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The safety of not implementing endoscopic nasobiliary drainage after elective clearance of choledocholithiasis: a systematic review and meta-analysis

Jie Yin[1], Dongying Wang[2], Yujing He[3], Hongcun Sha[1], Wenhao Zhang[2] and Wei Huang[1*]

Abstract

Background Endoscopic nasobiliary drainage (ENBD) is used as a drainage technique in patients with choledocholithiasis after stone removal. However, ENBD can cause discomfort, displacement, and other complications. This study aims to evaluate the safety of not using ENBD following elective clearance of choledocholithiasis.

Methods Relevant studies were identified by searching PubMed, Web of Science, EMBASE, EBSCO, and Cochrane Library from their inception until August 2023. The main outcomes assessed were postoperative complications and postoperative outcomes. Subgroup analyses were conducted based on study design types and treatment procedures.

Results Six studies, including three randomized controlled trials (RCTs) and three cohort studies, were analyzed. Among these, four studies utilized endoscopic techniques, and two employed surgical methods for choledocholithiasis clearance. The statistical analysis showed no significant difference in postoperative complications between the no-ENBD and ENBD groups, including pancreatitis (RR: 1.55, $p=0.36$), cholangitis (RR: 1.81, $p=0.09$), and overall complications (RR: 1.25, $p=0.38$). Regarding postoperative outcomes, the subgroup analysis indicated that the bilirubin normalization time was longer in the no-ENBD group compared to the ENBD group in RCTs (WMD: 0.24, $p=0.07$) and endoscopy studies (WMD: 0.23, $p=0.005$), although the former did not reach statistical difference. There was also no significant difference in the length of postoperative hospital stay between the groups (WMD: -0.30, $p=0.60$).

Conclusion It appears safe to no- ENBD after elective clearance of choledocholithiasis.

Keywords Choledocholithiasis, Endoscopic nasobiliary drainage, Endoscopic retrograde cholangiopancreatography, Laparoscopic common bile duct exploration, Meta-analysis

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Introduction

In recent years, changes in dietary factors and other influences have contributed to an increasing prevalence of choledocholithiasis as a significant health issue. Studies indicate that cholelithiasis affects 5-15% of the population, with choledocholithiasis accounting for 5-30% of these cases [1, 2]. Choledocholithiasis, a type of cholelithiasis, is classified into primary and secondary forms. Primary choledocholithiasis typically arises from biliary stasis, biliary tract infections, biliary strictures, or biliary parasite infections [3]. In contrast, secondary choledocholithiasis results from gallbladder stones [4]. Patients with choledocholithiasis often present with symptoms such as abdominal pain, chills, fever, and jaundice. Severe cases can lead to acute obstructive cholangitis, which significantly increases the risk of death, with mortality rates reaching up to 33% [5, 6].

Treatment options for choledocholithiasis have diversified in recent years, encompassing laparoscopic common bile duct exploration (LCBDE), endoscopic retrograde cholangiopancreatography (ERCP), endoscopic sphincterotomy (EST), endoscopic papillary balloon dilation (EPBD), and other endoscopic procedures [7–9]. Among these, endoscopic nasobiliary drainage (ENBD) has emerged as a technique used in conjunction with diagnostic ERCP. This procedure involves inserting one end of a nasal bile duct catheter into the appropriate part of the bile duct via duodenoscopy, with the other end exiting through the patient's nasal cavity [10]. ENBD was first utilized by Cotton et al. in conjunction with EST for the common bile duct [11]. Studies have shown that ENBD not only facilitates biliary drainage and perfusion but also allows for the evaluation of stone clearance rates through cholangiography [12, 13].

However, Lee et al. suggested that routine insertion of an ENBD tube may not be necessary [14]. Patients receiving ENBD can experience discomfort in the nostril and facial area and are required to use bile collection bags, which can be inconvenient. The necessity of ENBD as a treatment for patients undergoing elective clearance of choledocholithiasis remains a topic of debate. This study aims to systematically review and analyze previously published clinical studies to evaluate the safety of not implementing ENBD after elective clearance of choledocholithiasis, thereby providing updated guidance for postoperative care in these patients.

