Communication from the ASGE Standards of Practice Committee

SOCIETY DOCUMENTS

ASGE American Society for Gastrointestinal Endoscopy

American Society for Gastrointestinal Endoscopy guideline on the role of therapeutic EUS in the management of biliary tract disorders: methodology and review of evidence

Prepared by: American Society for Gastrointestinal Endoscopy Standards of Practice Committee

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This guideline article was prepared by the Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy using the best available scientific evidence and considering a multitude of variables including but not limited to adverse events, patient values, and cost implications. The purpose of these guidelines is to provide the best practice recommendations that may help standardize patient care, improve patient outcomes, and reduce variability in practice. We recognize that clinical decision-making is complex. Guidelines, therefore, are not a substitute for a clinician's judgment. Such judgements may, at times, seem contradictory to our guidance because of many factors that are impossible to fully consider by guideline developers. Any clinical decisions should be based on the clinician's experience, local expertise, resource availability, and patient values and preferences. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating for, mandating, or discouraging any treatment. Our guidelines should not be used in support of medical complaints, legal proceedings, and/or litigation as they were not designed for this purpose.

ERCP is the first-line therapy for the management of biliary tract obstruction. However, ERCP may fail for various reasons such as altered anatomy or an inability to access the major papilla. Therapeutic EUS has emerged as a minimally invasive alternative for biliary drainage when ERCP is unsuccessful or cannot be done because of altered anatomy.

The American Society for Gastrointestinal Endoscopy (ASGE) Standards of Practice Committee aimed to develop clinical practice guidelines for the role of therapeutic EUS for the management of biliary tract disease. This article details guideline methodology including formulation of clinical questions, literature searches, data analyses, panel composition, evidence profiles, and other considerations like cost-effectiveness, patient preferences, and health equity. These guidelines follow the Grading of Recommendations Assessment, Development and Evaluation methodology.[1] In formulating these guidelines, we conducted extensive literature reviews, including a formal systematic review of the literature and meta-analyses. For each clinical question, this article includes outcomes of interest, pooled-effects estimates, and evidence that was considered by the panel in making final recommendations. To ensure all the information we collected and analyzed was readily assessable, this guideline is presented in 2 documents. The "Summary and Recommendations" is published separately and provides a summary of our findings and final recommendations.

METHODS

This article describes the methodology guide and provides a detailed review of the evidence used to inform this guideline. It details the formulation of clinical questions, literature searches, data analyses, panel composition, evidence profiles, and other considerations such as cost-effectiveness, patient preferences, and health equity. For each clinical question, this article includes outcomes of interest, pooled-effects estimates, and evidence that was considered by the panel in making final recommendations. A separate publication provides a summary of the main findings and final recommendations of the ASGE Standards of Practice Committee.

Formulation of clinical questions

This guideline addressed 5 clinical questions (Table 1). For these questions, we followed the PICO format: P, population in question; I, intervention; C, comparator; and O, outcomes of interest. For all clinical questions, potentially

TABLE 1. Summary of population, intervention, comparator, and outcomes (PICO) questions

Population	Intervention	Comparator	Outcomes	Rating
Patients with biliary obstruction and failed ERCP	EUS-BD	PTBD	1. 30-day mortality	Critical
			2. Clinical success	Critical
			3. Technical success	Critical
			4. Adverse events	Critical
			5. Need for reintervention	Critical
			6. Cost	Critical
Patients with distal malignant biliary obstruction and failed ERCP	EUS-CDS	EUS-HGS	1. Technical success	Critical
			2. Clinical success	Critical
			3. Adverse events	Critical
			4. Need for reintervention	Critical
			5. Cost	Critical
Patients with Roux-en-Y gastric bypass anatomy and biliary obstruction	EDGE	E-ERCP / LA-ERCP6.	1. Technical success	Critical
			2. Clinical success	Critical
			3. Adverse events	Critical
			4. Need for reintervention	Critical
			5. Cost	Critical
Patients with non- Roux-en-Y gastric bypass surgically altered anatomy with biliary obstruction	EUS-BD	PTBD / ERCP5)	1. Technical success	Critical
			2. Clinical success	Critical
			3. Adverse events	Critical
			4. Need for reintervention	Critical
Patients with acute cholecystitis who are not surgical candidates	EUS-GBD	PT-GBD / ERCP9.	1. 30-day mortality	Critical
			2. Technical success	Critical
			3. Critical success	Critical
			4. Adverse events	Critical
			5. Recurrent cholecystitis	Critical
			6. Need for reintervention	Critical
			7. Need for hospital readmission	Critical
			8. Need for future cholecystectomy	Critical

E-ERCP, Enteroscopy-assisted ERCP; *EUS-BD*, EUS-guided biliary drainage; *EUS-CDS*, EUS-guided choledoduodenostomy; *EUS-HGS*, EUS-guided hepaticogastrostomy; *LA-ERCP*, laparoscopic-assisted ERCP; *PT-GBD*, percutaneous transhepatic gallbladder drainage; *PTBD*, percutaneous transhepatic biliary drainage.

relevant patient-important outcomes were identified a priori and rated from "critical" to "important" through a consensus process. These clinical questions were as follows:

1. In patients with biliary obstruction and failed ERCP, how does EUS-guided biliary drainage (EUS-BD) compare with percutaneous transhepatic biliary drainage (PTBD) in resolving biliary obstruction?
2. In patients with malignant distal biliary obstruction and failed ERCP, how does EUS-guided hepaticogastrostomy (EUS-HGS) compare with EUS-guided choledochoduodenostomy (EUS-CDS) in resolving biliary obstruction?
3. In patients who have undergone prior Roux-en-Y gastric bypass surgery and have biliary obstruction, how does EUS-guided transgastric ERCP (EDGE) compare with enteroscopy-assisted ERCP (E-ERCP) or laparoscopic-assisted ERCP (LA-ERCP) in resolving biliary obstruction?
4. In patients who have surgically altered anatomy (specifically, patients who have undergone prior Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II reconstruction) with biliary obstruction, how do EUS-guided interventions compare with E-ERCP and PTBD regarding rates of successful biliary drainage?
5. In nonsurgical patients with acute cholecystitis, how does EUS-GBD compare with percutaneous (PT)-GBD and endoscopic transpapillary transcystic (ET)-GBD in resolving acute cholecystitis?

Literature search and study selection criteria

To inform the guideline panel, a comprehensive literature search was performed with the help of an expert librarian (Robyn Rosasco, MSLIS, AHIP) using Ovid MEDLINE, EMBASE, and Wiley Cochrane from inception of the database to February 18, 2022. The searches were limited to studies published in the English language. We excluded case reports, conference abstracts, case series with <10 patients, and animal studies.

For each PICO question, existing systematic reviews and meta-analyses were identified, and studies meeting inclusion criteria were used in our analysis. If no existing systematic reviews or meta-analyses were identified, a full systematic review and meta-analysis was conducted (when possible) using the recommendations of the Preferred Reporting Items for Systematic reviews and Meta-Analyses criteria.[2] Citations were imported into EndNote (Thompson Reuters, Philadelphia, Pa, USA), and duplicates were removed. The EndNote library was then uploaded into Covidence (www.covidence.org). On rotation, studies were first screened by title and abstract and then by full text by 2

TABLE 2. Interpretation of the definitions of the strength of recommendation using Grading of Recommendations Assessment, Development and Evaluation framework

Implications for	Strong recommendation	Conditional recommendation
Patients	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	Most individuals in this situation would want the suggested course of action, but many would not.
Clinicians	Most individuals should receive the test. Formal decision aids are not likely to be needed to help individual patients make decisions consistent with their values and preferences.	Recognize that different choices will be appropriate for individual patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences. Decision aids may be useful in helping individuals to make decisions consistent with their values and preferences
Policymakers	The recommendation can be adopted as policy in most situations. Compliance with this recommendation according to the guideline could be used as a quality criterion or performance indicator.	Policymaking will require substantial debate and involvement of various stakeholders.

Adapted from Andrews et al.[1]

independent reviewers and all conflicts resolved by a third independent reviewer (N.B.M., N.R.T., and S.P.).

Data extraction and statistical analysis

Data were extracted by 3 independent reviewers (N.B.M., N.R.T., and S.P.) using Covidence (covidence.org) and Microsoft Excel (Microsoft Corporation, Redmond, Wash, USA). The primary estimates of effects were based on a priori–identified outcomes of interest. Meta-analyses were performed for all PICO questions. Heterogeneity was assessed using the I^2 statistic. Significant heterogeneity was noted if the I^2 was >50%. Random-effects models were used for analyzing, and studies were weighted based on size. Publication biases were assessed using funnel plots. Summary statistics for all PICO questions included odds ratios (ORs). Statistical analyses were performed using Comprehensive Meta Analysis V3 (Biostat Inc, Englewood, NJ, USA) by 1 author (S.N.).

Panel composition and conflict of interest management

We assembled a panel of stakeholders to review evidence and make recommendations. The panel consisted of lead authors (N.B.M., N.R.T., and S.P.); committee members with expertise in methodology, systematic reviews, and meta-analysis (N.F., N.C.T., and M.D.); and content experts (A.Y.B.T. and T.H.B.) and was chaired by the Standards of Practice committee chair (B.J.Q.). A patient representative was also included after a thorough review of patients who had undergone both endoscopic procedures and percutaneous procedures.

A virtual meeting was convened on January 18, 2023. All panel members were required to disclose potential financial and intellectual conflicts of interest, which were addressed according to ASGE policies set forth in the ASGE & Journal Policy for Managing Declared Conflicts of Interest found at https://www.asge.org/docs/default-source/default-document-library/coi-full-policy-for-asge-and-publications_edd_2-10-20.pdf. Panel members who received funding for any technologies or companies associated with any of the PICO questions or had other relevant conflicts of interest were asked to declare their conflicts before the discussion and did not vote on the final recommendation addressing that specific PICO question. Lead authors and methodologists were also excluded from voting.

Certainty in the evidence

The Grading of Recommendations Assessment, Development and Evaluation approach was used to determine the quality of the evidence and confidence in the estimated effects. The following domains were addressed: bias of individual studies, imprecision, inconsistency, indirectness, and publication bias. Certainty was categorized into 1 of 4 levels: high, moderate, low, and very low (Table 2).[3] The evidence profiles were generated using GRADEpro/GDT applications (https://gdt.guidelinedevelopment.org/app). Evidence profiles were then presented during the panel meeting and discussed in detail with all stakeholders before voting on final recommendations. Approval of the final recommendations was based on simple a majority.

Outcomes and definitions

For most clinical questions, outcomes included 30-day mortality, technical success, clinical success, adverse events (AEs), rates of pancreatitis, need for reintervention, length of hospitalization, recurrent cholecystitis, need for future cholecystectomy, procedure time, and cost. For PICOs 1, 2, 3, and 4, technical success was defined as successful access with subsequent intervention or stent placement of the bile duct. For PICO 5, technical success was defined as successful access and intervention or stent placement of the gallbladder. For PICOs 1, 2, 3 and 4, clinical success was defined as reduction in total bilirubin (most often by at least 50%) in the 1 to 4 weeks after the intervention. For PICO 5, clinical success was defined as resolution of cholecystitis. The need for reintervention referred to unplanned repeat interventions. AEs included bleeding, infection, perforation, and bile leak.

TABLE 3. Summary of recommendations

Recommendation	General concepts	Strength of recommendation	Quality of evidence
1. In patients with biliary obstruction and failed ERCP, the ASGE suggests EUS-BD over percutaneous biliary drainage to resolve biliary obstruction.	The EUS-guided rendezvous procedure is preferred over CDS or HGS in suspected benign disease. Transmural drainage can be performed with multidisciplinary input and patient counseling. PTBD is preferred in patients who are hemodynamically unstable, cannot tolerate general anesthesia, or have suspected malignancy as the cause of the obstruction.	*Conditional recommendation*	*Low*
2. In patients with distal malignant biliary obstruction and failed ERCP, the ASGE suggests either EUS-HGS or EUS-CDS be performed to resolve biliary obstruction.	CDS should be preferred if there is cancerous involvement of the stomach compromising puncture sites for HGS. EUS-HGS preferred for cancerous involvement of the duodenum or a pre-existing enteral stent compromising puncture sites for CDS, gastric outlet obstruction proximal to the pylorus, and a proximal/hilar biliary obstruction is present.	*Conditional recommendation*	*Low*
3. In patients with Roux-en-Y gastric bypass surgery needing biliary drainage, the ASGE suggests EDGE over E-ERCP or LA-ERCP in resolving biliary obstruction.	EDGE is preferred in patients with a suspected ampullary lesion, with malignant disease, or needing repeat ERCP. LA-ERCP may be preferred in patients who require surgery in the near future (eg, cholecystectomy).	*Conditional recommendation*	*Low*
4. In patients with biliary obstruction and non–gastric bypass surgically altered anatomy (specifically patients who have undergone prior Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II reconstruction), the ASGE suggests E-ERCP as an initial approach. If unsuccessful, the ASGE suggests EUS-BD or percutaneous biliary drainage.	Review the operative report to identify the length of the Roux limb (if feasible).	*Conditional recommendation*	*Very low*
5a. In patients with acute cholecystitis who are not candidates for cholecystectomy, the ASGE suggests EUS-GBD over percutaneous gallbladder drainage in resolving acute cholecystitis. 5b. In patients with acute cholecystitis who cannot undergo cholecystectomy, the ASGE suggests EUS-GBD over ET-GBD to resolve acute cholecystitis.	EUS-GBD is preferred in patients with gastric outlet obstruction, duodenal obstruction, indwelling metal stent occluding the cystic duct, and large stone burden within gallbladder. ET-GBD preferred in patients with ascites, malignant gallbladder infiltration, or severe coagulopathy, who have refused rescue surgery, liver transplant candidates, and patients who are not surgical candidates at the time of intervention but may be in the future. PT-GBD preferred in patients with gallbladder perforation, emphysematous cholecystitis, clinical instability, or inability to tolerate more than moderate sedation.	*Conditional recommendation*	*Moderate*

ASGE, American Society for Gastrointestinal Endoscopy; *E-ERCP*, enteroscopy-assisted ERCP; *EDGE*, EUS-directed transgastric ERCP; *ET-GBD*, endoscopic transpapillary transcystic gallbladder drainage *EUS-BD*, EUS-guided biliary drainage; *EUS-CDS*, EUS-guided choledoduodenostomy; *EUS-HGS*, EUS-guided hepaticogastrostomy; *LA-ERCP*, laparoscopic-assisted ERCP; *PT-GBD*, percutaneous transhepatic gallbladder drainage; *PTBD*, percutaneous transhepatic biliary drainage.

For PICOs 1 and 2, failed ERCP was defined as failed attempts at biliary cannulation despite commonly applied adjunctive maneuvers, such as cannulation over a pancreatic duct stent, double-wire technique, and needle-knife sphincterotomy or papillotomy. Additionally, failed ERCP included cases where the major papilla could not be accessed because of the presence of a luminal obstruction in the stomach or duodenum. For PICO 5, patients were nonsurgical candidates if they were deemed unlikely to ever receive a cholecystectomy even once their acute illness resolved. A summary of our final recommendations for the management of patients with biliary tract disease using therapeutic EUS is shown in Table 3.

External review

The final guideline was reviewed by the *Gastrointestinal Endoscopy* Editorial Board and made available for public comment on the ASGE website for 30 days before final approval by the ASGE Governing Board.

RESULTS

For this guideline, 2 important general concepts are noted and emphasized. First, the interventions considered in this guideline are highly technical and require specific skillsets. Therefore, the decision to perform these interventions is

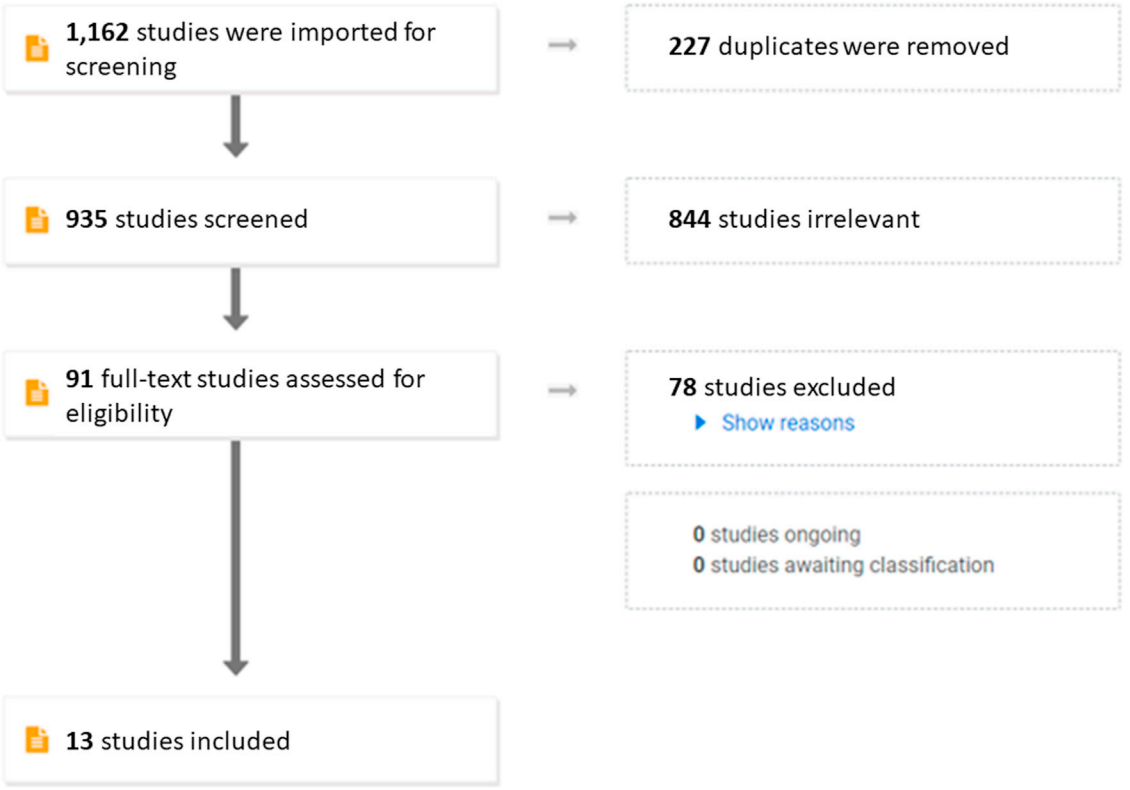


Figure 1. Preferred Reporting Items for Systematic reviews and Meta-Analyses diagram showing studies included in the systematic review evaluating the management strategy of biliary obstruction after failed ERCP (PICO 1).

predicated on the availability of such expertise in each institution. Second, in patients who may require future surgical management, it is recommended that endoscopists discuss options with appropriate teams (ie, surgery, oncology, and/or interventional radiology) before attempting EUS-BD or EUS-GBD.

Question 1: In patients with biliary obstruction and failed ERCP, how does EUS-BD compare with PTBD in resolving biliary obstruction?

Recommendation 1: In patients with biliary obstruction and failed ERCP, the ASGE suggests EUS-BD over PTBD to resolve biliary obstruction.

(Conditional recommendation, low quality of evidence)

General concepts:

- The EUS-guided rendezvous procedure is preferred over CDS or HGS in suspected benign disease.
- Transmural drainage can be performed with multidisciplinary input and patient counseling.
- PTBD is preferred in patients who are hemodynamically unstable, cannot tolerate general anesthesia, or have suspected malignancy as the cause of the obstruction.

We performed a systematic review of literature on this topic that can be found in Appendix 1 (available online at www.giejournal.org). The systematic review was restricted to those studies assessing outcomes of EUS-BD or PTBD as rescue therapy for patients requiring biliary drainage who have had a failed ERCP (Fig. 1). For this question, EUS-BD maneuvers included EUS-guided rendezvous procedure, EUS-CDS, and EUS-HGS. Studies evaluating either or both benign and malignant conditions as the presumed cause of failed ERCP were included in our review.

We identified 13 full-text studies (2 randomized controlled trials [RCTs] and 11 observational studies).[4-16] Of the RCTs, 1 was a single-center study and the other was a multicenter study from South Korea.[4,10] Both RCTs were of high quality with Jadad scores of $\geq$3.[17] All observational studies were retrospective and single-center with Qumseya scores $\geq$7.[18] Across the 13 studies, 379 patients underwent EUS-BD compared with 376 patients who underwent PTBD.

Outcomes. The results are summarized in an evidence profile (Table 4).

Mortality. Procedure-related mortality was reported in 8 studies (2 RCTs and 6 observational studies). Across the studies, there was no significant difference in mortality in

TABLE 4. Evidence profiles for Question 1: In patients with biliary obstruction and failed ERCP, how does EUS-BD compare with PTBD in resolving biliary obstruction?
Author(s):
Question: EUS-BD compared with PTBD for biliary obstruction and failed ERCP
Setting:
Bibliography:

Certainty assessment						
No. of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**
Mortality (2 RCTs, 6 OS)						
8	Nonrandomized studies	Not serious	Not serious	Not serious	Serious*	None
Clinical success (ie, decrease in bilirubin by 50% in 4 wk [2 RCTs])						
2	Randomized trials	Not serious	Not serious	Not serious	Serious*	None
Clinical success (defined as 50% decrease in bilirubin at 4 wk [10 cohort studies])						
10	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Technical success (all studies [2 RCTs, 11 OS])						
13	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Adverse events (RCTs)						
2	Randomized trials	Not serious	Not serious	Not serious	Serious*	None
Adverse events (cohort studies)						
10	Nonrandomized studies	Not serious	Serious†	Not serious	Not serious	None
Need for repeat intervention (unplanned [2 RCTs])						
2	Randomized trials	Not serious	Not serious	Not serious	Not serious	None
Need for repeat intervention (7 cohort studies)						
7	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious*	None
Length of hospital stay (days)						
1	Nonrandomized studies	Not serious	Not serious	Not serious	Serious*	None

EUD-BD, EUS-guided biliary drainage; *PTBD,* percutaneous transhepatic biliary drainage; *CI*, confidence interval; *OR*, odds ratio; *RCT*, randomized controlled trial; *OS*, observational studies.
*Low number of events.
†High I^2.

those patients undergoing EUS-BD versus PTBD (OR, .34; 95% confidence interval [CI], .09-1.19; I^2 = 0%) (Fig. 2).[4-7,10,13,15,16] Intervals during which procedure-related mortality was assessed ranged from 7 to 30 days after the intervention. While assessing the certainty of evidence, we rated down for imprecision. Overall, the judged quality of evidence from the 8 studies was very low.

Technical success. All 13 studies (11 observational studies and 2 RCTs) assessed technical success. In the 2 RCTs, technical success was similar for EUS-BD compared with PTBD (OR, .52; 95% CI, .04-5.99; I^2 = 48%).[4,10] This was further supported by data from 11 observational studies (OR, 1.50; 95% CI, .56-4.01; I^2 = 45%) (Fig. 3).[5-9,11-16]

Across all the included studies, technical success had a consistent definition, which was the successful placement of a stent or drain in the desired biliary system. The overall judged quality of evidence was found to be low.

Clinical success. Twelve studies (10 observational studies and 2 RCTs) assessed clinical success.[4,6-16] From the observational studies, clinical success was greater in patients undergoing EUS-BD compared with those undergoing PTBD (OR, 2.53; 95% CI, 1.22-5.28; I^2 = 58%).[6-9,11-16] For the RCTs, the OR for clinical success for EUS-BD relative to PTBD was nonsignificant (OR, .86; 95% CI, .24-3.17).[4,10] Finally, among all 12 studies, rate of clinical success was significantly higher in patients receiving EUS-BD compared with PTBD (OR, 2.27; 95% CI, 1.13-4.54; I^2 = 59%) (Fig. 4).

TABLE 4. Continued

No. of patients		Effect			
EUS-BD	PTBD	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
3/236 (1.3%)	10/250 (4.0%)	OR .34 (.09-1.19)	26 fewer per 1000 (from 36 fewer to 7 more)	⨁◯◯◯ Very low	CRITICAL
41/47 (87.2%)	39/44 (88.6%)	OR .86 (.24-3.17)	16 fewer per 1000 (from 235 fewer to 75 more)	⨁⨁⨁◯ Moderate	CRITICAL
256/307 (83.4%)	211/306 (69.0%)	OR 2.53 (1.22-5.28)	159 more per 1000 (from 41 more to 232 more)	⨁⨁◯◯ Low	CRITICAL
354/379 (93.4%)	342/376 (91.0%)	OR 1.39 (.55-3.48)	24 more per 1000 (from 63 fewer to 63 more)	⨁⨁◯◯ Low	CRITICAL
5/47 (10.6%)	13/44 (29.5%)	OR .29 (.09-.91)	187 fewer per 1000 (from 259 fewer to 19 fewer)	⨁⨁⨁◯ Moderate	CRITICAL
39/324 (12.0%)	115/317 (36.3%)	OR .26 (.12-.56)	234 fewer per 1000 (from 299 fewer to 121 fewer)	⨁◯◯◯ Very low	CRITICAL
8/47 (17.0%)	17/44 (38.6%)	OR .27 (.09-.78)	241 fewer per 1000 (from 333 fewer to 57 fewer)	⨁⨁⨁⨁ High	CRITICAL
13/189 (6.9%)	128/240 (53.3%)	OR .07 (.04-.14)	459 fewer per 1000 (from 490 fewer to 395 fewer)	⨁⨁◯◯ Low	CRITICAL
11.54	15.68	—	Mean difference, 4.14 higher (0 to 0)	⨁◯◯◯ Very low	CRITICAL

Clinical success was inconsistently defined across the included studies. One RCT reported clinical success but did not define it.[4] One observational study defined clinical success as the resolution of biliary obstruction without the need for reintervention.[14] Otherwise, the remaining studies defined clinical success as improvement in bilirubin by at least 50% across varying intervals from 1 to 4 weeks.[6-16] For this evaluation, clinical success across all studies was pooled. The overall judged quality of evidence from the RCTs was moderate, whereas the data from the observational studies were low.

Adverse events. Procedure-related AEs were described in 12 studies (10 observational studies and 2 RCTs).[4-10,12-16] In both RCTs, the performance of EUS-BD was associated with lower odds of AEs than PTBD (OR, .29; 95% CI, .09-.91; I^2 = 0%).[4,10] This was also supported by data from observational studies (OR, .26; 95% CI, .12-.56; I^2 = 59%) (Fig. 5).[5-9,12-16]

Most extracted studies determined the rate and severity of AEs according to the ASGE lexicon.[19] Studies, however, were inconsistent in qualifying AEs as being mild, moderate, or severe. Thus, we only reported total AEs in our analysis. AEs were reported on a per-patient basis as opposed to a per-event basis. Regarding the data extracted from the RCTs, we rated down for imprecision. The overall judged quality of evidence from the RCTs was found to be moderate. Regarding the data from observational studies, we rated down for inconsistency. The overall judged quality of evidence from the cohort studies was found to be very low.

Need for repeat intervention. The need for a repeat intervention after EUS-BD or PTBD was described in 9 studies (7 observational studies and 2 RCTs).[4-7,9-11,13,15] From the observational studies, the rate of repeat intervention for patients undergoing EUS-BD compared with those undergoing PTBD was lower (OR, .07; 95% CI, .04-.14; I^2 = 4%).[5-7,9,11,13,15] A similar pattern was seen in the RCTs, where the OR for having a repeat intervention for those undergoing EUS-BD relative to PTBD was .27 (95% CI, .09-.78).[4,10] Across all these studies, the OR for needing a repeat intervention after undergoing EUS-BD compared with PTBD was significantly lower at .27 (95% CI, .14-.51) (Fig. 6).

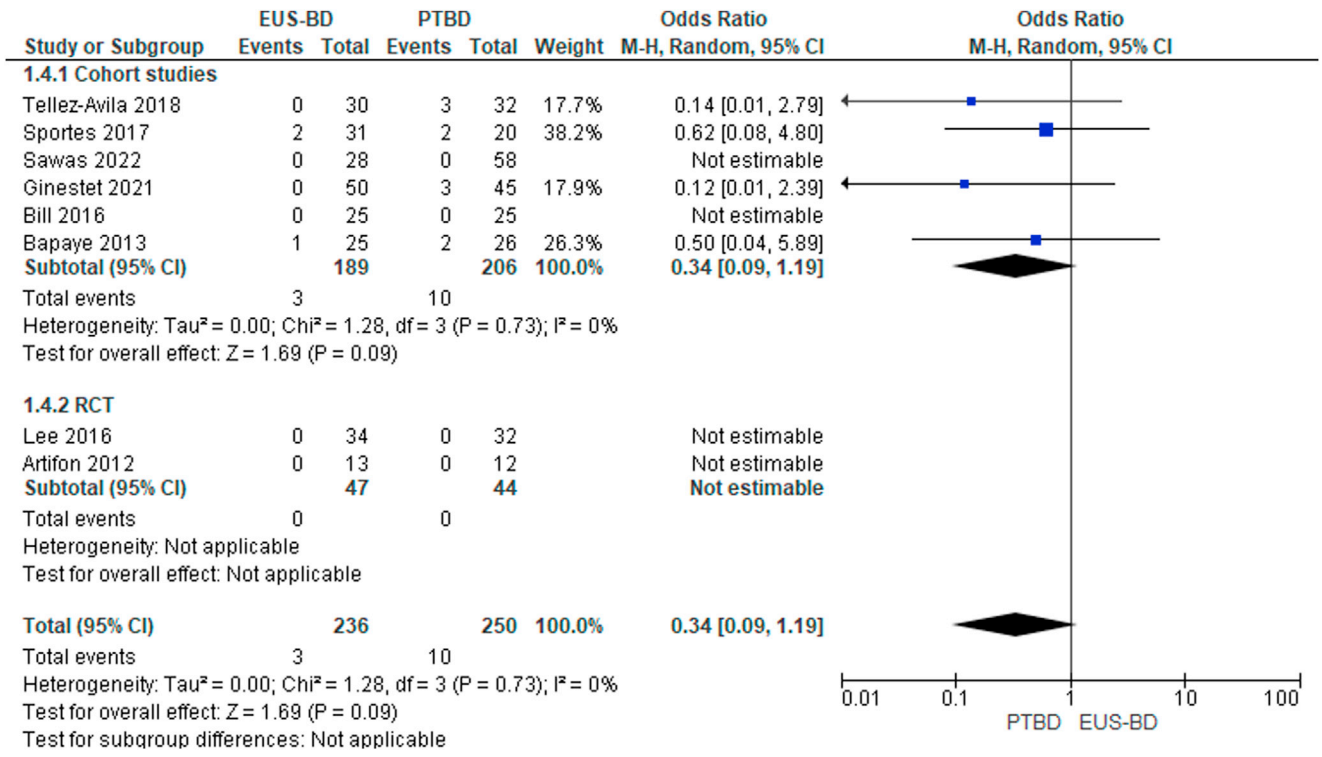


Figure 2. Forest plot of studies evaluating procedure-related mortality of EUS-BD compared with PTBD after failed ERCP. *EUS-BD*, EUS-guided biliary drainage; *PTBD*, percutaneous transhepatic biliary drainage; *CI*, confidence interval; *RCT*, randomized control trial.

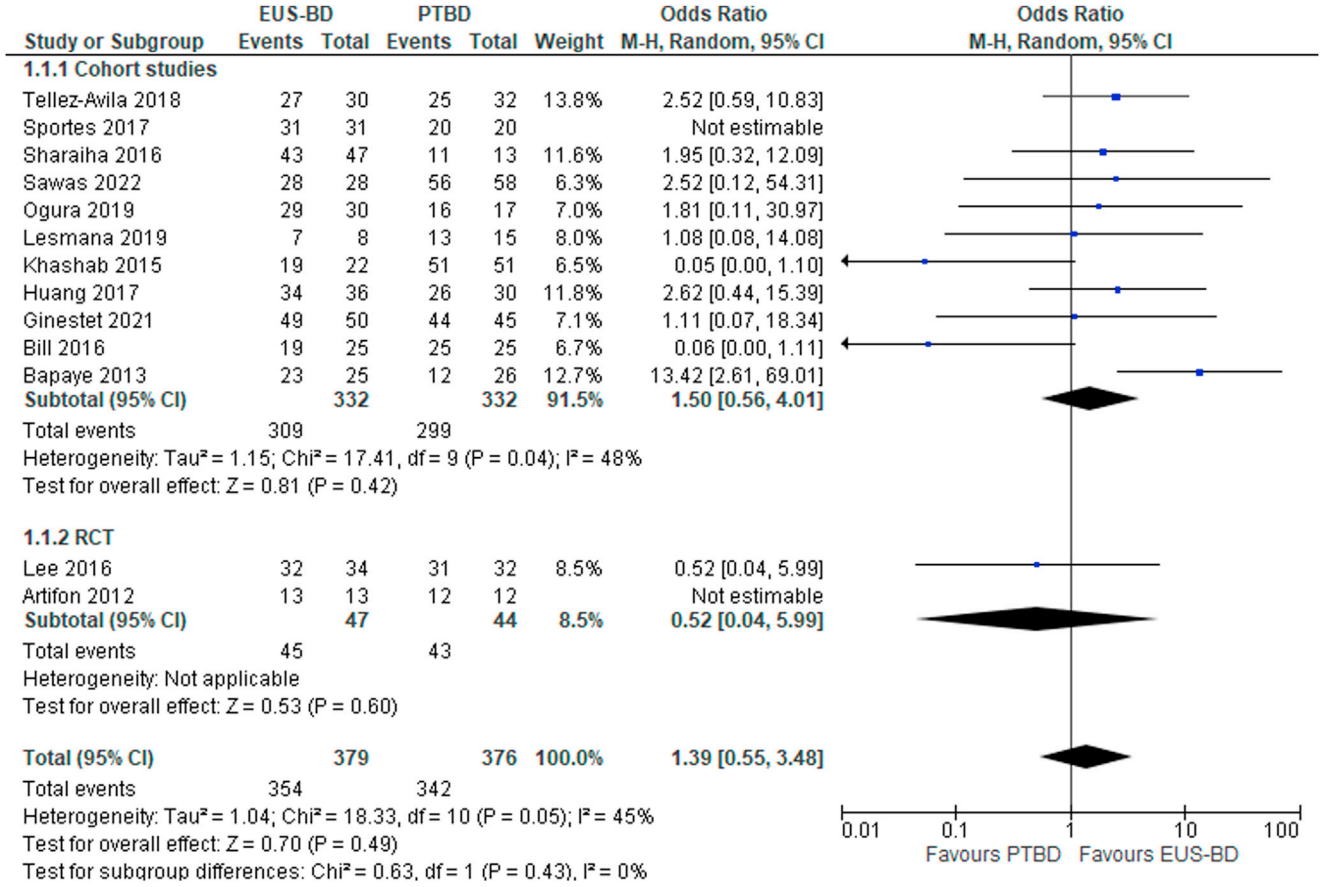


Figure 3. Forest plot of studies evaluating technical success of EUS-BD compared with PTBD after failed ERCP. *EUS-BD*, EUS-guided biliary drainage; *PTBD*, percutaneous transhepatic biliary drainage; *CI*, confidence interval; *RCT*, randomized control trial.

