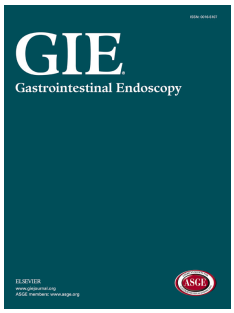

EUS-guided GastroEnterostomy for management of malignant Gastric Outlet Obstruction: a prospective cohort study with matched comparison with Enteral Stenting.

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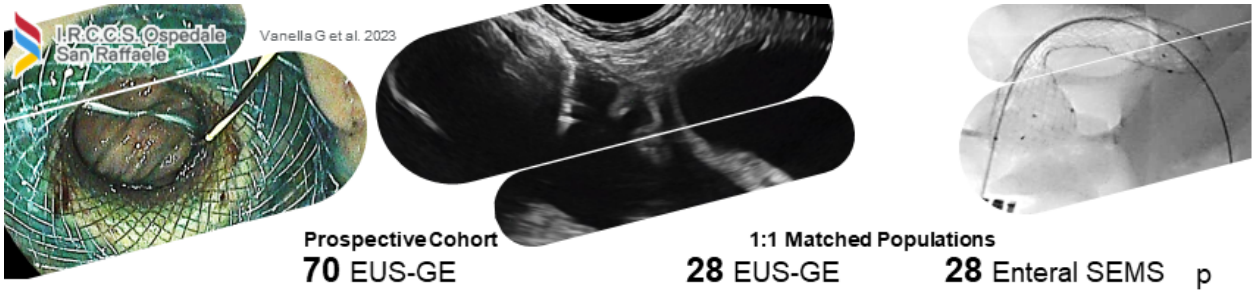

	Prospective Cohort	1:1 Matched Populations		
	70 EUS-GE	**28** EUS-GE	**28** Enteral SEMS	p
Technical success:	97.1%	96.4%	100%	0.32
Clinical success:	97.1%	100%	75.0%	0.006 *
Adverse events:	12.9%	7.1%	25%	0.07
Recurrence	7.6%	3.7%	33.3%	0.02 *
Time to chemotherapy	19 [14-26]	17 [14.8-24.3]	24 [22.3-39.3]	0.055

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GV, GC and PGA designed the study and the protocol. SC, DT, MM, GO, MR, ACG, LA and MF assured the engagement and follow-up of patients. GV and PGA performed the procedures. GV, GDA and PM performed statistics. GV, GDA, GC, PGA, PM, MB and SVDM interpreted the results and drafted the manuscript. All Authors critically revised the manuscript for important intellectual content. All Authors revised and approved the final version of the Manuscript and accept to be accountable for all aspects of the work.

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Abstract

Background and Aims

Retrospective studies on malignant Gastric Outlet Obstruction (mGOO) highlighted several advantages of EUS-guided Gastroenterostomy (EUS-GE) over enteral stenting (ES). However, no prospective evidence is available. The aim of this study was to report on clinical outcomes of EUS-GE in a prospective cohort study, with a subgroup comparison to ES.

Methods

All consecutive patients endoscopically treated for mGOO between Dec-2020 and Dec-2022 in a tertiary, academic center were enrolled in a Prospective Registry (PROTECT, NCT04813055) and followed every 30 days to register efficacy/safety outcomes. EUS-GE and ES cohorts were matched according to baseline frailty and oncological disease.

Results

104 patients were treated for mGOO during study interval, of which 70 [male 58.6%; median age=64 [IQR 58-73]; 75.7% pancreatic cancer, 60.0% metastatic] underwent EUS-GE through the Wireless Simplified Technique (WEST). Technical success was 97.1%, whereas clinical success was 97.1% after a median of 1.5 [IQR 1-2] days. Adverse events occurred in 9 (12.9%) patients. After median follow-up of 105 [49-187] days, symptoms recurrence was 7.6%.

In the matched comparison versus ES (28 patients per arm), EUS-GE patients experienced higher and faster clinical success (100% vs. 75.0%, p=0.006), reduced recurrences (3.7% vs. 33.3%, p=0.007) and a trend towards shorter time-to-chemotherapy.

Conclusions

In this first, prospective, single-center comparison, EUS-GE showed excellent efficacy in relieving mGOO, with an acceptable safety profile and long-term patency, and several clinically significant advantages over ES. Whilst awaiting randomized trials, these results might endorse EUS-GE as first line strategy for mGOO, where adequate expertise is available.

Keywords: Gastroenterostomy; Stent; Pancreatic neoplasms; Gastric Outlet Obstruction; LAMS;

Introduction

Gastric Outlet Obstruction (GOO) frequently affects the clinical course of patients with pancreato-biliary and gastrointestinal malignancies, and might be responsible for a significant delay, intolerance or interruption of oncological treatments[1,2], quality of life impairment and nutritional deficits.

The two standard treatment options for GOO have been surgical gastroenterostomy (s-GE) and endoscopic placement of enteral stents (ES), which are burdened, respectively, by invasiveness and unsatisfactory long-term patency[3]. Recent developments in therapeutic Endoscopic Ultrasound (EUS) and the advent of Lumen Apposing Metal Stent (LAMS) have allowed the creation of a EUS-guided gastroenterostomy (EUS-GE), theoretically combining reduced invasiveness with surgical-range efficacy and prolonged patency. More than 500 EUS-GE cases have been published to date, showing high technical (89-99%) and clinical success (82-94%), a varying adverse events (AEs) rate between 16-28%, with few reported cases of dysfunction[4,5].

Comparative retrospective data on EUS-GE have suggested a reduced invasiveness, time to clinical success and hospitalization with respect to s-GE[6] and increased efficacy and patency with respect to ES[7].

Despite these promising results, leading to a provisional inclusion of the technique in society recommendations[8–10], few prospective data are available yet.

We conducted a prospective cohort study in a single, academic, tertiary referral center to evaluate efficacy and safety of EUS-GE and to compare outcomes of EUS-GE matched with ES from the same time frame.

Methods

All consecutive patients endoscopically treated for mGOO in San Raffaele Scientific Institute between December 2020 and December 2022 were enrolled in a Prospective Registry Of Therapeutic EndoscopiC ulTrasound (PROTECT, ClinicalTrials.gov: NCT04813055). Informed consent was acquired for the procedure and for the inclusion in the registry. This research was conducted in compliance with the Declaration of Helsinki and Good Clinical Practice, and approved by local Ethics Committee (Id: 178/INT/2020).

For the scope of this paper, inclusion criteria were: a) symptomatic malignant GOO, b) endoscopic and/or radiological confirmation of an antro-duodenal obstruction, and c) GOO management through either EUS-GE or ES. Patients receiving EUS-guided anastomoses for different indications (afferent loop syndrome, EUS-guided ERCP, ileocolonic anastomosis) were excluded (see Table S1)

Demographic and procedural variables were registered, among which comorbidities, underlying disease, disease stage, previous procedures, technical details. An investigator unblinded to the procedure performed daily clinical evaluation during hospitalization and telephonic follow-up and review of the electronic medical file at least every 30 days after discharge to assess clinical status, efficacy of the procedure and eventual complications.

