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SYSTEMATIC REVIEWS AND META-ANALYSES

Can T-tube drainage be replaced by primary suture technique in laparoscopic common bile duct exploration? A meta-analysis of randomized controlled trials

Yuan Deng[1] · Hong-Wei Tian[1] · Lan-Juan He[2,3] · Yan Zhang[1] · Yuan-Hui Gu[1] · Yun-Tao Ma[1]

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Abstract

Background Although laparoscopic common bile duct exploration (LCBDE) is considered the best treatment and has the advantages of being minimally invasive for common bile duct (CBD) stones, the choice of T-tube drainage (TTD) or primary duct closure (PDC) after LCBDE is still controversial. Therefore, the aim of the study was to compare the superiority of PDC versus TTD after LCBDE for choledocholithiasis.

Methods All potential studies which compare the surgical effects between PDC with TTD were electronically searched for in PubMed, Web of Science, and the Cochrane library databases up to November 2019. Data synthesis and statistical analysis were carried out using RevMan 5.3 software.

Results In total, six randomized controlled trials with 604 patients (307 in the PDC group and 297 in the TTD group) were included in the current meta-analysis. As compared with the TTD group, the pooled data showed that PDC group had shorter operating time (WMD = −24.30; 95% CI = −27.02 to −21.59; $p < 0.00001$; $I^2 = 0\%$; $p < 0.88$), less medical expenditure (WMD = −2255.73; 95% CI = −3330.59 to −1180.86; $p < 0.0001$; $I^2 = 96\%$; $p < 0.00001$), shorter postoperative hospital stay (OR = −2.88; 95% CI = −3.22 to −2.54; $p < 0.00001$; $I^2 = 60\%$; $p < 0.03$), and lower postoperative complications (OR = 0.49; 95% CI = 0.31 to 0.78; $p = 0.77$; $I^2 = 0\%$; $p = 0.003$). There were no significant differences between the two groups concerning bile leakage (OR = 0.74; 95% CI = 0.36 to 1.53; $p = 0.42$; $I^2 = 0\%$; $p = 0.90$) and retained stones (OR = 0.96; 95% CI = 0.36 to 2.52; $p < 0.93$; $I^2 = 0\%$; $p < 0.66$).

Conclusions LCBDE with PDC should be performed as a priority alternative compared with TTD for choledocholithiasis.

Keywords Laparoscopic common bile duct exploration · Primary duct closure · T-tube drainage · Meta-analysis

Introduction

Choledocholithiasis is a common and frequent disease in biliary surgery, which has become the second most frequent complication in patients with gallbladder stones [1]. Approximately 10% to 18% of patients undergoing cholecystectomy for cholelithiasis have common bile duct (CBD) stones [2]. As we have known, choledocholithiasis can easily cause bile duct blockage, biliary colic, obstructive jaundice, cholangitis, bile pancreatitis and, if left untreated, liver cirrhosis [1, 3]. In the past, open choledocholithotomy with T-tube drainage was the traditional and effective method for the treatment of choledocholithiasis. Since Stoker successfully completed the first case of laparoscopic cholecystectomy and common bile duct exploration in 1991, the remedial model of gallbladder stone and choledocholithiasis has changed qualitatively. With the rapid development of minimally invasive endoscopic and laparoscopic surgical techniques, a variety of options are provided for clinical treatment of choledocholithiasis patients. Laparoscopic common bile duct exploration (LCBDE) with T-tube drainage (TTD), endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (EST), and primary suture after LCBDE have

Yuan Deng and Hong-Wei Tian contributed equally to this work.

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✉ Yun-Tao Ma
3575515665@qq.com

[1] Gansu Provincial Hospital, Lanzhou, China

[2] Gansu University of Chinese Medicine, Lanzhou, China

[3] Research Center Traditional Chinese Medicine, Gansu Province, Lanzhou, China

become an ideal surgical procedure compared with traditional open choledocholithotomy with T-tube drainage placement for choledocholithiasis. In addition, LCBDE was included in the guidelines of the British Society of Gastroenterology for the treatment of choledocholithiasis in 2008 [1].

