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Adverse events with endoscopic ultrasound-guided gastroenterostomy for gastric outlet obstruction—A systematic review and meta-analysis

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Abstract

Background: The technical and clinical effectiveness of endoscopic ultrasonography (EUS)-guided gastroenterostomy (GE) has been reported by several meta-analyses, but few of them have addressed the adverse events (AE). The goal of the current meta-analysis was to analyze the AEs associated with various types of EUS-GE.

Methods: All relevant studies reporting the AEs with EUS-GE were searched from 2000 to 31st March 2023 in MEDLINE, Embase, and Scopus. The event rates were pooled using a random effects model.

Results: A total of 36 studies (n = 1846) were included in the meta-analysis. The present meta-analysis reports a pooled technical success rate of 96.9% (95.9–98.0; I^2 = 29.3%) with a pooled clinical success rate of 90.6% (88.5–92.7; I^2 = 60.9%). The pooled incidence of overall AEs with EUS-GE was 13.0% (10.3–15.7; I^2 = 69.7%), with the commonest being maldeployment of the stent, seen in 4.6% (3.2–6.0; I^2 = 50.6%). The pooled incidences of serious AE and procedure-related mortality were 1.2% (0.7–1.8; I^2 = 1.9%) and 0.3% (0.0–0.7; I^2 = 0.0%), respectively. Subgroup analysis of studies using only the free-hand technique showed a significantly lower overall AE and maldeployment but not serious AE and other individual AEs. The pooled incidences of delayed stent migration and stent occlusion were 0.5% (0.0–1.1; I^2 = 0.0%) and 0.8% (0.2–1.3; I^2 = 0.0%), respectively.

Conclusion: Despite a technical and clinical success rate of >90%, AEs are seen in around one-seventh of the cases of EUS-GE, maldeployment being the commonest. However, the pooled incidence of serious AE and mortality remains low, which is reassuring.

KEYWORDS

endoscopic ultrasound, gastric outlet obstruction, gastroenterostomy, gastrojejunostomy, meta-analysis

INTRODUCTION

Palliation of gastric outlet obstruction (GOO) has seen a paradigm shift from surgical gastrojejunostomy to endoscopic interventions in the form of enteral stents initially.[1] The development of lumen apposing stents by Binmoeller et al. as devices to draw two luminal structures together brought the possibility of performing endoscopic ultrasound-guided gastroenterostomy or gastrojejunostomy (EUS-GE).[2] EUS-GE has the distinct advantage of a minimally invasive technique by placing the stent away from the tumor, thereby reducing ingrowth and the potential need for reintervention in the long term. The procedure requires endosonographically identifying the jejunal loop distal to the site of obstruction from the stomach with subsequent placement of lumen apposing metal stent (LAMS), thus creating a tight and sealed fistulous tract between the gastric and enteral lumen. Evidence from several recent meta-analyses, albeit mostly retrospective studies, concurred with the theory of EUS-GE being effective.[3–6] Therefore, European Society of Gastrointestinal Endoscopy and American Gastroenterological Association recommend EUS-GE as an alternative to surgical GJ or enteral stenting for malignant GOO at expert centers when longer life expectancy can be predicted.[7,8]

There are multiple studies attesting to the benefit of EUS-GE over enteral stents and surgical gastroenterostomy. However, data from prospective randomized trials are sparse. Widespread adoption of EUS-GJ is still an issue in practice, with the reasons being a steep learning curve, higher comparative cost to the patient, and risk of AE, especially stent maldeployment, which may require urgent surgical intervention.[9] With significant evolution in EUS availability, as well as training, and with more evidence on the efficacy of EUS-GE from several recent publications,[10,11] comprehensive data on AE related to this procedure will be a significant guide toward understanding risks and standardizing consents for patients. Various techniques of EUS-GE are described- Free-hand technique with an oroenteric catheter, E-PASS (EUS Balloon occluded GE Bypass) technique, and wire-guided technique. Data is limited on the outcomes of different techniques of EUS-GE.[10] Therefore, we conducted a systematic review of data to evaluate the safety profile of EUS-GE and its various techniques.

Key summary

Summarise the established knowledge on this subject

- Endoscopic ultrasound (EUS)-guided gastroenterostomy (GE) is a minimally invasive modality for the management of gastric outlet obstruction.
- Majority of the studies are focused on efficacy but not on safety, requiring analysis of adverse events (AE).

What are the significant and/or new findings of this subject

- The present meta-analysis reported that AEs are seen in around one-seventh of the cases of EUS-GE, of which maldeployment was the commonest.
- The pooled incidences of serious AEs and procedure-related mortality were 1.2% and 0.3%, respectively.
- Subgroup analysis of studies using only the free-hand technique showed a significantly lower overall AE and maldeployment.

METHODS

The current meta-analysis was conducted as per the updated Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[12]

Database search

All relevant studies were searched from 2000 to 31st March 2023 in MEDLINE, Embase, and Scopus using the following keywords: (EUS OR Endoscopic ultrasound) AND (Gastroenterostomy OR Gastrojejunostomy). The title and abstract of the retrieved studies were screened by two independent reviewers, who then assessed the full texts for eligibility prior to inclusion. Additionally, the bibliographies of the included studies were screened for relevant studies. A third reviewer resolved any disagreement.

