



Learning curve of EUS-guided biliary duct drainage: systematic review and meta-analysis

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Background and Aims: In recent years, EUS-guided biliary drainage (EUS-BD) has emerged as an alternative to ERCP. However, a recent meta-analysis of randomized controlled trials suggests comparable efficacy and safety between EUS and conventional ERCP for biliary drainage, highlighting the growing preference for EUS-BD. This study aims to contribute to this evolving landscape by investigating the technical and clinical success of EUS-BD and defining its learning curve.

Methods: A comprehensive search of electronic databases was conducted from January 2003 to November 2022 for publications evaluating the learning curve of EUS-BD. Pooled proportions were calculated using both fixed-effects and random-effects models, with a 95% confidence interval.

Results: The initial search yielded 380 studies, of which 88 relevant articles were reviewed. Data from 3 studies (261 patients) meeting inclusion criteria were analyzed. Proficiency in EUS-BD was achieved at 35.51 procedures. Pooled technical success was 92.45%, and clinical success was 84.84%. Adverse events occurred in 18.46% of cases, with specific rates for bleeding (4.31%), perforation (3.03%), sepsis (7.61%), procedure-related death (.31%), and all-cause mortality (2.29%). No bias was detected using the Egger bias indicator, which gave a value of -6.0 with a $P = .17$.

Conclusions: Our analysis revealed an EUS-BD proficiency at around 35 procedures, with a mean postproficiency procedure length of 68.07 minutes. Adverse events notably decrease after 66 procedures, informing a safety-driven recommendation: Endosonographers should complete a minimum of 60 supervised procedures before independent EUS-BD practice, enhancing procedural safety and proficiency. (iGIE 2024;3:202-9.)

ERCP is the first line of treatment for pancreaticobiliary decompression with a success rate of $>90\%$. However, cannulation is challenging in cases of altered anatomy (eg, Roux-en-Y gastric bypass, Whipple, Billroth), malignancies causing gastric outlet or duodenal obstruction, periampullary diverticulum, and in some cases of ampullary and pancreatic carcinomas.¹⁻⁷ Percutaneous transhepatic biliary drainage is an alternative option for biliary drainage but comes at a cost of a higher adverse event (AE) rate and physical and cosmetic discomfort related to the external drain.⁸

EUS-guided biliary drainage (EUS-BD) is a safe, efficacious, and first-line treatment in distal malignant biliary obstruction with a high probability of failed ERCP.⁹ EUS-BD was first described by Giovannini et al in 2001.¹⁰ EUS-BD can use multiple approaches; however, the overall technique remains similar. The initial step includes FNA-guided biliary access followed by placement of a guidewire under endosonographic and fluoroscopic visualization, resulting in a fistulous tract formation and finally stent placement.⁶

EUS-BD is a minimally invasive procedure but requires advanced training and technical skills. AEs associated with EUS-BD range from 3.5% to 38.6% and include bleeding, perforation, cholangitis, sepsis, bile leak, peritonitis, and stent migration.^{11,12} According to the American Society for Gastrointestinal Endoscopy, a minimum of 150 supervised EUS cases is recommended to achieve proficiency in basic diagnostic EUS. This number has been greatly disputed because of advances and an increase in the spectrum of EUS applications.¹³

Extending beyond diagnostic EUS, in the hand of experienced endosonographers, the modality can be used for performing a variety of interventions and therapeutic maneuvers. One EUS intervention of great interest is EUS-BD. Data on attaining proficiency for EUS-BD are disparate. The primary aim of this study was to determine the number of procedures needed to attain proficiency in EUS-BD. The secondary aim was to evaluate clinical success, technical success, and AEs associated with EUS-BD.

METHODS

Search methodology

For a systematic review with meta-analysis, a selective literature search was conducted using multiple electronic database engines including PubMed, MEDLINE, Ovid, Cochrane Library (Cochrane Central Register of Controlled Trials and Cochrane Database of Meta-Analysis), Embase, ACP Journal Club, and Database of Abstracts of Reviews of Effects according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses guidelines from inception through November 2022 to identify studies addressing the learning curve of EUS-BD. Keywords used were “EUS,” “EUS-BD,” “Endoscopic Ultrasound,” “Endoscopic Ultrasound guided biliary drainage,” and “Learning Curve.” We carefully examined the retrieved studies to exclude potential duplicates or overlapping data.

