



Value of T-tube in biliary tract reconstruction during orthotopic liver transplantation: a meta-analysis

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Abstract: Objective: To compare biliary complications after biliary tract reconstruction with or without T-tube in orthotopic liver transplantation. Methods: Randomized control trials (RCTs) and comparative studies were identified by a computerized literature search of the Cochrane Library, MEDLINE (1966/1–2010/4), Scopus (1980/1–2010/4), ClinicalTrials.gov (2010/4), the Cochrane Hepato-Biliary Group Controlled Trials Register, and the Cochrane Central Register of Controlled Trials. Studies and data were extracted and assessed independently. Dichotomous outcomes were reported as odds ratios (ORs) and weighted mean difference with 95% confidence intervals (CI). Results: Five RCTs and eight comparative studies with a total of 1608 subjects were identified. The data showed that the operation with T-tube had better outcomes for duct stenosis ($P=0.01$, $OR=0.45$, 95% CI 0.24–0.85). The operations with or without T-tube had equivalent outcomes as follows: overall biliary complications ($P=0.85$, $OR=1.15$, 95% CI 0.28–4.72), bile leaks ($P=0.38$, $OR=0.75$, 95% CI 0.39–1.42), and cholangitis ($P=0.24$, $OR=4.64$, 95% CI 0.36–60.62). These results were strengthened by the analysis of all thirteen non-randomized and randomized studies. Conclusions: Our systematic review and meta-analysis suggest that the insertion of a T-tube reduces the incidence of biliary stenosis without increasing the incidence of other biliary complications.

Key words: Liver transplantation, Drainage, Biliary tract, Meta-analysis, T-tube

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1 Introduction

Biliary tract reconstruction is a crucial factor in orthotopic liver transplantation (OLT) (Wojcicki *et al.*, 2008; Duailibi and Ribeiro, 2010), and biliary complications, particularly biliary leaks and strictures, are major causes of morbidity and mortality after surgery (Verdonk *et al.*, 2006; Welling *et al.*, 2008). The end-to-end or side-to-side choledochocholedochostomy (CCS) reconstruction program for OLT has been accepted by most transplant centers (Davidson *et al.*, 1999; Castaldo *et al.*, 2007). The T-tube is widely used in CCS as a stent of the biliary tract, for it can not only protect against anastomotic strictures, but also help to monitor the flow and color of bile, and

makes it easy to perform cholangiography when necessary (Lerut *et al.*, 1987; Shaked, 1997; de Simone *et al.*, 2005). However, some studies have found that the introduction of a T-tube may increase the risk of biliary complications such as bile leaks around the tube, cholangitis, and peritonitis after T-tube removal, as well as increasing the costs of diagnosis and treatment (Vougas *et al.*, 1996; Scatton *et al.*, 2001; Amador *et al.*, 2005).

Whether or not to use a T-tube in reconstruction remains controversial. In order to evaluate whether using a T-tube in CCS is associated with complications, a systematic review was conducted by Sotiropoulos *et al.* (2009). They found that CCS without a T-tube has better outcomes with lower incidences of cholangitis and peritonitis, and fewer overall biliary complications, favoring the abandonment of the T-tube in OLT. In fact, many transplantation centers

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advise reconstruction without a T-tube, while some still prefer to use a T-tube for its inherent advantages.

More recent trials have indicated that the use of a T-tube is associated with fewer overall biliary complications (Weiss *et al.*, 2009). In the present report, the new data were pooled and a new meta-analysis was conducted to evaluate whether the use of T-tubes is accompanied by fewer biliary complications.

2 Materials and methods

2.1 Search strategy and selection criteria

To find relevant studies, we used the standard search strategy of the Cochrane Review Group to search the English literature in the Cochrane Library, MEDLINE (1966/1–2010/4), Scopus (1980/1–2010/4), ClinicalTrials.gov (2010/4), the Cochrane Hepato-Biliary Group Controlled Trials Register, and the Cochrane Central Register of Controlled Trials. The search terms were “Liver Transplantation” and “T-tube” (or “T” or “T tube” or “Stents”) and “Biliary tract reconstruction” (or “Bile ducts reconstruction” or “Biliary tract” or “Bile ducts”). Further data from the reference lists of primary and review articles were also gathered by manual search.

