

Endoscopic ultrasonography-guided gastroenterostomy for malignant and benign gastric outlet obstruction: a systematic review and meta-analysis

Raffaele Manta^a, Angelo Zullo^b, Vincenzo De Francesco^c, Marco Spadaccini^{d,e}, Cesare Hassan^{d,e}, Luigi Gatta^f

ASL Toscana Nord-Ovest, Spedali Riuniti Hospital, Livorno; Nuovo Regina Margherita Hospital, Rome; Riuniti Hospital, University of Foggia; Humanitas University, Pieve Emanuele; Humanitas Clinical Research Center, Rozzano, UOC Screening Aziendali, Azienda USL Toscana Nord-Overst, Livorno, Italy

Abstract

Background Endoscopic ultrasonography-guided gastroenterostomy (EUS-GE) with a lumen-apposing metal stent has been proposed as a treatment for patients with gastric outlet obstruction (GOO). We performed a systematic review and meta-analysis to compute the technical success, clinical success and complication rates of EUS-GE in treating GOO due to either neoplastic or benign diseases.

Methods The literature search was conducted in PubMed, EMBASE and the Cochrane Central Register of Controlled Trials, from inception until January 23, 2025, according to the PRISMA and MOOSE statement guidelines. The primary objective was to assess both technical and clinical success. A secondary outcome was to rate the adverse events.

Results Data from 39 studies involving 2845 patients were analyzed. The pooled technical success rate was 95.1%, and the procedure was successful in 95.3% and 95.1% of patients with malignant or benign diseases, respectively. Clinical success was achieved in 93.5% of all patients where the procedure had technical success, and in 93.1% and 94.4% of those treated for malignant and benign conditions, respectively. The overall rate of adverse events was 18.5%, including perforation (4.4%), bleeding (2.7%), stent migration (1.4%), stent closure (3.3%), infection (4.4%), and fistula (2.3%). The procedure-related mortality was 1.4%.

Conclusion EUS-GE appears to be a viable approach for the treatment of GOO patients, for both malignant and benign diseases, with favorable outcomes and an acceptable safety profile.

Keywords Endoscopic ultrasonography, gastroenterostomy, gastric outlet obstruction, lumen-apposing metal stent

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Introduction

Gastric outlet obstruction (GOO), due to either malignant or benign conditions, is traditionally treated with surgery,

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Correspondence to: Raffaele Manta, MD, Digestive Endoscopy Unit, 'Spedali Riuniti' Hospital, Livorno, Italy, e-mail raffaelemanta4@gmail.com

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which improves the quality of life and survival of patients with the condition [1]. A less invasive approach, with endoscopic stenting of strictures, was subsequently introduced, but the technical unfeasibility in some cases and stent migration are potential limitations [2]. In the last decade, endoscopic ultrasonography-guided gastroenterostomy (EUS-GE) was pioneered as a novel endoscopic method to palliate neoplastic GOO and, more recently, to treat benign obstructions, mainly due to gastroduodenal or pancreatic diseases [3-6]. Basically, EUS-GE involves creating a gastrointestinal anastomosis between the stomach and an intestinal loop, through electrocautery-enhanced dilators and lumen-apposing metal stents (LAMS), bypassing the intestinal obstruction [7]. It is performed via different procedures, namely the direct EUS-GE technique, which involves puncturing a small bowel loop adjacent to the stomach, or by preventively identifying the intestinal loop using either a nasobiliary catheter or a double-

balloon device. A head-to-head comparison showed similar performance between the direct and assisted techniques [8].

Some studies reported the feasibility of EUS-GE for the treatment of GOO, and a few systematic reviews pooled the data coming from the early experiences, comparing EUS-GE with enteral stenting and surgery, and underlining its favorable profile in term of technical and clinical success [9-11]. In addition, EUS-GE was found to cause fewer adverse events (AEs) than surgery [12]. The current European Society of Gastrointestinal Endoscopy guidelines suggest considering EUS-GE in patients with malignant GOO who are poor surgical candidates, but the quality of evidence was low because of the lack of aggregate data [3]. Furthermore, evidence relating to EUS-GE in benign conditions is still limited to small case series. We therefore performed a systematic review and meta-analysis to investigate the efficacy and safety profile of EUS-GE in treating patients with GOO due to either neoplastic or benign diseases.

Materials and methods

Search strategy and study selection

This meta-analysis was developed according to the PRISMA and to the MOOSE statement guidelines [13,14]. A search of the medical literature was conducted using PubMed, EMBASE, and the Cochrane Central Register of Controlled Trials, from inception to January 23, 2025. Studies were identified using the following terms as free text and, where possible, as MeSH and/or Emtree Term: malignant or benign gastric outlet obstruction, gastrectomy, gastric bypass, gastroenterostomy, gastrojejunostomy, gastro-entero-anastomosis, endoscopic ultrasound guided gastroenterostomy, balloon-assisted gastroenterostomy, BAGE, Hot Axios, Niti-S SPAXUS, electrocautery lumen-apposing metal stents, pure natural orifice transluminal endoscopic, hanarostent, lumen-apposing metal stents. Only full papers published in English were considered. Inclusion criteria were: a) patients aged ≥ 18 years; b) EUS-GE performed for treatment of GOO due to either benign or malignant diseases; c) availability of (or clearly extrapolatable) data on both technical and clinical success; d) studies including ≥ 10 patients; and e) data on procedure-related AEs during the procedure and/or at follow up. When more than 1 publication from the same investigator group was available, only the most updated version, including the entire sample size, was considered for this meta-analysis. The above search strategy identified relevant studies, and bibliographies of

all identified relevant studies were used to perform a recursive search. Abstracts of the papers identified by the initial search were evaluated for appropriateness, in a blinded manner, independently by 2 authors (AZ and VDF), who independently extracted the following data: 1) total number of patients treated with EUS-GE; 2) number of patients treated for either malignant or benign diseases; 3) technical success rate; 4) clinical success rate; and 5) AEs, namely perforation, bleeding, stent migration, stent closure, infection, fistulas, and death. Any disagreement was resolved by discussion between the 2 authors. Risk of bias for randomized controlled trials (RCTs) was assessed as described by the Cochrane handbook [15]. The Newcastle-Ottawa scale (possible highest score: 9) was used to assess the quality of cohort studies [16]. Single-arm cohort studies (i.e., case series) [17] were evaluated using the 20-item quality appraisal checklist developed by the Institute of Health Economics (Canada) [17,18].

Outcomes

The primary objective was to assess both technical and clinical success. Technical success was defined as the successful placement of a stent across the site of obstruction, confirmed by endoscopy or fluoroscopy [7]. Clinical success was evaluated according to per-protocol analysis—i.e., in patients where the procedure achieved technical success—and was defined as at least a 1-point increase in the gastric outlet obstruction score system, which includes 4 stages (0: no oral intake; 1: liquid diet; 2: semi-solids/low-residue diet; and 3: unmodified diet) at follow up [2]. AEs were computed as secondary outcomes.

Statistical analysis

Data for primary and secondary outcomes were pooled from all kinds of studies, using a random-effects model to yield a more conservative estimate [19]. Heterogeneity between trials was assessed using the chi-squared test for heterogeneity, and the P statistic was also calculated [20]. StatsDirect (StatsDirect, Ltd. England) was used to generate forest plots for primary and secondary outcomes, with 95% confidence intervals (CIs), as well as funnel plots. If the number of studies was ≥ 10 , funnel plots were also assessed for evidence of asymmetry and possible publication bias or other small study effects, using Egger's linear regression [15, 21].

Results

Descriptive analysis

As shown in Fig. 1, the search identified 4384 citations. After duplicates had been removed, and records where the title and/or abstract were not pertinent excluded, 2600 reports were assessed for eligibility. At the end of the process, 39 studies, including 2485 patients (male 1341, 54%), were evaluated in the systematic review and meta-analysis (Table 1) [22-60]. The median number of enrolled patients

^aDigestive Endoscopy Unit, ASL Toscana Nord-Ovest, Spedali Riuniti Hospital, Livorno, Italy (Raffaele Manta); ^bGastroenterology Unit, Nuovo Regina Margherita Hospital, Rome, Italy (Angelo Zullo);

^cGastroenterology and Endoscopy Unit, Department of Medical and Surgical Sciences, Riunite Hospital, University of Foggia, Foggia, Italy (Vincenzo De Francesco); ^dHumanitas University, Department of Biomedical Sciences, Pieve Emanuele, Italy (Marco Spadaccini, Cesare Hassan); ^eHumanitas Clinical and Research Center, IRCCS, Endoscopy Unit, Rozzano, Italy (Marco Spadaccini, Cesare Hassan); ^fUOC Screening Aziendali, Azienda USL Toscana Nord-Ovest (ATNO), Livorno, Italy (Luigi Gatta)