Study eligibility

All comparative and cohort studies evaluating the learning curve of EUS-BD, with data and discussions on methodology, were included in the study. All studies not in the English language were excluded. Studies in animal models, editorials, reviews, abstracts, meta-analysis, and comments were also excluded.

Data extraction and quality assessment

The following data were independently abstracted by 2 authors (I.V. and H.G.) into a standardized form: study characteristics (author details, recruitment period, year of publication, country, median follow-up, methodologic quality), study design, baseline study population characteristics (number of patients enrolled, patient demographics, baseline characteristics), intervention details (number of EUS-BD procedures, technical details and indications of the procedure, length of procedure, number of operators, specialty and experience of the operator), primary outcomes (learning curve, number of procedures to attain proficiency, length of procedure after attaining proficiency), and secondary outcomes (technical success of EUS-BD, clinical success of EUS-BD, AEs). Each article was reviewed by 2 investigators independently (I.V. and H.G.). Eighty-eight articles matched the study criterion, and full-text articles were reviewed independently by 2 authors (I.V. and H.G.). Data were extracted, meeting both inclusion and exclusion criteria after review of the entire content of each study. Any differences were resolved by a third investigator (S.R.P.), discussion, or revision. The agreement was evaluated using Cohen's kappa.

Outcomes evaluated

The primary outcome of the study was to assess the learning curve of EUS-BD. Secondary outcomes were technical success, clinical success, and AEs associated with EUS-BD. The pooled estimates of the number of procedures to attain proficiency, length of the procedure after attaining

proficiency, overall clinical and technical success of EUS-BD, and AEs associated with EUS-BD were calculated.

Statistical analysis

Data analysis was performed using Microsoft Excel (Microsoft, Redmond, Calif, USA).¹⁴ The meta-analysis was performed by calculating pooled proportions. Individual study proportions were transformed into a quantity using the Freeman-Turkey variant of the arcsine square root-transformed proportion. The pooled proportion is calculated as the back-transform of the weighted mean of the transformed proportions, using inverse arcsine variance weights for the fixed-effects model and DerSimonian-Laird weights for the random-effects model. Forest plots were drawn to show the point estimates in each study in relation to the summary of pooled estimate. The width of point estimates in the forest plots indicates the assigned weight to that study. The effects of publication and selection bias on the summary estimates were tested by both Egger bias indicator and Begg-Mazumdar bias indicator.^{15,16} Funnel plots were constructed to assess potential publication bias using the standard error and diagnostic odds ratio.¹⁷

Study definitions

Proficiency in EUS-BD procedures was defined as the refinement of procedural skills aimed at reducing the operating time, specifically reaching a point on the learning curve where the procedure's duration had plateaued.^{17,18} The procedure time was defined as the duration from intubation to the initial puncture of the bile duct to successful transmural stent placement. Clinical success was defined as the resolution of jaundice and/or a decrease in pretreatment bilirubin levels by 30% or more within 1 week after placement, normalization of bilirubin within 30 days, and/or complete resolution of symptoms.^{18–20} Technical success was achieved when EUS-guided stent placement between the hepatic or common bile duct and the GI tract was completed.^{18–20} AEs included sepsis, bleeding, perforation, and procedure-related deaths. The inclusion criteria for the study encompassed all studies providing data on the learning curve, technical and clinical success, and AEs associated with EUS-BD. Conversely, studies lacking information on the learning curve, technical success, and clinical success of EUS-BD were excluded from the analysis.