Inclusion criteria were: (1) trials including adult OLT recipients (≥ 16 years), (2) trials using CCS to reconstruct the biliary tract, (3) primary reports including at least one biliary complication (bile leaks or fistula, anastomotic or nonanastomotic stricture, and cholangitis) and overall biliary complications. All randomized control trials (RCTs) and comparative studies were considered, while reviews and commentaries were excluded. The other exclusion criteria were (1) liver recipient age less than 16 years, and (2) re-transplantation or combined multiple organ transplantation.

2.2 Data extraction

Data were extracted and assessed independently. Differences in opinion were discussed by all authors and a consensus was reached. We recorded the first author, publication year, sex, and mean age of subjects, number of subjects, interventions, and complications.

2.3 Intervention and outcome definition

With T-tube: after completion of the end-to-end

or side-to-side CCS, a T-tube was inserted into the bile duct. Without T-tube: CCS was performed either end-to-end or side-to-side without any stent.

The main biliary complications included were bile leaks, duct stenosis, and cholangitis. Bile leaks were indicated by the presence of symptoms such as fever and abdominal pain, or proven by B-ultrasonography or X-ray. Duct stenosis was suspected in subjects whose total bilirubin levels increased without allograft rejection or hepatic artery thrombosis. Alternatively, strictures were confirmed by endoscopic retrograde cholangiography or X-ray cholangiography. Cholangitis was suspected when infectious symptoms occurred in combination with cholestatic parameters.

2.4 Quality assessment

The Jadad composite scale was used to determine the qualities of the selected studies. The main parameters were: randomized study, description of randomization, double-blinded study, description of double blinding, and descriptions of withdrawals and dropouts. Each of these was scored as one point. Thus, a greater score indicated higher quality.

2.5 Statistical analysis

Analyses were performed with RevMan 5.0.23 (freeware available from the Cochrane Collaboration; <http://www.cochrane.org>). Odds ratios (ORs) and weighted mean difference with 95% confidence intervals (CI) were calculated to describe the results of dichotomous outcomes. The χ^2 and I^2 statistics were used to assess heterogeneity (Higgins *et al.*, 2003) where $P < 0.01$ or $I^2 > 50\%$ were considered as significant heterogeneity. The fixed effects model was used to estimate the cases with homogeneity, and the random effects model was used for the cases with significant heterogeneity (Lau *et al.*, 1997; Biondi-Zoccai *et al.*, 2005). Bias was evaluated by funnel plots.

3 Results

3.1 Qualities and characteristics of studies

Of the 99 reports published between 1966 and 2010, 24 were considered to be potentially eligible and the full-text versions were retrieved. After

reviewing each study, five RCTs (Vougas *et al.*, 1996; Nuño *et al.*, 1997; Scatton *et al.*, 2001; Amador *et al.*, 2007; Weiss *et al.*, 2009) and eight comparative studies (Rouch *et al.*, 1990; Rolles *et al.*, 1994; Ferraz-Neto *et al.*, 1996; Randall *et al.*, 1996; Rabkin *et al.*, 1998; Shimoda *et al.*, 2001; Li *et al.*, 2007; Lin *et al.*, 2007) with a total of 1608 subjects were included (Fig. 1, Table 1).

The observation period was at least three months, except in one study, which lasted two months. In most studies, the T-tube was removed three months after operation, but in one study it was removed at nine weeks (Weiss *et al.*, 2009). Four RCTs scored three points on the Jadad scale and one scored two points. All comparative studies were retrospective, in which one was based on intention-to-treat (Shimoda *et al.*, 2001), and another had selection bias since the decision to insert a T-tube was made accordingly to the clinical needs of each individual (Li *et al.*, 2007). It

