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ORIGINAL ARTICLE

Primary closure versus T-tube drainage after common bile duct exploration for choledocholithiasis

Qian D. Zhu · Chong L. Tao · Meng T. Zhou · Zheng P. Yu · Hong Q. Shi · Qi Y. Zhang

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Abstract
Purpose The aim of this study was to evaluate the benefits and harms of primary closure versus T-tube drainage after common bile duct (CBD) exploration for choledocholithiasis.
Methods A literature search of MEDLINE (PubMed), EMBASE, and the Cochrane Library was done to identify randomized controlled trials assessing the benefits and harms of primary closure versus T-tube drainage after CBD exploration from Jan. 1990 to Apr. 2010. A meta-analysis was set up to distinguish overall difference between the primary closure and the T-tube drainage group.
Results There were statistically significant differences between groups: biliary complications (odds ratio (OR) 95% confidence interval (CI), 0.42 (0.19–0.92); $P=0.03$), main complications (OR 95% CI, 0.46 (0.23–0.90); $P=0.02$), operating time (weighted mean difference (WMD) 95% CI, −19.53 (−29.35 to −9.71); $P<0.0001$), and hospital stay (WMD 95% CI, −4.16 (−7.07 to −1.24); $P=0.005$) except peri-operative mortality (OR 95% CI, 0.83 (0.11–6.37); $P=0.86$), residual stones (OR 95% CI, 0.70 (0.22–2.25); $P=0.55$), and abdominal collections (OR 95% CI, 1.93 (0.34–10.76); $P=0.46$). And the result of wound infection (OR 95% CI, 0.38 (0.14–1.02); $P=0.05$) tended to favor the primary closure group.
Conclusion The primary closure might be as effective as T-tube drainage after choledochotomy in the prevention of the development of post-operative complications.

Keywords T tube · Cholelithiasis · Choledocholithiasis · Choledochotomy · Common bile duct exploration

Q. D. Zhu · C. L. Tao · M. T. Zhou · Z. P. Yu · H. Q. Shi · Q. Y. Zhang (✉)
Department of General Surgery, The First Affiliated Hospital, Wenzhou Medical College,
Wenzhou 325003 Zhejiang, China
e-mail: wzqyzhang@163.com

Q. D. Zhu
e-mail: sinozqd@163.com

Introduction

Choledocholithiasis develops in about 5–15% of patients with gallbladder stones and is the second most frequent complication of cholecystolithiasis [1–4], representing a significant danger to patients because it can result to biliary colic, obstructive jaundice, cholangitis, or pancreatitis [5]. These patients may require surgical intervention to remove stones, such as choledochotomy, in which indications include the history or presence of any of the following: history of elevated liver function tests, history or presence of jaundice, biliary pancreatitis, radiographic evidence of a dilated ductal system, and radiographic visualization of common bile duct stones. Following common bile duct (CBD) exploration and stone removal, the choice lies between primary closure and T-tube drainage [3, 6–8].

T-tube drainage of the CBD has been standard surgical practice for most of this century [9]. It is performed for the following reasons: (1) post-operative decompression of the CBD if outflow obstruction occurs, (2) post-operative visualization of the CBD by X-ray, and (3) availability of a T-tube to extract CBD stones with a Burhenne steerable catheter [9, 10]. However, its usage is not without morbidity and produces complications up to 10% of patients [3, 6]. Some of these complications are serious, such as tract infection and bile leak resulting from T-tube displacement or early removal without adequate tract formation [3], which can lead to reoperation and even death, particularly in elderly patients. In addition, the patients have to carry it for several weeks before removal and suffer from significant discomfort and delayed return to work [6, 8]. In particular, the availability and the routine application of choledochoscopy and endoscopic retrograde choledochopancreatography (ERCP) have reduced the importance of these indications for T-tube drainage [11–14].

On the other hand, primary closure has long history, too [15, 16]. There are also many advantages of primary closure after CBD exploration, including discharge and return to work early, decreased post-operative complications, and no discomfort due to T-tube. Many papers support the direct closure of the CBD immediately after exploration [9, 17–20].

There is no conclusive evidence displaying whether primary closure is better or worse than T-tube drainage after CBD exploration. It is appropriate to make a meta-analysis to evaluate the benefits and harms of primary closure versus T-tube drainage after CBD exploration with all the results of the most recent randomized controlled trials (RCTs) in the new era of management of biliary disease from Jan. 1990 to present (Apr. 2010).

