

Research Article

Efficacy and Safety of EUS-Guided Choledochoduodenostomy Using Electrocautery-Enhanced Lumen-Apposing Metal Stents (ECE-LAMS) in the Treatment of Biliary Obstruction: A Systematic Review and Meta-Analysis

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Background. Electrocautery-enhanced lumen-apposing metal stents (ECE-LAMS) have been newly developed to perform EUS-guided choledochoduodenostomy (EUS-CDS), but its benefits and harms remain obscure. We conducted a systematic review and meta-analysis to evaluate the efficacy and safety of EUS-CDS using ECE-LAMS. **Method.** In the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), we searched PubMed, Embase, and Scopus databases through January 1, 2001, and April 27, 2020. The primary outcomes of the pooled analysis were to determine the technical success, clinical success, and overall adverse events rates. The secondary outcomes were pooled rates of short-term and long-term adverse events. **Results.** Six studies with 270 patients were finally included in this meta-analysis. The pooled rates of technical, clinical success, and adverse events were 95.1% (95% CI = 90.6–97.5%, $I^2 = 25\%$), 93.3% (95% CI = 87.4–96.5%, $I^2 = 28\%$), and 15.3% (95% CI = 10.6–21.6%, $I^2 = 13\%$), respectively. The pooled rates of short-term and long-term adverse events were 3.6% (95% CI = 1.3–9.6%, $I^2 = 0\%$) and 11.3% (95% CI = 7.6–16.5%, $I^2 = 0\%$), respectively. **Conclusion.** EUS-CDS using ECE-LAMS provides favorable outcomes in patients with biliary obstruction. It has been associated with a higher success rate and a lower rate of adverse events when compared with the biliary drainage approaches previously used. Large and randomized controlled observational studies are required to further refine the findings in the present analysis.

1. Introduction

Over the last decades, endoscopic retrograde cholangiopancreatography (ERCP) with stent placement is prominently applied to perform biliary drainage in patients with biliary obstruction [1]. The failure rate is still about 10%, even though this treatment was performed by expert endoscopists [2–4]. When ERCP fails, percutaneous transhepatic biliary drainage (PTBD) and surgical bypass are reliable alternatives. However, such strategies have been associated with relatively high morbidity, prolonged hospitalization, poor life quality, and several drainage-related complications [5, 6].

EUS-guided choledochoduodenostomy (EUS-CDS) has emerged as one of the promising techniques for biliary drainage after ERCP failure. In 2001, Giovannini et al. first reported one case of successful EUS-CDS, which places a stent across the duodenal wall into the extrahepatic bile duct, in a patient with malignant biliary obstruction after failed ERCP [7–9]. A recent meta-analysis reported that EUS-CDS had a clinical success rate of 88.5% and an adverse event rate of 18.6% [10]. However, use of a plastic stent that initially served for EUS-CDS may result in early stent occlusion, bile leak, and subsequent peritonitis [11, 12]. More recently, EUS-CDS has been significantly changed with the advent of self-expanding metal stents (SEMSs), which are associated

with a longer survival, a lower rate of stent dysfunction, and a lower reintervention rate when compared with plastic stents [13]. We should, however, note that SEMSs migration may cause tissue injury, which is its main drawback [14, 15].

Intriguingly, electrocautery-enhanced lumen-apposing metal stent (ECE-LAMS) was developed to perform EUS-CDS [16]. Such stent reduces bile leakage and improves success rates. Nevertheless, to the best of our knowledge, it is unclear whether the EUS-CDS with ECE-LAMS is more appropriate than other drainage approaches for patients who had biliary obstruction. In the present study, we evaluate the efficacy and safety of EUS-CDS with ECE-LAMS by performing a comprehensive systematic review and meta-analysis.

