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Efficacy and safety of EUS-guided hepatogastrostomy: A systematic review and meta-analysis

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ABSTRACT

EUS-guided hepaticogastrostomy (EUS-HGS) is one of the preferred methods in biliary drainage where ERCP fails or is contraindicated. The clinical outcomes of EUS-HGS are not well studied because of variability in procedure technique. We conducted a search of multiple electronic databases and conference proceedings from inception through January 2023. The clinical outcomes studied were pooled technical success, clinical success, and adverse events. Standard meta-analysis methods were used using the random-effects model, and heterogeneity was studied by I^2 statistics. We analyzed 44 studies, which included 19 prospective and 25 retrospective studies. The pooled technical success rate of EUS-HGS was 94.4% (confidence interval [CI], 92.4%–95.9%; I^2 = 0%), and the pooled clinical success rate was 88.6% (CI, 83.7%–92.2%; I^2 = 0%). The pooled adverse outcomes with EUS-HGS were 23.8% (CI, 19.6%–28.5%; I^2 = 0%). The mild adverse event rate associated with HGS was 5.8% (4.2%–8.1%; I^2 = 0%), moderate adverse event rate was 12.1% (9.1%–15.8%; I^2 = 16%), and severe adverse event rate was 4.2% (3.0%–5.7%; I^2 = 61%), whereas fatal adverse event rate was 3.2% (1.9%–5.4%; I^2 = 62%). On subgroup analysis, the pooled rate of adverse events of EUS-guided hepaticogastrostomy with antegrade stenting was 13.3% (95% CI, 8.2%–21.0%). The pooled technical success with EUS-guided hepaticogastrostomy with antegrade stenting was 89.7% (95% CI, 82.6%–94.2%), and clinical success was 92.5% (95% CI, 77.9%–97.7%). On the basis of our analysis of EUS-HGS, the overall technical success was 94.4%, and the clinical success rate was 88.6%, and the overall adverse events were reported to be 23.8%. These data can also help improve the clinical benefits of EUS-HGS in the selected patients in whom it is performed.

Key words: EUS; Biliary drainage; Hepaticogastrostomy; Interventional; ERCP

INTRODUCTION

EUS-guided biliary drainage (EUS-BD) has emerged as a promising alternative to percutaneous transhepatic BD in patients following failed ERCP for the treatment of benign or malignant biliary obstruction including duodenal stenosis, surgically altered anatomy, and high-grade hilar stenosis, as well as failed biliary cannulation. [1–4]

EUS-guided approaches to BD can be categorized into antegrade stenting, rendezvous with ERCP, and bilioenterostomy, which comprises EUS-guided choledochoduodenostomy (EUS-CDD) and EUS-guided hepaticogastrostomy (EUS-HGS).[5] Using a transgastric approach, a drainage route is created by puncturing one of the intrahepatic bile ducts from the stomach, followed by injection of contrast medium and insertion of a guidewire. After dilating the newly formed tract, 1 or more stents are deployed over the guidewire(s) under EUS and fluoroscopic guidance. EUS-HGS combined with antegrade stenting (EUS-HGAS) is a modified technique wherein anterograde stenting is performed via a transgastric approach, followed by HGS, using the same biliary access route.[6] Theoretically, HGAS may have an advantage as compared with EUS-HGS in terms of time to recurrent biliary obstruction because it creates 2 separate BD routes: one to the stomach via HGS and the other to the duodenum via AGS.[7]

With increasing data being published on EUS-HGS and EUS-HGAS, there is a need to update the adverse outcomes that are associated with these procedures. Previous meta-analyses have largely focused on comparing the efficacy and safety of EUS-CDD with EUS-HGS. Moreover, there has been variability in reporting the success rate and the outcomes of the procedure in existing literature.[6–44] This meta-analysis reports the pooled clinical and technical success rate along with adverse outcomes associated with EUS-HGS. We additionally perform a subgroup analysis of similar outcomes associated with EUS-HGAS, which has not been reported so far.

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Table 1

Study and population characteristics.