Methods

Inclusion and exclusion criteria

Inclusion criteria were established before the search. The RCTs which evaluated the benefits and harms of primary closure versus T-tube drainage after CBD exploration were considered for inclusion. Its major outcomes were biliary complications, residual stones, and main complications. The language of the original articles was unlimited with a limit to date from Jan. 1990 to Apr. 2010. Reviews, articles, retrospective analyses, and quasi-randomized trials (where the method of allocating participants to a treatment are not strictly random) were not included, and studies were excluded from the results searched if there were none with post-operative major outcomes.

Identification of trials and search strategies

We searched all publications which compared primary closure with T-tube drainage after CBD exploration through computerized searches of MEDLINE (PubMed), EMBASE, and the Cochrane Library from Jan. 1990 to Apr. 2010 using the terms T tube, cholelithiasis, choledocholithiasis, common bile duct exploration, and choledochotomy with the Boolean operator. In addition, comprehensive randomized clinical trials would be sought through personal search of reference lists of published articles and reviews, and bibliographies concerned were searched by hand to identify additional trials to make sure that all the potential studies are included.

Definitions of complications

Peri-operative mortality was defined as the patients who died from any reason before discharge. Biliary complications meant complications which related to bile or biliary tract, including biliary peritonitis, biliary pancreatitis, jaundice due to post-operative CBD obstruction, and bile leakage, irrespective of which intervention was needed. Residual stones were detected by cholangiograhy, T-tubogram, or intra-abdominal sonography. Main complications included biliary complications and residual stones, which show the effect of operation. Wound infection was a wound requiring partial or complete opening for drainage, including T-tube tract infection. Abdominal collections meant intra-abdominal collections requiring intervention. Operating time was the number of minutes which the operation continues. Hospital stay was defined as the number of days from date of operation to discharge.

Data extraction

Data was independently extracted from every study applying a standardized review form by our two reviewers (Zhu and Tao), and then cross-checked. One of the two reviewers was blinded to the source of the publications and the authors' names to reduce the bias. Inconsistencies between reviews' data were resolved through discussion until a consensus was reached, or else, the third person (Zhou) would take part in the discussion. The methodological quality of each trial was assessed by the same two reviewers using the Jadad scoring system which based on perfect randomization (generation and concealment), proper blinding, and an adequate description of withdrawals and dropouts [21]. In this meta-analysis, proper blinding was not feasible, and inadequate blinding was given a 0 score. We considered the study to be of high quality if the Jadad score of a study is equal to, or more than 3.

Statistical analysis

Meta-analysis was performed according to recommendations from the Cochrane Collaboration and the Quality of Reporting of Meta-analyses guidelines [22]. The effect outcomes estimated were odds ratio (OR) for dichotomous data and weighted mean difference (WMD) for continuous data, both reported with 95% confidence intervals (CIs). The OR value represents the odds of an adverse event happening in the primary closure group compared with the T-tube drainage group, and the OR value of less than 1 favors the primary closure group. The point estimate of the OR value is considered statistically significant at P level of less than 0.05 if the 95% CI does not cross the value 1. The WMD value represents the difference of operating time or hospital stay happening in the primary closure group compared with the T-tube drainage group, and the WMD value of less than 0 favors the primary closure group. The point estimate of the WMD value is considered statistically significant at *P* level of less than 0.05 if the 95% CI does not cross the value 0.

Heterogeneity was evaluated using the Chi-square test, and a *P* value of less than 0.1 was considered statistically significant. Fixed effect model would be used throughout unless a *P* value of heterogeneity was less than 0.1. Analysis was performed using the statistical software Review Manager version 4.2 (Cochrane Collaboration, Software Update, Oxford, UK).

Results

The search strategy identified six randomized trials that met inclusion criteria, five [3, 6–8, 23] retrieved from MEDLINE (PubMed) and one [9] from reference reviews, excluding three [24–26] RCTs with different reasons (Fig. 1). They all estimate the benefits and harms of primary closure versus T-tube drainage after CBD exploration, but there are some differences between the two groups, such as Jadad score, antibiotic prophylaxis, surgical method, abdominal drains, suture techniques, T-tube type, and the time of T-tube removal (Table 1). There were 392 patients in all examined (Table 2). The demographics between groups were all similar including age, gender, and diagnosis.