Methods

Search strategy

The objective of this study was to evaluate the safety of no-ENBD after conventional choledocholithiasis treatment. We conducted a comprehensive search of electronic databases, including PubMed, Web of Science, EMBASE, EBSCO, and the Cochrane Library, covering studies published up to August 2023. The study was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and was registered with the international Prospective Register of Systematic Reviews (PROSPERO) under registration number CRD42023462494. To ensure thoroughness, manual retrieval of references was also performed to identify any potential omissions. The search terms used included: (Nasal Bile Duct OR Nasobiliary OR Endoscopic Nasobiliary Drainage OR ENBD) AND (Choledocholithiasis OR Gallstones OR Gallstone OR Gall Stones OR Biliary Calculi OR Calculi, Biliary OR Gall Stone OR Common Bile Duct Calculi OR Biliary Calculi, Common Bile Duct OR Gallstones, Common Bile Duct OR Common Bile Duct Gall Stone OR Common Bile Duct Gallstones OR Gall Stones, Common Bile Duct OR Common Bile Duct Gallstone OR Common Bile Duct Gall Stones).

Selection criteria

Inclusion criteria:

1. Patients diagnosed with choledocholithiasis who underwent elective clearance of choledocholithiasis by endoscopy or surgery (including those with cholangitis or gallstones).
2. Patients categorized into two groups based on whether ENBD was performed.
3. Study designs included randomized controlled trials (RCTs) and/or observational studies (including case-control studies, cohort studies).

Exclusion criteria:

1. Studies that provided only an abstract with no available full text.
2. Studies not written in English.
3. Studies where data could not be statistically analyzed.
4. Studies including patients with ENBD for conditions other than choledocholithiasis (e.g., pancreatic cancer, cholangiocarcinoma, pancreatitis).
5. Studies that were updates or supplements, with priority given to those with the largest data sets or most recent publications.

Data extraction

Two researchers independently screened potential studies based on the inclusion and exclusion criteria. Data extraction was performed using a pre-designed table, and any discrepancies were resolved through discussion. The data extracted included information on the study authors, year of publication, country of study, recruitment period,

participant characteristics, participant exclusion criteria, sample size, primary and secondary outcomes, follow-up duration, and other relevant details.

Quality assessment

The quality of the included studies was assessed independently by two researchers. For RCTs, the Cochrane Collaboration Risk of Bias Tool (CCRBT) was used, evaluating seven aspects: random sequence generation, allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other potential sources of bias. Case-control and cohort studies were evaluated using the Newcastle-Ottawa Scale (NOS), focusing on three dimensions.

Outcome measures

The primary outcomes of this study were postoperative complications and postoperative-related outcomes in patients after elective clearance of choledocholithiasis, treated primarily through endoscopic methods (including ERCP, EST, EPBD) or surgical methods (including LCBDE). The focus was on evaluating the safety of not using ENBD in these patients.

Statistical analysis

Dichotomous variables were assessed using risk ratios (RR) with 95% confidence intervals (95% CI), while continuous variables were evaluated using weighted mean differences (WMD) with 95% CI. The I^2 test was utilized to assess heterogeneity, categorized as follows: $I^2 \leq 25\%$ (no heterogeneity), I^2 between 25% and 50% (mild heterogeneity), $I^2 > 50\%$ and $\leq 75\%$ (moderate heterogeneity), and $I^2 > 75\%$ (severe heterogeneity) [15]. A random-effects model was applied to enhance the robustness of the findings, considering the variability in treatments among patients with choledocholithiasis. Subgroup analyses were conducted based on study design types (RCTs or cohort studies) and treatment procedures (endoscopy or surgery) to identify potential sources of heterogeneity. Egger's test was used to evaluate publication bias when the number of included studies exceeded 10 [16]. Sensitivity analyses were also performed to test the stability of the results. All statistical analyses were conducted using RevMan 5.3, with a bilateral p-value of <0.05 considered statistically significant.

Results

Description of included trials

Based on the search criteria, 1,292 search terms were initially screened from electronic databases. After removing duplicate studies, 659 unique studies were retained. Following a detailed review of titles and abstracts, 648 studies were excluded for not meeting the inclusion criteria. The remaining 11 studies were further evaluated, leading to the exclusion of one study that included patients with non-choledocholithiasis conditions, one study due to the lack of full text, and two studies due to insufficient data. Additionally, one study was excluded because it was an updated version. Ultimately, six studies, including three RCTs and three cohort studies, met the inclusion criteria and were analyzed [9, 14, 17–20] (Fig. 1).