Study	Study details	Total patients, *n* (EUS-HGS)	Male/ female, *n*	Mean age, SD/ range, y	HGS/ HGAS	Stent type	Stent size	Stent length	Technical success, *n*	Clinical success, *n*
Anderloni et al.,[43] 2023	Prospective, June 2020 to March 2021, single center, Italy	22	7/15	75.1	HGS	PCSEMS	NR	NR	9/9	9/9
Amano et al.,[56] 2017	Prospective, June 2015 to November 2015, single-arm study, single center, Japan	9	5/4	75.1	HGS	PCSEMS	NR	NR	9/9	9/9
Artifon et al.,[10] 2015	RCT, 2004 to 2015, single center, Brazil	25	13/11	63.5 (45–91)	HGS	PCSEMS	10 mm	8 cm	24/25	22/25
Bories et al.,[11] 2007	Retrospective, case series study, August 2001 to June 2005, single center, France	11	7/4	64	HGS	PS/SEMS	PS (7F, 8.5F, or 10F), CSEMS (10 mm)	NR	10/10	10/10
Canakis et al.,[12] 2022	Retrospective, June 2018 to May 2021, multicenter, USA	23	12/11	66.4 (12.1)	HGS	FCSEMS	8 mm/10 mm	6/8/10 cm	23/23	16/22
Cho et al.,[13] 2017	Prospective, September 2011 to May 2015, single center, South Korea	21	NR	65.5	HGS	Hybrid SEMS	8–10 mm	5–10 cm	21/21	18/21
Guo et al.,[14] 2016	Retrospective, March 2014 to October 2015, single center, China	7	NR	NR	HGS	FCSEMS	8–10 mm	4–10 cm	7/7	7/7
Honjo et al.,[15] 2018	Retrospective, 2015 to 2017, multicenter, Japan	49	27/22	68.9	HGS	PS/ PCSEMS	PS 6.8 mm; PS 7Fr or 8Fr	10–12 cm; 20 cm	49/49	NR
Imai et al.,[6] 2017	Retrospective, January 2006 to December 2014, single center, Japan	42	24/18	67.3 (13.9)	HGS *vs.* HGAS	SEMS	NR	NR	41/42	37/42
Inoue et al.,[57] 2023	Retrospective, 2017 to 2021, single center, Japan	57	34/23	79	HGAS	MS	8 mm/10 mm	6/8/10 cm	52/57	52/57
Ishiwatari et al.,[7] 2022	Retrospective, 2016 to 2020, single center, Japan	58	33/38	71 (64–78)	HGS *vs.* HGAS	PS/MS	PS 8 mm/MS 7F	PS 10 cm, MS 14 cm	58/58	55/58
Jagielski et al.,[16] 2021	Prospective, 2016 to 2019, single center, Poland	53	38/15	74.66 (56–89)	HGS	SEMS	NR	NR	52/53	46/53
Kawakubo et al.,[17] 2014	Retrospective, 2006 to 2012, multicenter, Japan	20	14/6	72	HGS	PS/MS	NR	NR	19/20	19/20
Khashab et al.,[18] 2016	Retrospective, July 2008 to April 2014, multicenter, USA	61	38/23	63.6 (13.8)	HGS	PS/MS	NR	NR	56/61	50/61

(*continued*)

Table 1

Study and population characteristics., Continued

Complications	Bleeding	Perforation	Bile leak/bile peritonitis	Stent migration	Stent occlusion	Cholangitis/ sepsis/ bacteremia	Recurrent obstruction	Stent patency, d	Procedure time, min	Follow-up
Peritonitis (1)	NR	NR	1	0	NR	NR	NR	NR	14	NR
Peritonitis (1)	NR	NR	1	0	NR	NR	NR	NR	14	NR
Bacteremia (1), biloma (2), puncture site minor bleeding (3)	3	0	2	0	0	1	NR	NR	48	90 d
Early occlusion (1), transient ileus (1), bilioma (1), cholangitis (1)	NR	NR	1	1	2	1	NR	NR	NR	212 (3 ± 610) d
Cholangitis (1), stent occlusion (1), recurrent obstruction (2)	NR	NR	NR	NR	1	1	2	NR	(30–78)	178.4 d ±185.9
Pneumoperitoneum (2), bleeding (1), abdominal pain (1), migration (0), cholangitis (0)	1	2	0	1	0	0	10	16	NR	148.5 (79.7–244) d
Sepsis (1)	0	0	1	0	NR	1	0	NR	NR	13 (3–21) mo
Abdominal pain (6), bleeding (5)	5	0	0	0	0	0	0	NR	MD (21.5 ± 6.5), CD (17.5 ± 5)	NR
Bile leakage (7), stent migration (2), cholangitis (2)	0	0	7	2	0	2	0	NR	73.5 ± 29.4	121 (68–354) d
Bleeding (1), cholangitis (1), liver abscess (1)	1	0	0	0	0	1	16	NR	NR	167 (120–204) d
Peritonitis (5), cholangitis (2), sepsis (1), pancreatitis (0), bleeding (0), pseudoaneurysm (1)	0	0	5	1	0	3	15	NR	NR	10 mo
Early complications (7), (bleeding (2), sepsis (1), stent occlusion (3), late endoscopic treatment complications (3)/ periprocedural mortality (4)	2	0	0	0	3	1	NR	NR	31.2 (11–84)	155 (8–434) d
Bile leakage (2), stent misplacement (2), bleeding (1), cholangitis (1), biloma (1)	1	0	2	2	0	1	NR	62	NR	71 (9–262) d
Peritonitis (3), bile leak (2), cholangitis (2), bleeding (1), intraperitoneal stent (2), pancreatitis (0), perforation (0), pneumoperitoneum (0), hepatic collection (1), sheared wire (1)	1	0	5	NR	0	2	16 (stent migration 4; stent occlusion 12)	NR	NR	152.2 ± 176.7 d

(*continued*)

Table 1
(continued).

