Journal of Zhejiang University-SCIENCE B (Biomedicine & Biotechnology) 2021 22(12):985-1001
www.jzus.zju.edu.cn; www.springer.com/journal/11585
E-mail: jzus_b@zju.edu.cn

Research Article
https://doi.org/10.1631/jzus.B2100523

Primary duct closure versus T-tube drainage after laparoscopic common bile duct exploration: a meta-analysis

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Abstract: Background and aims: Laparoscopic common bile duct exploration (LCBDE) is considered a safe and effective method for the removal of bile duct stones. However, the choice of primary duct closure (PDC) or T-tube drainage (TTD) technique after LCBDE is still controversial. This study aimed to compare the safety and effectiveness of PDC and TTD after LCBDE. Methods: Studies published before May 1, 2021 in PubMed, Web of Science, and Cochrane Library databases were searched to screen out randomized controlled trials (RCTs) and cohort studies to compare PDC with TTD. Meta-analyses of fixed effect and random effect models were performed using RevMan 5.3. Results: A total of 1865 patients were enrolled in six RCTs and ten cohort studies. Regarding RCTs, the PDC group was significantly better than the TTD group in terms of operation time, total postoperative complications, postoperative hospital stay, and hospitalization expenses (all $P<0.05$). Based on cohort studies of the subgroup, the PDC group had shorter operation time, shorter postoperative hospital stay, less intraoperative blood loss, and limited total postoperative complications. Statistically, there were no significant differences in bile leakage, retained stones, stone recurrence, bile duct stricture, postoperative pancreatitis, other complications, or postoperative exhaust time between the TTD and PDC groups. Conclusions: Based on the available evidence, compared with TTD, PDC is safe and effective, and can be used as the first choice after transductal LCBDE in patients with choledocholithiasis.

Key words: Laparoscopic common bile duct exploration; Primary duct closure; T-tube drainage; Meta-analysis

1 Introduction

Choledocholithiasis, the presence of gallstones in the common bile duct (CBD), is common in 10% to 20% of patients with symptomatic gallstones (Williams et al., 2017). Choledocholithiasis is linked to a number of health problems including biliary colic, jaundice, cholangitis, pancreatitis, and liver abscess (Caddy and Tham, 2006). Therefore, timely treatment of choledocholithiasis is important to prevent these complications.

With the rapid development of endoscopy and laparoscopy, two main methods for the treatment of choledocholithiasis have been advanced: a one-stage management (laparoscopic cholecystectomy (LC) plus laparoscopic common bile duct exploration (LCBDE)) or a two-stage management (LC preceded or followed by endoscopic retrograde cholangiopancreatography (ERCP)). The two-stage approach is usually combined with endoscopic sphincterotomy (EST) (Williams et al., 2017). Evidence from a previous study indicates that the two methods are equally effective in the treatment of choledocholithiasis (Yan et al., 2021). However, the one-stage method can significantly reduce the total hospital stay and costs compared with two-stage management (Lyu et al., 2019). Moreover, EST tends to cause loss of function or dysfunction of the sphincter of Oddi and even recurrent cholangitis, which is linked to long-term reflux of duodenal contents (Testoni et al., 2016). A growing body of research (Choi et al., 2021) has shown that LCBDE performed by experienced laparoscopic surgeons is a safe and effective way to remove bile duct stones. LCBDE can be performed through the cystic duct (transcystic) or CBD (transductal), according to the size, number, and

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Received June 16, 2021; Revision accepted Aug. 15, 2021;
Crosschecked Nov. 22, 2021

location of the stones (Al-Ardah et al., 2021). Though studies have shown that the transcystic route can be augmented with various techniques to increase successful stone clearance and reduce post-operative complications (Jones et al., 2019; Navaratne and Isla, 2021), transcystic LCBDE is technically more challenging than LCBDE via choledochotomy. When transcystic LCBDE is not possible because of equipment, anatomical or technical reasons, we advocate proceeding to choledochotomy and transductal stone clearance.

LCBDE is commonly practiced by surgeons globally. Nonetheless, there is still uncertainty regarding the optimal method of choledochotomy closure after transductal LCBDE. Based on this, two options, the T-tube drainage (TTD) technique and primary duct closure (PDC) technique, have been suggested and tested. TTD after LCBDE is the traditional method used to prevent bile leakage and biliary stricture, but PDC has become common in recent years. Unlike the TTD technique, PDC involves directly suturing the bile duct in only one step. TTD has some recognized shortcomings, including displacement, fracture, bile leakage, pain, difficulty in removal, and inconvenience to patients, and the tube needs to be carried for a long time before removal (Wills et al., 2002). Moreover, a study has shown that a large amount of bile loss may lead to electrolyte disorder, poor appetite, and constipation, among other complications (Vidagany et al., 2016). In the era of laparoscopy, the debate continues. Although many randomized controlled trials (RCTs) (Zhang LD et al., 2004; Leida et al., 2008; El-Geidie, 2010; Dong et al., 2014; Zhang WJ et al., 2015; Shakya et al., 2017) and cohort studies (Jameel et al., 2008; Cai et al., 2012; Zhang et al., 2014; Yi et al., 2015; Audouy et al., 2016; Wen et al., 2017; Parra-Membrives et al., 2018; Xiao et al., 2018; Fang et al., 2020; Zhou et al., 2020) have reported that the incidence of complications in PDC after LCBDE is lower than that in TTD, there is no consensus.

In recent years, several meta-analyses comparing PDC and TTD have been published (Jiang et al., 2019; Deng et al., 2020). However, there are still some shortcomings, such as a relatively small sample size or bias caused by combined analysis of RCTs and cohort studies. In addition, some outcome indicators, such as intraoperative blood loss, postoperative exhaust time, and hospitalization expenses, have not been incorporated. Herein, we used a more reasonable and comprehensive method to evaluate the potential advantages and limitations, safety, and effectiveness of PDC and TTD after LCBDE in 1865 patients.

2 Materials and methods

This meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher et al., 2009). Since meta-analysis is based on secondary data, ethical approval was not required.

2.1 Search strategy

Relevant articles published before May 1, 2021 were searched in PubMed, Web of Science, and Cochrane Library to screen out RCTs and cohort studies comparing PDC with TTD. The following search terms were used: laparoscopic/laparoscopy, common bile duct/choledochotomy/choledocholithotomy/LCBDE, primary closure/primary suture/one stage suture, and T-tube/biliary drainage/external drainage. In addition, the references for all retrieved reviews were manually searched to find other possible studies for inclusion.

2.2 Inclusion and exclusion criteria

The inclusion criteria were as follows: (1) studies involving RCTs, retrospective cohort studies, or prospective cohort studies; (2) clinical studies comparing PDC and TTD after LCBDE; (3) patients diagnosed as choledocholithiasis with or without cholecystolithiasis; (4) studies including at least one outcome indicator (total complications, bile leakage, retained stones, stone recurrence, biliary stricture, operation time, postoperative hospital stay, anal exhaust time, hospitalization expenses, or intraoperative blood loss); (5) for more than one article covering the same group, the latest or the most complete article was chosen for meta-analysis. The following exclusion criteria were considered: (1) patients with multiple hepatolithiasis, CBD stricture, acute pancreatitis, acute suppurative cholangitis, malignant biliary tumor, liver cirrhosis, bleeding tendency, or history of upper abdominal surgery; (2) non-controlled studies and non-human studies; (3) abstract only, case report, or review; (4) repeated publications or articles without sufficient data. There was no restriction on the language of the article. In the original literature, problems about data loss and methods were solved by contacting the authors. Preliminary screening and full-text evaluation were independently completed by Taifeng ZHU and Rui ZHANG. Differences were settled through mutual discussion.

2.3 Data extraction and outcomes of interest

The data were independently extracted by two reviewers (Taifeng ZHU and Rui ZHANG) and checked together. Data differences were resolved by referring to relevant knowledge and by discussion. Study and patient characteristics as well as surgical and post-operative outcomes were used to compare PDC and TTD after LCBDE. The study and patient characteristics included the type of study, year of publication, the first author, country, number of patients in each group, age, and sex. The surgical outcomes included the operation time, intraoperative blood loss, suture method, suture type, and T-tube type. The postoperative outcomes included total complications, bile leakage, retained stones, postoperative hospital stay, stone recurrence, biliary stricture, anal exhaust time, and hospitalization expenses.

2.4 Quality assessment

We used the Cochrane Collaboration Risk of Bias Tool (Higgins and Green, 2013) to assess the risk of bias in RCTs; the quality of retrospective and prospective cohort studies was assessed using the modified Newcastle-Ottawa scale (NOS) with a score of 0 to 9 for each cohort study, which was indicated with asterisks. Studies with at least six asterisks were considered high-quality studies.