Characteristics of trials and patients

The six studies, published between 2010 and 2023, included three RCTs and three cohort studies, with nearly 1,000 subjects recruited between 2006 and 2022. Of these, 477 patients did not receive ENBD. The patient population primarily consisted of individuals with choledocholithiasis, including cases with cholangitis and gallstones. Four studies implemented ENBD following endoscopic stone removal, while two studies applied ENBD post-surgery. The studies were conducted in two countries, with five in China and one in Korea. The primary postoperative complications examined included pancreatitis, hyperamylasemia, cholecystitis, bleeding, bile leakage, and overall complications. Postoperative outcomes focused on bilirubin normalization time and postoperative hospital stay. The basic characteristics of the included studies are detailed in Table 1 and Supplementary Table 1.

Quality of studies and risk of Bias

The quality of the three included RCTs was assessed using the CCRBT. All three studies reported the use of computer-generated random numbers and indicated that neither participants nor researchers could predict group allocation, suggesting a 'low risk' of selection bias. One study was rated as 'high risk' for implementation and measurement bias due to the lack of blinding among participants, testers, and outcome evaluators. The other two studies were rated as 'unclear' in this regard. All three studies were considered 'low risk' for follow-up bias, reporting bias, and other biases. The cohort studies, evaluated using the NOS, scored six or above. However, three studies did not account for important confounding factors in terms of inter-group comparability, two studies did not describe the evaluation of the results, and one study did not provide follow-up information, making it unclear if the follow-up duration was sufficient (Supplementary Table 2).

Postoperative complications

This study aimed to evaluate the safety of not using ENBD in patients with choledocholithiasis by examining postoperative complications. The analysis of six studies