Patients with a post-procedural follow-up <30 days were considered lost to follow-up and were excluded, unless death occurred earlier.

Procedures

EUS-GE

In our center EUS-GE is standardly performed through the Wireless Simplified Technique (WEST, see Figure 1)[11], under general anesthesia with orotracheal intubation in an endoscopy suite with fluoroscopy. Initially, prophylactic antibiotics were administered at the discretion of the endoscopist. However, after publication of society recommendations[8,12], universal single-dose prophylactic antibiotic is provided; in patients with ascites, a 7-day antibiotic course is prescribed[13].

A large-channel gastroscope (EG34-i10 or EG3470K, Pentax Medical) is advanced up to the level of the stenosis and a 0.035 guidewire is advanced through the stenosis and the Treitz. An oro-jejunal (7-10Fr) tube (OJT) is advanced over-the-wire, until the distal loop is in the first jejunal loop. The gastroscope is than carefully exchanged for a therapeutic linear echoendoscope (EG38-J10UT, Pentax Medical).

Jejunal distension with saline mixed with indigo carmine is initiated through the OJT. The echoendoscope is advanced into the stomach, and directed towards the dilated jejunal loop, preferably where the OJT might be visible by ultrasound (Figure 1B). Fluoroscopy can be used to check the relative position of the endoscope and OJT. Ultrasonographic perturbation of fluid content during fluid injection (Figure 1C) is considered as a sign of proximity to the OJT. When a suitable target loop has been selected, an antispasmodic (hyoscine butylbromide or glucagone) is administered and the electrocautery-enhanced LAMS (Hot Axios®, Boston Scientific) is advanced free-hand through the gastric and jejunal walls, applying pure cutting current; successful access is demonstrated by electrocautery-induced fluid perturbation (Figure 1D). The jejunal flange is then opened under endosonographic control, and retracted onto the gastric wall; the proximal flange is released inside the operative channel of the endoscope, and pushed outside under endoscopic view. A blue-dyed flow confirms correct placement. After a guidewire insertion through the LAMS, the stent is dilated through a CRE Balloon Catheter (Boston Scientific), usually between 15-18mm. Contrast injected through the OJT is aspirated through the LAMS in the stomach to confirm correct placement without extraluminal leakage (Figure 1H).

When an OJT cannot be advanced through the stenosis, a jejunal loop is searched under endosonographic guidance, and then punctured through a 19G needle. Contrast injection confirms the target. After antispasmodics are administered, the loop is distended through the needle and a LAMS is advanced.

Enteral Stenting

After a guidewire has been placed through the stenosis, contrast injection is used to depict the stenosis, sometimes with the help of a large-caliber (20mm) Fogarty balloon. An uncovered through-the-scope duodenal stent (Evolution®, Cook Medical or Wallflex®, Boston Scientific) 22mm in diameter and 6-12cm in length is thereafter released across the stenosis under fluoroscopic guidance.

Post-procedural care

During the first study period, EUS-GE patients were allowed to drink on post-operative day (POD) 1 and to eat a semisolid diet on POD2. Since October 2021, after internal protocol review acknowledged frequent post-procedural vomit, the endoscopist started to suggest: 1) post-procedural enema or laxatives in case of constipation to ensure post-procedural evacuation of the injected fluid; 2) prokinetic drug the evening of the procedure. With this protocol (optimized protocol), patients were allowed to drink the same evening and to eat on POD1.

Outcomes

The primary outcomes were the rate of technical success, clinical success and AEs of EUS-GE. Secondary outcomes were: symptoms recurrence during follow-up both as rate (proportion) and estimated Symptoms-Free Survival (SFS); time to fluid and solid oral intake; hospital stay; time to chemotherapy resumption; survival.

A secondary analysis was planned to evaluate the efficacy and safety of EUS-GE versus ES. All consecutive ES placements performed during the same study interval were included in the same registry and underwent the same variable collections and follow-up. Since allocation to the two treatments was not random, a 1:1 matching was planned to reduce selection bias. After statistical evaluation of variables potentially influencing efficacy/safety outcomes (age, sex, body mass index [BMI], comorbidities, primary disease, disease stage, etc, see Table S2), the two cohorts were matched according to significant differences at baseline (American Society of Anesthesiologists [ASA] score and presence of carcinomatosis)

For this comparison, based on the reported recurrence rate of the largest retrospective study[7] we calculated that 52 patients (26 per arm) would be required to have a 80% chance of detecting, with a 5% significance level, a reduction in post-procedural symptoms recurrence from 26% to 1% in the EUS-GE versus (vs.) ES group.

Definitions

Technical success (TS) was defined as the successful LAMS placement between stomach and jejunum, independently from eventual initial misdeployments, which were anyway registered according to an available classification[14].

The ability to eat was defined with the Gastric Outlet Obstruction Scoring System (GOOSS), an ordinal system ranging from 0 (no intake) to 3 (full diet) based on the highest intake tolerability.[15] Clinical success was defined as a GOOSS≥2 (soft solids) after the intervention.

Symptoms' recurrence was defined as recurrence of obstructive symptoms (GOOSS≤1) after former clinical success, regardless of whether it was caused by stent dysfunction or other reasons (e.g., downstream obstruction), which were nevertheless detailed.

Clinical success was analyzed both as intention-to-treat and as treated.

AEs were scored through the ASGE Lexicon[16]

Statistical analysis

Descriptive statistics is reported as frequencies (proportions) and medians [IQR] after exclusion of normality. SFS was analyzed by the Kaplan-Meier method, where patients were censored at recurrence, death, last telephonic follow-up or surgical removal of EUS-GE whichever came first.

Comparisons between groups were performed through the Chi-Squared or Fisher's test for qualitative data and the Mann-Whitney test for quantitative data as appropriate. Comparison of survival curves was performed by the log-rank test.

A p-value <0.05 was considered significant.

Analyses were performed using Medcalc (Ostende, Belgium).

Results

During study period, 104 patients were referred for endoscopic treatment of mGOO. 76 patients were candidate to EUS-GE, however in 5 (6.6%) cases the procedure was deemed unfeasible and converted to ES (see **Table S1** and **Figure 2A-C**). Eventually, 71 EUS-GE were performed. One (1.3%) case was lost to follow-up, with a final inclusion of 70 patients (see **Table 1**). Median age was 64 [58-73] years, median baseline BMI was 21.3 [18.9-24] Kg/m^2 and 58.6% of patients were male. Primary disease was pancreatic ductal adenocarcinoma in 75.7%, biliary/ampullary cancer in 12.9% and gastric cancer in 7.1%. 60% of patients harbored metastatic disease, whilst 4 (5.7%) a potentially resectable lesion. Ascites and peritoneal carcinomatosis were present in 18.6% and 20.0% of patients respectively. 90.0% of patients presented with complete obstruction (GOOSS=0), whereas in 4 (5.7%) cases EUS-GE was preventive considering a stenotic effect despite ability to eat.