2.5 Statistical analysis

The meta-analysis was performed using RevMan 5.3. Pre-specified subgroup analysis was conducted for the cohort studies. Cochran's Q test and Higgins I^2 statistics were used to evaluate the heterogeneity between studies. A fixed effect model (Mantel-Haenszel method) was used whenever no significant heterogeneity was detected ($I^2\leqslant50\%$; $P\geqslant0.10$). On the other hand, when significant heterogeneity was detected ($P<0.10$ or $I^2>50\%$), a random effect model (DerSimonian and Laird method) was used. The relative risk (RR) and weighted mean difference (WMD) were used to compare dichotomous and continuous variables, respectively. A P value of <0.05 was considered statistically significant. All results were reported with 95% confidence intervals (CIs). When the median and extreme deviations of continuous variables were reported, the mean and standard deviation (SD) were estimated using a method described by Hozo et al. (2005). Publication bias was measured using Begg's funnel plots.

3 Results

3.1 Literature search results

A total of 251 articles were identified using electronic database retrieval (248 articles) and manual retrieval (3 articles). The studies retrieved manually (Zhang LD et al., 2004; Zhang WJ et al., 2015; Shakya et al., 2017) were determined based on references of other related articles. After eliminating duplicate articles, the remaining 162 articles were screened based on their titles and abstracts. Following this, another 119 articles were excluded. The remaining 43 studies were screened by reading the full text, after which another 26 studies were excluded. Finally, 16 studies (Zhang LD et al., 2004; Jameel et al., 2008; Leida et al., 2008; El-Geidie, 2010; Cai et al., 2012; Dong et al., 2014; Zhang HW et al., 2014; Yi et al., 2015; Zhang WJ et al., 2015; Audouy et al., 2016; Shakya et al., 2017; Wen et al., 2017; Parra-Membrives et al., 2018; Xiao et al., 2018; Fang et al., 2020; Zhou et al., 2020) including 1865 patients (982 in the PDC group and 883 in the TTD group) were included in this study as they fully met the predefined inclusion criteria for the meta-analysis. Among them, six (Zhang LD et al., 2004; Leida et al., 2008; El-Geidie, 2010; Dong et al., 2014; Zhang WJ et al., 2015; Shakya et al., 2017) were RCTs, one (Jameel et al., 2008) was a prospective cohort study, and nine (Cai et al., 2012; Zhang HW et al., 2014; Yi et al., 2015; Audouy et al., 2016; Wen et al., 2017; Parra-Membrives et al., 2018; Xiao et al., 2018; Fang et al., 2020; Zhou et al., 2020) were retrospective cohort studies. The detailed filtering process is shown in Fig. 1.

3.2 Study characteristics and quality assessment

Comparable patient baseline characteristics and technical processes between the PDC and TTD groups for each study are shown in Tables 1 and 2. The meta-analysis included studies from, but not limited

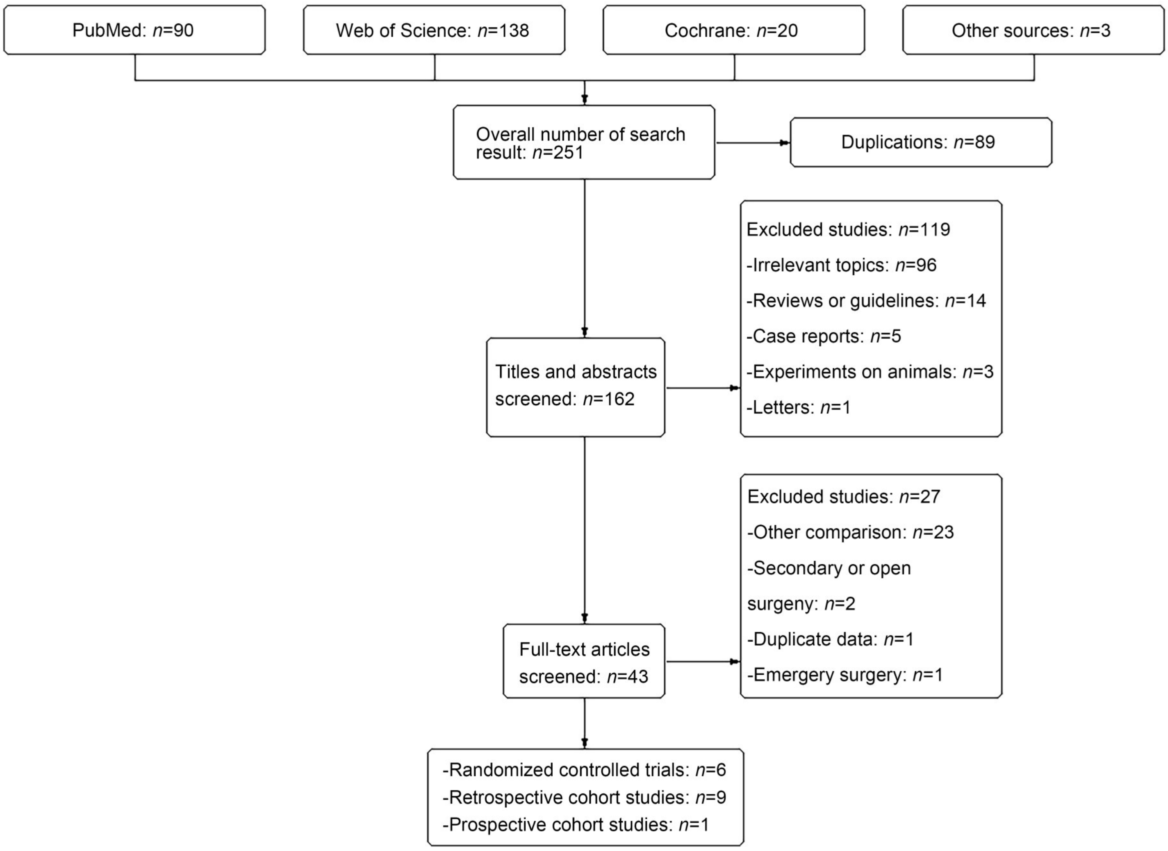


Fig. 1 Flowchart showing the process of study selection.

to, China, the UK, Egypt, France, Spain, and the Republic of Korea. The six RCTs used the Cochrane Collaboration Risk of Bias Tool for quality assessment (Fig. 2). The ten cohort studies used the modified NOS for quality assessment (Table 2). All the cohort studies included were of high quality.

3.3 Meta-analysis results

3.3.1 Operative outcomes

3.3.1.1 Operation time (minutes)

Data on operation time for the six RCTs were documented. Using the fixed effect model, the combined data showed that the average operation time of the PDC group was significantly shorter than that of the TTD group. Furthermore, the time difference was statistically significant (WMD=−25.28, 95% CI: −27.86 to −22.70, $P<0.00001$; no heterogeneity was found; $I^2=0\%$, $P=0.62$) (Fig. 3a).

In the subgroup, the operation time was compared in nine cohort studies. After combining the data, using the random effect model, the average operation time of the PDC group was significantly shorter than that of the TTD group. The difference in average operation time between the two groups was statistically significant (WMD=−17.76, 95% CI: −28.91 to −6.60, $P=0.002$; heterogeneity was found; $I^2=97\%$, $P<0.00001$) (Fig. 4a).

3.3.1.2 Intraoperative blood loss (mL)

Only one study (Dong et al., 2014) among the included RCTs reported intraoperative blood loss, and therefore no combined analysis was performed.

In the subgroup, three cohort studies provided data on intraoperative blood loss. The combined data, using the fixed effect model, showed that the average blood loss in the PDC group was less than that in the TTD group, and the difference was statistically significant (WMD=−4.65, 95% CI: −8.71 to −0.59, $P=0.02$; no heterogeneity was found; $I^2=0\%$, $P=0.78$) (Fig. 4b).