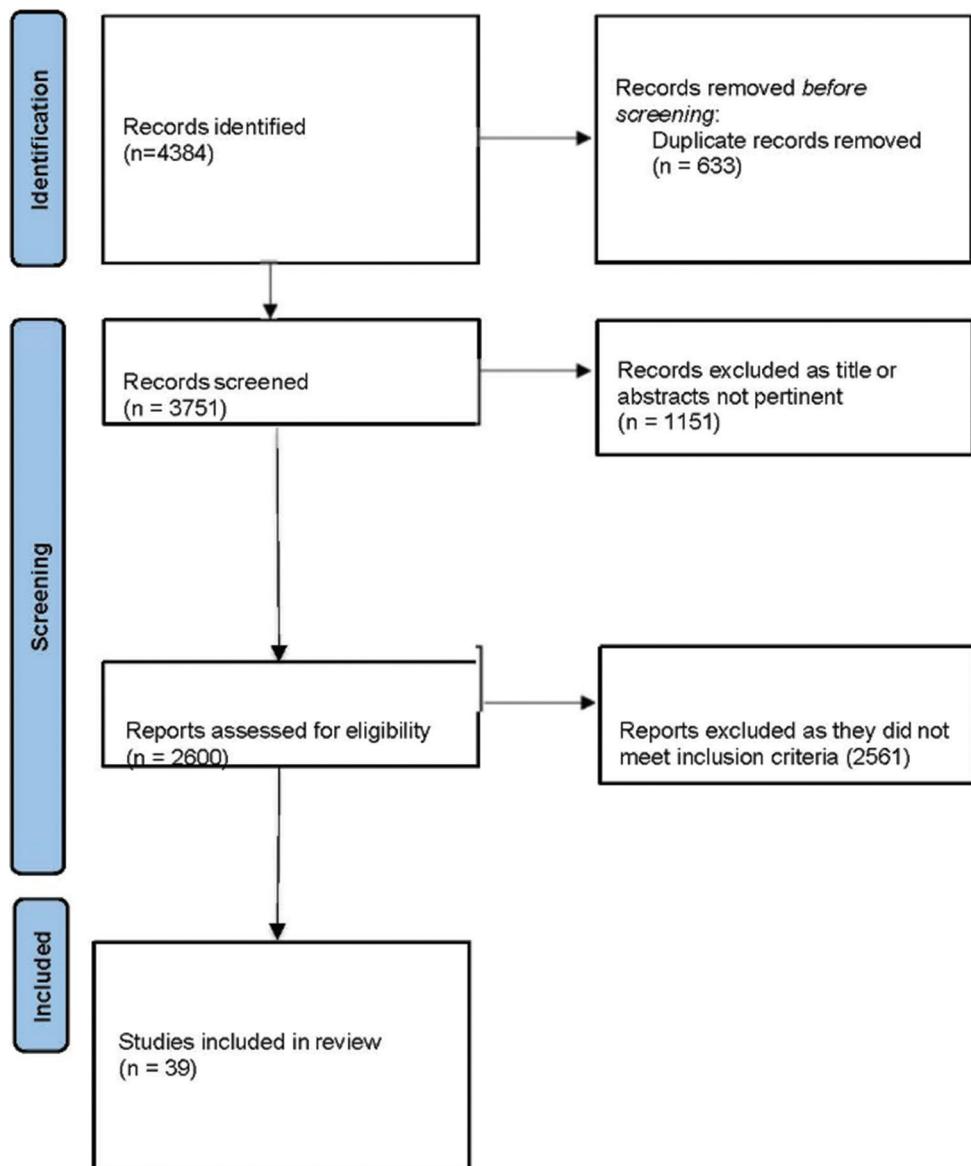


Figure 1 Flow chart showing the literature review

was 44, ranging from 11 to 267 among studies. There was 1 RCT [56], 9 cohort studies [24,39-42,47,49,53,55], and 29 case series [22,23,25-38,43-46,48,50-52,54,57-60]. Risk of bias was low for the RCT [56] (Supplementary Table 1), the quality of the cohort studies was good (Supplementary Table 2), and the value of case series studies ranged from 15-17 (Supplementary Table 3).

Technical success

As shown in Fig. 2, the pooled technical success rate was 95.1% (94.0-96.1), when all the 2485 treated patients in the 39 studies were considered [22-60], with evidence of publication bias (Egger's test: P=0.0014; Supplementary Fig. 1), and a moderate value of I^2 : 29.3%. In patients with malignant disease (N=1458; 21 studies; Supplementary Fig. 2), the procedure

was successful in 95.3% of cases (95%CI 94.2-96.4) [24,26,28,29,31,33,34,37-41,46,47,49,50,54-56,59,60], with no evidence of heterogeneity or publication bias (Supplementary Fig. 3). Similar results were found in patients with a benign disease (N=230; 9 studies; Supplementary Fig. 4) [25,28,29,31,46,48,50,57,59], with a pooled technical success rate of 95.1% (95%CI 92.0-97.5). As the number of studies was <10, no funnel plot or Egger's test was performed. Complete information on heterogeneity and publication bias is provided in Supplementary Table 4.

Clinical success

As shown in Fig. 3 (N=2398; 39 studies) [22-60], the overall clinical success rate was 93.5% (95%CI 91.5-95.3) in

Table 1 Characteristics of included studies*

Author [ref.]	Study design	Country	Centres	Cases (N)	Males (N)	Age (yrs)	Malignant/ Benign (N)	EUS-GE Type (N)	TS	CS
Tyberg <i>et al</i> [22]	R; CS	USA	2	26	11	66.2	17/9	Different methods	24	22
Chen <i>et al</i> [23]	R; CS	International	7	74	41	63±11.7	49/25	WEST: 52; EPASS: 22	69	68
Ge <i>et al</i> [24]	P; Co	USA	1	25	12	66.4±9.2	25/0	DTOG: 25	24	23
James <i>et al</i> [25]	R; CS	USA	1	22	13	54.2±13.4	0/22	WEST: 5; EPASS: 8; DTOG: 9	21	21
Kastelijn <i>et al</i> [26]	R; CS	International	7	45	22	69.9±12.3	45/0	DTOG: 36; EPASS: 9	39	33
Basha <i>et al</i> [27]	P; CS	India	1	31	20	61.6±10.6	29/2	WEST: 4; EPASS: 27	28	27
Betes <i>et al</i> [28]	R; CS	Spain	1	30	16	67.1±11.5	27/3	WEST: 30	30	27
Havre <i>et al</i> [29]	R; CS	Norway	2	33	20	73±15.3	28/5	DTOG: 33	33	30
Nguyen <i>et al</i> [30]	P; CS	USA	1	42	23	73.1±2.8	37/5	DTOG: 42	41	49
Sobani <i>et al</i> [31]	P; Co	USA	1	31	17	61.4±16.5	23/8	DTOG: 31	31	29
Tyberg <i>et al</i> [32]	P; CS	USA	1	23	9	65.8±18.5	11/12	Different methods	22	21
Abbas <i>et al</i> [33]	P; CS	USA	1	50	23	67±10	50/0	DTOG: 50	50	46
Bejjani <i>et al</i> [34]	R; CS	International	19	267	152	67.3±12.1	267/0	DTOG or EPASS (Not specified)	255	232
Choi <i>et al</i> [35]	P; CS	USA	1	52	30	64±NA	36/16	NA	48	42
Fisher <i>et al</i> [36]	R; CS	Germany	2	45	19	65 (36-84)	39/6	WEST: 45	44	42
Huang <i>et al</i> [37]	R; CS	China	1	51	27	65.8±13.8	51/0	EPASS: 51	50	47
Park <i>et al</i> [38]	R; CS	USA	1	41	21	70±NA	41/0	Different methods	39	33
van Wanrooij <i>et al</i> [39]	R; Co	International	3	88	44	66±11.8	44/0	WEST: 88	83	80
Canakis <i>et al</i> [40]	R; Co	USA	6	187	111	67.5±12.6	187/0	DTOG: 187	183	176
Chan <i>et al</i> [41]	R; Co	China; India	2	30	22	64 (32-88)	30/0	EPASS: 30	28	28
Jaruvongvanich <i>et al</i> [42]	R; Co	USA; Belgium	2	232	135	64.5±12.3	191/41	WEST: 22; DTOG: 186; EPASS: 24	228	228
Mangiavillano <i>et al</i> [43]	R; CS	International	5	25	16	68.7±9.3	22/3	DTOG: 25	25	17
Monino <i>et al</i> [44]	R; CS	International	4	71	30	66.2±10	57/14	DTOG: 30; WEST: 41	61	55
On <i>et al</i> 2023 [45]	R; CS	UK	3	25	15	63 (29-80)	22/3	DTOG: 19; WEST: 6	23	23
Stefanovic <i>et al</i> [46]	R; CS	Belgium	1	35	20	NA	24/11	NA	33	33
Vanella <i>et al</i> [47]	P; Co	Italy	1	70	41	64 (58-73)	70/0	WEST: 70	68	66
Abel <i>et al</i> [48]	R; CS	USA	1	18	7	63 (40-93)	0/18	DTOG: 15; WEST: 3	18	17

(Contd...)

Table 1 (Continued)

Author [ref.]	Study design	Country	Centres	Cases (N)	Males (N)	Age (yrs)	Malignant/ Benign (N)	EUS-GE Type (N)	TS	CS
Conti Bellocchi <i>et al</i> [49]	R; Co	Italy	2	66	38	69.6±11.4	66/0	WEST: 66	65	60
Gonzalez <i>et al</i> [50]	R; CS	France	1	87	46	66±16.2	53/34	DTOG: 33; WEST: 54	84	82
Harb <i>et al</i> [51]	R; CS	Australia	2	11	7	73±13	10/1	WEST: 11	10	10
Laohavichitra <i>et al</i> [52]	R; CS	Thailand	1	12	2	53±6.2	10/2	DTOG: 1; WEST: 4; EPASS: 7	11	11
Martinet <i>et al</i> [53]	R; Co	France	3	56	32	71 (60-79)	50/16	DTOG or WEST (Not specified)	51	49
Pasam <i>et al</i> [54]	R; CS	USA	1	137	70	66.4±12.9	137/0	DTOG: 137	127/137	44/50
Seitz <i>et al</i> [55]	P; Co	Germany	1	44	20	73 (44-92)	44/0	WEST: 42; DTOG: 2	41	34
Teoh <i>et al</i> [56]	RCT	International	7	48	25	69.5±12.6	48/0	EPASS: 48	46	44
Wannhoff <i>et al</i> [57]	R; CS	International	7	39	24	55 (27-76)	0/39	DTOG or WEST (not specified)	36	34
Gökce <i>et al</i> [58]	R; CS	Belgium	1	72	35	67 (NA)	50/22	DTOG: 72	70	68
Trieu <i>et al</i> [59]	R; CS	USA	1	207	104	62.3±14.1	117/90	DTOG: 207	198	174
Tsuchiya <i>et al</i> [60]	R; CS	Japan	1	37	21	71±12.5	37/0	EPASS: 37	35	33

*R, retrospective; P, prospective; CS, case series; Co, Cohort study; RCT, randomized controlled trial; DTOG, Direct technique over a guidewire; WEST, Wireless endoscopic simplified technique; EPASS, EUS-guided balloon-occluded gastrojejunostomy; TS, Technical success; CS, clinical success

patients with available data following a successful procedure, with substantial heterogeneity I^2 : 66.9% and no publication bias (Supplementary Fig. 5). In patients with malignant diseases (N=1371; 21 studies) [24,26,28,29,31,33,34,37-41,46,47,49,50,54-56,59,60], the clinical success was 93.1% (95%CI 91.0-95.0), with moderate heterogeneity I^2 : 45% and publication bias ($P=0.0162$; Supplementary Fig. 6,7). In patients with benign conditions (N=230; 9 studies) [25,28,29,31,46,48,50,57,59], clinical success was 94.4% (95%CI 86.1-99.1; Supplementary Fig. 8) with substantial heterogeneity ($I^2=72.8\%$). As the number of studies was <10, no funnel plot or Egger's test was performed. Complete information on heterogeneity and publication bias is provided in Supplementary Table 4.