The procedure was performed in general anesthesia and orotracheal intubation in all patients (see **Table S2**). 97.1% of patients underwent the procedures through the WEST technique, whereas in 2 cases a direct technique with needle puncture of the jejunal loop was used. A 20mm LAMS was used in 97.1% of cases and the LAMS was dilated in 97.1% of procedures, mostly up to 18mm.

Initial misdeployment of the LAMS was experienced in 4 (5.7%) patients. This resulted in two surgical rescue procedures, whereas misdeployment was solved intraprocedurally by redo-EUS-GE[17] in 2 cases, thus resulting in a technical success of 68 (97.1%) cases (see **Table 2**). Clinical success was reached in 66/68 (97.1%), with a median time to drink of 1 [0-1] and a median time to eat of 1.5 [1-2] day(s). Both clinical failures were due to periprocedural death (see below) with insufficient time to ascertain clinical success (see **Table S3**).

A post-procedural episode of vomiting not requiring any escalation of medical care was experienced by 8 patients (11.4%). However, after a postprocedural cathartic + prokinetic strategy (optimized protocol, see above) was suggested in the report, this rate decreased from 20.8% to 6.8% (p=0.09).

AEs were experienced in 9 patients (12.9%) (see **Table S3** for details, and **Figure 2D-F**), including one intraprocedural self-limiting bleeding and the 2 misdeployments which were classified as severe complications since required surgical exploration despite the absence of other complications. The most frequent AE was a moderate bleeding in 4 (5.7%) patients, requiring endoscopic epinephrine injection in 3. Two fatal events were registered, consisting of 2 (2.8%)

post-procedural cholangitis in patients with pre-existent suboptimal biliary drainage and elevated baseline cholestatic/inflammatory markers (see Discussion).

Median hospital stay was 6 [3-11] days.

During a median follow-up of 105 [49-187] days, 43 (61.4%) patients were candidates to receive active oncological medical treatment with a median time-to-chemotherapy (re-)initiation of 19 [14-26] days. During follow-up, 5 (7.6%) of 66 patients with clinical success experienced symptoms' recurrence after 78 [28-164] days, but 2 were due to a new onset of downstream neoplastic stenosis (see **Table S3** for details and **Figure 2G-I**).

SFS analyzed through Kaplan-Meier analysis is shown in **Figure 3A**. Mean estimated SFS was 480 (95% Confidence Interval 426-534) days, with a 3-, 6- and 12-months probability of SFS of 96.7%, 90.6% and 85%, respectively.

Subgroup comparison of EUS-GE versus ES

During the study interval, 35 patients were candidates for ES, and one was lost to follow-up. Reasoning behind selecting ES over EUS-GE is detailed in **Table S1,** and mostly relatable to EUS-GE contraindications (such as massive ascites, extensive carcinomatosis and diffuse gastric cancer). When the study interval was divided into 6 equivalent time frames (4 months each), there was a significant switch (p-for-trend=0.0075) towards predilection of EUS-GE over ES, with relative frequency ranging from 38.5% of patients during the first time frame to 46.2% in the second and 75% during the last four intervals (see **Table S4 and Supplementary Figure 1**).

When compared to patients undergoing EUS-GE (see **Table S5**), the candidates to ES exhibited higher frailty, reflected by a significantly higher ASA score (p=0.02) and a more prevalent peritoneal carcinomatosis (p=0.002). After exact matching for these 2 variables, 28 patients per group were retained, showing no baseline difference between the 2 groups (see **Table 3**), including comparable post-procedural survival.

In the matched population, technical success was 96.4% in the EUS-GE and 100% in the ES group (see **Table 4**). Patients treated with EUS-GE showed higher clinical success (100% vs. 75.0%, p=0.006) and shorter time-to-clinical success (2 vs. 3 days, p=0.03). A non-significant trend towards more AEs was noticed in the ES group (25.0% vs. 7.1%, p=0.07), mostly related to interference of duodenal SEMS with papillary region or pre-existing biliary SEMS. During follow-up, almost half of patients underwent active oncological medical treatment, with a trend towards shorter time-to-chemotherapy for patients receiving EUS-GE (17 vs. 24 days, p=0.055).

Among patients who reached clinical success, symptoms' recurrence was significantly lower during follow-up for the EUS-GE group (3.7% vs. 33.3%, p=0.007, Hazard Ratio=0.16 [95%CI 0.04-0.65]), with a 6-months probability of SFS of 95.5% for EUS-GE and 67.7% for ES (log-rank test, p=0.047, see Figure 3B).

Discussion

This single-center series confirms and details through a prospective design the retrospectively-reported acceptable risk-benefit ratio of EUS-GE, with excellent technical and clinical success and limited AEs. Moreover, in a matched prospective comparison to ES, EUS-GE showed higher and faster clinical success, longer patency and shorter time to chemotherapy initiation/resumption, without any reduced safety. Finally, when read together with the reported outcomes of surgical bypass[18], those of EUS-GE seem comparable (or even better) in terms of efficacy, with a significantly reduced invasiveness.

The present prospective evaluation of consecutive patients with mGOO treated in a large-volume referral center, might also give an insight on aspects which have been poorly explored in the existing literature.

During study interval a significant switch towards a relative preference of EUS-GE was noticed, ranging from 1/3 of procedures in the first 4 months, towards a gradual settlement around 75% of procedures, which has been maintained during the last 16 months. In the first study period, the relatively higher rate of ES adoption was due to a reluctance of referring physicians and gastroenterologists performing only ES to abandon the older strategy together with limited knowledge of potential advantages and risks associated with EUS-GE. Conversely, the recent stabilized rate of 25% might represent the real proportion of patients for which EUS-GE is deemed of no additional advantage with respect to ES due to short life expectancy or is contraindicated due to massive ascites, extensive peritoneal carcinomatosis, or gastric neoplastic infiltration[8]. Indeed, in this series of GI and HPB malignancies, almost 2/3 of patients exhibited metastatic disease, 1/4 with ascites and carcinomatosis, thus highlighting the association of mGOO with advanced disease courses and claiming for optimization of patients' selection. Recent society recommendations have suggested to abandon enteral stenting in patients with expected survival exceeding 2[19]-6[9] months, preferring surgical bypass and considering EUS-GE as an acceptable alternative to s-GE, where adequate expertise is available, as also recently proposed by the first available guidelines on Therapeutic EUS[8]. These considerations suggest a multidisciplinary evaluation of patients' and diseases' characteristics involving, amongst others, gastroenterologists, surgeons, oncologists and radiologists.

