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SYSTEMATIC REVIEW

Efficacy and safety of endoscopic ultrasonography (EUS) hepaticogastrostomy (HGS) versus choledochoduodenostomy (CDS) in ERCP-failed malignant biliary obstruction: A systematic review and META-analysis

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Key words
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Abstract

Endoscopic retrograde cholangiopancreatography (ERCP) is the gold standard in managing malignant biliary obstruction. The success of ERCP has limitations, whereas surgical biliary bypass and percutaneous transhepatic approaches, as alternative modalities, come with significant costs, longer durations, and higher levels of mortality and morbidity. Endoscopic ultrasonography (EUS)-guided biliary drainage with two approaches, hepaticogastrostomy (EUS-HGS) and choledochoduodenostomy (EUS-CDS), is a favored and evolving alternative modality. This study aims to compare the efficacy and safety of EUS-HGS and EUS-CDS. We conducted a systematic review and meta-analysis by searching PubMed, ScienceDirect, Cochrane Library, and Scholar databases up to August 2023, based on the 2020 PRISMA guidelines. We identified randomized and nonrandomized studies comparing the efficacy and safety of EUS-HGS and EUS-CDS. Outcome measures included technical and clinical success, side effects, and mean procedure time. Nine nonrandomized studies and two randomized controlled trials involving 537 patients (225 EUS-HGS, 312 EUS-CDS) were analyzed. No difference was found in technical success (OR, 0.83; 95% CI, 0.41–1.68; $I^2 = 0\%$) and clinical success between the two procedures (OR, 0.96; 95% CI, 0.51–1.81; $I^2 = 9.94\%$). Side effects were significantly higher in EUS-HGS (OR, 2.01, 95% CI, 1.14–3.59; $I^2 = 0\%$). No significant difference in mean procedure time was observed between the two procedures (0.13; 95% CI, −0.15–0.41; $I^2 = 34.89\%$). There are differences in efficacy and safety between EUS-HGS and EUS-CDS. EUS-CDS has a faster procedure time, lower risk of side effects, and ease of puncture during the procedure.

Introduction

Hepatobiliary malignancy poses a challenging management for gastroenterologists and general surgeons in resource-limited countries.[1] This may be attributed to the delayed and unspecified clinical manifestations of hepatobiliary malignancies causing obstructive jaundice. Late-stage lesions of malignant biliary obstruction (MBO) preclude curative resection due to organ spread, lympho-vascular and perineureal invasion, peritoneal deposits, and ascites.[2,3] The commonest causes of malignant obstructive jaundice include pancreatic-biliary tumor (pancreatic cancer or cholangiocarcinoma and ampullary tumors).[4]

Surgical resection for a cure or long-term survival is not usually feasible in many patients with late-stage MBO.[2,5] Palliative surgery, such as bilio-digestive drainage, is usually carried out with a primary goal of relieving symptoms and improving quality of life (QoL); meanwhile, percutaneous transhepatic biliary drainage (PTBD) and endoscopic retrograde cholangiopancreatography (ERCP) remain as a gold standard of biliary drainage in unresectable patients or patients with biliary sepsis.[2,6] PTBD or surgical interventions are conventionally performed as alternative biliary drainage methods after unsuccessful ERCP. However, both are associated with considerable morbidity and mortality.[7] Overall, the adverse event rates of endoscopic drainage were 8.6% and 12.3% for PTBD due to sepsis, peritonitis, hemorrhage, pancreatitis, pleural effusion, pneumothorax, dislodged catheter, pain that reduces the patients' QoL in long term.[6,8] Despite adverse events, even if ERCP is operated by experienced endoscopists, there is still a 3%–10% failure rate of ERCP in the management of MBO.[9]

Endoscopic ultrasound biliary drainage (EUS-BD) has been reported to have a better efficacy as an alternative biliary drainage method after unsuccessful ERCP, divided into three techniques: (i) EUS-guided transluminal biliary drainage including choledochoduodenostomy (EUS-CDS) and hepaticogastrostomy (EUS-HGS), (ii) EUS-rendezvous technique (EUS-RV), and (iii) EUS-antegrade approach (EUS-AG).[7,10] As of now, studies on the efficacy and safety of EUS-CDS and EUS-HGS remain limited. The meta-analysis by Yamazaki et al. (2024) presents a comparison of EUS-CDS and EUS-HGS; however, our study offers a distinct approach by integrating the latest clinical trials and a more detailed data extraction concerning patients with malignant biliary obstruction who have experienced ERCP failure.[11] While both studies seek to evaluate the efficacy and safety of EUS-HGS and EUS-CDS, our research places particular emphasis on pancreatic cancer patients—who are predominantly represented in ERCP failure cases. This focused analysis seeks to provide a deeper understanding of the effectiveness and safety of these techniques, thereby contributing to a more comprehensive understanding of their roles.