AEs

Based on the available data, the rate of AEs was 18.5%, including intestinal perforation in 4.4% (95%CI 2.8-6.0) of 2437 patients (38 studies; $I^2=64.9\%$ and no publication bias; Supplementary Fig. 9,10) [22-55,57-60]; intestinal bleeding in 2.7% (95%CI 1.8-3.7) of 2437 cases (38 studies; $I^2=39.5\%$ and publication bias: $P<0.0001$; Supplementary Fig. 11,12) [22-55,57-60]; stent migration in 1.4% (95%CI 0.9-1.2) of 2397 patients (37 studies; $I^2=13.7\%$ and publication bias: $P=0.0077$;

Supplementary Fig. 13,14) [22-36,38-59]; stent closure in 3.3% (95%CI 2.3-4.5) of 2158 cases (35 studies; $I^2=43.3\%$ and publication bias: $P<0.0001$; Supplementary Fig. 15,16) [22-34,36,38,39,41-59]; infection in 4.4% (95%CI 2.5-6.7) of 2041 patients (32 studies; $I^2=79.2\%$ and publication bias: $P=0.0015$; Supplementary Fig. 17,18) [22,24-27,29-34,37-39,41-47,49-59]; and fistulas in 2.3% (95%CI 1.3-3.7) of 590 cases (9 studies; $I^2=0\%$ and publication bias: $P<0.0011$; Supplementary Fig. 19) [28,33,36,38,44,46,57-59]. As the number of studies was <10, no funnel plot or Egger's test was performed. A procedure-related death occurred in 1.4% (95%CI 0.7-2.2) of 1671 patients (30 studies; $I^2=16.4\%$ and no publication bias; Supplementary Fig. 20,21) [22-29,31-34,36,39,41,43-45,47-53,55-59]. Complete information on heterogeneity and publication bias is provided in Supplementary Table 4." in Complete information on heterogeneity and publication bias is provided in Supplementary Table 4. The PRISMA 2020 and MOOSE checklists are reported in Supplementary Tables 5 and 6, respectively.

Discussion

Gastric and pancreatic cancers are the 5th and 6th largest contributors to cancer-related mortality worldwide, and both types of neoplasia may cause GOO syndrome in more advanced

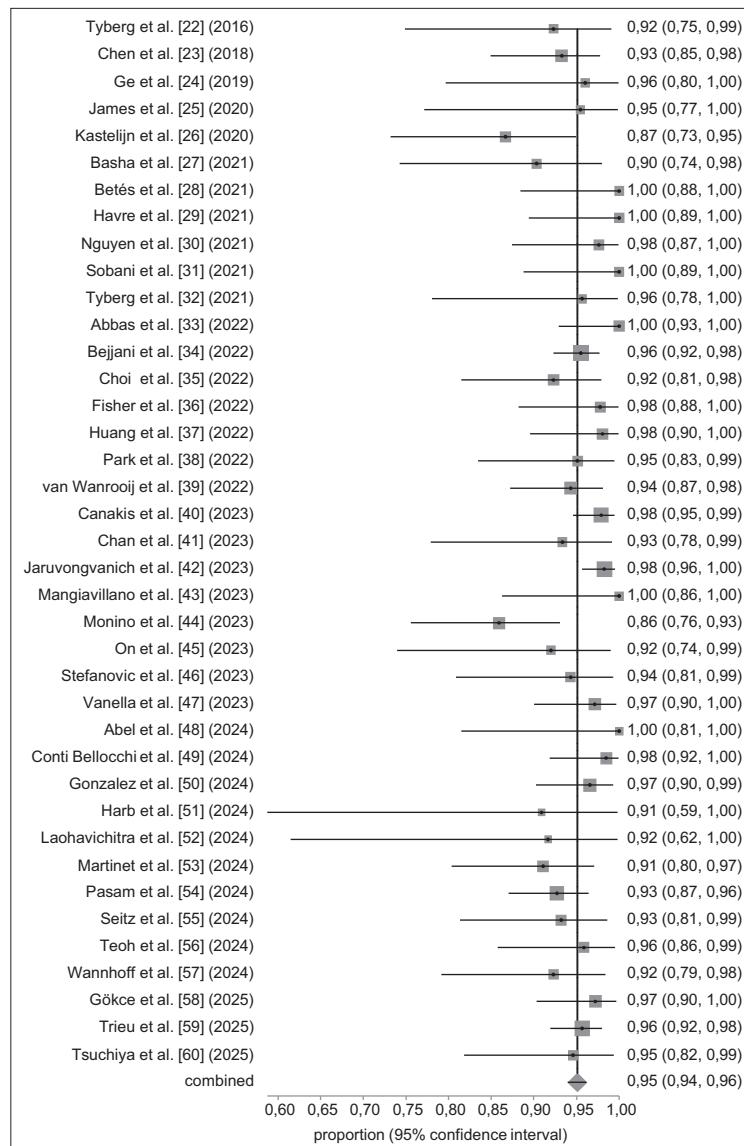


Figure 2 Forest plot of the technical success rate of all patients (with malignant or benign disease)

stages [61]. Moreover, some benign causes, such as peptic, non-steroidal anti-inflammatory drugs, radiation, anastomotic strictures, groove pancreatitis, polyps and stones may provoke GOO [62]. GOO syndrome entails persistent vomiting, dehydration, severe weight loss and cachexia, so that patients suffer a poor quality of life and are at increased risk of mortality, beyond the underlying diseases [62]. Surgical treatment aiming to bypass the intestinal obstruction is habitually performed as a palliative solution [63,64]. The introduction of the EUS-GE procedure has increased the possibilities of endoscopic treatment in these patients, as a less invasive approach when compared to surgery [12]. While EUS-GE could be pivotal in allowing clinical improvement towards recovery in patients with benign diseases, the indication for this procedure in oncological patients, often with poor life expectancy, should be opportunely discussed by multidisciplinary teams, since the approach has no

curative intent [65]. Currently, EUS-GE should be considered in GOO patients who are poor surgical candidates, but current guidelines could be improved by more evidence [7].

How feasible, successful and safe is the EUS-GE in resolving GOO? To answer this relevant question, we performed the present systematic review and meta-analysis. Taking into account the available data from almost 2500 patients, we found that EUS-GE is feasible in 95% of cases, irrespective of the underlining disease causing the GOO. Moreover, when the procedure is successful, a clinical improvement of obstructive symptoms, allowing at least the introduction of a liquid diet, occurs in 93.5% of all patients, with no difference between benign and malignant conditions. Overall, these findings suggest that GOO can be successfully treated via the EUS-GE approach in the large majority of patients. However, since the data on benign diseases involved less than 250 patients, more information is

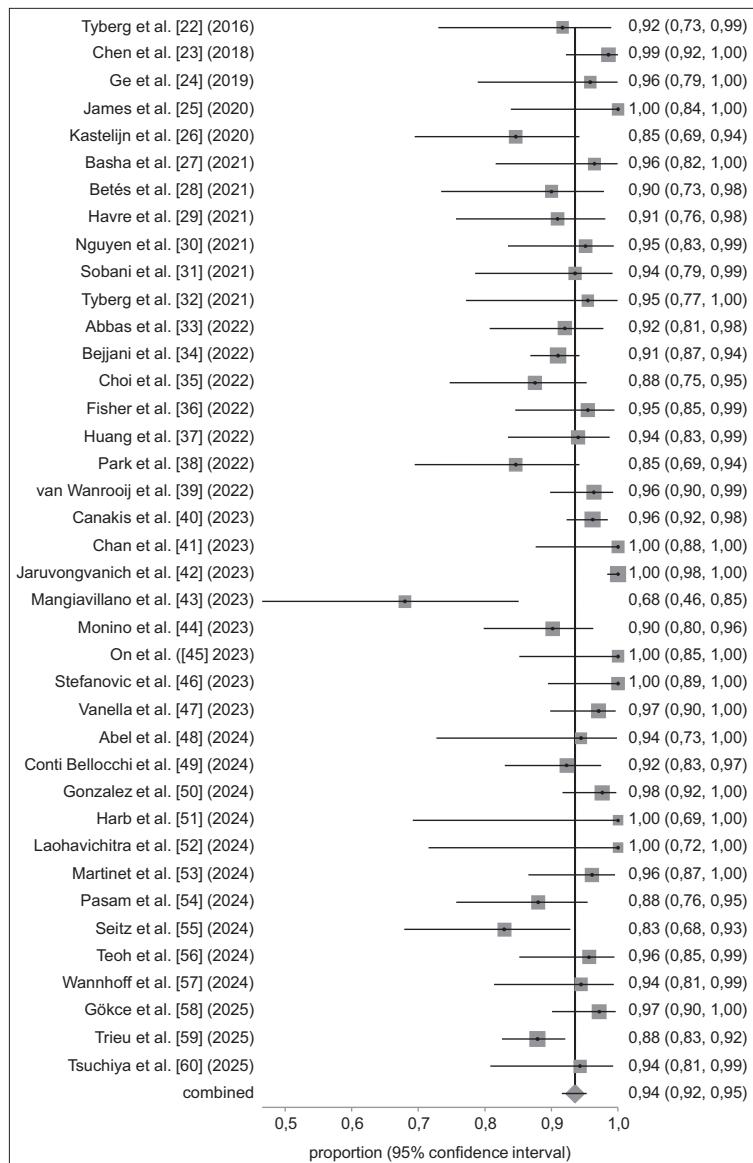


Figure 3 Forest plot of the clinical success rate of all patients (with malignant or benign disease)

needed. Besides being less invasive, EUS-GE is certainly cheaper as compared to surgical treatment, incurring both lower direct costs and a shorter hospital stay [9-11]. Although it is expected to be more costly than standard endoscopic stenting, the need for repeated procedures due to stent closure or migration was reported to be significantly higher following endoscopic stenting than with EUS-GE, and this may impact the overall costs [66]. Moreover, data from a recent systematic review demonstrated a significantly shorter hospital stay in favor of the EUS-GE group (mean difference: -2.82, 95%CI -5.05 to -0.59; $P=0.01$; $I^2=94\%$) as compared to duodenal stenting [10].