As misdeployment requiring surgery represents the worst-case scenario of EUS-GE, a general rule might be to propose EUS-GE only to those patients who are fit enough to tolerate eventual backup surgical bypass if needed. However, misdeployment in our series has been a rare event (5.7%), lower than expected from the larger available

retrospective study focused on this issue[14]. Furthermore, half of misdeployments in our series could be endoscopically rescued simply by performing a second salvage EUS-GE[17], as the most frequent cause of misdeployment does not implicate jejunal enterotomy (type 1) and the presence of the OJT allows to exclude contrast leakage and to maintain jejunal distention. In one case, a gastro-colostomy (type 4 misdeployment) was inadvertently created; in our opinion this was due to an early and excessive fluid injection of the small intestine and to a fast gastrointestinal transit, which caused an unexpected fluid flow to be endosonographically visible in the colon. Despite the absent peritoneal contamination and the described uneventful endoscopic management of this event[14], the referring surgeon felt more comfortable with surgical backup (s-GE + segmental colectomy). This case has made us pay increased attention to start jejunal distention only after EUS- and fluoroscopy-guided identification of the OJT, to minimize the quantity of injected fluid.

Two patients died close (1-3 days) after EUS-GE due to septic shock caused by worsening cholangitis, despite the excellent initial recovery from the procedure; biochemistry showed severely impaired pre-procedural cholestatic and inflammatory markers, in patients already bearing a biliary metal stent and an EUS-guided choledocho-duodenostomy. It might be speculated that OJT fluid injection might have increased the pressure on a contaminated biliary tree, despite in one case where contrast was used to distend the jejunum, this was never seen ascending the biliary tree. Although the causal link between these events and the procedure cannot be proven, these initial data might raise increased awareness that biliary clearance should be obtained before EUS-GE where possible, and are consistent with the growing evidence that malignant GOO significantly increase the complexity of jaundice management[20]; moreover, this might be one additional reason to keep the amount of injected fluid as low as possible and to use universal antibiotic prophylaxis during EUS-GE.

A relatively frequent event in our series was periprocedural bleeding (4.3%). In one intraprocedural case this followed LAMS dilation, whereas in another case this was due to close postprocedural administration of low molecular weight heparin. If LAMS dilation might represent a risk factor for periprocedural bleeding or rather prevent it by compressing small parietal vessels remains to be demonstrated in comparative studies. Our perception is that intraprocedural LAMS dilation might stabilize the stent reducing the risk of post-procedural migration, an event which has not been observed in our series.

This study has several strengths. First, the only available prospective EUS-GE series to date[21] describes only 20 EUS-GE performed with a different (double-balloon-occluded) technique; to the best of our knowledge, this study is the largest available prospective series of EUS-GE and the first prospective comparison of EUS-GE versus ES. The main difference with available literature is that patients were not only prospectively enrolled, but even prospectively and extensively followed, potentially reducing the risk of undetected outcomes of interest, as also demonstrated by the detection of AEs managed in other hospitals. Only 1 patient was lost to follow-up after a successful and uneventful procedure, whereas most patients were followed until death, further increasing the possibility to detail the natural history of the procedure. Second, contemporary ES were enrolled in the same database and underwent the same prospective follow-up, to give a real-life picture on reasons and temporal trends leading to allocation to one treatment or another. Third, these two cohorts were compared, representing the first prospective comparison of EUS-GE to the mostly used standard treatment for mGOO; a matching for baseline differences was performed to select two populations with homogeneous frailty and oncological disease. The comparison of these populations confirmed a significantly increased and faster clinical success for EUS-GE with significantly higher long-term patency, without increased invasiveness, and instead unexpectedly demonstrating a tendency towards more adverse events and longer time-to-chemotherapy resumption in the ES group, which has never been reported. These data turn the spotlight on the fact that the benefits of EUS-GE may not only show up in the long term but might also regard initial efficacy and earlier access to oncological treatments.

The study, however, also comes with several limitations. First, this is a single-centre experience of procedures performed in a tertiary referral centre by two fully trained endoscopists with extensive expertise in Therapeutic EUS, using the same (WEST) technique[11]: generalizability of these results outside this scenario cannot be guaranteed. Second, the comparison between EUS-GE and ES does not reflect random treatment allocation; since the two groups significantly differed at baseline for frailty (ASA score) and disease stage (carcinomatosis), an exact matching for these variables was used; nevertheless, results of randomized clinical trials are needed to confirm that these outcomes are replicable when all selection biases are controlled. Third, the study was not planned to record or analyse harder outcomes, such as quality of life or nutritional status, deserving further investigation.

In conclusion, our study shows that EUS-GE in the setting of mGOO achieves high and fast clinical relief of obstruction, with excellent long-term patency and an acceptable safety profile. When compared to ES, EUS-GE seems to achieve

higher clinical success, shorter time to access oncological treatments and reduced risk of symptoms' recurrence, without any increased invasiveness.

Whilst awaiting prospective, controlled, randomized data, these results point toward EUS-GE as a first line strategy for the management of malignant GOO management, in all patients fit enough for the procedure, if performed in centers where adequate expertise is available.

Tables

Table 1: Demographical variables of the population of patients undergoing Endoscopic UltraSound Gastro-Enterostomy (EUS-GE)

Characteristic	**EUS-GE (N=70)**
Age, years, median [IQR]	64 [58-73]
Male, n (%)	41 (58.6%)
Baseline BMI, Kg/m^2, median [IQR]	21.3 [18.9-24]
CCI, median [IQR]	7 [5-8]
ASA score, n (%)	
1	1 (1.4%)
2	36 (51.4%)
3	33 (47.1%)
GOO scoring system, n (%)	
0	63 (90.0%)
1	0
2	3 (4.3%)
3	4 (5.7%)
Primary disease, n (%)	
Pancreatic cancer	53 (75.7%)
Ampullary cancer	4 (5.7%)
Biliary / Gallbladder cancer	5 (7.1%)
Gastric cancer	5 (7.1%)
Others	3 (4.3%)
Staging, n (%)	
Resectable	2 (2.9%)
Borderline resectable	2 (2.9%)
Locally advanced	24 (34.3%)
Metastatic	42 (60.0%)
Ascites, n (%)	13 (18.6%)
Carcinomatosis, n (%)	14 (20.0%)
Previous biliary procedures, n (%)	36 (51.4%)
Median post-procedural survival, days, [IQR]	117 [57-188]

BMI, Body Mass Index; ASA, American Society of Anesthesiologists; CCI, Charlson ComorbidityComorbidity Index; IQR, Interquartile Range; GOO, Gastric Outlet Obstruction
* statistically significant

Table 2: Outcomes of Endoscopic UltraSound Gastro-Enterostomy (EUS-GE) procedures