Among these techniques, T-tube drainage (TTD) has been proven to be a safe and effective method for postoperative biliary decompression. Although TTD has the advantages of preventing bile leakage, postoperative cholangiography to detect any residual stones, and prevention of biliary stricture, it has a series of complications and inconvenience to the patients, such as wound infection around the T-tube, prolonged recovery, bile fistula after extraction, and obstruction caused by T-tube displacement [4–7]. As regards EST, it is a mature technology, but it also leads to postoperative complications such as pancreatitis, perforation, blood loss, and sepsis [8]. What is more, it destroys the physiological function of Oddi's sphincter and recovery of the physiological function of Oddi's sphincter cannot be restored. Besides, it may increase the risk for future pancreatic cancer and cholangiocarcinoma [9, 10]. In addition, so many surgeons considered that the improper use of EST should be avoided, even though the arguments against EST is really limited [11–13]. To avoid these complications associated with TTD occurring in LCBDE patients and to preserve sphincter function, primary duct closure (PDC) for CBD closure after LCBDE was recommended by some surgeons. Although there were many studies [14–16] reporting that the clinical effect of PDC was better than TTD after LCBD exploration, the clinical evidence is still insufficient and there is no consensus for now. Therefore, this meta-analysis was performed in order to obtain the best evidence comparing the safety and efficacy between PDC and TTD after LCBDE in the treatment of patients with CBD stones based on six randomized controlled trials (RCTs).

Materials and methods

Search strategy

The studies were identified by searching the major medical databases, such as PubMed, Web of Science, and the Cochrane Library, for all articles published until December 31, 2019. The detailed keywords for the database searches are as follows: laparoscopic/laparoscopy, choledochostomy/common bile duct, primary closure/primary suture/primary duct closure/and T-tube. Furthermore, our literature search was limited to publications on the design of the RCTs. RCT search strategy follows The Cochrane System Evaluation Handbook 5.0.2 and other searches were carried out by using Medical Subject Headings (MeSH) terms and free-text terms. In addition, reference lists of all retrieved articles were searched manually for additional studies that were missed by the electronic search. Finally, according to optimal literature search for systematic reviews in surgery [17], the validity of literature search strategy was verified.

Inclusion and exclusion criteria

Inclusion criteria were described for the meta-analysis as follows: (1) type of included studies were RCTs; (2) clinical studies that compared primary suture with T-tube after laparoscopic common bile duct exploration (LCBDE); (3) all the potentially eligible studies should contain at least one of the following outcomes: operating time, postoperative hospital stay, hospital expenses, total complications, bile leakage, retained stones, or follow-up; (4) participating patients were diagnosed choledocholithiasis with or without cholecystolithiasis and that no intrahepatic bile duct stones, no obvious common bile duct stenosis, no acute pancreatitis, no malignant bile duct tumors, and without previous history of upper abdominal surgery; (5) if there was an overlap between authors or institution, the higher quality or the most recent publication will be included in the research to avoid including the same patients.

Exclusion criteria were as follows: (1) non-RCTS and non-human studies; (2) abstract only or case reports or review articles; (3) duplicate publication or the publication did not provide sufficient data for the analyses.

Data extraction and quality assessment

Data extraction and quality assessment were performed using a structured sheet and the data were entered into a database by three investigators independently. The extracted general information were as follows from each included study: first author, year of publication, country, number of patients, baseline characteristics (gender and age), suture techniques, type of T-tube, length of follow-up, and short- and long-term outcomes. When we found the reports overlapped, the longest follow-up was selected. Risk of bias of included studies was assessed by using the criteria suggested by the Cochrane Collaboration Risk of Bias Tool in this meta-analysis. The Cochrane risk-of-bias tool included six criteria items, as follows: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias [18]. The blinding of included studies were evaluated based on recommendations issued by Pascal Probst et al. [19]. Disagreements in data extraction and quality assessment were resolved through discussion and consensus of the research team.