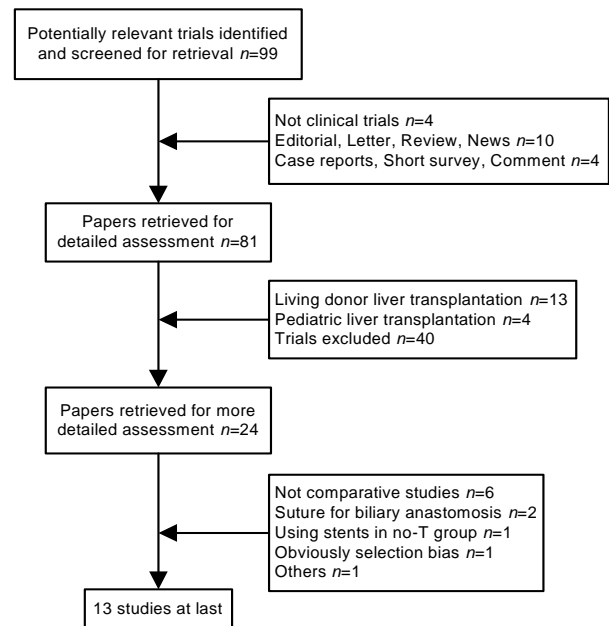


Fig. 1 Flowchart of the selection process of relevant articles

Table 1 Characteristics and results of included studies

Study	T-tube	Sample size ¹	Mean age ² (year)	Mean CIT ²	Jadad score	Number of subjects			
						Overall biliary complications	Bile leaks	Duct stenosis	Cholangitis
Weiss <i>et al.</i> (2009)	Y	99 (30/69)	53.34±9.81	597±159	3	27	5	7	5
	N	95 (35/60)	55.34±6.66	559±178		50	9	8	11
Lin <i>et al.</i> (2007)	Y	51 (6/45)	50.14±9.96	NR	1	5	1	5	NR
	N	53 (6/47)	51.95±9.91	NR		9	1	8	NR
Li <i>et al.</i> (2007)	Y	33 (3/30)	47.20±9.40	479±98	1	10	4	5	1
	N	51 (5/46)	42.50±13.50	457±89		6	1	4	1
Amador <i>et al.</i> (2007)	Y	53 (21/32)	51.80±9.40	362	3	32	6	2	8
	N	54 (24/30)	50.60±10.60	390		6	3	3	0
Shimoda <i>et al.</i> (2001)	Y	76 (33/43)	51.80±11.70	NR	1	25	4	5	NR
	N	71 (32/39)	52.90±12.30	NR		11	5	6	NR
Scatton <i>et al.</i> (2001)	Y	90 (28/62)	48.30±9.90	604±194	3	30	2	3	10
	N	90 (32/58)	49.20±9.50	570±153		14	2	6	0
Rabkin <i>et al.</i> (1998)	Y	118 (43/75)	47.70	610	1	43	3	7	NR
	N	44 (7/37)	48.00	522		11	1	10	NR
Nuño <i>et al.</i> (1997)	Y	50 (NR)	NR	NR	2	5	3	1	NR
	N	48 (NR)	NR	NR		16	8	8	NR
Ferraz-Neto <i>et al.</i> (1996)	Y	110 (NR)	NR	NR	1	26	18	3	NR
	N	89 (NR)	NR	NR		10	3	5	NR
Randall <i>et al.</i> (1996)	Y	59 (NR)	NR	NR	1	13	5	8	NR
	N	51 (NR)	NR	NR		7	0	7	NR
Vougas <i>et al.</i> (1996)	Y	30 (12/18)	42.00	678	3	5	1	2	2
	N	30 (13/17)	45.00	696		6	0	6	0
Rolles <i>et al.</i> (1994)	Y	16 (NR)	NR	NR	1	4	4	0	NR
	N	90 (NR)	NR	NR		20	10	10	NR
Rouch <i>et al.</i> (1990)	Y	22 (NR)	NR	NR	1	6	1	1	1
	N	35 (NR)	NR	NR		2	4	1	0

Y: yes; N: not; NR, not recorded; CIT, cold ischemia time. ¹ Total number (female/male); ² Mean±SD or mean

should be noted that five cases of living donor liver transplantation were included in the group without T-tube in one comparative study (Lin *et al.*, 2007). No statistical differences among the studies were found in age, gender, and cold ischemia time (data not shown).

3.2 Overall biliary complications

With regard to overall biliary complications, the I^2 statistics revealed significant heterogeneity in

the five RCTs (92%) and in all thirteen non-randomized and randomized studies combined (82%). And in the random effects model, no significant difference between “with T-tube” and “without T-tube” was detected by analysis of the RCTs ($P=0.85$, $OR=1.15$, 95% CI 0.28–4.72). This finding was mirrored by the results from the eight non-randomized studies ($P=0.15$, $OR=1.58$, 95% CI 0.85–2.94) (Figs. 2 and 3).