3.3.2 Postoperative outcomes

3.3.2.1 Total postoperative complications

The six RCTs included in the present study provided information about postoperative complications. Postoperative complications were noted in 33 cases

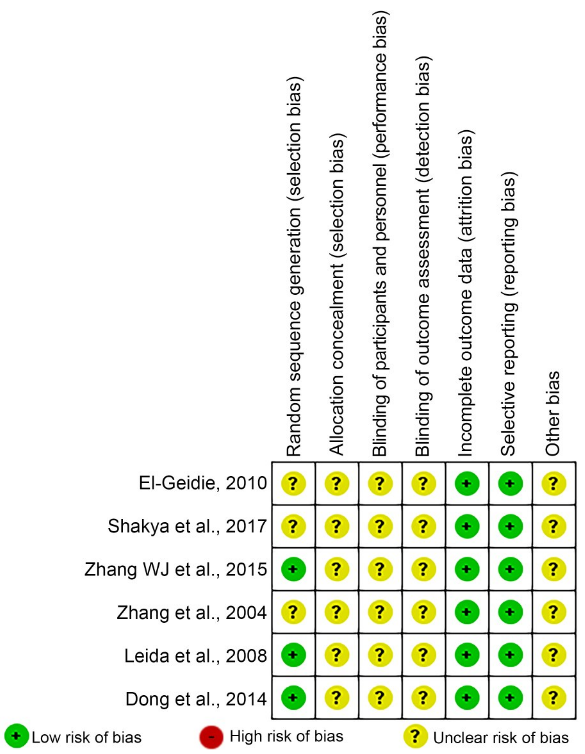


Fig. 2 Risk of bias summary: review of authors' judgments about each risk of bias item for each included randomized controlled trial (RCT) study.

among the PDC group and 57 cases in the TTD group. The comprehensive results showed that the incidence of postoperative complications in the PDC group was significantly lower than that in the TTD group, when the fixed effect model was employed (RR=0.56, 95% CI: 0.38 to 0.83, P=0.004; no heterogeneity was found; I^2=0%, P=0.78) (Fig. 3b).

Among the ten cohort studies included in the subgroup, there were 54 cases belonging to the PDC group and 66 belonging to the TTD group. Combined analysis, using the fixed effect model, showed that the incidence of postoperative complications in the PDC group was significantly lower than that in the TTD group (RR=0.70, 95% CI: 0.49 to 0.99, P=0.04; no heterogeneity was found; I^2=0%, P=0.90) (Fig. 4c).

3.3.2.2 Bile leakage

In the six included RCTs, data on postoperative bile leakage in the PDC and TTD groups were compared. The incidence of bile leakage in the PDC group was lower than that in the TTD group when a fixed effect model was used. However, the difference was not statistically significant (RR=0.76, 95% CI: 0.39 to 1.50, P=0.43; no heterogeneity was found; I^2=0%, P=0.78) (Fig. 3c).

Table 1 Baseline characteristics of the 16 studies included

Study	Country	Design	Number of patients		Gender (M/F)		Age (years)	
			PDC	TTD	PDC	TTD	PDC	TTD
El-Geidie, 2010	Egypt	RCT	61	61	22/39	16/45	43 (20–67)	39 (20–71)
Dong et al., 2014	China	RCT	101	93	43/58	40/53	57.60±4.20	58.30±4.40
Leida et al., 2008	China	RCT	40	40	17/23	18/22	52.00±14.00	45.00±12.00
Shakya et al., 2017	Egypt	RCT	20	20	4/16	3/17	41.8 (22.0–60.0)	45.7 (22.0–70.0)
Zhang WJ et al., 2015	China	RCT	47	46	22/25	19/27	52.30±16.60	52.00±15.90
Zhang et al., 2004	China	RCT	27	28	11/16	12/16	44.60±18.30	42.40±17.60
Jameel et al., 2008	UK	PCS	50	12	13/37	3/9	70.5 (19.0–90.0)	71.5 (29.0–84.0)
Zhou et al., 2020	China	RCS	38	41	18/20	17/24	52.70±11.60	50.90±10.80
Zhang et al., 2014	China	RCS	100	92	47/53	45/47	55.40±10.48	53.08±9.00
Xiao et al., 2018	China	RCS	114	116	56/58	54/62	52.22±13.10	51.09±12.57
Fang et al., 2020	China	RCS	43	41	16/27	15/26	50.00±13.00	47.00±11.00
Parra-Membrives et al., 2018	Spain	RCS	36	52	15/21	25/27	70 (23–87)	66 (25–86)
Cai et al., 2012	China	RCS	137	102	59/78	41/61	64.6 (23.0–78.0)	66.9 (26.0–83.0)
Yi et al., 2015	Republic of Korea	RCS	91	51	45/46	29/22	67.25±15.78	65.51±15.25
Audouy et al., 2016	France	RCS	25	55	7/18	13/42	62.30±26.10	66.00±19.30
Wen et al., 2017	China	RCS	52	33	22/30	10/23	56.60±14.50	54.10±15.10

Age is expressed as mean±standard deviation (SD) or average (range). PDC: primary duct closure; TTD: T-tube drainage; M: male; F: female; RCT: randomized controlled trial; PCS: prospective cohort study; RCS: retrospective cohort study.

Table 2 Technical processes of the 16 studies included

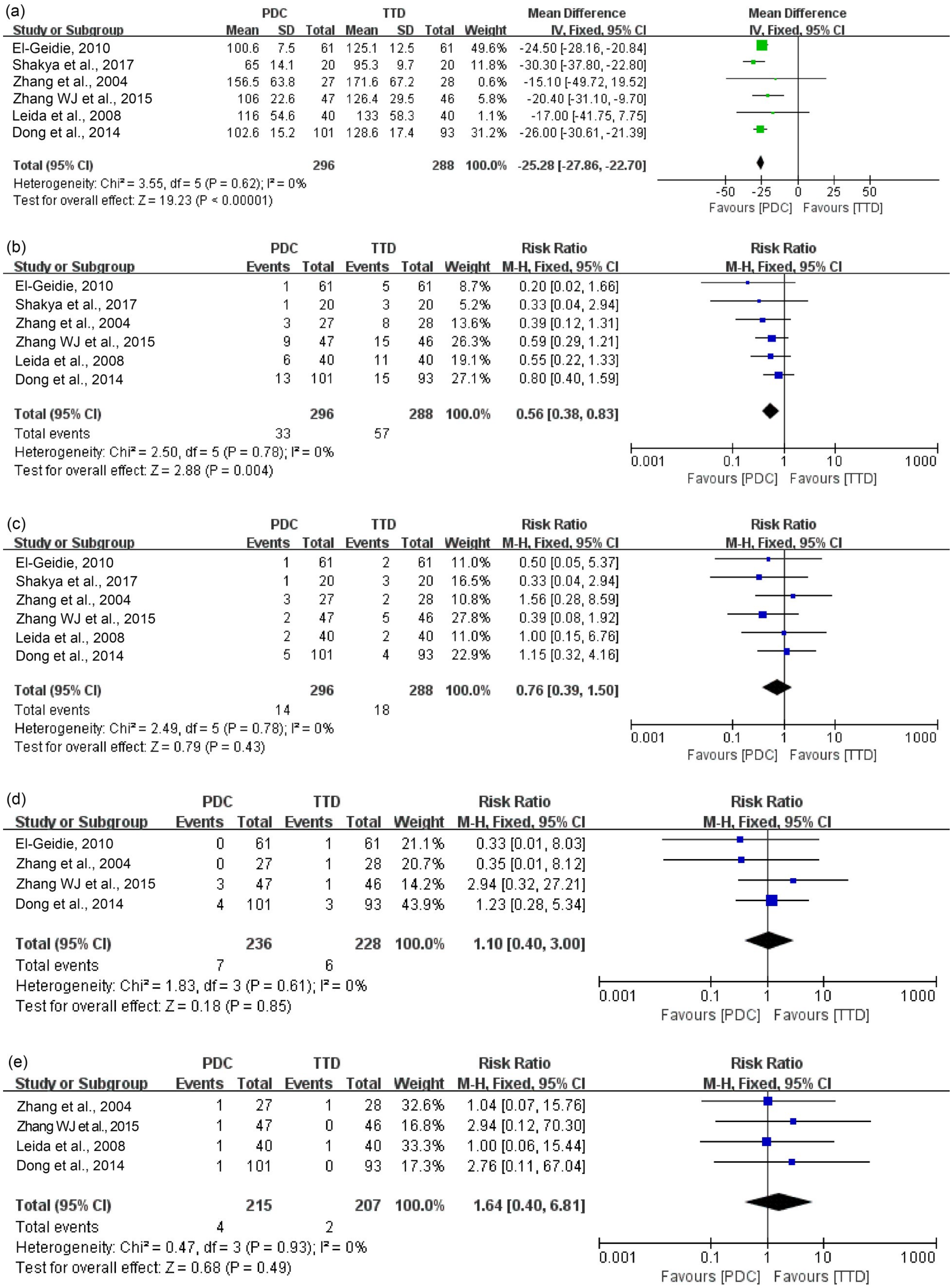
Study	Suture techniques		T-tube type and removal time	Follow-up	Quality score[a]
	PDC	TTD			
El-Geidie, 2010	4/0 absorbable sutures (4/0 Vicryl) and intracorporeal knotting	Continuous sutures (4/0 Vicryl)	A latex rubber T-tube (14–16 Fr); on the 10th day	At early (2 weeks) or late (2 months)	
Dong et al., 2014	Interrupted 4/0 Vicryl sutures	Interrupted 4/0 Vicryl sutures	A latex rubber T-tube (14–20 Fr); 3–4 weeks later	The median follow-up was 12 months	
Leida et al., 2008	Running absorbable suture (4/0 Vicryl)	Interrupted sutures (4/0 Vicryl)	A latex rubber T-tube (14–20 Fr); 3–4 weeks after the operation	The follow-up period was 6 to 54 months (average 25 months)	
Shakya et al., 2017	Interrupted 3/0 Vicryl sutures round body	Interrupted 3/0 Vicryl sutures round body	A T-tube of 12/14 Fr; on 10th post-operative day	Unclear	
Zhang WJ et al., 2015	4/0 absorbable sutures (4/0 Vicryl) and intracorporeal knotting	Interrupted sutures (4/0 Vicryl)	A latex rubber T-tube (14–20 Fr); 3–5 weeks after the operation	3 to 24 months	
Zhang et al., 2004	Running absorbable suture (4/0 Vicryl)	Interrupted sutures (4/0 Vicryl)	A latex rubber T-tube (18/20 Fr); 1 to 2 months after the operation	3 to 40 months (average (22.6±11.3) months)	
Jameel et al., 2008	Interrupted 3/0 Vicryl sutures on a ski needle	Interrupted 3/0 Vicryl sutures on a ski needle	Unclear; 3–4 weeks later	Six weeks after discharge	*******
Zhou et al., 2020	Continuous suture using 4–0 knotless Stratafix™	Continuous suture using 4–0 knotless Stratafix™	Unclear; 1 month postoperatively	6 to 47 months	******
Zhang et al., 2014	Continuous 5–0 PDS	Continuous 5–0 PDS	Unclear; on Day 14 postoperatively	The median follow-up was 40 months	*******
Xiao et al., 2018	Continuous or interrupted suture with 4–0 PDS	Continuous or interrupted suture with 4–0 PDS	Unclear; in postoperative 4 to 6 weeks	The median follow-up was 20 months	*******
Fang et al., 2020	Unclear	Unclear	Unclear; unclear	The median follow-up was 18 months	*****
Parra-Membrives et al., 2018	Running 4/0 absorbable suture	Running 4/0 absorbable suture	Gutter fashioned rubber drainages sized from 10 to 16 Fr; at least 1 month after surgery	At 1 or 6 months	******
Cai et al., 2012	Interrupted 3/0 Vicryl sutures	Interrupted 3/0 Vicryl sutures	Unclear; 12 weeks later	The median follow-up was 26 months	*******
Yi et al., 2015	Continuous suture using 3/0 Vicryl suture material	Continuous suture using 3/0 Vicryl suture material	A T-tube of 16 Fr; 2 weeks postoperatively	Average 48.8 months	*******
Audouy et al., 2016	4/0 absorbable interrupted monofilament stitches	4/0 absorbable interrupted monofilament stitches	Latex T-tube drains of between 12 and 14 Fr; between the 3rd and 7th days after surgery	Four weeks after hospital discharge	******
Wen et al., 2017	Continuous 5–0 PDS	Continuous 5–0 PDS	Unclear; 4 weeks later	At least 2 years	******

