sample sizes were not performed in the study designs, and an adequate assessment of each outcome was reported by the authors in three trials only. In particular, universal definitions of postoperative biliary leak and common bile duct obstruction were not provided by all authors, and consequently a degree of author subjectivity may be a potential limitation in the assessment of complications. Moreover, no studies reported their intention-to-treat analysis for the outcomes. So while this systematic review and meta-analysis presents evidence to suggest that PDC is the optimal technique for dochotomy closure after LCBDE, properly powered and well-constructed RCTs are required to validate the preliminary results presented in this study.

In summary, this comprehensive meta-analysis suggests that PDC after LCBDE is as safe as TTD. Furthermore, PDC is associated with a lower rate of postoperative biliary peritonitis when compared with TTD, and also shorter operating times, postoperative hospital stay, and a reduction in median hospital expenses. These results suggest that primary bile duct closure may be the optimal strategy for dochotomy closure after LCBDE. However, large well-designed and adequately powered RCTs that compare primary duct closure and T-tube insertion, as well as primary duct closure with and without biliary stenting are still required to validate these observations and also to give further clarity on whether there should be selective internal drainage of the biliary system in certain circumstances.

Disclosures Mauro Podda, Francesco Maria Polignano, Andreas Luhmann, Michael Samuel James Wilson, Christoph Kulli, Iain Stephen Tait, have no conflicts of interest or financial ties to disclose.

References

1. Collins C, Maguire D, Ireland A, Fitzgerald E, O'Sullivan GC (2004) A prospective study of common bile duct calculi in patients undergoing laparoscopic cholecystectomy: natural history of choledocholithiasis revisited. Ann Surg 239:28–33
2. Williams EJ, Green J, Beckingham I, Parks R, Martin D, Lombard M, British Society of Gastroenterology (2008) Guidelines on the management of common bile duct stones (CBDS). Gut 57:1004–1021
3. Hungness ES, Soper NJ (2006) Management of common bile duct stones. J Gastrointest Surg 10:612–619
4. Martin IJ, Bailey IS, Rhodes M, O'Rourke N, Nathanson L, Fielding G (1998) Towards T-tube free laparoscopic bile duct exploration: a methodologic evolution during 300 consecutive procedures. Ann Surg 228:29–34
5. Millat B, Atger J, Deleuze A, Briandet H, Fingerhut A, Guillon F, Marrel E, De Seguin C, Soulier P (1997) Laparoscopic treatment for choledocholithiasis: a prospective evaluation in 247 consecutive unselected patients. Hepatogastroenterology 44:28–34
6. Cuschieri A, Lezoche E, Morino M, Croce E, Lacy A, Toouli J, Faggioni A, Ribeiro VM, Jakimowicz J, Visa J, Hanna GB (1999) E.A.E.S multicenter prospective randomized trial comparing two-stage vs single stage management of patients with gallstone disease and ductal calculi. Surg Endosc 13:952–957
7. Ding G, Cai W, Qin M (2014) Single-stage vs. two stage management for concomitant gallstones and common bile duct stones: a prospective randomized trial with long-term follow-up. J Gastrointest Surg 18:947–951
8. Rhodes M, Sussman L, Cohen L, Lewis MP (1998) Randomised trial of laparoscopic exploration of common bile duct versus postoperative endoscopic retrograde cholangiography for common bile duct stones. Lancet 351:159–161
9. Lyass S, Phillips EH (2006) Laparoscopic transcystic duct common bile duct exploration. Surg Endosc 20(Suppl 2):S441–S445
10. Verbesey JE, Birkett DH (2008) Common bile duct exploration for choledocholithiasis. Surg Clin North Am 88:1315–1328
11. Williams JA, Treacy PJ, Sidey P, Worthley CS, Townsend NC, Russell EA (1994) Primary duct closure versus T-tube drainage following exploration of the common bile duct. Aust N Z J Surg 64:823–826
12. Isla AM, Griniatsos J, Karvounis E, Arbuckle JD (2004) Advantages of laparoscopic stented choledochorrhaphy over T-tube placement. Br J Surg 91:862–866
13. Wills VL, Gibson K, Karihaloot C, Jorgensen JO (2002) Complications of biliary T-tubes after choledochotomy. ANZ J Surg 72:177–180
14. Ahmed M, Diggory RT (2013) Case-based review: bile peritonitis after T-tube removal. Ann R Coll Surg Engl 95:383–385
15. Leida Z, Ping B, Shuguang W, Yu H (2008) A randomized comparison of primary closure and T-tube drainage of the common bile duct after laparoscopic choledochotomy. Surg Endosc 22:1595–1600
16. Ha JP, Tang CN, Siu WT, Chau CH, Li MK (2004) Primary closure versus T-tube drainage after laparoscopic choledochotomy for common bile duct stones. Hepatogastroenterology 51:1605–1608
17. Zhang HW, Chen YJ, Wu CH, Li WD (2014) Laparoscopic common bile duct exploration with primary closure for management of choledocholithiasis: a retrospective analysis and comparison with conventional T-tube drainage. Am Surg 80:178–181
18. Dong ZT, Wu GZ, Luo KL, Li JM (2014) Primary closure after laparoscopic common bile duct exploration versus T-tube. J Surg Res 189:249–254
19. El-Geidie AA (2010) Is the use of T-tube necessary after laparoscopic choledochotomy ? J Gastrointest Surg 14:844–848
20. Gurusamy KS, Koti R, Davidson BR (2013) Primary closure versus T-tube drainage after open common bile duct exploration. Cochrane Database Syst Rev 6:CD005640. doi:10.1002/14651858.CD005640.pub3
21. Gurusamy KS, Koti R, Davidson BR (2013) Primary closure versus T-tube drainage after laparoscopic common bile duct exploration. Cochrane Database Syst Rev 6:CD005641. doi:10.1002/14651858.CD005641.pub3
22. Kim EK, Lee SK (2004) Laparoscopic treatment of choledocholithiasis using modified biliary stents. Surg Endosc 18:303–306
23. Griniatsos J, Karvounis E, Arbuckle J, Isla AM (2005) Cost-effective method for laparoscopic choledochotomy. ANZ J Surg 75:35–38