RESULTS

The initial search identified 380 studies, of which 88 relevant articles were reviewed. Data were extracted from 3 studies comprising 261 patients that met the inclusion criteria and were included in the final analysis. In studies that used propensity-matched analysis, the data reported from the propensity-matched cohorts were used for the

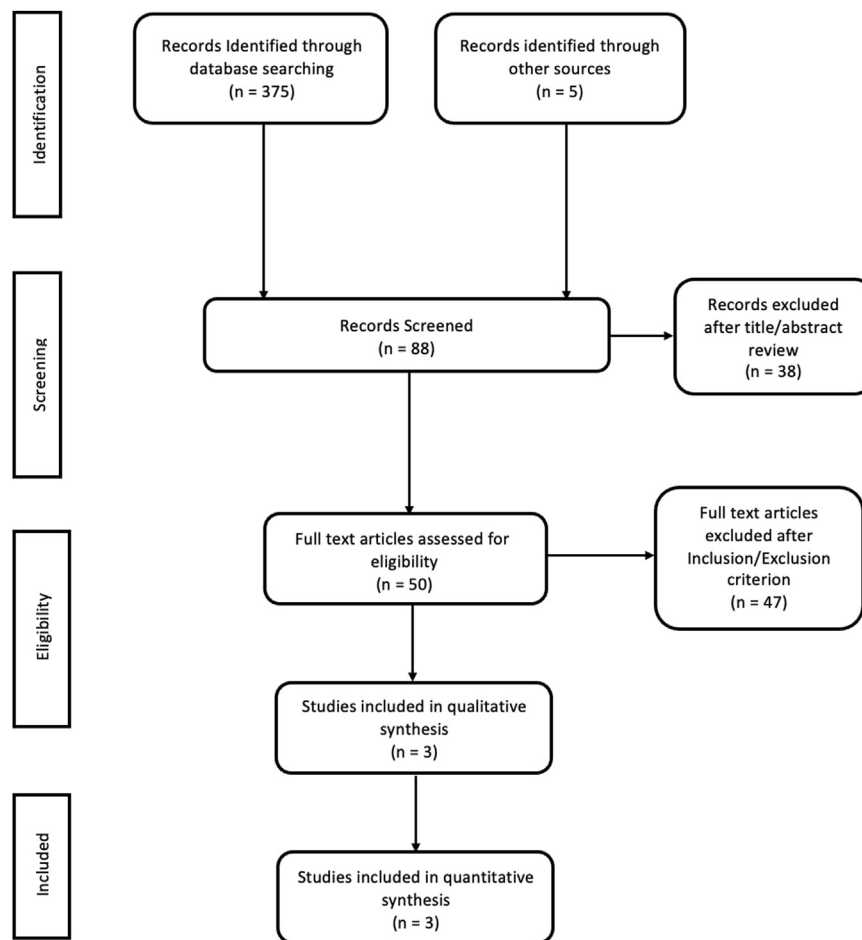


Figure 1. Study flow diagram based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

final analysis. Preferred Reporting Items for Systematic Reviews and Meta-Analysis describing the details of the review process are shown in [Figure 1](#).

All included studies are available in full-text articles.^{18–20} Baseline demographics and study characteristics are shown in [Table 1](#). On pooled analysis, mean patient age was 65.3 years (standard deviation, 13.53), and 55.17% of patients were men. The etiology of biliary obstruction was malignant in 87.71% and benign in 12.29% of cases. EUS-guided hepatogastrostomy (EUS-HGS) was performed in 64.02%, EUS-guided choledochoduodenostomy (EUS-CDS) in 28.01%, and extrahepatic rendezvous procedures in 7.97%. Self-expandable metallic stents were placed in 89.36% of cases and plastic stents in 10.64%.

Outcomes

On pooled analysis, technical success was achieved in 92.45% (95% confidence interval [CI], 88.05–96.32) and clinical success in 84.84% (95% CI, 80.26–88.91). The forest plot showing individual study estimates and the pooled

estimate for clinical and technical success rates of EUS-BD are shown in [Figure 2A and B](#).