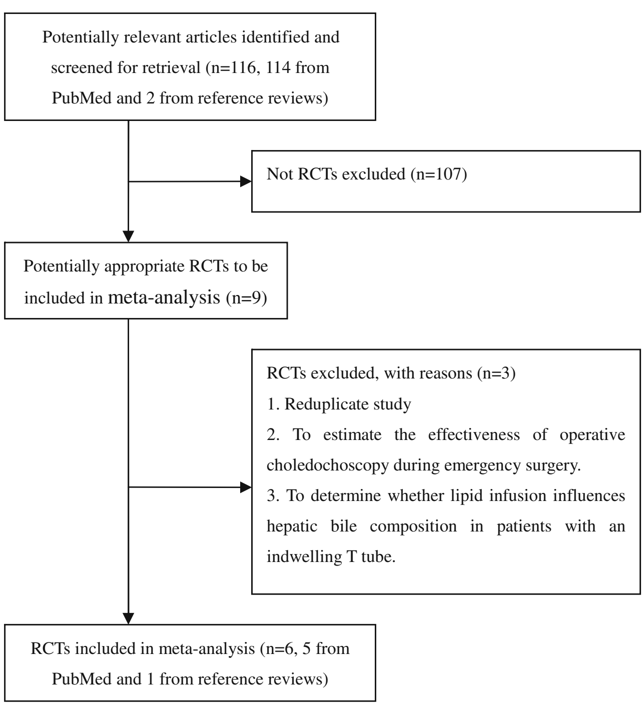

Fig. 1 Search strategy for randomized controlled trials evaluating the benefits and harms of primary closure versus T-tube drainage after common bile duct exploration. *RCT* randomized controlled trial

Forest plots (Figs. 2, 3) were constructed to compare peri-operative mortality, biliary complications, residual stones, main complications, wound infection, abdominal collections, operating time, and hospital stay between the two groups. Heterogeneity between studies was not significant, and fixed effect model was used, exceeding hospital stay, then the random effect model was used.

Peri-operative mortality

Peri-operative mortality was examined in five studies. One patient died from an acute myocardial infarction in the primary closure group and the other from rapidly spreading necrotizing fasciitis of abdominal wall and septicemic shock in the T-tube drainage group. And there was no statistically significant difference between the two groups (OR 95% CI, 0.83 (0.11–6.37); *P*=0.86).

Biliary complications

Biliary complications related to bile or biliary tract in straight-way, which is one of the main evaluation criteria for CBD exploration, and was mentioned in six studies. The difference was statistically significant between groups (OR 95% CI, 0.42 (0.19–0.92); *P*=0.03), and the result favored the primary closure group.

Residual stones

Residual stones were referred to in six trials. And the rate of residual stones all maintained at an acceptable level (4/197 and 6/195, respectively, in the primary closure group and T-tube drainage group). There was no statistically significant difference between the two groups (OR 95% CI, 0.70 (0.22–2.25); *P*=0.55).

Main complications

Main complications included biliary complications and residual stones, which show the effect of operation, and were reported in six studies. The statistically significant difference was achieved, and the result favored the primary closure group (OR 95% CI, 0.46 (0.23–0.90); *P*=0.02).

Wound infection

Wound infection was investigated in five studies. There was no statistically significant difference between the groups (OR 95% CI, 0.38 (0.14–1.02); *P*=0.05). However, the result tended to favor the primary closure group.

Table 1 Characteristics of included studies

Study	Antibiotic prophylaxis	Surgical method	Abdominal drains	Suture techniques	T-tube type	T-tube removal	Follow-up
Williams 1994	Yes	Open	Yes	NM	NM	10th day	No patients in either group developed jaundice or pancreatitis, nor needed further biliary surgery after the operation for a median of 2.7 years in the primary closure group and 2.8 years in the T-tube group.
Marwah 2004	Yes	Open	Yes	Continuous 4-0 vicryl suture in the primary closure group	Guttered T-tube of 12 F diameter	12th day	At one month, 3 months, and 6 months follow-up, neither the symptoms nor the ultrasonography was suggestive of retained stones or biliary stricture in any patient.
Perez 2005[a]	NM	Open	Yes	Interrupted absorbable sutures (Vicryl 3-0 or 4-0)	12 F, 14 F, or 16 F	14–30 days	NM
Zhang 2008	NM	Laparoscopic	Yes	Running absorbable suture (4-0 vicryl) in the primary group and interrupted sutures (4-0 vicryl) in the T-tube group	Latex rubber T-tube of appropriate size (14–20 F)	3 to 4 weeks	The follow-up period was 6–54 months (average, 25 months). There was no occurrence of bile duct stones or bile duct stricture in either group.
Ambreen 2009	Yes	Open	NM	NM	NM	20th day	There was not any recurrence of common bile duct stones seen up to 6 months follow up and post-operative ultrasound findings were almost normal.
Zhang 2009	NM	Laparoscopic	Yes	4-0 absorbable sutures (4-0 vicryl) in the primary closure group and interrupted sutures in the T-tube group (4-0 vicryl)	Latex rubber T-tube of appropriate size (14–20 F)	3 to 5 weeks	Follow-up assessment using ultrasound was carried out for 3 to 24 months in the outpatient clinic, with MRCP or ERCP used when indicated.