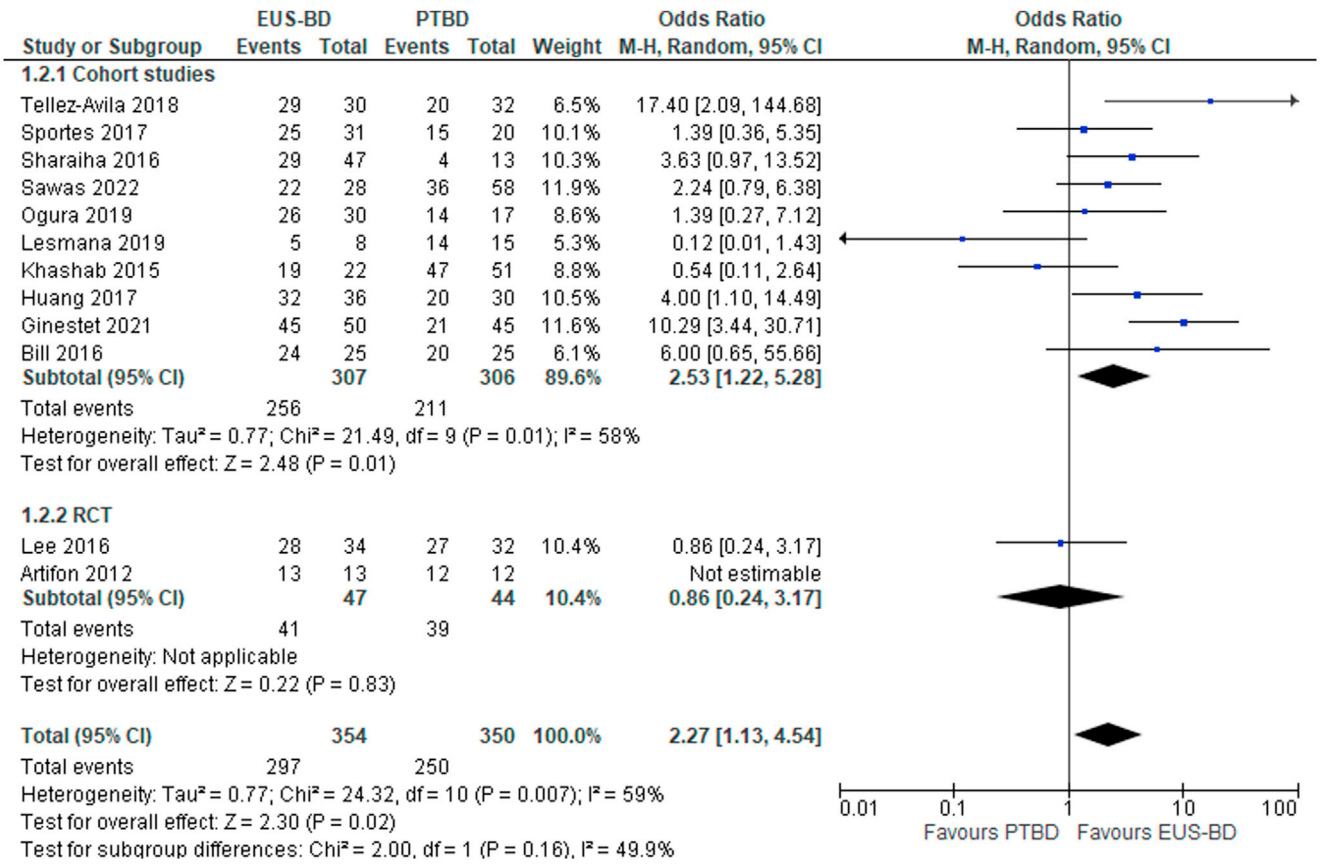


Figure 4. Forest plot of studies evaluating clinical success of EUS-BD compared with PTBD after failed ERCP. *EUS-BD*, EUS-guided biliary drainage; *PTBD*, percutaneous transhepatic biliary drainage; *CI*, confidence interval; *RCT*, randomized control trial.

From the observational studies, it was not clear if all reinterventions were unplanned; however, in the RCTs we were able to clearly identify that the reported reinterventions were those that were unplanned. Thus, the overall quality of evidence from the RCTs was found to be excellent, whereas the evidence from the cohort studies was found to be low.

Length of hospital stay. Length of hospital stay was reported in 1 observational study.[8] From this study, the average length of hospital stay for patients undergoing EUS-BD was significantly shorter compared with PTBD (11.54 days vs 15.68 days, $P < .05$). The panel noted it is possible that sicker patients were undergoing PTBD and were more likely to have longer hospital stays irrespective of their intervention. The panel rated down the evidence for imprecision, and the overall quality of evidence was very low.

Cost. Cost was addressed in 5 studies in our systematic review (1 RCT and 4 observational studies).[4,7-9,16] The studies performed cost analyses quite differently, and thus a meta-analysis could not be performed. The RCT reported on procedure costs only using U.S. Medicare rates and found no significant difference in cost for EUS-BD compared with PTBD ($5673 vs $7570, $P = .39$). Two observational studies evaluated hospital costs associated with each procedure. Huang et al[8] found that EUS-BD was significantly less-expensive than PTBD ($3439 vs $4798, $P < .05$). Similarly, Ginestet et al[7] demonstrated that hospital costs incurred by EUS-BD were significantly lower than those of PTBD ($5438 vs $9987, $P < .001$). The other 2 observational studies performed more in-depth analyses when studying cost. Tellez-Avila et al[16] investigated costs associated with procedural fees, anesthesia, material, medications, facility fees, and costs associated with length of stay. After their analysis, they identified that EUS-BD was less costly than PTBD ($1440.15 vs $2165.87, $P = .03$). Finally, Khashab et al[9] performed not only a detailed analysis of costs associated with procedure and hospital stay, but also an evaluation of costs associated with rehospitalization and reintervention. The results of that analysis again demonstrated that EUS-BD incurred a significantly lower cost than PTBD ($9072 vs $18261, $P = .003$). Based on these studies, the panel voted that EUS-BD was associated with "moderate savings" compared with PTBD.

Other considerations. For patient values, we identified no studies that reported on this outcome. Based on our discussion with the patient representative, the panel assumed that most patients would prefer to have internal drainage opposed to percutaneous interventions, when possible, given the need for frequent maintenance and

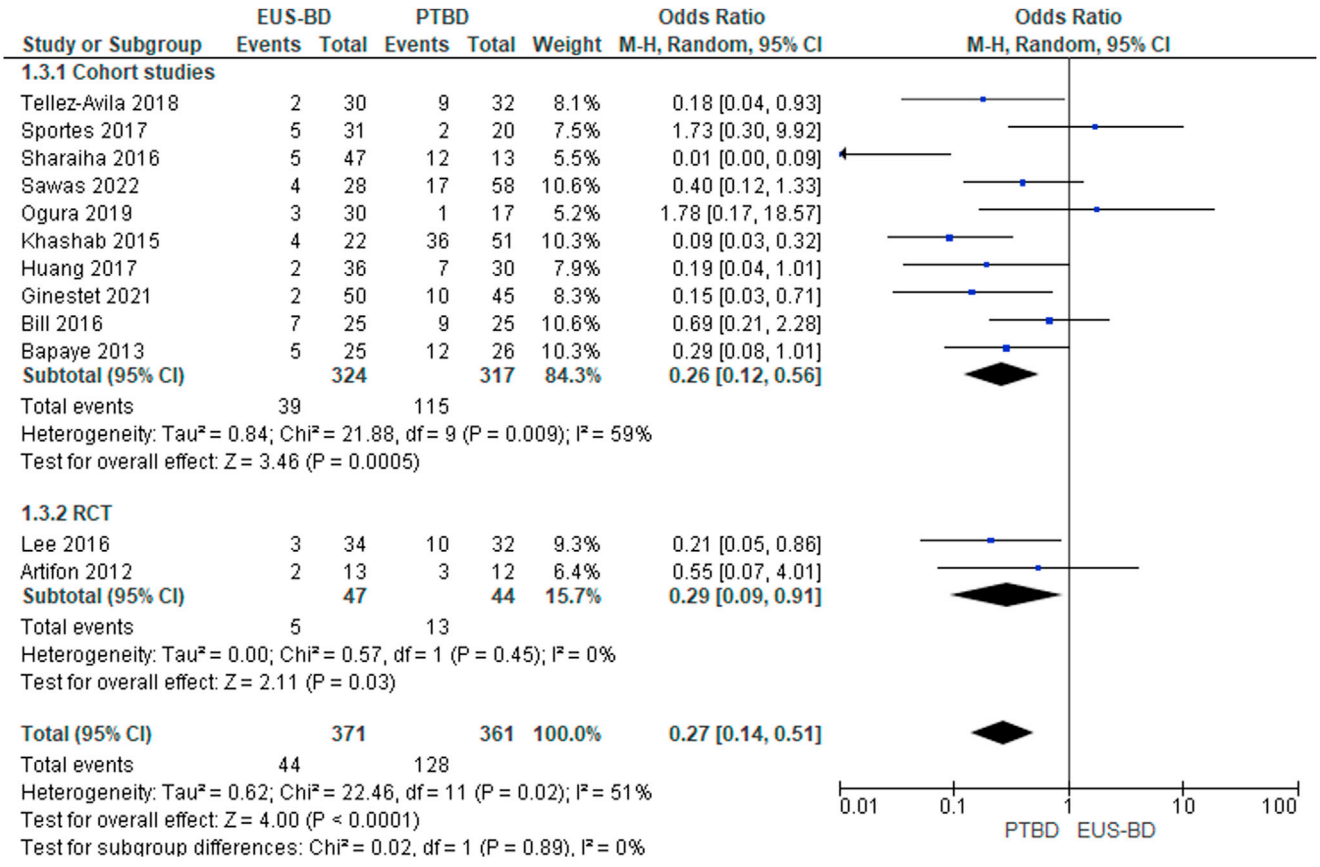


Figure 5. Forest plot of studies evaluating rates of adverse events for EUS-BD compared with PTBD after failed ERCP. *EUS-BD*, EUS-guided biliary drainage; *PTBD*, percutaneous transhepatic biliary drainage; *CI*, confidence interval; *RCT*, randomized control trial.

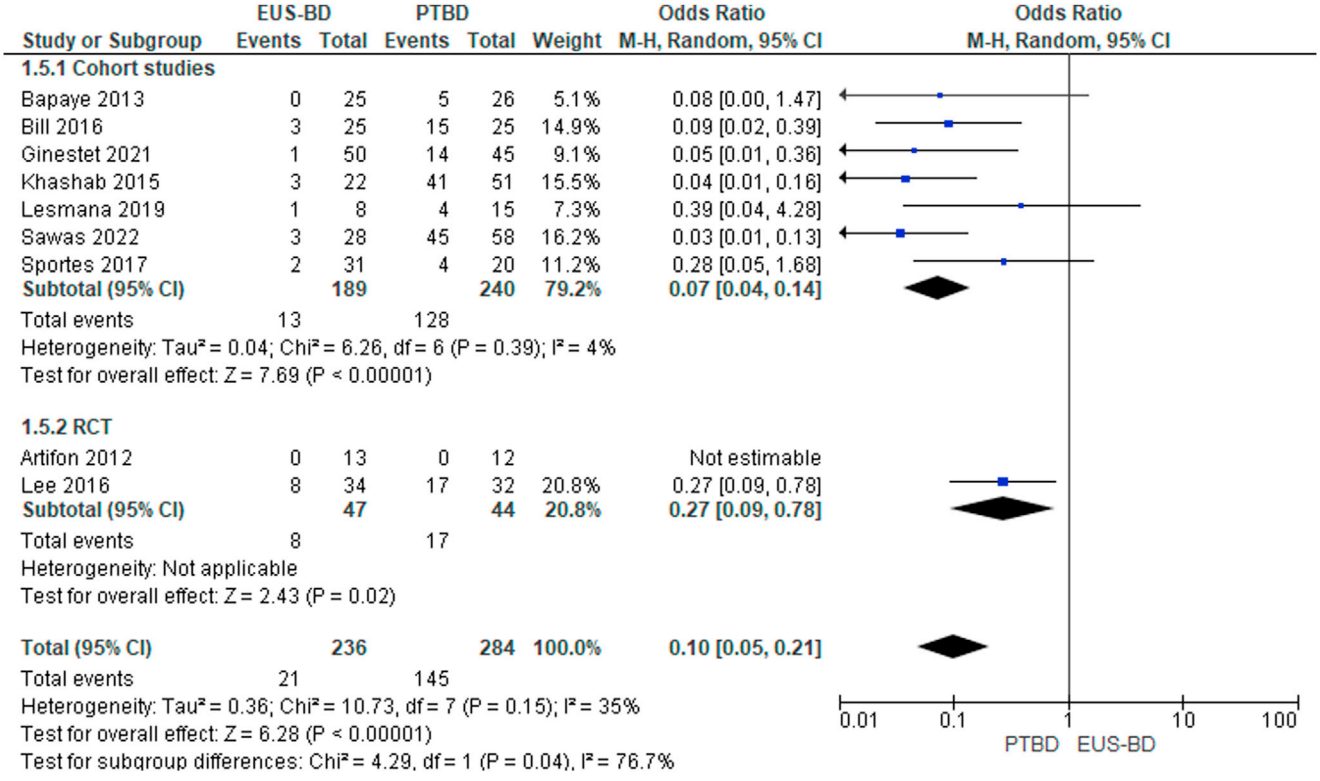


Figure 6. Forest plot of studies evaluating the need for reintervention for EUS-BD compared with PTBD after failed ERCP. *EUS-BD*, EUS-guided biliary drainage; *PTBD*, percutaneous transhepatic biliary drainage; *CI*, confidence interval; *RCT*, randomized control trial.

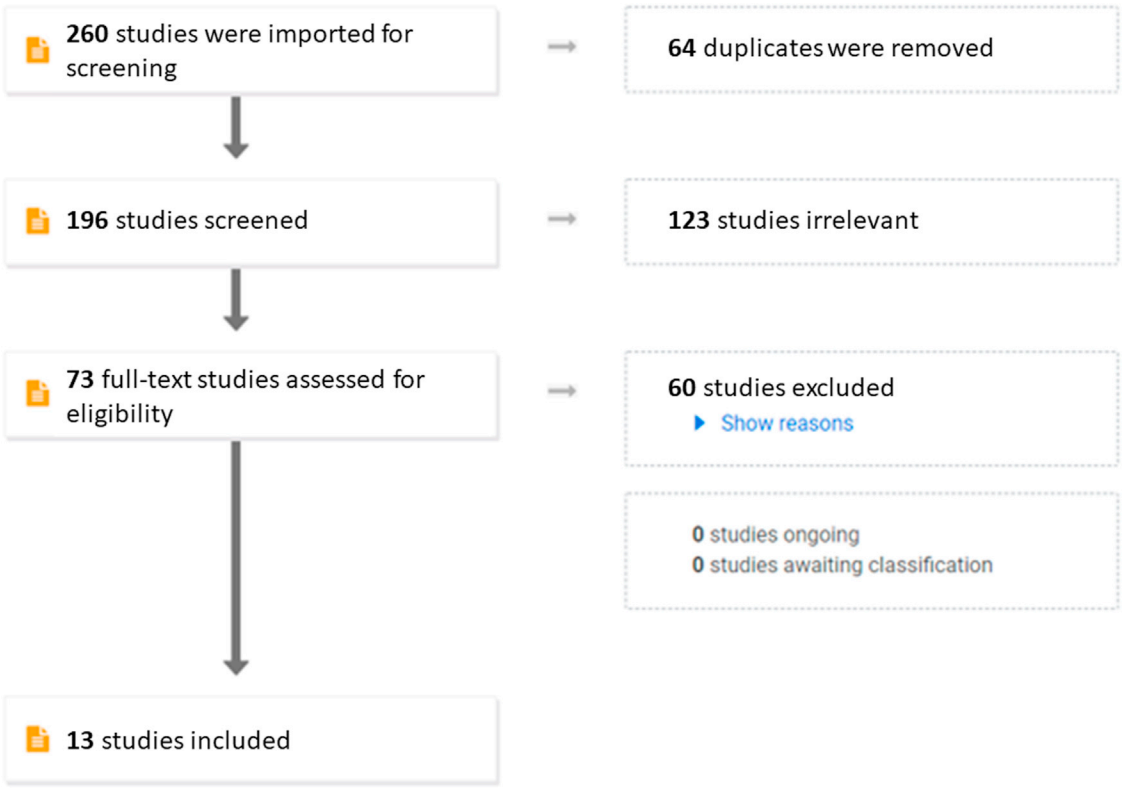


Figure 7. Preferred Reporting Items for Systematic reviews and Meta-Analyses diagram showing studies included in the systematic review evaluating the preferred EUS-guided biliary drainage strategy of malignant biliary obstruction after failed ERCP (PICO 2).

reintervention. Regarding cost-effectiveness, we also identified no studies that properly addressed this outcome. For equity, the panel noted that EUS-BD is technically difficult and requires focused training and is unavailable in many gastroenterology practices, whereas referrals to interventional radiology are commonplace in most centers. This would suggest a limited role for the EUS-BD technique beyond tertiary care centers. Considering all outcomes together, the overall quality of evidence was found to be low.

Panel discussion. Much of the panel's discussion focused on the technical challenges associated with EUS-BD and concerns that even advanced endoscopy training programs have limited exposure to this technique. Concerns were also raised that some of the studies were reporting on EUS-BD procedures that had been performed in expert centers, and thus the results may not be generalizable to practices where EUS-BD is not currently offered and centers with low volume. Other panel members countered this argument by suggesting that similarly PTBD procedures included in the reviewed studies were performed by high-level experts as well. The panel members agreed that endoscopy societies should provide EUS-BD training opportunities for clinicians already in practice so the technique could be safely integrated into practices around the country. Panel members emphasized that in situations where EUS-BD is unavailable, clinicians should consider PTBD as an option.

Question 2: In patients with malignant distal biliary obstruction and a failed ERCP, how does EUS-HGS compare with EUS-CDS in resolving biliary obstruction?

Recommendation 2: In patients with distal malignant biliary obstruction and failed ERCP, the ASGE suggests either EUS-HGS or EUS-CDS should be performed to resolve biliary obstruction.

(Conditional recommendation, low quality of evidence)

General concepts:

- CDS should be preferred if cancerous involvement of the stomach compromises puncture sites for HGS.
- EUS-HGS is preferred if cancerous involvement of the duodenum or a pre-existing enteral stent compromises puncture sites for CDS, a gastric outlet obstruction proximal to the pylorus, and a proximal/hilar biliary obstruction is present.

For this question, we performed a systematic review of the literature as seen in Appendix 2 (available online at www.giejournal.org). In this systematic review, studies assessing the outcomes of EUS-CDS or EUS-HGS as a salvage maneuver for patients with suspected or established malignant distal biliary obstruction after failed ERCP were included (Fig. 7). Reasons for failed ERCP for patients with

TABLE 5. Evidence profiles for Question 2: In patients with malignant biliary obstruction and failed ERCP, how does EUS-HGS compare with EUS-CDS in resolving biliary obstruction?
Author(s):
Question: EUS-HGS compared with EUS-CDS for biliary obstruction with failed ERCP
Setting:
Bibliography:

Certainty assessment						
No. of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**
Clinical success						
2	Randomized trials	Not serious	Not serious	Not serious	Serious*	None
Clinical success (cohort studies)						
5	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Technical success						
2	Randomized trials	Not serious	Not serious	Not serious	Serious*	None
Technical success (cohort studies)						
6	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Adverse events						
1	Randomized trials	Not serious	Serious†	Not serious	Serious*	None
Adverse events (cohort studies)						
11	Nonrandomized studies	Not serious	Not serious	Not serious	Serious*	None
Unplanned reintervention						
1	Randomized trials	Not serious	Not serious	Not serious	Very serious‡	None
Unplanned reintervention (cohort studies)						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Serious*	None

EUS-HGS, EUS-guided hepaticogastrostomy; *EUS-CDS*, EUS-guided choledochoduodenostomy; *CI*, confidence interval; *OR*, odds ratio.
*Low number of events.
†High I^2.
‡One study.

malignant distal biliary obstruction included malignant gastric outlet obstruction , high-grade malignant biliary strictures, and cancerous infiltrations involving the major papilla.

We identified 13 full-text studies comparing EUS-CDS and EUS-HGS (2 RCTs and 11 observational studies).[20-32] Of the RCTs, 1 was a multicenter study and 1 a single-center study.[21,27] Both RCTs were of high quality, with Jadad scores >3. The remaining 11 observational studies all had Qumseya scores >7.[20,22-26,28-32] For the observational studies, 3 were prospective studies performed at a single center and 8 were retrospective. Across the 13 studies, 281 patients underwent EUS-CDS and 267 patients underwent EUS-HGS. Considering our analysis of all outcomes, the overall quality of evidence was found to be low.

Outcomes. The results are summarized in an evidence profile (Table 5).

Technical success. All 13 studies (11 observational studies and 2 RCTs) evaluated the technical success of EUS-CDS and EUS-HGS.[20-32] Across the observational studies, the technical success for those undergoing EUS-CDS compared with EUS-HGS was similar (OR, 1.16; 95% CI, .36-3.76; $I^2 = 0\%$).[20,22-26,28-32] For the RCTs, the OR for technical success for EUS-CDS compared with EUS-HGS was 1.66 (95% CI, .43-6.43; $I^2 = 0\%$).[21,27] Across all studies, the OR for technical success for EUS-CDS compared with EUS-HGS was 1.35 (95% CI, .56-3.29; $I^2 = 0\%$).

Like PICO 1, all studies defined technical success as the successful placement of a stent in the desired biliary system. The overall judged quality of evidence for this outcome was low (Fig. 8).

Clinical success. Eight studies (6 observational studies and 2 RCTs) evaluated the clinical success of EUS-CDS and EUS-HGS. Of the observational studies, clinical success for patients undergoing EUS-CDS compared with those undergoing EUS-HGS was similar (OR, .77; 95% CI, .29-2.09; $I^2 = 0\%$).[22,23,26,29,30,32] For the RCTs, the OR for clinical success

TABLE 5. Continued

No. of patients		Effect			
EUS-HGS	EUS-CDS	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
43/49 (87.8%)	35/47 (74.5%)	OR 2.45 (.83-7.21)	133 more per 1000 (from 37 fewer to 210 more)	⨁⨁⨁◯ Moderate	CRITICAL
91/103 (88.3%)	105/114 (92.1%)	OR .77 (.29-2.09)	21 fewer per 1000 (from 149 fewer to 40 more)	⨁⨁◯◯ Low	CRITICAL
45/49 (91.8%)	41/47 (87.2%)	OR 1.66 (.43-6.43)	47 more per 1000 (from 126 fewer to 105 more)	⨁⨁⨁◯ Moderate	CRITICAL
222/227 (97.8%)	228/234 (97.4%)	OR 1.16 (.36-3.76)	3 more per 1000 (from 42 fewer to 19 more)	⨁⨁◯◯ Low	CRITICAL
5/25 (20.0%)	3/24 (12.5%)	OR 1.75 (.37-8.30)	75 more per 1000 (from 75 fewer to 417 more)	⨁⨁◯◯ Low	CRITICAL
35/238 (14.7%)	24/221 (10.9%)	OR .68 (.29-1.57)	32 fewer per 1000 (from 74 fewer to 52 more)	⨁◯◯◯ Very low	CRITICAL
1/25 (4.0%)	2/24 (8.3%)	OR .46 (.04-5.41)	43 fewer per 1000 (from 80 fewer to 246 more)	⨁⨁◯◯ Low	CRITICAL
19/53 (35.8%)	18/89 (20.2%)	OR 2.11 (.96-4.63)	146 more per 1000 (from 7 fewer to 338 more)	⨁◯◯◯ Very low	CRITICAL

for those undergoing EUS-CDS compared with those undergoing EUS-HGS was similar (OR, 2.45; 95% CI, .83-7.21; $I^2 = 0\%$).[21,27] Across all 8 studies, the OR for clinical success for patients undergoing EUS-CDS versus those undergoing EUS-HGS was 1.31 (95% CI, .63-2.72; $I^2 = 0\%$).

Like PICO 1, studies were inconsistent in their definitions of clinical success. One study defined clinical success as the resolution of biliary obstruction,[26] whereas others defined clinical success as improvement in bilirubin by at least 50% across varying intervals from 1 to 4 weeks.[21,30,32] The overall judged quality of evidence from the RCTs was moderate and from the observational studies was low (Fig. 9).

Adverse events. Procedure-related AEs were described in 11 studies (10 observational studies and 1 RCT).[20-26,28-30,32] Among the observational studies, the rates of procedure-related AEs for patients undergoing EUS-CDS compared with those undergoing EUS-HGS was similar (OR, .68; 95% CI, .29-1.57; $I^2 = 42\%$).[20,22-26,28-30,32] For the 1 RCT that reported this outcome, the OR for enduring a procedure-related AE after EUS-CDS compared with EUS-HGS was 1.75 (95% CI, .37-1.57; $I^2 = 40\%$).[21]

Like PICO 1, some studies reported AEs using the ASGE lexicon.[19] Studies were inconsistent in describing the overall severity of AEs. We solely extracted data pertaining to per-patient occurrences of AEs. The overall judged quality of evidence from the RCT was low and from the cohort studies was very low (Fig. 10).

Need for repeat intervention. The need for an unplanned repeat intervention was evaluated in 4 studies (3 observational studies and 1 RCT).[21,22,25,26] Among the observational studies, rates of needing an unplanned procedure for those patients undergoing EUS-CDS compared with those undergoing EUS-HGS were similar (OR, 2.11; 95% CI, .96-4.63; $I^2 = 0\%$).[22,25,26] For the RCT that reported on this outcome, the OR for needing an unplanned procedure after the intervention for patients undergoing EUS-CDS compared with those undergoing EUS-HGS was .46 (95% CI, .04-5.41).[21] Across all studies, the OR for needing an unplanned intervention after EUS-CDS compared with EUS-HGS was 1.83 (95% CI, .86-3.87; $I^2 = 0\%$). The overall judged quality of evidence from the RCT was low and from the observational studies was very low (Fig. 11).

Other considerations. For patient values, we identified no studies that analyzed this outcome. After discussions regarding the different techniques, the patient

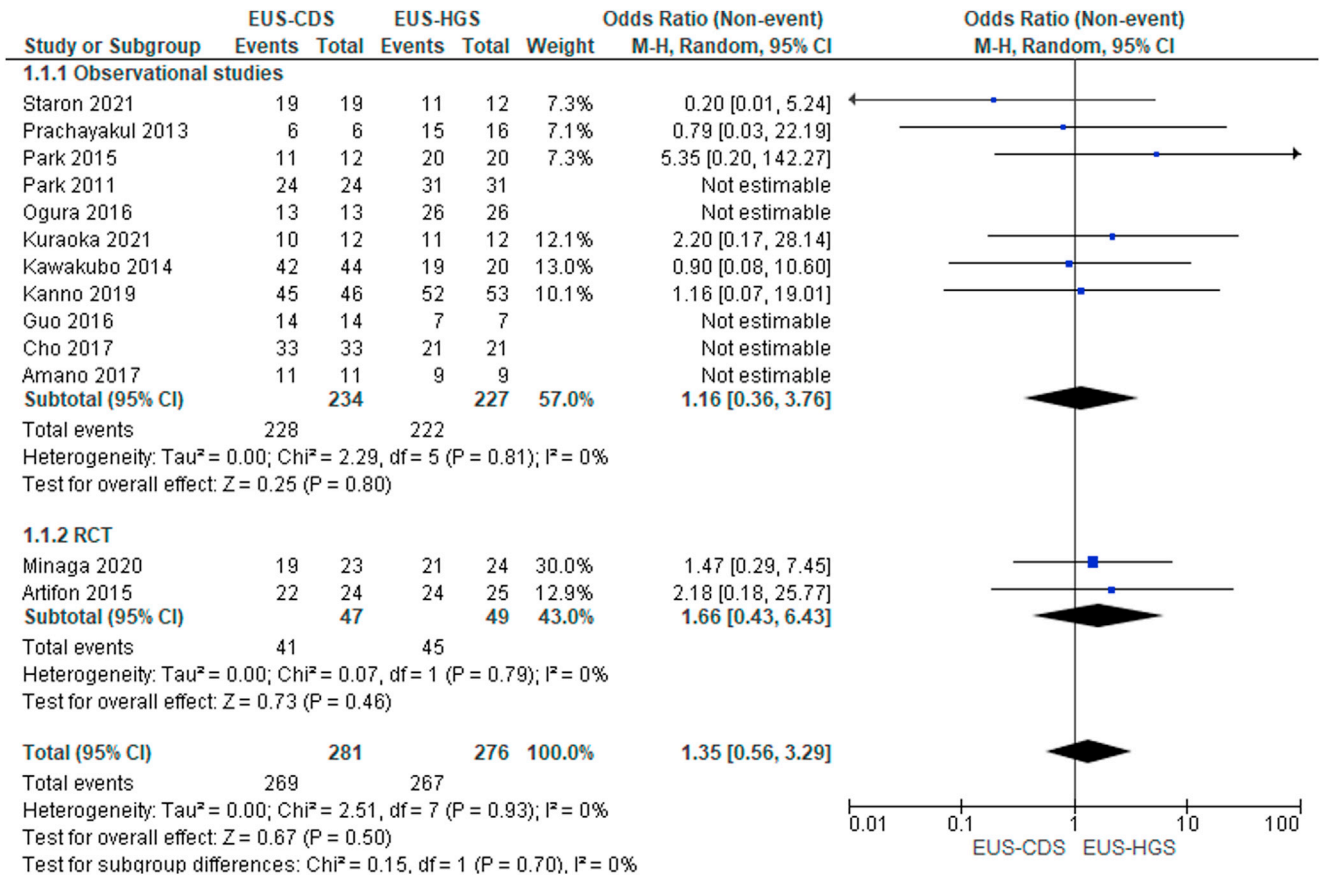


Figure 8. Forest plot of studies evaluating technical success for EUS-CDS compared with EUS-HGS in patients with malignant biliary obstruction after failed ERCP. *EUS-CDS*, EUS-guided choledochoduodenostomy; *EUS-HGS*, EUS-guided hepaticogastrostomy; *CI*, confidence interval; *RCT*, randomized control trial.

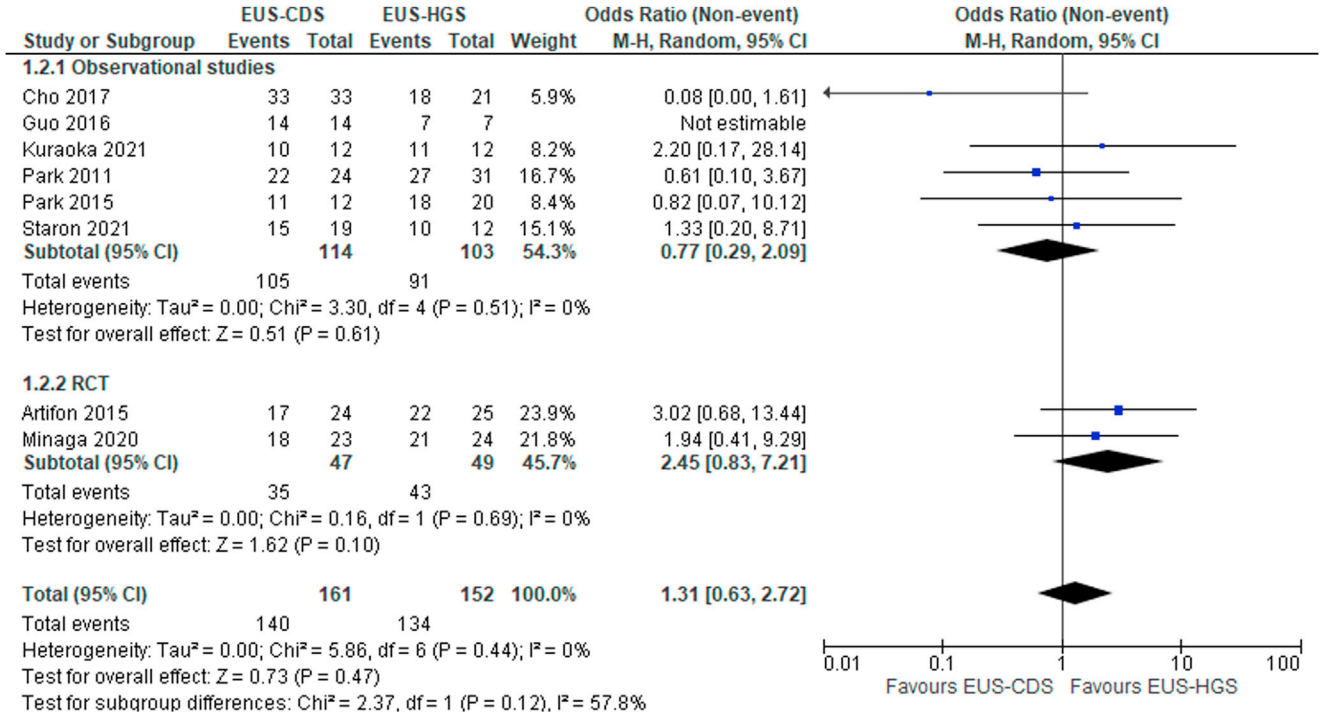


Figure 9. Forest plot of studies evaluating clinical success for EUS-CDS compared with EUS-HGS in patients with malignant biliary obstruction after failed ERCP. *EUS-CDS*, EUS-guided choledochoduodenostomy; *EUS-HGS*, EUS-guided hepaticogastrostomy; *CI*, confidence interval; *RCT*, randomized control trial.

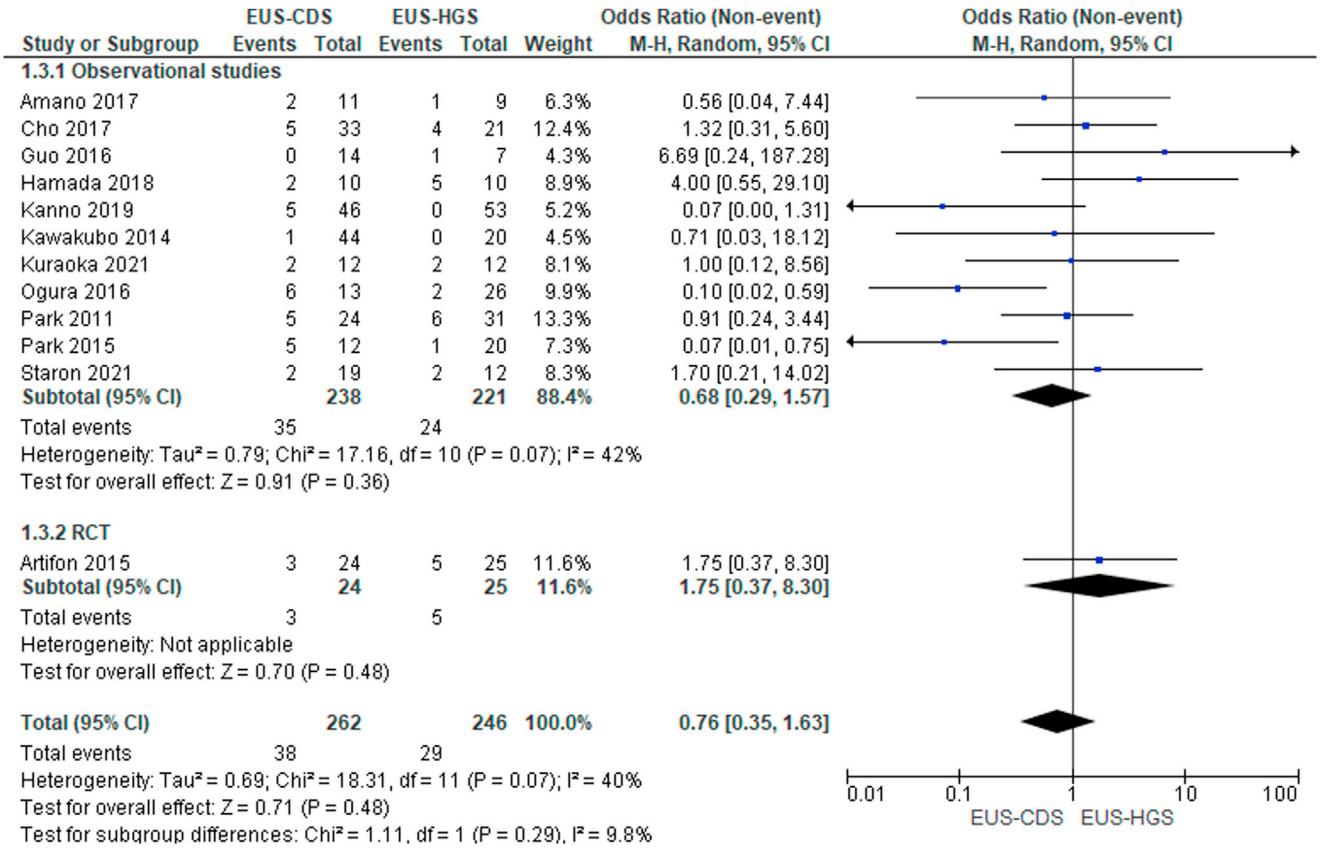


Figure 10. Forest plot of studies evaluating adverse events for EUS-CDS compared with EUS-HGS in patients with malignant biliary obstruction after failed ERCP. *EUS-CDS*, EUS-guided choledochoduodenostomy; *EUS-HGS*, EUS-guided hepaticogastrostomy; *CI*, confidence interval; *RCT*, randomized control trial.