Study	Study details	Total patients, *n* (EUS-HGS)	Male/ female, *n*	Mean age, SD/ range, y	HGS/ HGAS	Stent type	Stent size	Stent length	Technical success, *n*	Clinical success, *n*
Kim et al.,[19] 2012	Retrospective, February 2009 to September 2010, multicenter, Korea	4	4/0	67	HGS	FCSEMS	10 mm	6 cm	3/4	2/4
Maehara et al.,[20] 2020	Retrospective, December 2018 to February 2019, single center, Japan	4	NR	74	HGS	FCSEMS	6 mm	8 cm	4/4	4/4
Marx et al.,[44] 2022	Retrospective, October 2002 and November 2018, single center, Spain	205	104/101	68	HGS	PS/ FCSEMS	PS 7F, MS 8–10 mm	PS 10 cm, MS 8–10 cm	NR	143/153
Minaga et al.,[21] 2017	Retrospective, December 2008 to May 2016, single center, Japan	30	11/19	66	HGS	PS/CSEMS	SEMS 8 mm, PS 7F	SEMS 8–10 cm, PS 10/12 cm	29/30	22/29
Minaga et al.,[9] 2019	RCT, September 2013 to March 2016, multicenter, Japan	24	14/10	72.5	HGS	PCSEMS	8 mm	10 cm	21/24	24/24
Miyano et al.,[22] 2018	Prospective, October 2015 to March 2016, single center, Japan	41	27/14	72.5 (57–82)	HGS	PCSEMS	10 mm	10/12 cm	41/41	41/41
Moryoussef et al., 2017	Observational cohort, November 2013 to November 2015, single center, France	18	11/7	68.8	HGS	FCSEMS	10 mm	8 cm	17/18	13/17
Nakai et al.,[23] 2016	Retrospective, April 2012 to May 2015, multicenter, Japan	33	19/12	70	HGS	PCSEMS	10 mm	10/12 cm	33/33	33/33
Ogura et al.,[59] 2014	Prospective, pilot study, 2014, single center, Japan	12	5/8	71.4 (5.8)	HGAS	FCSEMS	10 mm	10 cm	12/12	12/12
Ogura et al.,[24] 2016	Retrospective, April 2012 to August 2015, single center, Japan	26	13/13	70	HGS	SEMS	10 mm	10 cm	26/26	24/26
Ogura et al.,[25] 2019	Retrospective, April 2012 to April 2017, single center, Japan	29	15/14	67	HGS	PCSEMS	8 mm	10 cm	29/30	26/29
Oh et al.,[26] 2017	Prospective, June 2008 to February 2012, single center, Korea	129	81/48	62.2 (13)	HGS	PS/CSEMS	Plastic stent (7–10F), FCSEMS (6–10 mm)	PS 6–10 cm, SEMS 6–10 cm	120/129	105/120
Ohno et al.,[27] 2022	Retrospective, July 2015 to March 2021, multicenter, Japan	79	NR	NR	HGS	PS/ PCSEMS	PS (7F), MS 8–10 mm	PS 14 cm, MS 10–12 cm	72/79	67/79
Okuno et al.,[28] 2018	Prospective, 2018, single center, Japan	20	12/8	68	HGS	FCSEMS	6 mm	12, 15 cm	20/20	19/20
Okuno et al.,[29] 2023	Prospective, 2022, single center, Japan	20	12/8	68	HGS	FCSEMS	6 mm, 8 mm	10 cm, 12 cm	20/20	NR
Paik et al.,[30] 2014	Prospective, phase 1, 2012 to 2013, single center, South Korea	28	20/7	63 (29–87)	HGS	FCSEMS	8 mm	5–10 cm	27/28	24/27

(*continued*)

Table 1
(continued).

Complications	Bleeding	Perforation	Bile leak/bile peritonitis	Stent migration	Stent occlusion	Cholangitis/ sepsis/ bacteremia	Recurrent obstruction	Stent patency, d	Procedure time, min	Follow-up
Mild peritonitis (1), stent migration (1)	0	0	1	1	2	0	NR	NR	NR	1–12 mo
Stent occlusion (1), stent migration (1)	0	0	0	1	1	0	0	NR	18 (12–35)	76.5 (8–212) d
Stent migration (19), stent occlusion (8), cholangitis (5), bile leakage (3), pneumoperitoneum (5), bleeding (3), stent migration (1)	3	0	3	19	1	5	8	153	NR	6.4 (4.1–10) mo
Bile peritonitis (3), stent dysfunction (7)	0	0	3	NR	NR	0	NR	91	NR	64 (31–314) d
Pancreatitis (1), bile peritonitis (1), cholecystitis (0), stent occlusion (4), stent migration (0)	0	0	1	0	4	0	4	306	37.7	September 2013 to March 2017
Bile peritonitis (4), cholangitis (1), stent migration (1)	0	0	4	1	0	1	NR	NR	NR	119 d (extrascope), 141 d (intrascope)
Bleeding and death (1)	1	0	0	0	0	0	0	NR	NR	210 (32–390) d
Bleeding (1), abscess (1), cholangitis (1)	1	0	0	0	0	2	8	NR	45 (30–80)	4.5 (3.0–6.3) mo
Mild pancreatitis (1)	0	0	0	0	0	0	0	NR	35 (19–50)	122 (62–210) d
Stent occlusion (2)	0	0	0	0	2	0	0	113	NR	152 d
Bile peritonitis (3)	0	0	3	0	0	0	0	NR	NR	248.6 d
Bacteremia (6), bleeding (5), bile peritonitis (4), pneumoperitoneum (4), stent migration (3)	5	4	4	3	0	6	13	137.1 ± 243.5	30.1 ± 13.1	288.9 ± 358.1 d
Bile peritonitis (4), hemorrhage (2), fever (3), abdominal pain (8)	2	0	4	0	0	0	0	NR	With dilatation (29–133), without dilatation (24–153)	6 mo
Mild cholangitis (2), moderate fever (1)	0	0	0	0	0	2	0	NR	30 (16–98)	73 (5–726) d
Fever (2), bile leakage (0), peritonitis (0), bleeding (0), stent deviation (0), stent migration (0)	0	0	0	0	0	0	0	NR	13 (7–25)	NR
Pseudoaneurysm (1), stent migration (1)	0	0	0	1	0	0	0	216 (73–359)	15.3 (5.2)	1, 3, 6 mo

(*continued*)

Table 1
(continued).