NM not mentioned

[a] The stent (5 F or 6 F depending on the common bile duct diameter) was positioned at the distal end in the duodenum and the proximal end in the biliary tract and removed by upper gastrointestinal endoscopy mean 34.9 days after surgery

Table 2 Basic data of included studies

Study	Country	Jadad score	Grouping	Peri-operative mortality	Biliary complications	Residual stones	Main complications	Wound infection	Abdominal collections	Hospital stay d (SD or range)	Operating time min (SD or range)
Williams 1994	Australia	3	37 vs 26	1 vs 0	0 vs 1	0 vs 1	0 vs 2	3 vs 1	1 vs 0	8 (4–24) vs 11 (8–28)	120 (80–180) vs 120 (50–210)
Marwah 2004	India	3	20 vs 20	0 vs 1	0 vs 2	0 vs 0	0 vs 2	0 vs 4	–	4.4 vs 15.4	87.75 vs 116.65
Perez 2005	Chile	2	37 vs 44	0 vs 0	1 vs 1	0 vs 3	1 vs 4	0 vs 2	1 vs 0	5.2 (3.3) vs 6.8 (4.7)	–
Zhang 2008	China	3	40 vs 40	0 vs 0	3 vs 7	1 vs 1	4 vs 8	1 vs 1	1 vs 1	5.2 (2.2) vs 8.3 (3.6)	116 (54.6) vs 133 (58.3)
Ambreen 2009	Pakistan	2	16 vs 19	–	1 vs 3	0 vs 0	1 vs 3	–	–	5.1 (1.1) vs 13.6 (2.3)	–
Zhang 2009	China	2	47 vs 46	0 vs 0	4 vs 7	3 vs 1	7 vs 8	1 vs 5	–	5.1 (1.6) vs 8.4 (2.8)	106 (22.6) vs 126 (29.5)

Primary closure group vs T-tube drainage group

Abdominal collections

There were three studies reporting the result of abdominal collections, and the difference between the groups was not statistically significant. (OR 95% CI, 1.93 (0.34–10.76); P=0.46).

Operating time

There were four trials providing information regarding operating time, but only two studies reported the mean and standard deviation, including 173 patients, on which we calculated the WMD. The result of pooled analysis showed statistically significant difference between the two groups (WMD 95% CI, −19.53 (−29.35 to −9.71); P<0.0001).

Hospital stay

Hospital stay was involved in six RCTs, and four studies reported the mean and standard deviation. We calculated the WMD based on these four studies. The random effect model was used because of significant heterogeneity (P< 0.00001) between studies, and the overall effect suggested a significant difference between the two groups (WMD 95% CI, −4.16 (−7.07 to −1.24); P=0.005).

Sensitivity analysis

When the studies of low quality (Jadad scores less than 3) were deselected, Williams 1994, Marwah 2004, and Zhang 2008 were included, and their major outcomes were analyzed again. The results were almost the same as those when all studies selected: biliary complications (OR 95% CI, 0.31 (0.09–1.03); P=0.06), residual stones (OR 95% CI, 0.51 (0.07–3.83); P=0.51), and main complications (OR 95% CI, 0.32 (0.11–0.95); P=0.04) (Fig. 4).