In the pooled analysis, proficiency was achieved at 35.51 procedures (95% CI, 35.57–37.44); however, a decrease in AEs and safe performance of EUS-BD were achieved at 66.28 procedures (95% CI, 62.21–71.12). The mean procedure time after attaining proficiency was 68.07 minutes (95% CI, 57.24–74.31). There was no heterogeneity for technical and clinical success, with an I^2 score of 62.5% (95% CI, 0–82.6) and 62.4% (95% CI, 0–83.7), respectively.

No evidence of publication bias occurred when calculated using the Egger bias indicator (−3.32; 95% CI, −5.35 to 1.29; $P = .45$) or Harbord bias indicator (1.08; 95% CI, −10.05 to 12.21; $P = .83$) for the technical and clinical success rates of EUS-BD. A funnel plot demonstrating no evidence of publication bias is shown in [Figure 3A and B](#).

The pooled AE rate was 18.46% (95% CI, 15.23–22.36). Among the AEs, bleeding was noted in 4.31% (95% CI, 2.41–6.87), perforation in 3.03% (95% CI, 1.71–5.43), sepsis

TABLE 1. Baseline study characteristics and demographics of included patients

Study	Year	Country	Study type	No. of operators	No. of centers	No. of patients	No. of procedures needed in the learning curve	No. of malignant biliary obstructions	No. of adverse events
Tyberg et al ¹⁸	2020	USA	Prospective	1	1	72	32	56	7
Oh et al ¹⁹	2017	South Korea	Prospective	1	1	129	33	113	32
James and Baron ²⁰	2019	USA	Retrospective	1	1	60	40	23	9

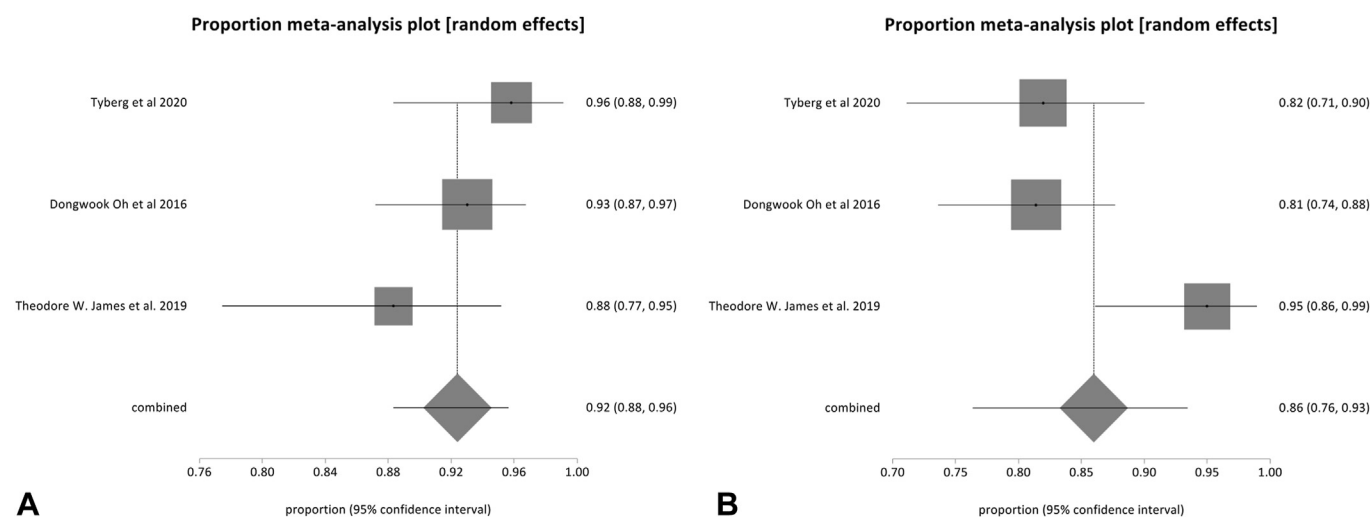


Figure 2. A, Forest plot showing the technical success rate of EUS-guided biliary drainage in the management of biliary obstruction. **B,** Forest plot showing the clinical success rate of EUS-guided biliary drainage in the management of biliary obstruction.