Study	Study details	Total patients, *n* (EUS-HGS)	Male/ female, *n*	Mean age, SD/ range, y	HGS/ HGAS	Stent type	Stent size	Stent length	Technical success, *n*	Clinical success, *n*
Paik et al.,[30] 2014	Prospective, phase 2, matched case-control, 2012 to 2013, single center, South Korea	23	12/11	64.1 (12.8)	HGS	FCSEMS	8 mm	5–10 cm	20/23	20/23
Paik et al.,[31] 2017	Retrospective, January 2009 to March 2016, multicenter, South Korea, Japan	16	13/3	67.6 (9.3)	HGS	FCSEMS, PCSEMS	NR	9 cm	16/16	13/16
Paik et al.,[8] 2018	RCT, May 2015 to January 2017, multicenter, South Korea	32	NR	NR	HGS	PCSEMS	8 mm	15 cm	31/32	26/31
Park et al.,[32] 2011	Prospective, June 2008 to May 2010, single center, South Korea	31	NR	61.7 (13)	HGS	PS/MS	PS 7F, MS 8–10 mm	PS 6–8 cm, MS 4–10 cm	31/31	27/31
Park et al.,[3] 2015	RCT, April 2014 to September 2014, multicenter, South Korea	20	NR	66.2	HGS	FCSEMS	6 mm, 8 mm	6–10 cm/ 15 cm	20/20	18/20
Poincloux et al.,[33] 2015	Retrospective, 2006 to 2013, single center, France	66	NR	70 (38–91)	HGS	PS/MS	10 mm (MS)	6–8 cm	65/66	61/65
Prachayakul et al.,[34] 2013	Retrospective, October 2010 to July 2012, single center, Thailand	15	NR	62.8 (46–84)	HGS	FCSEMS	80–100 mm	NR	14/15	13/15
Song et al.,[35] 2014	Prospective, observational study, September 2011 to August 2013, single center, South Korea	10	5/5	69 (48–82)	HGS	PCSEMS	8–10 mm	9 cm	10/10	10/10
Sportes et al.,[36] 2017	Retrospective, April 2012 to August 2015, Multicenter, France	31	17/14	69.2	HGS	FCSEMS	NR	NR	31/31	25/31
Takahashi et al.,[37] 2022	Retrospective, 2019 to 2022, single center, Japan	14	8/6	76 (55–93)	HGS	PS/MS	NR	NR	11/14	11/14
Takenaka et al.,[38] 2022	Retrospective, October 2017 to March 2019, single center, Japan	45	33/12	73	HGS/ HGAS	PCSEMS/ PS	8 mm, 10 mm	8 cm, 10 cm	43/45	40/43
Tyberg et al.,[39] 2022	Retrospective, 2021, multicenter, USA	95	52/43	69.9 (12.7)	HGS	PS/MS	PS (7F or 10F) MS (8/10 mm)	NR	87/95	25/87
Umeda et al.,[40] 2015	Prospective, 2013 to 2014, single center, Japan	23	15/8	77	HGS	PS	8F	15 cm	23/23	23/23
Zhang et al.,[41] 2022	Retrospective, September 2015 to October 2020, multicenter, China	24	20/4	69.3 (6.8)	HGS/ HGAS	PS	NR	NR	21/21	21/21

CD: cautery dilator; FCSEMS: Fully covered self-expandable metal stent; HGAS: Hepaticogastrostomy with antegrade stenting; HGS: Hepaticogastrostomy MD: mechanical dilator; MS: Metal stent; NR: Not reported; PCSEMS: Partially covered self-expandable metal stent; PS: Plastic stent; RCT: Randomized clinical trial; SEMS: Self-expandable metal stent.

Table 1
(continued).

Complications	Bleeding	Perforation	Bile leak/bile peritonitis	Stent migration	Stent occlusion	Cholangitis/ sepsis/ bacteremia	Recurrent obstruction	Stent patency, d	Procedure time, min	Follow-up
Pneumoperitoneum (2), proximal migration (1), partial proximal migration (1), partial distal migration (1), abdominal pain (1), distal migration (2)	0	0	0	2	0	0	0	129 (64–194)	22.3 (6)	NR
Stent migration (2), cholecystitis (1), stent occlusion (4)	0	0	0	2	4	0	4/16	402 (97–707) d	33.4 (20.6)	208 d
Cholangitis (1)	0	0	0	0	0	1	NR	NR	39 (90.7)	155 (100–234) d
6 (bile peritonitis, mild bleeding, and self-limited pneumoperitoneum)	1	1	NR	NR	NR	NR	NR	132 d	18.5 (9.6)	120 d
Bleeding (1), bile leak (1), stent occlusion (9), cholangitis (2)	1	0	1	0	1	2	0	121 ± 11.2 d	13 (10–21)	120 d
Bleeding (1), bile leak (5), stent occlusion (2), cholangitis (2)	1	0	5	0	9	2	0	146 d	NR	280 d
Biloma 1	0	0	1	4	0	0	0	93 d	NR	93 d
Pneumoperitoneum (3), perforation (3), stent migration (4)	1	3	0	4	0	0	0	181 (36–431) d	22.5 (15–35)	181 (36–431) d
Severe sepsis (2), bile leak (2), bleeding death (2)	1	0	2	0	0	2	0	NR	71	NR - till death
Biliary peritonitis (4), biloma (1)	0	0	4	0	0	0	0	NR	35 (15–93)	NR
Peritonitis (2), bleeding (2), stent migration (0)	2	0	2	0	0	0	0	NR	29.0 (24.5–36)	NR
Biloma (1), cholangitis (2), bleeding (6), peritonitis (1), perforation (2), migration (1), infection (2), others (5)	6	2	2	1	0	2	0	NR	NR	6 mo
Abdominal pain (3), bleeding (1)	1	0	0	0	0	0	13.7% (3/22)	4 mo	NR	5 (0.5–12.5) mo
Bile leakage (2), bleeding (2), stent occlusion (1)	2	0	2	0	1	2	0	141.0 ± 73.6 d	NR	NR