Discussion

The successful introduction of laparoscopic cholecystectomy by Muhe in 1985 ushered in a new era of management of gallbladder and biliary disease [27]. In the new era about two decades, the management of CBD stones has significantly changed and the prognosis of cholelithiasis has greatly been improved with the progress of surgical techniques and laboratory examinations. For choledocholithiasis, there are two methods for CBD exploration to extract stones: either endoscopically, by ERCP with or without sphincterotomy, or surgically, by an open or laparoscopic method [7]. ERCP is a good starting point in

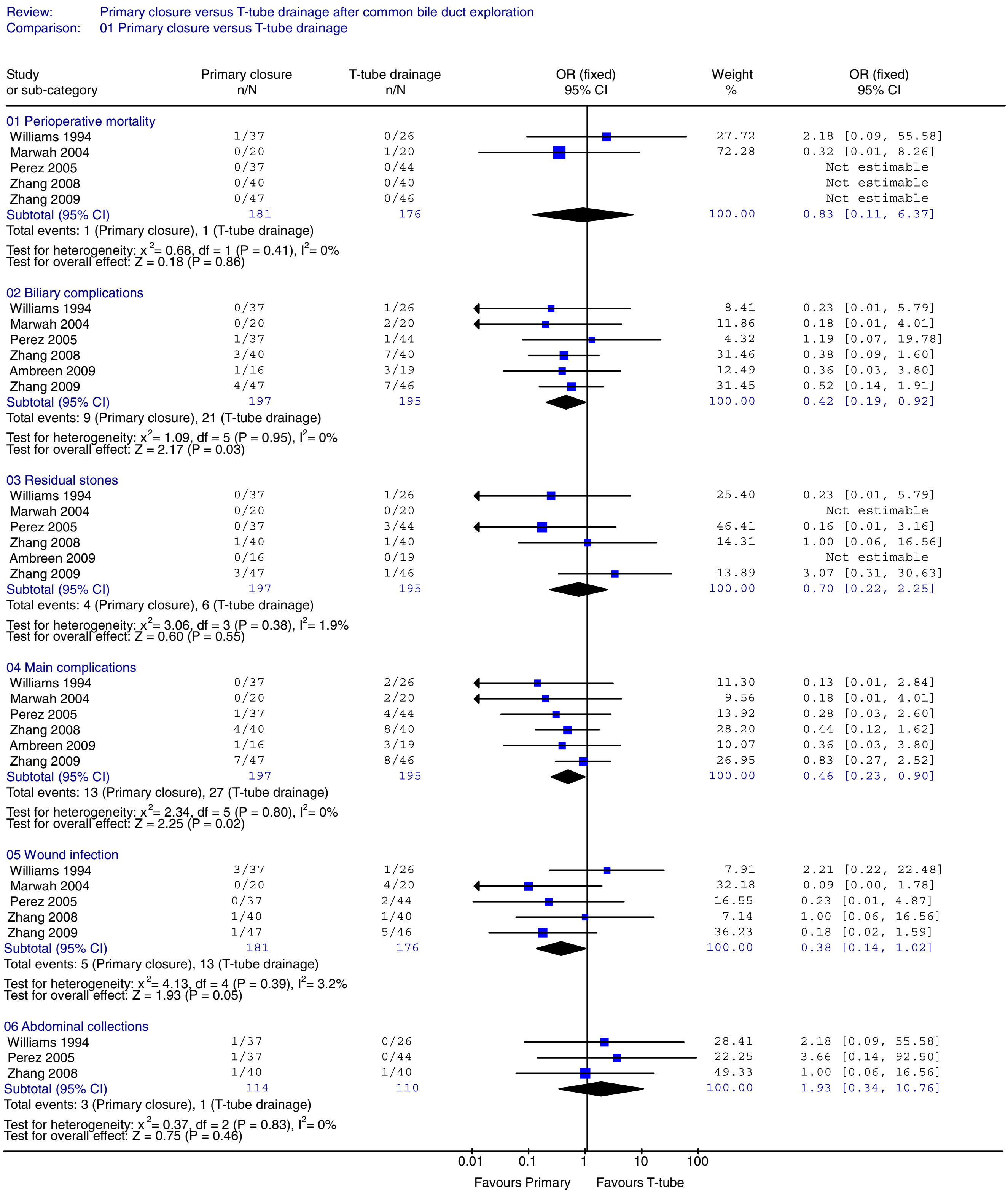

Fig. 2 Forest plot illustrating all dichotomous results of meta-analysis comparing primary closure group with T-tube drainage group. *OR* odds ratio, *CI* confidence interval. Test for heterogeneity: chi-squared statistic with its degrees of freedom (*df*) and *P* value. Inconsistency among results: I^2. Test for overall effect: *Z* statistic with *P* value. Fixed effect model was used