Statistical analysis

For statistical analysis in this meta-analysis, weighted mean differences (WMD) with 95% CIs were used for analyzing continuous variables and ORs for dichotomous variables. Furthermore, when the study had reported medians and ranges instead of means and SDs, the means and SDs were estimated as described by Hozo et al. [20]. Methodological heterogeneity among the RCTs was evaluated by using the I^2 statistic and P value; $I^2 > 50\%$ or $P < 0.10$ was regarded as significant heterogeneity. If no significant heterogeneity was observed among the included studies ($I^2 > 50\%$ or $P < 0.10$), the fixed-effects model (Mantel and Haenszel 1959; DerSimonian and Laird 1986) was used; otherwise, random-effects model was used. All statistical calculations were performed using the Review Manager software version 5.3 downloaded from the Cochrane Collaboration and risk of publication bias was assessed by use of funnel plots in the meta-analysis.

Results

Trial selection and description of studies

A total of 123 potential references were retrieved according to the initial search strategy. After repetitive articles and screening the titles and abstracts, 28 repetitive articles and 81 articles not comparing primary closure versus T-tube drainage after laparoscopic choledochotomy were excluded, respectively. Through screening the full text of the 14 remaining studies, 8 were non-RCTs and ultimately 6 RCTs [21–26] comparing PDC and TTD qualified for inclusion were included in the meta-analysis. Figure 1 summarizes the flow diagram of study selection. Among the six included studies, four studies were from China, one was from Egypt, and one was from India, respectively. The basic data, including publication year, country, age, gender, number of patients, suture techniques, type of T-tube, and follow-up from each trial, are revealed in Table 1.

Operating time (min)

All included studies compared the operating time. The pooled data demonstrated that mean operating time was significantly shorter in PDC group than in TTD group in a fixed-effects model (WMD = −24.30; 95% CI = −27.02 to −21.59; $p < 0.00001$; $I^2 = 0\%$; $p < 0.88$; Fig. 2).

Hospital expenses (yuan)

Four researches [21, 22, 24, 26] from China that compared PDC with TTD provided data on hospital expenses. The combined result showed that significantly less medical expenditure in the PDC group compared with the TTD group in a random-effect model (WMD = −2255.73; 95% CI = −3330.59 to −1180.86; $p < 0.0001$; $I^2 = 96\%$; $p < 0.00001$; Fig. 3).

Postoperative hospital stay (days)

All included studies revealed the duration of postoperative hospital stay; the PDC group had a significantly shorter postoperative hospital stay duration in a fixed-effects model (OR = −2.88; 95% CI = −3.22 to −2.54; $p < 0.00001$; $I^2 = 60\%$; $p < 0.03$; Fig. 4).

Bile leakage

All the included studies compared PDC with TTD and provided data on postoperative bile leakage. The combined results of these included studies revealed that there was no significant difference (OR = 0.74; 95% CI = 0.36 to 1.53; $p = 0.42$) between the two groups in a fixed-effects model ($I^2 = 0\%$; $p = 0.90$; Fig. 5).

Retained stones

Retained stones results were reported in all included studies. Among the six included studies, one study [22] reported that there were no retained stones between the two groups. The overall pooled estimate of postoperative retained stones complications was with no statistically significant difference between PDC and TTD in a fixed-effects model (OR = 0.96; 95% CI = 0.36 to 2.52; $p < 0.93$; $I^2 = 0\%$; $p < 0.66$; Fig. 6).

