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Endoscopic gallbladder drainage for symptomatic gallbladder disease: a cumulative systematic review meta-analysis

Thomas R. McCarty[1,2] · Kelly E. Hathorn[1,2] · Ahmad Najdat Bazarbashi[1,2] · Kunal Jajoo[1,2] · Marvin Ryou[1,2] · Christopher C. Thompson[1,2]

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Abstract

Background Endoscopic ultrasound (EUS)-guided transmural or endoscopic retrograde cholangiography (ERC)-based transpapillary drainage may provide alternative treatment strategies for high-risk surgical candidates with symptomatic gallbladder (GB) disease. The primary aim of this study was to perform a systematic review and meta-analysis to investigate the efficacy and safety of endoscopic GB drainage for patients with symptomatic GB disease.

Methods Searches of PubMed, EMBASE, Web of Science, and Cochrane Library databases were performed in accordance with PRISMA and MOOSE guidelines. Pooled proportions were calculated for measured outcomes including technical success, clinical success, adverse event rate, recurrence rate, and rate of reintervention. Subgroup analyses were performed for transmural versus transpapillary, transmural lumen apposing stent (LAMS), and comparison to percutaneous transhepatic drainage. Heterogeneity was assessed with I^2 statistics. Publication bias was ascertained by funnel plot and Egger regression testing.

Results Thirty-six studies ($n = 1538$) were included. Overall, endoscopic GB drainage achieved a technical and clinical success of 87.33% [(95% CI 84.42–89.77); $I^2 = 39.55$] and 84.16% [(95% CI 80.30–87.38); $I^2 = 52.61$], with an adverse event rate of 11.00% [(95% CI 9.25–13.03); $I^2 = 7.08$]. On subgroup analyses, EUS-guided transmural compared to ERC-assisted transpapillary drainage resulted in higher technical and clinical success rates [OR 3.91 (95% CI 1.52–10.09); $P = 0.005$ and OR 4.59 (95% CI 1.84–11.46); $P = 0.001$] and lower recurrence rate [OR 0.17 (95% CI 0.06–0.52); $P = 0.002$]. Among EUS-guided LAMS studies, technical success was 94.65% [(95% CI 91.54–96.67); $I^2 = 0.00$], clinical success was 92.06% [(95% CI 88.65–94.51); $I^2 = 0.00$], and adverse event rate was 11.71% [(95% CI 8.92–15.23); $I^2 = 0.00$]. Compared to percutaneous drainage, EUS-guided drainage possessed a similar efficacy and safety with significantly lower rate of reintervention [OR 0.05 (95% CI 0.02–0.13); $P < 0.001$].

Discussion Endoscopic GB drainage is a safe and effective treatment for high-risk surgical candidates with symptomatic GB disease. EUS-guided transmural drainage is superior to transpapillary drainage and associated with a lower rate of reintervention compared to percutaneous transhepatic drainage.

Keywords Gallbladder disease · Cholecystitis · Endoscopic ultrasound (EUS) · Percutaneous transhepatic drainage

Symptomatic gallbladder (GB) disease, including biliary colic, calculous cholecystitis, and acalculous cholecystitis, represent a significant healthcare burden in the USA, affecting approximately 10%–15% of the US adults [1–5]. The treatment of choice for symptomatic GB disease has long been considered surgical resection, performed via an open or preferably a laparoscopic approach. However, for patients who are high-risk surgical candidates due to malignancy, underlying cirrhosis, severe cardiac disease, or other high-risk comorbid conditions, clinicians have searched for alternative, less invasive therapeutic options [6].

One of the most well-known and utilized non-surgical options for management of GB disease in non-surgical candidates has been percutaneous transhepatic GB drainage performed by interventional radiology. However, percutaneous

✉ Christopher C. Thompson
cthompson@hms.harvard.edu

[1] Division of Gastroenterology, Hepatology and Endoscopy, Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115, USA

[2] Harvard Medical School, Boston, MA 02115, USA

drainage is limited by the risk of inadvertent self-removal of the catheter and risk of serious adverse events such as pneumoperitoneum, pneumothorax, and catheter leakage associated with this technique [7, 8]. Additionally, many patients continue to experience significant pain and decreased quality of life in the setting of an external drainage catheter in situ, and similar to the surgical technique, certain patient populations are at increased risk of complications with percutaneous GB drainage—including those with ascites, coagulopathy, and dementia [7–11]. Thus, in more recent years, clinicians have turned towards endoscopic gallbladder drainage as a less invasive approach for management of symptomatic GB disease.

Endoscopic GB drainage can be achieved via one of two methods: transpapillary GB drainage or transmural GB drainage. Transpapillary drainage is a well-established technique of GB drainage, achieved through an endoscopic retrograde cholangiography (ERC) approach. After successful biliary cannulation, a guidewire can be used to selectively access the cystic duct and GB, and a catheter or stent can then be left in place for continuous GB drainage [6]. In the more novel, transmural approach, endoscopic ultrasound (EUS) is used to perform either a transgastric or transduodenal GB puncture, and similarly, a catheter or stent can be left in place for ongoing GB drainage [6, 7]. While both of these endoscopic modalities provide a less invasive strategy to achieve GB drainage among patients who are not otherwise surgical candidates, there remains a paucity of data to summarize endoscopic drainage as well as to compare various endoscopic techniques relative to percutaneous transhepatic GB drainage.

Thus, the primary aim of this study was to perform a structured systematic review and meta-analysis to investigate the technical success rates, clinical success rates, and adverse events rates of endoscopic gallbladder drainage for symptomatic GB disease. Secondary aims were to compare efficacy and safety of endoscopic approaches (i.e., EUS-guided transmural versus ERC-based transpapillary), as well as to compare these endoscopic methods to percutaneous transhepatic GB drainage.

Methods

Literature review

A comprehensive search of the literature was performed to identify articles that examined endoscopic GB drainage for the specific treatment of symptomatic GB disease. Systematic searches of PubMed, EMBASE, Web of Science, and the Cochrane Library databases were performed from inception through August 31, 2019. The following medical subject heading (MESH) terms included: *endoscopic gallbladder drainage*. For articles related to endoscopic gallbladder drainage, subject heading search terms and title and abstract were reviewed for: *transpapillary gallbladder drainage*, *transmural gallbladder drainage*, *endoscopic cholangiopancreatography (ERCP) gallbladder drainage*, *endoscopic ultrasound (EUS) gallbladder drainage*, *naso-biliary drainage*, *lumen apposing metal stent (LAMS)*, *self-expanding metal stent (SEMS)*, and *plastic stent*.

All relevant English language articles irrespective of year of publication, type of publication, or publication status were included. The titles and abstracts of all potentially relevant studies were screened for eligibility with reference lists of studies of interest then manually reviewed for additional articles by cross checking bibliographies. Two reviewers (TRM and KH) independently screened the titles and abstracts of all the articles according to predefined inclusion and exclusion criteria. Any differences were resolved by mutual agreement and in consultation with the third reviewer (ANB). In the case of studies with incomplete information, contact was attempted with the principal authors to obtain additional data.

Study selection criteria

This study was prospectively submitted in PROSPERO, an international database of prospectively registered systematic reviews in health and social care. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement outline and Meta-Analysis of Observational Studies in Epidemiology (MOOSE) reporting guidelines for reporting systematic reviews and meta-analyses was used to report findings—Appendixes 1 and 2 [12, 13]. Studies were only included if the manuscript reported technical success, clinical success, or procedure-associated adverse events. Studies were excluded if deemed to have insufficient data, as were review articles, editorials, and correspondence letters that did not report independent data. Case series and reported studies with <5 patients were excluded to minimize selection bias. Multiple published work from similar authors was evaluated for overlapping enrollment times to preserve independence of observations. Studies that were excluded from cumulative analysis due to overlapping enrollment periods were subsequently re-evaluated for inclusion in subgroup analyses of direct comparative studies as long as independence of observations was preserved.

Outcome measures

The primary outcome measurement in this study was the efficacy and safety of endoscopic GB drainage in patients with symptomatic GB disease. Efficacy was defined as technical success rate (characterized by successful EUS-guided transmural or ERC-based transpapillary catheter or stent placement endoscopically) and clinical success rate (described as resolution of patient-specific symptoms post-intervention). Adverse events included both early and late procedure-associated complications. Additional analyses were stratified by method of endoscopic GB drainage: EUS-guided transmural and ERC-based transpapillary approaches. Furthermore, subgroup analyses were performed for direct comparator studies to determine specific outcome differences between EUS-guided transmural GB drainage and ERC-based transpapillary drainage as well as percutaneous transhepatic GB drainage. Other measured outcomes included baseline patient and study characteristics (i.e., mean age, gender, average follow-up period, type of GB pathology, and GB size) as well as procedural-related characteristics (i.e., procedure duration [in minutes], reintervention rate, rate of recurrence, and number of patients with eventual cholecystectomy and route, if applicable).