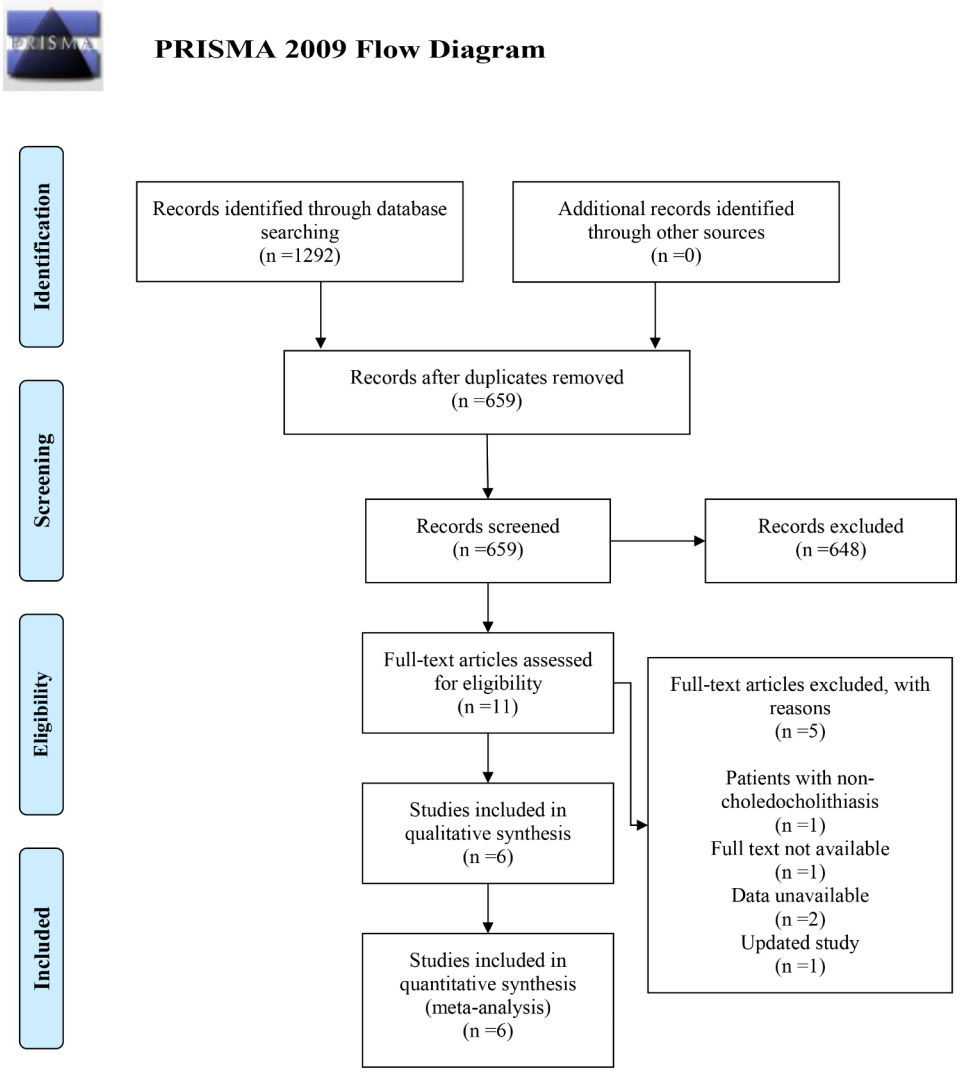

Fig. 1 Flow diagram of study selection

showed no significant difference in the incidence of pancreatitis between the no-ENBD group and the ENBD group (RR: 1.55, 95% CI: 0.61–3.96, $p=0.36$) (Fig. 2). Subgroup analyses revealed no significant differences in pancreatitis incidence between the groups, regardless of study design (RCTs, $p=0.38$; cohort studies, $p=0.83$) or treatment type (endoscopic, $p=0.23$; surgical, $p=0.73$) (Table 2). Additionally, two RCTs focusing on endoscopic treatment reported no significant difference in the incidence of hyperamylasemia between the groups ($p=0.73$). The incidence of cholangitis, reported in six studies, showed no significant difference between the no-ENBD and ENBD groups (RR: 1.81, 95% CI: 0.90–3.63, $p=0.09$) (Fig. 3). Further subgroup analysis by study design type and treatment procedure also showed no significant differences between the groups (Table 2).

For bleeding, there was no statistically significant difference between the no-ENBD and ENBD groups, whether in RCTs ($p=0.30$) or in endoscopic treatment ($p=0.41$). Two cohort studies focusing on surgical treatment found no significant difference in the incidence of bile leakage between the groups ($p=0.14$). Regarding overall postoperative complications, four studies reported no significant difference between the no-ENBD and ENBD groups (RR: 1.25, 95% CI: 0.76–2.06, $p=0.38$) (Fig. 4). Subgroup analyses confirmed no significant differences in overall complications between the groups, irrespective of study design or treatment method (Table 3).

Postoperative outcomes

This study also examined the impact of no-ENBD on postoperative outcomes, including the time to normalize serum total bilirubin and the duration of postoperative hospital stay. In RCTs, subgroup analysis showed that the bilirubin normalization time was longer in the no-ENBD group compared to the ENBD group, though this

Table 1 Characteristics of included studies in the meta-analysis

Autor	Year	Country	Disease	Procedure	No. of participants		Outcomes		Study design
					no-ENBD	ENBD	Primary	Secondary	
Huang	2018	China	Choledocholithiasis	ERCP + EPBD + EST	77	78	PEP	Hyperamylasemia	RCT
Lee	2010	Korea	Choledocholithiasis-induced acute cholangitis	ERCP + EST	53	51	Cholangitis; PHD	Operation time; Patient discomfort on day 1 after the procedure; Normalization time of TB and AST; Remnant CBD stones; Complication	RCT
Xu	2015	China	Choledocholithiasis	ERCP + EPBD ERCP + EST ERCP	105	113	Normalization time of TB, ALT and CRP; PHD; Complications; OPC		RCT
Yang	2013	China	Choledocholithiasis	ERCP + EST	89	99	Complications; Normalization time of TB; PHD		Cohort study
Yang	2020	China	Choledocholithiasis	LC + LCBDE + PC	81	83	Closure methods; Suture materials; Operation time; Intraoperative bleeding; Postoperative first flatus; Abdominal drainage time; Postoperative antibiotic therapy; PHD; Cost; Complications		Cohort study
Zhang	2023	China	cholecystolithiasis combined with choledocholithiasis	LC + LCBDE + PC	72	96	Operation time; Intraoperative bleeding; PHD; Cost; Abdominal drainage time; Complications; The stone clearance and recurrence rates		Cohort study