2. Methods

2.1. Search Strategy. This systematic review and meta-analysis have been designed and conducted following the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [17]. We searched PubMed, Embase, and Scopus databases through January 1, 2001, and April 27, 2020, for studies regarding biliary drainage with EUS-CDS. The following search terms were used: “endoscopic ultrasound, EUS, lumen-apposing metal stents, LAMS, lumen-apposing fully covered metal stent, lumen-apposing stents, choledochoduodenostomy, CDS, transmural biliary drainage, EUS-guided choledochoduodenostomy, and EUS-CDS.” Manual searches for reference lists of retrieved articles from published literatures were also performed. The search was restricted to studies on humans, which were published only in English. Only published data are retrieved in this meta-analysis. Ethical approval was not required as the study is a systematic review and meta-analysis.

2.2. Inclusion and Exclusion Criteria. After removal of duplicates, two authors (Z.P. and S.L.) independently screened titles and abstracts. To avoid duplicate or overlap results retrieved from the same study cohort, only the most recent study and/or the publication presenting the largest datasets was included in further analysis. We included studies investigating (1) EUS-CDS using ECE-LAMS; (2) outcome measures (technical success rate, clinical success rate, and adverse events); (3) a sample size of more than ten patients. We excluded studies investigating (1) EUS-CDS using LAMS; (2) EUS-guided drainage of pancreatic fluid collections using LAMS; (3) EUS-guided gallbladder drainage with LAMS. Case reports, reviews, letters, comments, and editorials were also excluded. Any differences were resolved by discussion. We retrieved the full text for further evaluation if it seemed to meet the eligibility criteria.

2.3. Data Extraction. Two authors (Z.P. and S.L.) independently extracted information from the original articles using a predetermined data extraction sheet, with discrepancies resolved by discussion. If any disagreement persisted, the final decision was made by a third author (Y.T.) after

reviewing the original articles. The study details included study characteristics (first author, country, year of publication, study design, and follow-up period), study population (total number of patients analyzed, patient demographics, etiology, stent diameter, and causes of ERCP failure), and outcome (technical success rate, clinical success rate, and details of adverse events).

2.4. Assessment of Outcome. The primary outcomes assessed in this meta-analysis were the pooled technical success, clinical success, and overall adverse event rates. The secondary outcomes were the pooled rates of short-term and long-term adverse events associated with EUS-CDS using ECE-LAMS.

We followed the definitions of technical and clinical success as defined by individual studies. According to the American Society for Gastrointestinal Endoscopy lexicon [18], short-term adverse event was defined as all complications occurring within 14 days after stent placement. Long-term adverse event was defined as any event occurring 14 days after placement.

2.5. Statistical Analysis. Continuous variables were presented as means (standard deviation, SD) or medians (interquartile range, IQR). Categorical variables were presented as numbers and proportions. We calculated the pooled technical success rate, clinical success rate, and incidence of adverse events and 95% confidence intervals (CIs). These were analyzed and pooled using the random-effects model [19]. Heterogeneity was assessed using I^2 statistics [20, 21]. The I^2 values <30%, 30% to 60%, 61% to 75%, and >75% were suggestive of low, moderate, substantial, and considerable heterogeneity, respectively [22]. In all cases, $p < 0.05$ was considered statistically significant. We used R software (R version 4.0.2) for all analyses.

3. Results

3.1. Characteristics of Included Studies. We collected 247 records from PubMed, 355 records from Scopus, and 549 records from Embase in the primary search and removed 448 duplicates from the initial 1,151 records. Following the inspection of titles and abstracts, 20 studies were selected for full-text assessment. Six studies were included in the final analysis [23–28]. Figure 1 shows the flow diagram for study selection. Four studies [25–28] were multicenter, and the other two [23, 24] were single-center studies. Two studies [26, 28] were prospective, and the others were retrospective cohort studies. All studies were published between 2018 and 2020. Two studies were conducted in France [26, 27], one in Asia [28], two in Italy [23, 24], and one in North America [25]. Four studies [23, 26–28] used the American Society for Gastrointestinal Endoscopy lexicon for grading of adverse events [18], whereas the other two were defined individually. In most of the studies, technical success was defined as a successful ECE-LAMS deployment between the bile duct and duodenal lumen, and clinical success was defined as a reduction of at least 50% in total serum bilirubin levels.