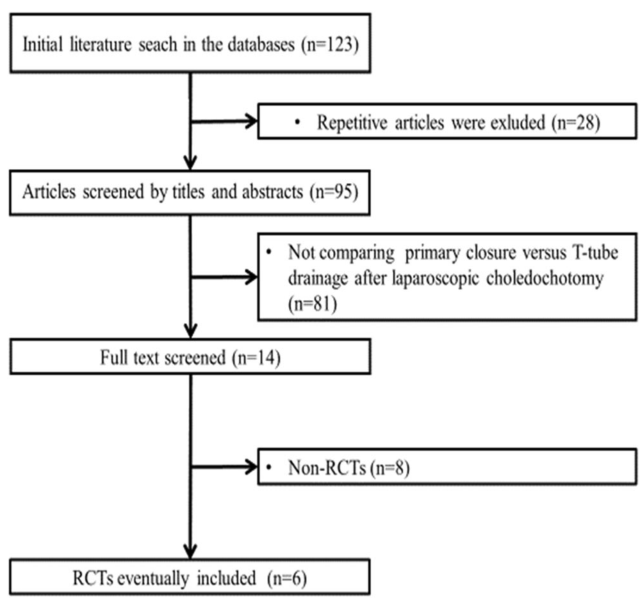

Fig. 1 Flow diagram of study selection

Table 1 Characteristics of included studies

References	Year	Country	Number of patients		Gender (M/F)	
			PDC	TTD	PDC	TTD
Zhang et al. [21]	2004	China	27	28	11/16	12/16
Zhang et al. [22]	2008	China	40	40	17/23	18/22
El-Geidie et al. [23]	2009	Egypt	61	61	39/22	45/16
Zhang et al. [24]	2009	China	47	46	22/25	19/27
Mangla et al. [25]	2012	India	31	29	9/22	5/24
Dong et al. [26]	2014	China	101	93	43/58	40/53

References	Age (M ± SD)/range		Suture techniques		Type of T-tube	Follow-up range (months)
	PDC	TTD	PDC	TTD		
Zhang et al. [21]	44.6 ± 18.3	42.4 ± 17.6	4-0 absorbable sutures and continuous sutures	Interrupted Vicryl 4-0 sutures	A latex rubber T-tube of appropriate size (18–20 Fr)	3–40
Zhang et al. [22]	52 ± 14	45 ± 12	Running absorbable suture (4-0 Vicryl)	Interrupted sutures (4-0 Vicryl)	A latex rubber T-tube of appropriate size (14–20 Fr)	3–6
El-Geidie et al. [23]	39 (20–71)	43 (20–67)	4-0 absorbable sutures (4-0 Vicryl; Ethicon, NJ) and intracorporeal knotting	Continuous sutures (4-0 Vicryl; Ethicon)	A latex rubber T-tube of appropriate size (14–16 Fr)	2
Zhang et al. [24]	52.3 ± 16.6	52.0 ± 15.9	4-0 absorbable sutures (4-0 Vicryl; Ethicon, NJ) and intracorporeal knotting	Interrupted sutures (4-0 Vicryl; Ethicon)	A latex rubber T-tube of appropriate size (14–20 Fr)	3–24
Mangla et al. [25]	46.8 ± 14.8	47.17 ± 12.3	Interrupted or continuous 4-0 Vicryl sutures (Ethicon, Johnson & Johnson, Somerville, NJ) with intracorporeal suturing	3-0 Vicryl interrupted sutures (Ethicon, Johnson & Johnson, Somerville, NJ)	An appropriate size T-tube	1–1.6
Dong et al. [26]	57.6 ± 4.2	58.3 ± 4.4	Interrupted Vicryl 4-0 sutures (Ethicon, NJ)	Interrupted Vicryl 4-0 sutures (Ethicon)	A latex rubber T-tube of appropriate size (14–20 Fr)	12