Study inclusion

Both prospective and retrospective studies fulfilling the following criteria were included in the present systematic review: (a) *Study population*—Patients with GOO; (b) Intervention—EUS-GE performed via different techniques; (c) Outcomes—safety and efficacy. Editorials, correspondences, case reports, case series with <10 cases, and review articles were excluded. Studies with insufficient or irrelevant clinical data were also excluded.

Data extraction and quality assessment

Two reviewers independently extracted the data, while a third reviewer arbitrated any conflicts. Each study's title, first author, year of publication, country, number of patients, age and sex distribution, indication for EUS-GE, outcome metrics, and follow-up time were all listed on the form. Using a Newcastle-Ottawa scale for cohort studies,[13] two independent reviewers evaluated the quality of the included studies. In the event of a disagreement, a third reviewer was contacted.

Definition of outcomes

The primary outcome of the study was the incidence of AE. The severity of AE was defined as per the ASGE lexicon for grading the severity of procedural AE with endoscopy.[14] Technical success was defined as the confirmed placement of the stent as determined endoscopically and radiographically. Clinical success was defined as the ability to tolerate at least a full liquid diet without vomiting.[7] With respect to the type of procedure, we compared studies using free-hand techniques and using either free-hand or balloon-assisted techniques (mixed technique). Free-hand technique was in which there was no use of wire or balloon assistance. This included both direct technique (LAMS puncture after the small-bowel loop is punctured with a 19 G FNA needle and dilated with saline mixed with contrast) and wireless endoscopic simplified technique (WEST) (LAMS puncture after filling small bowel with saline using a catheter or ultra-slim scope).[15]

Data analysis

Using a random-effects inverse-variance model, the pooled proportions were calculated. I^2 and the *p*-value for heterogeneity were used to evaluate the studies' degree of heterogeneity. I^2 values of 25%, 50%, and 75% were considered the cutoffs for low, moderate, and considerable heterogeneity, respectively.[13] A *p*-value of less than 0.1 was considered statistically significant. For assessing publication bias, funnel plots were visually inspected. The sensitivity analysis utilized a leave-one-out meta-analysis, where one study is removed from each analysis, to analyze each research's impact on the overall effect-size estimate and find influential studies. A subgroup analysis was performed based on the sample size, study quality, indication for EUS-GJ, and type of procedure used. Meta-regression was used to assess the source of heterogeneity by analyzing the linear relationship between study-level covariates and the effect size. STATA software (version 17, StataCorp.) was used for statistical analysis.

RESULTS

Baseline study characteristics and quality assessment

A total of 1873 records were retrieved using the search strategy. Figure 1 shows the PRISMA flowchart for the study selection and inclusion process. Finally, 36 studies[16–51] were included in the present analysis, with sample sizes varying from 10 to 267. Table 1 shows the baseline characteristics of the studies included in the meta-analysis. Most of the studies were from the USA, followed by European countries. Except for the studies by Itoi et al.[17] and Alonso et al.,[47] the rest were retrospective in nature. The mean age of the patients included in the studies varied from 55.8 to 77.3 years. Two studies included only benign etiologies,[21,26] 14 studies included only

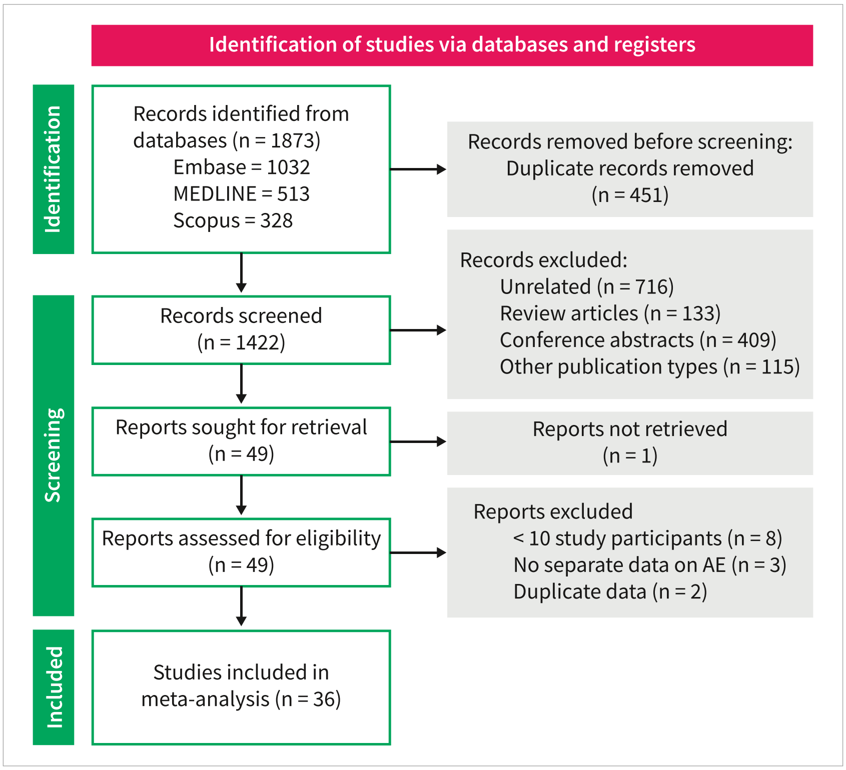

FIGURE 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart for study identification, screening, and inclusion process.