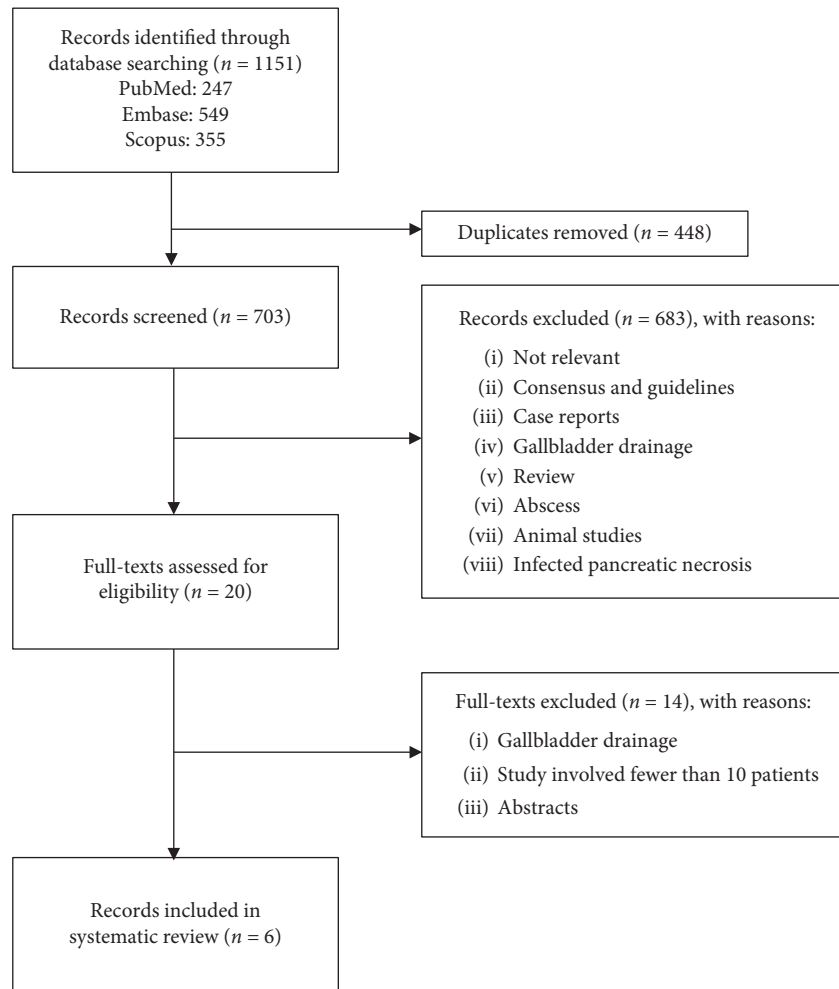


FIGURE 1: Flow diagram of literature search and selection.

A total of 270 patients were included in the analysis, comprising 144 men (53.3%) and 126 women (46.7%), and the mean age ranged from 69.9 to 78 years. The most common cases, in a descend trend, were pancreatic cancer (54.4%), ampullary cancer, metastatic cancer, and cholangiocarcinoma. Five studies [23, 25–28] reported the mean diameter of common bile duct (CBD), ranging from 17.2 to 17.7 mm. Duodenal stenosis was the most common causes of ERCP failure (77/270). All the included studies had detailed follow-up information. The median follow-up period ranged from 83 to 157 days, and 20 patients were lost to follow-up. In most of the studies, the selection of stent size depended on the CBD diameter but was ultimately at the discretion of the endosonographer. In all the studies, 6 mm, 8 mm, 10 mm, and 15 mm stents were used in 143 (53.0%), 48 (17.8%), 77 (28.5%), and 2 (0.7%) cases, respectively. In all included studies, the ECE-LAMS was manufactured by Boston Scientific Corporation. Table 1 shows the characteristics of the studies.