EPBD: Endoscopic papillary balloon dilation; EST: Endoscopic sphincterotomy; ERCP: Endoscopic retrograde cholangiopancreatography; LCBDE: Laparoscopic common bile duct exploration; PC: Primary closure; LC: Laparoscopic cholecystectomy; ENBD: Endoscopic nasobiliary drainage; PEP: Post-endoscopic retrograde cholangiopancreatography pancreatitis; PHD: Postoperative hospitalization duration; TB: Total serum bilirubin; AST: Aspartate aminotransferase; CBD: Common bile duct; ALT: Alanine aminotransferase; CRP: C-reactive protein; OPC: Overall patient complications; RCT: Randomized controlled trial

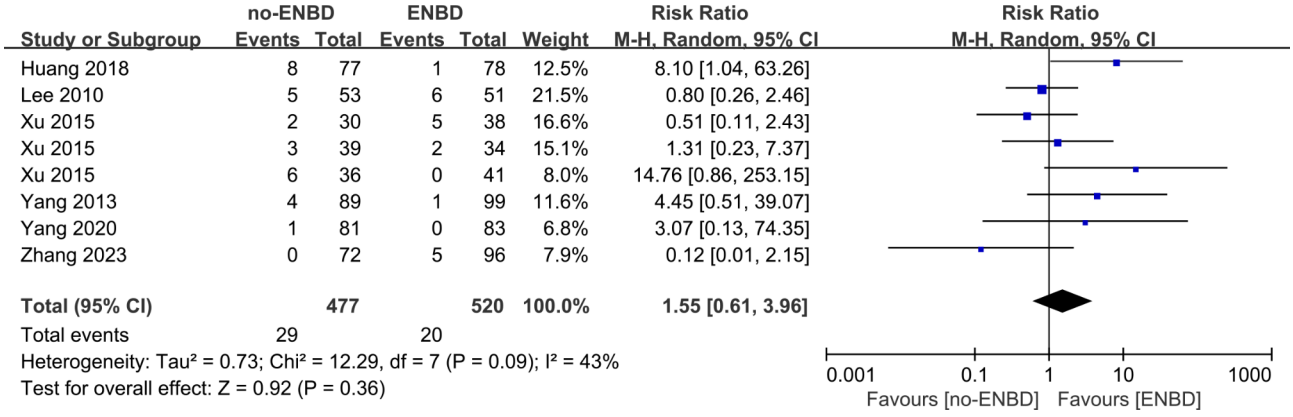

Fig. 2 Forest plot depicting the relationship between the absence of endoscopic nasobiliary drainage (no-ENBD) and the incidence of pancreatitis

difference was not statistically significant (WMD: 0.24, 95% CI: -0.02–0.49, $p=0.07$). In endoscopic studies, the bilirubin normalization time was also longer in the no-ENBD group compared to the control group (WMD: 0.23, 95% CI: 0.07–0.39, $p=0.005$) (Table 3). Regarding postoperative hospital stay, four studies demonstrated no significant difference between the no-ENBD and ENBD groups (WMD: -0.30, 95% CI: -1.42–0.82, $p=0.60$) (Fig. 5). The difference in postoperative hospital stay between the groups did not reach statistical significance, regardless of study design or treatment type (Table 3).

Discussion

This meta-analysis aimed to assess the safety of no-ENBD following elective clearance of choledocholithiasis. The analysis included three RCTs and three cohort studies, comprising nearly a thousand participants. The findings indicated that the no-ENBD group did not experience an increased risk of postoperative complications such as pancreatitis, hyperamylasemia, cholangitis, bleeding, or overall complications compared to the ENBD group. Moreover, the postoperative outcomes indicated that only the normalization time of total bilirubin in the no-ENBD group was significantly longer than that in the

Table 2 Subgroup analysis of postoperative complications

Subgroup analysis	No. of studies	RR	95%CI	*p*	Heterogeneity (I^2)
Pancreatitis					
Study design					
RCT	3	1.67	0.53, 5.25	0.38	54%
Cohort study	3	1.28	0.13, 12.93	0.83	54%
Procedure					
Endoscope	4	1.87	0.67, 5.21	0.23	49%
Surgery	2	0.57	0.02, 14.01	0.73	55%
Hyperamylasemia					
Study design, Procedure					
RCT, Endoscope	2	1.17	0.48, 2.83	0.73	53%
Cholangitis					
Study design					
RCT	3	1.77	0.73, 4.26	0.20	0%
Cohort study	3	2.53	0.53, 12.05	0.25	31%
Procedure					
Endoscope	4	2.04	0.88, 4.74	0.10	0%
Surgery	2	1.59	0.33, 7.71	0.56	21%
Bleeding					
Study design					
RCT	3	0.53	0.16, 1.75	0.30	0%
Procedure					
Endoscope	4	0.65	0.24, 1.80	0.41	0%
Bile leakage					
Study design, Procedure					
Cohort study, Surgery	2	3.34	0.68, 16.38	0.14	11%
Overall complications					
Study design, Procedure					
RCT, Endoscope	2	1.31	0.61, 2.83	0.49	66%
Cohort study, Surgery	2	1.14	0.60, 2.16	0.69	20%