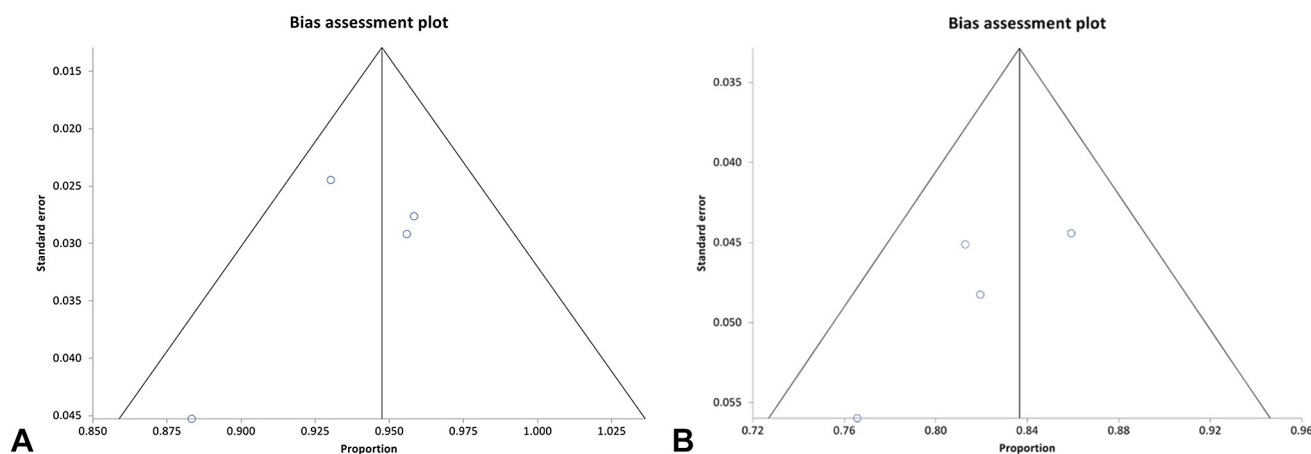


Figure 3. A, Funnel plot showing no publication bias for the technical success rate of EUS-guided biliary drainage therapy in the management of biliary obstruction. **B,** Funnel plot showing no publication bias for the clinical success rate of EUS-guided biliary drainage therapy in the management of biliary obstruction.

in 7.61% (95% CI, 5.39-8.83), procedure-related death in 7.61% (95% CI, 5.39-8.83), and all-cause mortality in 2.29% (95% CI, 1.84-3.41). The forest plot showing individual study estimates and the pooled estimate for AEs is presented in Figure 4.

There was no heterogeneity, with an I^2 score of 56.5% (95% CI, 0-80.50). The Egger bias indicator calculated was 3.64 (95% CI, -9.34 to 16.62), indicating no evidence of publication bias, as shown in Figure 5.