[a] The quality was assessed using the modified Newcastle-Ottawa scale (NOS) with a score of 0 to 9 for each cohort study, which was indicated with asterisks, and studies with at least six asterisks were considered high-quality ones. PDC: primary duct closure; TTD: T-tube drainage; PDS: polydioxanone suture.

In the subgroup, data on postoperative bile leakage were obtained from nine cohort studies. Using the fixed effect model, the data showed that the incidence of bile leakage in the PDC group was higher than that in the TTD group. Nonetheless, the difference was not statistically significant (RR=1.44, 95% CI: 0.79 to 2.61, P=0.23; no heterogeneity was found; I^2=0%, P=0.76) (Fig. 4d).

3.3.2.3 Retained stones

Results regarding retained stones were reported in four RCTs. Combining the results, the incidence of retained stones in the PDC group was slightly higher


(a)
PDC
TTD
Mean Difference
Mean Difference
Study or Subgroup Mean SD Total Mean SD Total Weight IV, Fixed, 95% CI IV, Fixed, 95% CI
El-Geidie, 2010 100.6 7.5 61 125.1 12.5 61 49.6% -24.50 [-28.16, -20.84]
Shakya et al., 2017 65 14.1 20 95.3 9.7 20 11.8% -30.30 [-37.80, -22.80]
Zhang et al., 2004 156.5 63.8 27 171.6 67.2 28 0.6% -15.10 [-49.72, 19.52]
Zhang WJ et al., 2015 106 22.6 47 126.4 29.5 46 5.8% -20.40 [-31.10, -9.70]
Leida et al., 2008 116 54.6 40 133 58.3 40 1.1% -17.00 [-41.75, 7.75]
Dong et al., 2014 102.6 15.2 101 128.6 17.4 93 31.2% -26.00 [-30.61, -21.39]
Total (95% CI) 296 288 100.0% -25.28 [-27.86, -22.70]
Heterogeneity: Chi² = 3.55, df = 5 (P = 0.62); I² = 0%
Test for overall effect: Z = 19.23 (P < 0.00001)
-50 -25 0 25 50
Favours [PDC] Favours [TTD]
(b)
PDC
TTD
Risk Ratio
Risk Ratio
Study or Subgroup Events Total Events Total Weight M-H, Fixed, 95% CI M-H, Fixed, 95% CI
El-Geidie, 2010 1 61 5 61 8.7% 0.20 [0.02, 1.66]
Shakya et al., 2017 1 20 3 20 5.2% 0.33 [0.04, 2.94]
Zhang et al., 2004 3 27 8 28 13.6% 0.39 [0.12, 1.31]
Zhang WJ et al., 2015 9 47 15 46 26.3% 0.59 [0.29, 1.21]
Leida et al., 2008 6 40 11 40 19.1% 0.55 [0.22, 1.33]
Dong et al., 2014 13 101 15 93 27.1% 0.80 [0.40, 1.59]
Total (95% CI) 296 288 100.0% 0.56 [0.38, 0.83]
Total events 33 57
Heterogeneity: Chi² = 2.50, df = 5 (P = 0.78); I² = 0%
Test for overall effect: Z = 2.88 (P = 0.004)
0.001 0.1 1 10 1000
Favours [PDC] Favours [TTD]
(c)
PDC
TTD
Risk Ratio
Risk Ratio
Study or Subgroup Events Total Events Total Weight M-H, Fixed, 95% CI M-H, Fixed, 95% CI
El-Geidie, 2010 1 61 2 61 11.0% 0.50 [0.05, 5.37]
Shakya et al., 2017 1 20 3 20 16.5% 0.33 [0.04, 2.94]
Zhang et al., 2004 3 27 2 28 10.8% 1.56 [0.28, 8.59]
Zhang WJ et al., 2015 2 47 5 46 27.8% 0.39 [0.08, 1.92]
Leida et al., 2008 2 40 2 40 11.0% 1.00 [0.15, 6.76]
Dong et al., 2014 5 101 4 93 22.9% 1.15 [0.32, 4.16]
Total (95% CI) 296 288 100.0% 0.76 [0.39, 1.50]
Total events 14 18
Heterogeneity: Chi² = 2.49, df = 5 (P = 0.78); I² = 0%
Test for overall effect: Z = 0.79 (P = 0.43)
0.001 0.1 1 10 1000
Favours [PDC] Favours [TTD]
(d)
PDC
TTD
Risk Ratio
Risk Ratio
Study or Subgroup Events Total Events Total Weight M-H, Fixed, 95% CI M-H, Fixed, 95% CI
El-Geidie, 2010 0 61 1 61 21.1% 0.33 [0.01, 8.03]
Zhang et al., 2004 0 27 1 28 20.7% 0.35 [0.01, 8.12]
Zhang WJ et al., 2015 3 47 1 46 14.2% 2.94 [0.32, 27.21]
Dong et al., 2014 4 101 3 93 43.9% 1.23 [0.28, 5.34]
Total (95% CI) 236 228 100.0% 1.10 [0.40, 3.00]
Total events 7 6
Heterogeneity: Chi² = 1.83, df = 3 (P = 0.61); I² = 0%
Test for overall effect: Z = 0.18 (P = 0.85)
0.001 0.1 1 10 1000
Favours [PDC] Favours [TTD]
(e)
PDC
TTD
Risk Ratio
Risk Ratio
Study or Subgroup Events Total Events Total Weight M-H, Fixed, 95% CI M-H, Fixed, 95% CI
Zhang et al., 2004 1 27 1 28 32.6% 1.04 [0.07, 15.76]
Zhang WJ et al., 2015 1 47 0 46 16.8% 2.94 [0.12, 70.30]
Leida et al., 2008 1 40 1 40 33.3% 1.00 [0.06, 15.44]
Dong et al., 2014 1 101 0 93 17.3% 2.76 [0.11, 67.04]
Total (95% CI) 215 207 100.0% 1.64 [0.40, 6.81]
Total events 4 2
Heterogeneity: Chi² = 0.47, df = 3 (P = 0.93); I² = 0%
Test for overall effect: Z = 0.68 (P = 0.49)
0.001 0.1 1 10 1000
Favours [PDC] Favours [TTD]