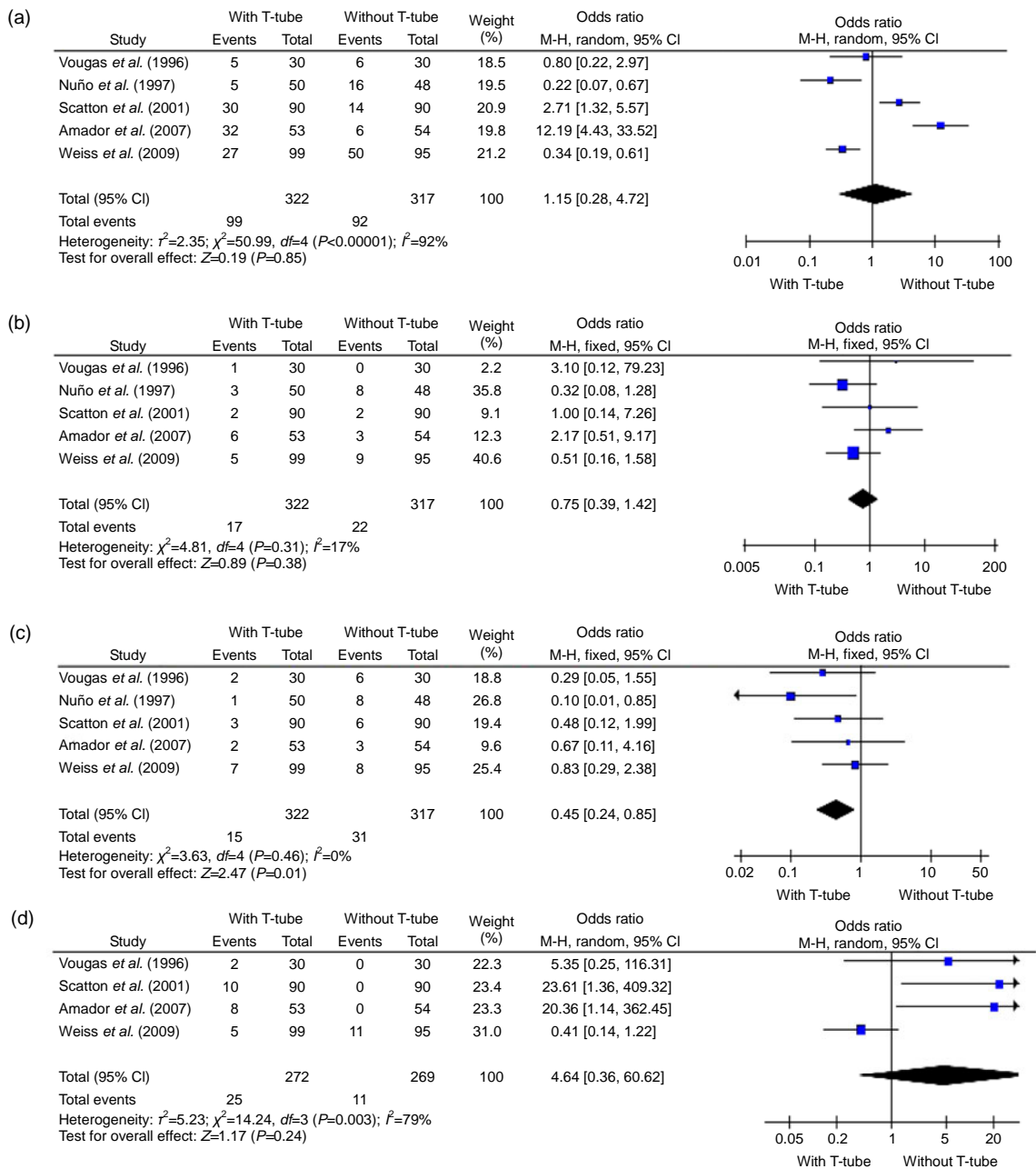


Fig. 2 Results from the meta-analyses of five RCTs

(a) Overall biliary complications; (b) Bile leaks; (c) Duct stenosis; (d) Cholangitis