PDC primary duct closure, *TTD* T-tube drainage

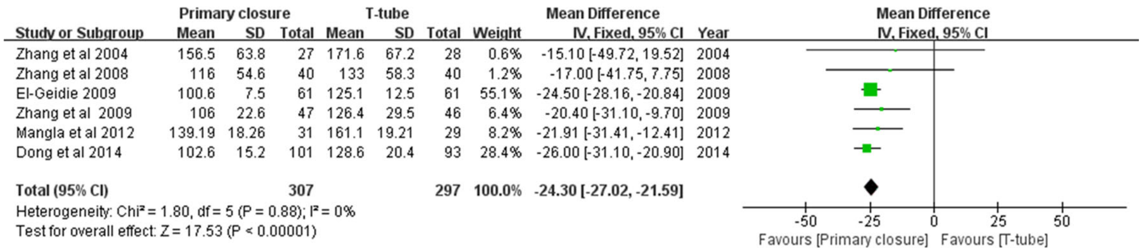

Fig. 2 Meta-analysis of operating time, CI: confidence interval, primary closure vs. T-tube drainage

Total complications

All included trials provided information regarding postoperative complications, which were reported for 34 patients in the PDC group and for 59 patients in the TTD group. The pooled results suggested that lower incidence of postoperative complications in PDC than in TTD in a fixed-effects model (OR = 0.49; 95% CI = 0.31 to 0.78; $p = 0.77$; $I^2 = 0\%$; $p = 0.003$; Fig. 7).

Postoperative mortality and follow-up

All included studies reported postoperative mortality and follow-up period or median follow-up. There was no mortality in all trials except one trial [21]. The present study showed that there was one death due to pancreatic adenocarcinoma at 21 months and stroke at 13 months after surgery in the PDC group and the TTD group, respectively.

Heterogeneity and risk of bias

By evaluating the quality of each included study, the results of risk of bias are shown in Fig. 8. In the pooled data analysis, only two indicators that postoperative hospital stay and hospital expenses showed significant heterogeneity. The value of I^2 was 60% and 96%, respectively.

Discussion

With the development of minimally invasive surgery, many surgeons are actively trying to find the best management for choledocholithiasis since the first laparoscopic cholecystectomy was performed in 1985 [27]. To date, many previous studies [15, 28, 29] have indicated the superiority of LCBDE without T-tube drainage in terms of its lower rate of postoperative complications, shorter postoperative hospital stay, and lower hospital expenses. However, Zhang et al. [30] considered that there was no evidence provided for clinical benefits of using TTD after LCBDE. Hence, it is still controversial which therapy is optimal for the management of choledocholithiasis [28, 31, 32]. In the current meta-analysis, clinical trials that compared PDC versus TTD after laparoscopic common bile duct exploration were comprehensively retrieved, and six RCTs with 604 patients (307 in the PDC group and 297 in the TTD group) were included. Therefore, the present study obtained relatively reliable conclusions through quantitative analysis of the included studies.

As regards operating time, the study found that patients with PDC had shorter operating times than those with TTD. A recent meta-analysis [14] and a comparative study [16] demonstrated that the operating time was significantly shorter in the PDC group than in the TTD group, consistent with our results. The result is understandable because additional time is needed to insert the T-tube, and the procedure is an extra surgery step during surgery compared with PDC. In our view, subsequent closure techniques after insertion of the T-tube were more complex to perform than PDC. Besides, shorter operating time is beneficial to reduce duration of anesthesia, infection incidence during surgery, and reduce the incidence of postoperative thrombosis, respiratory and cardiac complications, especially in elderly patients with cardiovascular risk [33]. However, Wu et al. [34] showed that there was no significant difference in operating time between the two groups. The reason probably is that as the team gained extensive experience, the operating time has not become a significant distinction.

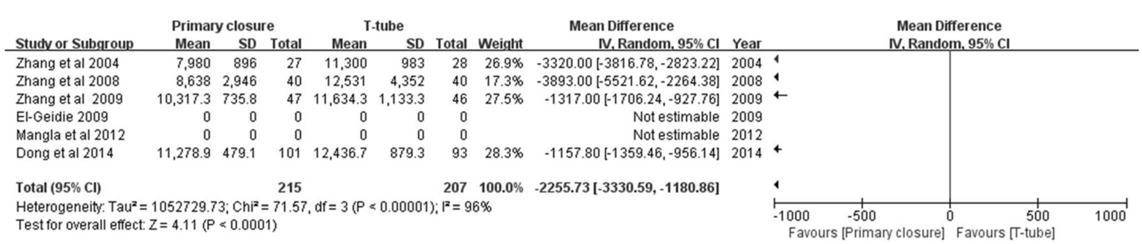

Fig. 3 Meta-analysis of hospital expenses, CI: confidence interval, primary closure vs. T-tube drainage