Statistical analysis

This systematic review and meta-analysis was performed by calculating pooled proportions. After appropriate studies were identified through systematic literature search and review, the individual study proportion was transformed into a quantity using the Freeman–Tukey variant of the arcsine square root transformed proportion. From this, the pooled proportion was calculated as the back transform of the weighted mean of the transformed proportions using DerSimonian–Laird weights for a random effects model [14, 15]. These pooled rates were estimated using random effects models and presented as point estimates (rates) with 95% confidence intervals [16, 17]. In contrast to fixed effect models, which are used to estimate a common effect, random effect models estimate an average effect, and the variability of the effects represented by their average may have clinical implications.

Sensitivity analyses were performed for only randomized controlled trials and prospective studies, excluding retrospective observational studies. Additionally, subgroup analyses based upon EUS-guided transmural studies utilizing the LAMS and comparison between endoscopic approaches and percutaneous drainage was also performed. All calculated P values were 2-sided, and $P < 0.05$ was considered statistically significant. Tabular and graphical analyses were performing using Comprehensive Meta-Analysis software, version 3 (BioStat, Englewood, NJ). Combined weighted proportions were determined by use of the Stata 15.0 software package (Stata Corp LP, College Station, TX).

Risk of bias and quality assessment

Risk of bias and quality of observational studies was evaluated using the Newcastle–Ottawa Quality Assessment Scale and JADAD score for quality of randomized trials [18, 19]. In this study, high quality was defined as a Newcastle–Ottawa Quality Assessment Scale score of ≥ 4. Assessment of study quality using the Newcastle–Ottawa Quality Assessment Scale detailed type of study (population-based, multi-center, or single-center study), sample size of cohort, reporting technical and clinical success, information on reported adverse events, full-manuscript or abstract, attrition or loss to follow-up rate (maximum score of 7) [18]. High quality for randomized studies was characterized by a JADAD score of ≥ 3. The JADAD scoring system incorporates description of study randomization (as well as appropriateness), double-blinding of study and method, and description of loss to follow-up or participant withdrawal [19]. Two authors (TRM and KH) independently extracted data and assessed the risk of bias and study quality for each of the articles. Any disagreements were resolved by discussion and consensus, and in consultation with the third reviewer (ANB).

Investigations of heterogeneity and prediction interval

Heterogeneity was assessed for the individual meta-analyses using the Chi-squared test and the I^2 statistic [20]. Significant heterogeneity was defined as $P > 0.05$ using the Cochran Q test or $I^2 > 50\%$, with values $> 50\%$ indicating substantial heterogeneity. Further quantification of heterogeneity was categorized based upon I^2 with values of 25%, 50%, and 75% indicating low, moderate, and high amounts of heterogeneity, respectively. Given the use of random effects model to estimate average effect, a 95% prediction interval was calculated to determine the dispersion of effects and clearly illustrate heterogeneity in the calculated effect size [16, 21–24].

Publication bias

To assess for publication bias, a funnel plot was created and visually inspected for asymmetry and quantitatively using Egger regression testing [25, 26]. The trim and fill method was used to correct for funnel plot asymmetry and provide an adjusted effect [27]. The classic fail-safe test was also applied to assess risk of bias across studies.

Results

Search results and study characteristics

This systematic review and meta-analysis included a total of 36 studies ($n = 1538$) [9, 12, 25–58]. A PRISMA flow chart of search results is shown in Fig. 1. Thirty-five included studies were published as full-text manuscripts

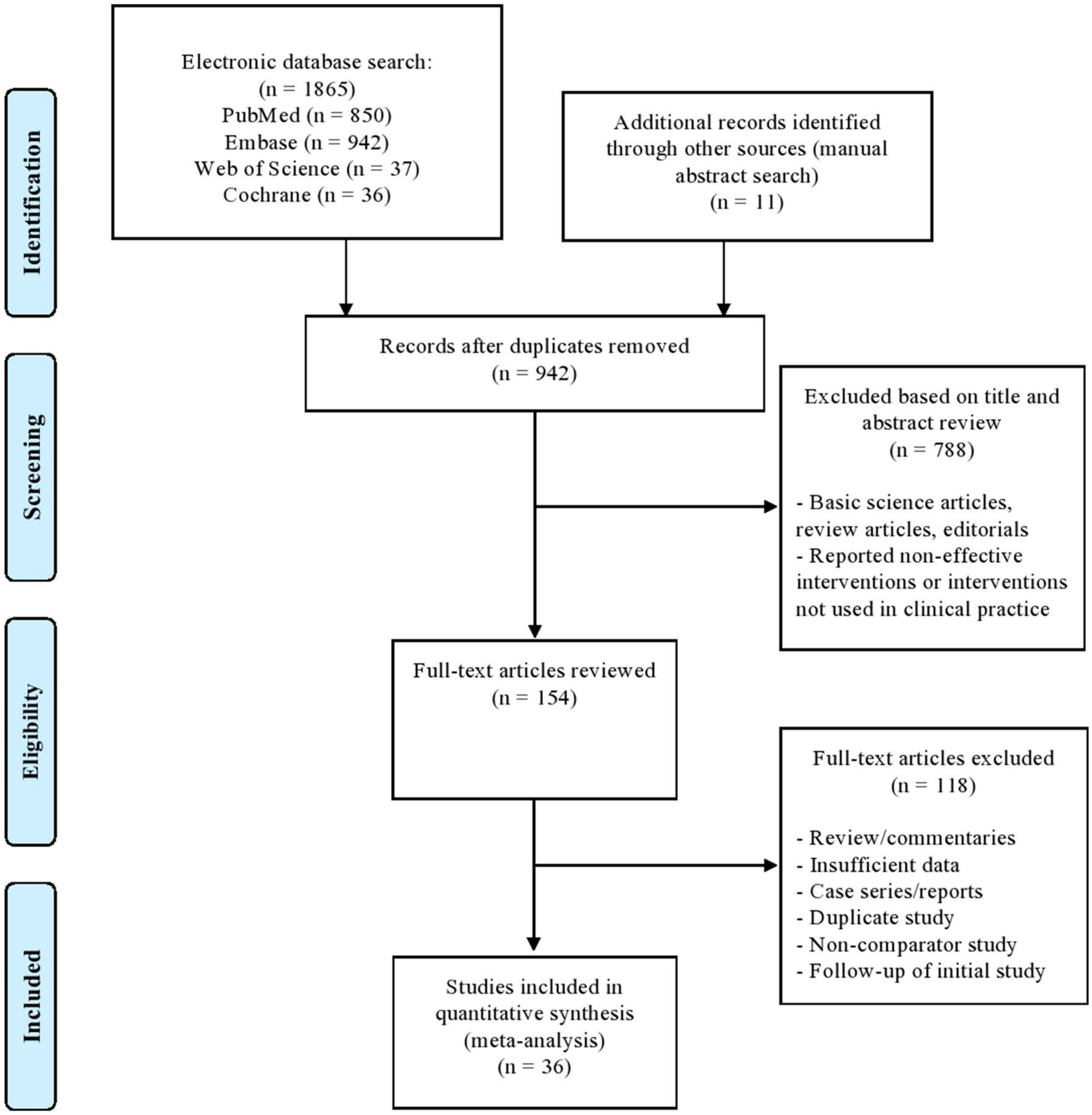

Fig. 1 Preferred reporting items for systematic reviews and meta-analyses (PRISMA) flow chart of literature search results

ranging from 1991 to 2019 with one abstract from 2019. Four randomized controlled trials, 8 prospective studies, and 24 retrospective studies were included in this analysis. Twenty-six studies were single-center in nature with the remaining studies being multi-center in design. A total of 17 studies ($n = 558$) reported outcomes for EUS-guided transmural GB drainage with 22 articles ($n = 980$) documenting measured outcomes of ERC-assisted transpapillary drainage. A cumulative table of included studies with patient and study characteristics is highlighted in Table 1.