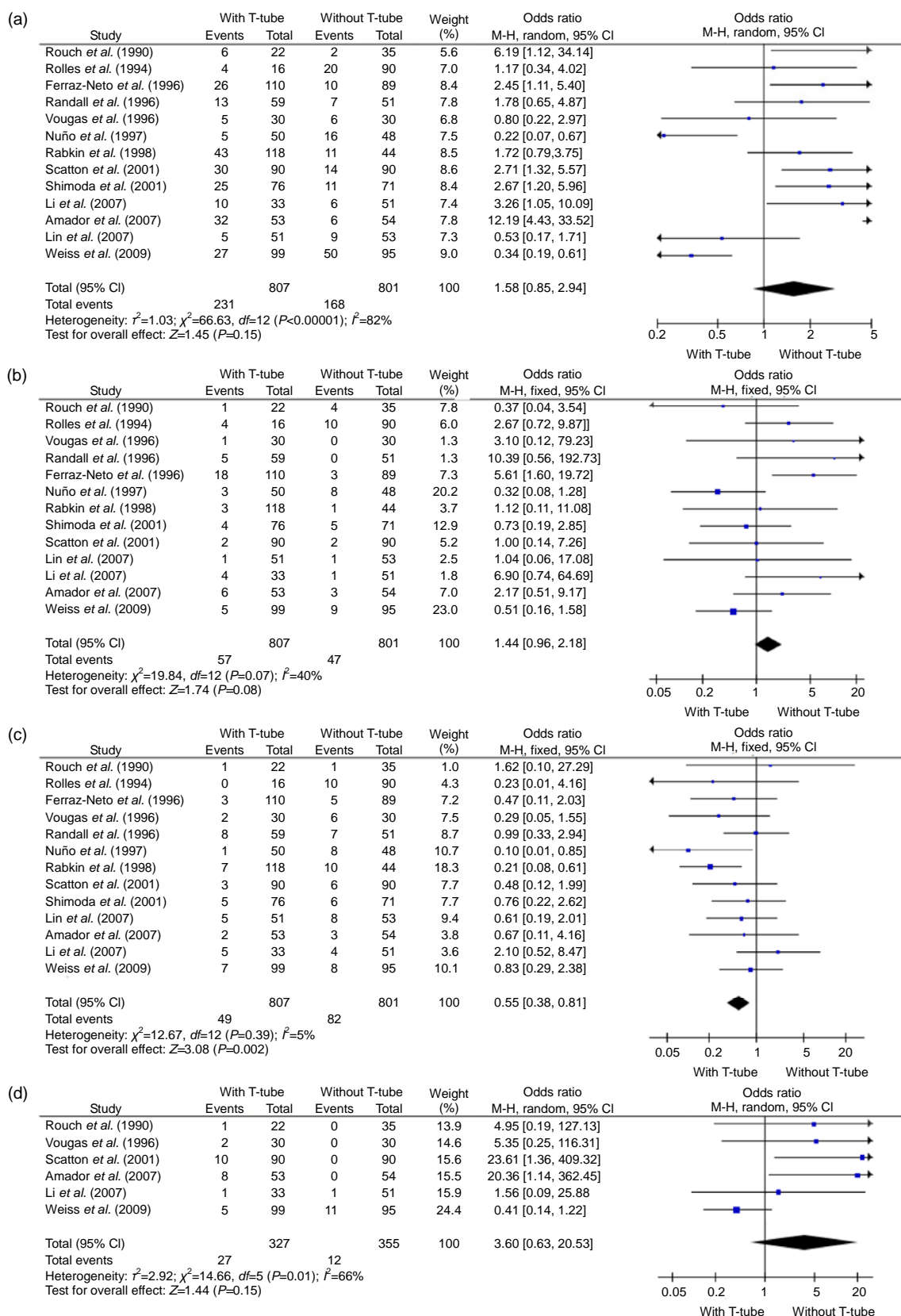


Fig. 3 Results from meta-analyses of non-randomized and randomized studies

(a) Overall biliary complications; (b) Bile leaks; (c) Duct stenosis; (d) Cholangitis

3.3 Bile leaks

Meta-analyses of the five RCTs showed no significant difference between “with T-tube” and “without T-tube” for the risk of bile leaks ($P=0.38$, OR=0.75, 95% CI 0.39–1.42). Similar results were seen in the analysis of all thirteen studies ($P=0.08$, OR=1.44, 95% CI 0.96–2.18). No significant heterogeneity was detected ($I^2=17%$ in RCTs and $I^2=40%$ in all studies) (Figs. 2 and 3).