TABLE 1 Baseline characteristics of the studies included in the present meta-analysis.

Author, year	Country	Study design	No. of patients	Age, in year	Male/Female	Malignant indication	Type of procedure	New-castle Ottawa scale	Quality
Khashab, 2015[16]	USA	Retrospective	10	55.8 (48–81)	7/3	3 (30%)	Direct: 1, balloon-assisted: 9	S2C0O2	Poor
Itoi, 2016[17]	Japan	Prospective	20	-	10/10	20 (100%)	EPASS: 20		Fair
Tyberg, 2016[18]	USA	Retrospective	26	66.2 (34–90)	11/15	17 (65.4%)	Direct: 3, balloon-assisted: 13, WEST: 8	S3C1O1	Fair
Chen, 2017[19]	USA, Japan	Retrospective	30	70 ± 13.3	17/13	30 (100%)	Direct: 2, balloon-assisted: 6, EPASS: 22	S3C2O2	Good
Perez-Miranda, 2017[20]	USA, Spain, France	Retrospective	25	63.9	11/14	17 (68%)	Direct: 6, balloon-assisted: 9, WEST: 10	S3C1O1	Fair
Chen, 2018[21]	USA, Canada, Denmark, Japan	Retrospective	26	57.7 ± 13.9	14/12	0 (0%)	Direct: 15, balloon-assisted: 7, EPASS: 4	S3C1O2	Good
Chen, 2018[22]	USA, Denmark	Retrospective	74	63 ± 11.7	33/41	74 (100%)	Direct: 52, balloon-assisted: 22	S3C2O2	Good
Ge, 2019[23]	USA	Retrospective	22	66.4 ± 9.2	9/13	22 (100%)	WEST: 22	S3C2O2	Good
Kerdsirichairat, 2019[24]	USA	Retrospective	57	65	28/29	48 (84.2%)	Direct: 57	S3C1O3	Good
Hu, 2020[25]	China	Retrospective	10	63.2 ± 5.8	4/6	9 (90%)	Retrieval anchor-assisted: 10	S2C1O1	Fair
James, 2020[26]	USA	Retrospective	22	54.2 ± 13.4	13/9	22 (0%)	Direct: 9, balloon-assisted: 8, WEST: 5	S2C1O3	Fair
Kastelijn, 2020[27]	Netherlands, Spain, Germany, Italy	Retrospective	45	69.9 ± 12.3	22/23	45 (100%)	Direct: 36, balloon-assisted: 9	S3C2O2	Good
Xu, 2020[28]	China	Retrospective	36	69 (45–88)	17/19	36 (100%)	EPASS: 36	S3C2O2	Good
Basha, 2021[29]	India	Retrospective	31	61.65 ± 10.65	20/11	29 (93.5%)	Direct 4, EPASS: 27	S3C1O1	Fair
Bronswijk, 2021[30]	Italy, The Netherlands	Retrospective	77	65 ± 12.3	41/36	74 (96.1%)	WEST: 77	S3C2O1	Fair
Havre, 2021[31]	Norway, Denmark	Retrospective	33	73 ± 13.3	20/13	28 (84.8%)	WEST: 33	S3C1O1	Fair
Jovani, 2021[32]	USA	Retrospective	73	60	37/36	64 (87.7%)	Direct: 73	S3C1O2	Good
Nguyen, 2021[33]	USA	Retrospective	42	73.1 ± 11.5	23/19	37 (88.1%)	WEST: 42	S3C1O2	Good
Sobani, 2021[34]	USA	Retrospective	31	61.35 ± 16.52	17/14	23 (74.2%)	WEST: 31	S3C1O1	Fair
Tyberg, 2021[35]	USA	Retrospective	23	65.8 ± 18.5	9/14	11 (47.8%)	Free-hand: 9, balloon-assisted: 13	S2C1O2	Fair
Abbas, 2022[36]	USA	Retrospective	50	67 ± 10	23/27	50 (100%)	WEST: 50	S3C2O2	Good
Sanchez-Aldehuelo, 2022[37]	Spain	Retrospective	79	72.4 ± 10.7	43/36	79 (100%)	WEST: 79	S3C2O2	Good

TABLE 1 (Continued)