Patient and procedure characteristics

Of the 1538 patients included in this study, 57.35% were male. The mean age of all patients who underwent endoscopic GB drainage was 68.45 ± 7.58 years with average follow-up of 11.10 ± 7.68 months. Mean procedure time for all endoscopic procedures was 28.33 ± 14.94 min. Figure 2 provides a diagram of EUS-guided transmural, ERC-assisted transpapillary, and percutaneous transhepatic GB drainage. Stratifying by type of procedure, mean age for

Table 1 Patient and study characteristics of endoscopic gallbladder drainage

Author	Year	Country	Study type and design	Catheter or stent type	No of Pts	No male	Mean age (yrs)	Follow-up (months)	Gallbladder pathology	Procedure time (min)	Technical success rate (%)	Clinical success rate %)	Adverse event rate (%)	Reintervention rate (%)	Recurrence rate (%)	Quality assessment
EUS-guided transmural drainage																
Lee SS et al	2007	Korea	Single-center prospective non-comparator study	Nasobiliary tube	9	5 (55.56%)	68.78 ± 9.47	–	–	20 (10 to 35)	9/9 (100.00%)	9/9 (100.00%)	1/9 (11.11%)	–	–	5
Song et al	2010	Korea	Single-center prospective non-comparator study	Plastic stent	8	3 (37.50%)	72 (59–81)	6.2 (0.73–10)	4 calculous cholecystitis, 4 acalculous cholecystitis	28 (17 to 32)	8/8 (100.00%)	8/8 (100.00%)	3/8 (3.50%)	–	0/8 (0.00%)	5
Itoi et al	2012	Japan	Single-center retrospective non-comparator study	LAMS (AXIOS)	5	3 (60.00%)	72.60 ± 7.27	9	–	23.40 ± 5.96	5/5 (100.00%)	5/5 (100.00%)	0/5 (0.00%)	–	–	5
Jang et al	2012	Korea	Single-center randomized controlled trial vs percutaneous cholecystostomy	Nasobiliary tube or pigtail drain	30	17 (56.67%)	62 ± 15	3	25 calculous cholecystitis, 5 acalculous cholecystitis	23 ± 7	29/30 (96.67%)	29/30 (96.67%)	2/30 (6.67%)	–	–	4
de la Serna-Higuera et al	2013	Spain	Single-center retrospective non-comparator study	LAMS (AXIOS)	13	8 (61.54%)	79.92 (57–97)	3.36	13 calculous cholecystitis	–	11/13 (84.62%)	11/13 (84.62%)	2/13 (15.38%)	–	–	5
Choi et al	2014	Korea	Single-center retrospective non-comparator study	SEMS	63	33 (52.38%)	68 (38 to 90)	9.17 (1.33–39.50)	50 calculous cholecystitis, 13 acalculous cholecystitis	22.40 ± 3.50	62/63 (98.41%)	62/63 (98.41%)	7/63 (11.11%)	2/63 (3.17%)	2/63 (3.17%)	6

Table 1 (continued)

Author	Year	Country	Study type and design	Catheter or stent type	No of Pts	No male	Mean age (yrs)	Follow-up (months)	Gallbladder pathology	Procedure time (min)	Technical success rate (%)	Clinical success rate %)	Adverse event rate (%)	Reintervention rate (%)	Recurrence rate (%)	Quality assessment
Moon et al	2014	Korea	Multi-center retro-spective non-com-parator study	LAMS (AXIOS)	7	5 (71.43%)	–	5 (3–6)	–	–	7/7 (100.00%)	7/7 (100.00%)	0/7 (0.00%)	–	–	5.5
Walter et al	2015	Interna-tional	Multi-center prospec-tive non-com-parator study	LAMS (AXIOS)	30		–	9.93 ± 2.73	–	–	27/30 (90.00%)	26/30 (86.67%)	4/30 (13.33%)	–	2/30 (6.67%)	6.5
Ge et al	2016	China	Single-center retro-spective non-com-parator study	LAMS	7	3 (42.86%)	73.2 (65–85)		–	9.8	7/7 (100.00%)	7/7 (100.00%)	0/7 (0.00%)	–	0/7 (0.00%)	5
Kahalel et al. (SEMS)	2016	Interna-tional	Multi-center retro-spective non-com-parator study	Fully Covered SEMS	6		81 (13.7)	3.05	–	–	6/6 (100.00%)	6/6 (100.00%)	3/6 (50.00%)	0/6 (0.00%)	0/6 (0.00%)	5.5
Kahalel et al. (Plastic)	2016	Interna-tional	Multi-center retro-spective non-com-parator study	Plastic stent	6		81 (13.7)	3.05	–	–	6/6 (100.00%)	6/6 (100.00%)	2/6 (33.33%)	0/6 (0.00%)	0/6 (0.00%)	5.5
Kahalel et al. (Com-bined Stents)	2016	Interna-tional	Multi-center retro-spective non-com-parator study	Combina-tion of stents	7		81 (13.7)	3.05	–	–	7/7 (100.00%)	7/7 (100.00%)	0/7 (0.00%)	0/6 (0.00%)	0/6 (0.00%)	5.5
Kamata et al	2017	Japan	Single-center retro-spective non-com-parator study	Partially covered SEMS (Wall-Flex)	12	9 (75.00%)	76.3 ± 2.1	10.13	–	–	12/12 (100.00%)	12/12 (100.00%)	0/12 (0.00%)	–	1/12 (8.33%)	5

Table 1 (continued)

Author	Year	Country	Study type and design	Catheter or stent type	No of Pts	No male	Mean age (yrs)	Follow-up (months)	Gallbladder pathology	Procedure time (min)	Technical success rate (%)	Clinical success rate %)	Adverse event rate (%)	Reintervention rate (%)	Recurrence rate (%)	Quality assessment
Dollhopf et al	2017	International	Multi-center retro-spective non-comparator study	LAMS (AXIOS)	75	36 (48%)	75 ± 11	16.75 ± 18.83	53 calculous cholecystitis	26 (8–60)	74/75 (98.7%)	71/74 (95.9%)	9/75 (10.7%)	5/75 (6.7%)	3/71 (4.23%)	6.5
Manta et al	2018	Italy	Single-center retro-spective non-comparator study	LAMS (AXIOS)	16	9 (56.25%)	84.8 (49–97)	3.73	12 calculous cholecystitis, 3 acalulous cholecystitis, 2 biliary obstructions	–	16/16 (100.00%)	15/16 (93.75%)	2/16 (12.5%)	2/16 (12.5%)	1/16 (6.25%)	5.5
Higa et al	2019	USA	Single-center retrospective comparator study vs trans-papillary drainage	LAMS (AXIOS)	40	24 (60.0%)	69.5 (31–96)	7 (< 1–20)	16 calculous cholecystitis, 24 acalculous cholecystitis	–	39/40 (97.5%)	38/40 (95%)	7/39 (17.9%)	7/39 (17.9%)	1/39 (2.6%)	6
Oh et al	2019	Korea	Single-center retrospective comparator study vs trans-papillary drainage	LAMS (AXIOS)	83	33 (39.8%)	68.4 ± 11.4	18.6 ± 21.1	50 calculous cholecystitis, 33 acalculous cholecystitis	18.3 ± 4.9	82/83 (98.8%)	82/83 (98.8%)	6/83 (7.25)	–	3/76 (3.61%)	6
Siddiqui et al	2019	International	Multi-center retrospective comparator study vs trans-papillary drainage vs percutaneous cholecystostomy	LAMS (AXIOS)	102	58 (56.6%)	72.4 ± 13.4	4 (3–9)	75 calculous cholecystitis, 27 acalculous cholecystitis	–	96/102 (94%)	92/102 (90%)	12/102 (11.8%)	4/102	–	6.5

Table 1 (continued)

Author	Year	Country	Study type and design	Catheter or stent type	No of Pts	No male	Mean age (yrs)	Follow-up (months)	Gallbladder pathology	Procedure time (min)	Technical success rate (%)	Clinical success rate %)	Adverse event rate (%)	Reintervention rate (%)	Recurrence rate (%)	Quality assessment
Teoh et al. (Abstract)	2019	International	Multi-center randomized controlled trial of EUS-guided transmural versus percutaneous	LAMS (AXIOS)	39	22 (56.41%)	81.9 ± 9.6		–	22.9 ± 13.1	38/39 (97.44%)	36/39 (92.31%)	4/39 (10.26%)	–	2/39 (5.13%)	5
ERC-Based Transpapillary Drainage																
Tamada et al	1991	Japan	Single-Center Retrospective Non-Comparator Study	Plastic Stent	14	9 (64.3%)	65		–	–	14/14 (100%)	9/14 (64%)	0/14 (0%)	–	–	5
Feretis et al	1993	Greece	Single-Center Prospective Non-Comparator Study	Nasobiliary tube	18	8 (4%)	67 (42–81)		18 calculous cholecystitis	–	16/18 (89%)	16/18 (88.89%)	0/16 (0%)	10/16 (62.5%)	–	5.5
Nakatsu et al	1997	Japan	Single-Center Retrospective Non-Comparator Study	Nasobiliary tube or aspiration	21	6 (28.57%)	66 ± 11		17 calculous cholecystitis	–	17/21 (81%)	17/21 (81%)	0/21 (00)	0/17 (0%)	0/17 (0%)	5.5
Schlenker et al	2006	USA	Single-Center Prospective Non-Comparator Study	Plastic stent	23	18 (78.3%)	48.52 (29–62)		–	–	23/23 (100%)	23/23 (100%)	0/23 (0%)	8/23 (34.8%)	3/23 (13%)	5.5
Kjaer et al	2007	Denmark	Single-Center Prospective Non-Comparator Study	Nasobiliary tube or plastic stent	34				31 calculous cholecystitis, 3 acalculous cholecystitis	–	24/34 (70.6%)	21/34 (61.76%)	4/34 (11.8%)	0/24 (0%)	–	6