Characteristic	**EUS-GE (N=70)**
Technical success, n (%)	68 (97.1%)
Initial misdeployment	4 (5.7%)
Classification[&], n (%)	
Type I → Redo-EUS-GE[$]	2 (2.9%)
Type II → Surgery	1 (1.4%)
Type IV → Surgery	1 (1.4%)
Clinical success, n (%)	
Intention-to-treat population	66 (94.3%)
As-treated population	66/68 (97.1%)
Procedural duration, min, median [IQR]	45 [35-56.8]
Any post-procedural complaint, n (%)	
None	62 (88.6%)
Post-procedural vomiting	8 (11.4%)
Adverse events, n (%)	9 (12.9%)
Severity according to ASGE Lexicon[#]	
Mild	1 (1.4%)
Moderate	4 (5.7)
Severe	2 (2.9%)
Fatal	2 (2.9%)
Time to first tolerated fluid, days, median [IQR]	1 [0-1]
Time to first tolerated soft solid (GOOSS≥2), days, median [IQR]	1.5 [1-2]
Hospital stay, days, median [IQR]	6 [3-11]
Chemotherapy initiation/resumption, n (%)	43 (61.4%)
Time to chemotherapy, days, median [IQR]	19 [14-26]
Total post-procedural follow-up, days, median [IQR]	105 [49-187]
Symptoms recurrence, n (%)[£]	5/66[£] (7.6%)
Time to recurrence, days, median [IQR]	78 [28-164]
Kaplan-Meier analysis (see Figure 3A)	
Mean estimated Symptoms-Free-Survival, days (95%CI)	480 (426-534)
Symptoms-Free Survival probability	
30 days	98.4%
3 months	96.7%
6 months	90.6%
1 year	85%
Deaths, n (%)	54 (77.1%)
Time to death, days, median [IQR]	84 [49-144]

ASGE, American Society of Gastrointestinal Endoscopy; GOOSS, Gastric Outlet Obstruction Scoring System; IQR, Interquartile Range.
[&] according to Ghandour et al., GIE, 2021; doi:10.1016/J.GIE.2021.07.023
[$] see Vanella et al, Endoscopy, 2022; doi:10.1055/A-1792-2755
[#] according to Cotton et al, GIE 2010; doi:10.1016/j.gie.2009.10.027
[£] among patients with technical and clinical success

Table 3: Demographical variables of the matched population of patients undergoing Endoscopic UltraSound Gastro-Enterostomy (EUS-GE) versus Endoscopic Stent (ES)

Variable	**EUS-GE (N=28)**	**ES (N=28)**	***P* value**
Age, years, median [IQR]	64 [59-73]	67 [61-77]	0.25
Male, n (%)	14 (50.0%)	10 (35.7%)	0.28
Baseline BMI, Kg/m^2, median [IQR]	20.9 [18.9-25.6]	22.8 [20.4-25.4]	0.15
CCI, median [IQR]	7.5 [5.5-8.5]	7.5 [4.5-9.0]	0.80
ASA score, n (%)			1.00
2	8 (28.6%)	8 (28.6%)	
3	20 (71.4%)	20 (71.4%)	
GOO scoring system[#], n (%)			0.36
0	24 (85.7%)	24 (85.7%)	
1	0	1 (3.6%)	
2	2 (7.1%)	3 (10.7%)	
3	2 (7.1%)	0	
Primary disease, n (%)			0.83
Pancreatic cancer	18 (64.3%)	20 (71.4%)	
Ampullary cancer	2 (7.1%)	3 (10.7%)	
Biliary / Gallbladder cancer	3 (10.7%)	2 (7.1%)	
Gastric cancer	2 (7.1%)	2 (7.1%)	
Others	3 (10.7%)	1 (3.6%)	
Staging, n (%)			0.51
Resectable	1 (3.6%)	1 (3.6%)	
Borderline resectable	0	2 (7.1%)	
Locally advanced	7 (25.0%)	8 (28.6%)	
Metastatic	20 (71.4%)	17 (60.7%)	
Ascites, n (%)	8 (28.6%)	7 (25.0%)	0.77
Carcinomatosis, n (%)	11 (39.3%)	11 (39.3%)	1.00
Previous biliary procedures, n (%)	14 (50.0%)	16 (57.1%)	0.60
Median post-procedural survival, days, [IQR]	73 [41-131]	113 [38-197]	0.31

BMI, Body Mass Index; ASA, American Society of Anesthesiologists; CCI, Charlson Comorbifity Index; IQR, Interquartile Range, GOO, Gastric Outlet Obstruction
[#] according to Adler DG et al, AJG 2002; doi:10.1111/j.1572-0241.2002.05423.x

Table 4: Clinical Outcomes of Endoscopic UltraSound Gastro-Enterostomy (EUS-GE) versus Endoscopic Stent (ES) matched population

Characteristic	**EUS-GE (N=28)**	**ES (N=28)**	***P* value**
Technical success, n (%)	27 (96.4%)	28 (100%)	0.32
Clinical success, n (%)	27/27 (100%)[$]	21/28 (75.0%)[$]	0.006 *
Time to Clinical Success [IQR], days	2 [1-2]	3 [2-7]	0.03 *
Adverse events, n (%)	2 (7.1%)	7 (25%)	0.07
ASGE Lexicon[#]			0.24
Mild-Moderate	1 (3.6%)	1 (3.6%)	
Severe-Fatal	1 (3.6%)	6 (21.4%)	
Hospital Stay [IQR], days	6.5 [3-10.5]	7 [4-21]	0.45
Median follow-up [IQR], days	73 [41-131]	78 [50-188]	0.45
Chemotherapy resumption, n (%)	13 (46.4%)	15 (53.6%)	0.60
Time to chemotherapy [IQR], days	17 [14.8-24.3]	24 [22.3-39.3]	0.055
Symptoms Recurrence, n (%)	1/27 (3.7%)[&]	7/21 (33.3%)[&]	0.007 *
Kaplan-Meier analysis (see Figure 3B)			
Mean estimated SFS (95%CI), days	469 (429-509)	341 (246-436)	0.047[£]*
3-months SFS	95.5%	77.4%	
6-months SFS	95.5%	67.7%	
Deaths during follow-up, n (%)	25 (89.3%)	21 (75%)	0.17
Mean estimated Overall Survival (95%CI), days	121 (67-175)	212 (126-298)	0.12[£]

* statistically significant
[$] among patients with technical success (as-treated population)
[&] among patients with technical and clinical success
[£] log-rank test at Kaplan-Meier analysis
[#] according to Cotton et al, GIE 2010; doi:10.1016/j.gie.2009.10.027
IQR, Interquartile range; CI, Confidence Interval; CHT, chemotherapy; ASGE, American Society of Gastrointestinal Endoscopy; SFS, Symptoms-Free Survival.

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Conflict of Interests:

GV report travel grants from Pentax Medical; GDA reports travel grants from Pentax Medical; MB has consultancy agreements with Dekra, Taewoong/Prion Medical, and reports travel grants from Taewoong, Norgine and Prion Medical; SvdM co-chairs the Boston Scientific Chair in Therapeutic Biliopancreatic Endoscopy, holds the Cook Medical chair in Portal Hypertension and holds consultancy agreements with Boston Scientific, Cook Medical and Pentax. All other Authors disclose no COI relevant for this article.