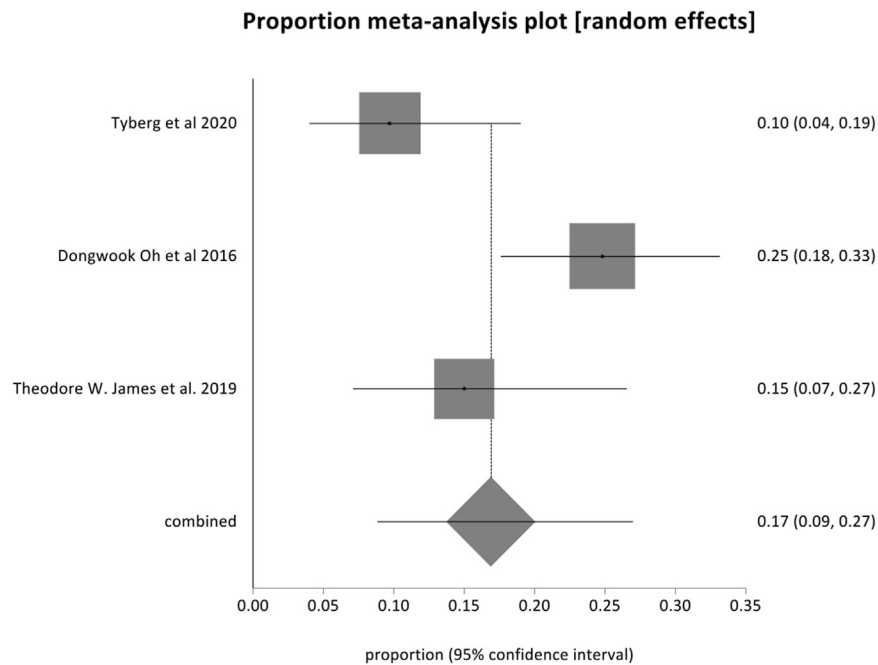


Figure 4. Forest plot showing the pooled adverse event rate of EUS-guided biliary drainage.

DISCUSSION

Since the introduction of EUS-BD in 2001, comprehensive data on the learning curve and technical and clinical success rates of EUS-BD are notably lacking.¹⁰ EUS-BD is a procedure known for its technical complexity, and the scarcity of data can largely be attributed to the absence of an approved indication with dedicated tools.⁹ ERCP is the procedure of choice for providing biliary decompression. However, ERCP is not technically feasible in cases of inaccessible papilla because of altered anatomy or malignant infiltration.^{21–23} An ongoing prospective randomized trial, the ELEMENT trial, is comparing EUS-BD as a first-line approach with a lumen-apposing metal stent with ERCP in the management of malignant distal biliary obstruction.⁹

Based on our pooled analysis of individual studies, proficiency in EUS-BD was achieved after 35 procedures, and a decrease in AEs while safely performing EUS-BD was observed after 66 cases. The mean procedure time after attaining proficiency was 68.07 minutes. Because advanced endoscopy is establishing its niche in minimally invasive procedures, it is crucial to define the operator learning curve for EUS-BD. This will help standardize training programs and procedural expectations for both trainees and experienced gastroenterologists.

Individual studies on the number of procedures required to become proficient in EUS-BD demonstrate procedural ranges between 32 and 50. However, the data are disparate regarding the number of EUS-BD procedures needed to minimize AEs.^{18–20} In a single-center study by Attasaranya

et al,²⁴ the failure rate of EUS-BD was found to be 38% during the first 3 years of training and 11% in the last 2 years of training. In a national survey database from Spain, the EUS-BD technical success rate was 67.2%, which was lower than the previously reported data from more experienced gastroenterologists.²⁵ In a single-center study of 101 patients with obstructive jaundice, 5 EUS-BD–related deaths occurred among the first 50 patients within the first 5 years versus 1 EUS-BD–related death in the last 2 years.²² Because of the observed learning curve, Hara et al²⁶ recommended that the first 20 EUS-BD procedures should be performed under a mentor's supervision.

In a meta-analysis, the pooled technical and clinical success of EUS-BD was 91.5% and 87%, respectively, with an AE rate of 17.9%, which corroborates with our findings in the current study.²³ High heterogeneity percentages of 62.5%, 62.4%, and 71% were found for technical success, clinical success, and the learning rate for EUS-BD, respectively. The heterogeneity potentially stems from 1 of the following reasons: different techniques to access the biliary tree, including EUS-HGS, EUS-CDS, and rendezvous procedures; use of different modalities to drain the bile ducts, such as plastic stents, metallic stents, lumen-apposing metal stents, nasobiliary drainage tubes, and combinations of these; and operators' prior experience in EUS and ERCP. The third point—operator experience in EUS and ERCP—may be the most important. Even after training in interventional endoscopy, the learning curve for "basic" EUS and ERCP continues for the first 5 years of practice. Nevertheless, in the current study, 87% of patients underwent EUS-BD because of malignant