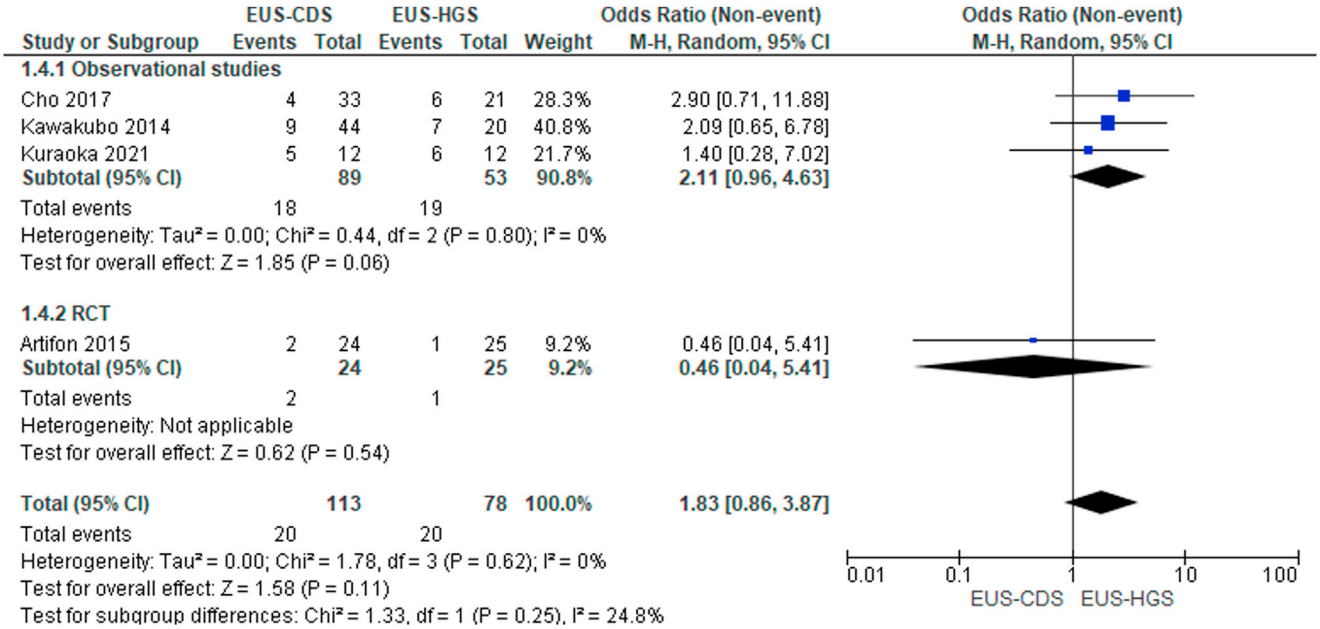


Figure 11. Forest plot of studies evaluating the need for reintervention for EUS-CDS compared with EUS-HGS in patients with malignant biliary obstruction after failed ERCP. *EUS-CDS*, EUS-guided choledochoduodenostomy; *EUS-HGS*, EUS-guided hepaticogastrostomy; *CI*, confidence interval; *RCT*, randomized control trial.

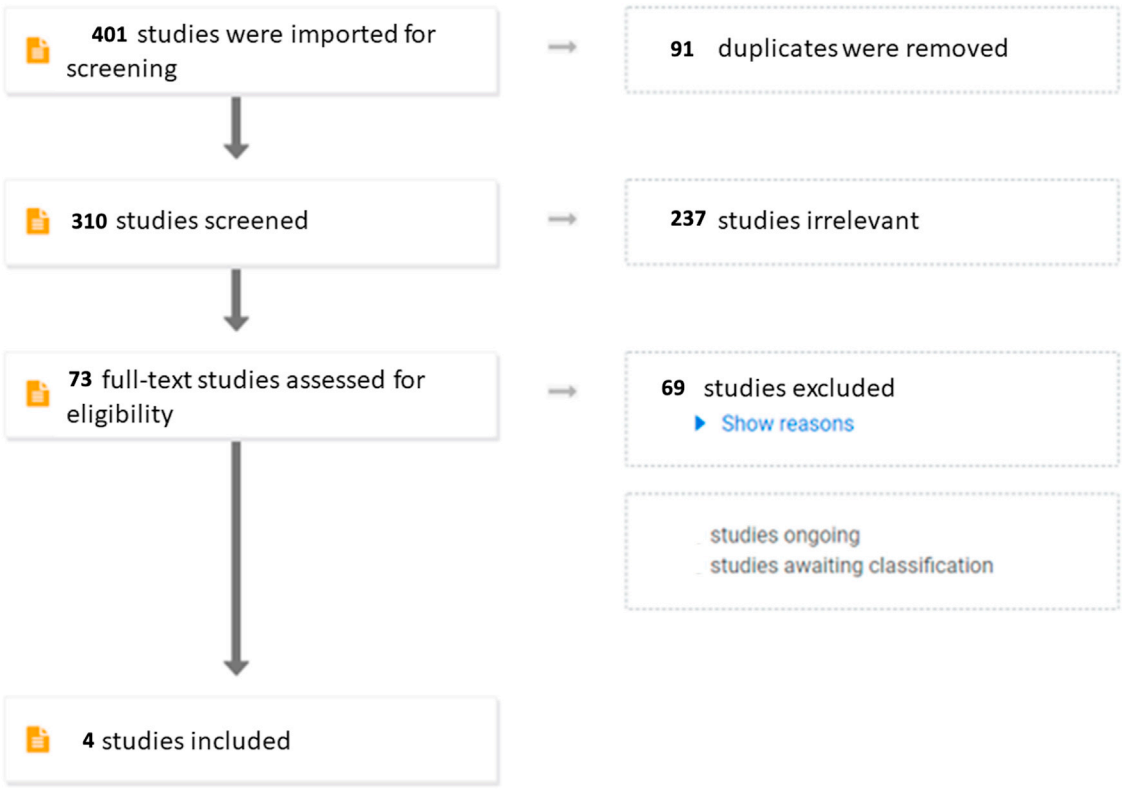


Figure 12. Preferred Reporting Items for Systematic reviews and Meta-Analyses diagram showing studies included in the systematic review evaluating the management strategy of biliary obstruction in patients with Roux-en-Y gastric bypass (PICO 3).

representative reported no particular preference for EUS-CDS or EUS-HGS. We discussed with the patient representative that questions have been raised about the impact of EUS-HGS or EUS-CDS on future surgical interventions (ie, Whipple operation for pancreatic cancer). We also noted that a more recent multicenter study in France demonstrated that the Whipple procedure was not negatively impacted by EUS-CDS.[33] Although no direct evidence exists regarding the impact of EUS-HGS on future surgery, members of the panel noted that their surgical colleagues may or may not consider EUS-HGS to be a contraindication for future surgeries. The patient advocate mentioned that if multidisciplinary discussions were held with all interested parties (including oncologists and surgeons), then she would defer to the opinion of her treating physicians regarding EUS-BD techniques. In addition, for cost and cost-effectiveness, we identified no studies that directly compared these outcomes for EUS-HGS and EUS-CDS. Also, no equity issues were identified.

Panel discussion. As noted above, the panel discussed the impact of EUS-BD procedures on future surgical operations. Based on panel experience and available literature, no evidence was found to suggest that 1 technique versus the other had a more deleterious impact on surgical outcomes. The panel recommended that gastroenterologists should communicate with surgical oncologists before performing EUS-BD procedures. The panel also discussed that EUS-CDS is likely easier to perform (particularly in the United States), provided that a single-step, cautery-enhanced lumen-apposing metal stent (LAMS) is available.

At the completion of the discussions of PICOs 1 and2, the panel voted on a flowchart diagram (provided in the "Summary and Recommendations" article) designed to help clinicians identify when to perform EUS-BD and what techniques to consider depending on various clinical situations. Given that the available literature did not provide enough evidence to perform subgroup analyses, some of the recommendations provided in the flowchart are based on expert opinion. However, the overall evidence-based principles are that EUS-BD should be performed over PTBD and that in malignant distal biliary obstruction, either EUS-CDS or EUS-HGS can be performed.

Question 3: In patients who have undergone Roux-en-Y gastric bypass surgery and have biliary obstruction, how does EDGE compare with E-ERCP or LA-ERCP in resolving biliary obstruction?

Recommendation 3: In patients with Roux-en-Y gastric bypass surgery needing biliary drainage, the ASGE suggests EDGE over E-ERCP or LA-ERCP in resolving biliary obstruction.

(*Conditional recommendations/very low quality of evidence)*

General concepts:

- EDGE is preferred in patients with a suspected ampullary lesion, malignant disease, or needing repeat ERCP.
- LA-ERCP may be preferred in patients who require surgery in the near future (eg, cholecystectomy).

We performed a systematic review of the literature on this topic as seen in Appendix 3 (available online at www.giejournal.org). The systematic review was restricted to those studies assessing outcomes of EDGE, E-ERCP, or LA-ERCP as therapy for patients needing biliary drainage who have undergone prior Roux-en-Y gastric bypass (Fig. 12). For this question, EDGE involves the placement of a LAMS between the gastric pouch (or jejunum) and the excluded stomach to allow the duodenoscope to advance into the duodenum and to the major papilla. E-ERCP most often involves using a balloon enteroscope to advance through the gastrojejunal anastomosis, jejunojejunal anastomosis, and the Roux limb to reach the major papilla. LA-ERCP involves surgically placing a laparoscopic port into the excluded stomach to facilitate the duodenoscope advancement into the duodenum. In addition, studies evaluating both benign and malignant causes of biliary obstruction were included in our review. Examples of benign etiologies include choledocholithiasis and biliary sludge. Examples of malignant etiologies include pancreatic adenocarcinoma and cholangiocarcinoma.

At the completion of our review, we identified 4 full-text studies (4 observational studies).[34-37] All studies were retrospective and single-center with Qumseya scores ≥7. In aggregate, across all 4 studies included in this analysis, 176 patients underwent EUS-BD, 396 patients underwent LA-ERCP, and 172 patients underwent E-ERCP. Considering all outcomes together, the overall quality of evidence was found to be very low.

Outcomes. A summary of outcomes and their assessments can be seen in Tables 6 and 7.

Technical success. All 4 studies from the systematic review assessed technical success.[34-37] Among 3 observational studies comparing EDGE and E-ERCP, technical success of those undergoing EDGE relative to those undergoing E-ERCP was significantly higher (OR, 28.01; 95% CI, 5.17-151.6; I^2 = 0%) (Fig. 13).[34-36] For 3 observational studies that compared EDGE and LA-ERCP, there was no difference in technical success (OR, 1.09; 95% CI, .01-5.55; I^2 = 0%) (Fig. 14).[35-37]

Across all included studies, technical success had a consistent definition, that of successfully reaching the major papilla with successful biliary cannulation and intervention. The overall quality of evidence was found to be moderate for studies comparing E-ERCP and EDGE and low for studies comparing EDGE and LA-ERCP.

Adverse events. Procedure-related AEs were described in all 4 observational studies in the systematic review.[34-37] The 3 observational studies comparing EDGE and E-ERCP found fewer procedure-related AEs in patients undergoing EDGE as compared with those undergoing E-ERCP (OR, .32; 95% CI, .11-.93; I^2 = 0%) (Fig. 15). The 3 observational studies that compared EDGE and LA-ERCP found no difference between both techniques in the rates of AEs (OR, .62; 95% CI, .17-2.29; I^2 = 49%) (Fig. 16).[35-37]

Most extracted studies determined the rate and severity of AEs according to the ASGE lexicon.[19] Studies, however, were inconsistent in qualifying AEs as mild, moderate, or severe. Thus, we solely reported total AEs in our analysis. AEs were reported on a per-patient basis as opposed to a per-event basis. Regarding data from the observational studies, we rated down for inconsistency. The overall judged quality of evidence from the cohort studies was found to be low.

Need for repeat intervention. From 3 observational studies comparing EDGE and E-ERCP, EDGE had significantly lower odds of patients undergoing repeat biliary intervention than E-ERCP (OR, .05; 95% CI, .01-.35; I^2 = 0%) (Fig. 17). Thus, the overall judged quality of evidence from the observational studies comparing E-ERCP and EDGE was found to be low.

Procedure time. Two observational studies examined the total procedure times for EDGE and E-ERCP.[34,35] The combined stages of EDGE had overall shorter procedure times than E-ERCP (mean difference, 34.4 minutes; 95% CI, 17.5-51.3). Two observational studies examined procedure times between EDGE and LA-ERCP.[35,37] EDGE had lower procedure times than LA-ERCP, with a mean difference of 95.1 fewer minutes shorter (95% CI, 63.8-126.5). Thus, the overall judged quality of evidence from the observational studies comparing E-ERCP and EDGE from the cohort studies was found to be low.

Cost. Cost was addressed in only 1 observational study.[36] In this study, LA-ERCP ($20,000) had higher direct healthcare costs compared with EDGE ($11,300, $P < .01$) and E-ERCP ($13,000, $P < .01$). Based on this study, the panel voted that EDGE was associated with "moderate savings" compared with LA-ERCP.

Cost-effectiveness. One study performed a cost-effectiveness analysis using a decision tree model with a 1-year time

TABLE 6. Evidence profiles for Question 3a: In patients who have undergone prior Roux-en-Y gastric bypass surgery and have biliary obstruction, how does EDGE compare with LA-ERCP in resolving biliary obstruction?
Author(s):
Question: EDGE compared with LA-ERCP for Roux-en-Y gastric bypass needing bilairy access
Setting:
Bibliography:

Certainty assessment						
No. of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**
Technical success						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Serious*	None
Clinical success						
2	Nonrandomized studies	Not serious	Not serious	Not serious	Serious*	None
Adverse events						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Serious*	None
Procedure time						
2	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None

EDGE, EUS-directed transgastric ERCP; *LA-ERCP,* laparoscopic-assisted ERCP; *CI*, confidence interval; *OR*, odds ratio.
*Low number of events.

TABLE 7. Evidence profiles for Question 3b: In patients who have undergone prior Roux-en-Y gastric bypass surgery and have biliary obstruction, how does EDGE compare with E-ERCP in resolving biliary obstruction?
Author(s):
Question: EDGE compared with E-ERCP for gastric bypass needing biliary drainage
Setting:
Bibliography:

Certainty assessment						
No. of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**
Technical success						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious*	Strong association
Clinical success						
1	Nonrandomized studies	Not serious	Not serious	Not serious	Serious*	None
Adverse events						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Serious*	None
Need for reintervention						
2	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious*	Strong association
Procedure time						
2	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None

EDGE, EUS-directed transgastric ERCP; *E-ERCP,* enteroscopic-assisted ERCP; *CI*, confidence interval; *OR*, odds ratio.
*Low number of events.

horizon and a healthcare sector perspective and compared LA-ERCP, E-ERCP, and EDGE.[38] When compared with both LA-ERCP and E-ERCP, EDGE was dominant in that it was less costly and more effective. When 10,000 Monte Carlo iterations were performed as part of probabilistic sensitivity analyses (where each parameter is varied randomly with each iteration), EDGE was the cost-effective option in 95% of iterations compared with LA-ERCP and 98% of iterations when compared with E-ERCP. Based on these data, the panel voted that the cost-effectiveness data probably favor EDGE over LA-ERCP and E-ERCP.

Other considerations. For patient values, we identified no studies that reported on this outcome. Based on our discussion with the patient advocate who had undergone both prior Roux-en-Y gastric bypass and the EDGE procedure, the panel assumed that most patients would prefer to avoid surgery and that achieving internal biliary drainage was very important. The patient also noted that weight gain with EDGE was not a worry becasue she had significant symptoms related to biliary obstruction.

Regarding weight gain, 2 studies examined weight gain at 52 weeks and 28 weeks after EDGE and demonstrated that

TABLE 6. Continued

No. of patients		Effect			
EDGE	LA-ERCP	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
72/73 (98.6%)	101/103 (98.1%)	OR 1.09 (.01-5.55)	2 more per 1000 (from 645 fewer to 16 more)	⨁◯◯◯ Very low	CRITICAL
46/47 (97.9%)	83/85 (97.6%)	OR .90 (.11-7.53)	3 fewer per 1000 (from 156 fewer to 20 more)	⨁◯◯◯ Very low	CRITICAL
11/73 (15.1%)	24/103 (23.3%)	OR .62 (.17-2.29)	75 fewer per 1000 (from 184 fewer to 177 more)	⨁◯◯◯ Very low	CRITICAL
55	60	—	Mean difference, 95.1 minutes lower (126.5 lower to 63.8 lower)	⨁⨁◯◯ Low	CRITICAL

TABLE 7. Continued

No. of patients		Effect			
EDGE	E-ERCP	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
74/74 (100.0%)	68/112 (60.7%)	OR 28.01 (5.17-151.63)	370 more per 1000 (from 282 more to 389 more)	⨁⨁⨁◯ Moderate	CRITICAL
18/18 (100.0%)	41/70 (58.6%)	OR 26.30 (1.52-453.00)	388 more per 1000 (from 97 more to 413 more)	⨁◯◯◯ Very low	CRITICAL
6/74 (8.1%)	19/112 (17.0%)	OR .32 (.11-.93)	108 fewer per 1000 (from 148 fewer to 10 fewer)	⨁◯◯◯ Very low	CRITICAL
0/48 (.0%)	29/100 (29.0%)	OR .05 (.01-.35)	270 fewer per 1000 (from 286 fewer to 165 fewer)	⨁⨁⨁◯ Moderate	CRITICAL
56	42	—	Mean difference, 34.4 minutes lower (51.3 lower to 17.5 lower)	⨁⨁◯◯ Low	IMPORTANT

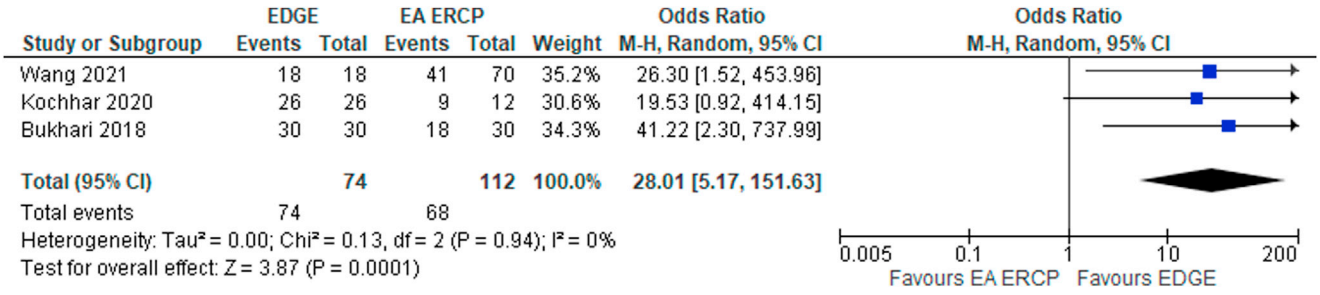


Figure 13. Forest plot of studies evaluating the technical success of EDGE compared with enteroscopy-assisted ERCP in patients with Roux-en-Y gastric bypass with biliary obstruction. *EDGE*, EUS-guided transgastric ERCP; *EA-ERCP*, enteroscopy-assisted ERCP; *CI*, confidence interval.

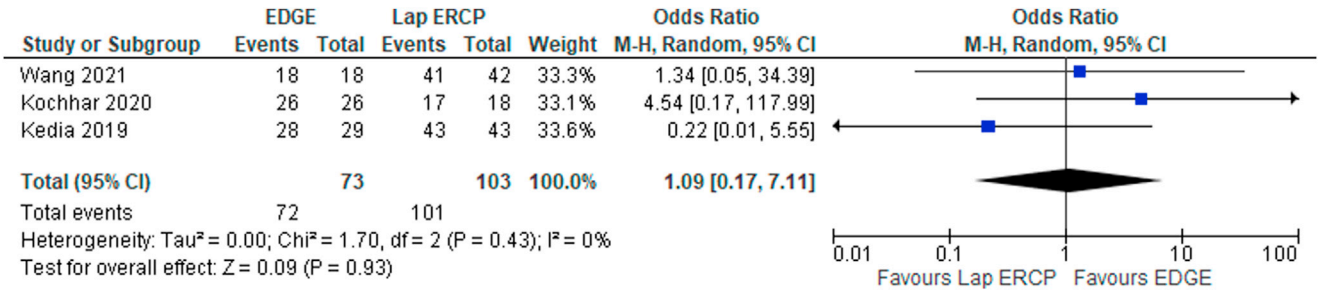


Figure 14. Forest plot of studies evaluating the technical success of EDGE compared with laparoscopic-assisted ERCP in patients with Roux-en-Y gastric bypass with biliary obstruction. *EDGE*, EUS-guided transgastric ERCP; *Lap ERCP*, laparoscopic-assisted ERCP; *CI*, confidence interval.

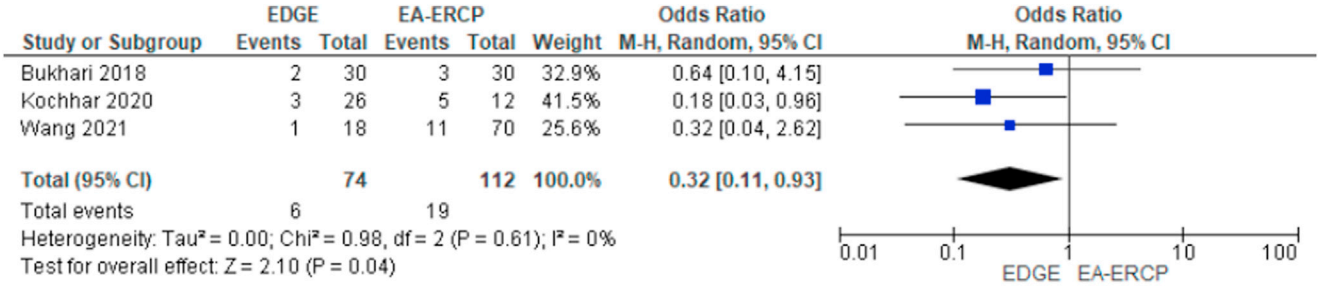


Figure 15. Forest plot of studies evaluating the rate of adverse events of EDGE compared with enteroscopy-assisted ERCP in patients with Roux-en-Y gastric bypass with biliary obstruction. *EDGE*, EUS-guided transgastric ERCP; *EA-ERCP*, enteroscopy-assisted ERCP; *CI*, confidence interval.

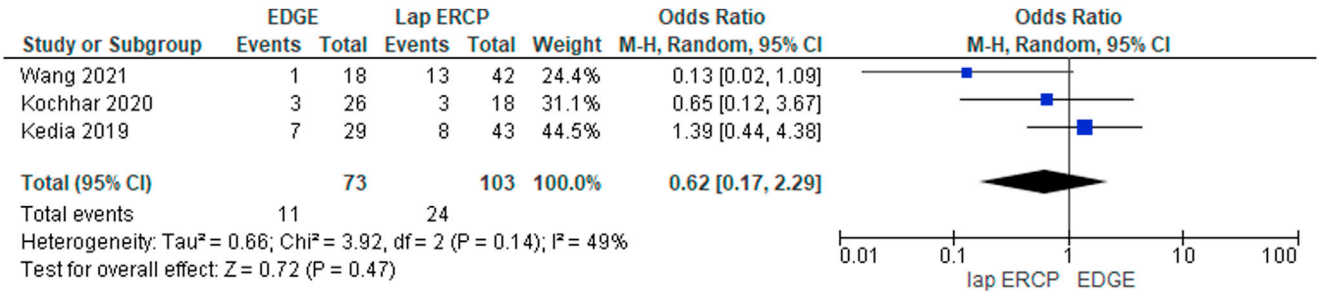


Figure 16. Forest plot of studies evaluating the technical success of EDGE compared with laparoscopic-assisted ERCP in patients with Roux-en-Y gastric bypass with biliary obstruction. *EDGE*, EUS-guided transgastric ERCP; *Lap ERCP*, laparoscopic-assisted ERCP; *CI*, confidence interval.

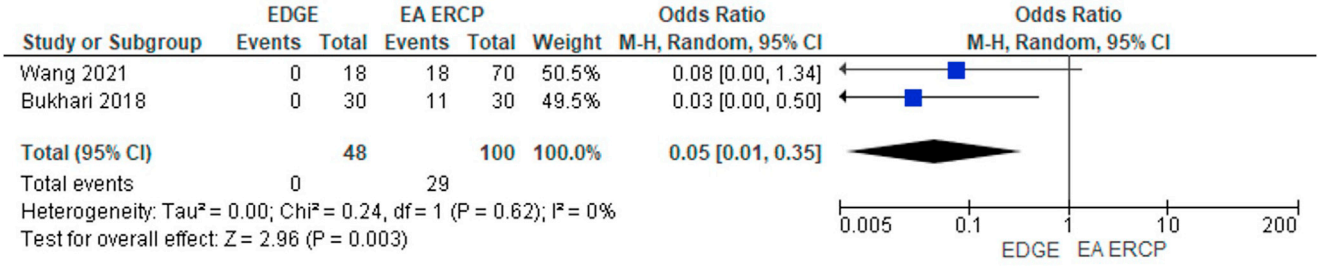


Figure 17. Forest plot of studies evaluating the need for reintervention with EDGE compared with enteroscopy-assisted ERCP in patients with Roux-en-Y gastric bypass with biliary obstruction. *EDGE*, EUS-guided transgastric ERCP; *EA-ERCP*, enteroscopy-assisted ERCP; *CI*, confidence interval.

patients lost 6.28 pounds and 6.6 pounds, respectively.[37,39] Another study used fluoroscopic upper GI tract contrast studies to evaluate for persistent fistulas and demonstrated that only 9% of patients had a persistent fistula at a mean of 182 days of follow-up.[40]

Regarding equity, the panel noted throughout our discussion that both EDGE and E-ERCP require complex equipment, may be technically difficult, and require focused training that may not be available in all practices. However, LA-ERCP is also often only done in tertiary care centers,

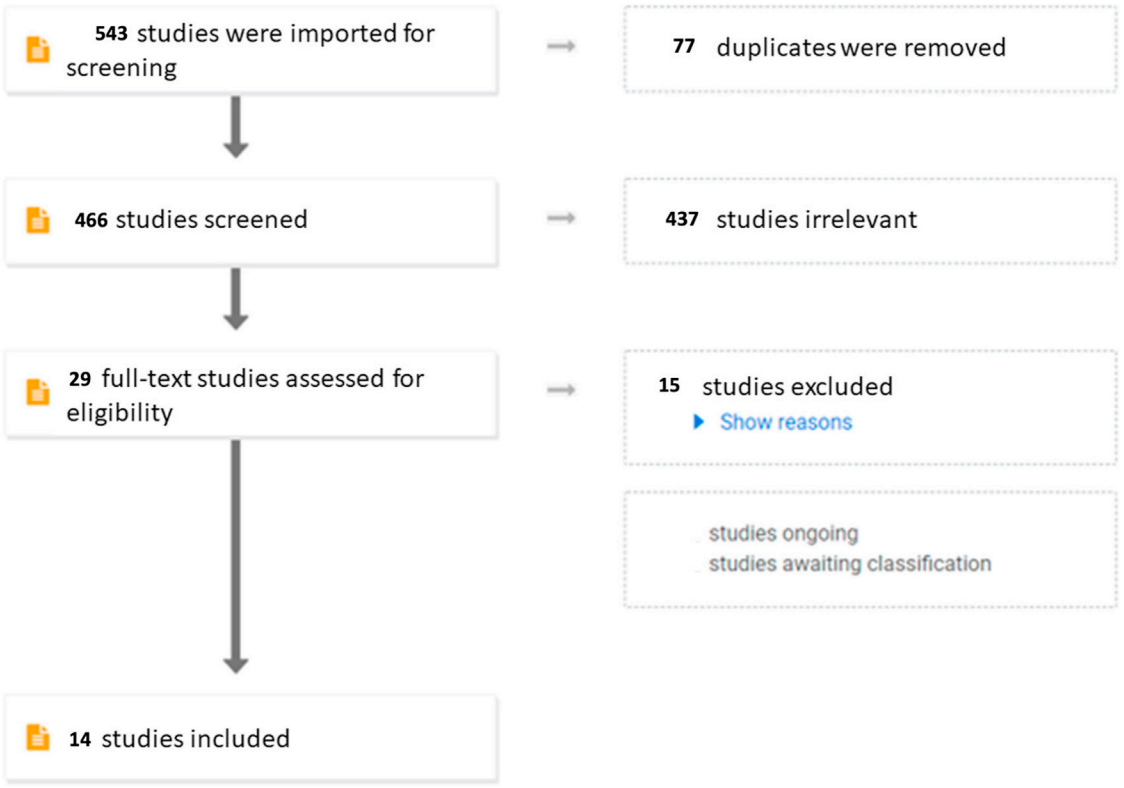


Figure 18. Preferred Reporting Items for Systematic reviews and Meta-Analyses diagram showing studies included in the systematic review evaluating the management strategy of biliary obstruction in patients with Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II anatomy (PICO 4).

suggesting a limited roll-out of all 3 techniques beyond tertiary care centers.

Panel discussion. Most of the panel's discussion focused on the technical challenges associated with EDGE and that because these studies had been performed in tertiary care centers, the results may not be generalizable to other practice settings. However, the panel noted that LA-ERCP and E-ERCP are also mainly performed in tertiary care centers. One panel member raised the importance of obtaining and reading the operative report from the Roux-en-Y gastric bypass to determine the Roux limb length, because this can significantly impact the success of E-ERCP. Another panel member noted their patients' concerns about weight gain with EDGE. However, the patient representative reported that she had no concern regarding weight gain as long as the EDGE was clinically successful. The patient also noted that LA-ERCP may be considered preferable for biliary indications if the patient requires laparoscopic cholecystectomy.

Question 4: In patients who have surgically altered anatomy (specifically, patients who have undergone prior Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II reconstruction) with biliary obstruction, how do EUS-guided interventions compare with E-ERCP and PTBD regarding rates of successful biliary drainage?

Recommendation 4: In patients with biliary obstruction and non–gastric bypass surgically altered anatomy (specifically patients who have undergone prior Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II reconstruction), the ASGE suggests E-ERCP as the initial approach. If unsuccessful, the ASGE suggests EUS-BD or percutaneous biliary drainage.

(*Conditional recommendation, low quality of evidence)*

(*Strong recommendation/moderate quality of evidence)*

General concept:

- Review the operative report to identify the length of the Roux limb (if feasible).

We performed a systematic review of literature on this topic, as seen in Appendix 4 (available online at www.giejournal.org). The systematic review was restricted to those studies assessing outcomes of E-ERCP, EUS-BD, or PTBD as therapy for patients with biliary obstruction who have undergone prior Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy (Whipple operation), or Billroth II reconstruction

TABLE 8. Evidence profiles for Question 4a: In patients who have surgically altered anatomy (specifically, patients who have undergone prior Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II reconstruction) with biliary obstruction, how does EUS-BD compare with PTBD regarding rates of successful biliary drainage?
Author(s):
Question: EUS-BD compared with PTBD for surgically altered anatomy (Whipple, Roux-en-Y hepaticojejunostomy, and BIllroth II)
Setting:
Bibliography:

Certainty assessment						
No. of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**
Technical success						
12	Nonrandomized studies	Not serious	Not serious	Serious*	Not serious	None
Clinical success						
10	Nonrandomized studies	Not serious	Not serious	Serious*	Not serious	None
Adverse events						
10	Nonrandomized studies	Not serious	Not serious	Serious*	Serious†	None
Need for reintervention						
6	Nonrandomized studies	Not serious	Not serious	Serious*	Not serious	None

EUD-BD, EUS-guided biliary drainage; *PTBD*, percutaneous transhepatic biliary drainage; *CI*, confidence interval.
*No direct comparison of intervention and comparator in 1 study.
†Low total number of events.

TABLE 9. Evidence profiles for Question 4b: In patients who have surgically altered anatomy (specifically, patients who have undergone prior Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II reconstruction) with biliary obstruction, how does EUS-BD compare with E-ERCP regarding rates of successful biliary drainage?
Author(s):
Question: EUS-BD compared with E-ERCP for surgically altered anatomy (Whipple, Roux-en-Y hepaticojejunostomy, and BIllroth II)
Setting:
Bibliography:

Certainty assessment						
No. of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**
Technical success						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Serious*	None
Clinical success						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Serious*	None
Adverse events						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Serious*	None

EUS-BD, EUS-guided biliary drainage; *E-ERCP*, enteroscopy-assisted ERCP; *CI*, confidence interval; *OR*, odds ratio.
*Low number of events.

(Fig. 18). For this question, EUS-BD involves either the creation of a hepaticogastrostomy tract or performing antegrade biliary interventions after obtaining transgastric transhepatic biliary access using EUS. E-ERCP involves using a pediatric colonoscope, single-balloon enteroscope, or double-balloon enteroscope to advance through the gastrojejunal anastomosis, jejujunojejunal anastomosis, and through the Roux limb to reach the ampulla. Examples of benign etiologies include choledocholithiasis and biliary sludge, whereas examples of malignant etiologies include recurrent pancreatic adenocarcinoma and cholangiocarcinoma. It should be noted that some endoscopists may consider using a traditional, side-viewing duodenoscope or a therapeutic endoscope in patients with Billroth II reconstruction; however, those techniques were not evaluated in this analysis.

At the completion of our review, we identified 15 full-text studies that all consisted of observational cohort studies.[41-55] No randomized controlled trials were identified. All 15 studies were retrospective and single-centered with Qumseya scores of ≥ 7.[18] In aggregate, across all 15 studies included in this analysis, 299 patients underwent EUS-BD, 92 underwent E-ERCP, and 89 underwent PTBD. Considering all outcomes together, the overall quality of evidence was found to be very low.