3.4 Duct stenosis

Meta-analyses of the five RCTs and all thirteen studies by fixed effects models showed that “with T-tube” decreased the incidence rate of duct stenosis, and there was no significant heterogeneity ($P=0.01$, OR=0.45, 95% CI 0.24–0.85, $I^2=0%$ for five RCTs; $P=0.002$, OR=0.55, 95% CI 0.38–0.81, $I^2=5%$ for all thirteen studies) (Figs. 2 and 3).

3.5 Cholangitis

Only six studies contained data referring to cholangitis, four of which were RCTs. Heterogeneity was found in both groups, $I^2=79%$ in RCTs and $I^2=66%$ in all six studies. The lack of a significant difference between “with T-tube” and “without T-tube” was confirmed by the random effects model. For the analysis that only included RCTs, $P=0.24$, OR=4.64, 95% CI 0.36–60.62; for the analysis that included non-randomized studies, $P=0.15$, OR=3.60, 95% CI 0.63–20.53 (Figs. 2 and 3).

4 Discussion

Although analyses of the RCTs indicated a trend for fewer anastomotic and non-anastomotic strictures in the groups using a T-tube, the current results suggest that there was no significant difference between CCS with and without T-tube in terms of overall biliary complications, while no statistically significant difference was found in bile leaks. These findings were supported by the non-randomized studies. Considering the significant heterogeneity, we suggest that both groups have an equal risk of cholangitis. Our findings are in contrast to the conclusions drawn from the previous meta-analyses concerning overall biliary complications and cholangitis (Sotiropoulos *et al.*,

2009). Our analysis added three new studies: one was an RCT with a high Jadad score and the other two were comparative studies, among which one had selection bias and the other had five cases of living donor liver transplantation in the group without T-tube.

Reduction of the incidence of anastomotic or non-anastomotic strictures is considered an inherent advantage of using a T-tube in CCS. As in most studies, this was also demonstrated in our analysis. Actually, inserting a T-tube or other kinds of stent is still a useful method to treat biliary complications like strictures or leaks in no T-tube group (Qin *et al.*, 2006). It seems, however, to provide no advantage in controlling overall biliary complications, since bile leaks and cholangitis did not significantly differ between the “with T-tube” and “without T-tube” groups in our study. However, this may be partly due to the presence of biliary complications other than those considered in our study. Peritonitis and hepatic artery thrombosis were evaluated in a previous meta-analysis (Sotiropoulos *et al.*, 2009), which showed that peritonitis had a higher incidence rate in the group with a T-tube, while hepatic artery thrombosis did not significantly differ between the two groups. Since the new studies did not provide data about these complications, we did not include them in this study.

Bile leak is an inherent complication with T-tube, occurring either early at insertion or later when the tube is removed, but our results showed no significant difference between the groups with or without T-tube. Insertion site leaks in the early stage may be related to downstream obstruction or papillary dysfunction, but this kind of leaks can be resolved by non-surgical methods (Tan *et al.*, 2003). In addition, new techniques for removing the T-tube have been developed, and show good results (Cozzi *et al.*, 1995; Urbani *et al.*, 2002; Liao *et al.*, 2007). The surgeon’s experience with T-tube removal may be an important factor (Weiss *et al.*, 2009).

Cholangitis often seems to be a complication related directly to T-tube insertion. Interestingly, our results showed no difference between the two groups. Two main reasons account for cholangitis in the T-tube group: one is infection after cholangiography despite the prophylactic use of antibiotics, and the other is the risk at the time of T-tube removal. Both factors appear directly related to T-tube insertion.

Some studies have shown that not all cases with positive bile culture in the T-tube group go on to develop cholangitis (Scatton *et al.*, 2001; Weiss *et al.*, 2009). Thus, positive bile culture should not be equated to cholangitis.

The main limitation in this meta-analysis is that not all the included studies were RCTs, and three of the comparative studies had some kinds of bias. There were also a relatively small number of RCTs.

In conclusion, our systematic review and meta-analysis suggest that the use of a T-tube favored fewer strictures, although the overall biliary complications showed no significant difference. This also means that inserting a T-tube will reduce the incidence of biliary stenosis without increasing the incidence of other biliary complications. Surgeons should first consider the use of T-tube, especially if there are higher risks of the incidence of anastomotic or non-anastomotic strictures. Further large-scale clinical trials, especially with a longer observation period, should be designed to carefully evaluate the risks and the advantages of using a T-tube in OLTs.

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