3.2. Efficacy of EUS-CDS with ECE-LAMS. All included studies reported technical success rates. The pooled rate of technical success was 95.1% (95% CI = 90.6–97.5%; $I^2 = 25\%$)

(Figure 2(a)). Five studies [23, 24, 26–28] were included in the final analysis of the clinical success rate; one study was excluded since the clinical success was not assessed in 35.8% of the patients (24/67) [25]. The pooled clinical success rate was 93.3% (95% CI = 87.4–96.5%; $I^2 = 28\%$) (Figure 2(b)).

3.3. Adverse Events of EUS-CDS with ECE-LAMS. Due to the high rate of lost to follow-up, El Chafic et al. [25] was excluded from the analysis of adverse event rates. Of the 203 patients included in the final analysis, adverse events associated with EUS-CDS using ECE-LAMS were reported in 31 patients (15.3%, 95% CI = 10.6–21.6%, $I^2 = 13\%$) (Figure 2(c)). In the pooled patient population, the percentage of short-term adverse events was 3.6% (95% CI = 1.3–9.6%, $I^2 = 0\%$) (Figure 2(d)). The most common short-term adverse event was cholangitis (2.0%). The pooled rate of long-term adverse events was 11.3% (95% CI = 7.6–16.5%, $I^2 = 0\%$) (Figure 2(e)). The most frequently reported long-term adverse events were tumoral obstruction of the stent ($n = 12$), stent migration ($n = 3$), food residue ($n = 2$), bleeding ($n = 2$), and sump syndrome ($n = 2$). The median time from ECE-LAMS placement to onset of stent obstruction due to tumoral invasion was 130 days (range: 44–282) (Table 2).

TABLE 1: Characteristics of studies included in the meta-analysis.

Author (year)	Country	Design	Setting	Total patient (n)	Age, mean (SD or range)	Male	Etiology (n)	Reason for failed ERCP (n)	Stent diameter	CBD diameter (mm)	Median follow-up (day)
Jacques et al. (2020), [26]	France	Prospective	Multicenter	70	75 (61–92)	38	Pancreatic cancer (54), Cholangiocarcinoma (3), Ampullary cancer (4), Duodenal cancer (2), Others (7)	Duodenal stenosis (31), Tumoral involvement of papilla (15), Cannulation failure (17), Other (1)	6 mm (60), 8 mm (9), 10 mm (1)	17.7 ± 5	153
							Pancreatic cancer (43), Cholangiocarcinoma (2), Duodenal lymphoma (1), Duodenal cancer (2), Degenerated IPMN (2), Peritoneal carcinomatosis (1), Stones (1)	Duodenal stenosis (18), Tumoral involvement of papilla (10), Cannulation failure (14), Prior duodenal stent (9), Other (1)	6 mm (43), 8 mm (7), 15 mm (2)	17.2 (9–25)	157
							Peri-ampullary cancer (56) Metastatic cancer (11)	Tumoral involvement of papilla (28), Cannulation failure (9)	10 mm (67)	17.6 ± 3.6	119 [#]
El Chafic et al. (2019), [25]	USA	Retrospective	Multi-center	67	68.8 ± 11.8	21	Pancreatic cancer (10), Cholangiocarcinoma (2), Ampullary cancer (1), Duodenal cancer (1), Metastatic cancer (4), Sarcoma (1)	Duodenal stenosis (4), Cannulation failure (15)	6 mm (10), 8 mm (9)	17.3 ± 5.5	145
Anderloni et al. (2019), [23]	Italy	Retrospective	Single-center	46	73.1 ± 12.6	24	Pancreatic cancer (40), Cholangiocarcinoma (1), Ampullary cancer (2), Duodenal cancer (3)	Duodenal stenosis (9), Tumoral involvement of papilla (19), Cannulation failure (12), Prior duodenal stent (6)	6 mm (21), 8 mm (19), 10 mm (6)	17.26 ± 3.34	83
							NA	NA	6 mm (9), 8 mm (4), 10 mm (3)	NA	138.7

CBD, Common bile duct; IPMN, intraductal papillary mucinous neoplasm; ERCP, endoscopic retrograde cholangiopancreatography; NA, not available; [#]20 patients were lost follow-up.