Outcomes. A summary of outcomes and their assessments can be seen in Tables 8 and 9.

Technical success. All 15 studies assessed technical success.[41-55] Among 3 studies that compared EUS-BD and E-ERCP, technical success was higher with EUS-BD relative

TABLE 8. Continued

No. of patients		Effect		Certainty	Importance
EUS-BD	PTBD	Relative (95% CI)	Absolute (95% CI)		
EUS-BD 208/224 (92.9%) vs PTBD 7889 (87.6%), $P = .26$				⨁◯◯◯ Very low	
EUS-BD 106/121 (87.6%) vs PTBD 59/7389 (80.8%), $P = .44$				⨁◯◯◯ Very low	
EUS-BD 42/224 (18.8%) vs PTBD 20/69 (29%), $P = .11$				⨁◯◯◯ Very low	
EUS-BD 29/168 (18.8%) vs PTBD 6/39 (29%), $P = .63$				⨁◯◯◯ Very low	

TABLE 9. Continued

No. of patients		Effect		Certainty	Importance
EUS-BD	E-ERCP	Relative (95% CI)	Absolute (95% CI)		
71/75 (94.7%)	63/91 (69.2%)	OR 5.56 (1.04-29.68)	234 more per 1000 (from 8 more to 293 more)	⨁◯◯◯ Very low	CRITICAL
66/75 (88.0%)	60/92 (65.2%)	OR 4.08 (1.82-9.16)	232 more per 1000 (from 121 more to 293 more)	⨁◯◯◯ Very low	CRITICAL
21/75 (28.0%)	12/92 (13.0%)	OR 3.24 (1.33-7.90)	197 more per 1000 (from 36 more to 412 more)	⨁◯◯◯ Very low	CRITICAL

to E-ERCP (OR, 5.56; 95% CI, 1.04-29.68; $I^2 = 46\%$) (Fig. 19).[34-36] When EUS-BD and PTBD were compared indirectly from 12 observational studies, there were similar pooled rates of technical success (92.9% vs. 87.6%, $P = .26$) (Fig. 20).[44-51,53-55]

Across all included studies, technical success had a consistent definition—successful biliary cannulation and intervention. The overall judged quality of evidence was found to be very low for both studies comparing EUS-BD and E-ERCP and studies comparing EUS-BD and PTBD.

Clinical success. Thirteen studies assessed clinical success.[41-51,53-55] Among 3 studies that compared EUS-BD and E-ERCP, clinical success was higher with EUS-BD as compared with E-ERCP (OR, 4.08; 95% CI, 1.82-9.16; $I^2 = 0\%$) (Fig. 21).[41-43] When EUS-BD and PTBD were compared indirectly from 10 observational studies, there were similar pooled rates of technical success (87.6% vs 80.8%, $P = .44$) (Fig. 22).[44-50,53-55]

Like PICOs 1 and 2, studies were inconsistent in their definitions of clinical success. Some studies defined clinical success as the resolution of biliary obstruction, whereas others required a decrease in the total bilirubin by 50% at 4 weeks. The overall judged quality of evidence was found to be very low for both studies comparing EUS-BD and E-ERCP and studies comparing EUS-BD and PTBD.

Adverse events. Procedure-related AEs were described in 13 observational studies.[41-52,54] From 3 studies comparing EUS-BD and E-ERCP, procedure-related AEs occurred more often with EUS-BD as compared with E-ERCP (OR, 3.24; 95% CI, 1.33-7.90; $I^2 = 0\%$) (Fig. 23).[41-43] This was primarily related to an increase in mild-to-moderate AEs for EUS-BD. When EUS-BD and PTBD were compared indirectly from 10 observational studies, there was a trend toward a lower pooled rate of AEs with EUS-BD compared with PTBD, although it did not reach statistical significance (18.8% vs 29%, respectively; $P = .11$) (Fig. 24).[44-52,54]

Most extracted studies determined the rate and severity of AEs according to the ASGE lexicon.[19] Studies, however, were inconsistent in qualifying AEs as mild, moderate, or severe. Thus, we solely reported total AEs in our analysis. AEs were reported on a per-patient basis as opposed to a per-event basis. The overall judged quality of evidence was found to be very low for both studies comparing EUS-BD and E-ERCP and studies comparing EUS-BD and PTBD.

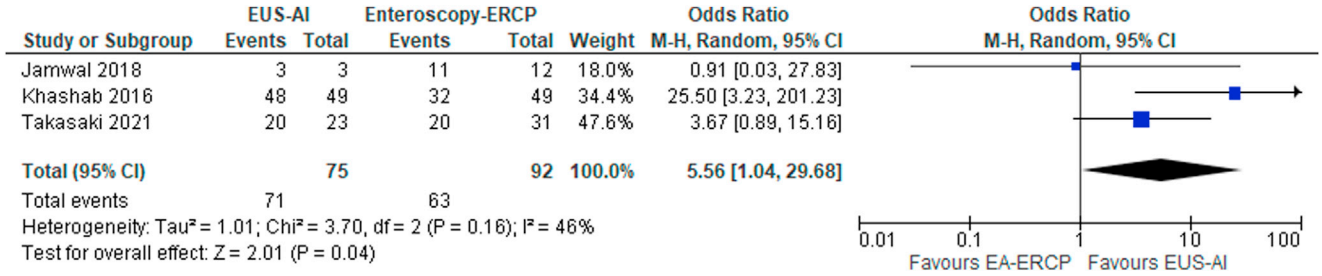


Figure 19. Forest plot of studies evaluating the technical success of EUS-guided biliary drainage compared with enteroscopy-assisted ERCP in patients in patients with biliary obstruction and Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II anatomy (PICO 4). *EUS-AI*, EUS-guided antegrade intervention; *EA-ERCP*, enteroscopy-assisted ERCP; *CI*, confidence interval.

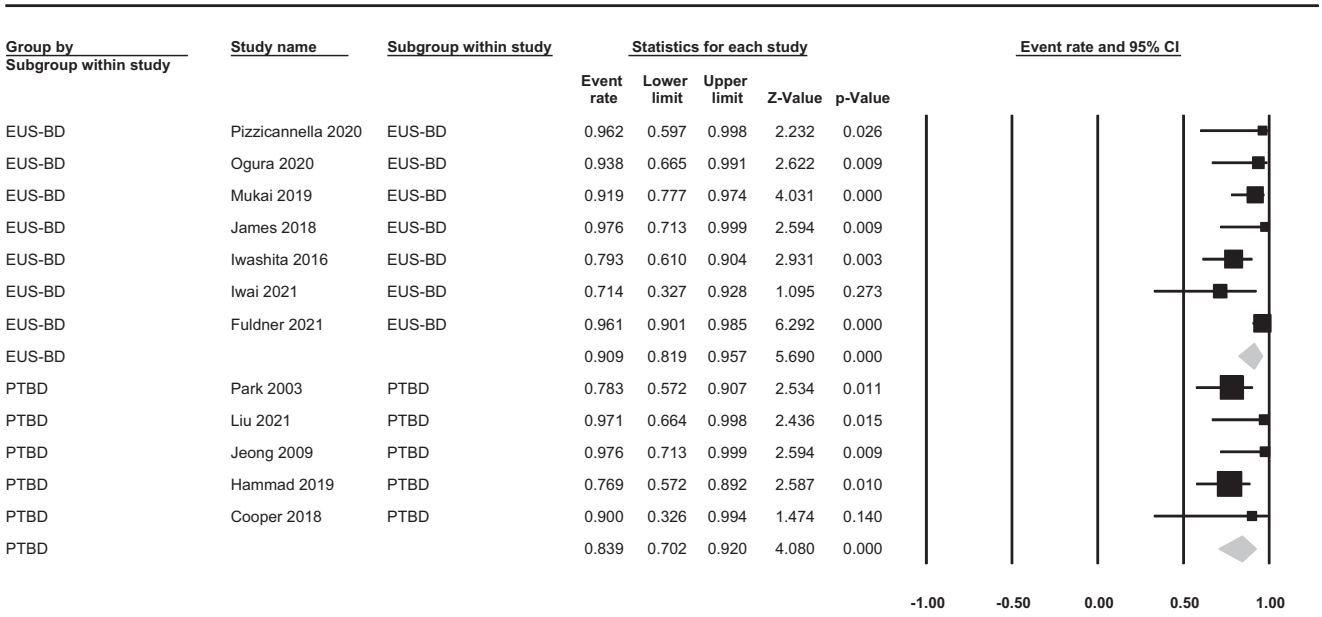


Figure 20. Pooled analysis of studies evaluating the technical success of EUS-BD compared with PTBD in patients with biliary obstruction and Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II anatomy (PICO 4). *EUS-BD*, EUS-guided biliary drainage; *PTBD*, percutaneous transhepatic biliary drainage; *CI*, confidence interval.

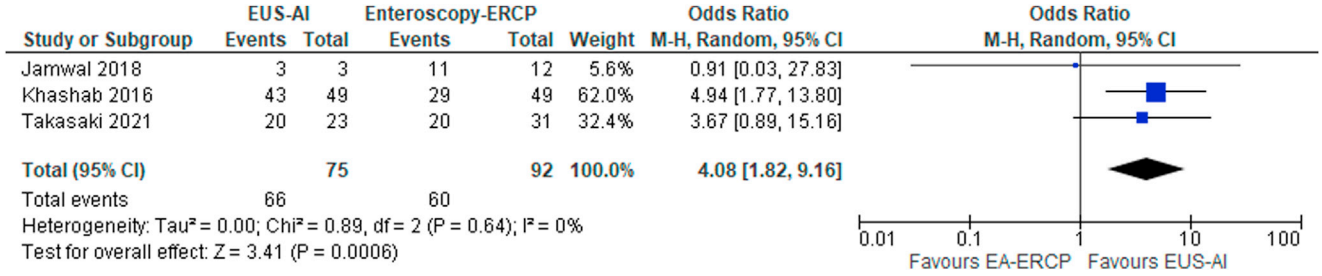


Figure 21. Forest plot of studies evaluating the clinical success of EUS-guided biliary drainage compared with enteroscopy-assisted ERCP in patients in patients with biliary obstruction and Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II anatomy (PICO 4). *EUS-AI*, EUS-guided antegrade intervention; *EA-ERCP*, enteroscopy-assisted ERCP; *CI*, confidence interval.

Need for repeat intervention. No studies compared the need for repeat intervention between EUS-BD and E-ERCP. Five studies were used to indirectly compare the need for reintervention, and no difference was seen in the need for reintervention between EUS-BD and PTBD (19% vs 29%, $P = .63$) (Fig. 25).[45,48,49,51,54] Thus, the overall judged quality of evidence from the observational studies comparing EUS-BD and PTBD was found to be very low.

Other considerations. For costs and cost-effectiveness, no studies were identified that evaluated those outcomes. In addition, we identified no studies that reported on patient values. Based on our discussion with the patient

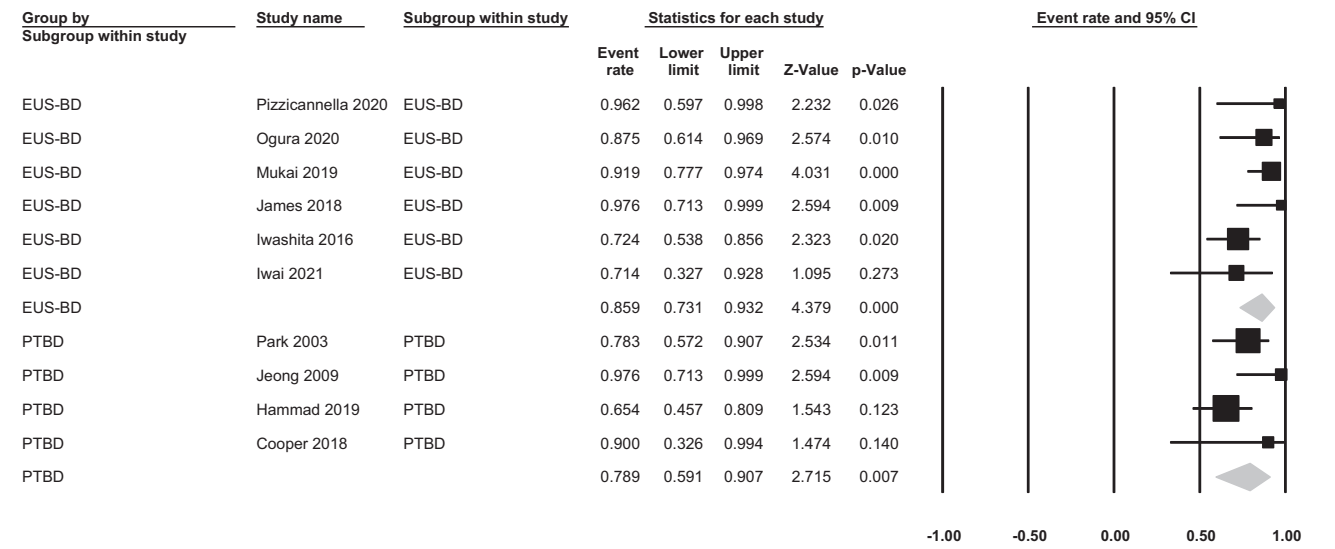


Figure 22. Pooled analysis of studies evaluating the clinical success of EUS-BD compared with PTBD in patients with biliary obstruction and Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II anatomy (PICO 4). *EUS-BD*, EUS-guided biliary drainage; *PTBD*, percutaneous transhepatic biliary drainage; *CI*, confidence interval.

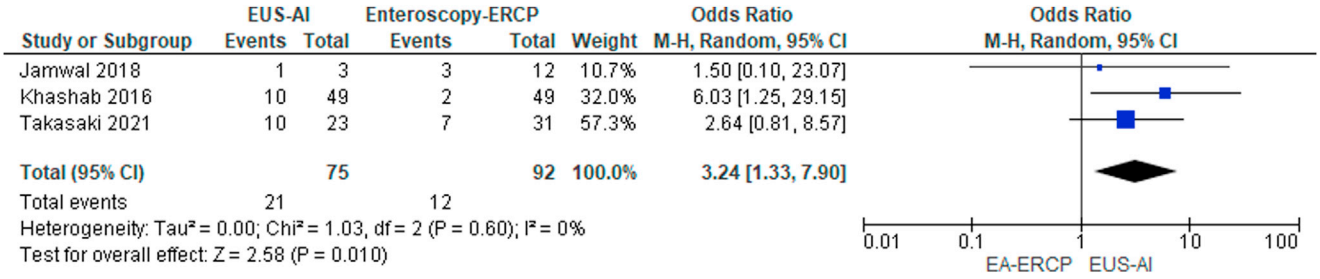


Figure 23. Forest plot of studies evaluating the rate of adverse events with EUS-guided biliary drainage compared with enteroscopy-assisted ERCP in patients in patients with biliary obstruction and Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II anatomy (PICO 4). *EUS-AI*, EUS-guided antegrade intervention; *EA-ERCP*, enteroscopy-assisted ERCP; *CI*, confidence interval.

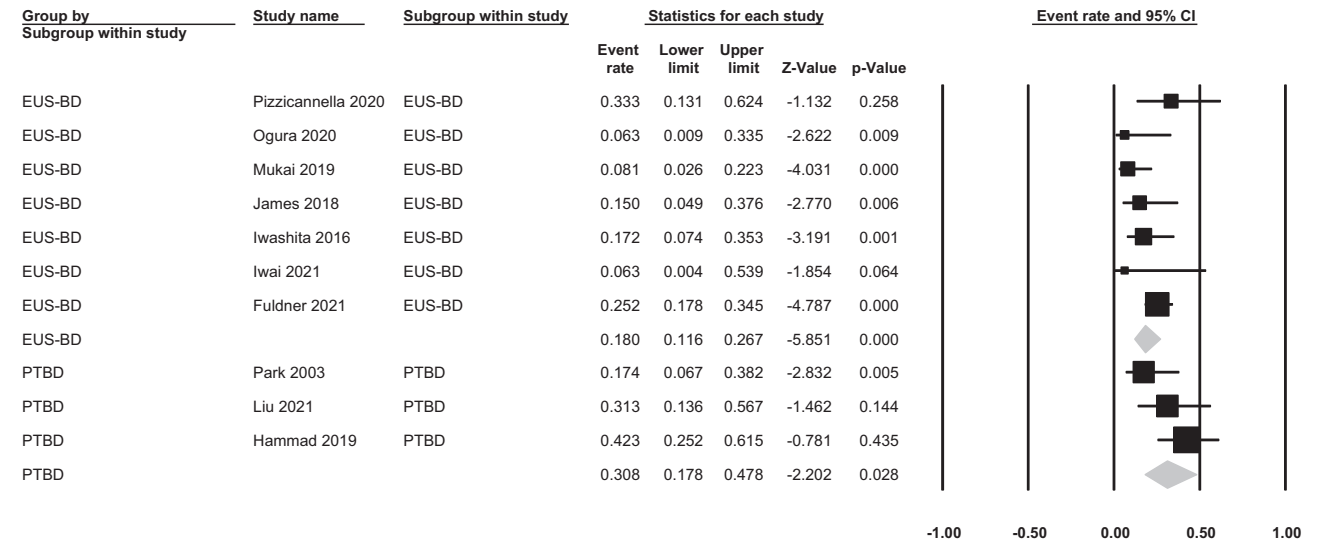


Figure 24. Pooled analysis of studies evaluating the rate of adverse events with EUS-BD compared with PTBD in patients with biliary obstruction and Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II anatomy (PICO 4). *EUS-BD*, EUS-guided biliary drainage; *PTBD*, percutaneous transhepatic biliary drainage; *CI*, confidence interval.

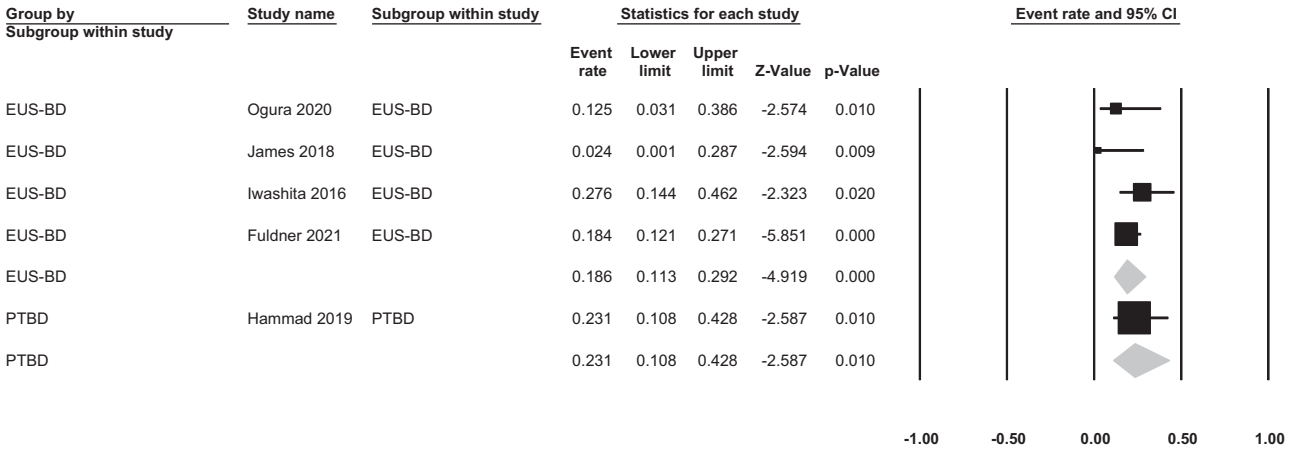


Figure 25. Pooled analysis of studies evaluating the need for reintervention with EUS-BD compared with PTBD in patients with biliary obstruction and Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II anatomy (PICO 4). *EUS-BD*, EUS-guided biliary drainage; *PTBD*, percutaneous transhepatic biliary drainage; *CI*, confidence interval.

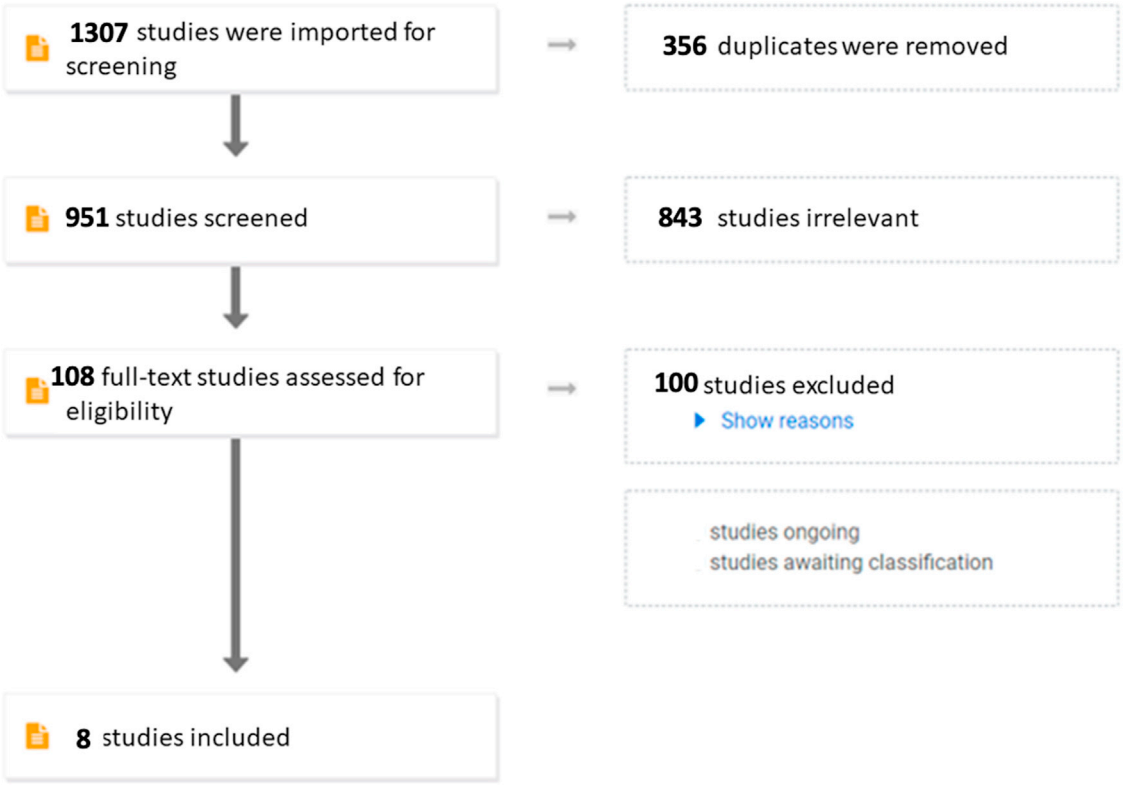


Figure 26. Preferred Reporting Items for Systematic reviews and Meta-Analyses diagram showing studies included in the systematic review evaluating the management strategy for acute cholecystitis in nonsurgical candidates (PICO 5).

advocate who had undergone prior PTBD, the panel assumed that most patients would prefer to avoid external drainage catheters and that achieving internal biliary drainage was very important. For equity, the panel noted throughout our discussion that EUS-BD, PTBD, and E-ERCP require complex equipment, may be technically difficult, require focused training, and may not be available in community practice.

Panel discussion. Most of the panel's discussion focused on the fact that although EUS-BD had higher clinical and technical success rates than E-ERCP, E-ERCP had a much lower rate of AEs. It is important to note that the data favoring EUS-BD over E-ERCP for this question are limited by the lack of patient stratification by type of post-surgical anatomy. Given the safety of E-ERCP and the fact that based on different Roux limb lengths and certain

anatomy types like Billroth II being more favorable and easier to reach the ampulla, the panel recommended starting with E-ERCP. If E-ERCP is unsuccessful, either PTBD or EUS-BD can be performed based on local expertise and patient values.

Question 5: In nonsurgical patients with acute cholecystitis, how does EUS-GBD compare with percutaneous (PT)-GBD and endoscopic transpapillary transcystic (ET)-GBD in resolving acute cholecystitis?

Recommendation 5a: In patients with acute cholecystitis who are not candidates for cholecystectomy, the ASGE suggests EUS-GBD over PT-GBD in resolving acute cholecystitis.

(*Conditional recommendation/moderate quality of evidence)*

General concepts:

- EUS-GBD is preferred in patients with gastric outlet obstruction, duodenal obstruction, indwelling metal stent occluding the cystic duct, and large stone burden within the gallbladder.
- ET-GBD is preferred in patients with ascites, malignant gallbladder infiltration, or severe coagulopathy who have refused rescue surgery, liver transplant candidates, and patients who are not surgical candidates at the time of intervention but may be in the future.

We performed a systematic review of literature on this topic (Appendix 5, available online at www.giejournal.org). The systematic review was restricted to studies that assessed outcomes of EUS-GBD, ET-GBD, or PT-GBD as therapy for nonsurgical patients with acute cholecystitis. (Fig. 26). Only comparative studies evaluating EUS-GBD versus PT-GBD and EUS-GBD versus ET-GBD were included.

Nonsurgical patients included elderly patients and those patients with multiple comorbidities, hemodynamic instability, and intra-abdominal malignancies that required gallbladder drainage.[56-58] Nonsurgical drainage was used either as a bridge for subsequent surgery or as definitive treatment in patients who remained unfit for surgery. Therapeutic nonsurgical endoscopic approaches include EUS-GBD and ET-GBD. EUS-GBD allows the creation of a fistulous tract between the gallbladder and GI tract (transduodenal or transgastric) using plastic stents, covered self-expandable metal stents, or LAMSs.[59] Cautery-enhanced LAMSs have emerged as the preferred stent for gallbladder drainage. This is because cautery-enhanced LAMSs obviate the need for multiple steps and instrument exchanges.[30] ET-GBD allows placement of a double-pigtail stent by cystic duct cannulation as an internal drainage during ERCP. Studies evaluating both benign and malignant cystic duct obstruction were included. Benign conditions include calculous and acalculous cholecystitis, whereas malignant conditions include gallbladder cancer, pancreatic cancer, hepatocellular carcinoma, cholangiocarcinoma, and metastatic disease. Acute cholecystitis was defined by a combination of clinical features (abdominal pain, fever, and/or Murphy sign), laboratory markers (increased white blood cell count and/or increased C-reactive protein), and typical radiologic findings (CT or US-based). Severity was graded based on the Tokyo criteria.[60]

The main outcomes of interest were 30-day mortality, technical success (defined as successful access and drainage of the gallbladder by placement of a transmural stent or transpapillary gallbladder stent using ERCP confirmed by endoscopy and fluoroscopy or percutaneous drainage tube and maintenance of good drainage), clinical success (defined inconsistently across all studies from improvement in clinical symptoms and laboratory tests without a time frame[61,62] to within 5 days[63] to resolution of clinical symptoms, laboratory and/or radiologic abnormalities within 3 days of intervention[64] vs complete resolution of symptoms with improvement in laboratory parameters[65]), AEs (which included bile leaks, perforation, peritonitis, bleeding, and pneumoperitoneum), need for repeat intervention (unplanned only, which included any endoscopic or interventional procedure required to replace, check, or remove the previously placed stent or drain), risk of recurrent acute cholecystitis defined according to the Tokyo guidelines,[66] need for hospital readmission, and future need for cholecystectomy.

We identified 5 full-text studies (1 RCT and 4 observational cohort studies) comparing EUS-GBD and PT-GBD. The RCT took place in a single tertiary care center in Hong Kong.[63] All 4 observational studies were retrospective in nature and compared consecutive patients with EUS-GBD and PT-GBD.[61,62,64,65] Three observational studies were international multicenter studies,[61,62,64] and the remaining observational study was performed at a single center.[65] The RCT had Jadad scores of $\geq$3,[17] whereas the 4 observational studies had Qumseya scores $\geq$7.[18] In aggregate, across all 5 studies included in this analysis, 199 patients underwent EUS-GBD and 276 patients underwent PT-GBD. Considering all outcomes together, the overall quality of evidence was found to be moderate.

Outcomes. A summary of outcomes and their assessments can be seen in Table 10.

Mortality. All 5 studies (4 observational studies and 1 RCT) reported mortality.[61-65] We identified 1 RCT that reported 30-day mortality and 4 observational studies that reported overall mortality. The RCT demonstrated no significant difference in 30-day mortality for patients undergoing EUS-GBD compared with those undergoing PT-GBD (OR, .75; 95% CI, .16-3.59).[63] The 4 observational studies also demonstrated no significant difference in overall mortality for patients undergoing EUS-GBD compared with those undergoing PT-GBD (OR, 1.21; 95% CI, .24-6.09; I^2 = 35%). Across all 5 studies no difference in mortality was seen

TABLE 10. Evidence profiles for Question 5a: In nonsurgical patients with acute cholecystitis, how does EUS-GBD compare with PT-GBD in resolving acute cholecystitis?
Author(s):
Question: EUS-GBD compared with PT-GBD for acute cholecystitis who are not surgical candidates
Setting:
Bibliography:

Certainty assessment						
No. of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**
30-day mortality (RCT)						
1	Randomized trials	Not serious	Not serious	Not serious	Serious*	None
Technical success (RCTs only with LAMSs: ability to access and drain the gallbladder by placement of a transmural stent or percutaneous drainage tube and maintenance of good drainage)						
1	Randomized trials	Not serious†	Not serious	Not serious	Serious	None
Technical success (all studies with LAMSs [1 RCT, 2 OS])						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Clinical success (RCTs: improvement in clinical symptoms and laboratory test)						
1	Randomized trials	Not serious	Not serious	Not serious	Serious	None
Clinical success (all studies with LAMSs [1 RCT, 2 OS])						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Adverse events (RCTs)						
1	Randomized trials	Not serious†	Not serious‡	Not serious	Serious	None
Adverse events (all studies with LAMSs [1 RCT, 2 OS])						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Recurrent cholecystitis (RCTs)						
1	Randomized trials	Not serious	Not serious	Not serious	Serious	None
Recurrent cholecystitis (all studies with LAMSs [1 RCT, 2 OS])						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Need for reintervention because of gallstone disease (RCTs)						
1	Randomized trials	Not serious	Not serious	Not serious	Serious†	None
Need for reintervention (all studies [1 RCT, 2 OS] using LAMSs, SEMSs, and plastic stents)						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Need for hospital readmission (RCTs)						
1	Randomized trials	Not serious	Not serious	Not serious	Serious	None
Need for hospital readmission (all studies with LAMSs [1 RCT, 1 OS])						
2	Nonrandomized studies	Not serious	Not serious	Not serious	Serious*	None
Future need for cholecystectomy (all studies)						
2	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Mortality (all studies)						
5	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Technical success (all studies [1 RCT, 4 OS])						
5	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Clinical success (all studies [1 RCT, 4 OS])						
5	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Adverse events (all studies [1 RCT, 4 OS])						
5	Nonrandomized studies	Not serious	Serious	Not serious	Not serious	None
Recurrent cholecystitis (all studies [1 RCT, 4 OS])						
5	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Need for hospital readmission (all studies [1 RCT, 2 OS] using LAMSs, plastic stents, and SEMSs)						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Serious‡	None

EUS-GBD, EUS-guided gallbladder drainage; *PT-GBD,* percutaneous gallbladder drainage; *RCT*, randomized controlled trial; *OS*, observational study; *CI*, confidence interval; *OR*, odds ratio; *LAMS*, lumen-apposing metal stent; *SEMS*, self-expandable metal stent.
*Low number of events.
†One study.
‡High I^2.

TABLE 10. Continued

No. of patients		Effect		Certainty	Importance
EUS-GBD	PT-GBD	Relative (95% CI)	Absolute (95% CI)		
3/39 (7.7%)	4/40 (10.0%)	OR .75 (.16-3.59)	23 fewer per 1000 (from 83 fewer to 185 more)	⨁⨁⨁◯ Moderate	
38/39 (97.4%)	40/40 (100.0%)	OR .32 (.01-8.02)	0 fewer per 1000 (from 0 fewer to 0 fewer)	⨁⨁⨁◯ Moderate	CRITICAL
139/143 (97.2%)	144/144 (100.0%)	OR .27 (.04-1.67)	0 fewer per 1000 (from 0 fewer to 0 fewer)	⨁⨁◯◯ Low	
36/39 (92.3%)	37/40 (92.5%)	OR .97 (.18-5.14)	2 fewer per 1000 (from 236 fewer to 59 more)	⨁⨁⨁◯ Moderate	CRITICAL
132/143 (92.3%)	134/144 (93.1%)	OR .89 (.36-2.25)	8 fewer per 1000 (from 102 fewer to 37 more)	⨁⨁◯◯ Low	
10/39 (25.6%)	31/40 (77.5%)	OR .10 (.04-.28)	519 fewer per 1000 (from 654 fewer to 284 fewer)	⨁⨁⨁◯ Moderate	CRITICAL
37/143 (25.9%)	89/144 (61.8%)	OR .20 (.08-.46)	374 fewer per 1000 (from 503 fewer to 191 fewer)	⨁⨁◯◯ Low	
1/39 (2.6%)	8/40 (20.0%)	OR .11 (.01-.89)	173 fewer per 1000 (from 198 fewer to 18 fewer)	⨁⨁⨁◯ Moderate	CRITICAL
4/143 (2.8%)	16/144 (11.1%)	OR .27 (.06-1.12)	78 fewer per 1000 (from 104 fewer to 12 more)	⨁⨁◯◯ Low	
1/39 (2.6%)	12/40 (30.0%)	OR .06 (.01-.50)	275 fewer per 1000 (from 296 fewer to 124 fewer)	⨁⨁⨁◯ Moderate	
5/95 (5.3%)	49/172 (28.5%)	OR .14 (.04-.55)	232 fewer per 1000 (from 269 fewer to 105 fewer)	⨁⨁◯◯ Low	
6/39 (15.4%)	20/40 (50.0%)	OR .18 (.06-.53)	347 fewer per 1000 (from 443 fewer to 154 fewer)	⨁⨁⨁◯ Moderate	
10/98 (10.2%)	62/99 (62.6%)	OR .07 (.01-.44)	521 fewer per 1000 (from 610 fewer to 202 fewer)	⨁◯◯◯ Very low	
2/101 (2.0%)	32/177 (18.1%)	OR .15 (.04-.58)	149 fewer per 1000 (from 172 fewer to 67 fewer)	⨁⨁◯◯ Low	
10/199 (5.0%)	12/276 (4.3%)	OR 1.03 (.34-3.17)	1 more per 1000 (from 28 fewer to 82 more)	⨁⨁◯◯ Low	
191/199 (96.0%)	275/276 (99.6%)	OR .21 (.06-.78)	13 fewer per 1000 (from 54 fewer to 1 fewer)	⨁⨁◯◯ Low	CRITICAL
183/199 (92.0%)	248/276 (89.9%)	OR 1.09 (.49-2.44)	8 more per 1000 (from 86 fewer to 57 more)	⨁⨁◯◯ Low	CRITICAL
50/199 (25.1%)	117/276 (42.4%)	OR .38 (.15-1.01)	205 fewer per 1000 (from 325 fewer to 2 more)	⨁◯◯◯ Very low	CRITICAL
7/199 (3.5%)	26/276 (9.4%)	OR .46 (.19-1.13)	49 fewer per 1000 (from 75 fewer to 11 more)	⨁⨁◯◯ Low	
16/140 (11.4%)	89/212 (42.0%)	OR .15 (.03-.74)	322 fewer per 1000 (from 399 fewer to 71 fewer)	⨁◯◯◯ Very low	

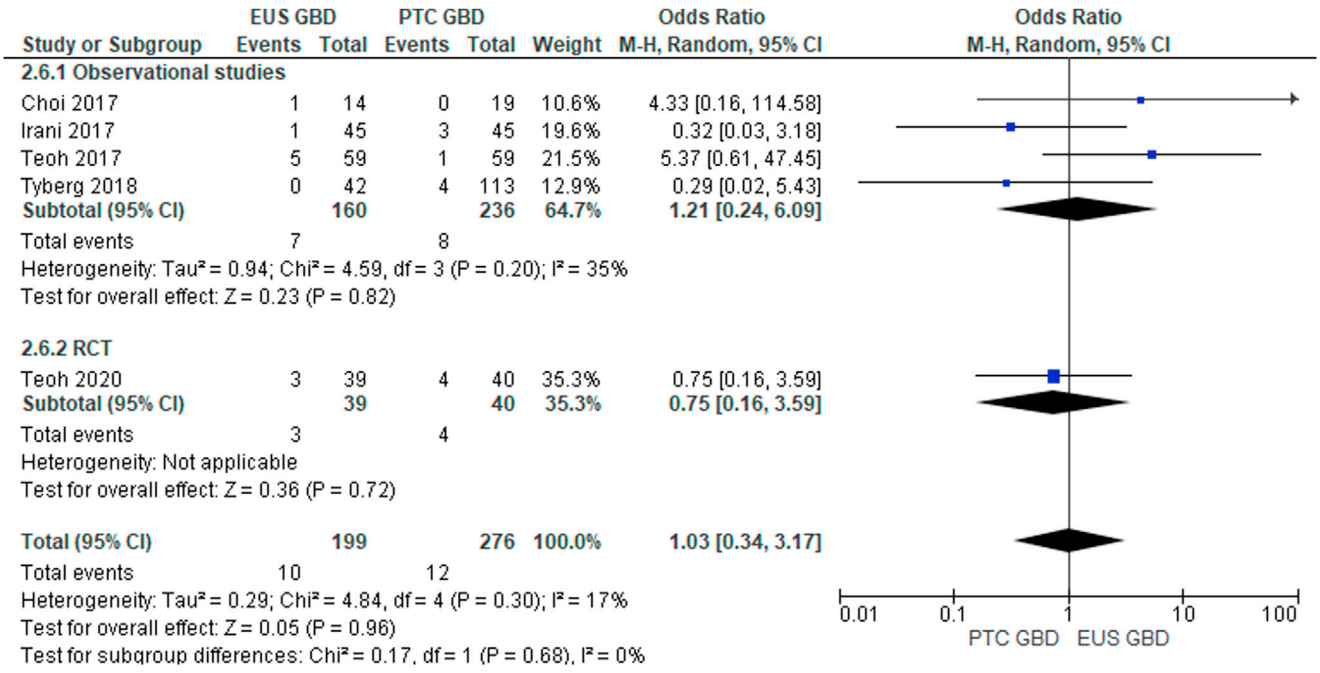


Figure 27. Forest plot of studies evaluating mortality for EUS-GBD compared with PTC-GBD showed no difference. *EUS-GBD,* EUS-guided gallbladder drainage; *PTC-GBD,* percutaneous gallbladder drainage; *CI*, confidence interval; *RCT*, randomized control trial.