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Figure Legends

Figure 1. **Endoscopic Ultrasound Guided Gastroenterostomy (EUS-GE) according to Wireless Simplified Technique (WEST). A)** An oro-jejunal tube (OJT; red asterisk) is placed across the stenosis and Treitz, through which saline + indigo carmine is injected in the jejunum **B)** Under EUS guidance, the OJT is identified within the first jejunal loop. **C)** Endosonographic appearance of fluid injection in the first jejunal loop; **D)** EUS-GE is performed by free-hand placement of an electrocautery-enhanced Lumen Apposing Metal Stent (LAMS) into the dilated jejunal loop; the cautery effect can be seen as a perturbation of the fluid within the loop (blue asterisk) by the catheter tip (yellow asterisk). **E)** release of the distal flange under EUS guidance; **F)** release of the proximal flange under endoscopic guidance; the outflow of blue-stained fluid confirms correct LAMS placement. **G)** After LAMS dilation, jejunal folds and OJT (red asterisk) can be visualised through the LAMS. **H)** contrast injected through the OJT (red asterisk) can be aspirated in the stomach confirming correct placement without any leak.

Figure 2. **Contraindications**, **Adverse events and Recurrences of Endoscopic Ultrasound Guided Gastroenterostomy (EUS-GE).**

A-C) Contraindications.

A) Diffuse malignant gastric wall infiltration. A) EUS showing diffuse neoplastic infiltration of the gastric wall (total thickness 1.8 cm; muscular layer 0.6 cm; A1) corresponding endoscopic picture; **B) Massive ascites**. EUS showing a jejunal loop containing the oro-jejunal tube (red asterisk), «swimming» with its stretched meso into a large volume ascites. **C) Extensive peritoneal carcinomatosis**. Radiologic Gastrointestinal Follow-through showing diffuse gastro-jejunal dilatation due to multiple stenosis in a patient with peritoneal carcinomatosis.

D-F) Adverse events.

D-D1) Bleeding. Patient presenting melena and anemia the day following the procedure. Esophagogastroduodenoscopy (EGD) showed the Lumen Apposing Metal Stent (LAMS) occluded by a clot that was removed; norepinephrine injection of the gastrojejunal fistula was performed through the meshes of the LAMS. **E) EUS-Gastrocolostomy**. After prolonged attempts to identify the target jejunal loop, the LAMS was placed; after release endoscopic view and contrast injection showed access to the colon; in the picture red lines contour the colonic lumen filled with air; E1) corresponding surgical picture. **F) Late ulceration**. Patient with metastatic pancreatic cancer under anticoagulant therapy for pulmonary thromboembolism underwent EGD for melena 302 days following the procedure: a fibrinous ulcer was visible on the jejunal side of the EUS-GE.

G-I) Recurrences.

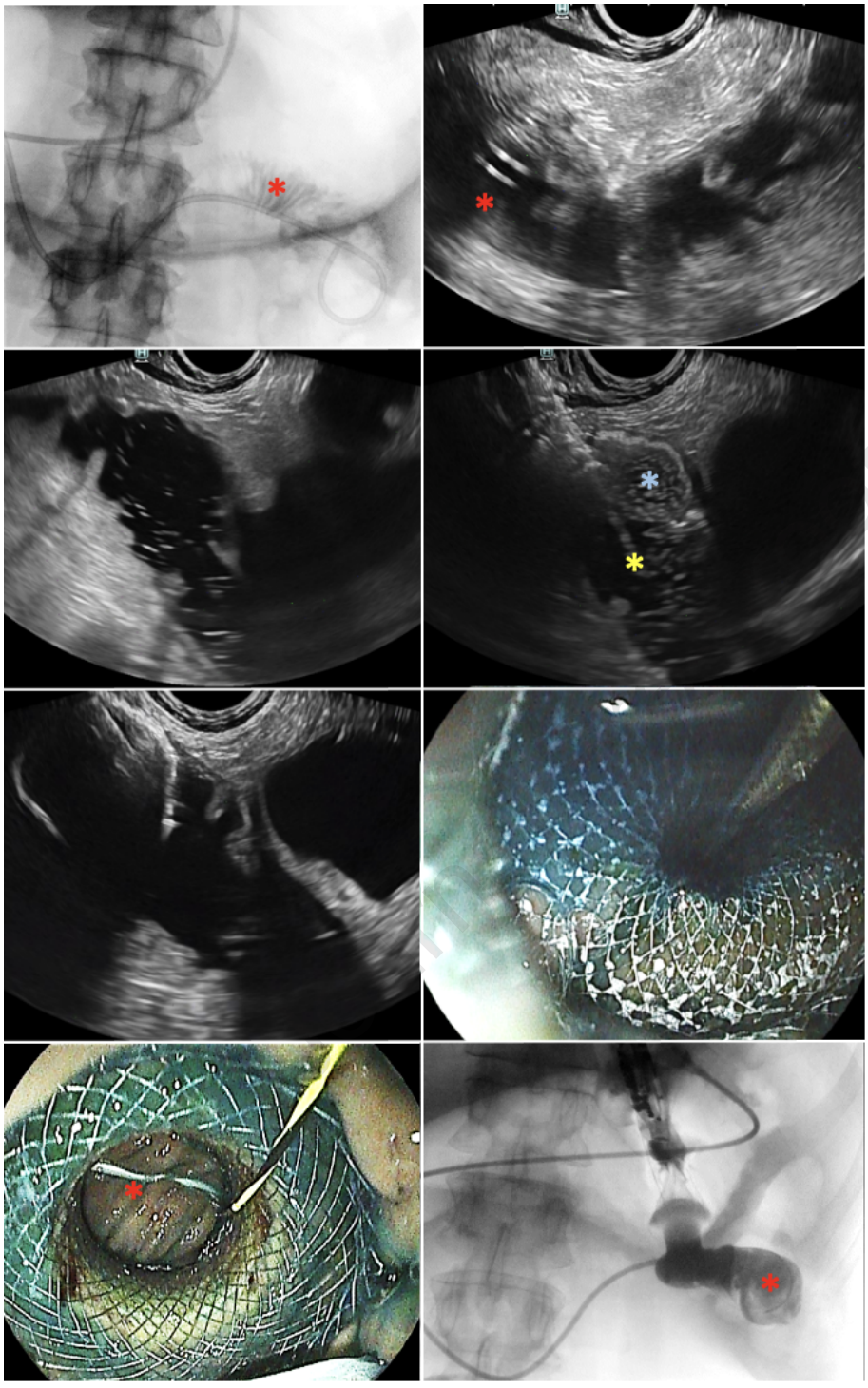
G) Patient with difficulty in achieving clinical success underwent EGD for repeated vomiting 7 days following EUS-GE: the LAMS appeared occluded by redundant gastric mucosa; G1) A through-the-LAMS temporary (7 days) naso-jejunal feeding tube was placed. After achieving clinical success, the same event determined a recurrence after 20 days from procedure; **H)** Patient experiencing symptoms recurrence after 30 days from clinical success. EGD showed oedematous jejunal mucosa occluding LAMS lumen, at Treitz angle. **I)** EUS-GE was performed in a patient with neoplastic recurrence after partial gastrectomy; 194 days after EUS-GE, the patient experienced GOO symptoms recurrence. Radiologic follow-through showed complete exclusion of the LAMS (red circle); EGD showed neoplastic infiltration of the gastric LAMS flange which was successfully treated by through-the-LAMS fully covered self-expandable metal stent placement.