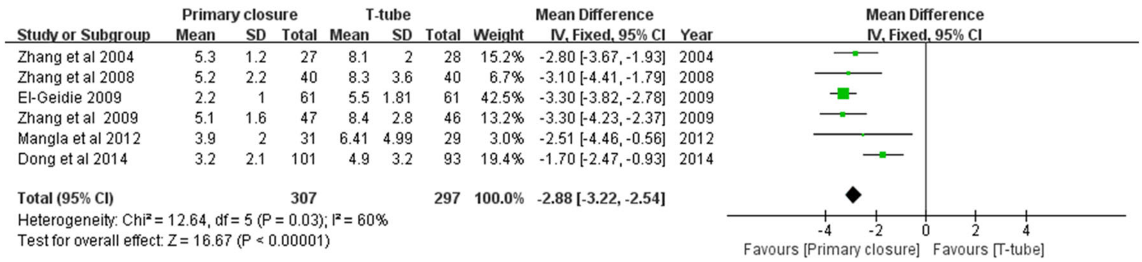

Fig. 4 Meta-analysis of postoperative hospital stay, CI: confidence interval, primary closure vs. T-tube drainage

In terms of postoperative hospital stay and hospital expenses, there was significantly shorter postoperative hospital stay and less medical expenditure when compared with the TTD group. These results were in agreement with those of previously published meta-analyses [31, 35, 36] and comparative studies [25, 37]. Many reasons have been supported for this conclusion. In the study of Jiang et al. [14], TTD patients need a longer time for postoperative recovery and ensuring the patency of the T-tube. In addition, accidental displacement of the T-tube, biliary leakage, persistent biliary fistula, and cholangitis caused by micro-organisms migrating through the T-tube may prolong hospital stay and delay postoperative recovery and reduce the quality of life [38]. Absolutely, extension in hospital stay could increase medical expenditure. Furthermore, length of hospital stay and medical costs may be influenced by the patient's financial condition, local medical policies, or man-made factors.

The current meta-analysis indicates that patients treated by the method of PDC had a significantly lower postoperative complications compared with those who underwent TTD procedure. It is known that the insertion of a T-tube was designed to prevent bile leakage or bile duct stenosis or provide access to remove retained stones or provide an effective biliary decompression in cases of incomplete stone removal after choledochotomy closure. Furthermore, the specific rate of complications following T-tube insertion is said to occur approximately 10–15% according to literature [24, 38]. However, the latest meta-analysis based on a larger sample size of 2552 patients by Jiang et al. [14] also showed that the incidence of postoperative complications was significantly decreased in primary closure of the CBD. Moreover, the latest clinical trial by Wu et al. [34] and retrospective study by Zhou et al. [39] revealed that no differences were found regarding the incidence of postoperative complications between the two groups, and the majority of studies also advocated for this conclusion. Put differently, T-tube drainage not only fails to reduce postoperative complications but also increases the risk of postoperative complications. There was one study indicating that T-tube removal or accidental dislodgement may lead to increasing significant postoperative bile leak and that T-