Author, year	Country	Study design	No. of patients	Age, in year	Male/ Female	Malignant indication	Type of procedure	New-castle Ottawa scale	Quality
Bejjani, 2022[38]	Multicentric	Retrospective	267	67.3 ± 12.1	152/115	-	Free-hand or balloon-assisted	S3C1O2	Fair
Chan, 2022[39]	Hong Kong, India, China	Retrospective	30	64 (32–88)	22/8	30 (100%)	EPASS: 30	S3C2O2	Good
Choi, 2022[40]	USA	Retrospective	52	64	30/22	-	Free-hand: 43, balloon-assisted: 9	S3C2O2	Good
Fischer, 2022[41]	Germany	Retrospective	45	65 (36–84)	19/26	39 (86.7%)	WEST: 45	S3C2O2	Good
Huang, 2022[42]	China	Retrospective	51	65.8 ± 13.8	27/24	51 (100%)	EPASS: 51	S3C1O1	Poor
Mahmoud, 2022[43]	USA	Retrospective	55	67 ± 11.3	33/22	55 (100%)	Free-hand: 47, balloon-assisted: 8	S3C2O3	Good
Marino, 2022[44]	Canada	Retrospective	11	64.9 ± 8.6	6/5	11 (100%)	Modified-EPASS	S2C2O2	Fair
Perez-Cuadrado, 2022[45]	France	Retrospective	28	63 ± 17.2	17/11	28 (100%)	WEST: 28	S2C2O2	Fair
Van Wanrooij, 2022[46]	Netherlands, Italy, Belgium	Retrospective	88	-	-	88 (100%)	WEST: 88	S3C2O3	Good
Garcia-Alonso, 2023[47]	Spain	Prospective	65	77.3 (65.5–86.5)	33/32	65 (100%)	WEST: 65	S3C2O2	Good
Jaruvongvanich, 2023[48]	USA, Belgium	Retrospective	232	64.5 ± 12.3	135/97	191 (82.3%)	Free-hand: 22, WEST: 196, balloon-assisted: 14	S3C1O3	Good
Mangiavillano, 2023[49]	Italy	Retrospective	25	68.7 ± 9.3	16/9	21 (84%)	WEST: 25	S2C1O3	Fair
On, 2023[50]	UK	Retrospective	25	61.4 ± 14.3	15/10	22 (88%)	Free-hand or balloon-assisted	S2C1O2	Fair
Rai, 2023[51]	India	Retrospective	30	59.1 ± 10.6	10/20	26 (86.7%)	WEST: 30	S2C1O2	Fair

Abbreviations: (S/C/O), Selection/ Comparability/ Outcome; EPASS, endoscopic ultrasonography-guided double-balloon-occluded gastrojejunostomy bypass; New-Castle, Ottawa scale; WEST, Wireless endoscopic simplified technique (puncture after filling small bowel with saline using catheter or ultra-slim scope).

malignant etiologies,[19,22,23,27,28,36,37,39,42–47] and the rest included both benign as well as malignant cases, with malignant being the majority. Eighteen studies were of good quality,[19,21–24,27,28,32,33,36,37,39–41,43,46–48] 16 were of fair quality,[17,18,20,25,26,29–31,34,35,38,44,45,49–51] and two were of poor quality.[16,42]

Technical and clinical success

All 36 studies ($n = 1846$) reported the technical and clinical success of EUS-GE. The pooled technical success rate was 96.9% (95.9–98.0; $I^2 = 29.3\%$) without significant heterogeneity between the studies. The pooled clinical success rate was 90.6% (88.5–92.7; $I^2 = 60.9\%$) with moderate heterogeneity between the studies. On subgroup analysis, there was no significant difference in the event rates for technical and clinical success (Table 2).

Early adverse events and procedure-related mortality

Early procedure-related AEs were reported in all 36 studies with 1846 patients. The pooled incidence of AEs with EUS-GE was 13.0% (95% CI: 10.3–15.7; $I^2 = 69.7\%$) (Table 2). On subgroup analysis, studies that used only the free-hand technique reported a significantly lower pooled AE rate of 8.4% (95% CI: 5.4–11.3; $I^2 = 57.9\%$) compared to 17.3% (95% CI: 13.2–21.5; $I^2 = 68.2\%$) with studies using other techniques ($p = 0.001$) (Figure 2). The pooled incidence of serious AE was 1.2% (95% CI: 0.7–1.8; $I^2 = 1.9\%$), with no difference between studies using only free-hand technique 1.3% (95% CI: 0.4–2.3; $I^2 = 0.0\%$) and studies using other techniques 1.5% (95% CI: 0.6–2.5; $I^2 = 0.0\%$) ($p = 0.759$). The pooled incidence of procedure-related mortality was 0.3% (95% CI: 0.0–0.7; $I^2 = 0.0\%$). There was no difference in AE, serious AE, and mortality between the WEST and EPASS techniques (Table 3).

TABLE 2 Summary of findings table with sub-group analysis.