Figure 3: Probability of symptoms' recurrence analyzed as Symptoms-Free Survival (SFS) through Kaplan-Meier curves (dotted lines represent 95% confidence interval). Recurrence was analyzed amongst patients achieving Technical and Clinical Success (see Definitions):

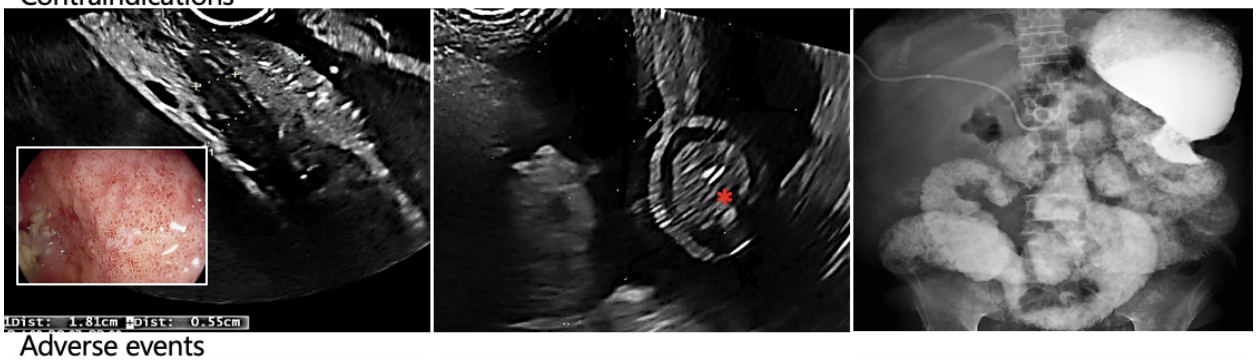
A) SFS of the whole EUS-Gastroenterostomy (EUS-GE) cohort (N=66).

B) Comparison of SFS of the matched cohorts of EUS-GE (N=27) versus enteral stents (ES, N=21); log-rank test, p=0.047.

Supplementary Figure 1: Relative frequencies of adoption of Endoscopic Stent (ES) versus Endoscopic UltraSound Gastro-Enterostomy (EUS-GE). When the study interval was divided into 6 equivalent time frames (4 months each), there was a significant switch (p-for-trend= 0.0075) towards predilection of EUS-GE over ES, with relative frequency ranging from 38.5% of patients during the first-time frame to 46.2% in the second and 75% during the last four intervals (see **Table S4**).