On the other hand, the type of EUS-GE procedure performed does not seem to be a matter for concern. Indeed, data from a multicenter study showed similar rates for both technical and clinical outcomes between the balloon-assisted and direct techniques—the latter being the preferred method, given its shorter procedure time when compared with the balloon-assisted approach [23].

Unfortunately, the EUS-GE procedure is not without risks. Data we analyzed found that an AE developed in up to 18.5% of patients, including intestinal perforation and bleeding, which occurred in 7% of procedures. However, in at least some cases, perforation and bleeding were successfully managed with clipping during endoscopy, even in the same session, so that the procedure was accomplished with a second LAMS without resorting to a surgical approach. Following a successful procedure, 7% of patients developed stent closure, stent migration or fistula at follow up. Therefore, the endoscopist should keep in mind that, in contrast to the EUS-guided biliary LAMS, a fistula may develop following EUS-GE, mainly involving the colon (gastro-colic; gastro-jejuno-colonic; gastro-colonic-jejunal), which may be temporarily interposed or adjacent to the jejunal loop during the procedure. Overall, the procedure-related mortality rate was 1.4%, which appears to be acceptable, particularly when considering the general

frailty of the treated patients, and lower than that reported with the surgical approach [11].

Undeniably, a limitation is that EUS-GE is a technically challenging procedure, requiring high expertise on the part of the endoscopist; thus it is currently performed only in some referral centers, and not widely in all geographic areas. A study assessing learning curve showed that a progressive reduction in procedure times and AEs, indicating that a satisfactory level of competence is generally achieved after 25 procedures, while full competence is reached following 40 procedures [67]. The introduction of electrocautery-assisted lumen-apposed metallic stents (Hot-LAMS), which enabled the development of the wireless (or freehand) EUS-GE technique, was an advantage in reducing the number of procedural steps. However, the operator's skill with the wireless technique remains a critical factor in ensuring safety and optimal results. Finally, a limitation of our systematic review is that nearly half of the considered studies were retrospective in nature, which may have produced biases [15].

In conclusion, the data from this comprehensive review showed that, in referral centers, EUS-GE appears to be a viable approach for the treatment of patients with GOO, for both malignant and benign diseases, with favorable efficacy outcomes and an acceptable safety profile.

Summary Box

What is already known:

- Gastric outlet obstruction (GOO) is generally treated with a surgical approach
- Endoscopic ultrasonography-guided gastroenterostomy (EUS-GE) with lumen-apposing metal stents was recently introduced to treat patients with GOO

What the new findings are:

- This comprehensive systematic review showed that EUS-GE is feasible in more than 95% of patients, with clinical success achieved in 93.5% of these cases
- No difference in either technical and clinical success rate emerged between patients treated for malignant or benign conditions
- Adverse events overall occurred in almost 20% of patients, with a procedure-related mortality of 1.4%

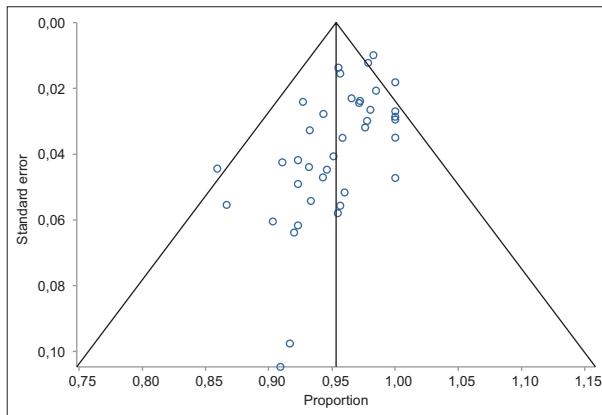
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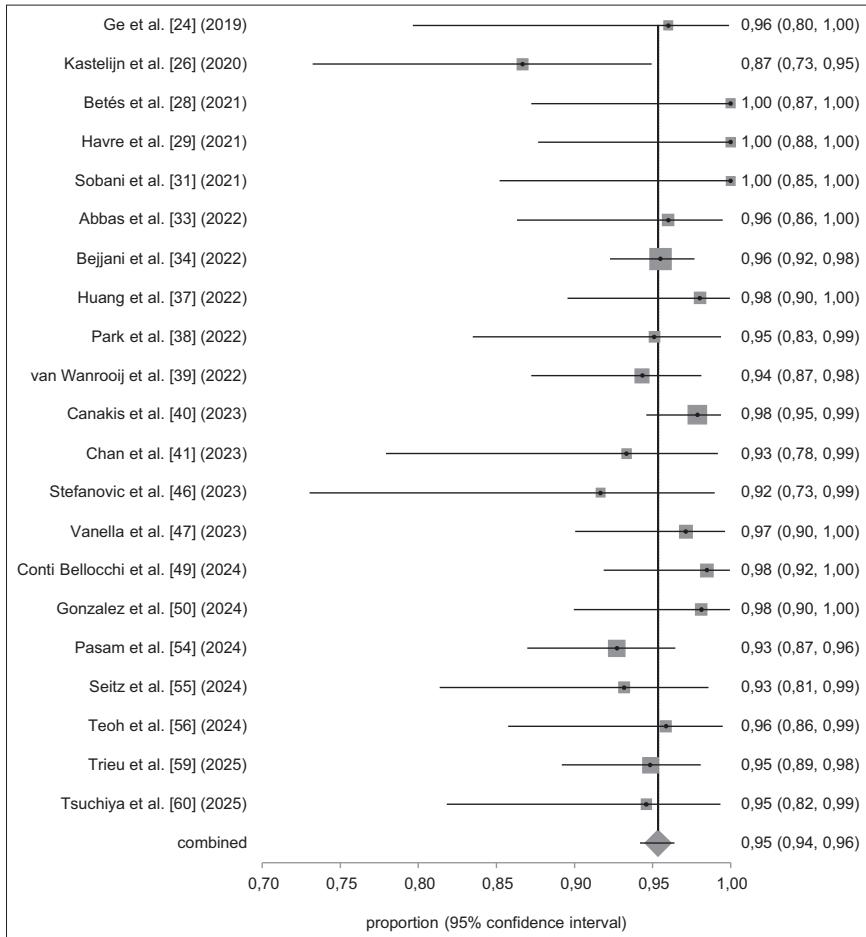
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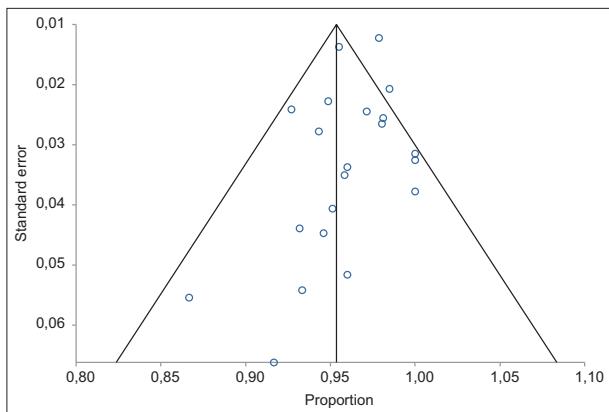
Supplementary material



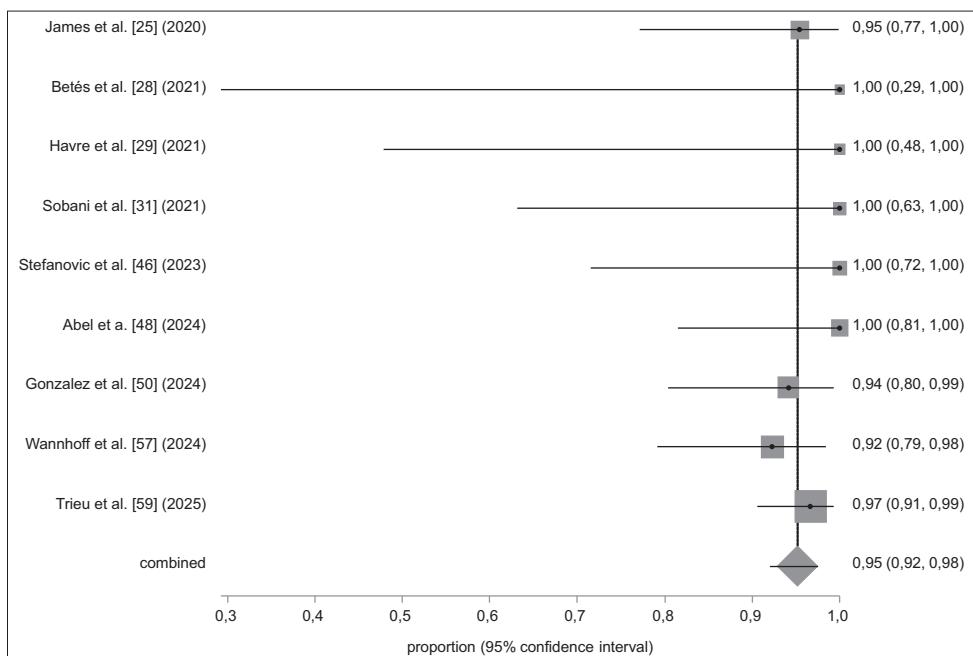
Supplementary Figure 1 Funnel plot of the technical success rate of all patients (with malignant or benign disease)



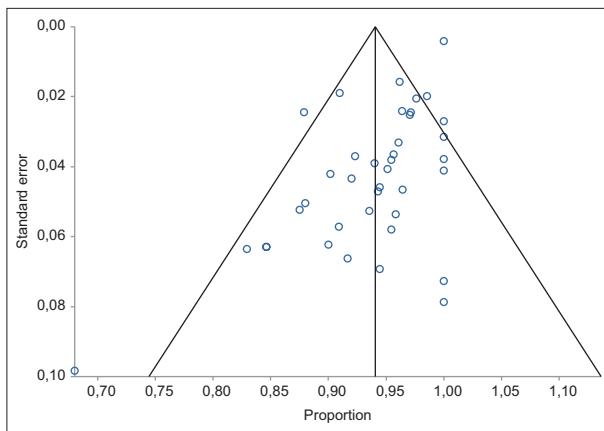
Supplementary Figure 2 Forest plot of the technical success rate in patients with malignant disease