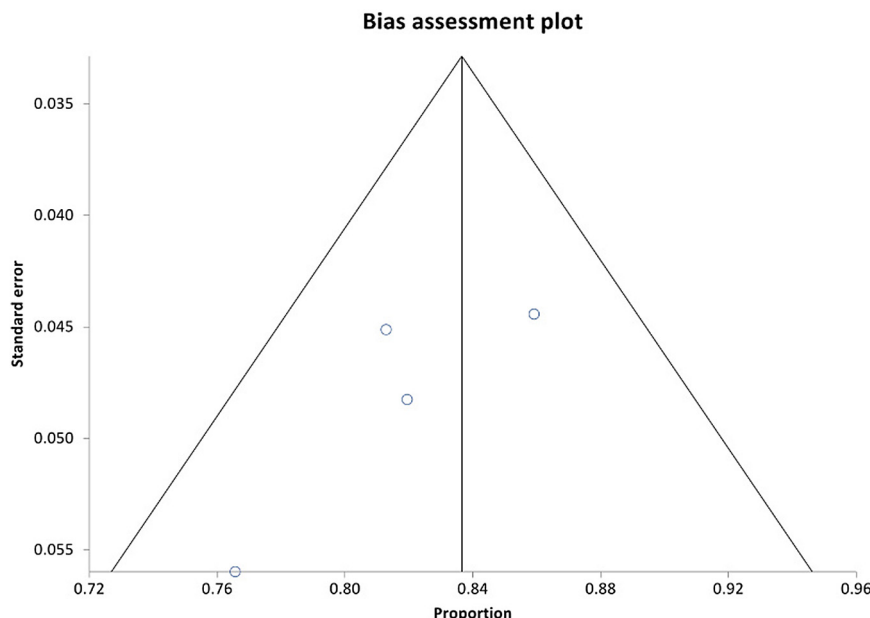


Figure 5. Funnel plot showing no publication bias for the adverse event rate of EUS-guided biliary drainage.

biliary obstruction, 64% had EUS-HGS to access the biliary tree, and 89% had metallic stent placement for bile duct drainage, which approximates other studies.^{18–20}

In the current pooled analysis, the procedure time was 68.07 minutes (95% CI, 57.24–74.31) after the 35th case, which is similar to Tyberg et al's¹⁸ procedural time of 59 minutes (range, 36–138) after the 32nd case. However, Oh et al¹⁹ reported 24 cases to reduce the procedure time to 30.1 ± 13.1 minutes and 33 cases to plateau the procedure time. The differences in procedure time in individual studies could be attributed to the variation in EUS-BD techniques, including different numbers of EUS-HGS and EUS-CDS procedures.

Other factors affecting procedure time are patient-related, such as surgically altered anatomy or complex biliary strictures that result in the difficult passage of a guidewire and insufficient intrahepatic bile duct dilation.^{22,27} Factors can also be procedure-related; for instance, under EUS, the bile duct appears to be close to the GI tract, but on puncturing the bile duct is displaced, potentially resulting in the failure of the procedure.²⁸ The most challenging step is guidewire manipulation into the bile ducts, which requires an appropriate plane and insertion into the biliary duct that might have an angular offset.^{18,27}

Different techniques may also be intrinsically more challenging than others, such as EUS-HGS compared with EUS, because it requires scope stabilization and fixed biliary access.^{18,19} Given the various nuances and complexities of EUS-BD, repetition is key to becoming familiar with technical maneuvers. In vitro models are evolving to approxi-

mate human anatomy and teach the cognitive and technical challenges of EUS-BD.

Dhir et al²⁹ devised a hybrid model for training in EUS-BD and EUS-guided rendezvous procedures. The model comprised a pig esophagus and stomach, a synthetic duodenum, and a biliary system. The biliary system was submerged under gelatin for easy passage of sonographic waves. Twenty-eight trainees underwent initial didactic and live procedure training, followed by hands-on EUS-BD and EUS-guided rendezvous training on the hybrid model. All trainees completed EUS-BD and EUS-guided rendezvous steps within an average of 11 minutes (range, 8–18). Technical difficulties were most pronounced in the order of EUS-guided rendezvous followed by EUS-HGS and EUS-CDS. After a 10-day follow-up, 9 of 28 trainees had independently conducted 3 EUS-guided rendezvous and 7 EUS-BD procedures successfully.²⁹