METHODS

Search strategy

We conducted a comprehensive search of several databases and conference proceedings including PubMed, EMBASE, and Web of Science databases (earliest inception to July 2023). An experienced medical librarian using inputs from the study authors helped with the literature search to identify studies reporting EUS-guided HGS. The detailed literature search strategy is provided in Appendix A (http://links.lww.com/ENUS/A359). Two authors (V.M., B.P.M.) independently reviewed the title and abstract of studies identified in the primary search and excluded studies that did not address the research question, based on prespecified exclusion and inclusion criteria. The full text of the remaining articles was reviewed to determine whether it contained relevant information. Any discrepancy in article selection was resolved by consensus and in discussion with a coauthor (S.C.). The bibliographic sections of the selected articles, as well as the systematic and narrative articles on the topic, were manually searched for additional relevant articles.

We adhered to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines and MOOSE (Meta-analysis of Observational Studies in Epidemiology) checklist (checklists provided in Supplementary Materials: Appendix B and Appendix C [http://links.lww.com/ENUS/A359], respectively).[45,46]

Study selection

We included studies that reported on the clinical and technical outcomes of EUS-guided HGS and met the following criteria: (1) EUS-guided BD using HGS as the drainage route and (2) specific information provided on technical and clinical outcomes of EUS-HGS. Studies were included irrespective of the geography and abstract/manuscript status as long as they provided adequate data for the analysis. We excluded the studies that (1) provided insufficient data to allow estimation of outcomes of interest, (2) BD access other than HGS, and (3) studies in the pediatric population. In the case of multiple publications from the same cohort, data from the most recent comprehensive report were included.

Data abstraction and quality assessment

Data on study-related outcomes in the individual studies were abstracted onto a standardized form by 2 authors (V.M., B.G.) independently, and 2 authors (V.M., S.R.K.) did the quality scoring independently, using the Newcastle-Ottawa Scale for cohort studies.[47] The details of the study quality assessment are summarized in Supplementary Table 1 (http://links.lww.com/ENUS/A359).

Outcomes assessed

The primary analysis of this study focused on calculating the pooled rate of technical success, clinical success and adverse events with EUS-HGS. Pooled rates were calculated for commonly encountered adverse event subcategories with EUS-HGS, which were perforation, bile leak, bleeding, stent migration, stent occlusion, and sepsis. In addition, when possible, the adverse events were categorized based on the ASGE lexicon, and pooled rates were planned for mild, moderate, severe, and fatal adverse events. Subgroup analysis was planned to study the pooled rate of technical success, clinical success, and adverse outcomes of EUS-HGAS.

Statistical analysis

We used meta-analysis techniques to calculate the pooled estimated in each case following the methods suggested by DerSimonian and Laird[48] using the random-effects model, and our application can be seen to fit within their general approach (where the effect is measured by the probability of risk). When the incidence of an outcome was 0 in a study, a correction of 0.01 was added to the number of incident cases before statistical analysis.[49] We assessed heterogeneity between study-specific estimates by Cochrane Q statistics and I^2 statistics.[50,51] In this, values of <30%, 30% to 60%, 61% to 75%, and >75% were suggestive of low, moderate, substantial, and considerable heterogeneity, respectively.[52] In addition, we calculated the 95% prediction interval, which deals with the dispersion of the effects.[53,54] Publication bias was ascertained, qualitatively, by visual inspection of the funnel plot and quantitatively, by the Egger test.[55] All analyses were performed by using the Comprehensive Meta-Analysis software, version 4 (BioStat, Englewood, NJ, USA).

RESULTS

Search results and population characteristics

From a total of 2248 citations identified by using our search criteria, 1998 records were screened after removing duplicates. Of 850 full-length articles assessed, 56 studies reported on EUS-HGS. Of these, 46 studies reported the outcomes of EUS-HGS. Four EUS-HGS studies were excluded because they did not meet the inclusion criteria. Forty-four EUS-HGS cohorts (1576 patients) were included in the final analysis. The schematic diagram of study selection is illustrated in Supplementary Figure 1 (http://links.lww.com/ENUS/A359).

Table 1 describes the population characteristics. The majority of the patients were male (58.56%), with a mean age of 60.70 years (29–91 years). Technical success was defined as the successful stent placement following EUS needle puncture, guidewire placement, and fistula tract dilation with successful stenting, along with the flow of contrast medium and/or bile through the stent. Clinical success was defined as the completion of stent placement with reduction of total serum bilirubin levels to less than half of the pretreatment level within 1 week and/or less than a quarter of the pretreatment level within 4 weeks.[55] Detailed definitions, degree of adverse events, reintervention, and stent occlusion were defined following the ASGE report.[60]

Metal stents (either partially covered self-expandable metal stent/fully covered self-expandable metal stent/hybrid self-expandable metal stent) were used in 18 studies, whereas 40 studies used plastic stents. Various sizes and lengths of the stents were used in different studies, which are categorized in Table 1.