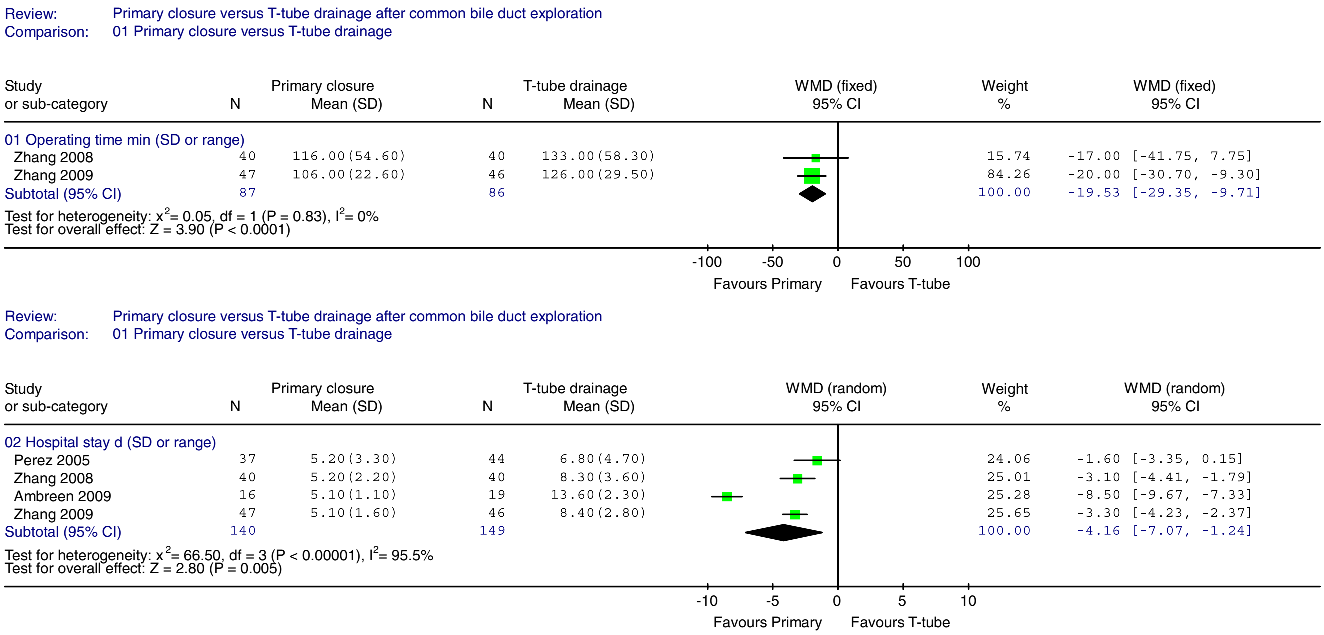

Fig. 3 Forest plot illustrating all continuous results of meta-analysis comparing primary closure group with T-tube drainage group. *WMD* weighted mean difference, *CI* confidence interval, *SD* standard deviations. Test for heterogeneity: chi-squared statistic with its degrees of freedom (*df*) and *P* value. Inconsistency among results: I^2 Test for overall effect: *Z* statistic with *P* value. Fixed effect model was used for operating time and random effect model was used for hospital stay