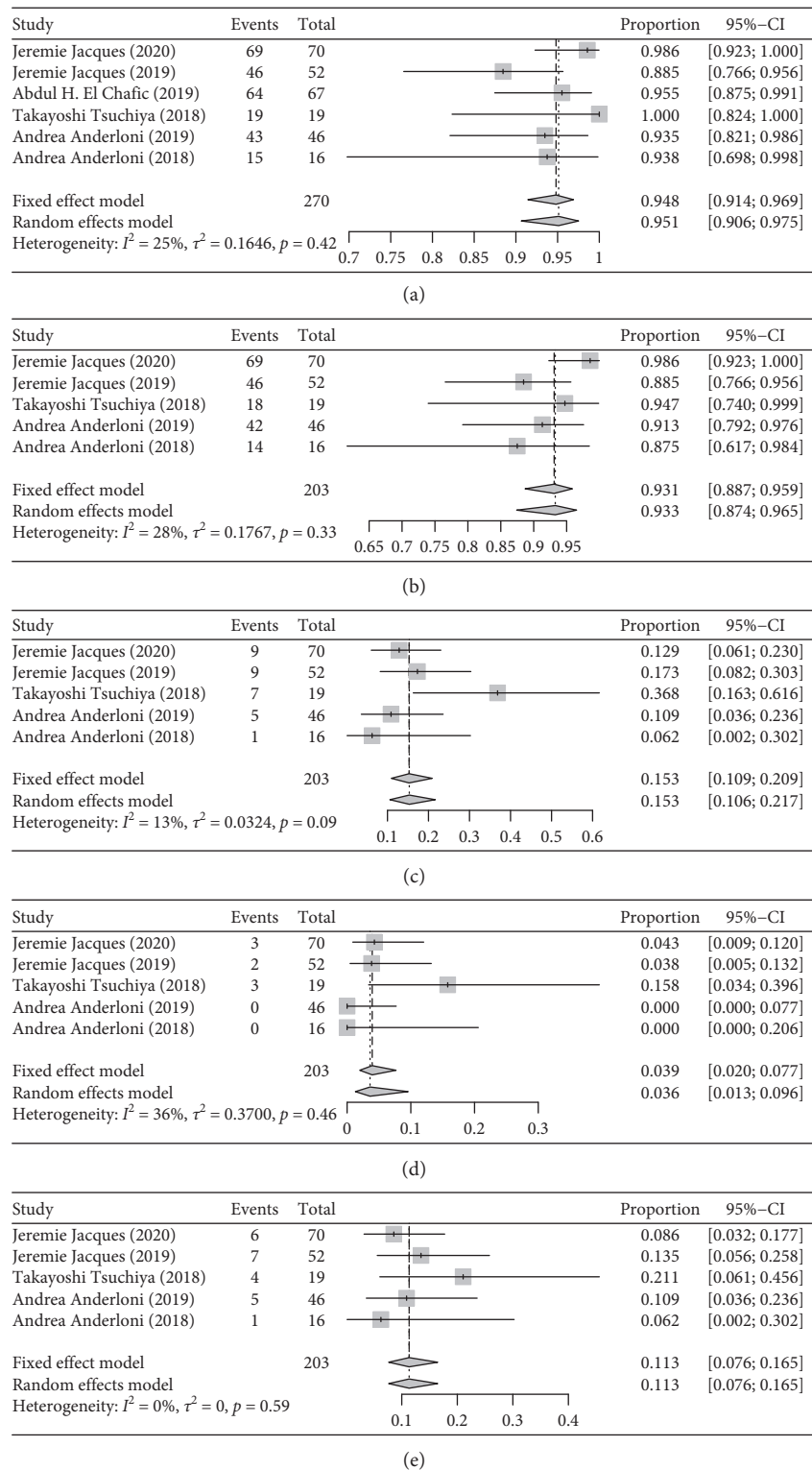


FIGURE 2: Forest plot clinical outcomes. (a) Technical success rate. (b) Clinical success rate. (c) Overall adverse event rate. (d) Short-term adverse event rate. (e) Long-term adverse event rate.

TABLE 2: Outcomes from studies included in the meta-analysis.

Author (year)	Total patient (n)	Technical success (n)	Clinical success (n)	Overall adverse events (n)	Short-term adverse events (n)	Long-term adverse events (n)
Jacques et al. (2020), [26]	70	69	69	9	Bleeding (1), Technical success was not achieved (1), Cholangitis (1)	Tumoral obstruction (4), Stent migration (1), Bacteremia (1)
Jeremie Jacques (2018), [27]	52	46	46	9	Bleeding (1), Cholangitis (1)	Tumoral obstruction (4) ^a , Sump syndrome (2) ^a , Stent migration (1)
El Chafic (2019), [25]	67	64	NA	NA	NA	NA
Tsuchiya (2018), [28]	19	19	18	7	Cholangitis (2) ^b , Fever (1)	Food residue (1), Stent kinking (1), Tumor obstruction (1), Stent migration (1)
Anderloni (2018), [23]	46	43	42	5	0	Bleeding (1), Tumoral obstruction (3), Food residue (1)
Andrea Anderloni (2018), [24]	16	15	14	1	0	Bleeding (1)

^aRecurrence of jaundice with symptoms of cholangitis; ^bone patient underwent cholangitis because of food residue. NA, not available.

4. Discussion

LAMS was originally designed for EUS-guided drainage of pancreatic fluid collections [29–31]. In 2014, Itoi et al. firstly reported one case of successful EUS-CDS with LAMS for biliary drainage after ERCP failure in a patient with unresectable pancreatic cancer [32]. The EUS-CDS using LAMS or ECE-LAMS has been gradually performed for