Characteristics and quality of included studies

The meta-analysis included 44 independent cohort studies, with a total of 1576 patients,[6–44] described in Table 1. None of the studies were population-based. All of the included studies had clear information reported on the technical success, clinical success, and adverse event rates, including the subcategory of adverse events. All the studies included were original articles. None of the studies had patients lost to follow-up. Twenty-seven studies were considered to be of high quality, and 9 were considered as medium quality. Eight studies were considered low quality. Supplementary Table 1 (http://links.lww.com/ENUS/A359) details the study quality assessment.

Meta-analysis outcomes

A total of 44 studies were included in the final analysis. The cumulative pooled rate of technical success with EUS-HGS was

94.4% (95% confidence interval [CI], 92.4%–95.9%; I^2 = 46.3%) [Figure 1], and the cumulative pooled rate of clinical success was 88.6% (95% CI, 83.7%–92.2%; I^2 = 0) [Figure 2]. The overall pooled rate of adverse events with EUS-HGS was 23.8% (95% CI, 19.6%–28.5%). The pooled rates of mild, moderate, and severe adverse events were 5.8% (95% CI, 4.2%–8.1%; I^2 = 0%), 12.1% (95% CI, 9.1%–15.8%; I^2 = 16%), and 4.2% (95% CI, 3.0%–5.7%; I^2 = 61%), respectively. The pooled rate of fatal adverse events was 3.7% (95% CI, 2.6%–5.4%; I^2 = 62%), found to be the lowest among others. The results are summarized in Table 2, and the corresponding forest plots are illustrated in Supplementary Figures 2 to 5 (http://links.lww.com/ENUS/A359).

Data pertaining to EUS-HGAS were analyzed separately. The pooled rate of technical success with EUS-HGAS was 89.7% (95% CI, 82.6%–94.2%; I^2 = 29.6), and the pooled rate of clinical success with EUS-HGAS was 92.5% (95% CI, 77.9%–97.7%; I^2 = 0). Overall adverse events with EUS-HGAS occurred in 13.3% (95% CI, 8.2%–21%; I^2 = 0) of patients. The pooled rates of mild, moderate, severe, and fatal EUS-HGAS were found to be 2.1%, 5.2%, 1.9%, and 1.9%, respectively [Figure 3]. These are summarized in Table 2, and the corresponding forest plots of mild, moderate, severe, and fatal EUS-HGAS adverse events are illustrated in Supplementary Figures 6 to 9 (http://links.lww.com/ENUS/A359).

In terms of specific adverse events, pooled rates were calculated for EUS-HGS. The rate of stent migration was the highest at 5.3%, whereas others calculated were bleeding, which was 4.9%; perforation, 3.5%; bile leak/bile peritonitis, 4.9%; stent occlusion, 4.2%; and cholangitis/sepsis/bacteremia, 4.9%. The pooled rates are summarized in Table 2, and the corresponding forest plots are illustrated in Supplementary Figures 10 to 15 (http://links.lww.com/ENUS/A359).

Subgroup analysis

Subgroup analysis was performed based on study type (prospective, retrospective) and geography (Asia, America, Europe). The reported technical success rate was 94.4% (95% CI, 91.8%–96.2%), and the clinical success rate was 91% (95% CI, 83%–95.5%) in the prospective studies. The rates of clinical and technical success in the retrospective study were 83.2% (95% CI, 73.5%–89.8%) and 93.4% (95% CI, 91.2%–95.1%), respectively. The rates of technical success observed in Europe were 95.8% (95% CI, 88.4%–99.0%), 92.5% (95% CI, 87.8%–95.4%) in America, and 93.8% (95% CI, 91.8%–95.4%) in Asia. The rates of clinical success in Asia were reported to be 87.9% (95% CI, 85.2%–90.1%), 70.1% (95% CI, 34.4%–94.3%) in America, and 91.5% (95% CI, 80.8%–96.5%) in Europe. The numbers of mild, moderate, severe, and fatal adverse events reported in studies from America were 7.6% (95% CI, 3.8%–14.8%), 10.4% (95% CI, 5.9%–17.9%), 10.1% (95% CI, 3.8%–24.1%), and 13.4% (95% CI, 1.5%–21.5%), respectively. Although the numbers of mild, moderate, severe, and fatal adverse events reported in studies from Asia were 6.3% (95% CI, 3.7%–10.5%), 12.5% (95% CI, 8.7%–17.8%), 2.4% (95% CI, 1.6%–3.8%), and 3.3% (95% CI, 2.2%–4.9%), respectively. In Europe, the number of mild adverse events reported was 4.6% (95% CI, 2.6%–7.8%), and the numbers of moderate, severe, and fatal adverse events were 10.2% (95% CI, 4.4%–21.9%), 8.4% (95% CI, 2.3%–2.61%), and 7.4% (95% CI, 2.4%–20.3%), respectively. These outcomes are summarized in Supplementary Table 2 (http://links.lww.com/ENUS/A359) and illustrated in Supplementary Figures 16 and 17 (http://links.lww.com/ENUS/A359).