Methods

This review was performed based on Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines to determine the efficacy and safety of EUS-CDS and EUS-HGS in malignant obstructive jaundice. The review question of this study was "comparison of efficacy and safety EUS-HGS to EUS-CDS in malignant obstructive jaundice patients that failed in ERCP procedure." Primary outcomes were technical success and clinical success. Secondary outcomes were adverse events and mean procedural time.

Eligibility criteria. Studies that met the eligibility criteria are nine observational studies and two randomized controlled trials from 2012 to 2023 regarding malignant obstructive jaundice, comparing the efficacy and safety of EUS-CDS and EUS-HGS. The screening of eligible publications was independently evaluated by the authors. Studies that are not well identified independently will be solved through discussion with the other authors.

Studies were included if they met one of these population criteria: intervention, comparison, or outcome. Unsuitable study designs such as reviews, case reports, series, and proceeding books are not included.

Search strategy. A thorough search of the literature was conducted using a variety of databases, including PubMed, ScienceDirect, Google Scholar, Proquest, and TandFord, up until July 2023. Only English-language articles containing human participants and both observational studies and randomized controlled trials were included in the analysis and research from the previous 10 years. The search process was established by reading the study's full text, abstract, and title. The authors conducted a thorough investigation to determine whether a study was acceptable. A study that was considered eligible was included in this meta-analysis study. When there are any differences in study selection, the author analyzes them comprehensively. Databases with the following keywords were used to search ("*Failed ERCP*") *AND* ("*EUS-HGS*" *OR* "*Hepaticogastrostomy*") *AND* ("*EUS-CDS*" *OR* "*Choledochoduodenostomy*"). The reference list was examined during the search to identify studies that might be relevant.

Data extraction and analysis. Five authors were divided to identify the articles that had been found. Differences and problems are resolved through discussion. Full text of articles that met the inclusion criteria was screened for inclusion in the final analysis after being screened from exclusion. Standard forms are used to extract data from included studies to assess the points of each article. Data aggregation includes the author's name, publication years, study design, population of the study, study settings, sample sizes, main etiologies, stent used, efficacy and safety of EUS-HGS dan EUS-CDS, adverse events, and mean procedural times. Outcome data are extracted using comprehensive meta-analysis (CMA) and GraphadPrism 4.5, and data are evaluated using odd's ratio for the primary outcomes and standardized mean difference (SMD) for continuous data.

Risk of bias assessment. The risk of bias in the extracted data was determined using the Review Manager version 5.4.1. The criteria include random sequence generation (selection bias), allocation concealment (selection bias), binding of participants and personnel (performance bias), binding of outcome assessment (detection bias), incomplete outcome data (attrition bias), and selective reporting (reporting bias), and other biases. We judged each of these criteria relating to the risk of bias: low, high, or unclear (indicating unclear or unknown risk of bias). It is done by five members of the authors, and discrepancies are solved by discussion.

Quantitative analysis. Statistical analyses were performed using Review Manager version 5.4.1 for interventional review. The standardized mean difference (SMD) combined treatment effect data. The SMD and 95% confidence interval (CI) were calculated and represented in the forest plot. Notably, we preferred to use the standardized mean difference (SMD) in our meta-analysis. P values < 0.05 were considered statistically significant. We evaluated the heterogeneity of the included studies by calculating the I^2 statistic. The random-effects model was applied when heterogeneity existed ($I^2 > 50\%$); otherwise, the fixed-effects model was applied when $I^2 < 50\%$.

Results

Study selection and identification. Our searches yielded 1364 potentially relevant studies, of which 1262 were excluded after assessing the titles and abstracts, and 20 duplicates were found. Subsequently, further review of the complete texts was performed for 82 potential studies. In the full-text review, we excluded 64 studies because of insufficient data, and seven were review articles. Finally, we assessed 11 studies in this meta-analysis. The paper selection process adopted in our study is summarized in Figure 1.