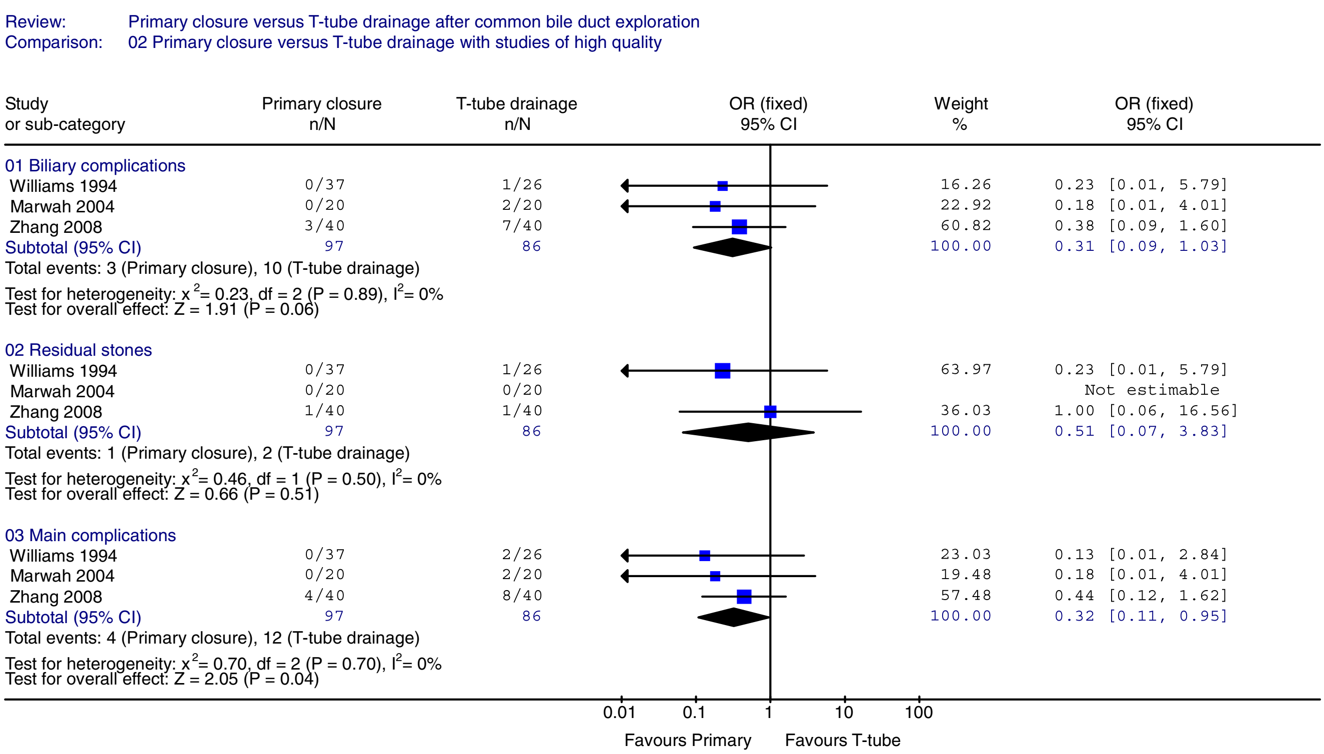

Fig. 4 Forest plot illustrating main outcomes of the meta-analysis excluding the studies of low quality comparing primary closure group with T-tube drainage group. *OR* odds ratio, *CI* confidence interval. Test for heterogeneity: chi-squared statistic with its degrees of freedom (*df*) and *P* value. Inconsistency among results: I^2 Test for overall effect: *Z* statistic with *P* value. Fixed effect model was used

patients in whom stones are known to be present or strongly suspected pre-operatively. But it is most logical to continue with CBD exploration if the stones are found during the course of operation. The inherent risk of the post-operative ERCP is that, if stones could not be removed successfully, the patients have to return to the operating room for another procedure.

Open CBD exploration has been the principal treatment for almost 100 years and still is considered the gold standard for the removal of CBD stones [5]. At the same time, the laparoscopic management is well known these days gradually, with over 80% of gallbladders removed laparoscopically [7, 28]. However, biliary complications cannot be avoided completely in any way. They are the most dangerous post-operative disadvantages and occur more easily when the pressure of biliary tract is higher, which is associated with high mortality, particularly in elderly patients. And patients who developed biliary complications have a significantly longer hospital stay than those with an uncomplicated course.

To decompress the biliary tree and avoid biliary complications, T-tube is employed. And it has been the method of choice for years [9, 29, 30]. It is true that the T-tube drainage has been proven to be a safe and effective method for post-operative biliary decompression, but it is not exempt from complications, which are present in up to 10% of patients [3]. The T-tube acts as a foreign body around which bile pigments and bile salts may precipitate [31], and the incidence of recurring stones would be greater in patients with choledochotomy followed by T-tube drainage. And significant bile leak following T-tube removal is said to occur in 1.2%–30% of cases [32]. Moreover, T-tube drainage is associated with increased bile infection and wound infection.

The other reasons for considering the employment of T-tube drainage after choledochotomy are to extract the residual stones through the T-tube tract and to make post-operative visualization of the CBD [9, 29, 30]. But these objectives can also achieved with intra-operative choledochoscopy and post-operative ERCP. Intra-operative choledochoscopy can decrease residual stones to a large extent and make sure unobstructed CBD under direct observation during operation. If there are residual stones by any chance, the stones can be extracted by ERCP, and biliary drainage can recover similarly.