24. Wei Q, Hu HJ, Cai XY, Li LB, Wang GY (2004) Biliary drainage after laparoscopic choledochotomy. World J Gastroenterol 10:3175–3178
25. Tang CN, Tai CK, Ha JP, Tsui KK, Wong DC, Li MK (2006) Antegrade biliary stenting versus T-tube drainage after laparoscopic choledochotomy. A comparative cohort study. Hepatogastroenterology 53:330–334
26. Kanamaru T, Sakata K, Nakamura Y, Yamamoto M, Ueno N, Takeyama Y (2007) Laparoscopic choledochotomy in management of choledocholithiasis. Surg Laparosc Endosc Percutan Tech 17:262–266
27. Martinez-Baena D, Parra-Membrives P, Diaz-Gomez D, Lorente-Herce JM (2013) Laparoscopic common bile duct exploration and antegrade biliary stenting: leaving behind the Kehr tube. Rev Esp Enferm Dig 105:125–129
28. Mangla V, Chander J, Vindal A, Lal P, Ramteke VK (2012) A randomized trial comparing the use of endobiliary stent and T-tube for biliary decompression after laparoscopic common bile duct exploration. Surg Laparosc Endosc Percutan Tech 22:345–348
29. Zhu QD, Tao CL, Zhou MT, Yu ZP, Shi HQ, Zhang QY (2011) Primary closure versus T-tube drainage after common bile duct exploration for choledocholithiasis. Langenbecks Arch Surg 396:53–62
30. Wu X, Yang Y, Dong P, Gu J, Lu J, Li M, Mu J, Wu W, Yang J, Zhang L, Ding Q, Liu Y (2012) Primary closure versus T-tube drainage in laparoscopic common bile duct exploration: a meta-analysis of randomized clinical trials. Langenbecks Arch Surg 397:909–916
31. Yin Z, Xu K, Sun J, Zhang J, Xiao Z, Wang J, Niu H, Zhao Q, Lin S, Li Y (2013) Is the end of the T-tube drainage era in laparoscopic choledochotomy for common bile duct stones is coming? A systematic review and meta-analysis. Ann Surg 257:54–66
32. Cai H, Sun D, Sun Y, Bai J, Zhao H, Miao Y (2012) Primary closure following laparoscopic common bile duct exploration combined with intraoperative cholangiography and choledochoscopy. World J Surg 36:164–170
33. Morcillo IA, Qurashi K, Carrion JA, Isla AM (2014) Laparoscopic common bile duct exploration. Lessons learned after 200 cases. Cir Esp 92:341–347
34. Higgins JP, Green S (2011) Cochrane handbook for systematic reviews of interventions, version 5.1.0. The Cochrane collaboration. http://www.cochrane-handbook.org
35. Wells GA, Shea B, O'Connell D, Peterson J, Welch V, Losos M, Tugwell P (2013) The Newcastle–Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp
36. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, Clarke M, Devereaux PJ, Kleijnen J, Moher D (2009) The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. Ann Intern Med 151:W65–W94
37. DerSimonian R, Laird N (1986) Meta-analysis in clinical trials. Control Clin Trials 7:177–188
38. Review Manager (RevMan) [computer program]. Version 5.3.5, 2014. The Nordic Cochrane Centre, Cochrane Collaboration, www.cochrane-handbook.org
39. Zhang WJ, Xu GF, Wu GZ, Li JM, Dong ZT, Mo XD (2009) Laparoscopic exploration of common bile duct with primary closure versus T-tube drainage: a randomized clinical trial. J Surg Res 157:1–5
40. Huang SM, Yao CC, Cheng YW, Chen LY, Pan H, Hsiao KM, Yang MD, Wu CW, Lui WY, Lai TJ (2010) Laparoscopic primary closure of common bile duct combined with percutaneous cholangiographic drainage for treating choledocholithiasis. Am Surg 76:517–521