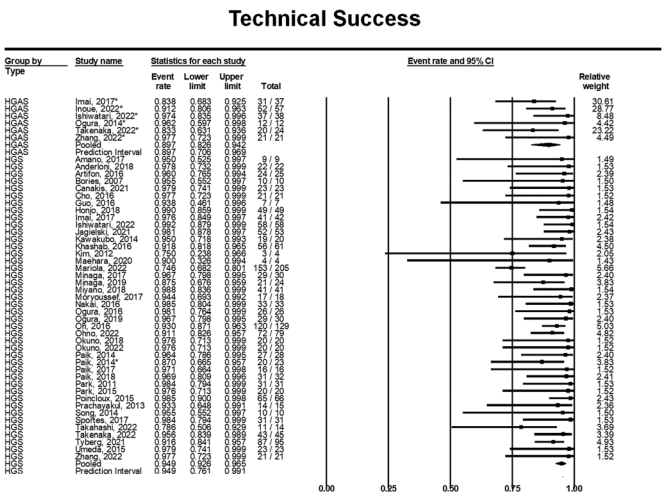

Figure 1. Forest plot, technical success of EUS-HGS and EUS-HGAS. EUS-HGAS: EUS-guided hepaticogastrostomy with antegrade stenting; EUS-HGS: EUS-guided hepaticogastrostomy.

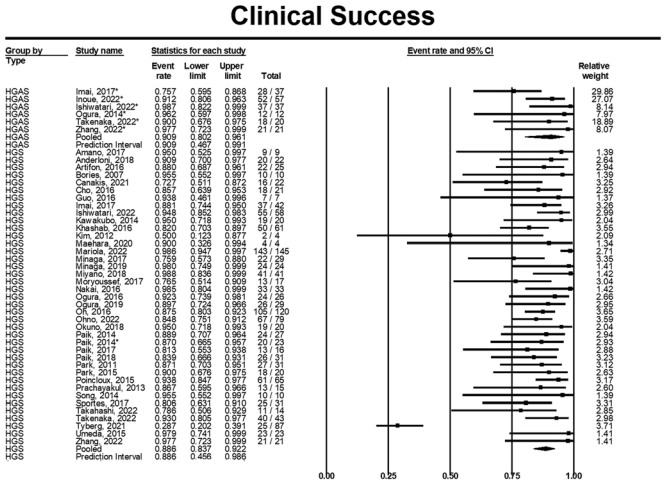

Figure 2. Forest plot, clinical success of EUS-HGS and EUS-HGAS. EUS-HGAS: EUS-guided hepaticogastrostomy with antegrade stenting; EUS-HGS: EUS-guided hepaticogastrostomy.

Validation of meta-analysis results

Sensitivity analysis

To assess the possible dominant effect of individual studies on the meta-analysis, we excluded one study at a time and analyzed its effect on the main summary estimate. We did not find any single study that significantly affected the outcomes of interest or the heterogeneity. Additional analyses were performed based on study type (prospective, retrospective) and study site (America, Asia, Europe). No major variations in the pooled rates were noted, except for severe and fatal adverse events, which were 2.3% and 2% in retrospective studies, respectively.

Table 2

Cumulative outcomes and adverse effects associated with EUS-HGS and EUS-HGAS.

Cumulative outcomes	Pooled rates (95% confidence interval), I^2, no. of studies	
	EUS-HGS	EUS-HGAS
Technical success	94.4% (92.4–95.9), 0%, 43	89.7% (82.6–94.2), 29.6%, 3
Clinical success	88.6% (83.7–92.2), 0%, 43	92.5% (77.9–97.7), 0%, 6
ASGE lexicon	23.8% (19.6–28.5)	13.3% (8.2–21.0)
Mild	5.8% (4.2–8.1), 0%, 38	2.1% (5.9–23.0), 51.65%, 6
Moderate	12.1% (9.1–15.8), 16%, 38	5.2% (2.6–1.01), 0%, 6
Severe	4.2% (3.0–5.7), 61%, 38	1.9% (0.6–5.8), 0%, 6
Fatal	3.7% (2.6–5.4), 62%, 40	1.9% (0.6–5.8), 0%, 6
	Pooled rates for types of adverse events related to EUS-HGS (95% confidence interval), I^2, no. of studies	
Bleeding	4.9% (3.7–6.5), 0%, 39	
Perforation	3.5% (2.4–5.1), 0%, 38	
Bile leak (bile peritonitis)	4.9% (3.7–6.4), 0%, 40	
Stent migration	5.3% (3.6–7.9), 40%, 39	
Stent occlusion	4.2% (2.7–6.5), 0%, 39	
Cholangitis/sepsis/bacteremia	4.9% (3.7–6.4), 0%, 40	

EUS-HGAS: EUS-guided hepaticogastrostomy with antegrade stenting; EUS-HGS: EUS-guided hepaticogastrostomy.

Publication bias, 2-tailed $P < 0.01$.

Heterogeneity

Based on Q statistics and I^2 analysis for heterogeneity, overall low heterogeneity was reported in this study. I^2% values are summarized in Table 2, along with the pooled rates. No heterogeneity ($I^2 = 0$) was noted with the analysis of technical success and clinical success ($I^2 = 0$). High heterogeneity was observed in severe ($I^2 = 61$) and fatal ($I^2 = 62$) adverse outcomes in HGS, which could be due to a low number of these events. Moderate heterogeneity ($I^2 = 16$) was associated with moderate adverse effects with HGS and none ($I^2 = 0$) with mild adverse effects. No heterogeneity ($I^2 = 0$) was noted with bleeding, cholangitis/sepsis/bacteremia, bile leak, stent migration, stent occlusion, and perforation.

Moderate heterogeneity ($I^2 = 29.6\%$) was noted in the pooled outcomes of technical success related to HGAS, whereas none ($I^2 = 0\%$) was reported with clinical outcomes.