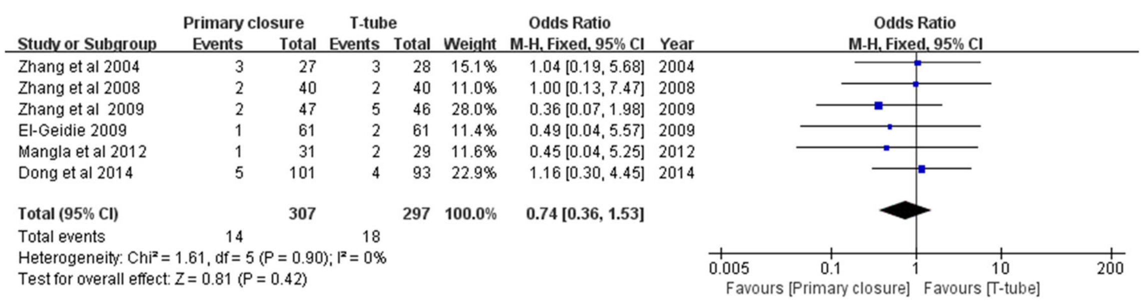

Fig. 5 Meta-analysis of bile leakage, CI: confidence interval, primary closure vs. T-tube drainage

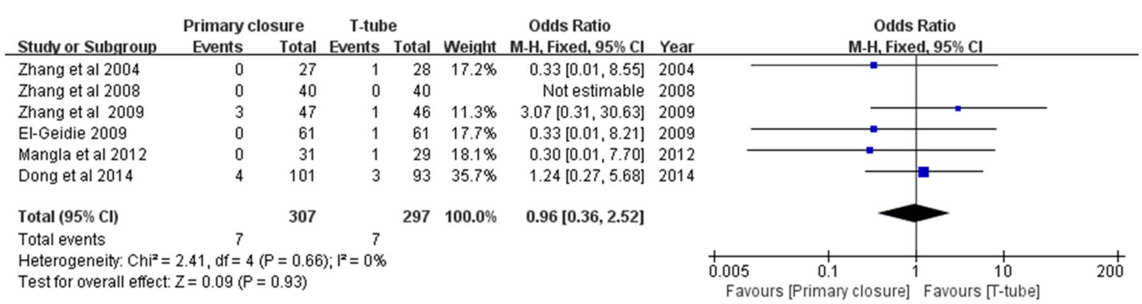

Fig. 6 Meta-analysis of retained stones, CI: confidence interval, primary closure vs. T-tube drainage

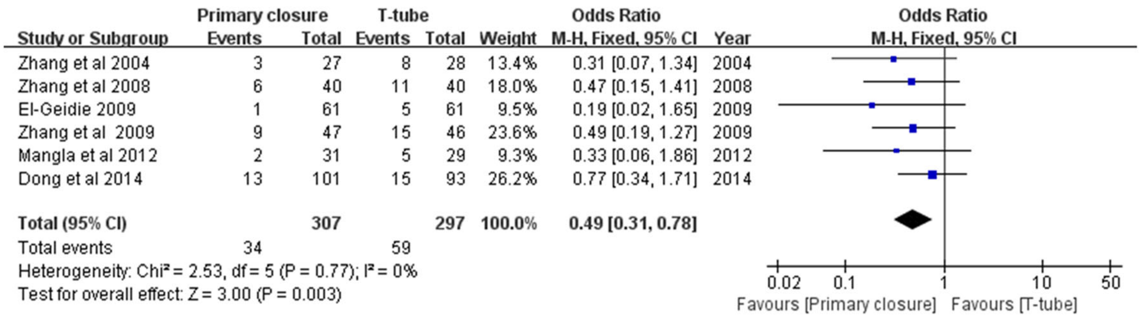

Fig. 7 Meta-analysis of total complications, CI: confidence interval, primary closure vs. T-tube drainage

tube drainage increased the incidence of postoperative bile infection and wound infection [40]. Therefore, the use of the T-tube may just be prescriptive for the surgeon.

Moreover, consistent with other studies [39, 41, 42], there were no statically significant differences for the incidence of residual stones between the two groups. According to the point of view of Khaled et al. [43], the rate of residual stones varies from 0 to 3.5% in patients with primary closure. Even several studies [22, 44] have shown that the incidence of residual stones reached up to 0%. The main reason was due to the use of choledochoscopy. In addition, laser-assisted bile duct exploration by laparoendoscopy and trans-infundibular approach both showed that ensured high rates of transcystic laparoscopic common bile duct exploration and low stone clearance failure rates when faced with most complex cases [45, 46]. Therefore, we considered that it was unnecessary to use T-tube for cholangiography and extraction of residual stones, and residual stones could be removed by EST after primary closure.