Contraindications



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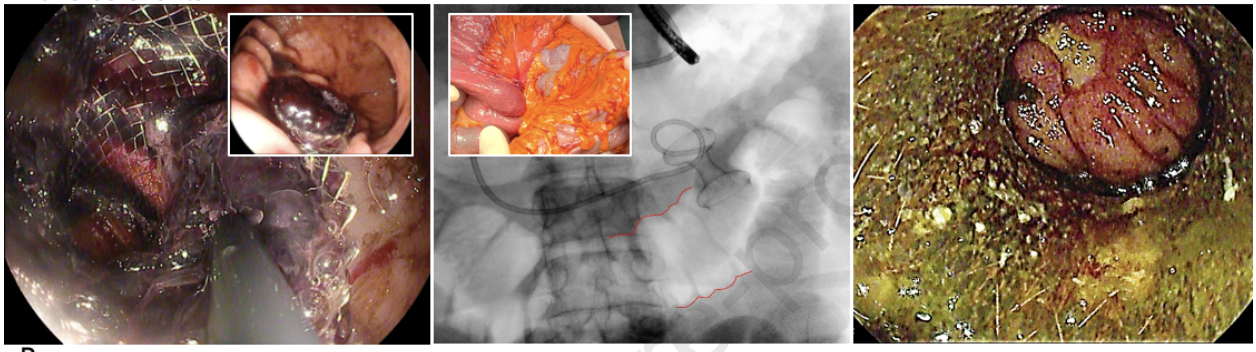
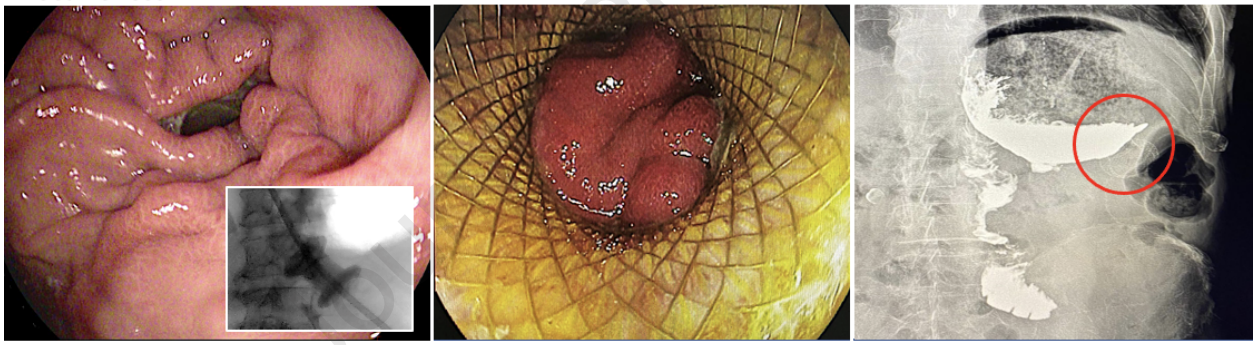
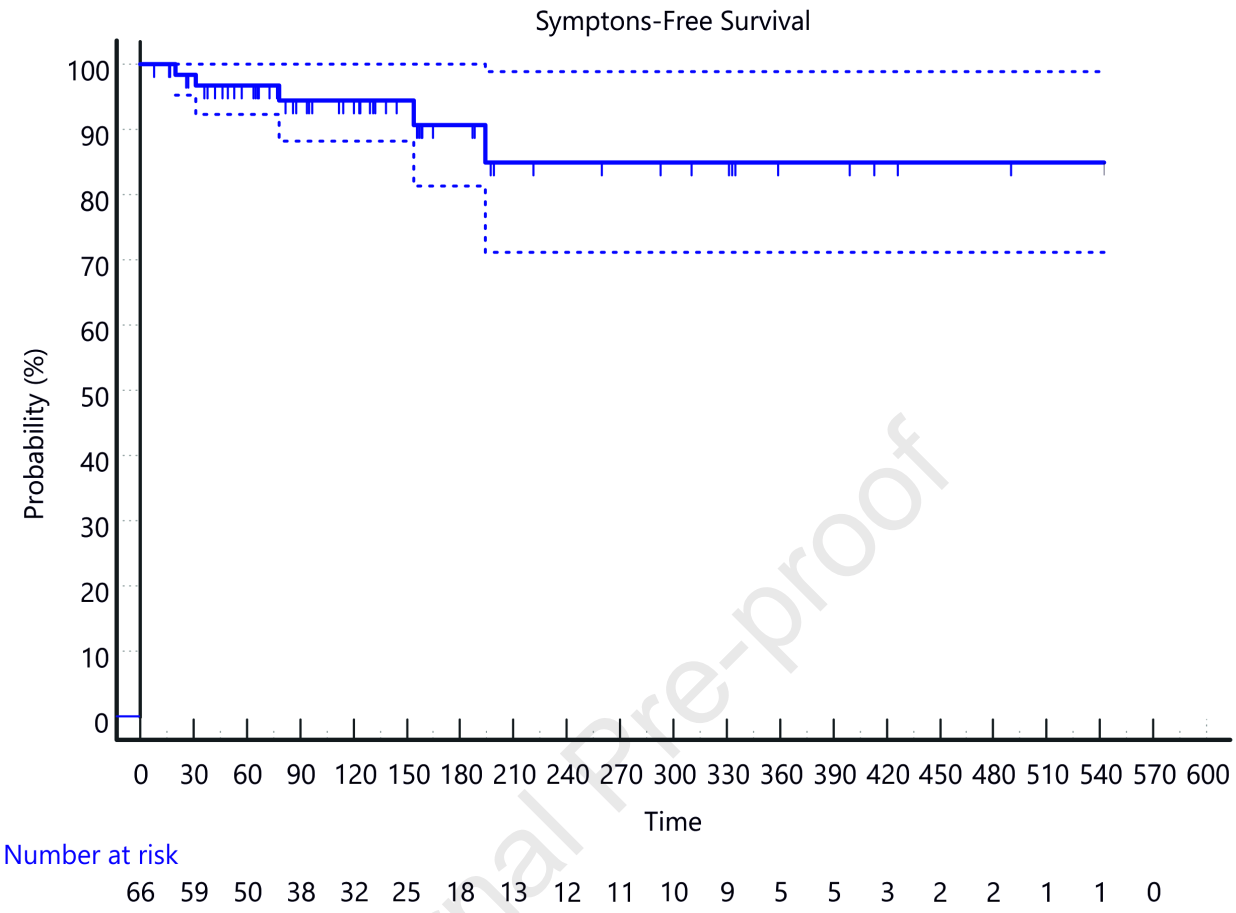
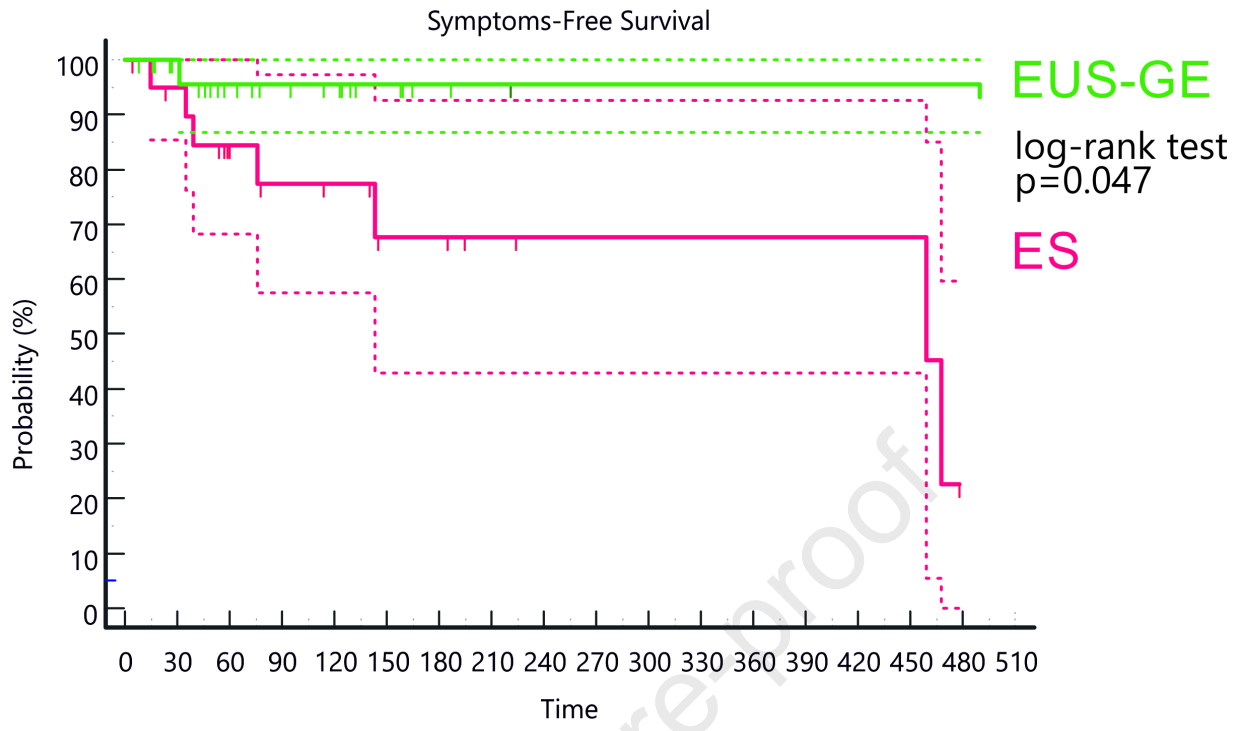


Recurrences







Number at risk

Group: ES

21	18	12	10	9	6	6	4	3	3	3	3	3	3	3	0	0

Group: GE

27	22	16	12	10	6	3	2	1	1	1	1	1	1	1	1	1	0

EUS-guided GastroEnterostomy for management of malignant Gastric Outlet Obstruction: a prospective cohort study with matched comparison with Enteral Stenting.

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Acronyms and Abbreviations

ASA: American Society of Anesthesiologists

ASGE: American Society of Gastrointestinal Endoscopy

BMI: Body Mass Index

GOO: Gastric Outlet Obstruction

GOOSS: Gastric Outlet Obstruction Scoring System

mGOO: malignant Gastric Outlet Obstruction

ERCP: Endoscopic Retrograde Cholangiopancreatography

ES: Enteral stenting

EUS: Endoscopic Ultrasound

EUS-GE: EUS-guided Gastroenterostomy

LAMS: Lumen Apposing Metal Stent

OJT: Oro-Jejunal tube

POD: post-operative day

s-GE: surgical gastroenterostomy

SFS: Symptoms-Free Survival

WEST: Wireless Simplified Technique

vs. : versus