Risk of bias assessment. Nine studies had some concerns about the risk of bias, according to the Risk of Bias 2 summary (RevMan 5.4.1). This is because the studies were not randomized, which means they did not meet the requirements of the first

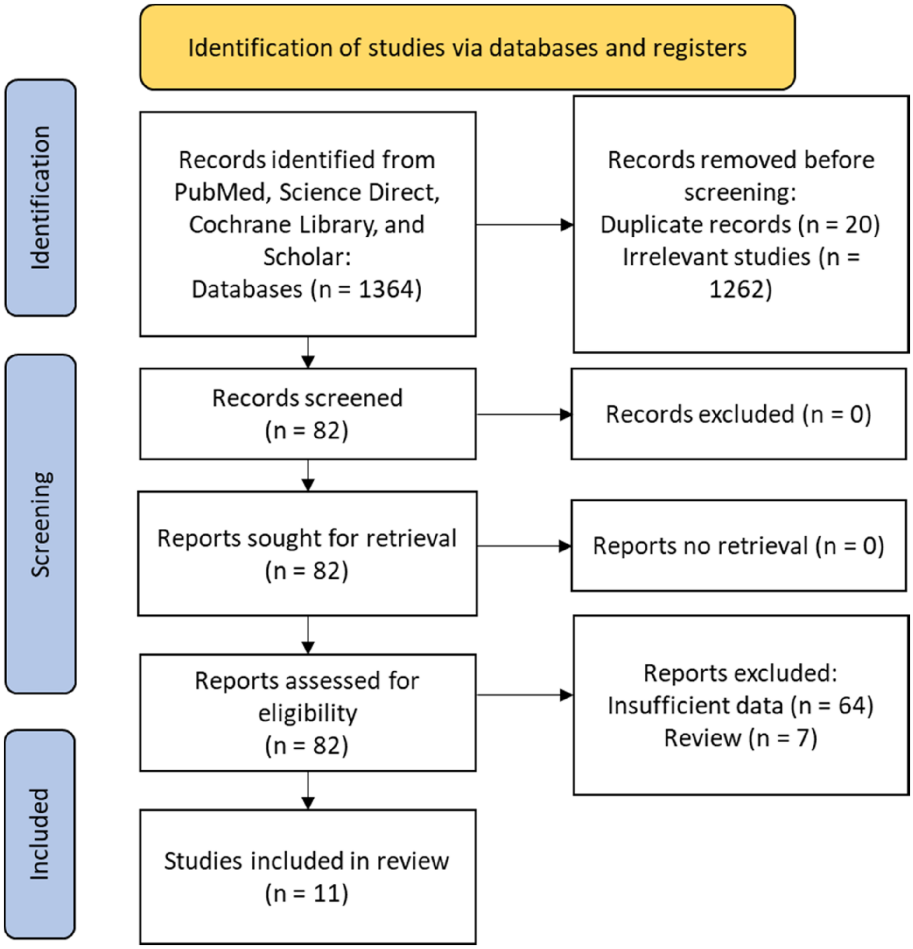

Figure 1 A flowchart of paper selection in our study.

domain of the Risk of Bias 2. The remaining studies are believed to have a low-risk bias (Fig. 2). Even if the included studies have varied degrees of bias, most of the data have been thoroughly addressed. Reviewers interpret this as indicating that they are adequately appropriate for this analysis.

Summaries of the included studies. Eleven studies were included in this review, focusing on the EUS-HGS compared with EUS-CDS. Table 1 shows the included studies. Besides that, the authors also summarized the value of the data based on the outcome of interest, as shown in Table 2. Heterogeneity was detected in all of the data among the outcomes analyzed. Therefore, we used the fixed-effect model on Technical Success, Clinical Success, Adverse Event, and Mean procedure time to analyze the data. We used Egger's test to assess the potential publication bias. Our cumulative calculation revealed that no evidence for publication bias ($P > 0.05$) existed in Technical Success, Clinical Success, Adverse Event, and Mean procedure time.

Technical success. Technical success was defined as placing a stent in the biliary system. In this review, we confirmed that ERCP-failed MBO patients who had undergone EUS-HGS and EUS-CDS had no significant difference in technical success (OR, 0.83; 95% CI, 0.41–1.68; $I^2 = 0\%$). Figure 3 shows the forest plot of technical success based on quantitative analysis.

Clinical success. Clinical success was defined as greater than 50% reduction in the bilirubin value after 2 weeks from the procedure compared with the preprocedural value. In this review, we found ERCP-failed MBO patients who had undergone EUS-HGS and EUS-CDS had no significant difference in clinical success (OR, 0.96; 95% CI, 0.51–1.81; $I^2 = 9.94\%$). Figure 4 shows the forest plot of clinical success based on quantitative analysis.