41. (in Japanese)
42. Ryan R (2013) Cochrane Consumers and Communication Review Group: meta-analysis. http://cccrg.cochrane.org
43. Coppola R, Riccioni ME, Ciletti S, Cosentino L, Coco C, Magistrelli P, Picciocchi A (1997) Analysis of complications of endoscopic sphincterotomy for biliary stones in a consecutive series of 546 patients. Surg Endosc 11:129–132
44. Lu J, Xiong XZ, Cheng Y, Lin YX, Zhou RX, You Z, Wu SJ, Cheng NS (2013) One stage versus two-stage management for concomitant gallbladder stones and common bile duct stones in patients with obstructive jaundice. Am Surg 79:1142–1148
45. Li MK, Tang CN, Lai EC (2011) Managing concomitant gallbladder stones and common bile duct stones in the laparoscopic era: a systematic review. Asian J Endosc Surg 4:53–58
46. Bansal VK, Misra MC, Rajan K, Kilambi R, Kumar S, Krishna A, Kumar A, Pandav CS, Subramaniam R, Arora MK, Garg PK (2014) Single-stage laparoscopic common bile duct exploration and cholecystectomy versus two-stage endoscopic stone extraction followed by laparoscopic cholecystectomy for patients with concomitant gallbladder stones and common bile duct stones: a randomized controlled trial. Surg Endosc 28:875–885
47. Patelin JB (2003) Laparoscopic common bile duct exploration. Lessons learned from >12 years' experience. Surg Endosc 17:1705–1715
48. Khaled YS, Malde DJ, de Souza C, Kalia A, Ammori BJ (2013) Laparoscopic bile duct exploration via choledochotomy followed by primary duct closure is feasible and safe for the treatment of choledocholithiasis. Surg Endosc 27:4164–4170
49. Taylor CJ, Kong J, Ghusn M, White S, Crampton N, Layani L (2007) Laparoscopic bile duct exploration: results of 160 consecutive cases with 2-year follow-up. ANZ J Surg 77:440–445
50. Decker G, Borie F, Millat B, Berthou JC, Deleuze A, Drouard F, Guillon F, Rodier JG, Fingerhut A (2003) One hundred laparoscopic choledochotomies with primary closure of the common bile duct. Surg Endosc 17:12–18
51. Egger M, Davey Smith G (1997) Meta-analysis. Potentials and promise. BMJ 315:1371–1374
52. Gigot JF, Navez B, Etienne J, Cambier E, Jadoul P, Guiot P, Kestens PJ (1997) A stratified intraoperative surgical strategy is mandatory during laparoscopic common bile duct exploration for common bile duct stones. Lessons and limits from an initial experience of 92 patients. Surg Endosc 11:722–728
53. Uchiyama K, Onishi H, Tani M, Kinoshita H, Kawai M, Ueno M, Yamaue H (2003) Long-term prognosis after treatment of patients with choledocholithiasis. Ann Surg 238:97–102
54. Schreurs WH, Juttmann JR, Stuifbergen WN, Oostvogel HJ, van Vroonhoven TJ (2002) Management of common bile duct stones: selective endoscopic retrograde cholangiography and endoscopic sphincterotomy: short- and long-term results. Surg Endosc 16:1068–1072
55. Paganini AM, Guerrieri M, Sarnari J, De Sanctis A, D'Ambrosio G, Lezoche G, Perretta S, Lezoche E (2007) Thirteen years' experience with laparoscopic transcystic common bile duct exploration for stones. Effectiveness and long-term results. Surg Endosc 21:34–40