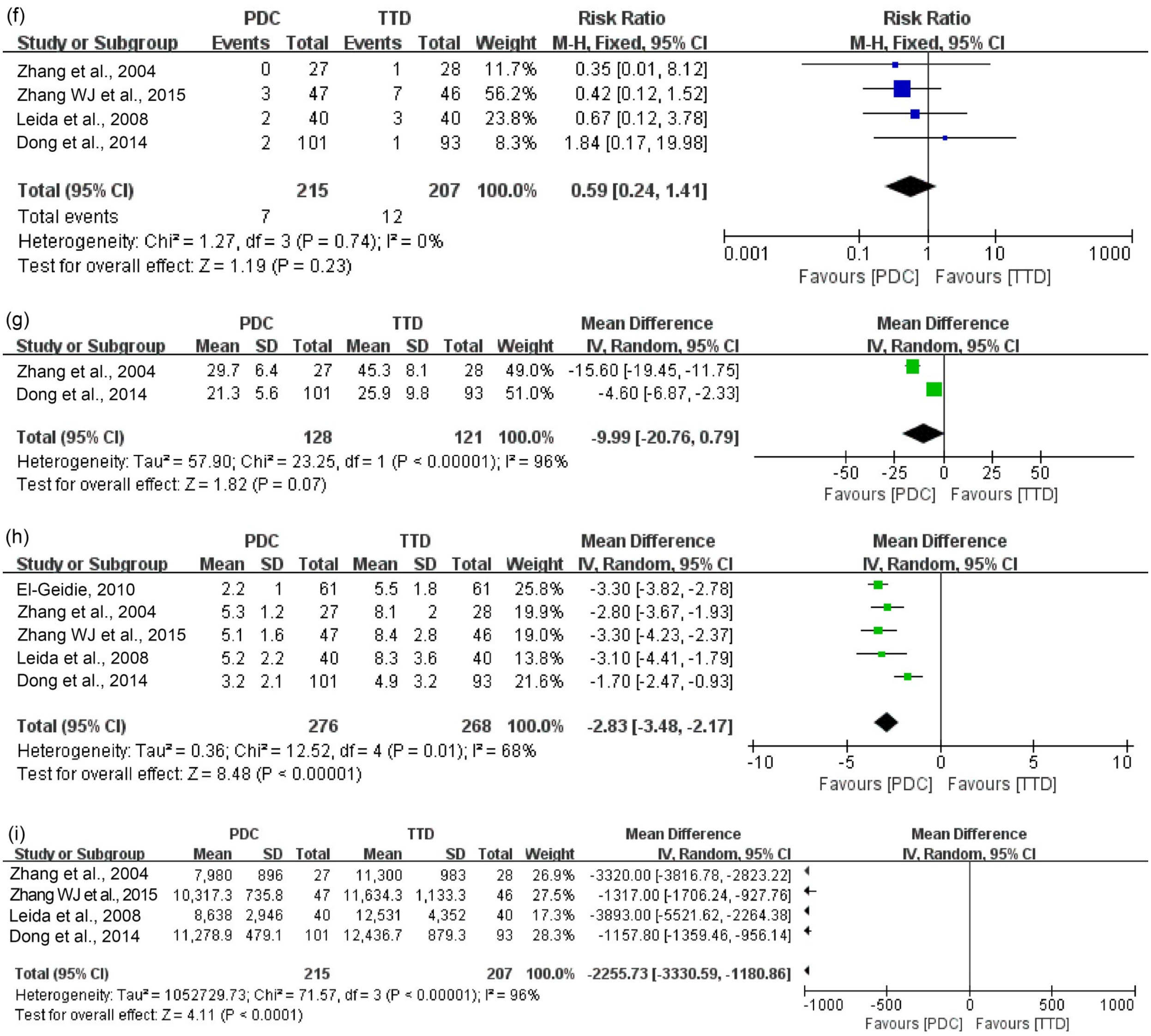


Fig. 3 Forest plots of the outcome indicators of RCT studies. (a) Operation time; (b) Total postoperative complications; (c) Bile leakage; (d) Retained stones; (e) Postoperative pancreatitis; (f) Other complications; (g) Postoperative exhaust time; (h) Postoperative hospital stay; (i) Hospitalization expenses. RCT: randomized controlled trial; PDC: primary duct closure; TTD: T-tube drainage; CI: confidence interval; SD: standard deviation.

than that in TTD group, using the fixed effect model. However, again the difference was not statistically significant (RR=1.10, 95% CI: 0.40 to 3.00, P=0.85; no heterogeneity was found; I^2=0%, P=0.61) (Fig. 3d).

In the subgroup, two cohort studies provided data on retained stones. The data showed that the incidence of retained stones in the PDC group was lower than that in the TTD group, using the fixed effect model, but the difference was not statistically significant between the two groups (RR=0.45, 95% CI: 0.10 to 1.97, P=0.29; no obvious heterogeneity was found; I^2=16%, P=0.27) (Fig. 4e).

3.3.2.4 Stone recurrence

Stone recurrence is defined as the occurrence of choledocholithiasis more than six months after the complete removal of the initial choledocholithiasis (Zhang RC et al., 2015). No data of stone recurrence were reported in the RCTs included.

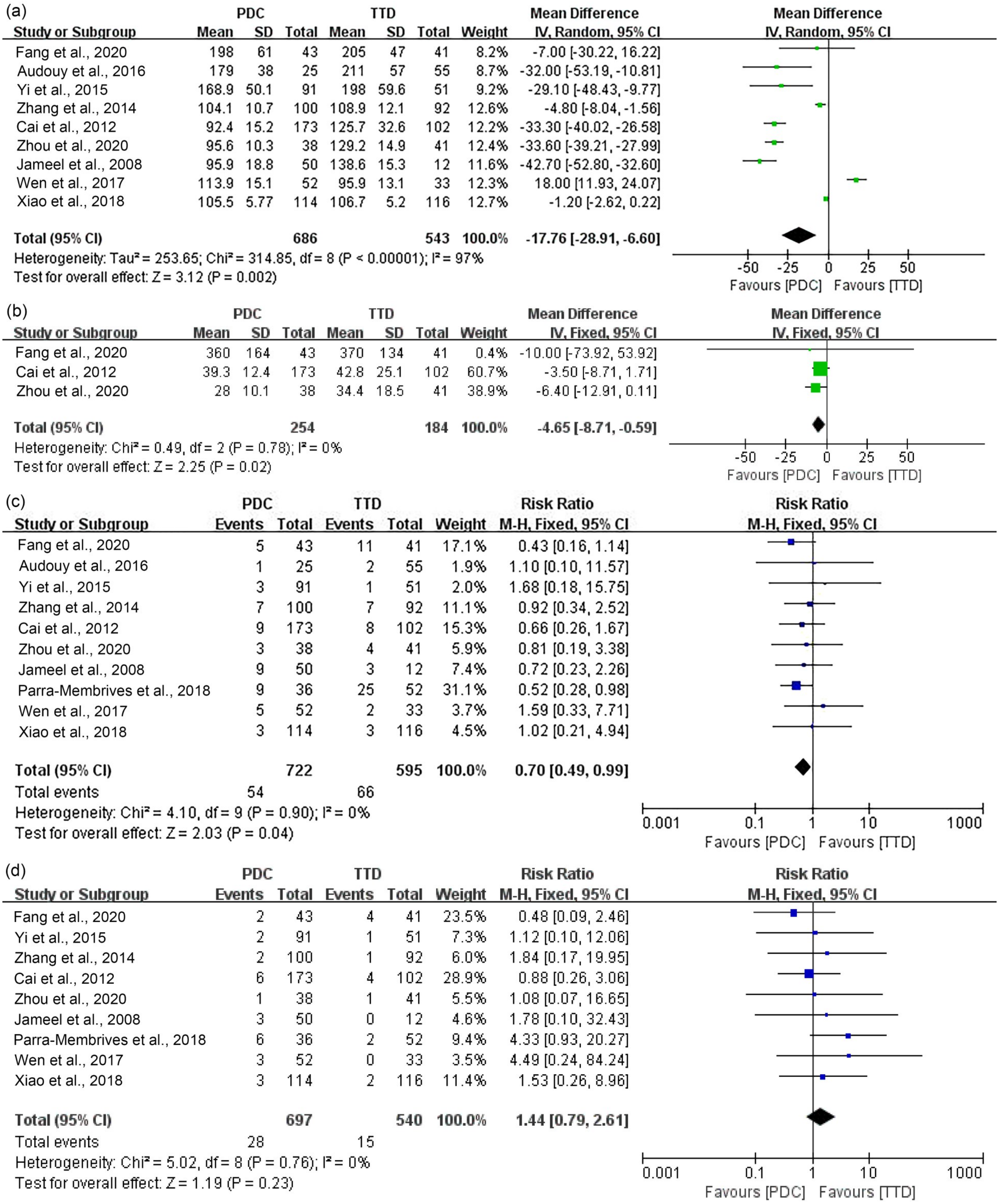
In contrast, four cohort studies provided data on stone recurrence in the subgroup. The combined data, using the fixed effect model, showed that the stone recurrence rate in the PDC group was lower than that in the TTD group. However, the difference was not statistically significant (RR=0.79, 95% CI: 0.31 to 1.98,