RR: Risk ratio; CI: Confidence interval; RCT: Randomized controlled trial

ENBD group. For postoperative hospital stay, there was no statistically significant difference between the two groups.

Endoscopic techniques, particularly ERCP, have become preferred methods for biliary stone removal due to their safety and minimally invasive nature. However, complications such as pancreatitis, cholangitis, and bleeding remain concerns [21]. The development of pancreatitis post-ERCP is often linked to factors like pancreatic duct cannulation, contrast injection, pancreatic duct obstruction from nipple edema, residual stones, or sphincter spasms [22]. While various strategies, including patient assessment, pharmacological prevention, and procedural techniques, have been explored to prevent ERCP-related pancreatitis. For procedural technical prevention mainly involving ENBD seemed to be related to a reduction in the incidence of pancreatitis [23–25], which could ensure reliable biliary drainage and perfusion [9]. However, this study found no increase in pancreatitis incidence in the absence of ENBD, possibly due to the concurrent use of EST and/or EPBD in the included studies, which may have masked ENBD's role. Additionally, markers like hyperamylasemia and serum amylase are often used to diagnose acute pancreatitis, with a significant rise in serum amylase levels post-ERCP being indicative [26–28]. The present study similarly found no increase in hyperamylasemia incidence in the no-ENBD group.

Regarding post-ERCP cholangitis, this study corroborates findings by Yang et al., indicating no significant association between no-ENBD and increased cholangitis incidence [18]. While ENBD is generally believed to facilitate bile drainage and excretion, obstruction and poor drainage from the nasobiliary duct could pose a risk for bile duct infections post-ERCP [21]. This study confirmed that there was no significant difference in cholangitis incidence between the two groups.

In terms of bleeding, the statistical analysis of the four ERCP studies included in this review indicated that the risk of bleeding was not associated with the use or omission of ENBD. The studies highlighted that ERCP was performed by experienced physicians, significantly reducing bleeding risk, thus making the use of ENBD less impactful in this regard [21].

Additionally, two surgical studies found no significant difference in bile leakage incidence between the two groups. Bile leakage is often linked to rapid changes in Oddi sphincter dynamics and increased common bile duct pressure post-cholecystectomy. The placement of the nasobiliary duct could effectively drain and reduce the pressure of the common bile duct and reduce the occurrence of bile leakage [29, 30]. However, some other studies have pointed out that the incidence of T-tube-related complications after common bile duct exploration was approximately 15.3%, including bile leakage, early shift, electrolyte disorder, etc. [31]. Similarly, ENBD, as an alternative to biliary drainage, faced the same problems. A meta-analyses have noted that different drainage techniques, whether internal or external, do not offer significant advantages over initial suture closure [32]. This aligns with our study's findings, suggesting that choledochoscopy in LCBDE might mitigate ductal pressure