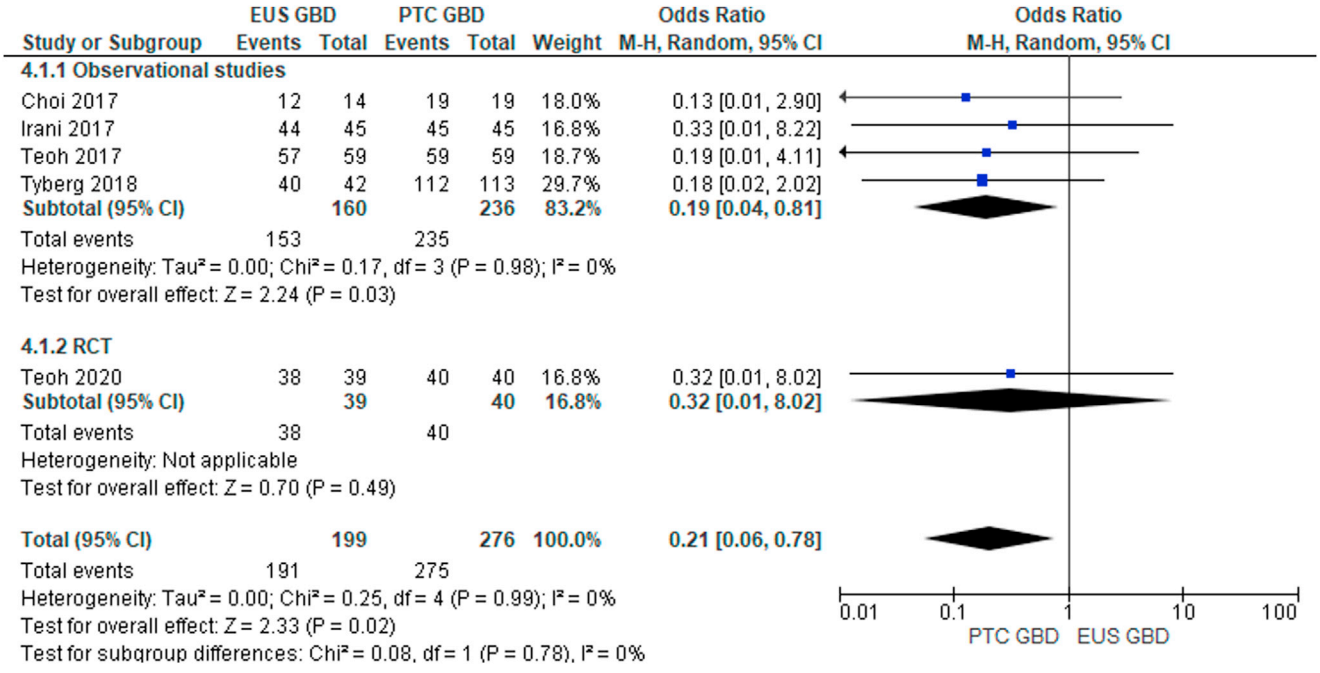


Figure 28. Forest plot of studies evaluating technical success of EUS-GBD compared with PTC-GBD showed a higher technical success with PTC-GBD in the 4 observational studies and no difference in the RCT. *EUS-GBD,* EUS-guided gallbladder drainage; *PTC-GBD,* percutaneous gallbladder drainage; *CI*, confidence interval; *RCT*, randomized control trial.

between EUS-GBD and PT-GBD (OR, 1.03; 95% CI, .34-3.17; I^2 = 17%) (Fig. 27). Overall, the judged quality of evidence from the RCT was moderate and from the 4 observational studies was low.

Technical success. All 5 studies (4 observational studies and 1 RCT) assessed technical success.[61-65] Unlike the RCT that identified no difference in technical success between EUS-GBD and PT-GBD (OR, .32; 95% CI, .01-8.02), the 4 observational studies demonstrated that EUS-GBD had significantly lower odds of achieving technical success (OR, .19; 95% CI, .04-.81; I^2 = 0%) relative to PT-GBD. Across all 5 studies comparing EUS-GBD and PT-GBD, the

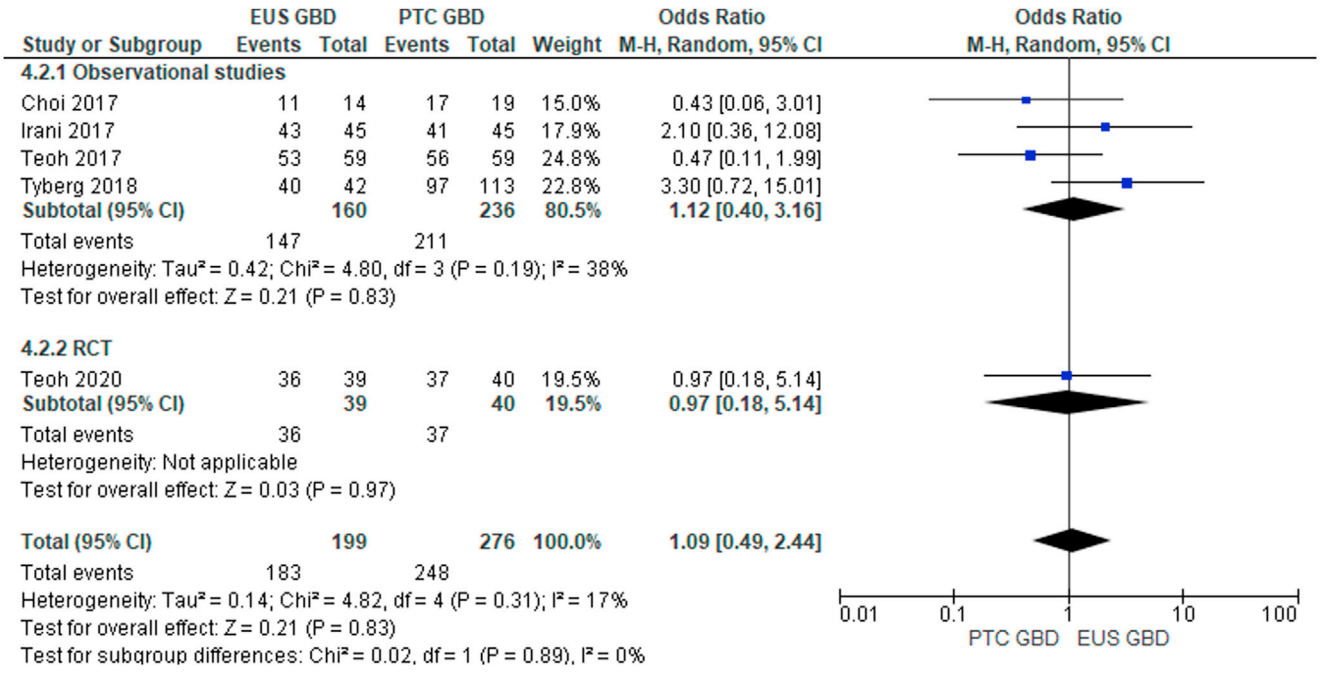


Figure 29. Forest plot of studies evaluating clinical success of EUS-GBD compared with PTC-GBD with no difference. *EUS-GBD,* EUS-guided gallbladder drainage; *PTC-GBD,* percutaneous gallbladder drainage; *CI*, confidence interval; *RCT*, randomized control trial.

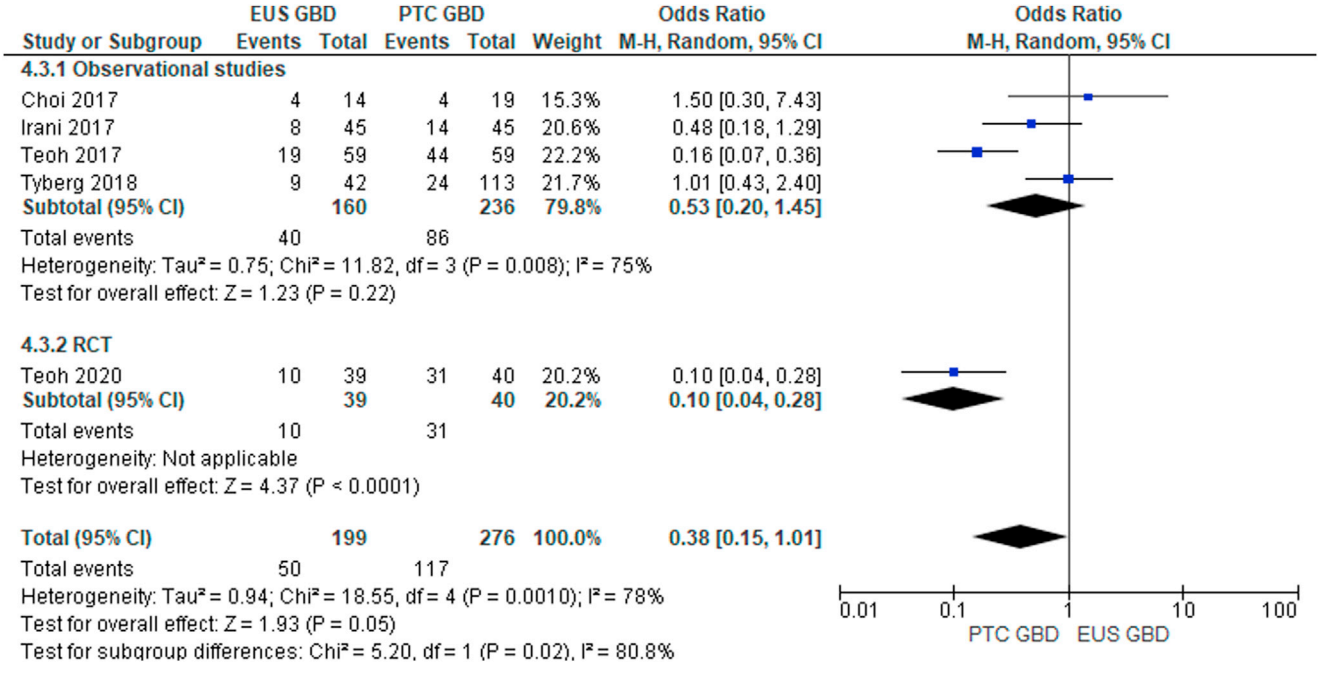


Figure 30. Forest plot of studies evaluating adverse events for EUS-GBD compared with PTC-GBD with no difference in observational studies and lower rates of adverse events in EUS-GBD in the RCT. *EUS-GBD,* EUS-guided gallbladder drainage; *PTC-GBD,* percutaneous gallbladder drainage; *CI*, confidence interval; *RCT*, randomized control trial.

OR for technical success of those undergoing EUS-GBD relative to those undergoing PT-GBD was .21 (95% CI, .06-.78; I^2 = 0%) (Fig. 28). The overall judged quality of evidence for the RCT was found to be moderate and for the 4 observational studies was found to be low.

Clinical success. All 5 studies (4 observational studies and 1 RCT) assessed clinical success.[61-65] No difference was found in clinical success between EUS-GBD and PT-GBD in the RCT (OR, .97; 95% CI, .18-5.14)[63] and in the observational studies (OR, 1.12; 95% CI, .40-3.16; I^2 =

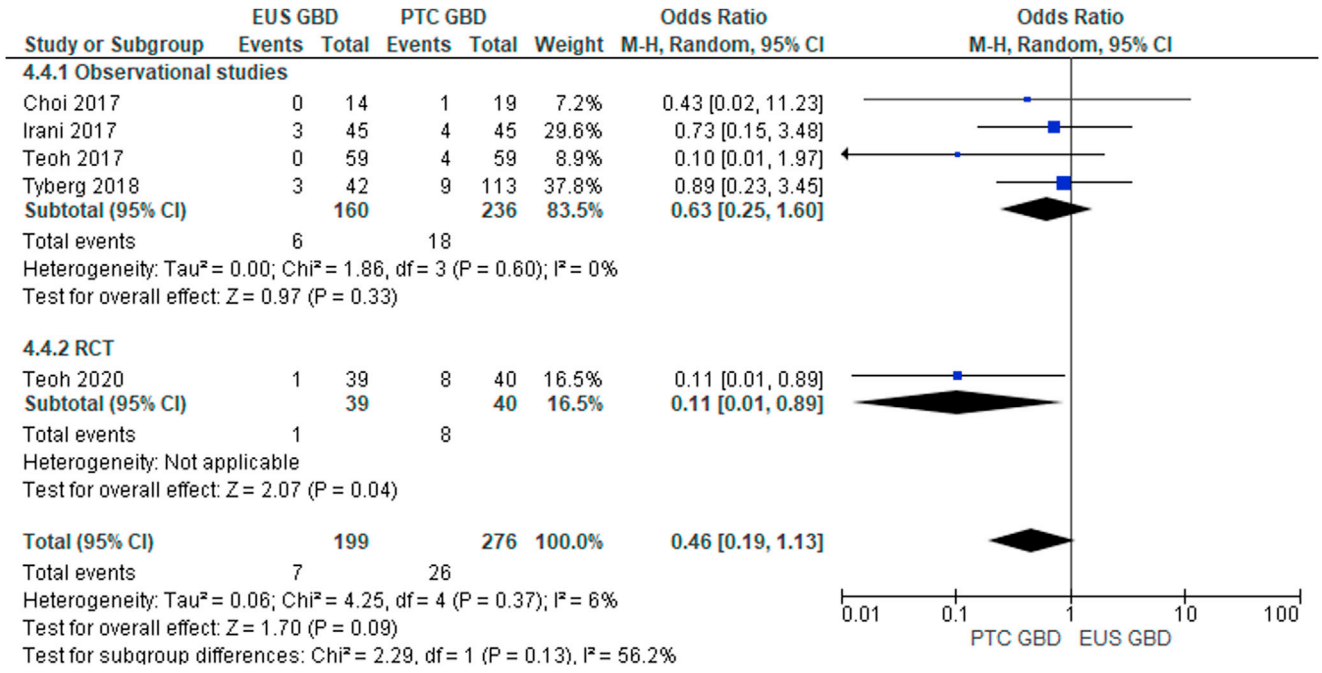


Figure 31. Forest plot of studies evaluating recurrent cholecystitis for EUS-GBD compared with PTC-GBD. *EUS-GBD,* EUS-guided gallbladder drainage; *PTC-GBD,* percutaneous gallbladder drainage; *CI*, confidence interval; *RCT*, randomized control trial.

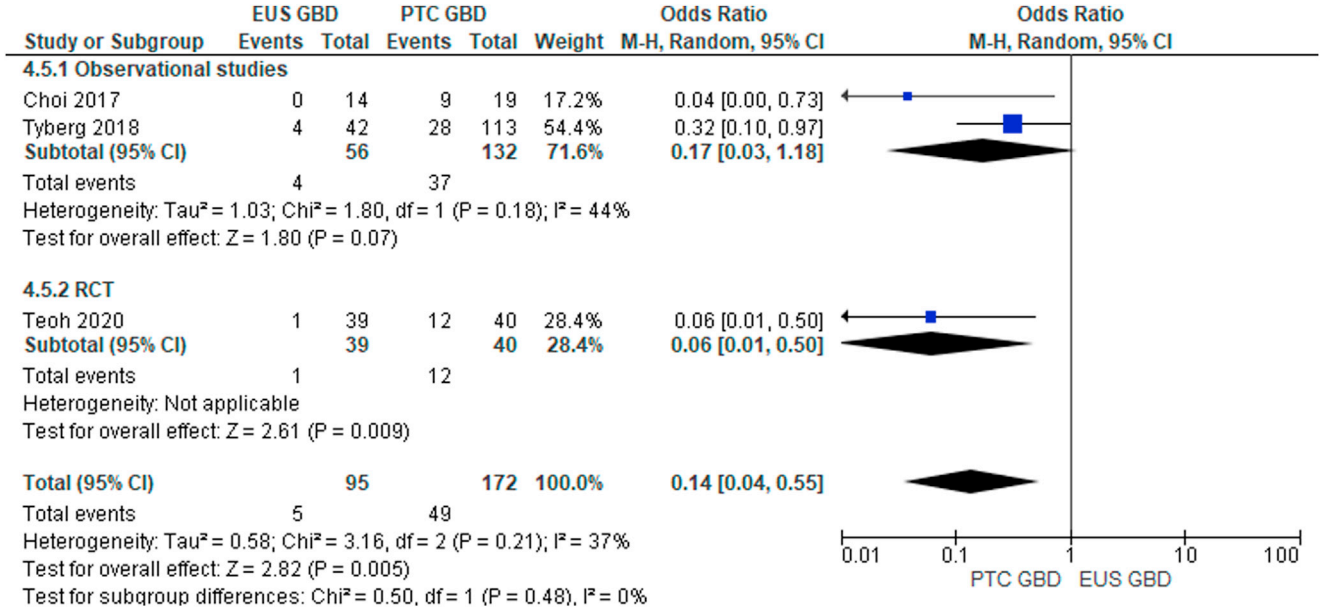


Figure 32. Forest plot of studies evaluating the need for reintervention for EUS-GBD compared with PTC-GBD showed a lower need for reintervention with EUS-GBD. *EUS-GBD,* EUS-guided gallbladder drainage; *PTC-GBD,* percutaneous gallbladder drainage; *CI*, confidence interval; *RCT*, randomized control trial.

38%) (Fig. 29).[61,62,64,65] The overall judged quality of evidence from the RCT was moderate and from the observational studies was low.

Adverse events. Procedure-related AEs were described in all 5 studies (4 observational studies and 1 RCT) in the systematic review.[61-65] The RCT showed 90% lower odds of AEs in patients undergoing EUS-GBD when compared with PT-GBD (OR, .10; 95% CI, .04-.28).[63] However, the observational studies showed no difference in AEs between the 2 groups (OR, .53; 95% CI, .20-1.45; I^2 = 75%) (Fig. 30).[61,62,64,65]

The RCT calculated a cumulative rate of AEs in 1 year as their primary outcome.[63] Only biliary tract–related AEs were recorded after a 30-day period. The severity of AEs was graded according to the Clavien-Dindo classification.[67] Most were because of tube dislodgements. EUS-GBD when

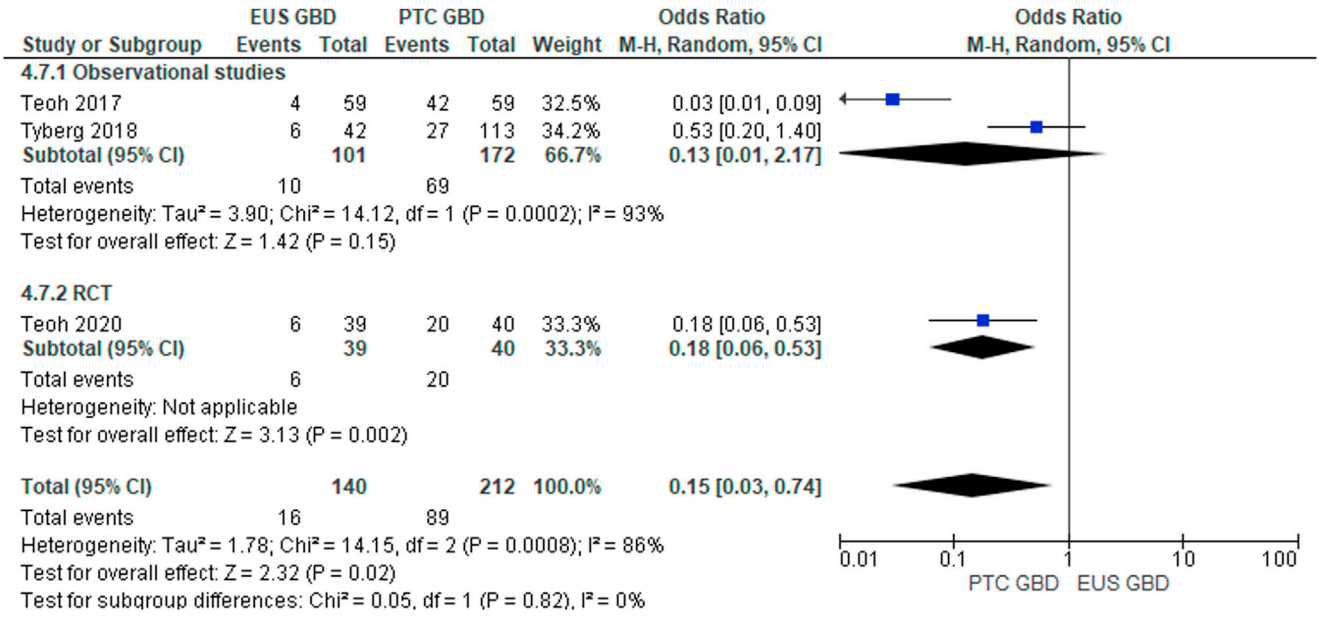


Figure 33. Forest plot of studies evaluating the need for readmission for EUS-GBD compared with PTC-GBD showed a lower need for readmission with EUS-GBD. *EUS-GBD,* EUS-guided gallbladder drainage; *PTC-GBD,* percutaneous gallbladder drainage; *CI*, confidence interval; *RCT*, randomized control trial.

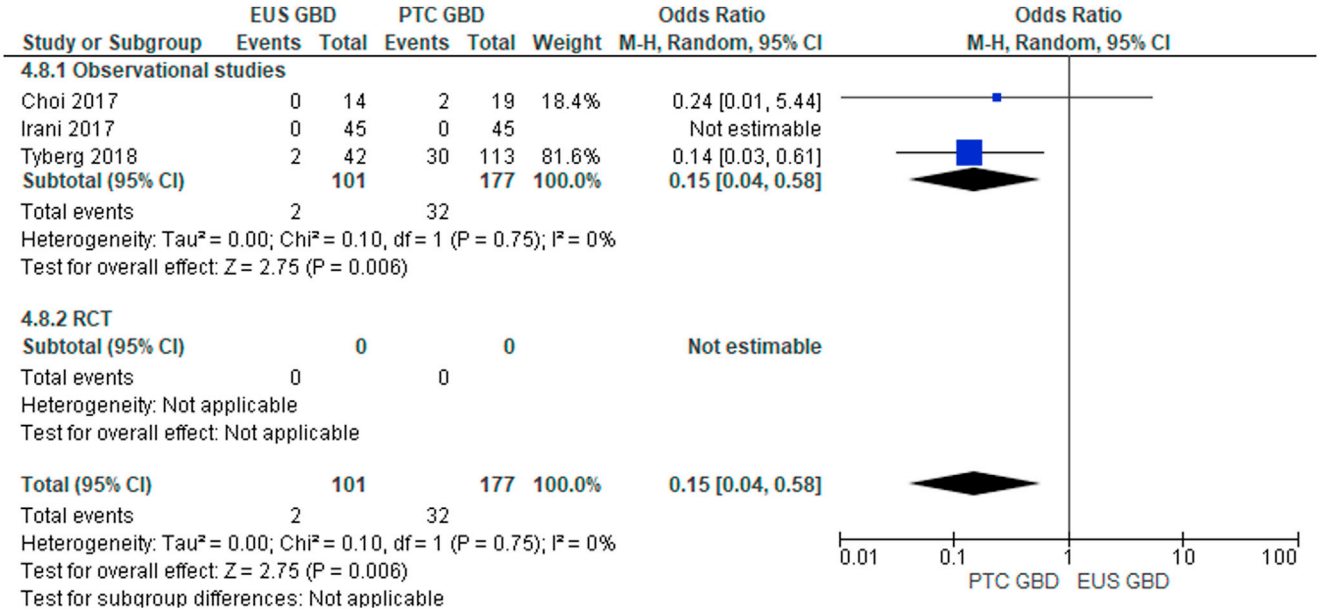


Figure 34. Forest plot of studies evaluating the need for cholecystectomy for EUS-GBD compared with PTC-GBD showed a lower need for cholecystectomy with EUS-GBD. *EUS-GBD,* EUS-guided gallbladder drainage; *PTC-GBD,* percutaneous gallbladder drainage; *CI*, confidence interval; *RCT*, randomized control trial.

compared with PT-GBD had significantly reduced 1-year AEs (25.6% vs 77.5%, $P < .001$) and 30-day AEs (12.8% vs 47.5%, $P = .001$).

Three of 4 observational studies[62,64,65] determined the rate and severity of AEs according to the ASGE lexicon.[19] AEs were defined as any procedure, drain, or stent-related event occurring during or within 30 days after the procedure. AEs were reported on a per-patient basis as opposed to a per-event basis. We reported total AEs in our analysis. Two studies were limited by variable technical approaches in EUS-GBD (LAMS vs self-expandable metal stent vs plastic stent)[61] and use of a self-expandable metal stent only. One study found that the type of stent was not a predictor of AEs.[61]

While assessing the certainty of evidence from the RCT, we rated down evidence for imprecision because of small number of studies and patients and overall judged the quality of

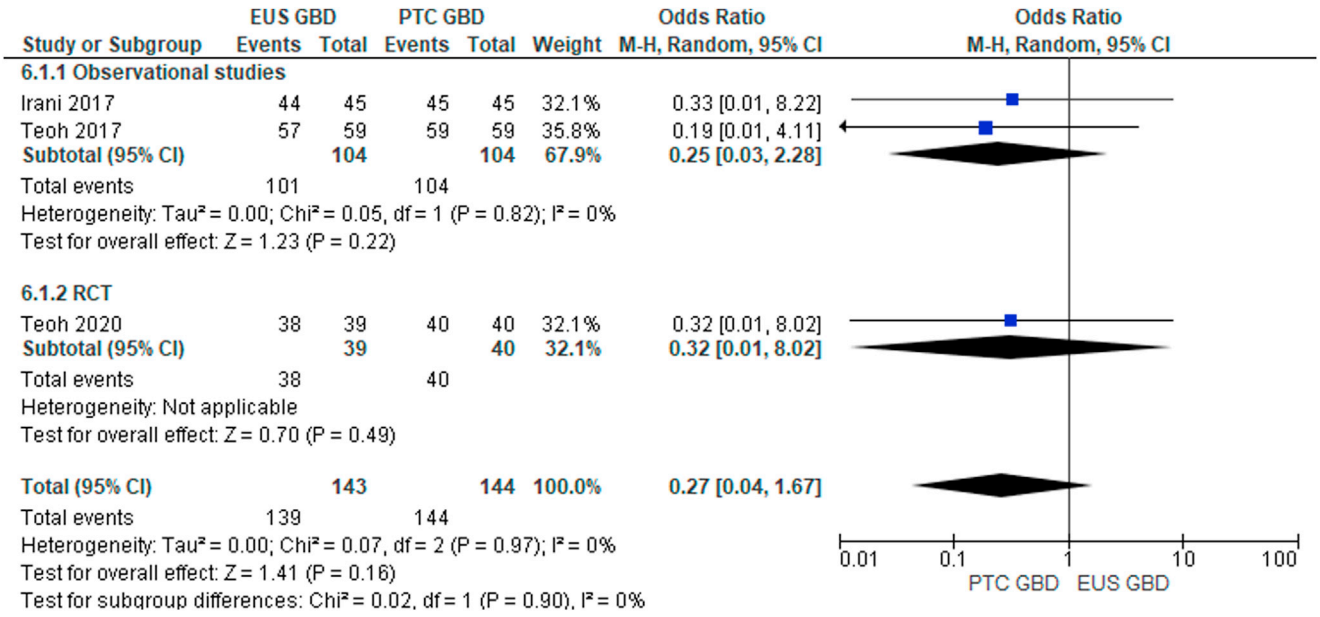


Figure 35. Forest plot of studies evaluating technical success of EUS-GBD (lumen-apposing metal stent only) compared with PTC-GBD showed no difference. *EUS-GBD,* EUS-guided gallbladder drainage; *PTC-GBD,* percutaneous gallbladder drainage; *CI*, confidence interval; *RCT*, randomized control trial.

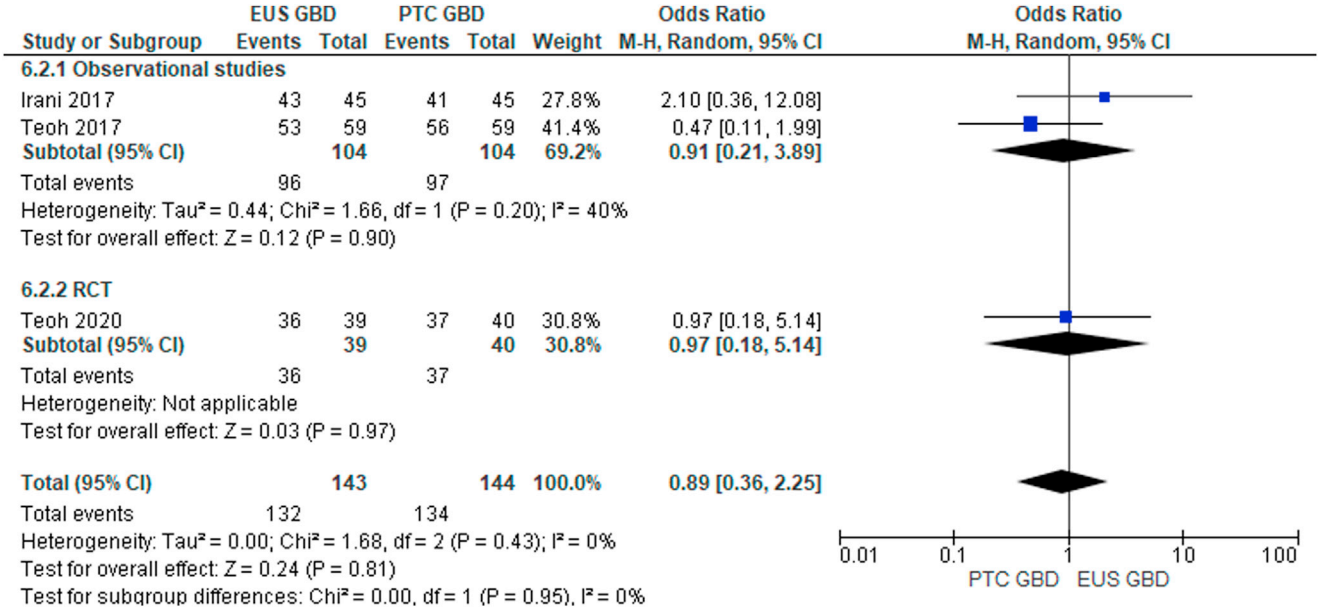


Figure 36. Forest plot of studies evaluating clinical success of EUS-GBD (lumen-apposing metal stent only) compared with PTC-GBD. *EUS-GBD,* EUS-guided gallbladder drainage; *PTC-GBD,* percutaneous gallbladder drainage; *CI*, confidence interval; *RCT*, randomized control trial.

evidence to be moderate. The overall judged quality of evidence from the cohort studies was found to be low.

Recurrent cholecystitis. All 5 studies (4 observational studies and 1 RCT) assessed recurrent cholecystitis.[61-65] The RCT showed lower odds of developing recurrent cholecystitis (OR, .11; 95% CI, .01-.89) in patients undergoing EUS-GBD compared with those undergoing PT-GBD.[63] The observational studies showed no difference in rates of development of recurrent cholecystitis between EUS-GBD and PT-GBD (OR, .63; 95% CI, .25-1.60; I^2 = 0%).[61,62,64,65] Across all studies, no difference in rate of recurrent cholecystitis was seen between EUS-GBD and PT-GBD (OR, .46; 95% CI, .19-1.13; I^2 = 6%) (Fig. 31). The overall judged quality of evidence from the RCTs was rated down for imprecision and was moderate, whereas the data from the observational studies was low.