P=0.62; no heterogeneity was found; I^2=0%, P=0.77) (Fig. 4f).

3.3.2.5 Bile duct stricture

Among the included RCTs, only one study (Leida et al., 2008) reported on postoperative bile duct stricture. Therefore, the data could not be combined for analysis.

In the subgroup, two cohort studies reported data on postoperative bile duct stricture. The combined data, using the fixed effect model, showed that the



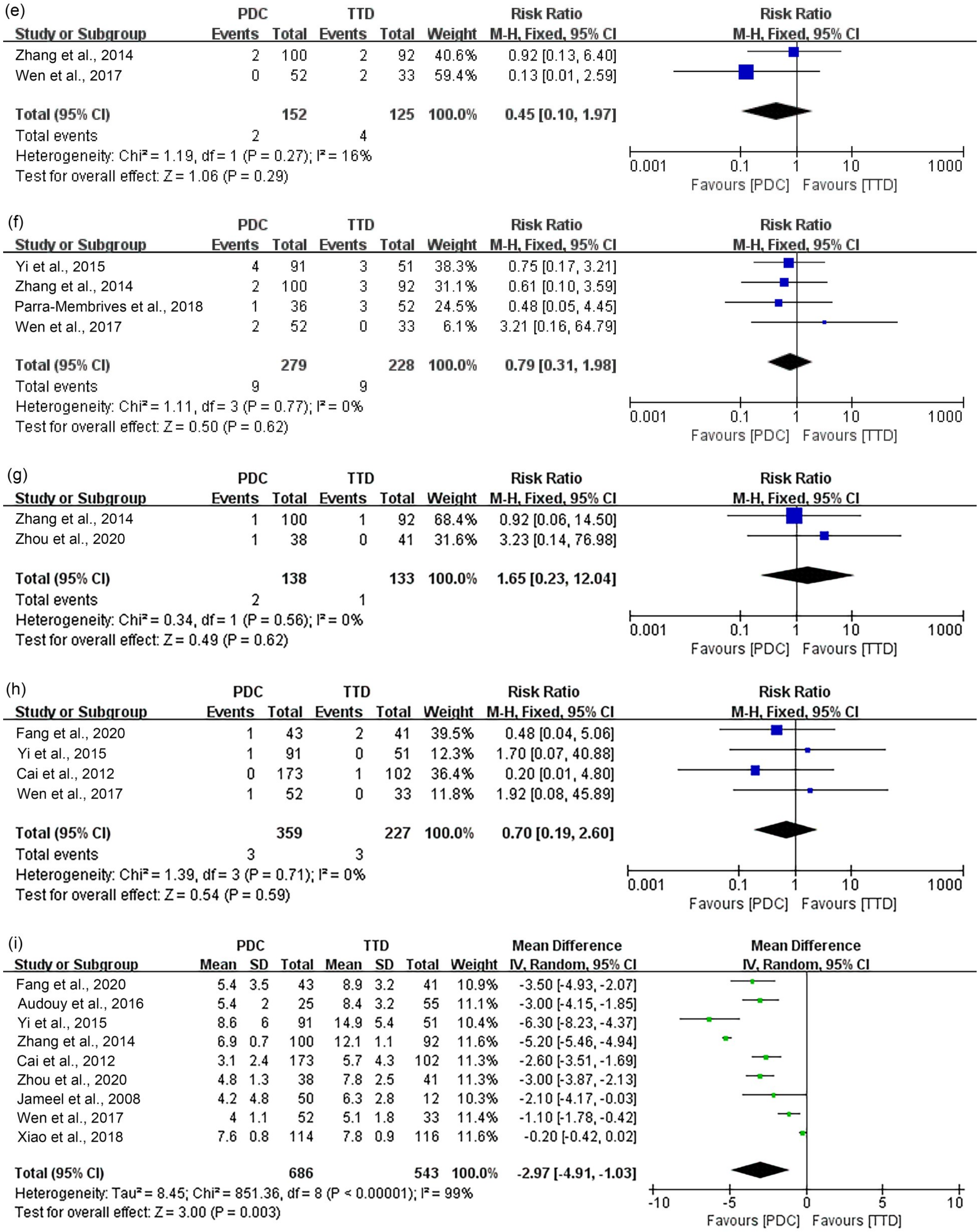


Fig. 4 Forest plots of the outcome indicators of cohort studies. (a) Operation time; (b) Intraoperative blood loss; (c) Total postoperative complications; (d) Bile leakage; (e) Retained stones; (f) Stone recurrence; (g) Bile duct stricture; (h) Other complications; (i) Postoperative hospital stay. PDC: primary duct closure; TTD: T-tube drainage; CI: confidence interval; SD: standard deviation.

incidence of postoperative bile duct stricture in the PDC group was higher than that in the TTD group, but the difference was not statistically significant (RR=1.65, 95% CI: 0.23 to 12.04, P=0.62; no heterogeneity was found; I^2=0%, P=0.56) (Fig. 4g).

3.3.2.6 Postoperative pancreatitis

In the RCTs, four studies reported data on postoperative pancreatitis. The combined data, using the fixed effect model, showed that the incidence of postoperative pancreatitis in the PDC group was higher than that in the TTD group, but the difference was not statistically significant (RR=1.64, 95% CI: 0.40 to 6.81, P=0.49; no heterogeneity was found; I^2=0%, P=0.93) (Fig. 3e).

Only one of the included cohort studies (Fang et al., 2020) reported data on postoperative pancreatitis, and thus we could not conduct a combined analysis.

3.3.2.7 Other complications

Other postoperative complications revealed in the study included mainly pneumonia, wound infection, and deep vein thrombosis. For instance, in RCTs, four studies reported data on other postoperative complications. The combined data, using the fixed effect model, showed that the incidence of other complications in the PDC group was lower than that in the TTD group, but the difference was not statistically significant (RR=0.59, 95% CI: 0.24 to 1.41, P=0.23; no heterogeneity was found; I^2=0%, P=0.74) (Fig. 3f).

Elsewhere, four cohort studies in the subgroup reported data on other complications. The combined data using the fixed effect model showed that the incidence of other complications in the PDC group was lower than that in the TTD group, but the difference was not statistically significant (RR=0.70, 95% CI: 0.19 to 2.60, P=0.59; no heterogeneity was found; I^2=0%, P=0.71) (Fig. 4h).

3.3.2.8 Postoperative exhaust time (hours)

The postoperative exhaust time was provided in two RCTs. The combined data using the random effect model showed that the average postoperative exhaust time in the PDC group was shorter than that in the TTD group, but the difference was not statistically significant (WMD=−9.99, 95% CI: −20.76 to 0.79, P=0.07; heterogeneity was found; I^2=96%, P<0.000 01) (Fig. 3g).

Only one cohort study (Cai et al., 2012) reported data on postoperative exhaust time, so a combined analysis was not possible.

3.3.2.9 Postoperative hospital stay (days)

The data of postoperative hospital stay were compared in five RCTs. The combined data using the random effect model showed that the average postoperative hospital stay in the PDC group was significantly shorter than that in the TTD group, and the difference was statistically significant (WMD=−2.83, 95% CI: −3.48 to −2.17, P<0.000 01; heterogeneity was found; I^2=68%, P=0.01) (Fig. 3h).