	Overall	Multicentric studies	Studies with sample size >30	Excluding poor-quality studies	Studies with only malignant cases	Studies with free-hand technique
Technical success	96.9% (95.9–98.0)	96.2% (94.8–97.6)	97.0% (95.8–98.2)	96.9% (95.8–98.0)	96.6% (94.8–98.4)	97.5% (96.1–98.9)
	I^2 = 29.3%	I^2 = 29.1%	I^2 = 43.0%	I^2 = 32.7%	I^2 = 45.2%	I^2 = 24.2%
Clinical success	90.6% (88.5–92.7)	89.5% (86.4–92.6)	91.1% (88.7–93.5)	90.5% (88.2–92.7)	91.0% (88.8–93.2)	91.5% (89.4–93.6)
	I^2 = 60.9%	I^2 = 72.3%	I^2 = 67.1%	I^2 = 64.0%	I^2 = 16.4%	I^2 = 11.9%
Adverse events	13.0% (10.3–15.7)	14.1% (10.7–17.6)	12.2% (9.4–15.0)	13.0% (10.1–15.8)	12.8% (9.3–16.3)	8.4% (5.4–11.3)
	I^2 = 69.7%	I^2 = 69.1%	I^2 = 67.2%	I^2 = 71.5%	I^2 = 56.8%	I^2 = 57.9%
Peritonitis without perforation	0.4% (0.0–0.9)	0.4% (0.0–0.9)	0.4% (0.0–0.8)	0.4% (0.0–0.8)	0.4% (0.0–1.1)	0.2% (0.0–0.9)
	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%
Perforation	0.2% (0.0–0.6)	0.3% (0.0–0.7)	0.2% (0.0–0.6)	0.2% (0.0–0.6)	0.3% (0.0–1.0)	0.2% (0.0–0.9)
	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%
Bleeding	0.4% (0.0–0.8)	0.3% (0.0–0.7)	0.7% (0.1–1.3)	0.4% (0.0–0.8)	0.7% (0.0–1.5)	0.9% (0.0–1.7)
	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%
Maldeployment/ early migration	4.6% (3.2–6.0)	5.3% (3.4–7.3)	4.0% (2.6–5.3)	4.8% (3.4–6.3)	3.5% (2.1–4.9)	2.8% (1.6–4.1)
	I^2 = 50.6%	I^2 = 59.5%	I^2 = 48.8%	I^2 = 48.2%	I^2 = 14.1%	I^2 = 0.0%
Serious adverse events	1.2% (0.7–1.8)	1.7% (0.9–2.6)	1.5% (0.8–2.3)	1.5% (0.8–2.2)	2.0% (1.0–3.1)	1.3% (0.4–2.3)
	I^2 = 1.9%	I^2 = 12.7%	I^2 = 21.4%	I^2 = 7.9%	I^2 = 0.0%	I^2 = 0.0%
Procedure-related mortality	0.3% (0.0–0.7)	0.3% (0.0–0.7)	0.3% (0.0–0.7)	0.3% (0.0–0.7)	0.4% (0.0–1.2)	0.3% (0.0–1.0)
	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%
Delayed migration	0.5% (0.0–1.1)	0.4% (0.0–1.0)	0.5% (0.0–1.1)	0.5% (0.0–1.1)	0.4% (0.0–1.3)	0.6% (0.0–1.5)
	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%
Stent occlusion	0.8% (0.2–1.3)	0.6% (0.0–1.3)	0.6% (0.1–1.2)	0.8% (0.2–1.3)	1.0% (0.2–2.0)	0.6% (0.0–1.5)
	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%

Individual adverse events

Individual AEs were reported in 35 studies with 1794 patients. The commonest AE associated with EUS-GE was maldeployment, which was seen in 4.6% (95% CI: 3.2–6.0; I^2 = 50.6%) of the cases. Patients with maldeployment were salvaged using either clip closure of the defect or placement of an additional stent. Pooled analysis of 10 (n = 429) and 13 (n = 468) studies showed that the rates of clip closure and additional stent placement were 2.3% (95% CI: 0.8–3.8; I^2 = 0.0%) and 5.6% (95% CI: 2.3–8.8; I^2 = 65.6%), respectively. The pooled incidence of perforation, peritonitis without perforation, and bleeding were 0.2% (95% CI: 0.0–0.6; I^2 = 0.0%), 0.4% (95% CI: 0.0–0.9; I^2 = 0.0%), and 0.4% (95% CI: 0.0–0.8; I^2 = 0.0%), respectively. There was no difference in the pooled proportion of individual AEs based on subgroup analysis, except for a lower incidence of maldeployment (2.8%, 95% CI: 1.6–4.1 vs. 7.1%, 95% CI: 4.5–9.6; $p = 0.004$) in studies using only the free-hand technique, compared to studies using mixed techniques.