Need for repeat intervention. The need for a repeat intervention after the index EUS-GBD or PT-GBD was

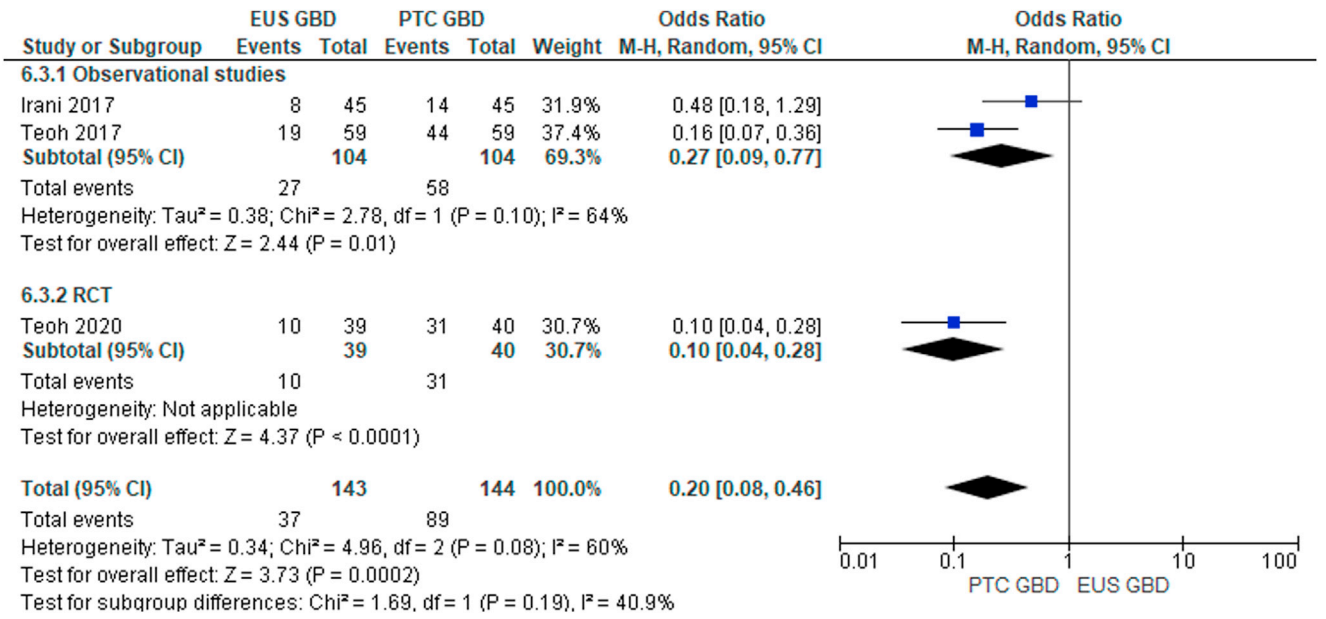


Figure 37. Forest plot of studies evaluating adverse events of EUS-GBD (lumen-apposing metal stent only) compared with PTC-GBD showed lower adverse events in EUS-GBD. *EUS-GBD,* EUS-guided gallbladder drainage; *PTC-GBD,* percutaneous gallbladder drainage; *CI*, confidence interval; *RCT*, randomized control trial.

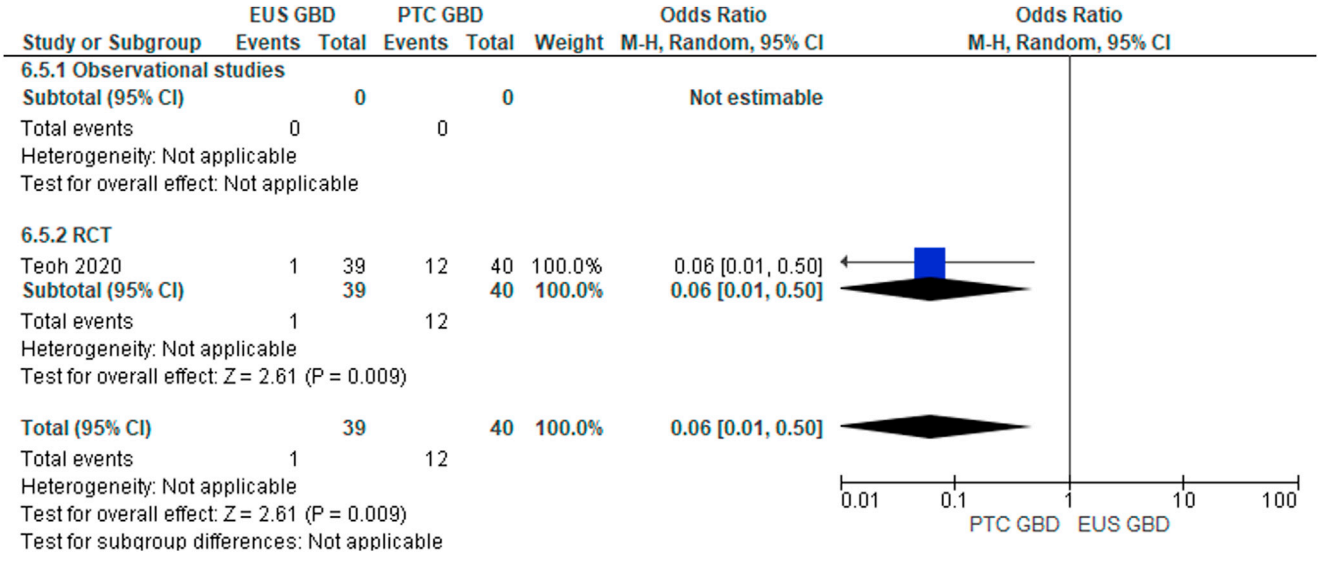


Figure 38. Forest plot of studies evaluating the need for reintervention for EUS-GBD (lumen-apposing metal stent [LAMS] only) compared with PTC-GBD showed a lower need for reintervention with EUS-GBD (LAMS only). *EUS-GBD,* EUS-guided gallbladder drainage; *PTC-GBD,* percutaneous gallbladder drainage; *CI*, confidence interval; *RCT*, randomized control trial.

described in 3 studies (2 observational studies and 1 RCT).[61,63,65] The RCT found that EUS-GBD had patients had lower odds of undergoing repeat gallbladder intervention than PT-GBD (OR, .06; 95% CI, .01-.50), whereas the 2 observational studies showed no difference in need for repeat gallbladder intervention (OR, .17; 95% CI, .03-1.18; I^2 = 44%). Across all studies comparing EUS-GBD and PT-GBD, EUS-GBD had significantly lower odds needing a repeat intervention compared with PT-GBD (OR, .14; 95% CI, .04-.55; I^2 = 37%) (Fig. 32). The overall judged quality of evidence from the RCTs was found to be moderate and was rated down for imprecision, whereas the evidence from the cohort studies was found to be low.

Need for hospital readmission. Three studies (2 observational studies and 1 RCT) reported hospital readmission rates between EUS-GBD and PT-GBD.[61-63] The RCT compared EUS-GBD and PT-GBD and found significantly lower readmission rates in EUS-GBD (OR, .18; 95% CI, .06-.53) relative to PT-GBD. The 2 observational studies

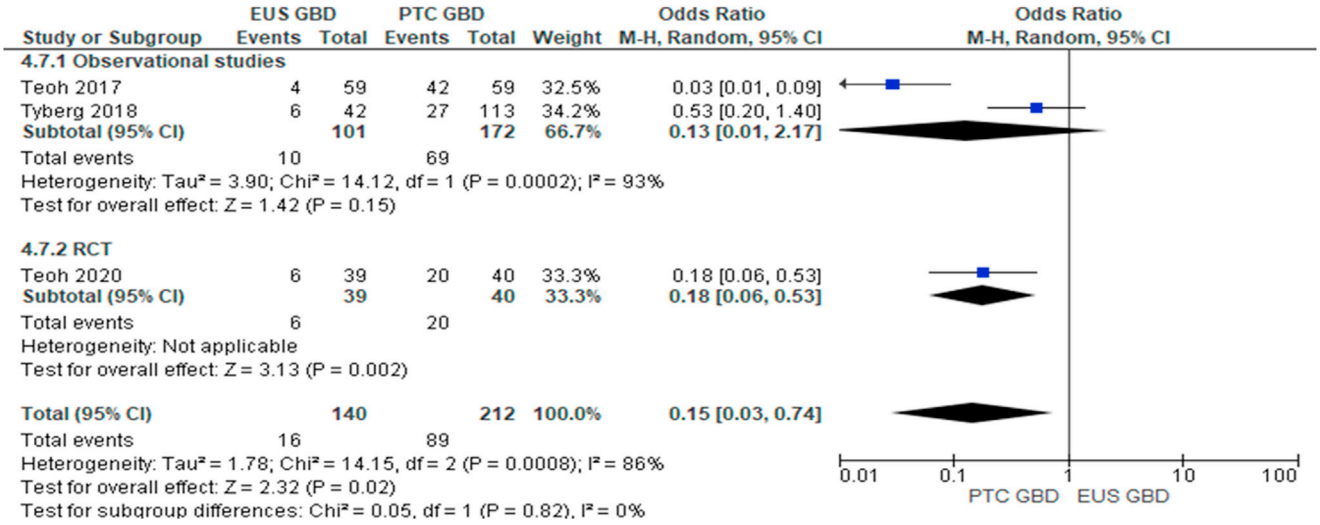


Figure 39. Forest plot of studies evaluating the need for readmission for EUS-GBD (lumen-apposing metal stent only) compared with PTC-GBD showed a lower need for readmission with EUS-GBD. *EUS-GBD,* EUS-guided gallbladder drainage; *PTC-GBD,* percutaneous gallbladder drainage; *CI*, confidence interval; *RCT*, randomized control trial.

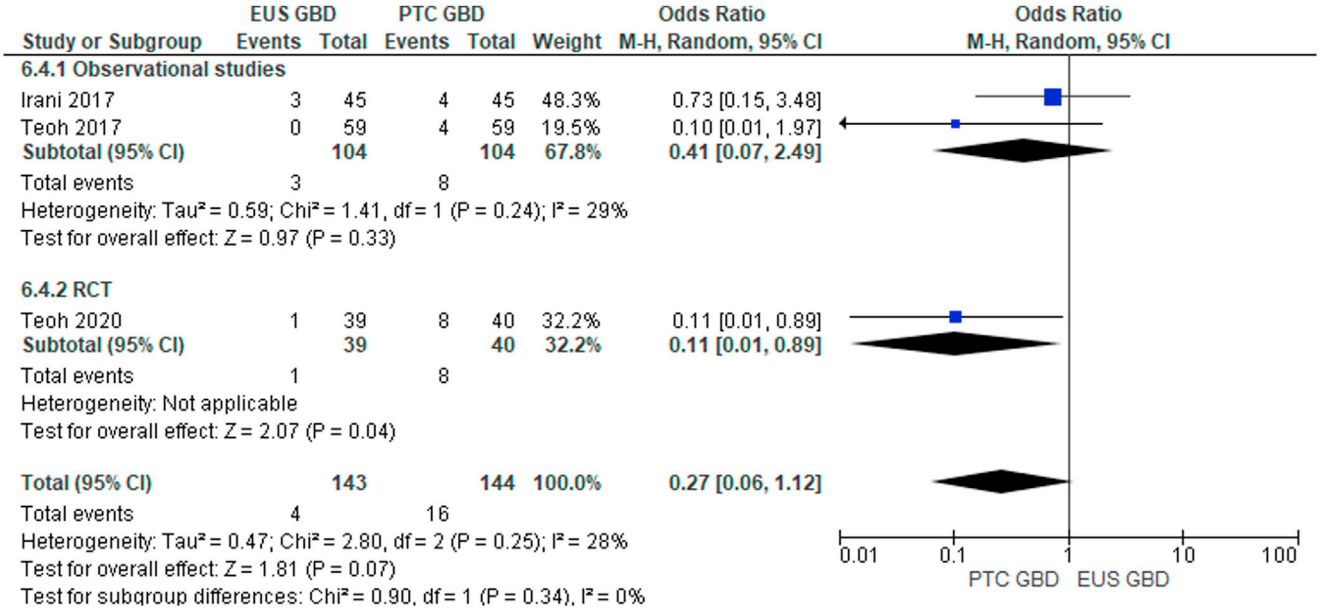


Figure 40. Forest plot of studies evaluating recurrent cholecystitis for EUS-GBD (lumen-apposing metal stent [LAMS] only) compared with PTC-GBD showed lower rates in the EUS-GBD (LAMS only) group. *EUS-GBD,* EUS-guided gallbladder drainage; *PTC-GBD,* percutaneous gallbladder drainage; *CI*, confidence interval; *RCT*, randomized control trial.

found no difference in the readmission rate between EUS-GBD and PT-GBD (OR, .13; 95% CI, .01-2.17; I^2 = 67%). Across all studies, hospital readmission was lower in the EUS-GBD group when compared with PT-GBD (OR, .15; 95% CI, .03-.74; I^2 = 86%) (Fig. 33). The overall judged quality of evidence from the RCTs was found to be moderate and was rated down for imprecision, whereas the evidence from the cohort studies was found to be low. One observational study reported on length of hospital stay and found that the median postintervention hospital length of stay was shorter (3 days vs 9 days, $P < .05$) with EUS-GBD.[64]

Need for future cholecystectomy. Three observational studies were included, but 1 study was not estimable. Among the 2 observational studies comparing EUS-GBD and PT-GBD, EUS-GBD had significantly lower odds for future need for cholecystectomy (OR, .15; 95% CI, .04-.58; I^2 = 0%) than PT-GBD (Fig. 34).[9,12] The overall judged quality of evidence for the observational studies was found to be low.

Subgroup analyses. A subgroup analysis of studies by whether the investigators used LAMSs only for EUS-GBD was performed. Three studies (1 RCT and 2 observational

cohort studies) met our inclusion and exclusion criteria.[8,10,11] In aggregate across all 3 studies included in this analysis, 143 patients underwent EUS-GBD with LAMSs and 144 patients underwent PT-GBD.[62-64] Similar to the RCT findings, we found no difference in technical success (OR, .27; 95% CI, .04-1.67; I^2 = 0%) (Fig. 35) and clinical success (OR, .89; 95% CI, .36-2.25; I^2 = 0%) (Fig. 36) between EUS-GBD with LAMSs and PT-GBD.[62-64] We found that EUS-GBD with LAMSs was associated with significantly lower odds of AEs (OR, .20; 95% CI, .08-.46; I^2 = 60%) (Fig. 37),[62-64] need for repeat intervention (OR, .06; 95%-CI, .01-.50) (Fig. 38), and need for hospital readmission (OR, .15; 95% CI, .03-.74; I^2 = 86%) (Fig. 39) relative to PT-GBD, mirroring the RCT findings described earlier. Unlike the RCT, EUS-GBD with LAMSs did not show any difference in the rates of recurrent cholecystitis (OR, .27; 95% CI, .06– 1.12; I^2 = 28%) (Fig. 40) between EUS-GBD and PT-GBD.

Other considerations. Cost was addressed in 2 studies in our systematic review.[65,68] Choi et al[65] found that the total cost of hospital stay and procedure was higher in EUS-GBD (median, $1360 [range, $1306-1605]) when compared with the PT-GBD group (median, $687 [range, $416-1154]; $P <$ .001). Chan et al[68] found that the net budget impact per year was higher for introducing EUS-GBD. Even though EUS-GBD saved on cost in management of AEs, reinterventions, and unplanned readmissions, these did not offset the cost of the stent. No study was identified that evaluated cost-effectiveness.

Regarding patient values, we found no studies that reported on this outcome. Our patient advocate (who had previous experience with PTBD) expressed that she suffered greatly with an external drainage catheter. The panel believed most patients would prefer to avoid external drainage catheters and that achieving internal biliary drainage was preferable when possible.

For equity, the panel noted throughout our discussion that EUS-GBD requires complex equipment including knowledge of therapeutic EUS, wire exchange, and stent deployment and can be technically difficult. The panel agreed that performance of EUS-GBD requires dedicated training and may not be available in community practice.

Panel discussion. In the RCT comparing EUS-GBD with PT-GBD, significantly reduced 1-year AEs, 30-day AEs, reinterventions, unplanned readmissions, and recurrent cholecystitis were seen with EUS-GBD.[63] Postprocedural pain scores and analgesic requirements were also lower with EUS-GBD (P = .034). The panel agreed that these results are promising, but larger comparative studies are needed to confirm these results.

The panel noted throughout our discussion that EUS-GBD is technically difficult and requires training. Thus, EUS-GBD may not be available in many gastroenterology practices, whereas referrals to interventional radiology are commonplace in most centers because of their ubiquitous presence. The panel strongly believed that clinicians should not feel obligated to refer every patient requiring gallbladder drainage to tertiary care centers if PT-GBD is available in their hospital but EUS-GBD is not. The panel was concerned that referrals for EUS-GBD could result in delays in patient care if a provider who performs the technique was not readily available. The panel also recognized that future cholecystectomy may could be challenging once EUS-GBD is done and stressed the importance of multidisciplinary collaboration with interventional radiology and surgery in choosing an optimal drainage method for each patient.

Recommendation 5b: In patients with acute cholecystitis who cannot undergo cholecystectomy, the ASGE suggests EUS-GBD over ET-GBD to resolve acute cholecystitis.

(Conditional recommendation/very low quality of evidence)

General concepts:

- PT-GBD is preferred in patients with gallbladder perforation, emphysematous cholecystitis, clinical instability, or inability to tolerate more than moderate sedation.

When comparing EUS-GBD and ET-GBD, our completed screening and review identified 3 full-text studies (observational cohort studies) that met inclusion and exclusion criteria.[69-71] No RCTs were identified. All 3 observational studies were retrospective in nature and compared consecutive patients with EUS-GBD and ET-GBD. All 3 observational studies were single-center studies and had Qumseya scores of ≥7. In total, across all 3 studies, 148 patients underwent EUS-GBD, and 163 patients underwent PT-GBD. Considering our analysis of all outcomes, the overall quality of evidence was found to be low.

Outcomes. A summary of outcomes and their assessments can be seen in Table 11.

Mortality. One observational study that was included reported the outcome of 30-day mortality.[69] One death occurred in the EUS-GBD group in a patient with terminal malignancy who presented with suspected gallbladder perforation on cross-sectional imaging after LAMS deployment. The authors' analysis demonstrated no significant difference in 30-day mortality for patients undergoing EUS-BD compared with those undergoing ET-GBD (OR, .34; 95% CI, .09-1.19).

Technical success and clinical success. All 3 studies assessed technical success and clinical success. When comparing EUS-GBD and ET-GBD, EUS-GBD had significantly higher odds of achieving technical success (OR, 11.26; 95% CI, 2.99-42.48; I^2 = 0%) (Fig. 41)[69-71] and clinical success (OR, 8.20; 95% CI, 2.75-24.49; I^2 = 0%) (Fig. 42) relative to ET-GBD.[69-71]

TABLE 11. Evidence profiles for Question 5a: In nonsurgical patients with acute cholecystitis, how does EUS-GBD compare with ET-GBD in resolving acute cholecystitis?
Author(s):
Question: EUS-GBD compared with ET-GBD for acute cholecystitis for nonsurgical candidates
Setting:
Bibliography:

Certainty assessment						
No. of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**
Mortality						
1	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Technical success (ie, successful placement of the stent across the stomach or duodenum into the gallbladder [EUS –GBD] or through the cystic duct [ET-GBD])						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious*	None
Clinical success (ie, resolution of clinical symptoms with normalization of laboratory tests)						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Not serious	None
Adverse events						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Serious†	None
Pancreatitis						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Serious†	None
Recurrent cholecystitis						
3	Nonrandomized studies	Not serious	Not serious	Not serious	Serious†	None
Need for reintervention						
2	Nonrandomized studies	Not serious	Not serious	Not serious	Serious†	None
Future need for cholecystectomy						
2	Nonrandomized studies	Not serious	Serious‡	Not serious	Serious†	None

EUS-GBD, EUS-guided gallbladder drainage; *ET-GBD,* endoscopic transpapillary transcystic gallbladder drainage; *CI,* confidence interval; *OR,* odds ratio.
*Wide CI.
†Low number of events.
‡High I^2.

Adverse events. Procedure-related AEs were described in all 3 observational studies. When comparing EUS-GBD and ET-GBD, the OR of a procedure-related AE was similar (OR, .87; 95% CI, .26-2.86; I^2 = 47%) (Fig. 43).[69-71] When comparing EUS-GBD and ET-GBD, postprocedure pancreatitis was more common in the ET-GBD group compared with the EUS-GBD group (OR, .11; 95% CI, .01-.91; I^2 = 0%) (Fig. 44).[69-71]

Recurrent cholecystitis. From the 3 observational studies, the odds for recurrent cholecystitis in EUS-GBD were lower than ET-GBD (OR, .23; 95% CI, .08-.66; I^2 = 0%) (Fig. 45).[69-71]

Need for repeat intervention. From the 2 observational studies comparing EUS-GBD and ET-GBD, there was no difference in the OR for repeat intervention (OR, .51; 95% CI, .15 -1.80; I^2 = 52%) (Fig. 46).[69,71]

Future need for cholecystectomy. From the 2 observational studies comparing EUS-GBD and ET-GBD, there was no difference in the OR for future need for cholecystectomy (OR, .19; 95% CI, .01-3.41; I^2 = 77%) (Fig. 47).[69,71]

Certainty in the evidence. While assessing the certainty of evidence, we rated down evidence for lack of prospective studies and imprecision because of the small number of studies and patients and overall judged the quality of evidence to be low in assessing technical success and clinical success and mortality. We judged the quality of evidence to be very low in assessing AEs, recurrent cholecystitis, need for reintervention, and future need for cholecystectomy.

Other considerations. No studies were identified that evaluated costs or cost-effectiveness. For patient values, we found no studies that reported on this outcome. The patient representative strongly favored internal drainage and

TABLE 11. Continued

No. of patients		Effect			
EUS-GBD	ET-GBD	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
1/39 (2.6%)	0/32 (.0%)	OR 2.530 (.099-64.360)	0 fewer per 1000 (from 0 fewer to 0 fewer)	⨁⨁◯◯ Low	CRITICAL
146/148 (98.6%)	136/163 (83.4%)	OR 11.26 (2.99-42.48)	148 more per 1000 (from 103 more to 161 more)	⨁⨁◯◯ Low	CRITICAL
144/148 (97.3%)	131/163 (80.4%)	OR 8.20 (2.75-24.49)	167 more per 1000 (from 115 more to 186 more)	⨁⨁◯◯ Low	CRITICAL
14/148 (9.5%)	17/163 (10.4%)	OR .87 (.26-2.86)	12 fewer per 1000 (from 75 fewer to 146 more)	⨁◯◯◯ Very low	CRITICAL
0/148 (.0%)	10/163 (6.1%)	OR .11 (.01-.91)	54 fewer per 1000 (from 61 fewer to 5 fewer)	⨁◯◯◯ Very low	CRITICAL
4/148 (2.7%)	20/163 (12.3u%)	OR .23 (.08-.66)	92 fewer per 1000 (from 112 fewer to 38 fewer)	⨁◯◯◯ Very low	CRITICAL
10/123 (8.1%)	19/134 (14.2%)	OR .51 (.15-1.80)	64 fewer per 1000 (from 118 fewer to 87 more)	⨁◯◯◯ Very low	CRITICAL
3/123 (2.4%)	17/134 (12.7%)	OR .19 (.01-3.41)	100 fewer per 1000 (from 125 fewer to 204 more)	⨁◯◯◯ Very low	CRITICAL

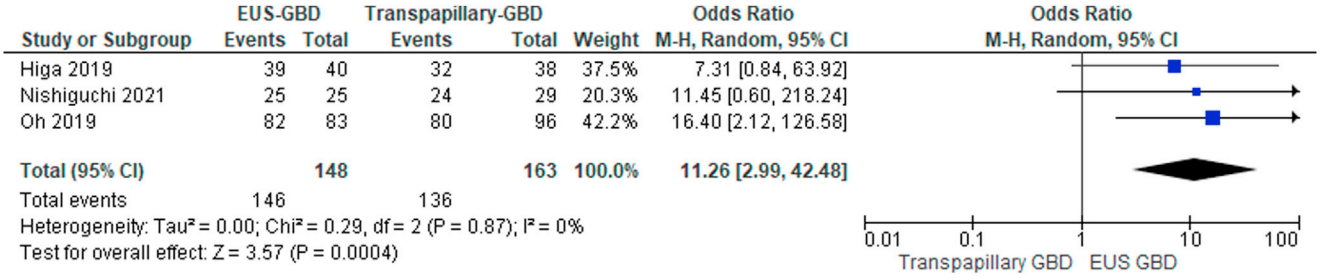


Figure 41. Forest plot of studies evaluating technical success of EUS-GBD compared with endoscopic transpapillary transcystic GBD showed higher technical success with EUS-GBD . *EUS-GBD,* EUS-guided gallbladder drainage; *CI*, confidence interval.

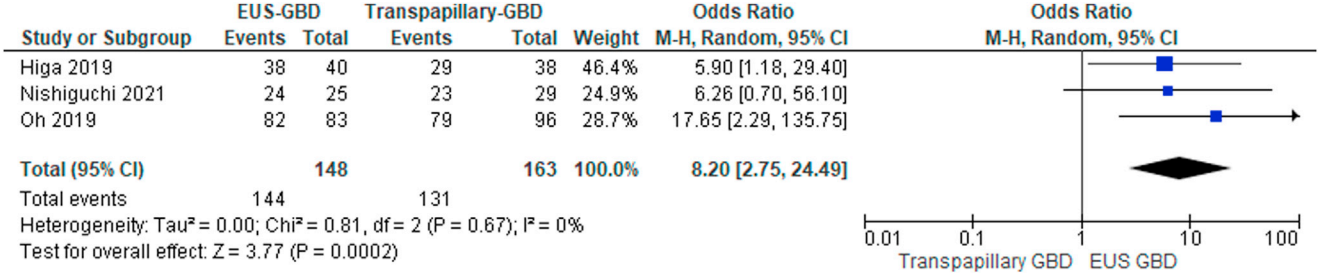


Figure 42. Forest plot of studies evaluating clinical success of EUS-GBD compared with endoscopic transpapillary transcystic GBD showed higher clinical success with EUS-GBD *EUS-GBD,* EUS-guided gallbladder drainage; *CI*, confidence interval.

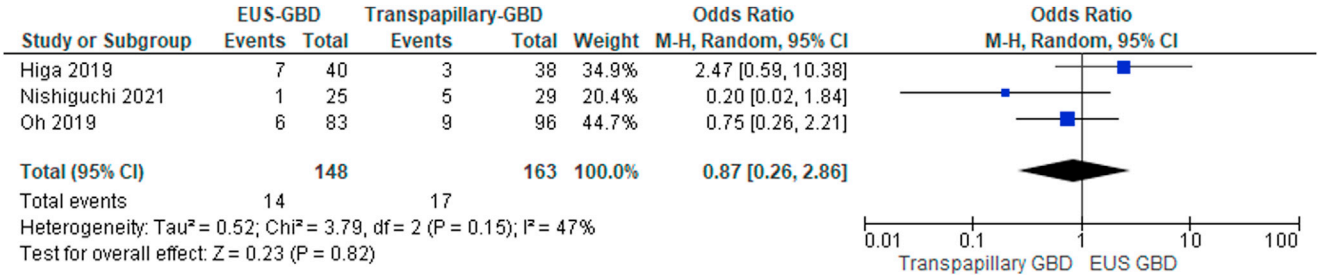


Figure 43. Forest plot of studies evaluating adverse events for EUS-GBD compared with endoscopic transpapillary transcystic GBD showed no difference. *EUS-GBD,* EUS-guided gallbladder drainage; *CI*, confidence interval.

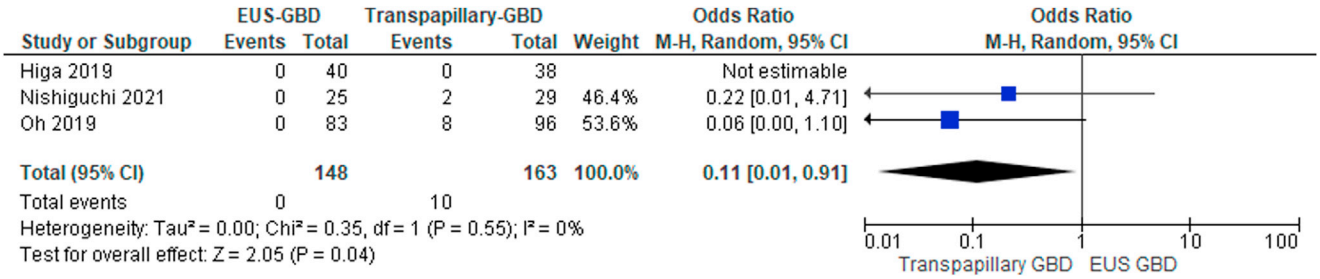


Figure 44. Forest plot of studies evaluating pancreatitis for EUS-GBD compared with endoscopic transpapillary transcystic GBD showed higher rates of pancreatitis in the endoscopic transpapillary transcystic GBD group. *EUS-GBD,* EUS-guided gallbladder drainage; *CI*, confidence interval.

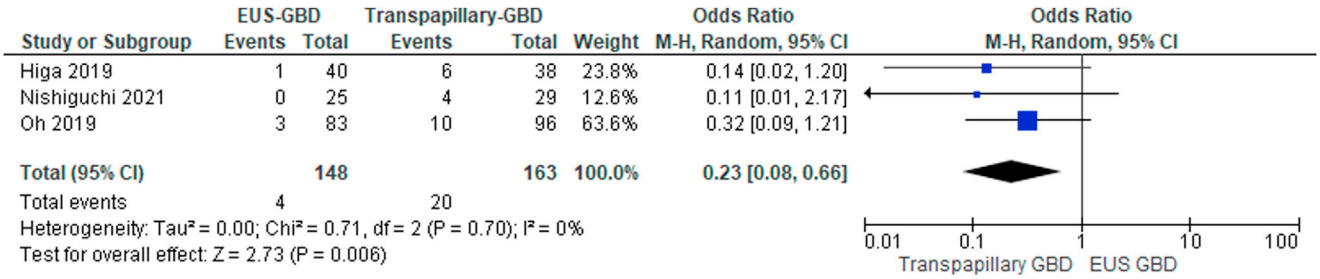


Figure 45. Forest plot of studies evaluating recurrent cholecystitis for EUS-GBD compared with endoscopic transpapillary transcystic GBD showed lower rates of recurrent cholecystitis in EUS-GBD. *EUS-GBD,* EUS-guided gallbladder drainage; *CI*, confidence interval.

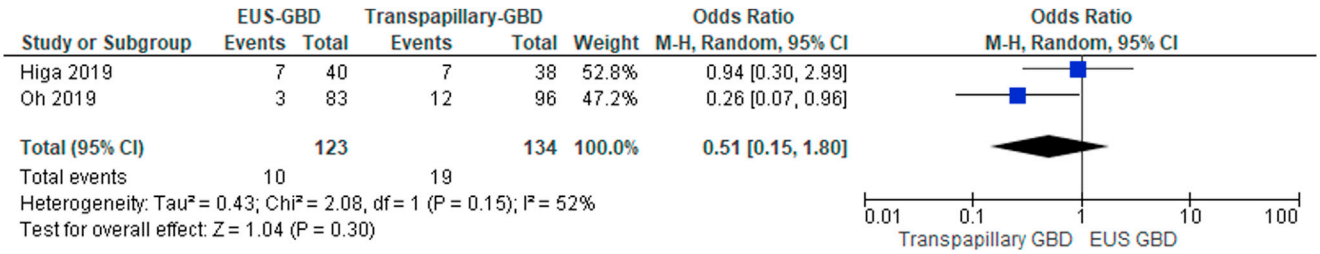


Figure 46. Forest plot of studies evaluating the need for reintervention for EUS-GBD compared with endoscopic transpapillary transcystic GBD showed no difference. *EUS-GBD,* EUS-guided gallbladder drainage; *CI*, confidence interval.

insisted that decisions between EUS-GBD and ET-GBD be made after multidisciplinary discussions were held between all specialties involved (including gastroenterology, radiology, and surgery). For equity, the panel noted throughout our discussion that both ET-GBD and EUS-GBD are technically difficult and may not be available in all practices.

Panel discussion. The panel's discussion focused on technical challenges associated with EUS-GBD and ET-GBD and whether most practices could offer such techniques. The panel noted that ET-GBD can easily be performed during an ERCP but is associated with lower technical and clinical success than EUS-GBD. It was

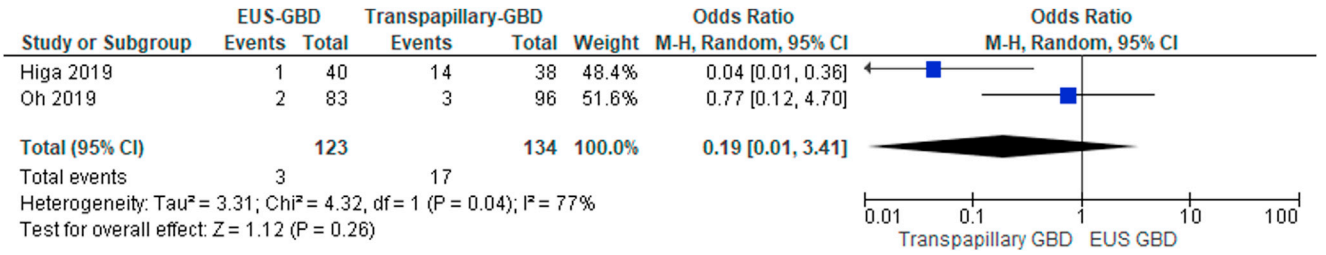


Figure 47. Forest plot of studies evaluating the need for cholecystectomy for EUS-GBD compared with endoscopic transpapillary transcystic GBD showed no difference. *EUS-GBD,* EUS-guided gallbladder drainage; *CI*, confidence interval.

additionally noted that even though differences in AEs between the 2 groups were not found, ET-GBD puts patients at risk for post-ERCP pancreatitis. The panel agreed that certain clinical conditions may benefit from ET-GBD over EUS-GBD, such as patients with ascites, malignant gallbladder infiltration, severe coagulopathy, or liver transplant candidates. A flowchart diagram designed to help clinicians identify various clinical situations is provided in the "Summary and Recommendations" article. Based on the above, the panel suggested EUS-GBD over ET-GBD based on local expertise and availability.

GUIDELINE UPDATE

ASGE guidelines are reviewed for updates approximately every 5 years or if new data may influence a recommendation. Updates follow the same ASGE guideline development process.

DISCLOSURE

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Abbreviations: AE, adverse event; ASGE, American Society for Gastrointestinal Endoscopy; CI, confidence interval; E-ERCP, enteroscopy-assisted ERCP; EDGE, EUS-guided transgastric ERCP; ET-GBD, endoscopic transpapillary transcystic gallbladder drainage; EUS-BD, EUS-guided biliary drainage; EUS-CDS, EUS-guided choledoduodenostomy; EUS-GBD, EUS-guided gallbladder drainage; EUS-HGS, EUS-guided hepaticogastrostomy; LA-ERCP, laparoscopic-assisted ERCP; LAMS, lumen-apposing metal stent; OR, odds ratio; PT-GBD, percutaneous transhepatic gallbladder drainage; PTBD, percutaneous transhepatic biliary drainage; RCT, randomized controlled trial.