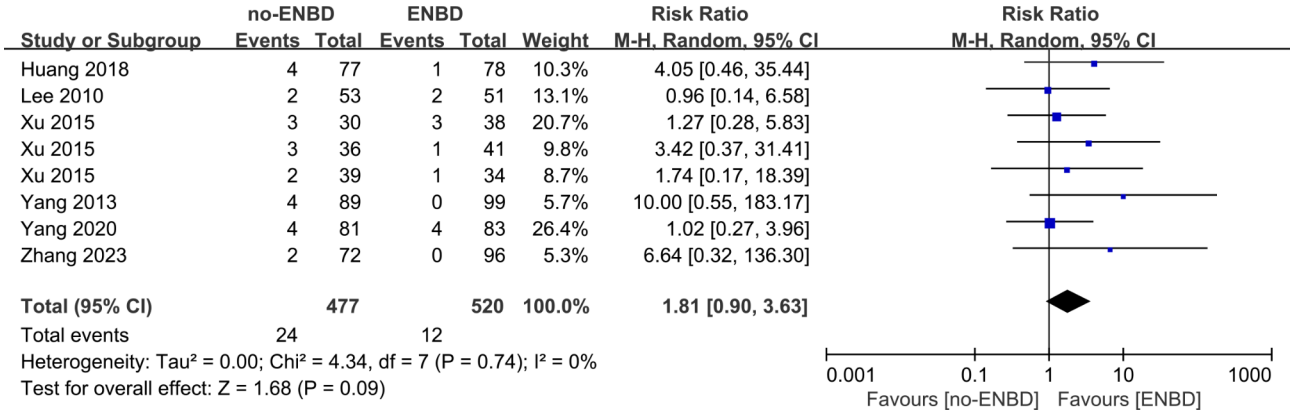

Fig. 3 Forest plot illustrating the relationship between no-ENBD and the incidence of cholangitis

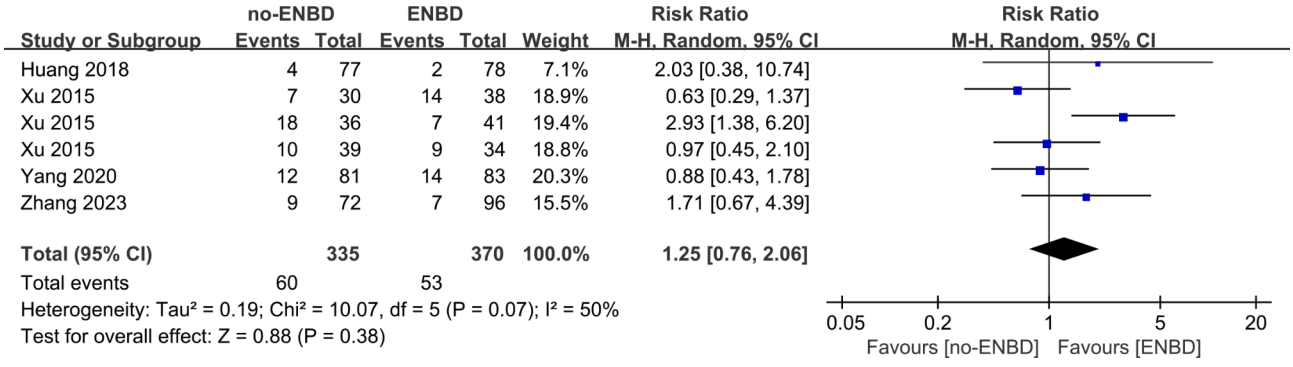

Fig. 4 Forest plot showing the relationship between no-ENBD and the incidence of overall complications

Table 3 Subgroup analysis of postoperative outcomes

Subgroup analysis	No. of studies	WMD	95%CI	*p*	Heterogeneity (I^2)
Normalization of total serum bilirubin (d)					
Study design					
RCT	2	0.24	-0.02, 0.49	0.07	34%
Procedure					
Endoscope	3	0.23	0.07, 0.39	0.005	16%
Postoperative hospitalization duration (d)					
Study design					
RCT	2	0.18	-0.07, 0.43	0.16	0%
Cohort study	2	-1.52	-7.46, 4.42	0.62	99%
Procedure					
Endoscope	3	0.45	-0.02, 0.92	0.60	72%

WMD: Weighted mean difference; CI: Confidence interval; RCT: Randomized controlled trial

increases to some extent. Martin et al. also noted that primary suturing is simpler, safer, and preferred by patients compared to T-tube insertion [33].

Overall, no significant difference in postoperative complications was observed between the no-ENBD and ENBD groups. The limited number of studies included in this meta-analysis might account for occasional anomalies in the data. In summary, this study demonstrated that omitting ENBD does not increase the risk of postoperative complications and presents similar safety outcomes compared to its use.

In patients undergoing elective clearance of choledocholithiasis, the recovery time of bilirubin was longer in the no-ENBD group, likely due to the nasobiliary drainage alleviating biliary obstruction and reducing biliary tract pressure, thereby aiding jaundice resolution [34]. The length of postoperative hospital stay showed no significant difference between the groups, which is generally influenced by the presence of postoperative complications [35]. Given that no increase in complications was observed in the no-ENBD group, it is reasonable that the length of hospital stay did not differ significantly between the groups. The longer bilirubin normalization time in the no-ENBD group likely reflects a slower decline rather than an impact on the overall hospital stay duration.