Adverse events. The definition of endoscopic adverse events (AEs) was adopted from the lexicon by the American Society for Gastrointestinal Endoscopy.[12] AE was defined as an event causing interruption of the procedure and/or requiring medical consultation, hospitalization, endoscopic, or surgical intervention. Adverse events appeared significantly higher in ERCP-failed MBO patients who had undergone EUS-HGS than EUS-CDS (OR, 2.01; 95% CI, 1.14–3.59; $I^2 = 0\%$). Figure 5 shows the forest plot of adverse events based on quantitative analysis.

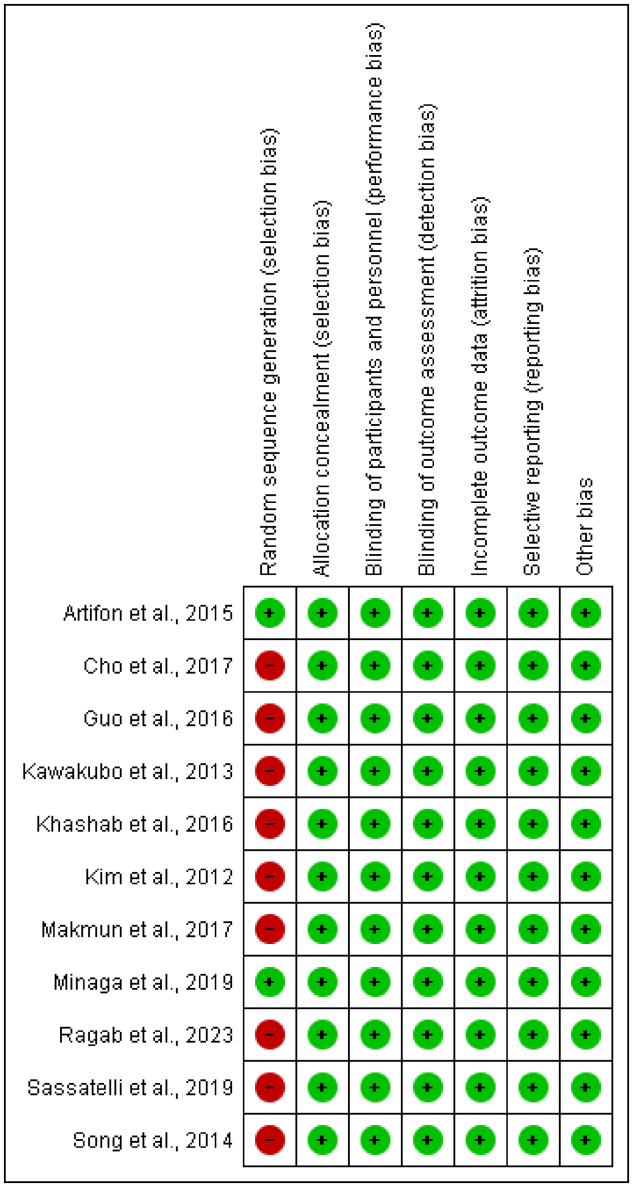

Figure 2 Risk of Bias 2 (RevMan 5.4.1).

Mean procedure time. In this review, we found ERCP-failed MBO patients who had undergone EUS-HGS and EUS-CDS had no significant difference in the mean procedure time (SMD, 0.13; 95% CI, −0.15–0.41; $I^2 = 34.89\%$). Figure 6 shows the forest plot of mean procedure time based on quantitative analysis.

Time to recurrent biliary obstruction (TRBO). Three of the nine studies analyzed in this meta-analysis were used to evaluate the mean TRBO. There was no significant difference between EUS-HGS and EUS-CDS for TRBO (SMD –0.30; 95% CI –0.65–0.05; $I^2 = 49\%$; P heterogeneity = 0.14; Fig. 7).

Discussion

This study assessed the efficacy and safety comparison between EUS-HGS and EUS-CDS intervention in ERCP-failed MBO patients. ERCP failure can be secondary to surgically altered anatomy, inaccessible papilla due to malignancy, or cannulation failure. Therefore, EUS-BD was described by Giovannini in 2001 and has emerged as an alternative to ERCP.[22] Given advantages such as internal drainage and a single procedure performed by the same operator without giving any discomfort of an external catheter. EUS-BD was associated with a better clinical success, less post-procedure adverse events, and lower re-intervention rates compared with other approaches.[23]