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APPENDIX 1: SEARCH PERFORMED FOR PICO 1

Database: Ovid MEDLINE ALL

Date run: February 18, 2022

Limits: English language; human design; randomized controlled trials, systematic reviews/meta-analyses, and cohort/observational studies

Results: 487

1 exp Bile Ducts/ 48887

2 exp Bile Duct Neoplasms/ or Biliary Tract Neoplasms/ 23270

3 (bile duct* or biliary or hilar or peri?hilar or klatskin).ti,ab,kf,kw. 133790

4 or/1-3 154096

5 exp Constriction, Pathologic/ 32513

6 (constriction or stricture* or stenos?s or obstruction or occlusion or blockage).ti,ab,kf,kw. 534208

7 5 or 6 542020

8 4 and 7 21774

9 exp Cholestasis/ 35139

10 cholestasis.ti,ab,kf,kw. 16339

11 ((Bile duct* or biliary or hilar or peri?hilar or klatskin) adj2 (carcinoma* or adenoma* or adenocarcinoma* or neoplasm* or tumor* or tumour* or cholangiocarcinoma* or malignan* or stricture* or obstruction or occlusion or stenos?s or blockage)).ti,ab,kf,kw. 19718

12 or/8-11 62708

13 ERCP.mp. or exp endoscopic retrograde cholangiopancreatography/ 21864

14 (endoscop* adj2 retrograd* adj2 (cholangiopancreatograph* or cholangio-pancreatograph*)).mp. 21992

15 exp Sphincterotomy, Endoscopic/ 3539

16 ((endoscop* adj3 sphincterotom*) or EST).tw,kw. 24738

17 papillotom*.tw,kw. or exp papillotomy/ 4498

18 rendezvous.tw,kw. 838

19 (((selective or difficult) adj2 biliary adj2 cannula*) or ((selective or difficult) adj2 biliary adj2 catheter*) or ((selective cannulation or difficult cannulation) adj3 (biliary or bile))).tw,kf. or (exp catheterization/ and (selective or difficult).ti,ab,kw,kf.) 7811

20 or/13-19 56157

21 Endoscopy, Digestive System/ or Endoscopy, Gastrointestinal/ or exp Endosonography/ or exp Ultrasonography, Interventional/ 69150

22 (EUS or EUS-guided or EUSRV or EUS-RV or EUSCDS or EUS-CDS or EUSHGS or EUS-HGS or (endoscop* adj2 ultraso*) or endosonograph*).ti,ab,kf,kw. 20602

23 21 or 22 79424

24 exp Drainage/ or exp Suction/ or (drain* or suction* or decompress* or dilat*).tw,kf. 386698

25 23 and 24 7526

26 Percutaneous.tw,kf. 158869

27 exp Drainage/ or exp Suction/ or exp Biliary Tract Surgical Procedures/ or exp Surgery, Computer-Assisted/ or (drain* or suction* or decompress* or dilat*).tw,kf. 452857

28 26 and 27 24836

29 12 and 20 7242

30 25 or 28 30767

31 29 and 30 1316

32 exp animals/ not humans.sh. 4960362

33 31 not 32 1314

34 limit 33 to english language 1170

35 exp "sensitivity and specificity"/ 630832

36 false negative reactions/ or false positive reactions/ 39874

37 (sensitivity or specificity).ti,ab. 1144285

38 (predictive adj value$1).ti,ab. 122636

39 (likelihood adj ratio$1).ti,ab. 17677

40 (false adj (negative$1 or positive$1)).ti,ab. 83851

41 (randomized controlled trial or controlled clinical trial).pt. 648768

42 double blind method/ or single blind method/ 200699

43 practice guideline.pt. 29631

44 consensus development conference.pt. 12266

45 random$.ti,ab. 1292267

46 random allocation/ 106612

47 (single blind$3 or double blind$3 or triple blind$3).ti,ab. 182204

48 (review or review academic).pt. 2939869

49 (meta analysis or systematic review).pt. or (systematic review or meta-analys* or "meta analys*").ti. 319646

50 (systematic adj review$).ti,ab. or (systematic* adj3 search*).ab. or (meta adj analy*).ti,ab. 362707

51 or/35-48 5856028

52 (51 and (49 or 50)) or 49 363417

53 Randomized controlled trials as Topic/ 152808

54 Randomized controlled trial/ 558939

55 Random allocation/ 106612

56 Double blind method/ 170096

57 Single blind method/ 31605

58 Clinical trial/ 533881

59 exp Clinical Trials as Topic/ 370519

60 or/53-59 1265993

61 (clinic$ adj trial$1).tw. 425735

62 ((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw. 186312

63 Placebos/ 35886

64 Placebo$.tw. 232990

65 Randomly allocated.tw. 32914

66 (allocated adj2 random).tw. 808

67 or/61-66 712545

68 60 or 67 1582631

69 Case report.tw. 355292

70 Letter/ 1170519

71 Historical article/ 367682

72 Review of reported cases.pt. 0

73 Review, multicase.pt. 0

74 or/69-73 1875942

75 68 not 74 1545109

76 Epidemiologic studies/ 9002

77 exp case control studies/ 1285757
78 exp cohort studies/ 2297885
79 Case control.tw. 140857
80 (cohort adj (study or studies)).tw. 262762
81 Cohort analy$.tw. 9987
82 (Follow up adj (study or studies)).tw. 52968
83 (observational adj (study or studies)).tw. 135236
84 Longitudinal.tw. 285439
85 Retrospective.tw. 643102
86 Cross sectional.tw. 435513
87 Cross-sectional studies/ 411707
88 or/76-87 3454203
89 52 or 75 or 88 4873232
90 34 and 89 487

Database: Embase.com (Elsevier)

Date run: February 18, 2022

Limits: English language; human design; randomized controlled trials, systematic reviews/meta-analyses, and cohort/observational studies; excluded conference abstracts, letters to the editor, editorials, case reports, notes, and other nonresearch papers

Results: 641

1 'bile duct'/exp

2 'bile duct tumor'/exp OR 'biliary tract tumor'/de

3 (bile duct* OR biliary OR hilar OR peri?hilar OR klatskin):ti,ab,kw

4 #1 OR #2 OR #3

5 'stenosis, occlusion and obstruction'/exp

6 (constriction OR stricture* OR stenos?s OR obstruction OR occlusion OR blockage):ti,ab,kw

7 #5 OR #6

8 #4 AND #7

9 'cholestasis'/exp

10 cholestasis:ti,ab,kw

11 (("Bile duct*" OR biliary OR hilar OR "peri?hilar" OR klatskin) NEAR/2 (carcinoma* OR adenoma* OR adenocarcinoma* OR neoplasm* OR tumor* OR tumour* OR cholangiocarcinoma* OR malignan* OR stricture* OR obstruction OR occlusion OR "stenos?s" OR blockage)):ti,ab,kw

12 #8 OR #9 OR #10 OR #11

13 ERCP:ti,ab,kw OR 'endoscopic retrograde cholangiopancreatography'/exp

14 (endoscop* NEAR/2 retrograd* NEAR/2 (cholangiopancreatograph* OR cholangio-pancreatograph*)):ti,ab,kw

15 'endoscopic sphincterotomy'/exp

16 ((endoscop* NEAR/3 sphincterotom*) OR EST):ti,ab,kw

17 papillotom*:ti,ab,kw OR 'endoscopic papillotomy'/exp

18 rendezvous:ti,ab,kw

19 (((selective OR difficult) NEAR/2 biliary NEAR/2 cannula*) OR ((selective OR difficult) NEAR/2 biliary NEAR/2 catheter*) OR (("selective cannulation" OR "difficult cannulation") NEAR/3 (biliary OR bile))):ti,ab,kw OR ('catheterization'/exp AND (selective OR difficult):ti,ab,kw)

20 #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19

21 'digestive tract endoscopy'/de OR 'gastrointestinal endoscopy'/de OR 'endoscopic ultrasonography'/exp OR 'interventional ultrasonography'/exp

22 (EUS OR EUS-guided OR EUSRV OR EUS-RV OR EUSCDS OR EUS-CDS OR EUSHGS OR EUS-HGS OR (endoscop* NEAR/2 ultraso*) OR endosonograph*):ti,ab,kw

23 #21 OR #22

24 'biliary tract drainage'/de OR 'drainage'/de OR 'suction'/de OR (drain* OR suction* OR decompress* OR dilat*):ti,ab,kw

25 #23 AND #24

26 (Percutaneous or surgical or surger*):ti,ab,kw

27 'surgical drainage'/de OR 'biliary tract drainage'/exp OR 'drainage'/de OR 'percutaneous drainage'/exp OR 'suction'/de OR 'biliary tract surgery'/exp OR 'computer assisted surgery'/exp OR (drain* OR suction* OR decompress* OR dilat*):ti,ab,kw

28 #26 AND #27

29 #12 AND #20

30 #25 OR #28

31 #29 AND #30

32 ('Clinical trial'/de OR 'Randomized controlled trial'/de OR 'Randomization'/de OR 'Single blind procedure'/de OR 'Double blind procedure'/de OR 'Crossover procedure'/de OR 'Placebo'/de OR Randomi?ed controlled trial*:ti,ab,kw OR Rct:ti,ab,kw OR Random allocation:ti,ab,kw OR Randomly allocated:ti,ab,kw OR Allocated randomly:ti,ab,kw OR (allocated NEAR/2 random):ti,ab,kw OR Single blind*:ti,ab,kw OR Double blind*:ti,ab,kw OR ((treble OR triple) NEAR (blind*)):ti,ab,kw OR Placebo*:ti,ab,kw OR 'Prospective study'/de) NOT ('Case study'/de OR Case report:ti,ab,kw OR 'Abstract report'/de OR 'letter'/de) OR 'Clinical study'/de OR 'Case control study'/de OR 'Family study'/de OR 'Longitudinal study'/de OR 'Retrospective study'/de OR ('Prospective study'/de NOT 'Randomized controlled trials'/de) OR 'Cohort analysis'/de OR (Cohort NEAR/1 (study OR studies)):ti,ab,kw OR ("Case control" NEAR/1 (study OR studies)):ti,ab,kw OR ("follow up" NEAR/1 (study OR studies)):ti,ab,kw OR (observational NEAR/1 (study OR studies)):ti,ab,kw OR (epidemiologic* NEAR/1 (study OR studies)):ti,ab,kw OR ("cross sectional" NEAR/1 (study OR studies)):ti,ab,kw OR ('Meta Analysis'/exp OR ((meta NEAR/1 analy*) OR metaanalys*):ti,ab,kw OR (systematic NEAR/1 (review*1 OR overview*1)):ti,ab,kw OR cancerlit:ab OR Cochrane:ab OR Embase:ab OR (psychlit OR psyclit):ab OR (psychinfo OR psycinfo):ab OR (cinahl OR cinhal):ab OR science citation index:ab OR bids:ab OR reference lists:ab OR bibliograph*:ab OR handsearch*:ab OR manual search*:ab OR relevant journals:ab OR ((data extraction:ab OR selection criteria:ab) AND review:it) OR 'sensitivity AND specificity'/exp OR (sensitivity OR specificity OR ((pre-test OR pretest) NEAR/1 probability) OR post-test probability OR predictive value* OR likelihood ratio*):ti,ab,kw OR 'Diagnostic Accuracy'/de/mj)

NOT (letter:it OR editorial:it OR ('animal'/de NOT ('animal'/de AND 'human'/de)))

33 #31 AND #32

34 ([conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [data papers]/lim OR [editorial]/lim OR [erratum]/lim OR [letter]/lim OR [note]/lim OR [review]/lim OR [short survey]/lim OR 'case report'/de OR 'review'/de) OR ((rat:ti,tt OR rats:ti,tt OR mouse:ti,tt OR mice:ti,tt OR swine:ti,tt OR porcine:ti,tt OR murine:ti,tt OR sheep:ti,tt OR lambs:ti,tt OR pigs:ti,tt OR piglets:ti,tt OR rabbit:ti,tt OR rabbits:ti,tt OR cat:ti,tt OR cats:ti,tt OR dog:ti,tt OR dogs:ti,tt OR cattle:ti,tt OR bovine:ti,tt OR monkey:ti,tt OR monkeys:ti,tt OR trout:ti,tt OR marmoset*:ti,tt) AND 'animal experiment'/de) OR ('animal experiment'/de NOT ('human experiment'/de OR 'human'/de))

35 #33 NOT #34

36 #35 AND English:LA

Database: Cochrane Library (Wiley)

Date run: February 18, 2022

Limits: N/A

Results: 34

1 [mh "Bile Ducts"]

2 [mh "Bile Duct Neoplasms"] OR [mh "Biliary Tract Neoplasms"]

3 (bile duct* OR biliary OR hilar OR peri?hilar OR klatskin):ti,ab,kw

4 #1 OR #2 OR #3

5 [mh "Constriction, Pathologic"]

6 (constriction OR stricture* OR stenos?s OR obstruction OR occlusion OR blockage):ti,ab,kw

7 #5 OR #6

8 #4 AND #7

9 [mh Cholestasis]

10 cholestasis:ti,ab,kw

11 ((Bile duct* OR biliary OR hilar OR peri?hilar OR klatskin) NEAR/2 (stricture* OR obstruction OR occlusion OR stenos?s OR blockage)):ti,ab,kw

12 #8 OR #9 OR #10 OR #11

13 ERCP:ti,ab,kw OR [mh "endoscopic retrograde cholangiopancreatography"]

14 (endoscop* NEAR/2 retrograd* NEAR/2 (cholangiopancreatograph* OR cholangio-pancreatograph*)):ti,ab,kw

15 [mh "Sphincterotomy, Endoscopic"]

16 ((endoscop* NEAR/3 sphincterotom*) OR EST):ti,ab,kw

17 papillotom*:ti,ab,kw OR [mh papillotomy]

18 rendezvous:ti,ab,kw

19 (((selective OR difficult) NEAR/2 biliary NEAR/2 cannula*) OR ((selective OR difficult) NEAR/2 biliary NEAR/2 catheter*) OR ((selective cannulation OR difficult cannulation) NEAR/3 (biliary OR bile))):ti,ab,kw OR ([mh catheterization] AND (selective OR difficult):ti,ab,kw)

20 #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19

21 [mh "Digestive System Neoplasms"] OR (carcinoma* OR adenoma* OR adenocarcinoma* OR neoplas* OR tumor* OR tumour* OR cholangiocarcinoma* OR malignan* OR cancer*):ti,ab,kw

22 #20 AND #21

23 [mh "Endoscopy, Digestive System"] OR [mh "Endoscopy, Gastrointestinal"] OR [mh Endosonography] OR [mh "Ultrasonography, Interventional"]

24 (EUSCDS OR EUS-CDS OR EUSHGS OR EUS-HGS OR (endoscop* NEAR/2 ultraso*) OR EUS OR EUS-guided OR endosonograph*):ti,ab,kw

25 [mh Drainage] OR [mh Suction] OR (drain* OR suction* OR decompress* OR dilat*):ti,ab,kw

26 [mh Stents] OR [mh Catheters] OR [mh Catheterization]

27 (stent* OR catheter* OR cannula* OR tube* OR pipe* OR "SEMS" OR SEM OR SEMTs OR SEM OR SEMs OR FCSEMS):ti,ab,kw

28 #23 OR #24 OR #25 OR #26 OR #27

29 [mh Choledochostomy] OR [mh Gastrostomy] OR (choledochoduodenostom* OR choledochostom* OR hepaticogastrostom* OR gastrostomy*):ti,ab,kw

30 #28 AND #29

31 #12 AND #22 AND #30

APPENDIX 2: SEARCH PERFORMED FOR PICO 2

Database: Ovid MEDLINE ALL

Date run: February 18, 2022

Limits: English language; human design; randomized controlled trials, systematic reviews/meta-analyses, and cohort/observational studies

Results: 79

1 exp Bile Ducts/ 48887

2 exp Bile Duct Neoplasms/ or Biliary Tract Neoplasms/ 23270

3 (bile duct* or biliary or hilar or peri?hilar or klatskin).ti,ab,kf,kw. 133790

4 or/1-3 154096

5 exp Constriction, Pathologic/ 32513

6 (constriction or stricture* or stenos?s or obstruction or occlusion or blockage).ti,ab,kf,kw. 534208

7 5 or 6 542020

8 4 and 7 21774

9 exp Cholestasis/ 35139

10 cholestasis.ti,ab,kf,kw. 16339

11 ((Bile duct* or biliary or hilar or peri?hilar or klatskin) adj2 (stricture* or obstruction or occlusion or stenos?s or blockage)).ti,ab,kf,kw. 12234

12 or/8-11 55950

13 ERCP.mp. or exp endoscopic retrograde cholangiopancreatography/ 21864

14 (endoscop* adj2 retrograd* adj2 (cholangiopancreatograph* or cholangio-pancreatograph*)).mp. 21992
15 exp Sphincterotomy, Endoscopic/ 3539
16 ((endoscop* adj3 sphincterotom*) or EST).tw,kw. 24738
17 papillotom*.tw,kw. or exp papillotomy/ 4498
18 rendezvous.tw,kw. 838
19 (((selective or difficult) adj2 biliary adj2 cannula*) or ((selective or difficult) adj2 biliary adj2 catheter*) or ((selective cannulation or difficult cannulation) adj3 (biliary or bile))).tw,kf. or (exp catheterization/ and (selective or difficult).ti,ab,kw,kf.) 7811
20 or/13-19 56157
21 exp Digestive System Neoplasms/ or (carcinoma* or adenoma* or adenocarcinoma* or neoplas* or tumor* or tumour* or cholangiocarcinoma* or malignan* or cancer*).tw,kf. 3846298
22 20 and 21 10015
23 Endoscopy, Digestive System/ or Endoscopy, Gastrointestinal/ or exp Endosonography/ or exp Ultrasonography, Interventional/ 69150
24 (EUSCDS or EUS-CDS or EUSHGS or EUS-HGS or (endoscop* adj2 ultraso*) or EUS or EUS-guided or endosonograph*).tw,kf. 20497
25 exp Drainage/ or exp Suction/ or (drain* or suction* or decompress* or dilat*).tw,kf. 386698
26 exp Stents/ or exp Catheters/ or exp Catheterization/ 280344
27 (stent* or catheter* or cannula* or tube* or pipe* or "SEMS" or SEM or SEMTs or SEM or SEMs or FCSEMS).tw,kf. 1060075
28 or/23-27 1549638
29 exp Choledochostomy/ or exp Gastrostomy/ or (choledochoduodenostom* or choledochostom* or hepaticogastrostom* or gastrostomy*).ti,ab,kf,kw. 15342
30 28 and 29 8977
31 12 and 22 and 30 168
32 exp animals/ not humans.sh. 4960362
33 31 not 32 168
34 limit 33 to english language 162
35 exp "sensitivity and specificity"/ 630832
36 false negative reactions/ or false positive reactions/ 39874
37 (sensitivity or specificity).ti,ab. 1144285
38 (predictive adj value$1).ti,ab. 122636
39 (likelihood adj ratio$1).ti,ab. 17677
40 (false adj (negative$1 or positive$1)).ti,ab. 83851
41 (randomized controlled trial or controlled clinical trial).pt. 648768
42 double blind method/ or single blind method/ 200699
43 practice guideline.pt. 29631
44 consensus development conference.pt. 12266
45 random$.ti,ab. 1292267
46 random allocation/ 106612
47 (single blind$3 or double blind$3 or triple blind$3).ti,ab. 182204
48 (review or review academic).pt. 2939869
49 (meta analysis or systematic review).pt. or (systematic review or meta-analys* or "meta analys*").ti. 319646
50 (systematic adj review$).ti,ab. or (systematic* adj3 search*).ab. or (meta adj analy*).ti,ab. 362707
51 or/35-48 5856028
52 (51 and (49 or 50)) or 49 363417
53 Randomized controlled trials as Topic/ 152808
54 Randomized controlled trial/ 558939
55 Random allocation/ 106612
56 Double blind method/ 170096
57 Single blind method/ 31605
58 Clinical trial/ 533881
59 exp Clinical Trials as Topic/ 370519
60 or/53-59 1265993
61 (clinic$ adj trial$1).tw. 425735
62 ((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw. 186312
63 Placebos/ 35886
64 Placebo$.tw. 232990
65 Randomly allocated.tw. 32914
66 (allocated adj2 random).tw. 808
67 or/61-66 712545
68 60 or 67 1582631
69 Case report.tw. 355292
70 Letter/ 1170519
71 Historical article/ 367682
72 Review of reported cases.pt. 0
73 Review, multicase.pt. 0
74 or/69-73 1875942
75 68 not 74 1545109
76 Epidemiologic studies/ 9002
77 exp case control studies/ 1285757
78 exp cohort studies/ 2297885
79 Case control.tw. 140857
80 (cohort adj (study or studies)).tw. 262762
81 Cohort analy$.tw. 9987
82 (Follow up adj (study or studies)).tw. 52968
83 (observational adj (study or studies)).tw. 135236
84 Longitudinal.tw. 285439
85 Retrospective.tw. 643102
86 Cross sectional.tw. 435513
87 Cross-sectional studies/ 411707
88 or/76-87 3454203
89 52 or 75 or 88 4873232
90 34 and 89 79

Database: Embase.com (Elsevier)

Date run: February 18, 2022

Limits: English language; human design; randomized controlled trials, systematic reviews/meta-analyses, and cohort/observational studies; excluded conference abstracts, letters to the editor, editorials, case reports, notes, and other nonresearch papers

Results: 138

1 'bile duct'/exp

2 'bile duct tumor'/exp OR 'biliary tract tumor'/de

3 (bile duct* OR biliary OR hilar OR peri?hilar OR klatskin):ti,ab,kw

4 #1 OR #2 OR #3

5 'stenosis, occlusion AND obstruction'/exp

6 (constriction OR stricture* OR stenos?s OR obstruction OR occlusion OR blockage):ti,ab,kw

7 #5 OR #6

8 #4 AND #7

9 'cholestasis'/exp

10 cholestasis:ti,ab,kw

11 (("Bile duct*" OR biliary OR hilar OR "peri?hilar" OR klatskin) NEAR/2 (carcinoma* OR adenoma* OR adenocarcinoma* OR neoplasm* OR tumor* OR tumour* OR cholangiocarcinoma* OR malignan* OR stricture* OR obstruction OR occlusion OR "stenos?s" OR blockage)):ti,ab,kw

12 #8 OR #9 OR #10 OR #11

13 ERCP:ti,ab,kw OR 'endoscopic retrograde cholangiopancreatography'/exp

14 (endoscop* NEAR/2 retrograd* NEAR/2 (cholangiopancreatograph* OR cholangio-pancreatograph*)):ti,ab,kw

15 'endoscopic sphincterotomy'/exp

16 ((endoscop* NEAR/3 sphincterotom*) OR EST):ti,ab,kw

17 papillotom*:ti,ab,kw OR 'endoscopic papillotomy'/exp

18 rendezvous:ti,ab,kw

19 (((selective OR difficult) NEAR/2 biliary NEAR/2 cannula*) OR ((selective OR difficult) NEAR/2 biliary NEAR/2 catheter*) OR (("selective cannulation" OR "difficult cannulation") NEAR/3 (biliary OR bile))):ti,ab,kw OR ('catheterization'/exp AND (selective OR difficult):ti,ab,kw)

20 #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19

21 'digestive system tumor'/exp OR (carcinoma* OR adenoma* OR adenocarcinoma* OR neoplas* OR tumor* OR tumour* OR cholangiocarcinoma* OR malignan* OR cancer*):ti,ab,kw

22 #20 AND #21

23 'digestive tract endoscopy'/de OR 'gastrointestinal endoscopy'/de OR 'endoscopic ultrasonography'/exp OR 'interventional ultrasonography'/exp

24 (EUSCDS OR EUS-CDS OR EUSHGS OR EUS-HGS OR (endoscop* NEAR/2 ultraso*) OR EUS OR EUS-guided OR endosonograph*):ti,ab,kw

25 'biliary tract drainage'/de OR 'drainage'/de OR 'suction'/de OR (drain* OR suction* OR decompress* OR dilat*):ti,ab,kw

26 'stent'/exp OR 'catheter'/exp OR 'catheterization'/exp

27 (stent* OR catheter* OR cannula* OR tube* OR pipe* OR "SEMS" OR SEM OR SEMTs OR SEM OR SEMs OR FCSEMS):ti,ab,kw

28 #23 OR #24 OR #25 OR #26 OR #27

29 'bile duct bypass'/exp OR 'gastrostomy'/exp OR (choledochoduodenostom* OR choledochostom* OR hepaticogastrostom* OR gastrostomy*):ti,ab,kw

30 #28 AND #29

31 #12 AND #22 AND #30

32 ('Clinical trial'/de OR 'Randomized controlled trial'/de OR 'Randomization'/de OR 'Single blind procedure'/de OR 'Double blind procedure'/de OR 'Crossover procedure'/de OR 'Placebo'/de OR Randomi?ed controlled trial*:ti,ab,kw OR Rct:ti,ab,kw OR Random allocation:ti,ab,kw OR Randomly allocated:ti,ab,kw OR Allocated randomly:ti,ab,kw OR (allocated NEAR/2 random):ti,ab,kw OR Single blind*:ti,ab,kw OR Double blind*:ti,ab,kw OR ((treble OR triple) NEAR (blind*)):ti,ab,kw OR Placebo*:ti,ab,kw OR 'Prospective study'/de) NOT ('Case study'/de OR Case report:ti,ab,kw OR 'Abstract report'/de OR 'letter'/de) OR 'Clinical study'/de OR 'Case control study'/de OR 'Family study'/de OR 'Longitudinal study'/de OR 'Retrospective study'/de OR ('Prospective study'/de NOT 'Randomized controlled trials'/de) OR 'Cohort analysis'/de OR (Cohort NEAR/1 (study OR studies)):ti,ab,kw OR ("Case control" NEAR/1 (study OR studies)):ti,ab,kw OR ("follow up" NEAR/1 (study OR studies)):ti,ab,kw OR (observational NEAR/1 (study OR studies)):ti,ab,kw OR (epidemiologic* NEAR/1 (study OR studies)):ti,ab,kw OR ("cross sectional" NEAR/1 (study OR studies)):ti,ab,kw OR ('Meta Analysis'/exp OR ((meta NEAR/1 analy*) OR metaanalys*):ti,ab,kw OR (systematic NEAR/1 (review*1 OR overview*1)):ti,ab,kw OR cancerlit:ab OR Cochrane:ab OR Embase:ab OR (psychlit OR psyclit):ab OR (psychinfo OR psycinfo):ab OR (cinahl OR cinhal):ab OR science citation index:ab OR bids:ab OR reference lists:ab OR bibliograph*:ab OR handsearch*:ab OR manual search*:ab OR relevant journals:ab OR ((data extraction:ab OR selection criteria:ab) AND review:it) OR 'sensitivity AND specificity'/exp OR (sensitivity OR specificity OR ((pre-test OR pretest) NEAR/1 probability) OR post-test probability OR predictive value* OR likelihood ratio*):ti,ab,kw OR 'Diagnostic Accuracy'/de/mj) NOT (letter:it OR editorial:it OR ('animal'/de NOT ('animal'/de AND 'human'/de)))

33 #31 AND #32

34 ([conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [data papers]/lim OR [editorial]/lim OR [erratum]/lim OR [letter]/lim OR [note]/lim OR [review]/lim OR [short survey]/lim OR 'case report'/de OR 'review'/de) OR ((rat:ti,tt OR rats:ti,tt OR mouse:ti,tt OR mice:ti,tt OR swine:ti,tt OR porcine:ti,tt OR murine:ti,tt OR sheep:ti,tt OR lambs:ti,tt OR pigs:ti,tt OR piglets:ti,tt OR rabbit:ti,tt OR rabbits:ti,tt OR cat:ti,tt OR cats:ti,tt OR dog:ti,tt OR dogs:ti,tt OR cattle:ti,tt OR bovine:ti,tt OR monkey:ti,tt OR monkeys:ti,tt OR trout:ti,tt OR marmoset*:ti,tt) AND 'animal experiment'/de) OR ('animal experiment'/de NOT ('human experiment'/de OR 'human'/de))

35 #33 NOT #34

36 #35 AND English:LA

Database: Cochrane Library (Wiley)

Date run: February 18, 2022

Limits: N/A

Results: 34

1 [mh "Bile Ducts"]

2 [mh "Bile Duct Neoplasms"] OR [mh ^"Biliary Tract Neoplasms"]

3 (bile duct* OR biliary OR hilar OR peri?hilar OR klatskin):ti,ab,kw

4 #1 OR #2 OR #3

5 [mh "Constriction, Pathologic/"]

6 (constriction OR stricture* OR stenos?s OR obstruction OR occlusion OR blockage):ti,ab,kw

7 #5 OR #6

8 #4 AND #7

9 [mh Cholestasis]

10 cholestasis:ti,ab,kw

11 ((Bile duct* OR biliary OR hilar OR peri?hilar OR klatskin) NEAR/2 (stricture* OR obstruction OR occlusion OR stenos?s OR blockage)):ti,ab,kw

12 #8 OR #9 OR #10 OR #11

13 ERCP:ti,ab,kw OR [mh "endoscopic retrograde cholangiopancreatography"]

14 (endoscop* NEAR/2 retrograd* NEAR/2 (cholangiopancreatograph* OR cholangio-pancreatograph*)):ti,ab,kw

15 [mh "Sphincterotomy, Endoscopic"]

16 ((endoscop* NEAR/3 sphincterotom*) OR EST):ti,ab,kw

17 papillotom*:ti,ab,kw OR [mh papillotomy]

18 rendezvous:ti,ab,kw

19 (((selective OR difficult) NEAR/2 biliary NEAR/2 cannula*) OR ((selective OR difficult) NEAR/2 biliary NEAR/2 catheter*) OR ((selective cannulation OR difficult cannulation) NEAR/3 (biliary OR bile))):ti,ab,kw OR ([mh catheterization] AND (selective OR difficult):ti,ab,kw)

20 #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19

21 [mh "Digestive System Neoplasms"] OR (carcinoma* OR adenoma* OR adenocarcinoma* OR neoplas* OR tumor* OR tumour* OR cholangiocarcinoma* OR malignan* OR cancer*):ti,ab,kw

22 #20 AND #21

23 [mh ^"Endoscopy, Digestive System"] OR [mh ^"Endoscopy, Gastrointestinal"] OR [mh Endosonography] OR [mh "Ultrasonography, Interventional"]

24 (EUSCDS OR EUS-CDS OR EUSHGS OR EUS-HGS OR (endoscop* NEAR/2 ultraso*) OR EUS OR EUS-guided OR endosonograph*):ti,ab,kw

25 [mh Drainage] OR [mh Suction] OR (drain* OR suction* OR decompress* OR dilat*):ti,ab,kw

26 [mh Stents] OR [mh Catheters] OR [mh Catheterization]

27 (stent* OR catheter* OR cannula* OR tube* OR pipe* OR "SEMS" OR SEM OR SEMTs OR SEM OR SEMs OR FCSEMS):ti,ab,kw

28 #23 OR #24 OR #25 OR #26 OR #27

29 [mh Choledochostomy] OR [mh Gastrostomy] OR (choledochoduodenostom* OR choledochostom* OR hepaticogastrostom* OR gastrostomy*):ti,ab,kw

30 #28 AND #29

31 #12 AND #22 AND #30

APPENDIX 3: SEARCH PERFORMED FOR PICO 3

Database: Ovid MEDLINE ALL

Date run: February 18, 2022

Limits: English language; human design; randomized controlled trials, systematic reviews/meta-analyses, and cohort/observational studies

Results: 236

1 exp Gastric Bypass/ 11191

2 exp gastroenterostomy/ 14694

3 exp anastomosis, roux-en-y/ 3737

4 (Roux-en-Y or Roux-Y or RYGB or "RY GB").tw,kw. 13341

5 ((Stomach or gastric or gastro*) adj3 bypass).tw,kw. 13525

6 (gastrojejunostom* or gastro-jejunostom* or ((gastro-jejunal or gastro-jejunal or jejunogastric or jejunum-gastric or jejuno-gastric) adj2 (anastom* or fixation* or reconstruct*))).tw,kw. 3352

7 (gastroenterostom* or gastro-enterostom* or gastroduodenostom* or gastro-duodenostom* or ((gastroduoden* or gastro-duoden*) adj2 (anastom* or fixation* or reconstruct*))).tw,kw. 2158

8 Billroth*.tw,kw. 3270

9 or/1-8 28624

10 ERCP.mp. or exp endoscopic retrograde cholangiopancreatography/ or Cholangiography/ 32422

11 (endoscop* adj2 retrograd* adj2 (cholangiopancreatograph* or cholangio-pancreatograph*)).mp. 21992

12 exp Sphincterotomy, Endoscopic/ 3539

13 ((endoscop* adj3 sphincterotom*) or EST).tw,kw. 24738

14 papillotom*.tw,kw. or exp papillotomy/ 4498

15 or/10-14 58467

16 Endoscopy, Digestive System/ or Endoscopy, Gastrointestinal/ or exp Endosonography/ or exp Ultrasonography, Interventional/ 69150

17 (EUSCDS or EUS-CDS or EUSHGS or EUS-HGS or (endoscop* adj2 ultraso*) or EUS or EUS-guided or endosonograph*).tw,kf. 20497

18 or/16-17 79335

19 (EDGE or EDGI or GATE or "gastric access for temporary endoscopy" or transgastr* or trans-gastr* or "trans gastr*" or gastrogastrostom* or gastro-gastrostom*).tw,kw. 112761

20 15 and 18 and 19 147

21 (enteroscop* or balloon* or BE-ERCP).tw,kf. or exp balloon enteroscopy/ 78309

22 (laparoscop* or peritoneoscop* or celioscop* or coelioscop* or LA-ERCP).tw,kf. or exp laparoscopy/ 158635
23 21 or 22 235386
24 15 and 23 5976
25 9 and (20 or 24) 573
26 exp animals/ not humans.sh. 4960362
27 25 not 26 571
28 limit 27 to english language 535
29 exp "sensitivity and specificity"/ 630832
30 false negative reactions/ or false positive reactions/ 39874
31 (sensitivity or specificity).ti,ab. 1144285
32 (predictive adj value$1).ti,ab. 122636
33 (likelihood adj ratio$1).ti,ab. 17677
34 (false adj (negative$1 or positive$1)).ti,ab. 83851
35 (randomized controlled trial or controlled clinical trial).pt. 648768
36 double blind method/ or single blind method/ 200699
37 practice guideline.pt. 29631
38 consensus development conference.pt. 12266
39 random$.ti,ab. 1292267
40 random allocation/ 106612
41 (single blind$3 or double blind$3 or triple blind$3).ti,ab. 182204
42 (review or review academic).pt. 2939869
43 (meta analysis or systematic review).pt. or (systematic review or meta-analys* or "meta analys*").ti. 319646
44 (systematic adj review$).ti,ab. or (systematic* adj3 search*).ab. or (meta adj analy*).ti,ab. 362707
45 or/29-42 5856028
46 (45 and (43 or 44)) or 43 363417
47 Randomized controlled trials as Topic/ 152808
48 Randomized controlled trial/ 558939
49 Random allocation/ 106612
50 Double blind method/ 170096
51 Single blind method/ 31605
52 Clinical trial/ 533881
53 exp Clinical Trials as Topic/ 370519
54 or/47-53 1265993
55 (clinic$ adj trial$1).tw. 425735
56 ((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw. 186312
57 Placebos/ 35886
58 Placebo$.tw. 232990
59 Randomly allocated.tw. 32914
60 (allocated adj2 random).tw. 808
61 or/55-60 712545
62 54 or 61 1582631
63 Case report.tw. 355292
64 Letter/ 1170519
65 Historical article/ 367682
66 Review of reported cases.pt. 0
67 Review, multicase.pt. 0
68 or/63-67 1875942
69 62 not 68 1545109
70 Epidemiologic studies/ 9002
71 exp case control studies/ 1285757
72 exp cohort studies/ 2297885
73 Case control.tw. 140857
74 (cohort adj (study or studies)).tw. 262762
75 Cohort analy$.tw. 9987
76 (Follow up adj (study or studies)).tw. 52968
77 (observational adj (study or studies)).tw. 135236
78 Longitudinal.tw. 285439
79 Retrospective.tw. 643102
80 Cross sectional.tw. 435513
81 Cross-sectional studies/ 411707
82 or/70-81 3454203
83 46 or 69 or 82 4873232
84 28 and 83 236