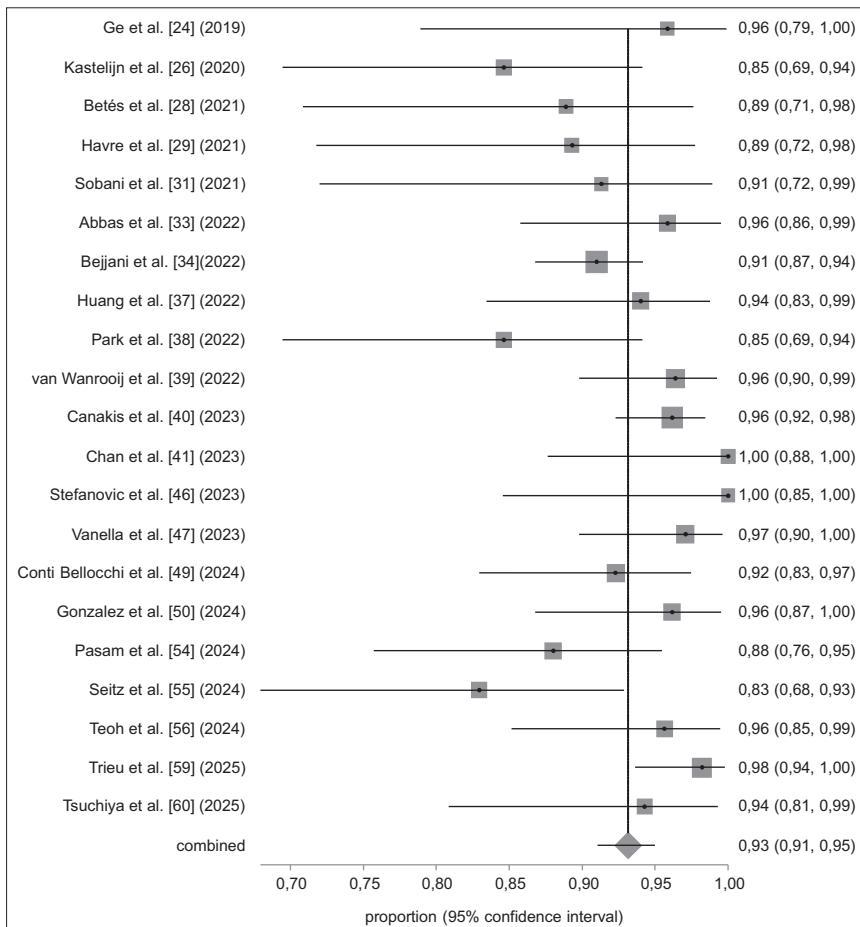
Supplementary Figure 3 Funnel plot of the technical success rate in patients with malignant disease



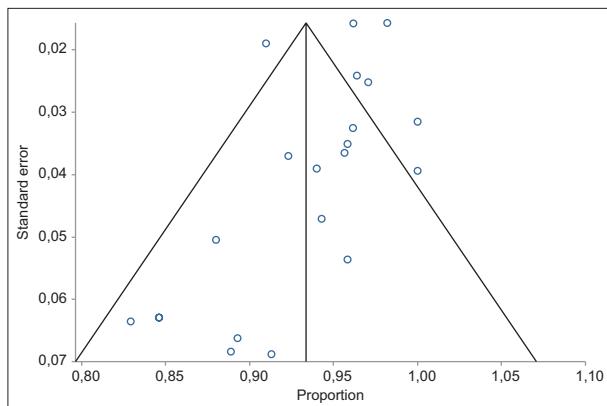
Supplementary Figure 4 Forest plot of the technical success rate in patients with benign disease



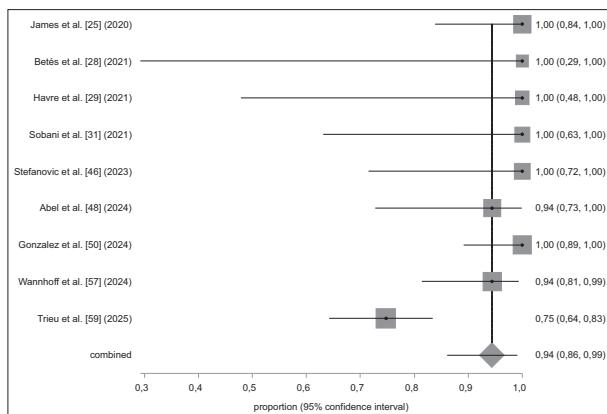
Supplementary Figure 5 Funnel plot of the clinical success rate of all patients (with malignant or benign disease)



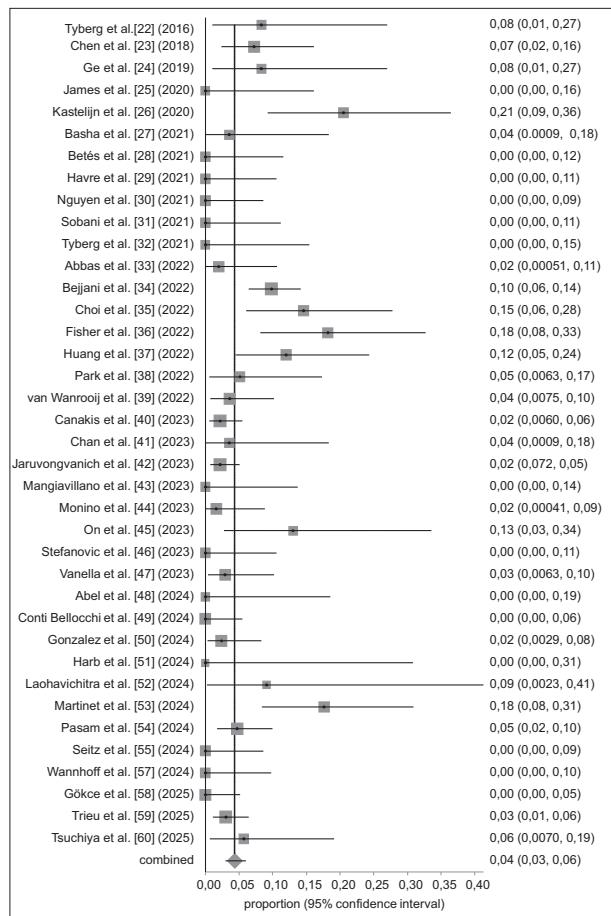
Supplementary Figure 6 Forest plot of the clinical success rate in patients with malignant disease



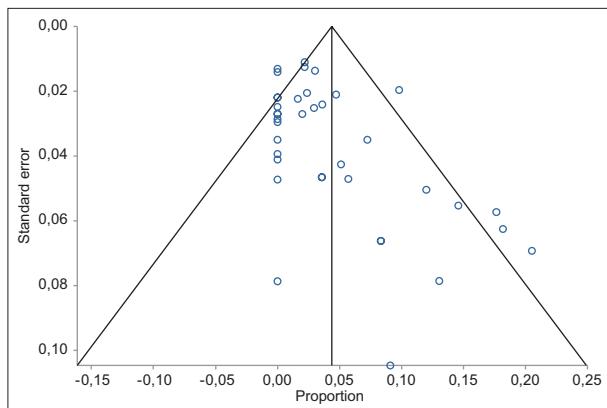
Supplementary Figure 7 Funnel plot of the clinical success rate in patients with malignant disease



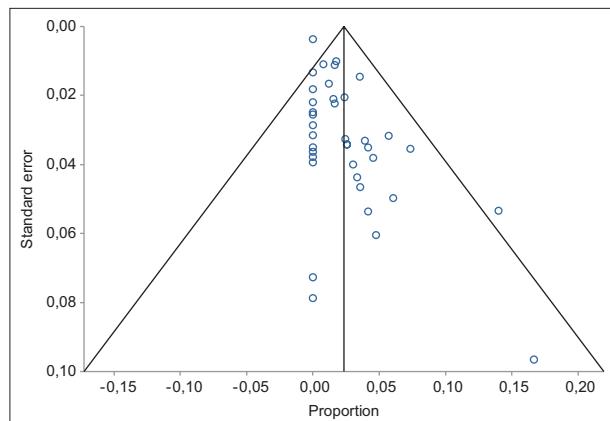
Supplementary Figure 8 Forest plot of the clinical success rate in patients with benign disease



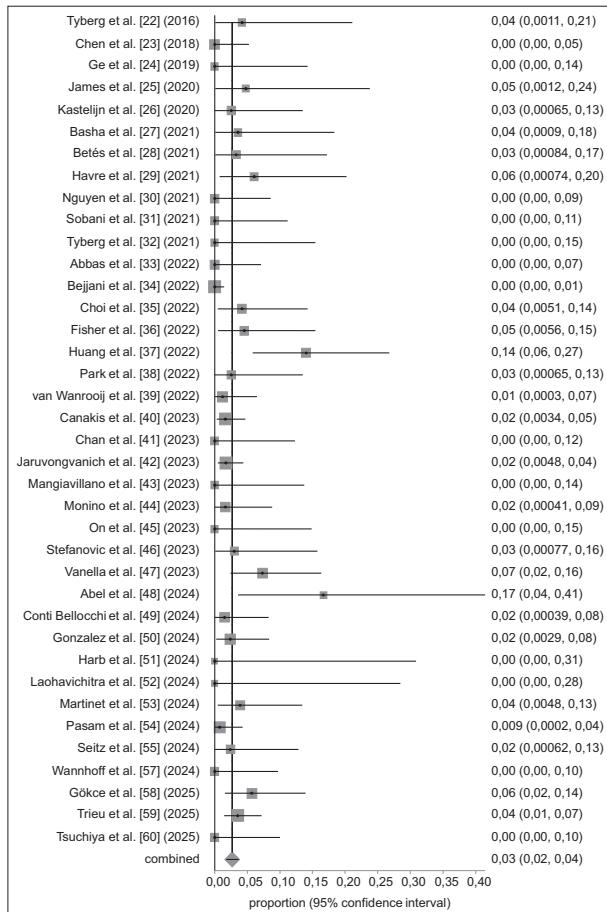
Supplementary Figure 9 Forest plot of the perforation rate of all patients (with malignant or benign disease)