biliary drainage. However, the risk and success rates of EUS-CDS using ECE-LAMS remain obscure. The present meta-analysis evaluated the efficacy and safety of EUS-CDS with ECE-LAMS. We observed that pooled rates of technical success, pooled rates of clinical success, and overall adverse events following EUS-CDS with ECE-LAMS were 95.1%, 93.3%, and 15.3%, respectively. Moreover, pooled rates of short-term adverse events and long-term adverse events of ECE-LAMS were 3.6% and 11.3%, respectively.

Over the past decade, EUS-CDS has been recognized as an alternative approach when ERCP fails, and its role as a first-line treatment for malignant biliary obstruction has also become increasingly recognized [33, 34]. A recent meta-analysis, which included three randomized trials conducted in the USA and Korea [35–37], compared the efficacy and safety between EUS-CDS with SEMS and ERCP-BD that serve for primary palliation of malignant biliary obstruction [38]. Though there was no difference between the approaches regarding the overall adverse events, clinical success rates, and occlusion rates, EUS-CDS using SEMS was associated with lower rate of postprocedural pancreatitis rate (RR=0.22, 95% CI=0.05–1.02). EUS-CDS could, therefore, be used as a primary biliary decompression for patients with malignant biliary obstruction. However, SEMS may cause

severe complication (i.e., tissue injury) due to stent migration [14]. Currently, LAMS, which was firstly served for drainage of pancreatic fluid collection, is being utilized for biliary drainage to overcome this drawback of SEMS [16].