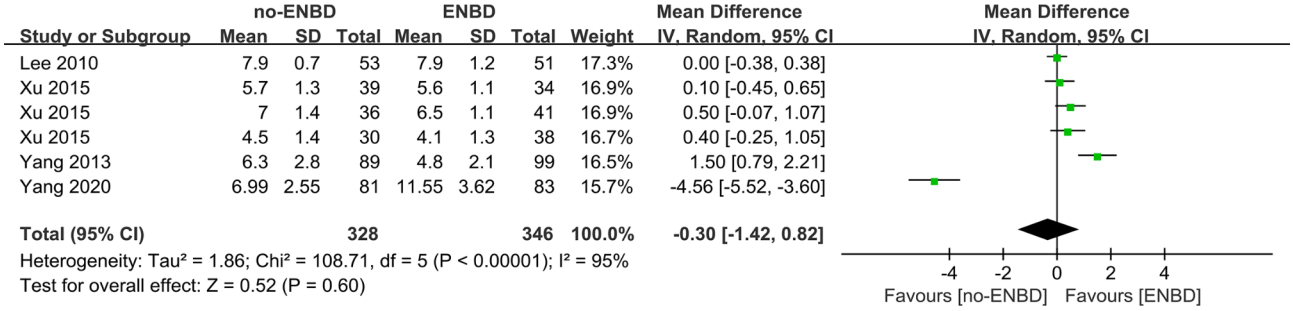

Fig. 5 Forest plot demonstrating the relationship between no-ENBD and the duration of postoperative hospitalization

Despite the recognized benefits of ENBD for biliary drainage, perfusion, pressure reduction, and cholangiography for residual stones, it has drawbacks. These include the potential for nasobiliary duct displacement, torsion, or obstruction, particularly in patients with impaired consciousness or frailty [18]. Moreover, patients may experience excessive secretions or bleeding due to pharyngeal reflex during nasobiliary duct removal, risking pulmonary infections if inhaled accidentally [14]. Additionally, the placement of a nasobiliary duct extends radiation exposure time for both patients and medical staff [14].

This meta-analysis systematically evaluated the safety of not performing ENBD after stone removal in patients with choledocholithiasis for the first time. Subgroup analyses were conducted to ensure the robustness of the findings across different study designs (RCTs or cohort studies) and treatment modalities (endoscopy or surgery). Importantly, this study focused on patients undergoing elective clearance of choledocholithiasis, excluding those with severe emergencies like acute suppurative cholangitis, acute pancreatitis, or severe symptomatic jaundice, as these conditions warrant biliary drainage as per relevant guidelines [36, 37]. However, this study has limitations, including a relatively small sample size of nearly a thousand participants, which could impact the analysis and conclusions. Furthermore, the included studies were predominantly from China, limiting the generalizability of the findings to other regions. Lastly, the limited number of studies, particularly RCTs, may affect the credibility of the results.

Conclusion

This meta-analysis found that it is safe to forgo ENBD after elective clearance of choledocholithiasis, with the only significant difference being a prolonged time for bilirubin normalization. However, large, multicenter RCTs are recommended to further validate these findings.

Abbreviations

LCBDE	Laparoscopic common bile duct exploration
ERCP	Endoscopic retrograde cholangiopancreatography
EST	Endoscopic sphincterotomy
EPBD	Endoscopic papillary balloon dilation
ENBD	Endoscopic nasobiliary drainage
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	International Prospective Register of Systematic Reviews
RCTs	Randomized controlled trials
CCRBT	Cochrane Collaboration Risk of Bias Tool
NOS	Newcastle-Ottawa Scale
RR	Relative risk
95%CI	95% Confidence interval
WMD	Weighted mean differences

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12893-024-02535-8.

Supplementary Table 1. Characteristics of the included studies in the meta-analysis

Supplementary Table 2. Quality assessment of the included studies

Supplementary Material 3

Acknowledgements

Not applicable.

Author contributions

All authors read and approved the manuscript. Jie Yin and Dongying Wang were responsible for writing the manuscript; Yujing He and Hongcun Sha performed the procedures and data analysis; Wenhao Zhang contributed to writing the manuscript; Wei Huang contributed to the conception and design of the study.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Dual publication

None.

Third party material
None.

Competing interests
The authors declare no competing interests.

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