With respect to bile leak, which was the most common postoperative complications after T-tube drainage removal or accidental dislodgement in the TTD group [47]. Our findings indicated that primary closure did not increase the risk of postoperative bile leak after the operation. Several studies [42, 48] also proved that no significant differences were found between these two surgical techniques. Hence, it would seem that the insertion of T-tube does not prevent the occurrence of bile leakage. As for bile leakage caused by primary suture, the operative techniques of choledochotomy could reduce its occurrence. In the retrospective study of Hua et al. [49], the diameter of the CBD and successful duct clearance were found to be two important risk factors for postoperative bile leak. In addition, the wall thickness of the CBD was another important factor to prevent bile leak after primary duct closure [34].

During the follow-up, biliary stricture and mortality are two main concerns for patients who have undergone LCBDE. The rate of biliary stricture and mortality was very low in most studies. In the retrospective study of 160 patients by Estellés et al. [15], no cases of biliary stricture and mortality were detected during the follow-up. Yi et al. [50] reported no biliary strictures after LCBDE at a median follow-up of 48.8 months. Other surgeons also reported similar results during the long-term follow-up [39, 44, 51].

As we all know, randomized controlled trials are the best research subjects for meta-analysis. Although all of our included studies were RCTs, several limitations still exist which may lead to a decrease in reliability of the results in the present study. First, four of the six included studies were from China which may increase the risk of potential publication bias. Second, the number of cases was small in many included single-center studies. Third, it is very necessary to prolong the follow-up duration to further evaluate the incidence of biliary stricture and recurrent stones between the two groups.

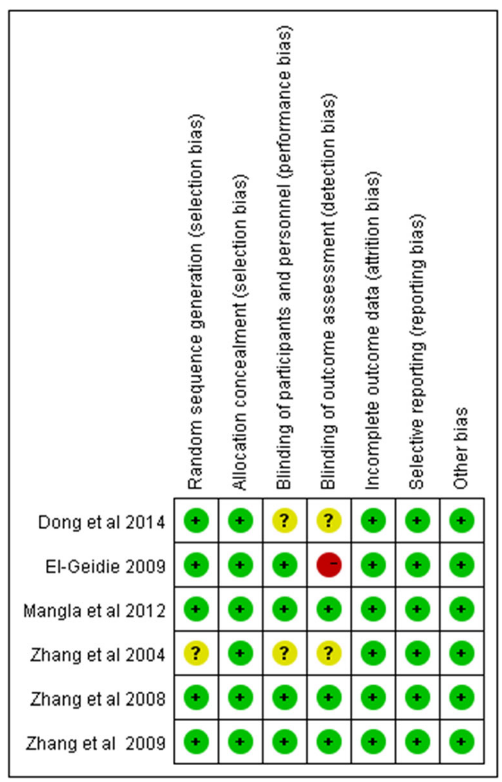

Fig. 8 Risk of bias summary: review authors' judgments about each risk of bias item for each included study. +: low risk of bias; −: low risk of bias; ?: unclear risk of bias

Conclusion

In conclusion, our findings demonstrate that LCBDE with PDC is a safe and useful procedure with shorter operating time, less medical expenditure, shorter postoperative hospital stay, and lower postoperative complications than TTD. What is more, PDC can achieve the same effect for the rate of bile leakage and stone clearance compared with TTD and avoid the disadvantages associated with the insertion of T-tube. Therefore, we state that LCBDE with PDC should be performed as a priority alternative compared with TTD for choledocholithiasis. On the other hand, cholecystectomies are usually performed by surgical trainees, and also transcystic intraoperative cholangiography can be safely performed. Of course, we expect large-sample, multicenter prospective randomized controlled trials to confirm these results.

Compliance with ethical standards

Conflict of interest The authors declare that they have no competing interests.

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