Table 1 (continued)

Author	Year	Country	Study type and design	Catheter or stent type	No of Pts	No male	Mean age (yrs)	Follow-up (months)	Gallbladder pathology	Procedure time (min)	Technical success rate (%)	Clinical success rate %)	Adverse event rate (%)	Reintervention rate (%)	Recurrence rate (%)	Quality assessment
Itoi et al	2008	Japan	Single-Center Retrospective Non-Comparator Study	Nasobiliary Tube	43	18 (41.9%)	72 (62–92)		39 calculous cholecystitis, 4 acalculous cholecystitis	–	36/43 (83.7%)	35/43 (81.40%)	0/43 (0%)	0/36 (0%)	0/36 (0%)	6
Ogawa et al	2008	Japan	Single-Center Retrospective Non-Comparator Study	Nasobiliary Tube	11	8 (72.7%)	68.73 ± 11.98		–	–	7/11 (63.6%)	7/11 (63.6%)	1/11 (9.1%)	–	–	5
Pannala et al	2008	USA	Single-Center Retrospective Non-Comparator Study	Nasobiliary tube or plastic stent	51	34 (66.67%)	62 ± 19		39 calculous, 3 acalculous, 5 malignancy, 3 others	75 ± 42		–	8/51 (15.69%)	–	–	6
Conway et al	2009	USA	Single-Center Retrospective Non-Comparator Study	Plastic stent	29	20 (69%)	46.9 ± 12.5	9.4	20 recurrent biliary colic, 7 calculous cholecystitis, 2 acalculous cholecystitis	43	26/29 (90%)	26/29 (90%)	2/29 (6.9%)	1/26 (3.8%)	1/26 (3.8%)	6
Mutignani et al	2009	Italy	Single-Center Retrospective Non-Comparator Study	Nasobiliary tube or plastic stent	35	23 (65.71%)	65 (34–92)	17	16 acalculous cholecystitis, 19 calculous cholecystitis	–	29/36 (83%)	24/36 (66.67%)	2/35 (6%)	2/21 (10%)	2/21 (10%)	6
Lee et TH al	2011	Korea	Multi-Center Prospective Non-Comparator Study	Plastic stent	29	14 (48.28%)		20	23 calculous cholecystitis, 6 acalculous cholecystitis	–	23/29 (79.31%)	23/29 (79.31%)	7/29 (24.14%)	0/20 (0.00%)	2/29 (6.90%)	6

Table 1 (continued)

Author	Year	Country	Study type and design	Catheter or stent type	No of Pts	No male	Mean age (yrs)	Follow-up (months)	Gallbladder pathology	Procedure time (min)	Technical success rate (%)	Clinical success rate %)	Adverse event rate (%)	Reintervention rate (%)	Recurrence rate (%)	Quality assessment
Maekewa et al	2013	Japan	Single-Center Retrospective Non-Comparator Study	plastic stent	46	25 (54.35%)	79.7 ± 197.96		40 calculous cholecystitis, 6 acalculous cholecystitis	27.6	37/46 (80.43%)	37/46 (80.43%)	1/46 (2.17%)	9/46 (19.57%)	1/31 (3.23%)	6
Widmer et al. also Kahalel	2015	USA	Multi-Center Retrospective Comparator Study Vs EUS-Guided Transmural Drainage	Plastic stent	128				–	–	117/128 (91.41%)	–	–	–	–	5.5
McCarthy et al	2015	USA	Single-Center Retrospective Non-Comparator Study	Plastic stent	29	17 (58.62%)	70 (40–91)		17 calculous cholecystitis, 5 acalculous, 5 biliary colic, 5 choledocholithiasis	–	22/29 (75.86%)	18/29 (62.07%)	2/29 (6.90%)	–	2/29 (6.90%)	5.5
Yane et al	2015	Japan	Single-Center Prospective Non-Comparator Study	Nasobiliary tube	27	12 (44.44%)	65.6 ± 15.2		24 calculous cholecystitis, 3 acalculous cholecystitis	35.5 ± 19.9	21/27 (77.78%)	20/27 (74.07%)	4/27 (14.81%)	–	–	5.5
Itoi et al. (Nasobiliary)	2015	Japan	Multi-Center Randomized Controlled Trial of Nasogallbladder Drainage vs Endoscopic Stenting	Nasobiliary tube	37	25 (67.57%)	69.5 ± 12.4		35 calculous cholecystitis, 2 acalculous cholecystitis	20.3 ± 12.1	34/37 (91.89%)	32/37 (86.49%)	2/37 (5.41%)	–	–	4

Table 1 (continued)

Author	Year	Country	Study type and design	Catheter or stent type	No of Pts	No male	Mean age (yrs)	Follow-up (months)	Gallbladder pathology	Procedure time (min)	Technical success rate (%)	Clinical success rate %)	Adverse event rate (%)	Reintervention rate (%)	Recurrence rate (%)	Quality assessment
Itoi et al. (Stent)	2015	Japan	Multi-Center Randomized Controlled Trial of Nasogallbladder Drainage vs Endoscopic Stenting	Plastic Stent	36	22 (61.11%)	67.3 ± 13.9		32 calculous cholecystitis, 4 acalculous cholecystitis	22.2 ± 14.5	31/36 (86.11%)	28/36 (77.78%)	1/36 (2.78%)	–	–	4
Yang et al. (Nasobiliary)	2015	Korea	Multi-Center Randomized Controlled Trial of Nasogallbladder Drainage vs Endoscopic Stenting	Nasobiliary tube	17	11 (64.71%)	62.5 ± 16.4		15 calculous cholecystitis, 2 acalculous cholecystitis	42.9 ± 17.3	14/17 (82.35%)	12/17 (70.59%)	3/17 (17.65%)	–	–	4
Yang et al. (Stent)	2015	Korea	Multi-Center Randomized Controlled Trial of Nasogallbladder Drainage vs Endoscopic Stenting	Plastic stent	18	7 (38.89%)	52.7 ± 15.9		16 calculous cholecystitis, 2 acalculous cholecystitis	35.9 ± 9.1	16/18 (88.89%)	15/18 (83.33%)	2/18 (11.11%)	–	–	4

Table 1 (continued)

Author	Year	Country	Study type and design	Catheter or stent type	No of Pts	No male	Mean age (yrs)	Follow-up (months)	Gallbladder pathology	Procedure time (min)	Technical success rate (%)	Clinical success rate %)	Adverse event rate (%)	Reintervention rate (%)	Recurrence rate (%)	Quality assessment
Inoue et al	2015	Japan	Single-Center Retrospective Comparator Study vs Percutaneous Cholecystostomy	Plastic stent	33	22 (66.67%)	76 (47–96)	15.77	33 calculous cholecystitis	–	29/35 (82.86%)	–	3/33 (9.09%)	–	0/33 (0.00%)	6
Iino et al	2018	Japan	Single-Center Retrospective Comparator Study vs Percutaneous Cholecystostomy	Nasobiliary tube or plastic stent	43	15 (34.09%)	77.9 ± 12.6		–	–	33/43 (76.74%)	–	4/43 (9.3%)	–	–	6
Higa et al	2019	USA	Single-Center Retrospective Comparator Study vs EUS-Guided Transmural Drainage	Plastic stent	38	25 (65.79%)	67.5 (31–95)	5	27 calculous cholecystitis, 11 acalculous cholecystitis	–	32/38 (84.21%)	29/38 (76.32%)	3/32 (9.38%)	7/32 (21.88%)	6/32 (18.75%)	6
Oh et al	2019	Korea	Single-Center Retrospective Comparator Study vs EUS-Guided Transmural Drainage	Plastic stent	96	66 (68.75%)	65.6 ± 14.4	25.5 ± 21.9	80 calculous cholecystitis, 16 acalculous cholecystitis	19.5	80/96 (83.33%)	79/96 (82.29%)	9/96 (9.38%)	–	12/69 (12.50%)	6

Table 1 (continued)

Author	Year	Country	Study type and design	Catheter or stent type	No of Pts	No male	Mean age (yrs)	Follow-up (months)	Gallbladder pathology	Procedure time (min)	Technical success rate (%)	Clinical success rate %)	Adverse event rate (%)	Reintervention rate (%)	Recurrence rate (%)	Quality assessment
Siddiqui et al	2019	International	Multi-Center Retrospective Comparator Study vs EUS-Guided Transmural Drainage vs Percutaneous Cholecystostomy	Plastic stent	124	84 (67.74%)	60.3 ± 16.8	3 (3–6)	85 calculous cholecystitis, 39 acalculous cholecystitis	–	109/124 (87.90%)	99/124 (79.84%)	9/124 (7.26%)	4/124 (11.29%)	–	6.5

EUS-guided transmural was 72.41 ± 5.38 years. Transmural access to the gallbladder was via a transduodenal route 51.23% of the time, with transgastric access accounting for 48.15% of cases, and 3 procedures (0.62%) utilizing a transjejunal approach. Average follow-up and mean procedure duration for studies evaluating transmural drainage was 9.67 ± 5.90 months and 22.11 ± 3.45 min. Only two studies documented gallbladder wall thickness and found a mean thickness of 4.89 ± 0.32 mm. Mean age in studies evaluating ERC-assisted transpapillary GB drainage was 65.83 ± 7.69 years. Average follow-up for transpapillary drainage was 12.96 ± 9.20 months. Procedure time for the ERC-assisted procedure was 33.89 ± 18.63 min.