At the same time, there are lots of RCTs arriving at a conclusion that the primary closure of CBD following routine choledochotomy was a safe alternative to the insertion of a T-tube [6–9, 33]. Even Marwah et al. [23] and Lygidakis [34] concluded that there were more post-operative morbidity and mortality with T-tube drainage compared with primary duct closure. However, the sample size was small.

Gurusamy et al performed two meta-analyses with regard to primary closure versus T-tube drainage after either open or laparoscopic common bile duct exploration in 2007 [19, 20] using data from six studies and one study, respectively, which reached a conclusion that primary closure after CBD exploration seemed at least as safe as T-tube drainage. But the number of patients included was small and the up-to-date studies were not included. And the early studies prior to lap chole era might not be useful to current practice because of improved effect of surgery nowadays.

Different from previous studies, such as the work of Gurusamhy and colleagues, this meta-analysis achieved a statistically significant difference between the primary closure group and the T-tube drainage group in the prevention of post-operative complications, such as biliary complications and main complications, which showed the different effects of the management of biliary disease. And it displayed that operating time and hospital stay were less statistically significant in the primary closure group. Sensitivity analysis confirmed that our results are reliable.

Our meta-analysis showed that the difference for peri-operative mortality was not statistically significant (P=0.86). Two deaths occurred: one patient died from an acute myocardial infarction in the primary closure group and the other from rapidly spreading necrotizing fasciitis of abdominal wall and septicemic shock because of peri-tubal bile leakage in the T-tube drainage group [23]. The former may be nothing to do with the surgical procedure. It seemed that most complications in the T-tube drainage group were related to the use of the T-tube [8]. A study illustrated that T-tube drainage after choledochotomy was associated with an increased incidence of post-operative bile infection, which had been seen to contribute to the observed high incidence of post-operative bacteremia and deaths from infection [34].

Biliary complications meant complications which are related to bile or biliary tract, including biliary peritonitis, biliary pancreatitis, jaundice due to post-operative CBD obstruction, and bile leakage, irrespective of which intervention was needed. And main complications included biliary complications and residual stones. This meta-analysis showed statistically significant difference between groups for biliary complications (P=0.03) and main complications (P=0.02). T-tube drainage not only failed to minimize the risk, but tended to increase the feasibility of dangerous complications and lower the effect of management of surgery.

The difference between the groups was not statistically significant for residual stones (P=0.55). Whether residual stones occurred or not had nothing to do with either primary closure or T-tube drainage. Several studies had showed that residual stone rate was low because of the application of intra-operative choledochoscopy, even up to 0% [6–8]. It was not of importance anymore for this T-tube drainage indication, and ERCP could be applied post-operatively in case of residual stones. Wound infection was investigated, too. The result tended to favor the primary closure group ($P=0.05$).

This meta-analysis demonstrated statistically significant difference for operating time ($P<0.0001$) and hospital stay ($P=0.005$) between the groups. Operative time was impacted by the complexity of surgery mainly, and hospital stay was influenced by the clinical outcome of individual patients. As the population ages and the number increases in elderly patients, it might be clinically significant to reduce operation time for reduction in peri-operative mortality. Reduction in hospital stay could save medical costs and decrease the incidence of nosocomial infections, especially in elderly patients.

In addition, the patients could not go home with a functioning T-tube until a T-tube cholangiogram had been performed, and the risks of dehydration and saline depletion in patients with open T-tube at home are contraindications to this technique [8]. On the other hand, the old latex tube was very irritant and could safely be removed within a week or so. But the current siliconised T-tube requires 4–6 weeks in situ to produce a reliable tract. This increases the morbidity and discomfort of T-tube drainage for the majority of our patients. It is unacceptable and uncomfortable for patients to go home with a functioning T-tube

Conclusions

Our meta-analysis tended to favor primary closure over T-tube drainage in the prevention of the development of post-operative complications and confirmed the safety and feasibility of primary closure after choledochotomy for choledocholithiasis. In effect, primary closure avoids the disadvantages associated with the use of T-tube, including significant discomfort, inconvenience to take along and longer hospital stay. To take all into account, primary duct closure might be recommended based on our meta-analysis, and it is urgent to carry out an RCT of high quality with large sample to further evaluate the efficacy of primary closure after CBD exploration.

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