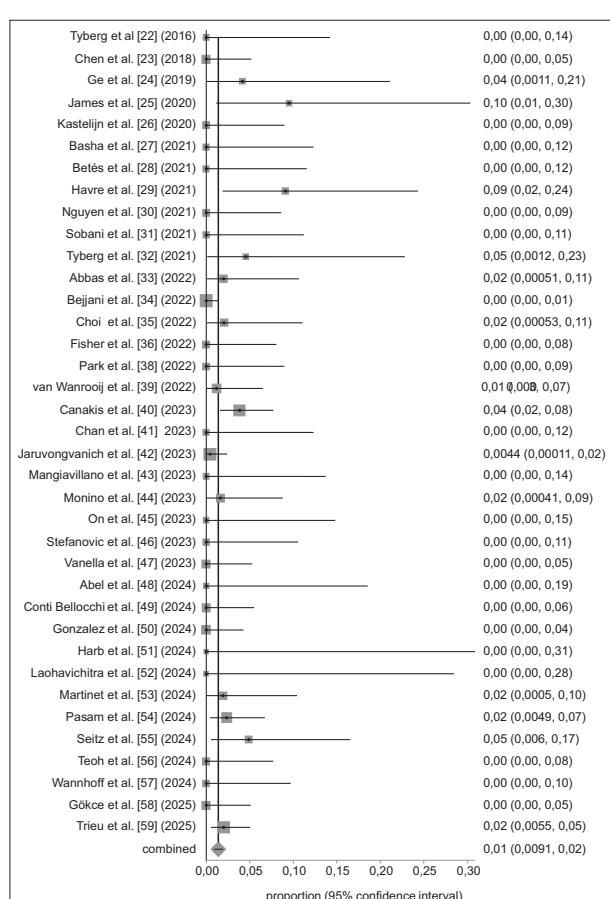
Supplementary Figure 10 Funnel plot of the perforation rate of all patients (with malignant or benign disease)



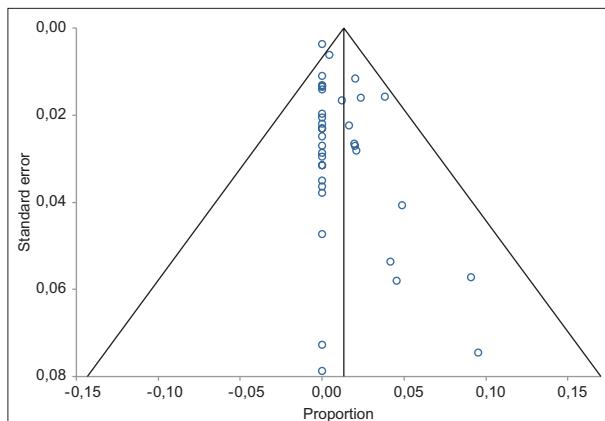
Supplementary Figure 12 Funnel plot of the bleeding rate of all patients (with malignant or benign disease)



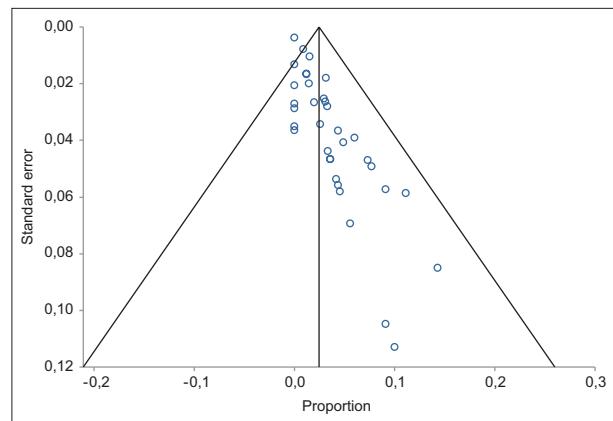
Supplementary Figure 11 Forest plot of the bleeding rate of all patients (with malignant or benign disease)



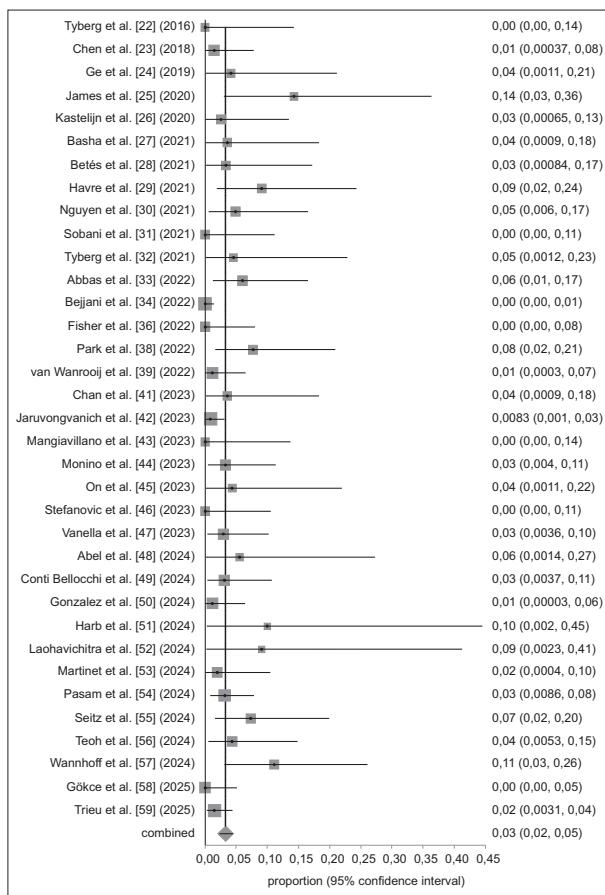
Supplementary Figure 13 Forest plot of the migration rate of all patients (with malignant or benign disease)



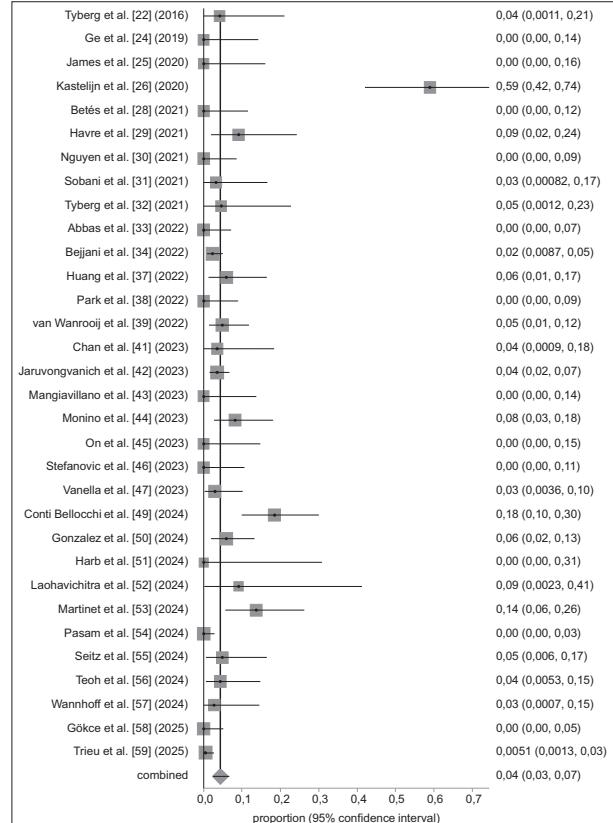
Supplementary Figure 14 Funnel plot of the migration rate of all patients (with malignant or benign disease)



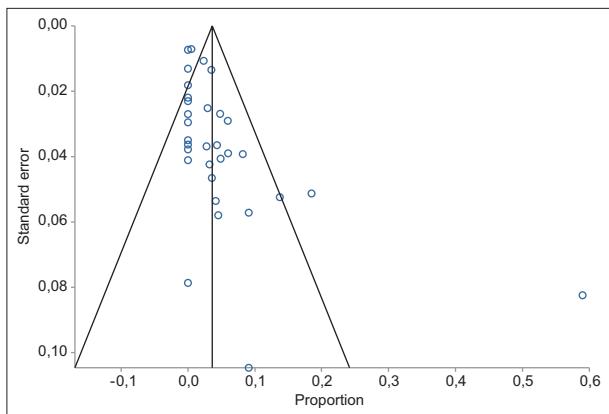
Supplementary Figure 16 Funnel plot of the stent closure rate of all patients (with malignant or benign disease)



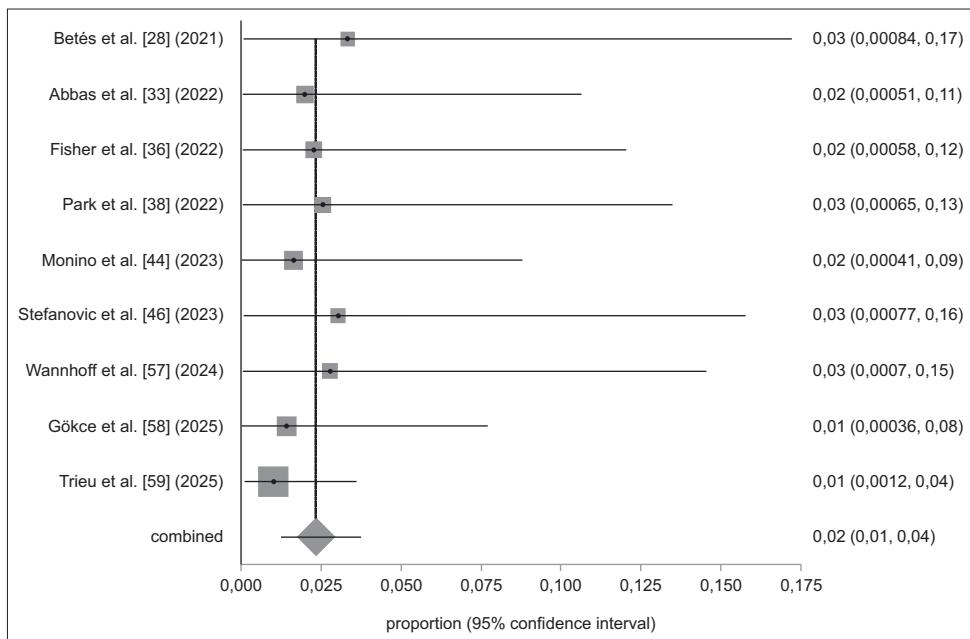
Supplementary Figure 15 Forest plot of the stent closure rate of all patients (with malignant or benign disease)