Our meta-analysis results revealed no significant difference between EUS-HGS and EUS-CDS in technical and clinical success. Our findings were also supported by Ragab et (2023)[19] and Lyu et al.[24] that technical success rates of EUS-BD ranged from 90.2% to 100%, while clinical success rates ranged from 84.4% to 98.2%. In comparison between EUS-HGS and EUS CBD, a systematic review and meta-analysis by Uemura et al.[25] also strengthen our findings that CDS and HGS were equally effective and safe with high technical and clinical success rates for both. The rates of technical success for CDS and HGS were 94.1% and 93.7%, respectively, while clinical success rates were 88.5% and 84.5% for CDS and HGS, respectively. There was no significant difference between CDS and HGS procedures regarding procedure time. Nonetheless, the median duration of CDS was 2 min less than HGS. A more recent meta-analysis by Li et al.[26] has supported that CDS was slightly faster, and it is recommended due to limited number of accessory changes during HGS to decrease the process duration. In our study, adverse events appeared two times more significantly in EUS-HGS procedures than in EUS-CDS. However, Yamazaki et al. found that the incidence rates of adverse events (AE) were not statistically significant between the two approaches, 23.8% for endoscopic ultrasound-guided hepatogastrostomy (EUS-HGS), and 18.6% for endoscopic ultrasound-guided choledochoduodenostomy (EUS-CDS). Furthermore, the analysis revealed that EUS-CDS generally required less time than EUS-HGS.[11]

Uemura et al. (2018) reviewed 10 studies involving 434 patients undergoing biliary drainage via HGS and CDS, reporting high technical success rates (94.1% for EUS-CDS and 93.7% for EUS-HGS) and similar adverse event rates. Clinical success rates were 88.5% for CDS and 84.5% for HGS. However, their study was limited by high heterogeneity and lacked data on Time to Recurrent Biliary Obstruction (TRBO).[25] In contrast, our review of 11 studies showed no significant differences in mean procedure time between EUS-HGS and EUS-CDS, and we provided TRBO data with low heterogeneity, minimizing bias in reporting. Our meta-analysis showed that TRBO did not differ significantly between EUS-HGS and EUS-CDS. A meta-analysis by Yamazaki et al. also supported our findings. They declared that TRBO might occur because of the patient's survival. In many cases, biliary obstruction was caused by advanced pancreaticobiliary cancer; therefore, patient survival time was short. Indeed, most patients died before the onset of RBO. This short survival time may have a marked effect on the occurrence of TRBO. By contrast, RBO rates may instead reflect real stent dysfunction.[11]

Table 1 Summary of studies

No.	Author and year	Country	Study type	Stent used	Study population	Etiology	Sample size	JADAD/ NOS
1	Kim et al., 2012[12]	Chonbuk, South Korea	Cohort	FCSMES	Obstructive jaundice failed after ERCP	CBD Cancer 5; Pancreatic Cancer 6; Klatskin's tumor 1; Intrahepatic cholangiocarcinoma 1	EUS-HGS 4 EUS-CDS 9	5
2	Makmun et al., 2017[13]	Jakarta, Indonesia	Retrospective	SEMS and plastic stent	Malignant biliary obstruction failed ERCP	Tumor of the head of pancreas 13; periampullary tumor 10; cholangiocarcinoma 1	EUS-HGS 1 EUS-CDS 18	7
3	Khashab et al., 2016[14]	Baltimore, USA	Retrospective	FCSEMS and plastic stent	Malignant biliary obstruction failed ERCP	Obscured ampulla by tumor or stent 45; distorted anatomy/difficult cannulation 43; gastric outlet obstruction 28; others 6	EUS-HGS 61 EUS-CDS 60	7
4	Artifon et al., 2015[15]	Sao Paulo, Brazil	Randomized Controlled Trial	FCSMES	Malignant biliary obstruction failed ERCP	Pancreatic Cancer 33; Metastatic adenopathy 8; papillary cancer 4; malignant neuroendocrine cancer 2; gallbladder cancer 1; duodenal cancer 1	EUS-HGS 25 EUS-CDS 24	5
5	Minaga et al., 2019[16]	Wakayama, Japan	Randomized Controlled Trial	SMES	Malignant distal biliary obstruction failed ERCP	Pancreatobiliary cancer 41; Other 6	EUS-HGS 24 EUS-CDS 23	6
6	Cho et al., 2017[17]	Ulsan, South Korea	Prospective	Partially covered self-expandable metal stent (PCSEMS)	Malignant biliary obstruction failed ERCP	Pancreatic Cancer 25; Cholangiocarcinoma 11; gallbladder cancer 3; Metastatic cancer 3; Neuroendocrine Tumor 2; Others 10	EUS-HGS 21 EUS-CDS 33	7
7	Song et al., 2014[18]	Seoul, South Korea	Prospective	Partially covered self-expandable metal stent (PCSEMS)	Malignant biliary obstruction failed ERCP	Pancreatic cancer 2; hilar cholangiocarcinoma 8; pancreatic neuroendocrine tumor 2; gallbladder cancer 2; ampulla of vater cancer 1; advanced gastric cancer 1; rectal cancer 1	EUS-HGS 10 EUS-CDS 17	6
8	Sassatelli et al., 2019[19]	Milan, Italy	Retrospective	FCSMES and plastic stent	Malignant biliary obstruction failed ERCP	Pancreatic adenocarcinoma 21; pancreatic cancer 4; metastatic disease 3; cholangiocarcinoma 3; gastric cancer 2; gallbladder cancer 2	EUS-HGS 20 EUS-CDS 13	6
9	Ragab et al., 2023[20]	Egypt, Africa	Prospective	FCSMES and plastic stent	Malignant biliary obstruction failed ERCP	Advanced pancreatic/ ampullary tumor with no duodenal obstruction 58; advanced pancreatic/ampullar tumor with duodenal obstruction 17; altered anatomy with tumor 7; cholangiocarcinoma 5; undifferentiated CBD 4	EUS-HGS 32 EUS-CDS 45	6