Efficacy and safety of endoscopic gallbladder drainage

Endoscopic gallbladder drainage achieved a cumulative pooled technical and clinical success of 87.33% [(95% CI 84.42–89.77); $I^2 = 39.55$; prediction interval 40.18–97.88] and 84.16% [(95% CI 80.30–87.38); $I^2 = 52.61$; prediction interval 10.90 to 98.18], respectively—Fig. 3A, B. The cumulative rate of procedure-related adverse events was 11.00% [(95% CI 9.25–13.03); $I^2 = 7.08$); prediction interval − 22.28 to 41.98]—Fig. 3C. A summary of reported adverse events by individual study is highlighted in Supplemental Table 1. Despite endoscopic treatment with either EUS-guided transmural or ERC-assisted transpapillary GB drainage, rate of recurrent disease and reintervention was 7.62% (95% CI 5.60–10.30); $I^2 = 9.56$) and 11.43% (95% CI 6.97–18.18); $I^2 = 70.00$)—Fig. 4A, B. Pooled primary and secondary outcomes as stratified by endoscopic method of GB drainage are shown in Table 2. Forest plots of primary outcomes for endoscopic transmural and transpapillary drainage are illustrated in Figs. 5 and 6. Among patients who eventually required surgical GB removal, EUS-guided transmural GB drainage did not increase complication rate or preclude laparoscopic or open cholecystectomy for any patient ($n = 53$ cholecystectomies eventually performed with 100% success rate).

Sensitivity analyses limited to only randomized controlled trials and prospective studies were also performed. Pooled technical and clinical success of endoscopic GB drainage was 86.70% [(95% CI 80.99–90.89); $I^2 = 31.70$] and 82.93% [(95% CI 76.12–88.10); $I^2 = 43.96$] with an adverse event rate of 12.44% [(95% CI 8.73–17.42); $I^2 = 18.59$]—Supplemental Fig. 1. In an effort to better reflect more current clinical practice, additional analyses were performed for EUS-guided outcomes with LAMS drainage as well as ERC-assisted drainage with plastic stents. Among studies that only evaluated LAMS placement for EUS-guided GB drainage, technical success was 94.65% [(95% CI 91.54–96.67); $I^2 = 0.00$], clinical success was 92.06% [(95%

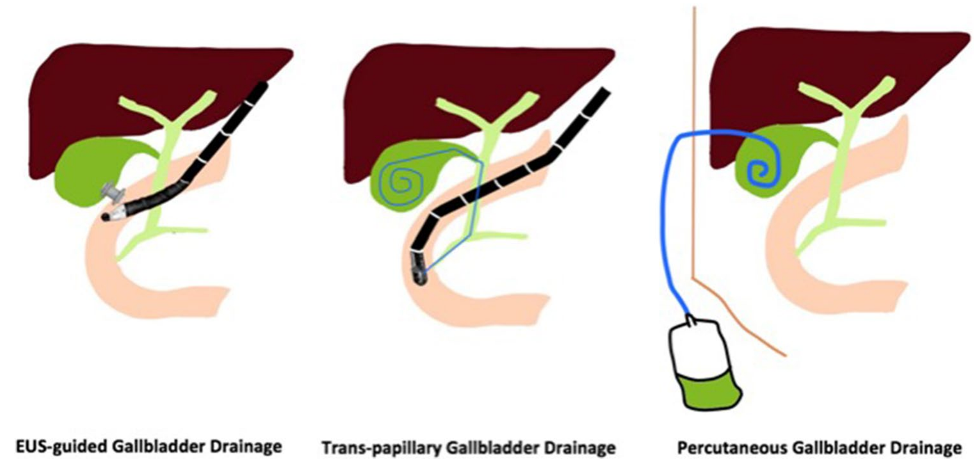

Fig. 2 Procedural diagram of EUS-guided transmural, ERC-assisted transpapillary, and percutaneous transhepatic gallbladder drainage

CI 88.65–94.51); $I^2=0.00$], and rate of adverse events was 11.71% [(95% CI 8.92–15.23); $I^2=0.00$]—Supplemental Fig. 2. Technical success, clinical success, and adverse event rate for studies that assessed plastic stent placement for transpapillary GB drainage was 85.58% [(95% CI 82.42–88.26); $I^2=4.14$], 78.74% [(95% CI 73.89–82.89); $I^2=20.65$], and 8.76% [(95% CI 6.11–12.40); $I^2=18.58$], respectively—Supplemental Fig. 3.

EUS-guided transmural versus ERC-assisted transpapillary gallbladder drainage

On subgroup analyses among direct comparator studies, EUS-guided transmural as compared to ERC-assisted transpapillary GB drainage resulted in a significantly higher technical and clinical success rate [OR 3.914 (95% CI 1.52–10.09); $P=0.005$ and OR 4.59 (95% CI 1.84–11.46); $P=0.001$; respectively] [27, 37, 38, 52, 59]. Endoscopic ultrasound-guided drainage also resulted in a lower rate of recurrence [OR 0.17 (95% CI 0.06–0.52); $P=0.002$]. There was no significant difference in adverse events or need for repeat intervention between the two endoscopic approaches [OR 1.35 (95% CI 0.72–2.52); $P=0.35$ and OR 0.94 (95% CI 0.38–2.31); $P=0.89$; respectively].

Endoscopic versus percutaneous transhepatic gallbladder drainage

Among studies comparing endoscopic versus percutaneous transhepatic GB drainage, EUS-guided drainage was associated with a significantly lower rate of reintervention [OR 0.05 (95% CI 0.02–0.13); $P<0.001$] [29, 38, 39, 57–62]. Technical success, clinical success, rate of adverse events, and recurrence rates between both approaches were similar [technical success: OR 0.37 (95% CI 0.14–1.00); $P=0.050$; clinical success: 0.62 (95% CI 0.30 to 1.29); $P=0.202$; adverse events: OR 0.50 (95% CI 0.15–1.68); $P=0.265$; recurrence: OR 0.49 (95% CI 0.12 to 1.99); $P=0.320$]—Table 2. For studies comparing ERC-assisted GB drainage to a percutaneous transhepatic approach, transpapillary endoscopic drainage demonstrated a lower technical and clinical success [OR 0.16 (95% CI 0.06–0.43); $P<0.001$ and OR 0.14 (95% CI, 0.06–0.36); $P<0.001$]. There was no difference in rate of adverse events [OR 1.77 (95% CI 0.78–4.0); $P=0.172$]. A transpapillary drainage approach also showed a lower rate of recurrence and decreased reintervention rate [OR 0.04 (95% CI 0.00–0.65); $P=0.024$ and OR 0.12 (95% CI 0.07–0.24); $P<0.00$].

Risk of bias assessment

All observational studies were evaluated using the Newcastle–Ottawa Quality Assessment Scale scores and randomized controlled trials with JADAD score. Quality assessment for each study shown in Table 1. All included studies were considered to be of high quality with Newcastle–Ottawa Quality Assessment Scale scores ≥ 4 or JADAD scores of ≥ 3. Publication bias was also assessed. Visual inspection of the funnel plot demonstrated that smaller and statistically insignificant studies appeared to be missing likely due to publication bias—Fig. 7A. With the Duval and Tweedie's trim and fill method, overall technical success was slightly decreased to 79.88% (95% CI 79.88–87.17)—Fig. 7B. Using the classic fail-safe test to assess for publication bias, it was determined it would take 4757 non-significant studies to nullify the results of this analysis.

Discussion

Although early laparoscopic cholecystectomy will remain the treatment of choice for patients with symptomatic GB disease, many patients may be poor surgical candidates necessitating an alternative treatment approach [16].