Nevertheless, EUS-CDS using the SEMS or LAMS is typically a four-step deployment process. When compared to the noncautery enhanced LAMS, ECE-LAMS is an updated technique that improves clinical outcomes attributable to its all-in-one device with simplified stent deployment. A recent meta-analysis indicated that the pooled rates of technical and clinical success of EUS-CDS with LAMS were 94.1% and 95.9%, respectively [39]. Notably, results from the present study showed that EUS-CDS using ECE-LAMS is associated with higher rates of technical success (95.1%) and clinical success (93.3%). Furthermore, ECE-LAMS is potentially safer than LAMS to perform EUS-CDS. Its one-step stent deployment reduces adverse event rates. For example, a Japanese observational study reported that the overall adverse events rate of EUS-CDS with LAMS was 36.8% (7/19) [28], because of its multisteps of deployment procedure. A meta-analysis reporting on EUS-CDS with the use of different stent types revealed an overall adverse event rate of 21.83% (43/197) [40]. Moreover, one recent meta-analysis reported the pooled adverse events rates of EUS-CDS was 10.1% [39]. However, this study was limited by small sample sizes, and inclusion of publications included a mix of LAMS and ECE-LAMS. In the present meta-analysis, we observed that the pooled rate of adverse events following deployment of ECE-LAMS was 15.3% (95% CI=10.6%–21.6%; $I^2=13\%$). The pooled rates of short-term and long-term adverse events with ECE-LAMS

were 4.4% and 11.3%, respectively. Therefore, the deployment of ECE-LAMS greatly reduces the risk of adverse events.

The pooled rate (11.3%) of long-term adverse events of ECE-LAMS in the present meta-analysis was mostly attributable to recurrent tumoral obstruction (5.9%), food impaction (1.0%), and sump syndrome (1.0%). Four patients who underwent stent malfunction due to food impaction or sump syndrome from three studies [23, 26, 27] then used a second stent inserted across the lumen of the ECE-LAMS to resolve this issue. It is noteworthy that a second stent simultaneously positioned inside the ECE-LAMS could prevent such adverse events. Though one recent study was excluded from our analysis due to high rate of lost to follow-up, the authors found that patients who received a second double-pigtail stent placed through the ECE-LAMS stent showed a significantly lower rate of recurrent biliary obstruction than the cases using ECE-LAMS alone [25].

There are some limitations in the present meta-analysis. As a limitation of our study was the small participant numbers since only six studies with 270 patients were included in the final analysis. Furthermore, the definitions for clinical outcomes were not uniform across the included studies. We cannot completely rule out the possibility of publication bias, but we have attempted to minimize this by using detailed search strategies and generalization of the definitions according to the American Society for Gastrointestinal Endoscopy lexicon [18]. One other limitation was that smaller LAMS (6 mm and 8 mm diameter) was unavailable in the USA, which may cause reporting bias [25]. Another limitation was the availability of EUS-CDS is restricted to only a few expert endoscopic centers. This could cause selection bias. However, the present meta-analysis adopted stringent inclusion criteria to ensure appropriate methodologic quality to evaluate the efficacy and safety of EUS-CDS using ECE-LAMS. Though the abovementioned limitations and biases in published studies warrant caution in interpretation of the results of our study, these results provide implications regarding selection of biliary drainage techniques.

In conclusion, our results suggest that EUS-CDS using ECE-LAMS is effective and safe in patients with biliary obstruction when ERCP failed. Large and randomized controlled observational studies are needed to further refine these findings.

Data Availability

The datasets used and/or analyzed during the current study are available from the corresponding author on request.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Authors' Contributions

Z.P., R.P., and Y.W. searched the databases. Z.P., S.L., and Y.T. assessed studies and extracted data. Z.P. and S.L. drafted the manuscript. X.L. and W.W. revised the manuscript and

language. H.L. contributed to the study design and critical revision of the manuscript. All authors reviewed and approved the manuscript.

Supplementary Materials

PRISMA checklist is available in the Supplementary Materials. (*Supplementary Materials*)

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