(*Continues*)

Table 1 (Continued)

No.	Author and year	Country	Study type	Stent used	Study population	Etiology	Sample size	JADAD/ NOS
10	Kawakubo et al., 2014[21]	Tokyo, Japan	Retrospective Cohort	FCSMES and plastic stent	Malignant biliary obstruction failed ERCP	Pancreatic cancer 42; bile duct cancer 5; gallbladder cancer 1; ampullary cancer 9; metastatic lymph nodes 7; previous biliary drainage 31	EUS-HGS 20 EUS-CDS 44	6
11	Guo et al., 2016[22]	Shenyang, China	Prospective	FCSMES	Malignant biliary obstruction failed ERCP	Pancreatic carcinoma 4, ampullary carcinoma 3, duodenal carcinoma 2	EUS-HGS 7 EUS-CDS 14	7

Table 2 The data for outcome of interest

Clinical characteristics	NS	Model	Value		pE	pHet	p	RR	95% CI
			EUS-HGS	EUS-CDS					
Technical success	11	Fixed	214 [95.1]	225 [96.1]	0.548	0.709	0.611	0.833	0.412–1.684
Clinical success	7	Fixed	152 [86.3]	168 [88.0]	0.836	0.353	0.894	0.958	0.507–1.810
Adverse events	8	Fixed	37 [23.0]	25 [12.3]	0.611	0.812	0.018	2.011	1.128–3.587

Clinical characteristics	NS	Model	Value		pE	pHet	p	SMD	95% CI
			EUS-HGS	EUS-CDS					
Mean procedure time	4	Fixed	24.93 ± 13.3	22.63 ± 12.45	0.965	0.203	0.360	0.131	−0.149-0.411
Time to recurrent biliary obstruction	3	Fixed	128.12 ± 128.09	106.71 ± 101.93	0,988	0.14	0.09	−0.30	−0.65–0.05

Value data were presented in number [%] and mean ± SD.
CI, confidence interval; NS, number of studies; OR, odd ratio; pE, p Egger; pHet, p heterogeneity.

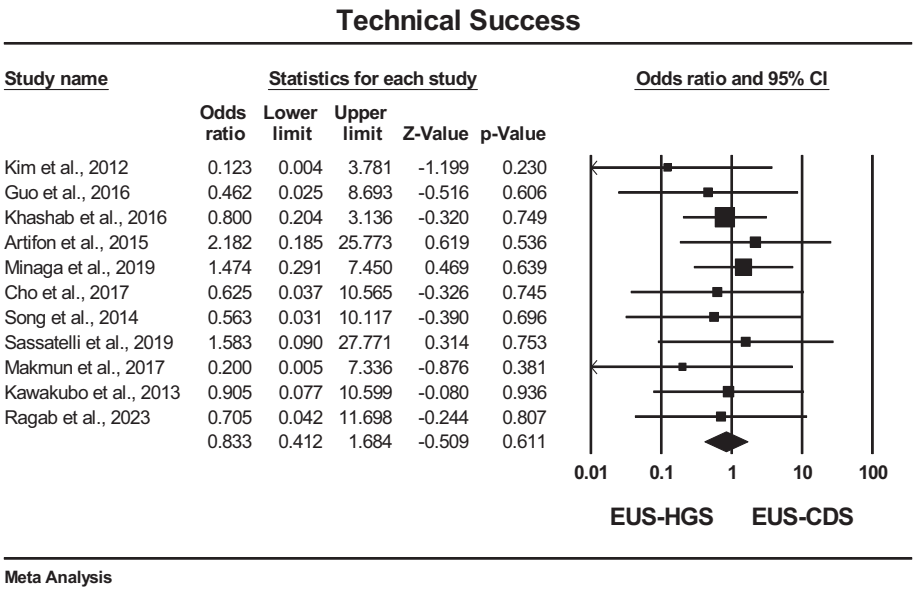

Figure 3 A forest plot of the technical success between EUS-HGS and EUS-CDS in ERCP-failed malignant obstructions patients.