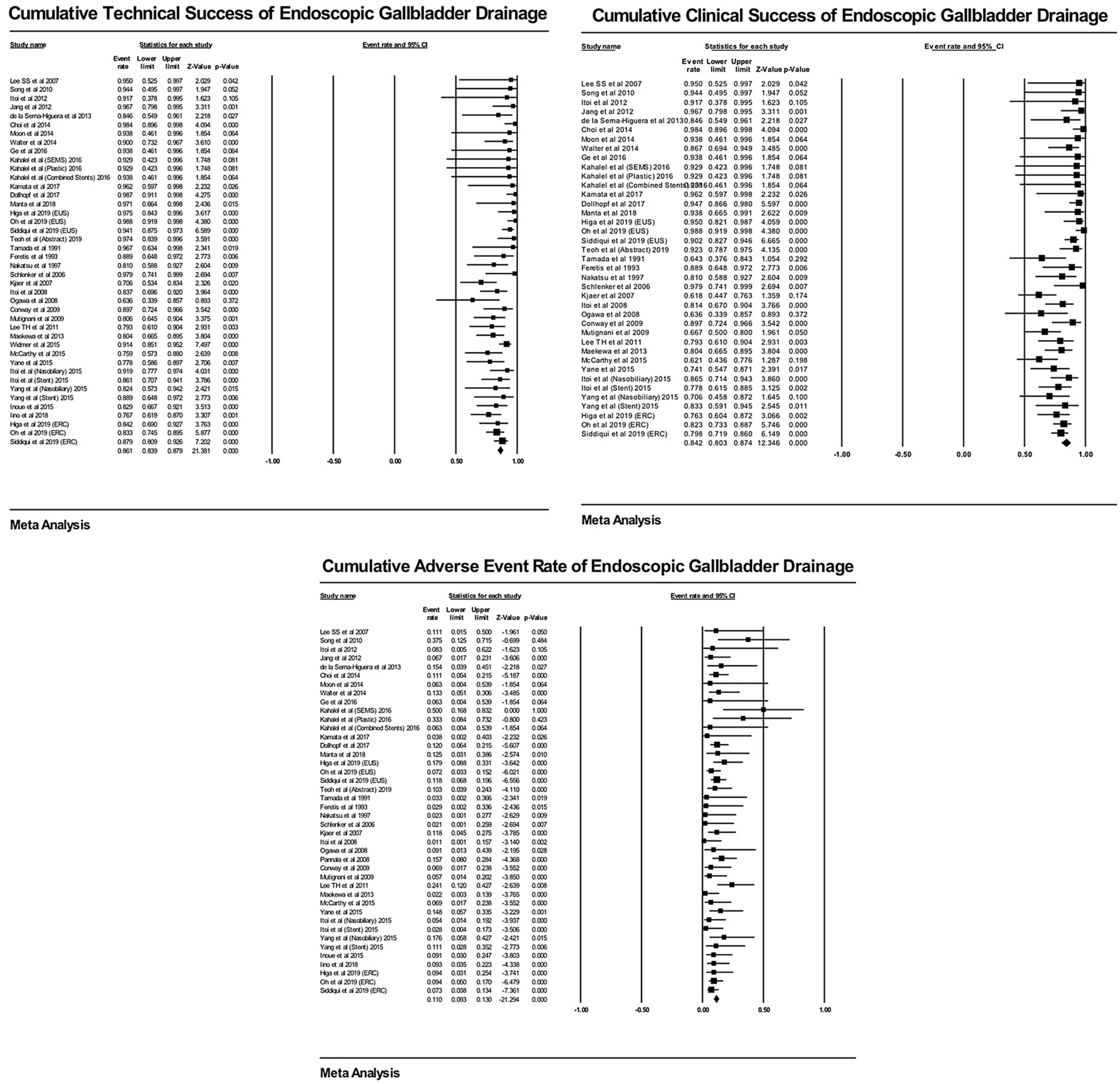

Fig. 3 Cumulative technical success, clinical success, and rate of adverse events for endoscopic gallbladder drainage

Endoscopic GB drainage was first proposed by Kozarek et al. in 1984, and first performed in 1990 by Feretis and colleagues [63, 64]. While the procedure has evolved significantly from a traditional transpapillary approach to more novel EUS-guided transmural GB drainage, both remain feasible options for patients with symptomatic GB disease who are high-risk surgical candidates. The results of this systematic review and meta-analysis suggest endoscopic GB drainage is a safe and effective alternative treatment strategy for patients with acute cholecystitis.

Endoscopic gallbladder drainage—evolution of technique

Endoscopic GB drainage may be accomplished utilizing either the transpapillary or transmural approach. The transpapillary method of GB drainage involves cannulation of the cystic duct using an ERC-assisted approach. Drainage is subsequently achieved with nasobiliary aspiration or placement of a plastic stent. In the transmural approach, a cholecystogastric or cholecystoduodenal fistula is created using EUS

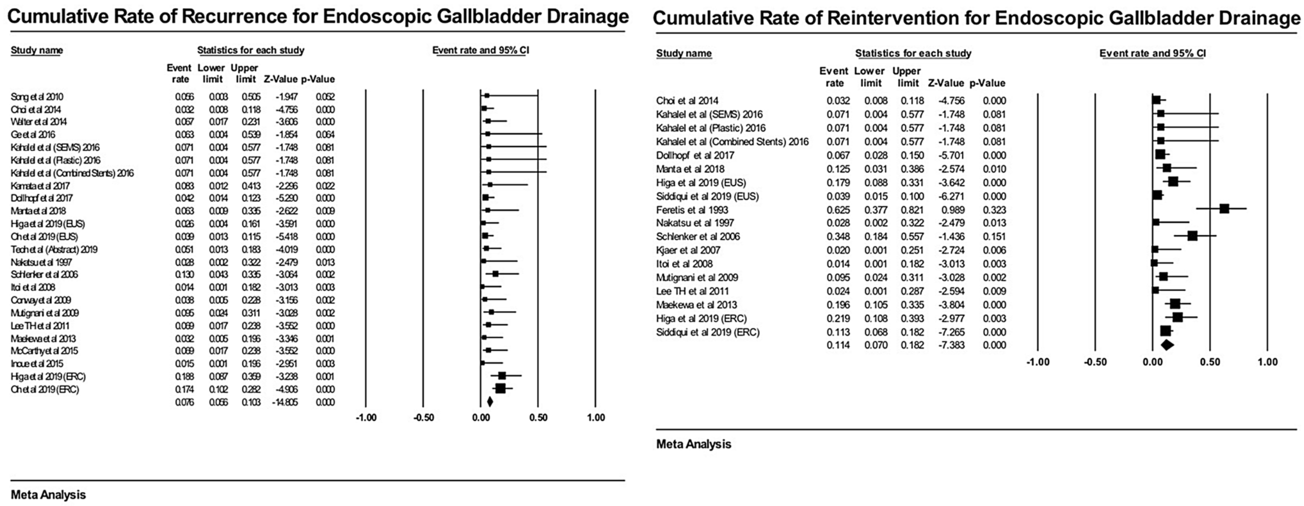

Fig. 4 Cumulative rate of recurrence and reintervention rate for endoscopic gallbladder drainage

Table 2 Cumulative and comparative data to assess EUS-guided transmural versus ERC-assisted transpapillary gallbladder drainage

	Cumulative data			Comparative data					
	Total (%)	EUS-guided transmural (%)	ERC-assisted transpapillary (%)	Transmural versus transpapillary odds ratio	*P* Value	Transmural versus percutaneous odds ratio	*P* value	Transpapillary versus percutaneous odds ratio	*P* Value
Technical Success Rate	87.33% (95% CI 84.42–89.77) $I^2=39.55$	95.01% (95% CI 92.52–96.70) $I^2=0.00$)	83.42% (95% CI 80.45–86.02) $I^2=14.60$)	3.91 (95% CI 1.52–10.09)	0.005	0.37 (95% CI 0.14–1.00)	0.050	0.16 (95% CI 0.06–0.43)	<0.001
Clinical Success Rate	84.16% (95% CI 80.30–87.38) $I^2=52.61$	92.80% (95% CI 90.04–94.83) $I^2=0.00$)	77.11% (95% CI 73.04–80.74) $I^2=24.76$)	4.59 (95% CI 1.84–11.46)	0.001	0.62 (95% CI 0.30–1.29)	0.202	0.14 (95% CI 0.06–0.36)	<0.001
Rate of Adverse Events	11.00% (95% CI 9.25–13.03) $I^2=7.08$	12.69% (95% CI 10.07–15.88) $I^2=0.00$)	9.58% (95% CI 7.52–12.15) $I^2=7.05$)	1.35 (95% CI 0.72–2.52)	0.35	0.50 (95% 015–1.68)	0.265	1.77 (95% CI 0.78–4.0)	0.172
Recurrence Rate	7.62% (95% CI 5.60–10.30) $I^2=9.56$	4.78% (95% CI 3.01–7.51) $I^2=0.00$	9.39% (95% CI 5.82–14.80) $I^2=29.93$	0.17 (95% CI 0.06–0.52)	0.002	0.49 (95% CI 0.12–1.99)	0.320	0.04 (95% CI 0.00–0.65)	0.024
Rate of Reintervention	11.43% (95% CI 6.97–18.18) $I^2=70.00$	7.70% (95% CI 4.53–12.81) $I^2=26.76$)	13.86% (95% CI 7.21–24.98) $I^2=73.90$)	0.94 (95% CI 0.38–2.31)	0.89	0.05 (95% CI 0.02–0.13)	<0.001	0.12 (95% CI 0.07–0.24)	<0.001

with a plastic or metal stent. The development of a LAMS has significantly improved the efficacy and safety, as well as the adoption of this procedure—especially as transpapillary drainage may be challenging to perform due to the anatomy of the cystic duct. Stent development and recent success of LAMS placement for drainage of pancreatic pseudocysts and walled-off pancreatic necrosis has also played a major role in the advancement of EUS-guided GB drainage [65, 66]. Despite more rapid adoption, one perceived risk of the EUS-guided procedure is the theoretical concern that it may result in creation of a permanent fistula [66]. Notably, no patient included in this systematic review and meta-analysis that eventually required a cholecystectomy was prohibited from receiving the surgery after EUS-guided transmural GB