Database: Embase.com (Elsevier)

Date run: February 18, 2022

Limits: English language; human design; randomized controlled trials, systematic reviews/meta-analyses, and cohort/observational studies; excluded conference abstracts, letters to the editor, editorials, case reports, notes, and other nonresearch papers

Results: 144

1 'gastric bypass surgery'/exp
2 'gastroenterostomy'/exp
3 'Roux Y anastomosis'/exp
4 (Roux-en-Y OR Roux-Y OR RYGB OR "RY GB"):ti,ab,kw
5 ((Stomach OR gastric OR gastro*) NEAR/3 bypass):ti,ab,kw
6 (gastrojejunostom* OR gastro-jejunostom* OR ((gastrojejunal OR gastro-jejunal OR jejunogastric OR jejunum-gastric OR jejuno-gastric) NEAR/2 (anastom* OR fixation* OR reconstruct*))):ti,ab,kw
7 (gastroenterostom* OR gastro-enterostom* OR gastroduodenostom* OR gastro-duodenostom* OR ((gastro-duoden* OR gastro-duoden*) NEAR/2 (anastom* OR fixation* OR reconstruct*))):ti,ab,kw
8 Billroth*:ti,ab,kw
9 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8
10 ERCP:ti,ab,kw OR 'endoscopic retrograde cholangiopancreatography'/exp OR 'cholangiography'/de
11 (endoscop* NEAR/2 retrograd* NEAR/2 (cholangiopancreatograph* OR cholangio-pancreatograph*)):ti,ab,kw
12 'endoscopic sphincterotomy'/exp
13 ((endoscop* NEAR/3 sphincterotom*) OR EST):ti,ab,kw
14 papillotom*:ti,ab,kw OR 'endoscopic papillotomy'/exp
15 #10 OR #11 OR #12 OR #13 OR #14
16 'endoscopic ultrasonography'/exp OR 'digestive tract endoscopy'/de OR 'gastrointestinal endoscopy'/de OR 'interventional ultrasonography'/exp
17 (EUSCDS OR EUS-CDS OR EUSHGS OR EUS-HGS OR (endoscop* NEAR/2 ultraso*) OR EUS OR EUS-guided OR endosonograph*):ti,ab,kw

18 #16 OR #17

19 (EDGE OR EDGI OR GATE OR "gastric access for temporary endoscopy" OR transgastr* OR trans-gastr* OR "trans gastr*" OR gastrogastrostom* OR gastro-gastrostom*):ti,ab,kw

20 #15 AND #18 AND #19

21 (enteroscop* OR balloon* OR BE-ERCP):ti,ab,kw 'balloon enteroscopy'/exp

22 (laparoscop* OR peritoneoscop* OR celioscop* OR coelioscop* OR LA-ERCP):ti,ab,kw OR 'laparoscopy'/exp

23 #21 OR #22

24 #15 AND #23

25 #9 AND (#20 OR #24)

26 ('Clinical trial'/de OR 'Randomized controlled trial'/de OR 'Randomization'/de OR 'Single blind procedure'/de OR 'Double blind procedure'/de OR 'Crossover procedure'/de OR 'Placebo'/de OR Randomi?ed controlled trial*:ti,ab,kw OR Rct:ti,ab,kw OR Random allocation:ti,ab,kw OR Randomly allocated:ti,ab,kw OR Allocated randomly:ti,ab,kw OR (allocated NEAR/2 random):ti,ab,kw OR Single blind*:ti,ab,kw OR Double blind*:ti,ab,kw OR ((treble OR triple) NEAR (blind*)):ti,ab,kw OR Placebo*:ti,ab,kw OR 'Prospective study'/de) NOT ('Case study'/de OR Case report:ti,ab,kw OR 'Abstract report'/de OR 'letter'/de) OR 'Clinical study'/de OR 'Case control study'/de OR 'Family study'/de OR 'Longitudinal study'/de OR 'Retrospective study'/de OR ('Prospective study'/de NOT 'Randomized controlled trials'/de) OR 'Cohort analysis'/de OR (Cohort NEAR/1 (study OR studies)):ti,ab,kw OR ("Case control" NEAR/1 (study OR studies)):ti,ab,kw OR ("follow up" NEAR/1 (study OR studies)):ti,ab,kw OR (observational NEAR/1 (study OR studies)):ti,ab,kw OR (epidemiologic* NEAR/1 (study OR studies)):ti,ab,kw OR ("cross sectional" NEAR/1 (study OR studies)):ti,ab,kw OR ('Meta Analysis'/exp OR ((meta NEAR/1 analy*) OR metaanalys*):ti,ab,kw OR (systematic NEAR/1 (review*1 OR overview*1)):ti,ab,kw OR cancerlit:ab OR Cochrane:ab OR Embase:ab OR (psychlit OR psyclit):ab OR (psychinfo OR psycinfo):ab OR (cinahl OR cinhal):ab OR science citation index:ab OR bids:ab OR reference lists:ab OR bibliograph*:ab OR handsearch*:ab OR manual search*:ab OR relevant journals:ab OR ((data extraction:ab OR selection criteria:ab) AND review:it) OR 'sensitivity AND specificity'/exp OR (sensitivity OR specificity OR ((pre-test OR pretest) NEAR/1 probability) OR post-test probability OR predictive value* OR likelihood ratio*):ti,ab,kw OR 'Diagnostic Accuracy'/de/mj) NOT (letter:it OR editorial:it OR ('animal'/de NOT ('animal'/de AND 'human'/de)))

27 #25 AND #26

28 ([conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [data papers]/lim OR [editorial]/lim OR [erratum]/lim OR [letter]/lim OR [note]/lim OR [review]/lim OR [short survey]/lim OR 'case report'/de OR 'review'/de) OR ((rat:ti,tt OR rats:ti,tt OR mouse:ti,tt OR mice:ti,tt OR swine:ti,tt OR porcine:ti,tt OR murine:ti,tt OR sheep:ti,tt OR lambs:ti,tt OR pigs:ti,tt OR piglets:ti,tt OR rabbit:ti,tt OR rabbits:ti,tt OR cat:ti,tt OR cats:ti,tt OR dog:ti,tt OR dogs:ti,tt OR cattle:ti,tt OR bovine:ti,tt OR monkey:ti,tt OR monkeys:ti,tt OR trout:ti,tt OR marmoset*:ti,tt) AND 'animal experiment'/de) OR ('animal experiment'/de NOT ('human experiment'/de OR 'human'/de))

29 #27 NOT #28

30 #29 AND English:LA

Database: Cochrane Library (Wiley)

Date run: February 18, 2022

Limits: N/A

Results: 19

1 [mh "Gastric Bypass"]

2 [mh gastroenterostomy]

3 [mh "anastomosis, roux-en-y"]

4 (Roux-en-Y OR Roux-Y OR RYGB OR "RY GB"):ti,ab,kw

5 ((Stomach OR gastric OR gastro*) NEAR/3 bypass):ti,ab,kw

6 (gastrojejunostom* OR gastro-jejunostom* OR ((gastrojejunal OR gastro-jejunal OR jejunogastric OR jejunum-gastric OR jejuno-gastric) NEAR/2 (anastom* OR fixation* OR reconstruct*))):ti,ab,kw

7 (gastroenterostom* OR gastro-enterostom* OR gastroduodenostom* OR gastro-duodenostom* OR ((gastro-duoden* OR gastro-duoden*) NEAR/2 (anastom* OR fixation* OR reconstruct*))):ti,ab,kw

8 Billroth*:ti,ab,kw

9 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8

10 ERCP:ti,ab,kw OR [mh "endoscopic retrograde cholangiopancreatography"] OR [mh ^"Cholangiography"]

11 (endoscop* NEAR/2 retrograd* NEAR/2 (cholangio-pancreatograph* OR cholangio-pancreatograph*)):ti,ab,kw

12 [mh "Sphincterotomy, Endoscopic"]

13 ((endoscop* NEAR/3 sphincterotom*) OR EST):ti,ab,kw

14 papillotom*:ti,ab,kw OR [mh papillotomy]

15 #10 OR #11 OR #12 OR #13 OR #14

16 [mh ^"Endoscopy, Digestive System"] OR [mh ^"Endoscopy, Gastrointestinal"] OR [mh Endosonography] OR [mh "Ultrasonography, Interventional"]

17 (EUSCDS OR EUS-CDS OR EUSHGS OR EUS-HGS OR (endoscop* NEAR/2 ultraso*) OR EUS OR EUS-guided OR endosonograph*):ti,ab,kw

18 #16 OR #17

19 (EDGE OR EDGI OR GATE OR "gastric access for temporary endoscopy" OR transgastr* OR trans-gastr* OR "trans gastr*" OR gastrogastrostom* OR gastro-gastrostom*):ti,ab,kw

20 #15 AND #18 AND #19

21 (enteroscop* OR balloon* OR BE-ERCP):ti,ab,kw OR [mh "balloon enteroscopy"]

22 (laparoscop* OR peritoneoscop* OR celioscop* OR coelioscop* OR LA-ERCP):ti,ab,kw OR [mh laparoscopy]

23 #21 OR #22
24 #15 AND #23
25 #9 AND (#20 OR #24)

APPENDIX 4: SEARCH PERFORMED FOR PICO 4

Database: Ovid MEDLINE ALL

Date run: February 18, 2022

Limits: English language; human design; randomized controlled trials, systematic reviews/meta-analyses, and cohort/observational studies

Results: 169

1 (alter* adj3 anatom*).ti,ab,kw,kf. or Reconstructive Surgical Procedures/ 59472
2 exp Jejunostomy/ 2906
3 Biliary Tract Surgical Procedures/ 4263
4 exp anastomosis, roux-en-y/ or anastomosis, surgical/ 37016
5 (Roux-en-Y or Roux-Y or RYGB or "RY GB").tw,kw. 13341
6 (hepaticojejunostom* or hepatico-jejunostom* or ((hepaticojejunal or hepatico-jejunal) adj2 (anastom* or fixation* or reconstruct* or alter*))).tw,kw. 2298
7 exp pancreaticoduodenectomy/ or (pancreaticoduodenectom* or pancreatico-enterostom* or duodenopancreatectom* or duodeno-pancreatectom* or ((pancreaticoduoden* or pancreatico-duoden*) adj2 (anastom* or fixation* or reconstruct* or alter*))).tw,kw. 12801
8 (Whipple or Billroth*).tw,kw. 5561
9 or/1-8 126395
10 ERCP.mp. or exp endoscopic retrograde cholangiopancreatography/ or Cholangiography/ 32422
11 (endoscop* adj2 retrograd* adj2 (cholangiopancreatograph* or cholangio-pancreatograph*)).mp. 21992
12 exp Sphincterotomy, Endoscopic/ 3539
13 ((endoscop* adj3 sphincterotom*) or EST).tw,kw. 24738
14 papillotom*.tw,kw. or exp papillotomy/ 4498
15 or/10-14 58467
16 (enteroscop* or balloon* or BE-ERCP).tw,kf. or exp balloon enteroscopy/ 78309
17 9 and 15 and 16 523
18 Endoscopy, Digestive System/ or Endoscopy, Gastrointestinal/ or exp Endosonography/ or exp Ultrasonography, Interventional/ 69150
19 (EUSCDS or EUS-CDS or EUSHGS or EUS-HGS or EUS-BD or EUSBD or EUS-RV or EUSV or EDGE or EUS-GB or EUSGB or (endoscop* adj2 ultraso*) or EUS or EUS-guided or endosonograph*).tw,kf. 110595
20 18 or 19 169091
21 Percutaneous.tw,kf. 158869
22 exp Drainage/ or exp Suction/ or exp Biliary Tract Surgical Procedures/ or exp Surgery, Computer-Assisted/ or (drain* or suction* or decompress* or dilat*).tw,kf. 452857
23 21 or 22 586890
24 17 and (20 or 23) 380
25 exp animals/ not humans.sh. 4960362
26 24 not 25 379
27 limit 26 to english language 356
28 exp "sensitivity and specificity"/ 630832
29 false negative reactions/ or false positive reactions/ 39874
30 (sensitivity or specificity).ti,ab. 1144285
31 (predictive adj value$1).ti,ab. 122636
32 (likelihood adj ratio$1).ti,ab. 17677
33 (false adj (negative$1 or positive$1)).ti,ab. 83851
34 (randomized controlled trial or controlled clinical trial).pt. 648768
35 double blind method/ or single blind method/ 200699
36 practice guideline.pt. 29631
37 consensus development conference.pt. 12266
38 random$.ti,ab. 1292267
39 random allocation/ 106612
40 (single blind$3 or double blind$3 or triple blind$3).ti,ab. 182204
41 (review or review academic).pt. 2939869
42 (meta analysis or systematic review).pt. or (systematic review or meta-analys* or "meta analys*").ti. 319646
43 (systematic adj review$).ti,ab. or (systematic* adj3 search*).ab. or (meta adj analy*).ti,ab. 362707
44 or/28-41 5856028
45 (44 and (42 or 43)) or 42 363417
46 Randomized controlled trials as Topic/ 152808
47 Randomized controlled trial/ 558939
48 Random allocation/ 106612
49 Double blind method/ 170096
50 Single blind method/ 31605
51 Clinical trial/ 533881
52 exp Clinical Trials as Topic/ 370519
53 or/46-52 1265993
54 (clinic$ adj trial$1).tw. 425735
55 ((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw. 186312
56 Placebos/ 35886
57 Placebo$.tw. 232990
58 Randomly allocated.tw. 32914
59 (allocated adj2 random).tw. 808
60 or/54-59 712545
61 53 or 60 1582631
62 Case report.tw. 355292
63 Letter/ 1170519
64 Historical article/ 367682
65 Review of reported cases.pt. 0
66 Review, multicase.pt. 0
67 or/62-66 1875942
68 61 not 67 1545109
69 Epidemiologic studies/ 9002
70 exp case control studies/ 1285757
71 exp cohort studies/ 2297885

72 Case control.tw. 140857
73 (cohort adj (study or studies)).tw. 262762
74 Cohort analy$.tw. 9987
75 (Follow up adj (study or studies)).tw. 52968
76 (observational adj (study or studies)).tw. 135236
77 Longitudinal.tw. 285439
78 Retrospective.tw. 643102
79 Cross sectional.tw. 435513
80 Cross-sectional studies/ 411707
81 or/69-80 3454203
82 45 or 68 or 81 4873232
83 27 and 82 169

Database: Embase.com (Elsevier)

Date run: February 18, 2022

Limits: English language; human design; randomized controlled trials, systematic reviews/meta-analyses, and cohort/observational studies; excluded conference abstracts, letters to the editor, editorials, case reports, notes, and other nonresearch papers

Results: 362

1 (alter* NEAR/3 anatom*):ti,ab,kw OR 'reconstructive surgery'/exp

2 'jejunostomy'/exp

3 'biliary tract surgery'/de OR 'bile duct reconstruction'/de

4 'Roux Y anastomosis'/exp OR 'anastomosis'/exp

5 (Roux-en-Y OR Roux-Y OR RYGB OR "RY GB"):ti,ab,kw

6 (hepaticojejunostom* OR hepatico-jejunostom* OR ((hepaticojejunal OR hepatico-jejunal) NEAR/2 (anastom* OR fixation* OR reconstruct* OR alter*))):ti,ab,kw

7 'pancreaticoduodenectomy'/exp OR (pancreaticoduodenectom* OR pancreatico-enterostom* OR duodenopancreatectom* OR duodeno-pancreatectom* OR ((pancreaticoduoden* OR pancreatico-duoden*) NEAR/2 (anastom* OR fixation* OR reconstruct* OR alter*))):ti,ab,kw

8 (Whipple OR Billroth*):ti,ab,kw

9 #1 OR #2 OR #3 OR $3 OR #5 OR #6 OR #7 OR #8

10 ERCP:ti,ab,kw OR 'endoscopic retrograde cholangiopancreatography'/exp OR 'cholangiography'/de

11 (endoscop* NEAR/2 retrograd* NEAR/2 (cholangiopancreatograph* OR cholangio-pancreatograph*)):ti,ab,kw

12 'endoscopic sphincterotomy'/exp

13 ((endoscop* NEAR/3 sphincterotom*) OR EST):ti,ab,kw

14 papillotom*:ti,ab,kw OR 'endoscopic papillotomy'/exp

15 #10 OR #11 OR #12 OR #13 OR #14

16 (enteroscop* OR balloon* OR BE-ERCP):ti,ab,kw OR 'balloon enteroscopy'/exp

17 #9 AND #15 AND #16

18 'digestive tract endoscopy'/de OR 'gastrointestinal endoscopy'/de OR 'endoscopic ultrasonography'/exp OR 'interventional ultrasonography'/exp

19 (EUSCDS OR EUS-CDS OR EUSHGS OR EUS-HGS OR EUS-BD OR EUSBD OR EUS-RV OR EUSV OR EDGE OR EUS-GB OR EUSGB OR (endoscop* NEAR/2 ultraso*) OR EUS OR EUS-guided OR endosonograph*):ti,ab,kw

20 #18 OR #19

21 Percutaneous:ti,ab,kw

22 'biliary tract drainage'/exp OR 'drainage'/de OR 'percutaneous drainage'/exp OR 'suction'/de OR 'biliary tract surgery'/exp OR 'computer assisted surgery'/exp OR (drain* OR suction* OR decompress* OR dilat*):ti,ab,kw

23 #21 OR #22

24 #17 AND (#20 OR #23)

25 ('Clinical trial'/de OR 'Randomized controlled trial'/de OR 'Randomization'/de OR 'Single blind procedure'/de OR 'Double blind procedure'/de OR 'Crossover procedure'/de OR 'Placebo'/de OR Randomi?ed controlled trial*:ti,ab,kw OR Rct:ti,ab,kw OR Random allocation:ti,ab,kw OR Randomly allocated:ti,ab,kw OR Allocated randomly:ti,ab,kw OR (allocated NEAR/2 random):ti,ab,kw OR Single blind*:ti,ab,kw OR Double blind*:ti,ab,kw OR ((treble OR triple) NEAR (blind*)):ti,ab,kw OR Placebo*:ti,ab,kw OR 'Prospective study'/de) NOT ('Case study'/de OR Case report:ti,ab,kw OR 'Abstract report'/de OR 'letter'/de) OR 'Clinical study'/de OR 'Case control study'/de OR 'Family study'/de OR 'Longitudinal study'/de OR 'Retrospective study'/de OR ('Prospective study'/de NOT 'Randomized controlled trials'/de) OR 'Cohort analysis'/de OR (Cohort NEAR/1 (study OR studies)):ti,ab,kw OR ("Case control" NEAR/1 (study OR studies)):ti,ab,kw OR ("follow up" NEAR/1 (study OR studies)):ti,ab,kw OR (observational NEAR/1 (study OR studies)):ti,ab,kw OR (epidemiologic* NEAR/1 (study OR studies)):ti,ab,kw OR ("cross sectional" NEAR/1 (study OR studies)):ti,ab,kw OR ('Meta Analysis'/exp OR ((meta NEAR/1 analy*) OR metaanalys*):ti,ab,kw OR (systematic NEAR/1 (review*1 OR overview*1)):ti,ab,kw OR cancerlit:ab OR Cochrane:ab OR Embase:ab OR (psychlit OR psyclit):ab OR (psychinfo OR psycinfo):ab OR (cinahl OR cinhal):ab OR science citation index:ab OR bids:ab OR reference lists:ab OR bibliograph*:ab OR handsearch*:ab OR manual search*:ab OR relevant journals:ab OR ((data extraction:ab OR selection criteria:ab) AND review:it) OR 'sensitivity AND specificity'/exp OR (sensitivity OR specificity OR ((pre-test OR pretest) NEAR/1 probability) OR post-test probability OR predictive value* OR likelihood ratio*):ti,ab,kw OR 'Diagnostic Accuracy'/de/mj) NOT (letter:it OR editorial:it OR ('animal'/de NOT ('animal'/de AND 'human'/de)))

26 #24 AND #25

27 ([conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [data papers]/lim OR [editorial]/lim OR [erratum]/lim OR [letter]/lim OR [note]/lim OR [review]/lim OR [short survey]/lim OR 'case report'/de OR 'review'/de) OR ((rat:ti,tt OR rats:ti,tt OR mouse:ti,tt OR mice:ti,tt OR swine:ti,tt OR porcine:ti,tt OR murine:ti,tt OR sheep:ti,tt OR lambs:ti,tt OR pigs:ti,tt OR piglets:ti,tt OR rabbit:ti,tt OR rabbits:ti,tt OR cat:ti,tt OR cats:ti,tt OR dog:ti,tt OR dogs:ti,tt OR cattle:ti,tt OR bovine:ti,tt OR monkey:ti,tt OR monkeys:ti,tt OR trout:ti,tt

OR marmoset*:ti,tt) AND 'animal experiment'/de) OR ('animal experiment'/de NOT ('human experiment'/de OR 'human'/de))

28 #26 NOT #27

29 #28 AND English:LA

Database: Cochrane Library (Wiley)

Date run: February 18, 2022

Limits: N/A

Results: 13

1 (alter* NEAR/3 anatom*):ti,ab,kw OR [mh ^"Reconstructive Surgical Procedures"]

2 [mh Jejunostomy]

3 [mh ^"Biliary Tract Surgical Procedures"]

4 [mh "anastomosis, roux-en-y"] OR [mh ^"anastomosis, surgical"]

5 (Roux-en-Y OR Roux-Y OR RYGB OR "RY GB"):ti,ab,kw

6 (hepaticojejunostom* OR hepatico-jejunostom* OR ((hepaticojejunal OR hepatico-jejunal) NEAR/2 (anastom* OR fixation* OR reconstruct* OR alter*))):ti,ab,kw

7 [mh pancreaticoduodenectomy] OR (pancreaticoduodenectom* OR pancreatico-enterostom* OR duodenopancreatectom* OR duodeno-pancreatectom* OR ((pancreaticoduoden* OR pancreatico-duoden*) NEAR/2 (anastom* OR fixation* OR reconstruct* OR alter*))):ti,ab,kw

8 (Whipple OR Billroth*):ti,ab,kw

9 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8

10 ERCP:ti,ab,kw OR [mh "endoscopic retrograde cholangiopancreatography"] OR [mh ^"Cholangiography"]

11 (endoscop* NEAR/2 retrograd* NEAR/2 (cholangiopancreatograph* OR cholangio-pancreatograph*)):ti,ab,kw

12 [mh "Sphincterotomy, Endoscopic"]

13 ((endoscop* NEAR/3 sphincterotom*) OR EST):ti,ab,kw

14 papillotom*:ti,ab,kw OR [mh papillotomy]

15 #10 OR #11 OR #12 OR #13 OR #14

16 (enteroscop* OR balloon* OR BE-ERCP):ti,ab,kw OR [mh "balloon enteroscopy"]

17 #9 AND #15 AND #16

18 [mh ^"Endoscopy, Digestive System"] OR [mh ^"Endoscopy, Gastrointestinal"] OR [mh Endosonography] OR [mh "Ultrasonography, Interventional"]

19 (EUSCDS OR EUS-CDS OR EUSHGS OR EUS-HGS OR EUS-BD OR EUSBD OR EUS-RV OR EUSV OR EDGE OR EUS-GB OR EUSGB OR (endoscop* NEAR/2 ultraso*) OR EUS OR EUS-guided OR endosonograph*):ti,ab,kw

20 #18 OR #19

21 Percutaneous:ti,ab,kw

22 [mh Drainage] OR [mh Suction] OR [mh "Biliary Tract Surgical Procedures"] OR [mh "Surgery, Computer-Assisted"] OR (drain* OR suction* OR decompress* OR dilat*):ti,ab,kw

23 #21 OR #22

24 #17 AND (#20 OR #23)

APPENDIX 5: SEARCH PERFORMED FOR PICO 5

Database: Ovid MEDLINE ALL

Date run: February 18, 2022

Limits: English language; human design; randomized controlled trials, systematic reviews/meta-analyses, and cohort/observational studies

Results: 655

1 (cholecystitis or colecystitis or colecistitis*).tw,kf. or exp cholecystitis/ 20874

2 Endoscopy, Digestive System/ or Endoscopy, Gastrointestinal/ or exp Endosonography/ or exp Ultrasonography, Interventional/ 69150

3 (EUS-GB or EUSGB or EUSC or (endoscop* adj2 ultraso*) or EUS or EUS-guided or endosonograph*).tw,kf. 20500

4 exp Drainage/ or exp Suction/ or (drain* or suction* or decompress* or dilat*).tw,kf. 386698

5 exp Stents/ or exp Catheters/ or exp Catheterization/ 280344

6 (stent* or catheter* or cannula* or tube* or pipe* or "SEMS" or SEM or SEMTs or SEM or SEMs or FCSEMS).tw,kf. 1060075

7 or/2-6 1549641

8 gallbladder*.tw,kf. or gallbladder/ or Gallbladder Diseases/ 44681

9 7 and 8 5886

10 (Percutaneous or transpapillary or trans-papillary or transcystic or trans-cystic or (laparoscop* or peritoneoscop* or celioscop* or coelioscop*)).tw,kf. or exp laparoscopy/ 313634

11 exp Drainage/ or exp Suction/ or (drain* or suction* or decompress* or dilat*).tw,kf. 386698

12 Gallbladder*.tw,kf. or gallbladder/ or Gallbladder Diseases/ 44681

13 and/10-12 1588

14 cholecystostom*.tw,kf. or exp cholecystostomy/ 1552

15 13 or 14 2842

16 1 and (9 or 15) 2147

17 exp animals/ not humans.sh. 4960362

18 16 not 17 2122

19 limit 18 to english language 1690

20 exp "sensitivity and specificity"/ 630832

21 false negative reactions/ or false positive reactions/ 39874

22 (sensitivity or specificity).ti,ab. 1144285

23 (predictive adj value$1).ti,ab. 122636

24 (likelihood adj ratio$1).ti,ab. 17677

25 (false adj (negative$1 or positive$1)).ti,ab. 83851

26 (randomized controlled trial or controlled clinical trial).pt. 648768

27 double blind method/ or single blind method/ 200699

28 practice guideline.pt. 29631

29 consensus development conference.pt. 12266

30 random$.ti,ab. 1292267
31 random allocation/ 106612
32 (single blind$3 or double blind$3 or triple blind$3).ti,ab. 182204
33 (review or review academic).pt. 2939869
34 (meta analysis or systematic review).pt. or (systematic review or meta-analys* or "meta analys*").ti. 319646
35 (systematic adj review$).ti,ab. or (systematic* adj3 search*).ab. or (meta adj analy*).ti,ab. 362707
36 or/20-33 5856028
37 (36 and (34 or 35)) or 34 363417
38 Randomized controlled trials as Topic/ 152808
39 Randomized controlled trial/ 558939
40 Random allocation/ 106612
41 Double blind method/ 170096
42 Single blind method/ 31605
43 Clinical trial/ 533881
44 exp Clinical Trials as Topic/ 370519
45 or/38-44 1265993
46 (clinic$ adj trial$1).tw. 425735
47 ((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw. 186312
48 Placebos/ 35886
49 Placebo$.tw. 232990
50 Randomly allocated.tw. 32914
51 (allocated adj2 random).tw. 808
52 or/46-51 712545
53 45 or 52 1582631
54 Case report.tw. 355292
55 Letter/ 1170519
56 Historical article/ 367682
57 Review of reported cases.pt. 0
58 Review, multicase.pt. 0
59 or/54-58 1875942
60 53 not 59 1545109
61 Epidemiologic studies/ 9002
62 exp case control studies/ 1285757
63 exp cohort studies/ 2297885
64 Case control.tw. 140857
65 (cohort adj (study or studies)).tw. 262762
66 Cohort analy$.tw. 9987
67 (Follow up adj (study or studies)).tw. 52968
68 (observational adj (study or studies)).tw. 135236
69 Longitudinal.tw. 285439
70 Retrospective.tw. 643102
71 Cross sectional.tw. 435513
72 Cross-sectional studies/ 411707
73 or/61-72 3454203
74 37 or 60 or 73 4873232
75 19 and 74 655

Database: Embase.com (Elsevier)

Date run: February 18, 2022

Limits: English language; human design; randomized controlled trials, systematic reviews/meta-analyses, and cohort/observational studies; excluded conference abstracts, letters to the editor, editorials, case reports, notes, and other nonresearch papers

Results: 482

1 (cholecystitis OR colecystitis OR colecistitis*):ti,ab,kw OR 'cholecystitis'/exp
2 'digestive tract endoscopy'/de OR 'gastrointestinal endoscopy'/de OR 'endoscopic ultrasonography'/exp 'interventional ultrasonography'/exp
3 (EUS-GB OR EUSGB OR EUSC OR (endoscop* NEAR/2 ultraso*) OR EUS OR EUS-guided OR endosonograph*):ti,ab,kw
4 'drainage'/exp OR 'suction'/exp OR (drain* OR suction* OR decompress* OR dilat*):ti,ab,kw
5 'stent'/exp OR 'catheter'/exp OR 'catheterization'/exp
6 (stent* OR catheter* OR cannula* OR tube OR tubes OR pipe* OR "SEMS" OR SEM OR SEMTs OR SEM OR SEMs OR FCSEMS):ti,ab,kw
7 #2 OR #3 OR #4 OR #5 OR #6
8 gallbladder*:ti,ab,kw OR 'gallbladder'/exp OR 'gallbladder disease'/de
9 #7 AND #8
10 (Percutaneous OR transpapillary OR trans-papillary OR transcystic OR trans-cystic OR (laparoscop* OR peritoneoscop* OR celioscop* OR coelioscop*)):ti,ab,kw OR 'laparoscopy'/exp
11 'drainage'/exp OR 'suction'/exp OR (drain* OR suction* OR decompress* OR dilat*):ti,ab,kw
12 Gallbladder*:ti,ab,kw OR 'gallbladder'/exp OR 'gallbladder disease'/de
13 #10 AND #11 AND #12
14 cholecystostom*:ti,ab,kw OR 'cholecystostomy'/exp
15 #13 OR #14
16 #1 AND (#9 OR #15)
17 ('Clinical trial'/de OR 'Randomized controlled trial'/de OR 'Randomization'/de OR 'Single blind procedure'/de OR 'Double blind procedure'/de OR 'Crossover procedure'/de OR 'Placebo'/de OR Randomi?ed controlled trial*:ti,ab,kw OR Rct:ti,ab,kw OR Random allocation:ti,ab,kw OR Randomly allocated:ti,ab,kw OR Allocated randomly:ti,ab,kw OR (allocated NEAR/2 random):ti,ab,kw OR Single blind*:ti,ab,kw OR Double blind*:ti,ab,kw OR ((treble OR triple) NEAR (blind*)):ti,ab,kw OR Placebo*:ti,ab,kw OR 'Prospective study'/de) NOT ('Case study'/de OR Case report:ti,ab,kw OR 'Abstract report'/de OR 'letter'/de) OR 'Clinical study'/de OR 'Case control study'/de OR 'Family study'/de OR 'Longitudinal study'/de OR 'Retrospective study'/de OR ('Prospective study'/de NOT 'Randomized controlled trials'/de) OR 'Cohort analysis'/de OR (Cohort NEAR/1 (study OR studies)):ti,ab,kw OR ("Case control" NEAR/1 (study OR studies)):ti,ab,kw OR ("follow up" NEAR/1 (study OR studies)):ti,ab,kw OR (observational NEAR/1 (study OR studies)):ti,ab,kw OR (epidemiologic* NEAR/1 (study OR studies)):ti,ab,kw OR ("cross sectional" NEAR/1 (study OR studies)):ti,ab,kw OR ('Meta Analysis'/exp OR ((meta NEAR/1 analy*) OR metaanalys*):ti,ab,kw OR (systematic NEAR/1 (review*1 OR overview*1)):ti,ab,kw

OR cancerlit:ab OR Cochrane:ab OR Embase:ab OR (psychlit OR psyclit):ab OR (psychinfo OR psycinfo):ab OR (cinahl OR cinhal):ab OR science citation index:ab OR bids:ab OR reference lists:ab OR bibliograph*:ab OR hand-search*:ab OR manual search*:ab OR relevant journals:ab OR ((data extraction:ab OR selection criteria:ab) AND review:it) OR 'sensitivity AND specificity'/exp OR (sensitivity OR specificity OR ((pre-test OR pretest) NEAR/1 probability) OR post-test probability OR predictive value* OR likelihood ratio*):ti,ab,kw OR 'Diagnostic Accuracy'/de/mj) NOT (letter:it OR editorial:it OR ('animal'/de NOT ('animal'/de AND 'human'/de)))

18 #16 AND #17

19 ([conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [data papers]/lim OR [editorial]/lim OR [erratum]/lim OR [letter]/lim OR [note]/lim OR [review]/lim OR [short survey]/lim OR 'case report'/de OR 'review'/de) OR ((rat:ti,tt OR rats:ti,tt OR mouse:ti,tt OR mice:ti,tt OR swine:ti,tt OR porcine:ti,tt OR murine:ti,tt OR sheep:ti,tt OR lambs:ti,tt OR pigs:ti,tt OR piglets:ti,tt OR rabbit:ti,tt OR rabbits:ti,tt OR cat:ti,tt OR cats:ti,tt OR dog:ti,tt OR dogs:ti,tt OR cattle:ti,tt OR bovine:ti,tt OR monkey:ti,tt OR monkeys:ti,tt OR trout:ti,tt OR marmoset*:ti,tt) AND 'animal experiment'/de) OR ('animal experiment'/de NOT ('human experiment'/de OR 'human'/de))

20 #18 NOT #19

21 #20 AND English:LA

Database: Cochrane Library (Wiley)

Date run: February 18, 2022

Limits: N/A

Results: 160

1 (cholecystitis OR colecystitis OR colecistitis*):ti,ab,kw OR [mh cholecystitis]

2 [mh ^"Endoscopy, Digestive System"] OR [mh "Endoscopy, Gastrointestinal"] OR [mh Endosonography] OR [mh "Ultrasonography, Interventional"]

3 (EUS-GB OR EUSGB OR EUSC OR (endoscop* NEAR/2 ultraso*) OR EUS OR EUS-guided OR endosonograph*):ti,ab,kw

4 [mh Drainage] OR [mh Suction] OR (drain* OR suction* OR decompress* OR dilat*):ti,ab,kw

5 [mh Stents] OR [mh Catheters] OR [mh Catheterization]

6 (stent* OR catheter* OR cannula* OR tube* OR pipe* OR "SEMS" OR SEM OR SEMTs OR SEM OR SEMs OR FCSEMS):ti,ab,kw

7 #2 OR #3 OR #4 OR #5 OR #6

8 gallbladder*:ti,ab,kw OR [mh ^"gallbladder"] OR [mh ^"Gallbladder Diseases"]

9 #7 AND #8

10 (Percutaneous OR transpapillary OR trans-papillary OR transcystic OR trans-cystic OR (laparoscop* OR peritoneoscop* OR celioscop* OR coelioscop*)):ti,ab,kw OR [mh laparoscopy]

11 [mh Drainage] OR [mh Suction] OR (drain* OR suction* OR decompress* OR dilat*):ti,ab,kw

12 Gallbladder*:ti,ab,kw OR [mh "gallbladder"] OR [mh "Gallbladder Diseases"]

13 #10 AND #11 AND #12

14 cholecystostom*:ti,ab,kw OR [mh cholecystostomy]

15 #13 OR #14

16 #1 AND (#9 OR #15)