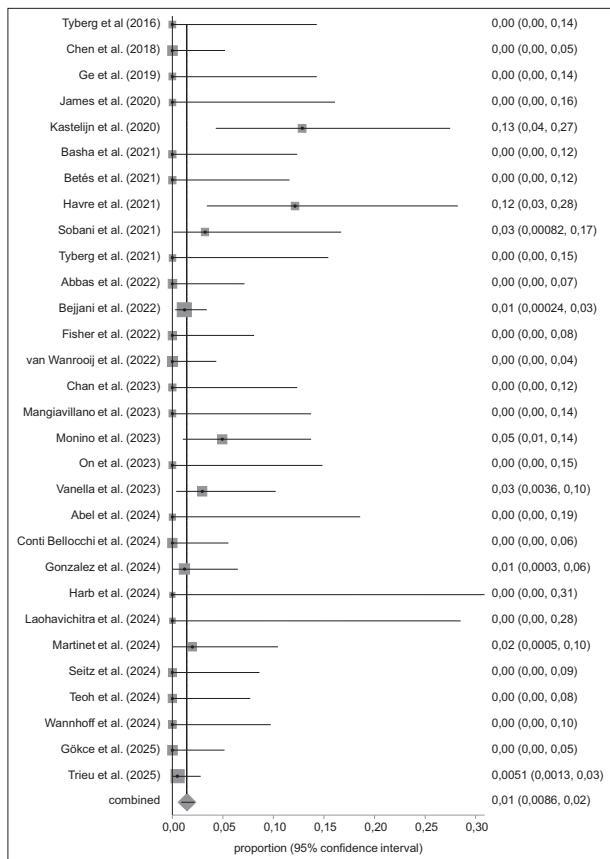
Supplementary Figure 17 Forest plot of development of infection rate of all patients (with malignant or benign disease)



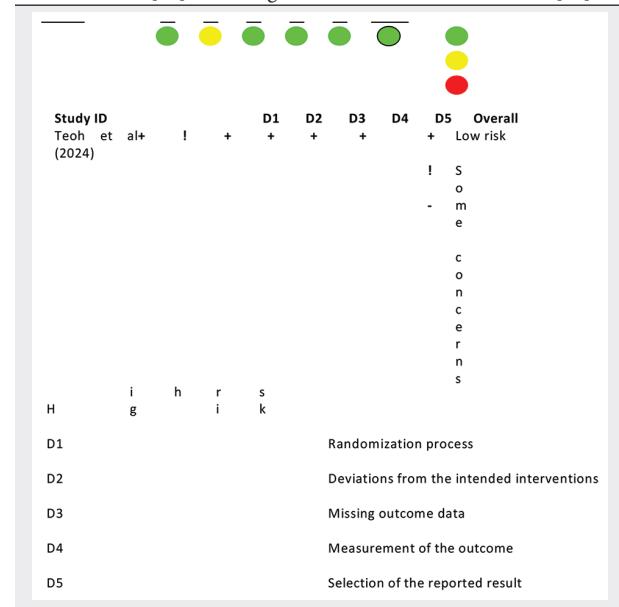
Supplementary Figure 18 Funnel plot of development of infection rate of all patients (with malignant or benign disease)



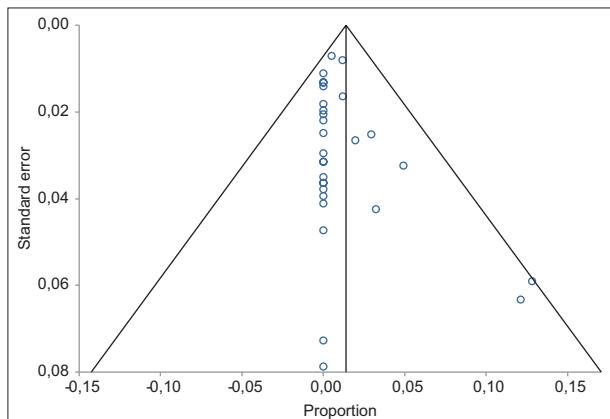
Supplementary Figure 19 Forest plot of the development of fistula rate of all patients (with malignant or benign disease)



Supplementary Table 1 Risk of bias of the only randomized controlled trial [56] according to the Cochrane Collaboration [15]



Supplementary Figure 20 Forest plot of death rate of all patients (with malignant or benign disease)



Supplementary Figure 21 Funnel plot of death rate of all patients (with malignant or benign disease)

Supplementary Table 2 Quality rating of included cohort studies according to the Newcastle-Ottawa Scale[19]

Study [ref.]	Representativeness of the exposed cohort	Selection of the non-exposed cohort	Ascertainment of exposure	Demonstration that outcome of interest was not present at the start of the study	Comparability of the cohorts	Assessment of the outcome	Was follow-up long enough for the outcomes to occur	Adequacy of follow-up of the cohorts	Total score
Ge <i>et al</i> [24]	1	1	1	1	1	1	1	1	8
van Wanrooij <i>et al</i> [39]	1	1	1	1	1	1	1	1	8
Canakis <i>et al</i> [40]	1	1	1	1	1	1	1	1	8
Chan <i>et al</i> [41]	1	1	1	1	1	1	1	1	8
Jaruvongvanichet <i>et al</i> [42]	1	1	1	1	1	1	1	1	8
Vanella <i>et al</i> [47]	1	1	1	1	1	1	1	1	8
Conti Bellocchi <i>et al</i> [49]	1	1	1	1	1	1	1	1	8
Matinnet <i>et al</i> [53]	1	1	1	1	1	1	1	1	8
Seitz <i>et al</i> [55]	1	1	1	1	1	1	1	1	8

Supplementary Table 3 IHE's quality appraisal checklist for assessing single-arm cohort studies (i.e. case-series studies)[18]

Studies	Studies					Studies				
	Tyberg <i>et al</i> [22]	Chen <i>et al</i> [23]	James <i>et al</i> [25]	Kastelijn <i>et al</i> [26]	Basha <i>et al</i> [27]	Betes <i>et al</i> [28]	Havre <i>et al</i> [29]	Nguyen <i>et al</i> [30]	Sobani <i>et al</i> [31]	Tyberg <i>et al</i> [32]
Criteria										
Study objective										
1. Was the hypothesis/aim/objective of the study clearly stated?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
2. Was the study conducted prospectively?	Y	N	N	N	Y	N	N	Y	Y	Y
3. Were the cases collected in more than one center?	Y	Y	N	Y	N	N	N	N	N	N
4. Were patients recruited consecutively?	U	Y	Y	Y	Y	Y	Y	Y	Y	Y

(Contd...)

Supplementary Table 3 (*Continued*)

Supplementary Table 3 (Continued)

	Studies					Studies				
	Tyberg et al [22]	Chen et al [23]	James et al [25]	Kastelijn et al [26]	Basha et al [27]	Betes et al [28]	Havre et al [29]	Nguyen et al [30]	Sobani et al [31]	Tyberg et al [32]
	Criteria									
	Results and conclusions									
16. Were losses to follow up reported?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
17. Did the study provided estimates of random variability in the data analysis of relevant outcomes?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
18. Were the adverse events reported?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
19. Were the conclusions of the study supported by the results?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Competing interests and sources of support									
20. Were both competing interests and sources of support for the study reported?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Studies					Studies				
	Abbas et al [33]	Bejjani et al [34]	Choi et al [35]	Fischer et al [36]	Huang et al [37]	Park et al [38]	Mangiavillano et al [43]	Monino et al [44]	On et al [45]	Stefanovic et al [46]
	Criteria									
	Study objective									
1. Was the hypothesis/aim/objective of the study clearly stated?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Study design									
2. Was the study conducted prospectively?	Y	N	N	N	N	N	N	N	N	N
3. Were the cases collected in more than one center?	N	Y	N	Y	N	N	Y	Y	Y	N
4. Were patients recruited consecutively?	U	U	Y	Y	Y	Y	Y	Y	Y	Y
	Study population									
5. Were the characteristics of the patients included in the study described?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

(Contd...)

Supplementary Table 3 (Continued)

	Studies						Studies			
	Abbas et al [33]	Beijani et al [34]	Choi et al [35]	Fischer et al [36]	Huang et al [37]	Park et al [38]	Mangiavillano et al [43]	Monino et al [44]	On et al [45]	Stefanovic et al [46]
	Criteria									
	Study population									
6. Were the eligibility criteria (ie, inclusion and exclusion criteria) for entry into the study clearly stated?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
7. Did patients enter the study at a similar point in the disease?	U	U	U	U	U	U	U	U	U	U
	Intervention and cointervention									
8. Was the intervention of interest clearly described?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
9. Were additional interventions (cointerventions) clearly described?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Outcome measures									
10. Were relevant outcome measures established a priori?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
11. Were outcome assessors blinded to the intervention that patients received?	N	N	N	N	N	N	N	N	N	N
12. Were the relevant outcomes measured using appropriate objective/subjective methods?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
13. Were the relevant outcome measures made before and after the intervention?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Statistical analysis									
14. Were the statistical tests used to assess the relevant outcomes appropriate?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Results and conclusions									
15. Was follow up long enough for important events and outcomes to occur?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
16. Were losses to follow up reported?	Y	Y	Y	Y	Y	Y	Y	Y	Y	U

(Contd...)