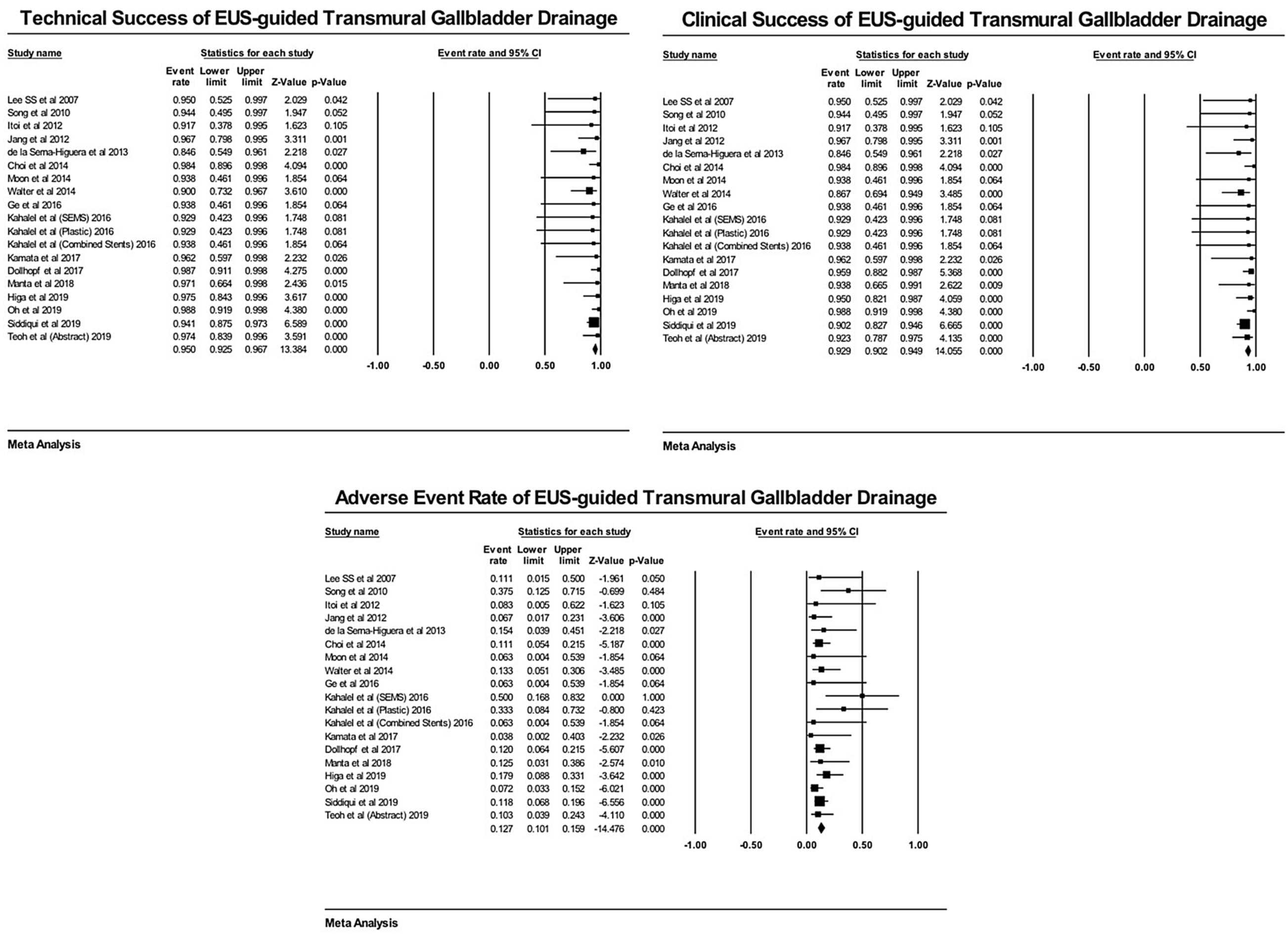

Fig. 5 Technical success, clinical success, and rate of adverse events for EUS-guided transmural gallbladder drainage

drainage. Additionally, EUS-guided transmural gallbladder drainage does not appear to increase risk of adverse events associated with post-procedure cholecystectomy.

Comparison of endoscopic drainage

Based upon the results of this systematic review and meta-analysis, EUS-guided transmural GB drainage was superior to ERC-assisted transpapillary GB drainage. EUS-guided transmural drainage was associated with higher technical and clinical success rates with similar rate of adverse events. While rate of repeat intervention was similar between the two strategies, EUS-guided drainage was also associated with a lower rate of recurrence. These results are not surprising, as the ERC-assisted approach can be limited by lack of visualization of the cystic duct on cholangiogram, potential failure of guidewire cannulation through the cystic duct into the GB, and potential for post-procedure pancreatitis. Other potential benefits of each technique, beyond efficacy and safety, require examination of individual patient comorbidities. Despite EUS-guided transmural drainage being a preferred endoscopic treatment, a transpapillary approach may be best among patients with coagulopathy or refractory ascites. While EUS-guided GB drainage may typically be considered for non-surgical patients with symptomatic GB disease, both endoscopic approaches should be recognized as effective, dependent upon individual patient characteristics.

Endoscopic and percutaneous drainage

Percutaneous transhepatic GB drainage has been the alternative treatment of choice for high-risk surgical patients for several decades. Despite being an efficacious therapy, the percutaneous transhepatic approach may result in patient discomfort as well as a significant risk of bleeding, pneumoperitoneum, bile leakage, and catheter dislodgement [67, 68]. Additionally, long-term adverse events and hospital readmissions related to the external drainage catheter have been reported in up to 12% of cases [69]. In contrast to a percutaneous method, EUS-guided transgastric or transduodenal does not require an external drainage catheter or