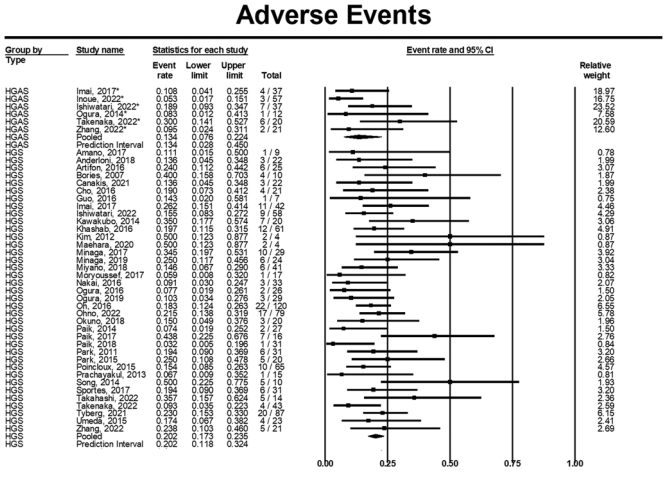

Figure 3. Forest plot, pooled adverse events of EUS-HGS and EUS-HGAS. EUS-HGAS: EUS-guided hepaticogastrostomy with antegrade stenting; EUS-HGS: EUS-guided hepaticogastrostomy.

Publication bias

On the basis of visual inspection of the funnel plot as well as quantitative measurement that used the Egger regression test, there was evidence of publication bias. The funnel plot study scatter indicated the possibility of a "small study effect" confound.[55] Further statistics using the fail-safe N test and Duval and Tweedie's "Trim and Fill" test revealed the impact of the possible publication bias to be minimal and not to change the calculated estimate or the conclusion of this meta-analysis. The funnel plot is summarized in Supplementary Figure 18 (http://links.lww.com/ENUS/A359).

DISCUSSION

In this meta-analysis of 44 studies, we analyzed the pooled technical success and clinical success with EUS-HGS, which were 94.4% and 88.6%, respectively. The overall risk of adverse events with EUS-HGS was 23.8%. Most of the existing studies on EUS-guided BD either have included a mix of EUS-HGS, EUS-CDD, and percutaneous transhepatic BD patients or have a very small sample size. This is the first meta-analysis of good-quality studies that consists of the largest comparative cohort of studies to date that report the overall pooled rates of technical and clinical success along with the adverse events exclusively in EUS-HGS.

A recent review performed by Paik and Park[61] that evaluated 27 clinical studies reported the technical and clinical success rates of EUS-HGS to be 96% (range, 65%–100%) and 90%, respectively. However, further subtyping as mild, moderate, severe, or fatal adverse events associated with the procedure was not reported. The results of our study showed that both the technical success (94.4% *vs.* 96%) and the clinical success rates were much lower (88.6% *vs.* 90%). The overall adverse event rates were higher in our study (23.8% *vs.* 18%).[61] This difference could be attributed to the variable sample size between the studies.

In this analysis, we also performed subtyping of the adverse outcomes. The rates of mild, moderate, severe, and fatal adverse events were reported to be 5.8%, 12.1%, 4.2%, and 3.7%, respectively. The calculated pooled rate of adverse events was as follows:

perforation: 3.5%, bile leak: 4.9%, bleeding: 4.9%, stent occlusion: 4.2%, stent migration: 5.3%, and cholangitis: 4.9%. This study is the first to report these rates in the EUS-HGS population via meta-analysis.

In the subgroup analysis, we analyzed the pooled rates of adverse events associated with EUS-HGAS, which was calculated to be 13.3%. The pooled technical success with EUS-HGAS was 89.7%, and clinical success was 92.5%. The pooled adverse rate associated with the procedure was lower than HGS alone. Our study did not show a statistically significant difference in the overall adverse events or the subcategories of the adverse events between the HGS and HGAS subgroups.

The strengths of this review are as follows: systematic literature search with well-defined inclusion criteria, carefully excluding redundant studies, inclusion of all high-quality studies, inclusion of randomized controlled trials, detailed extraction of adverse events, their subcategories, technical success and clinical success information, rigorous evaluation of study quality, subgroup analysis to evaluate the outcomes of HGAS, low to moderate heterogeneity, narrow range of prediction intervals, statistics to establish, and/or refuting the validity of the results of the analysis.

Our study has limitations. There is an inherent heterogeneity between the different studies in our analysis. Our study relies heavily on prospective studies and retrospective studies that compared the 2 subgroups of HGS and CDD. Despite these limitations, our study provides valuable information on the pooled success rates and adverse outcomes associated with HGS and HGAS.

In conclusion, the technical and clinical success rates of EUS-HGS were reported in our study to be 94.4% and 88.6%, respectively, which makes the procedure safe to be performed in select patient groups. The pooled rate of adverse events was highest for stent migration followed by bleeding, infections, and bile leak. Our study emphasizes the need to perform further studies to look into the risks of the procedure and develop further advancements in the technique used to improve the outcomes and reduce the burden of adverse events associated with the procedure.

Source of Funding

Not applicable.

Conflicts of Interest

Douglas G. Adler is consultant to Boston Scientific. He is also a Co-Editor-in-Chief of the journal. This article was subject to the journal's standard procedures, with peer review handled independently of the editor and his research group. The other authors declare that they have no financial conflict of interest with regard to the content of this report.

Author Contributions

Vishali Moond and Babu P. Mohan did the conception of study idea. Vishali Moond, Priyadarshini Loganathan, Bhargav Koyani, Shahab R. Khan, and Arkady Broder performed data collection, drafting of initial manuscript, and editing. Babu P. Mohan and Lena L. Kassab performed data curation and analysis. All authors reviewed, edited intellectual content, and did the final approval of the manuscript.

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