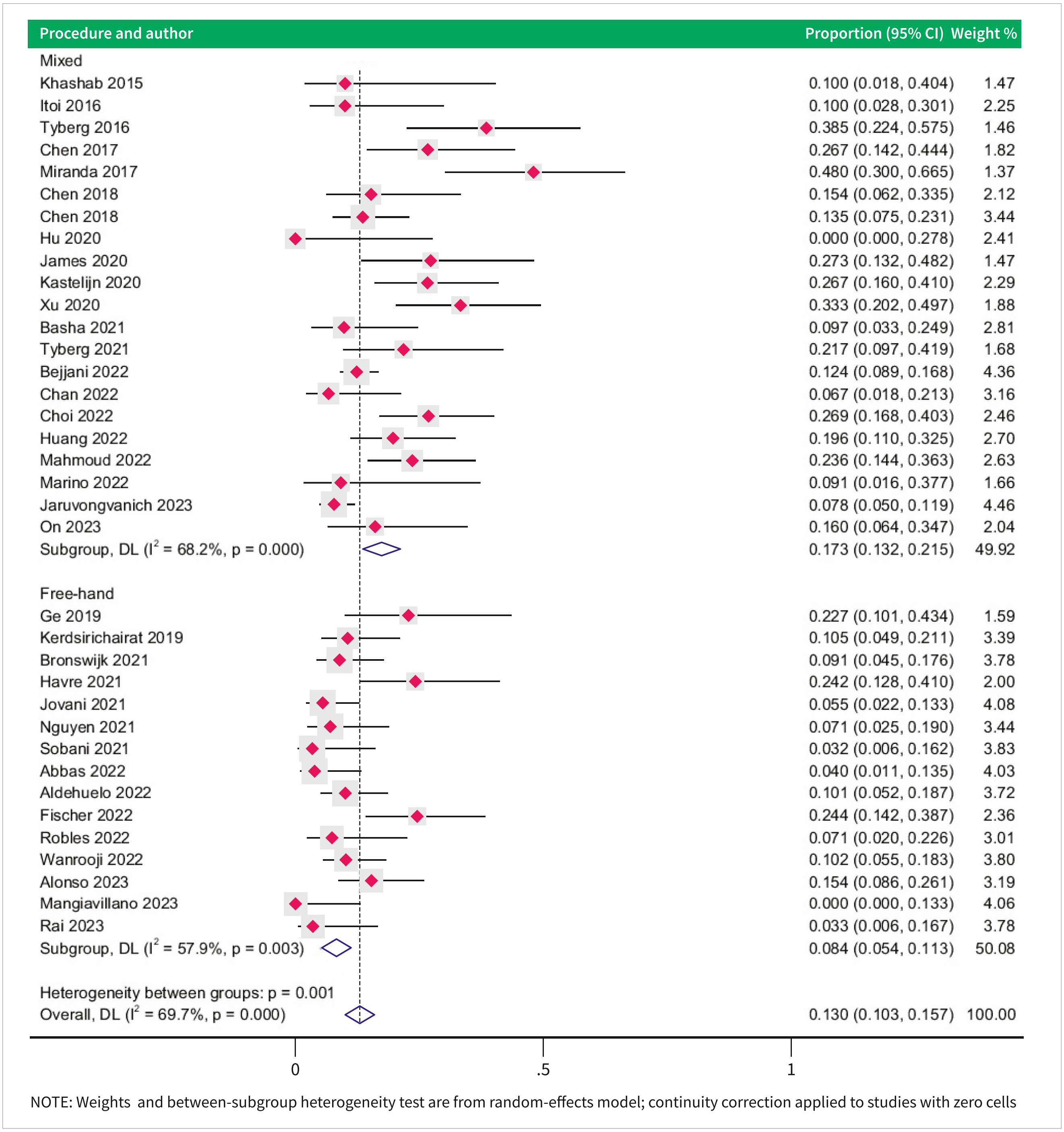

FIGURE 2 Forest plot showing the pooled proportion of adverse events with endoscopic ultrasound-guided gastrojejunostomy with subgroup analysis based on the type of procedure (Studies using only free-hand technique vs. other techniques).

Delayed adverse events

Delayed stent migration and occlusion were reported by 24 (n = 1151) and 26 (n = 1207) studies, respectively. The pooled incidence of delayed stent migration and occlusion was 0.5% (95% CI: 0.0–1.1; I^2 = 0.0%) and 0.8% (95% CI: 0.2–1.3; I^2 = 0.0%), respectively. On subgroup analysis, the pooled incidence of stent occlusion was comparable between studies using only the free-hand technique and those using mixed techniques (0.6%, 95% CI: 0.0–1.5 vs. 1.0%, 95% CI: 0.1–1.9; p = 0.538).

Publication bias and meta-regression

There was significant publication bias for most of the outcomes except for procedure-related mortality and delayed migration. On

TABLE 3 Comparison of outcome between wireless endoscopic simplified technique and endoscopic ultrasonography-guided double-balloon-occluded gastrojejunostomy bypass technique.

	Overall	WEST (15 studies, $n = 698$)	EPASS (6 studies, $n = 175$)	p-value
Technical success	97.0% (96.7–99.6)	97.8% (96.5–99.2)	97.6% (95.0–100)	0.872
	I^2 = 29.5%	I^2 = 15.1%	I^2 = 6.9%	
Clinical success	90.6% (88.4–92.7)	91.8% (89.6–94.1)	92.5% (88.6–96.3)	0.789
	I^2 = 61.9%	I^2 = 19.1%	I^2 = 0.0%	
Adverse events	13.1% (10.3–15.9) I^2 = 70.6%	7.9% (4.9–11.0) I^2 = 58.4%	12.7% (4.6–20.7) I^2 = 67.4%	0.278
Peritonitis without perforation	0.4% (0.0–0.9)	0.2% (0.0–0.9)	0.6% (0.0–2.8)	0.682
	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	
Perforation	0.2% (0.0–0.6)	0.2% (0.0–1.0)	0.0% (0.0–1.7)	0.800
	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	
Bleeding	0.4% (0.0–0.8)	0.8% (0.0–1.7)	3.1% (0.0–6.9)	0.235
	I^2 = 0.0%	I^2 = 0.0%	I^2 = 38.7%	
Maldeployment/early migration	4.6% (3.2–6.0)	2.5% (1.5–3.5)	1.9% (0.0–4.8)	0.722
	I^2 = 50.6%	I^2 = 0.0%	I^2 = 21.7%	
Serious adverse events	1.3% (0.7–2.0)	1.3% (0.3–2.3)	0.4% (0.0–2.3)	0.422
	I^2 = 4.4%	I^2 = 0.0%	I^2 = 0.0%	
Procedure-related mortality	0.3% (0.0–0.7)	0.3% (0.0–1.1)	0.3% (0.0–2.1)	0.996
	I^2 = 0.0%	I^2 = 0.0%	I^2 = 0.0%	

meta-regression, publication year was a significant covariate contributing to heterogeneity with respect to overall AE ($p = 0.0038$) and maldeployment ($p = 0.0028$) (Figure 3), but not for other outcomes.