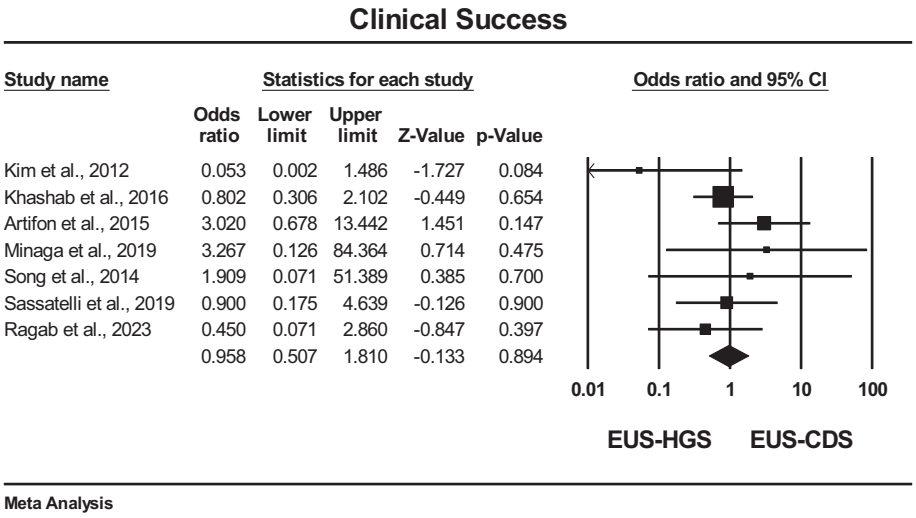

Figure 4 A forest plot of the clinical success between EUS-HGS and EUS-CDS in ERCP-failed malignant obstructions patients.

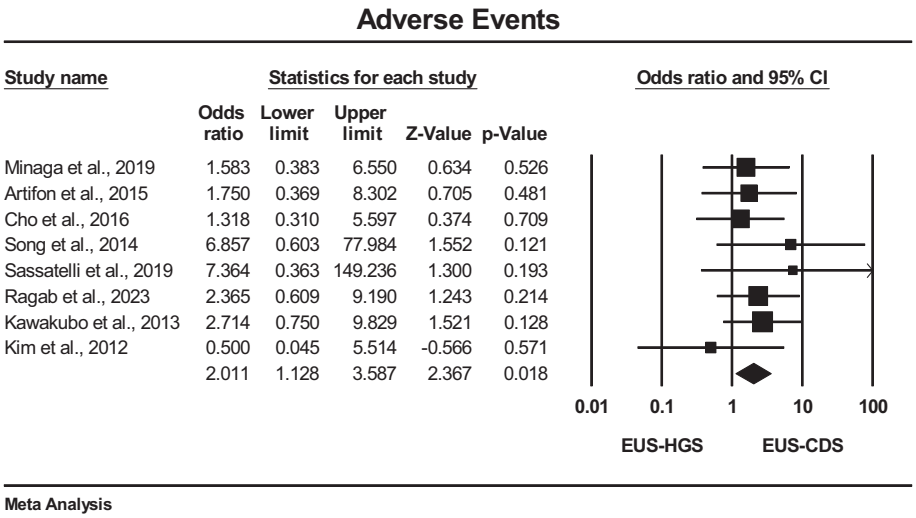

Figure 5 A forest plot of the adverse events between EUS-HGS and EUS-CDS in ERCP-failed malignant obstructions patients.