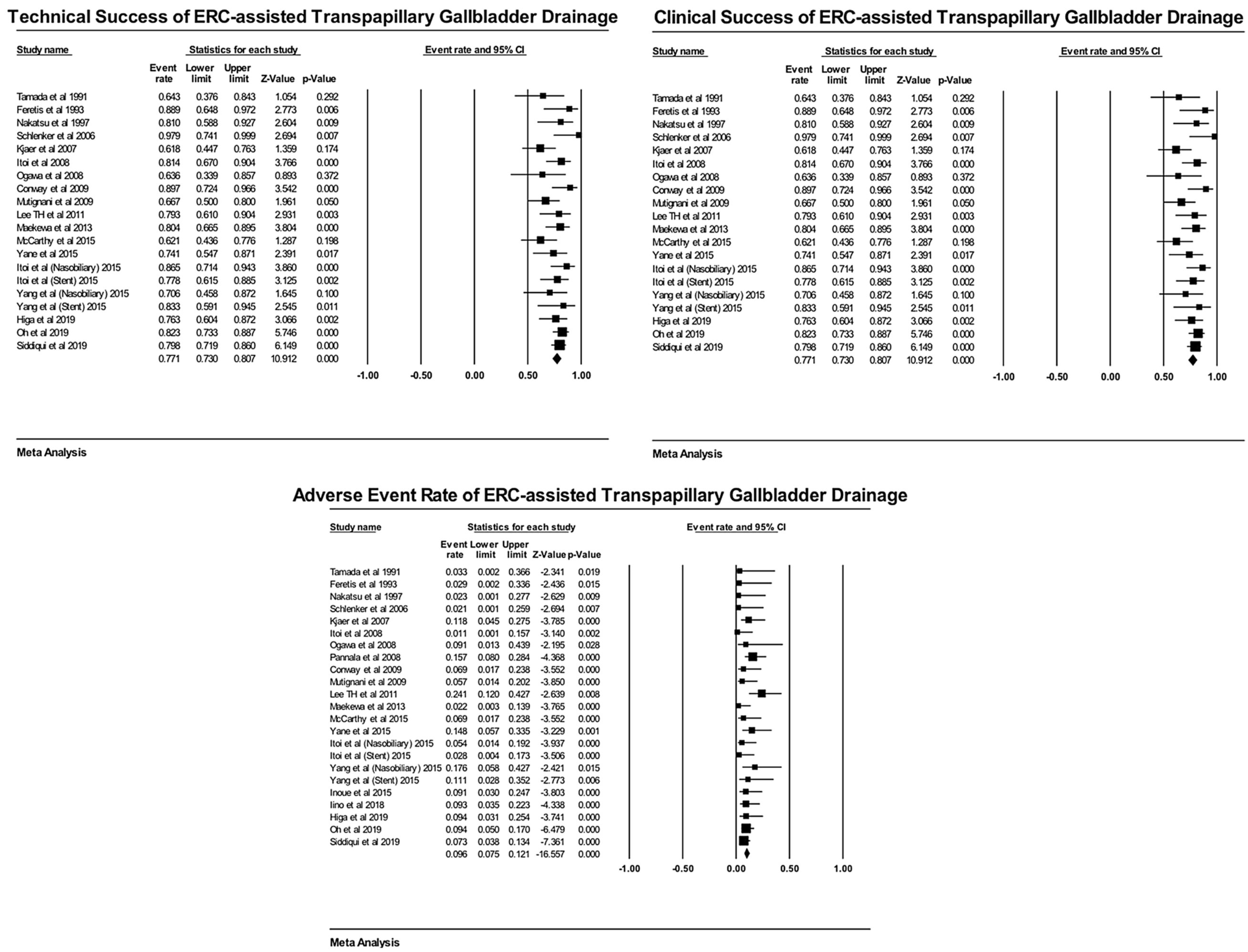

Fig. 6 Technical success, clinical success, and rate of adverse events for ERC-assisted transpapillary gallbladder drainage

management of a catheter and drainage bag, which may significantly affect quality of life [9, 67, 68]. Furthermore, percutaneous drainage has been demonstrated in randomized controlled trials to be associated with similar technical and clinical success but more short- and long-term adverse events when compared directly to EUS-guided transmural drainage with LAMS placement [39]. An additional randomized study included in this systematic review and meta-analysis found no difference in efficacy or safety between the two techniques [29]. Only two randomized trials have evaluated EUS-guided versus percutaneous drainage with no randomized studies comparing percutaneous drainage to an ERC-assisted transpapillary strategy. The results of this systematic review and meta-analysis were based on a majority of retrospective observational studies, but found no significant difference in efficacy and safety between a transmural or transpapillary approach compared to percutaneous transhepatic GB drainage. However, both endoscopic approaches were associated with a lower rate of reintervention.

Limitations and strengths

Specific limitations to this study include significant heterogeneity of included studies as it relates to patient population, follow-up duration, GB pathology and type of endoscopic treatment (including use of multiple types of transmural and transpapillary treatment devices). Furthermore, both randomized and non-randomized studies were included in this analysis with a large reliance upon retrospective observational studies. Publication bias was also assessed and present in this meta-analysis; however, correction of such did not significantly alter our findings given overlapping confidence intervals. Additionally, this study does not address specific patient selection factors which may be important to identify ideal candidates for endoscopic drainage. Lastly, despite the cumulative nature of this systematic review and meta-analysis, it remains important to underscore these results may have limited generalizability to centers with specific clinical expertise needed to perform effective procedures.

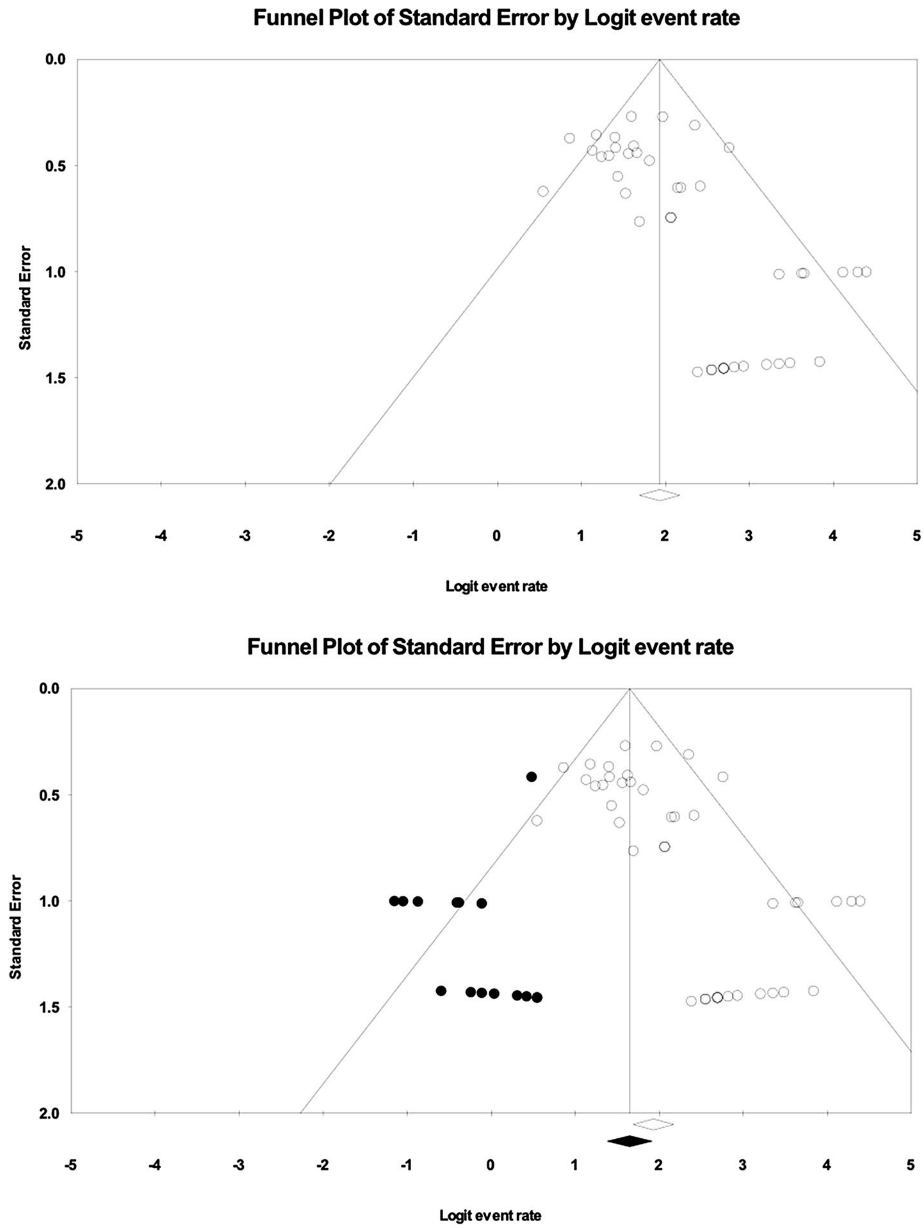

Fig. 7 **A** Funnel plot of publication bias and eggers regression test for included studies to evaluated endoscopic gallbladder drainage. **B** Funnel plot of publication bias with Duval and Tweedie's trim and fill method

Despite these limitations, this study has several strengths. While significant heterogeneity was noted in our meta-analysis and was not surprising given the cumulative nature of reporting results, the prediction interval was calculated to demonstrate and describe the variability, or heterogeneity, of our results within true clinical practice [16, 17, 21, 22, 35]. To these authors' knowledge, this is the first systematic review and meta-analysis to compare EUS-guided transmural and ERC-assisted transpapillary GB drainage as well as compare these findings to a percutaneous transhepatic approach. Sensitivity and subgroup analyses were further performed to improve the accuracy of these findings and better reflect current clinical practice. We hope these findings provide an important step forward in future research and impact clinical decision making among interventional endoscopists.

Conclusions

In conclusion, endoscopic GB drainage is associated with a high technical and clinical success rate and acceptable rate of adverse events among patients with symptomatic GB disease whom are high-risk surgical candidates. Although early laparoscopic cholecystectomy remains the treatment of choice for patients with acute cholecystitis, many individuals who are not surgical candidates will benefit from endoscopic drainage. Among direct comparator studies to evaluate endoscopic techniques, EUS-guided transmural drainage is associated with a superior efficacy and lower risk of recurrence when compared to ERC-assisted transpapillary drainage. Overall, endoscopic GB drainage, preferably with an EUS-guided transmural approach, provides a valuable tool for poor surgical candidates in the treatment of symptomatic GB disease.

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Compliance with ethical standards

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