Thus, our results should be interpreted with caution, considering that the number of procedures required to reach proficiency might be higher for gastroenterologists early in their careers. In our meta-analysis, the calculation of the number of cases required to reach proficiency was exclusively based on data from 3 specific studies: Tyberg et al,¹⁸ Oh et al,¹⁹ and James and Baron.²⁰ Although Poincloux et al,²² Kawakubo et al,²¹ and Dhir et al²⁹ did offer comprehensive information regarding various aspects of EUS-BD, including technical proficiency, clinical success rates, and AEs, they did not specify the exact numerical value representing the point of proficiency achievement. Therefore, these 3 studies were not included in our calculations for determining the number of cases needed to

reach proficiency. It is important to note that Kawakubo et al²¹ and Dhir et al²⁹ did not provide information on the number of operators involved in their respective studies. However, it is crucial to emphasize that we deliberately excluded these studies from our analysis when determining the proficiency threshold.

Additionally, it is worth mentioning that EUS-CDS procedures are often performed freehand, using cautery-enhanced lumen-apposing metal stents, which significantly distinguishes them from guidewire-directed HGS or CDS procedures in terms of equipment, associated risks, procedural time, and learning curve. Most procedures analyzed in this study were HGS or guidewire-directed CDS. Consequently, an updated study that primarily focuses on lumen-apposing metal stents CDS procedures could yield substantially different outcomes.

It is also essential to acknowledge that the findings presented in this review are primarily derived from studies conducted in high-volume centers. In these centers, the supporting staff, including assistants and specialists, demonstrate a commendable level of proficiency in performing EUS-BD procedures. We recognize the influence of these supporting team members on the outcomes of EUS-BD. Our research, focused on high-volume centers, inherently highlights the expertise of assistants and specialists who contribute significantly to the seamless execution of these procedures. The success of EUS-BD is undoubtedly a collaborative effort, and our findings prompt us to advocate for a holistic approach to training and skill development. This involves not only refining the capabilities of the primary operators but also investing in the continuous improvement of the supporting team's proficiency.

The collaborative nature of EUS-BD procedures necessitates a comprehensive strategy that acknowledges the intricate synergy between operators and their supporting staff. Therefore, we recommend future research and discussions explore avenues to augment the skill set of assistants and specialists, ensuring a well-coordinated and highly skilled team for the successful execution of EUS-BD interventions. Our systematic review advocates for a nuanced understanding of the multifaceted team dynamics involved in EUS-BD procedures, emphasizing the need for ongoing training and skill development across all members of the procedural team, with a particular focus on the indispensable role of assistants and specialists.

Our study has several strengths. It offers insights into the learning curve of EUS-BD, technical and clinical success rates of EUS-BD, and AEs associated with EUS-BD. This meta-analysis is the first to report the number of procedures required to reach proficiency in EUS-BD and the pooled length of the procedure after achieving proficiency.

In conclusion, proficiency in therapeutic EUS, especially EUS-BD, necessitates specialized training and years of experience in EUS and ERCP. This meta-analysis reveals that experienced interventional GI endoscopists achieve proficiency at 35 cases, reducing procedure time to 68 minutes.

Subsequent experience leads to continuous improvement, evidenced by a decline in AEs after 66 EUS-BD procedures. As a safety-focused refinement, we recommend a minimum of 60 supervised procedures before independent practice. Notably, most procedures in this study were HGS or guidewire-directed CDS. An updated study, primarily focusing on lumen-apposing metal stent CDS, could yield significantly different results.

DISCLOSURE

The following author disclosed financial relationships: N. R. Sharma: Consultant for Boston Scientific, Medtronic, Steris, and Olympus. All other authors disclosed no financial relationships.

Abbreviations: AE, adverse event; CI, confidence interval; EUS-BD, EUS-guided biliary drainage; EUS-CDS, EUS-guided choledochoduodenostomy; EUS-HGS, EUS-guided hepatogastrostomy.

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