Despite having comparable efficacy, EUS-CDS and EUS-HGS still possess some limitations. First, the limitations of EUS-CDS include the potential difficulty in achieving the procedure due to the extrahepatic bile duct, which is not always being right next to the duodenal wall, and it could lead to displacement between the puncture site of the duodenal wall and the bile duct, increasing the risk of procedure failure.[15,27] Additionally, the proximity of the extrahepatic bile duct to the portal vein in certain duodenal portions poses a risk during puncture, particularly in patients with mild dilation of the bile duct. EUS-HGS faces challenges due to potential displacement between the gastric wall and intrahepatic bile duct, increasing procedure failure risk.[14] This problem is especially prominent in livers with large levels of fibrous tissue, such as liver cirrhosis. Furthermore, there is a possibility of injury during puncture due to the proximity of the intrahepatic bile duct to the intrahepatic portal vein, especially in individuals with intrahepatic bile duct dilatation.[9,14] Second, indications for EUS-CDS preferably for unresectable distal MBO, particularly pancreatic cancer without proximal duodenal involvement or altered anatomy, as reported in a retrospective study that EUS-CDS has a longer stent patency and fever AEs. It has a better safety profile compared with EUS-HGS in a certain conditions.[28–30] EUS-HGS indicated in distal MBO with a duodenal invasion, and including individuals with altered anatomy, and hilar MBO requiring drainage of the left hepatic lobe[30] (Matsubara).

We used high-quality study articles for this meta-analysis, as the high-quality assessment score predicted. Our meta-analysis

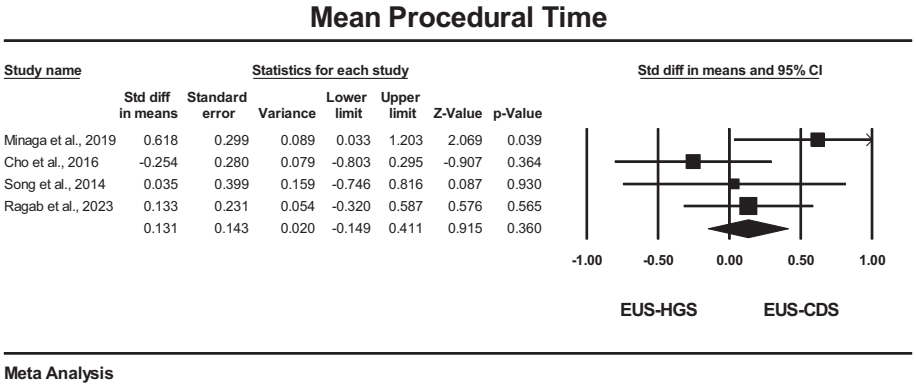

Figure 6 A forest plot of the mean procedure time between EUS-HGS and EUS-CDS in ERCP-failed malignant obstructions patients.

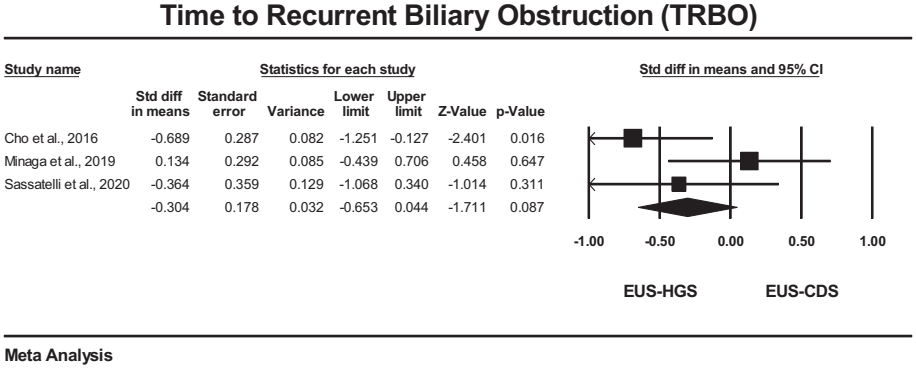

Figure 7 A forest plot of the time to recurrent biliary obstruction between EUS-HGS and EUS-CDS in ERCP-failed malignant obstructions patients.

has some important strengths. This study was the first report to compare the efficacy and safety of EUS-HGS and EUS-CDS. The Egger test report and visual inspection of the funnel plot showed no publication bias. However, we also acknowledge some limitations in this review. First, most studies were observational, and some used nonrandomized methods, which could lead to selection bias. Second, several studies have not differentiated the two distal or proximal malignant obstruction procedures. Third, some eligible studies reported incomplete adjustments for potential confounding factors. Thus, the possibility of residual confounding by unmeasured factors cannot be ruled out. These limitations might affect the final findings. Therefore, further studies about the effect of stent use on efficacy and safety and randomized controlled trial (RCT) studies with large sample sizes are needed to compare the techniques and better elucidate our findings.

Conclusion

In summary, there are differences in efficacy and safety between EUS-HGS and EUS-CDS; however, EUS-CDS has a faster procedural time, lower risk of side effects, and ease of puncture during the procedure.

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