Postoperative hospital stay was compared among nine cohort studies in the subgroup. The combined data using the random effect model showed that the postoperative hospital stay in the PDC group was significantly shorter than that in the TTD group, and the difference was statistically significant (WMD=−2.97, 95% CI: −4.91 to −1.03, P=0.003; heterogeneity was found; I^2=99%, P<0.000 01) (Fig. 4i).

3.3.2.10 Hospitalization expenses

Four RCTs reported data on hospitalization expenses. The combined data using the random effect model showed that the average hospitalization expenses of the PDC group were significantly lower than those of the TTD group, and the difference was statistically significant (WMD=−2255.73, 95% CI: −3330.59 to −1180.86, P<0.0001; heterogeneity was found; I^2=96%, P<0.000 01) (Fig. 3i).

Only one cohort study (Xiao et al., 2018) reported data on hospitalization costs and so a combined analysis was not possible.

3.4 Publication bias

Based on the total postoperative complications and bile leakage, funnel plots of the RCT group and the cohort studies group are shown in Fig. 5. The funnel plots for both groups showed that all the studies were within 95% CIs. There was also a relatively uniform longitudinal distribution, and no obvious publication bias was found. However, because only six studies were included in the RCT group, the efficiency of the test was limited.

4 Discussion

LCBDE has been suggested as a comparatively effective approach for treating choledocholithiasis, and is included in the guidelines of the British Society of Gastroenterology for the treatment of choledocholithiasis

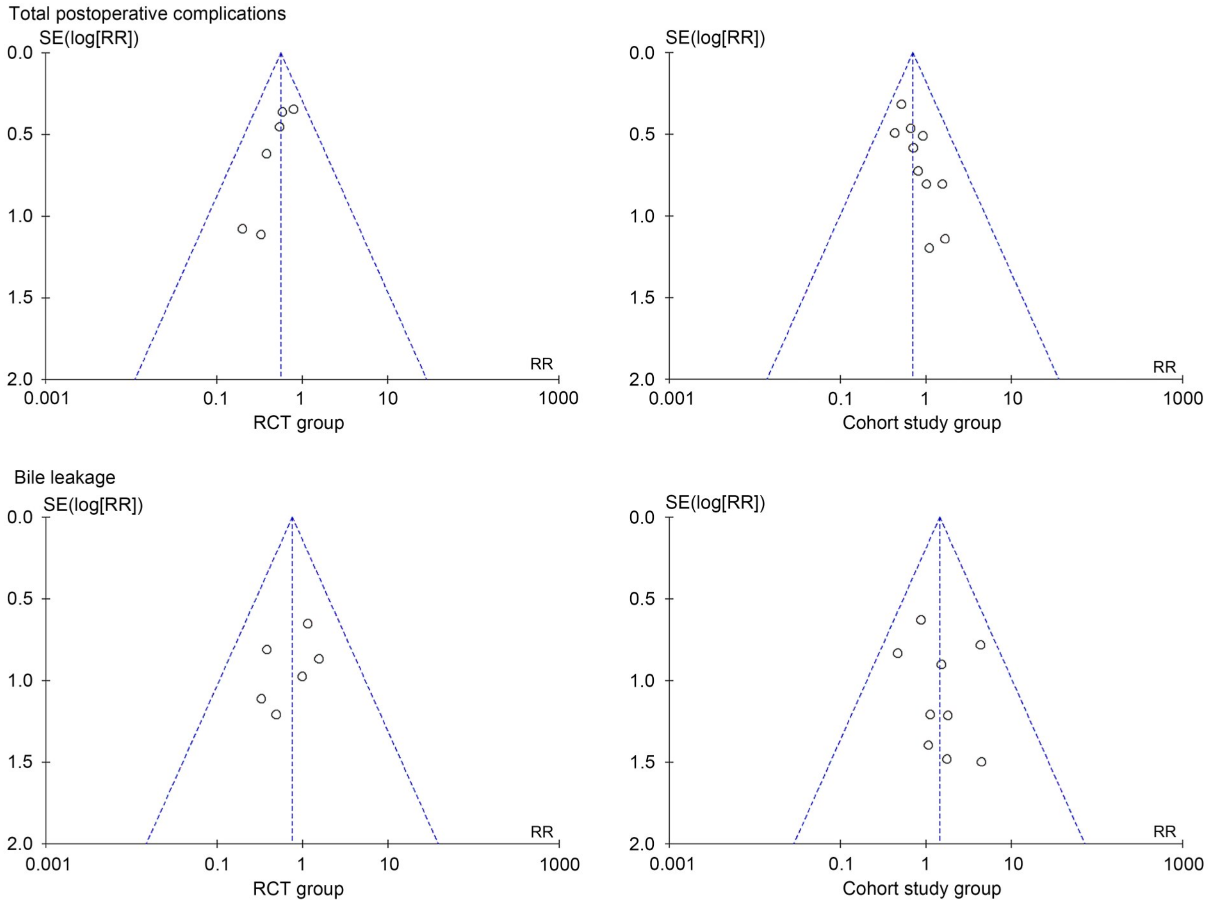


Fig. 5 Funnel plots showing the distribution of the RRs for total postoperative complications and bile leakage for RCT and cohort study groups. RR: relative risk; RCT: randomized controlled trial; SE: standard error.

(Williams et al., 2008). There is overwhelming evidence that transcystic LCBDE is preferred to transductal LCBDE (Jones et al., 2019; Navaratne and Isla, 2021). It has been proposed that, after LCBDE, PDC without the use of a T-tube is an alternative to TTD (Lou et al., 2019). Nonetheless, from laparotomy to LCBDE, postoperative TTD has been in use for more than 100 years. The technique is common during postoperative biliary decompression to recover post-traumatic edema of Watt's ampulla. Furthermore, postoperative TTD is traditionally used in detecting retained stones and bile duct stricture using cholangiography (Chen et al., 2010). However, hosts of complications following the application of this technique have been reported. At present, there are many questions regarding the practicability of T-tube use. This has led to limited application of TTD after transductal LCBDE. Furthermore, there is still controversy regarding the conventional performance of TTD. Therefore, we performed a meta-analysis of six RCTs and ten cohort studies (a total of 1865 patients) to provide strong evidence on the safety and efficacy of PDC and TTD after transductal LCBDE.

The results of meta-analysis showed that the PDC group had shorter operation time and less blood loss than the TTD group, and the difference was statistically significant, as expected. Short operation time and reduced bleeding are important as they minimize perioperative complications, especially for elderly patients with more underlying diseases (Wu et al., 2012). LCBDE is a specialized laparoscopic technique. A previous study observed that each surgeon has a learning curve which determines the operation time: the operation time decreases as the experience of the surgeon increases (Zhu et al., 2015).

The safety of patients is always a priority with the application of any technology. However, the use of T-tubes is often associated with a higher incidence of complications (10%–15%) (Wills et al., 2002). In our study, the combined results of total postoperative complications showed that the incidence of complications in the TTD group was significantly higher than that of the PDC group. The complications generally included biliary complications like bile leakage, T-tube-related complications, biliary peritonitis, acute biliary pancreatitis, and biliary stricture. Also, some other complications, such as pneumonia and wound infection, were revealed in the present study. Regardless of the included RCTs or the cohort studies of the subgroup, the heterogeneity between study groups was very low, an indication that our results were reliable. Previous studies suggested that there was no significant difference in the incidence of postoperative complications between the TTD and PDC groups (Wu et al., 2019; Zhou et al., 2020). In our study, it was revealed that TTD not only failed to minimize the risk, but also greatly increased the probability of complications and affected the outcomes of the surgery.

Bile leakage is a common complication after transductal LCBDE. If not correctly recognized and treated, serious bile leakage may be life-threatening. In our study, although there was no statistical difference in the incidence of bile leakage between the TTD and PDC groups, a tendency for bile leakage was more obvious in the TTD group. This could be caused by bile leaking out of the small hole left after removing the T-tube. Bile leakage may lead to complications that could otherwise have been prevented. In addition, bile leakage and biliary peritonitis may occur due to immaturity of the T-tube sinus tract after T-tube removal (Wills et al., 2002; Leida et al., 2008). A previous study showed that the type of material of the T-tube also affects the quality of sinus tract formation (Apalakis, 1976). Our study demonstrates that PDC is at least as safe as TTD and does not increase the risk of postoperative bile leakage. Appropriate patient selection is also important to reduce bile leakage after PDC. Wen et al. (2017) confirmed that any factor leading to distal bile duct obstruction may increase the pressure in the bile duct and lead to ischemia of the suture site, thus increasing the chance of bile leakage. Another important influencing factor is the diameter of the CBD. Hua et al. (2017) suggested that an undilated CBD (<8 mm) is a risk factor for bile leakage. Since a general definition of bile leakage was lacking in the studies we included, the author's subjectivity may have influenced the assessment of complications to some extent. Moreover, patients with bile leakage of different severity were not counted separately. Most of the bile leakage was mild, without further intervention, and would not have had serious consequences.