Supplementary Table 3 (*Continued*)

Supplementary Table 3 (Continued)

	Studies				Studies					
	Abel <i>et al</i> [48]	Gonzalez <i>et al</i> [50]	Hart <i>et al</i> [51]	Laohavichitra <i>et al</i> [52]	Pasam <i>et al</i> [54]	Wannhoff <i>et al</i> [55]	Gokce <i>et al</i> [58]	Trieu <i>et al</i> [59]	Tsuchiya <i>et al</i> [60]	
	Criteria									
Study population										
6. Were the eligibility criteria (i.e., inclusion and exclusion criteria) for entry into the study clearly stated?	Y	Y	Y	Y	Y	Y	Y	Y	Y	
7. Did patients enter the study at a similar point in the disease?	U	U	U	U	U	U	U	U	U	
Intervention and cointervention										
8. Was the intervention of interest clearly described?	Y	Y	Y	Y	Y	Y	Y	Y	Y	
9. Were additional interventions (cointerventions) clearly described?	Y	Y	Y	Y	Y	Y	Y	Y	Y	
Outcome measures										
10. Were relevant outcome measures established a priori?	Y	Y	Y	Y	Y	Y	Y	Y	Y	
11. Were outcome assessors blinded to the intervention that patients received?	N	N	N	N	N	N	N	N	N	
12. Were the relevant outcomes measured using appropriate objective/subjective methods?	Y	Y	Y	Y	Y	Y	Y	Y	Y	
13. Were the relevant outcome measures made before and after the intervention?	Y	Y	Y	Y	Y	Y	Y	Y	Y	
Statistical analysis										
14. Were the statistical tests used to assess the relevant outcomes appropriate?	Y	Y	Y	Y	Y	Y	Y	Y	Y	
Results and conclusions										
15. Was follow up long enough for important events and outcomes to occur?	Y	Y	Y	Y	Y	Y	Y	Y	Y	
16. Were losses to follow up reported?	Y	Y	Y	Y	Y	Y	Y	Y	Y	

(Contd...)

Supplementary Table 3 (Continued)

Criteria	Studies						Studies	
	Abel <i>et al</i> [48]	Gonzalez <i>et al</i> [50]	Harb <i>et al</i> [51]	Laohavichitra <i>et al</i> [52]	Pasam <i>et al</i> [54]	Wannhoff <i>et al</i> [55]	Gökce <i>et al</i> [58]	Trieu <i>et al</i> [59]
Results and conclusions								
17. Did the study provided estimates of random variability in the data analysis of relevant outcomes?								
Y	Y	Y	Y	Y	Y	Y	Y	Y
18. Were the adverse events reported?								
Y	Y	Y	Y	Y	Y	Y	Y	Y
19. Were the conclusions of the study supported by the results?								
Competing interests and sources of support								
20. Were both competing interests and sources of support for the study reported?								
Y	Y	Y	N	Y	Y	Y	Y	Y

IHE, Institute of Health Economics; Y, Yes; N, No; P, Partial; U, Undeclared.

Supplementary Table 4 Overall studies including patients with malignant and benign disease

	No of Studies	No of patients	Pooled rate (95%CI)	Cochrane			I2	Egger's test		
				Q	df	P-value		Value	(95%CI)	P-value
All studies included in the meta-analysis (i.e., including patients with malignant and benign disease)										
Technical Success	39	2485	95.1% (94.0 to 96.1)	53.8	38	0.0464	29.3%	-0.94	-1.49 to -0.39	0.0014
Clinical Success	39	2398	93.5% (91.5 to 95.3)	114.7	38	<0.0001	66.9%	-0.26	-1.60 to -1.07	0.7174
Studies including patients with only malignant disease.										
Technical Success	21	1458	95.3% (94.2 to 96.4)	20.8	20	0.4107	3.7%	-0.61	-1.52 to 2.9	0.1711
Clinical Success	21	1371	93.1% (91.0 to 95.0)	36.3	20	0.014	45.0%	-1.30	-2.34 to -0.27	0.0162
Studies including patients with only benign disease										
Technical Success	9	230	95.1% (92.0 to 97.5)	2.80	8	0.9463	0%	n.a.	n.a.	n.a.
Clinical Success	9	230	94.4% (86.1 to 99.1)	29.4	8	0.0003	72.8	n.a.	n.a.	n.a.
Overall AEs in studies the overall studies (i.e., including patients with malignant and benign disease)										
Intestinal Perforations	38	2437	4.4%(3.0 to 5.9)	105.3	37	<0.0001	64.9%	0.01	-1.48 to 1.51	0.9866
Intestinal Bleeding	38	2437	2.7%(1.8 to 3.7)	61.1	37	0.0076	39.5%	0.82	-0.42 to 1.85	< 0.0001
Stent Migration	37	2397	1.4%(0.9 to 1.2)	41.7	36	0.2364	13.7%	0.44	0.13 to 0.77	0.0077
Stent Closure	35	2158	3.3%(2.3 to 4.5)	62.2	34	0.0022	45.3%	1.02	0.76 to 1.27	< 0.0001
Infection	32	2041	4.4%(2.5 to 6.7)	149.3	31	< 0.0001	79.2%	1.44	0.60 to 2.28	0.0015
Fistulas	9	590	2.3%(1.3 to 3.7)	3.0	8	0.9295	0%	n.a.	n.a.	n.a.
Death	30	1671	1.4%(0.7 to 2.2)	33.2	29	0,2673	12.8%	0.32	-0.11 to 0.76	0.141

No, number; CI, confidence interval; df, degree of freedom; n.a., not assessed as the number of studies was < 10

Supplementary Table 5: PRIMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review	1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge	3
Objectives	4	Provide an explicit statement of the objective (s) or question (s) the review addresses	3
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses	4
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted	4
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	4
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process	4-5
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process	4-5
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect	5
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information	4
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool (s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process	5
Effect measures	12	Specify for each outcome the effect measure (s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results	5
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5))	4
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions	4-5
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses	4-5
	13d	Describe any methods used to synthesize results and provide a rationale for the choice (s). If meta-analysis was performed, describe the model (s), method (s) to identify the presence and extent of statistical heterogeneity, and software package (s) used	4-5
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression)	4-5

(Contd...)

Supplementary Table 5: PRIMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
METHODS			
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results	4-5
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases)	4-5
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome	4-5
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram	Figure 1
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded	Not applicable
Study characteristics	17	Cite each included study and present its characteristics	11-12
Risk of bias in studies	18	Present assessments of risk of bias for each included study	Supplementary materials: 2 to 9
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots	Supplementary materials: 10
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies	Supplementary materials: 2 to 9
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect	Supplementary materials: 2 to 9
	20c	Present results of all investigations of possible causes of heterogeneity among study results	Not applicable
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results	Not applicable
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed	Not applicable
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed	Supplementary materials: 2 to 9
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence	8-9
	23b	Discuss any limitations of the evidence included in the review	8-9
	23c	Discuss any limitations of the review processes used	8-9
	23d	Discuss implications of the results for practice, policy, and future research	8-9
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered	5
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared	Not applicable
	24c	Describe and explain any amendments to information provided at registration or in the protocol	Not applicable
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review	1

(Cintd...)

Supplementary Table 5: PRIMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
OTHER INFORMATION			
Competing interests	26	Declare any competing interests of review authors	1
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review	4-5

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71. This work is licensed under CC BY 4.0. To view a copy of this license, visit <https://creativecommons.org/licenses/by/4.0/>

Supplementary Table 6: MOOSE Checklist for meta-analyses of observational studies

Item No	Recommendation	Reported on Page No
Reporting of background should include		
1	Problem definition	3
2	Hypothesis statement	3
3	Description of study outcome (s)	5 and 10-12
4	Type of exposure or intervention used	10-12
5	Type of study designs used	10-12
6	Study population	5 and 10-12
Reporting of search strategy should include		
7	Qualifications of searchers (eg, librarians and investigators)	1
8	Search strategy, including time period included in the synthesis and key words	4
9	Effort to include all available studies, including contact with authors	4
10	Databases and registries searched	4
11	Search software used, name and version, including special features used (eg, explosion)	5
12	Use of hand searching (eg, reference lists of obtained articles)	4
13	List of citations located and those excluded, including justification	Figure 1
14	Method of addressing articles published in languages other than English	Not applicable
15	Method of handling abstracts and unpublished studies	Not applicable
16	Description of any contact with authors	Not applicable
Reporting of methods should include		
17	Description of relevance or appropriateness of studies assembled for assessing the hypothesis to be tested	6
18	Rationale for the selection and coding of data (eg, sound clinical principles or convenience)	6 and 10-12
19	Documentation of how data were classified and coded (eg, multiple raters, blinding and interrater reliability)	6 and 10-12
20	Assessment of confounding (eg, comparability of cases and controls in studies where appropriate)	Supplementary materials: 2 to 9
21	Assessment of study quality, including blinding of quality assessors, stratification or regression on possible predictors of study results	Supplementary materials: 2 to 9
22	Assessment of heterogeneity	Supplementary materials: 10

(Cintd...)

Supplementary Table 6: MOOSE Checklist for meta-analyses of observational studies

Item No	Recommendation	Reported on Page No
Reporting of methods should include		
23	Description of statistical methods (eg, complete description of fixed or random effects models, justification of whether the chosen models account for predictors of study results, dose-response models, or cumulative meta-analysis) in sufficient detail to be replicated	5
24	Provision of appropriate tables and graphics	Figure 2, 3 and Supplementary Figures
Reporting of results should include		
25	Graphic summarizing individual study estimates and overall estimate	Figure 2 and 3 and Supplementary Figures
26	Table giving descriptive information for each study included	10-12
27	Results of sensitivity testing (eg, subgroup analysis)	6
28	Indication of statistical uncertainty of findings	6 , 7 and Figure 2, 3 and Supplementary materials: 10
Item No	Recommendation	Reported on Page No
Reporting of discussion should include		
29	Quantitative assessment of bias (eg, publication bias)	Supplementary Figures
30	Justification for exclusion (eg, exclusion of non-English language citations)	Not applicable
31	Assessment of quality of included studies	Supplementary materials: 2 to 9
Reporting of conclusions should include		
32	Consideration of alternative explanations for observed results	8-9
33	Generalization of the conclusions (ie, appropriate for the data presented and within the domain of the literature review)	8-9
34	Guidelines for future research	8-9
35	Disclosure of funding source	1

From: Stroup DF, Berlin JA, Morton SC, et al., for the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) Group. *Meta-analysis of Observational Studies in Epidemiology. A Proposal for Reporting.* JAMA. 2000;283 (15):2008-2012. doi: 10.1001/jama. 283.15.2008