DISCUSSION

The present meta-analysis reports a pooled technical success rate of 97% (95.9–98.0) with a pooled clinical success rate of 90.6% (88.4–92.7). The pooled incidence of overall AEs with EUS-GE was 13.1% (10.3–15.9), with the commonest being maldeployment of the stent, seen in 4.6% (3.2–6.0). The pooled incidence of serious AE and procedure-related mortality were 1.3% (0.7–2.0) and 0.3% (0.0–0.7), respectively.

Unlike peripancreatic cysts, which are usually fixed, the bowel is freely mobile. Puncturing a freely moving bowel using an LAMS delivery catheter is often tricky and associated with a higher risk of complications as compared to peripancreatic cysts. The commonest AE associated with EUS-GE was maldeployment of the stent, which was seen in 4.6% of the cases. Even in competent hands, the rate of maldeployment is considerable, ranging from 6% to 27%, and is the primary cause of technical failure.[18,52] For successful deployment of the stent, the targeted bowel loop must be within 1–1.5 cm of the stomach wall. This ensures a safe puncture and formation of a mature anastomotic tract. In a recent large multicentre retrospective study of 464 patients, stent maldeployment was observed in 9.85% of cases. The authors also devised a classification system with management and outcomes different for each type. Most of them could be managed endoscopically, and surgical intervention was required in only 11% of cases.[10]

The technique of choice for EUS-GE is still based on the endoscopist's discretion and logistics. While two dedicated E-PASS balloon catheters are available, their use remains limited to the countries of origin due to medical device restrictions and regulations. There are currently five different techniques described for performing EUS-GE, including direct and assisted techniques.[8] Few studies have compared AE rates with respect to the technique employed. Prior studies have demonstrated a higher AE rate with direct technique than with balloon-assisted technique.[8,16] The reason stated was that a direct unassisted procedure may result in inadvertent puncture of the distal small bowel or colon, as fluoroscopy alone may not differentiate these structures. Modification of this technique by distending the small bowel with saline/methylene blue resulted in reducing the risk of inadvertent distal bowel puncture. The direct “free-hand” technique allows immediate deployment of the stent at the puncture site. This circumvents the constraints of wire-guided insertion, which necessitates exchange over the guide wire, prolonging the process and potentially allowing the small bowel to travel away from the stomach wall. Furthermore, the direct approach offers the greatest degree of freedom in selecting the target small bowel limb. Distending the target small bowel is also

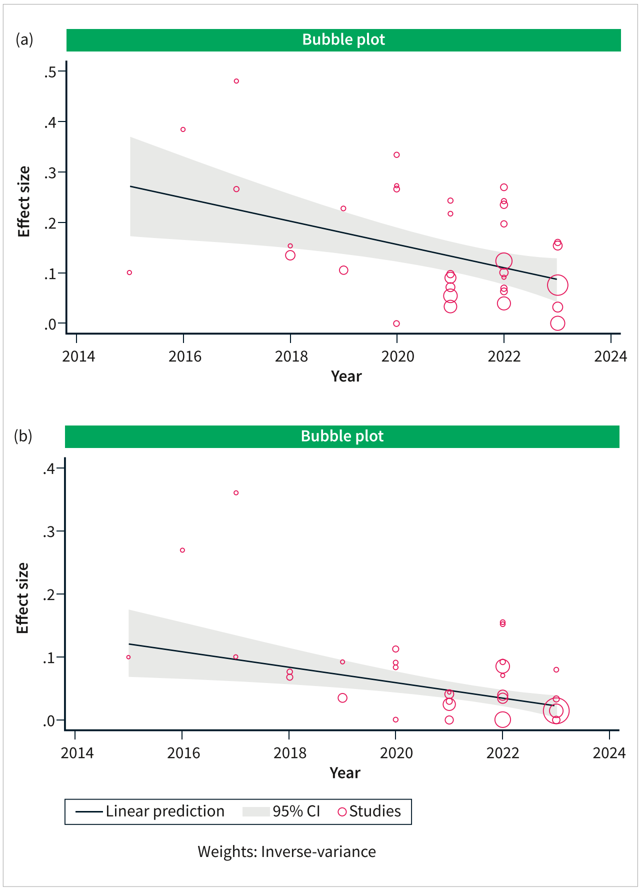

FIGURE 3 Meta-regression analysis showing the publication year as a significant covariate contributing to heterogeneity with respect to (a) overall adverse events and (b) maldeployment.

easy with the instillation of contrast mixed with a paralytic agent (hyoscine or glucagon) to expand and visualize the small bowel. This permits numerous potential targets to emerge, allowing the endoscopist to choose the most appropriate target.

The learning curve may play an important role in the success and adoptability of any novel procedure. Jovani et al. analyzed the learning curve of EUS-GE and reported that at least 25 cases were required to become proficient, and 40 cases were required to become an expert in EUS-GE. Although not statistically significant, all the immediate AEs associated with EUS-GE occurred during the first 39 cases.[32] The direct technique was associated with a shorter procedure time and is more user-friendly as it requires less resources to perform, which decreases the learning curve.[19] Hence, operator expertise may also be a determinant of AEs with EUS-GE. We also observed that on meta-regression analysis, publication year was a significant contributor to heterogeneity.