In terms of the rate of retained stones, our study showed that there was no statistically significant difference between the TTD and PDC groups. Because of the application of intraoperative choledochoscopy, the existence of stones can be clearly and intuitively observed during the operation. This is helpful as it largely prevents the retention of stones. Some studies have reported a residual rate as low as 0% (Ambreen et al., 2009). In particular, the maturity and routine use of ERCP and EST have reduced the importance of TTD. Once retained stones are found, treatment can be done properly without relying on T-tubes (Manes et al., 2019). The choice of PDC or TTD after LCBDE is not the cause of retained stones, and has no impact on subsequent treatment. Therefore, it is of little clinical significance for this index to guide the choice of closure mode.

Our meta-analysis showed that there was no significant difference in stone recurrence or bile duct stricture between the TTD and PDC groups. Although there was no statistical difference in the recurrence rate of stones, the results were more inclined to a lower recurrence rate in the PDC group. These findings may be linked to the deposition of bile pigment and bile salt around a T-tube, which is a foreign body (Rienhoff, 1960). In addition, poor nursing can lead to the entry of bacteria into the biliary tract. In this case, a T-tube acts as a transmission corridor for bacteria, whereby bacterial infection plays an important role in the pathogenesis of stone recurrence (Lygidakis, 1983). Even if there is recurrent choledocholithiasis, ERCP combined with EST is safe and feasible (Sugiyama et al., 2004). Bile duct stricture is a long-term complication after LCBDE, but it seems to be rare in both transverse and longitudinal choledochotomy. During the follow-up period, some patients with bile duct stenosis even could not been found (Vidagany et al., 2016). The previous literature, supported by our findings, suggested that PDC does not increase the risk of long-term complications such as bile duct stricture. However, these studies generally had a short follow-up period, and longer follow-up studies are needed to assess the potential risk of stone recurrence and bile duct stricture.

In this study, we also compared the incidence of postoperative pancreatitis and other complications between the PDC and TTD groups. The results showed that there were no statistically significant differences between the two groups. Regarding postoperative pancreatitis, the lower incidence of the TTD group may be associated with reduced pressure related to Oddi sphincter dysfunction. The T-tube is responsible for the reduction of pressure. Other complications included mainly pneumonia, wound infection, and deep vein thrombosis. Factors associated with pneumonia and deep vein thrombosis may include the long time in bed and the duration of the operation. A previous study has suggested that TTD can increase the incidence of infection (Lygidakis, 1983). A reasonable explanation seems to be that TTD can cause exogenous invasion of microorganisms in the environment, leading to infection. However, as doctors may use different criteria to identify complications, it was difficult to compare the incidence of other complications between the two groups in the present study.

Postoperative exhaust time refers to the recovery time of intestinal function. The results of the meta-analysis showed that the postoperative exhaust time was shorter in the PDC group than in the TTD group. However, the time difference between the two groups was not statistically significant. These findings can be related to a number of physiological aspects. For instance, TDD can destroy the integrity of the bile duct, lead to bile loss, slow intestinal peristalsis, and affect intestinal digestion. PDC is known to maintain physiological function of the bile duct, enabling bile to flow into the duodenum to exert digestive function (Guan et al., 2019). In our meta-analysis, there was no significant difference between the two groups, probably because only two RCTs were included and the sample size was small.

In our meta-analysis, the PDC group had a significantly shorter postoperative hospital stay and lower hospitalization expenses than the TTD group. Because of the lower incidence of complications in the PDC group, the time and expense involved in subsequent treatment of complications were reduced. In addition, patients in the TTD group need T-tube cholangiography to confirm the patency of the biliary tract after the operation. This may prolong the hospital stay and increase costs. A shorter hospital stay can not only save medical expenses, but also reduce the incidence of nosocomial infection and increase bed turnover rates. Differences in local economic conditions, management preferences of postoperative patients, and discharge standards may lead to variable results. Prospect studies are needed to confirm this in well-designed RCTs.

After performing this review, we have found that not all patients undergoing choledochotomy are suitable for primary closure. For patients with severe acute cholecystitis or acute suppurative cholangitis, PDC is limited because they require decompression and drainage of the CBD (Leida et al., 2008). After clearing the bile duct, a ureteric catheter (5 Fr) can be inserted into the CBD through the choledochoscope to confirm that the distal bile duct is unobstructed (Wen et al., 2017). TTD may be a better choice for patients with a distal bile duct obstruction. PDC should be performed with caution if the patient has a history of gastrectomy, as endoscopy cannot be used for examination and treatment when bile leakage and retained stones occur. To prevent bile duct stricture after choledochotomy, it is recommended that the diameter of the CBD should be larger than 8 mm (Yi et al., 2015). In addition, the suture method is also important to prevent postoperative bile leakage. After intermittent or continuous suture of the bile duct, a second layer of intermittent suture on the surface is recommended to reduce tension (Zhang et al., 2014).

Our meta-analysis included not only six RCTs, but also ten cohort studies (a total of 1865 patients). The cohort studies were analyzed separately as a subgroup to control the risk of bias while expanding the sample size. In addition, we did not use the odds ratio (OR) to compare dichotomous variables as in other meta-analyses (Jiang et al., 2019; Deng et al., 2020). We chose the RR as the first choice, because if the incidence of events is high, the effect values obtained by the OR are often over estimated (Egger et al., 1997b). Patients with a history of biliary tract surgery were excluded from the screening criteria to minimize heterogeneity. It can be seen from our analysis that heterogeneity among studies was very small for most of the outcome indicators. As well, the distribution of RR in the funnel plots was generally symmetrical, indicating that the quality of our evidence was relatively high.

5 Limitations

There were some limitations in our work which could have led to a low quality of evidence. First, the included RCTs did not mention the specific blinding method and allocation concealment, which may have affected the reliability of the results (Egger et al., 1997a). Second, there was no unified identification standard for some result indicators, such as bile leakage and other complications, which may have caused errors due to the subjective judgment of doctors. Third, in terms of postoperative exhaust time, postoperative hospital stays, and hospitalization expenses, the heterogeneity between studies was obvious. Although we used a random effect model to reduce the influence of heterogeneity, it could not be completely eliminated. More large-scale multicenter RCTs and longer follow-up periods are needed in future to provide reliable data on PDC and TTD.

6 Conclusions

This meta-analysis provided the best available evidence that, compared with TTD, PDC significantly reduced operative time, intraoperative blood loss, total postoperative complications, postoperative hospital stay, and hospitalization expenses. In addition, there were no differences in bile leakage, retained stones, stone recurrence, bile duct stricture, postoperative pancreatitis, other complications, or postoperative exhaust time between the TTD and PDC groups. Therefore, we strongly recommend the application of PDC over TTD after transductal LCBDE.

Acknowledgments

This work was supported by the National Natural Science Foundation of China (Nos. 81972262, 81972255, 81772597, 81801999, and 81702904), the Guangdong Basic and Applied Basic Research Foundation (Nos. 2020A1515010117 and 2018A030313645), the Fundamental Research Funds for the Central Universities (No. 18ykpy22), the Key Laboratory of Malignant Tumor Molecular Mechanism and Translational Medicine of Guangzhou Bureau of Science and Information Technology (No. [2013]163), the Key Laboratory of Malignant Tumor Gene Regulation and Target Therapy of Guangdong Higher Education Institutes (No. KLB09001), the Guangdong Science and Technology Department (Nos. 2015B050501004 and 2017B030314026), and the Shangrao Science and Technology Department (No. 2020D001), China.

Author contributions

Rui ZHANG and Chao LIU: study concept and design; Taifeng ZHU: drafting of the manuscript; Taifeng ZHU and Rui ZHANG: preliminary screening, acquisition of data and full-text evaluation; Haoming LIN and Jian SUN: critical revision of the manuscript; Chao LIU: study supervision. All authors have contributed to the revision of the manuscript. All authors have read and approved the final manuscript, and therefore, have full access to all the data in the study and take responsibility for the integrity and security of the data.

Compliance with ethics guidelines

Taifeng ZHU, Haoming LIN, Jian SUN, Chao LIU, and Rui ZHANG declare that they have no conflict of interest.

This article does not contain any studies with human or animal subjects performed by any of the authors.

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