The primary prerequisite for a successful procedure is the availability of a distended limb of the small bowel that is distal to the site of obstruction and near the stomach. However, in a subset of patients, this may not be possible due to fixity of the proximal small bowel due to adhesions, peritoneal carcinomatosis or post-surgical anatomy, or intervening ascites or lymph node mass. Furthermore, tumor invasion of the gastric wall precludes puncture and deployment of the stent. Kastelijn et al. first reported successful outcomes with EUS-GE in patients with ascites and/or peritoneal carcinomatosis. Of the 24 patients, Clinical success was achieved in eight of 10 patients (80.0%) with peritoneal carcinomatosis and in 22 of 24 patients (91.7%) without peritoneal carcinomatosis. Ten of 11 (90.9%) patients with ascites and 21 of 25 patients (84.0%) without ascites had clinical success.[27] Basha et al., in their study of 31 patients, of which 12 patients had ascites, demonstrated similar technical and clinical success with a similar AE rate compared to patients without ascites.[29] Mahmoud et al. reported that the incidence of AEs was higher in patients with ascites than in those without ascites (37.5% vs. 19.4%). However, most of these were mild AEs, and the incidence of moderate to severe AEs was comparable between patients with and without ascites. Patients with ascites were also found to develop peritonitis followed by sepsis.[43] In the study by van Wanrooij et al., peritoneal carcinomatosis was present in a significantly higher proportion of patients undergoing EUS-GE than ES (41.1% vs. 25.2%, $p = 0.02$). Despite this, the clinical success rate was significantly higher in the EUS-GE group (90% vs. 77%) with a lower incidence of stent dysfunction (3% vs. 30%).[46] Although the procedure can be performed in this difficult subset of patients, multiple studies have shown a lower overall survival and increased rates of recurrent obstruction in these patients.[12,20] Hence, a multi-disciplinary discussion with a careful review of radiological findings as well as shared decision-making with the patient/caregiver is important.

The pooled incidence of delayed stent migration and stent occlusion was 0.5% (95% CI: 0.0–1.1) and 0.8% (95% CI: 0.2–1.3), respectively. Aldehuelo et al., in a recent study, compared the 3-month stent failure rate between duodenal self-expanding metal stent (SEMS) and EUS-GE. The technical and clinical success were similar, but the patency rates for EUS-GE were better. The failures in the SEMS group were due to delayed stent dysfunction due to tumor ingrowth, whereas most failures in the EUS-GE group occurred immediately at the time of stent implantation. Stent dysfunction was reported in only 2.5% of cases.[37] This may be because of improved stent design and delivery systems. Also, a number of salvage techniques have been described in this scenario. Kerdsirichairat et al. described two methods - either placement of a second LAMS or SEMS inside the previous one or removal of the LAMS, closing the defect, and reattempting.[24] Hence, with increasing experience in performing this procedure, there is greater confidence in managing both early as well as delayed AE. Abbas et al. prospectively evaluated a Standardized Clinical and Assessment Management Plan for EUS-GE (36). This ensured high technical success (100%) in a series of 50 cases, while AE were minimized to 4%. Hence, standardizing techniques from indication to post-procedure care may help optimize outcomes further.

The present meta-analysis is the first to focus on the AEs associated with EUS-GE and its various techniques. Our strengths were a comprehensive review of literature with well-defined inclusion and exclusion criteria. There are a few limitations to the present study. First, the majority were retrospective single-center studies, which have their inherent limitations. Second, the timeline of the studies included extended across several years. With time, there has been a continuous change and improvement in the performance, technique, and devices used in EUS-GE, which may have affected the overall outcomes and AE rates. Third, we were not able to stratify the types of stent maldeployment due to the paucity of data in the included studies. Also, due to variations in study designs and reporting issues, the incidence of delayed AE is likely to be prone to inaccuracies. Lastly, all the studies were conducted with large tertiary care referral institutes with substantial endoscopic expertise, which limits the generalizability of these data.

To conclude, EUS-GE is an effective technique for managing GOO with a high technical and clinical success rate of more than 90%. Although AEs are seen in around one out of seven cases, the pooled incidences of serious AE, procedure-related mortality, and delayed AE remain low. The free-hand technique showed a lower incidence of overall and serious AEs. The results of our analysis may guide healthcare professionals and international societies in developing guidelines for the safety of EUS-GE and defining acceptable limits for AEs associated with EUS-GE.

AUTHOR CONTRIBUTIONS

Conception and design: Suprabhat Giri, Sridhar Sundaram; Analysis and interpretation of the data: Suprabhat Giri, Sidharth Harindranath, Babu P. Mohan, Vaneet Jearth, Aditya Kale, Jijo Varghese, Marko Kozyk, Sridhar Sundaram; drafting of the article: Suprabhat Giri, Sidharth Harindranath, Babu P. Mohan, Vaneet Jearth, Sridhar Sundaram; critical revision of the article for important intellectual content: Suprabhat Giri, Babu P. Mohan, Aditya Kale, Sridhar Sundaram; final approval of the article: Suprabhat Giri, Sidharth Harindranath, Babu P. Mohan, Vaneet Jearth, Jijo Varghese, Marko Kozyk, Aditya Kale, Sridhar Sundaram.

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None.

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Data not available as no new data was generated or analyzed.

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