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Endoscopic or surgical gastroenterostomy for malignant gastric outlet obstruction: a randomised trial

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ABSTRACT

Background Although surgical gastrojejunostomy (SGJ) is the standard method for palliation of gastric outlet obstruction (GOO), an endoscopic method—endoscopic ultrasound-guided gastroenterostomy (EUS-GE)—has been proposed as a novel, less invasive approach.

Objective We compared both methods to determine whether clinical outcomes for EUS-GE are superior to surgery.

Design We conducted a multicentre, randomised superiority trial of patients with malignant GOO to receive either EUS-GE or SGJ. Primary endpoint was composite measure, consisting of Gastric Outlet Obstruction Scoring System (GOOSS) score of 0 or 1 at hospital discharge, need for reinterventions or supplemental nutrition, or procedure-related adverse events during 6-month follow-up or until death. Secondary endpoints were time to solid diet, length of hospitalisation, health-related quality of life (HRQoL) and treatment costs.

Results 74 patients were randomly assigned to EUS-GE (38 patients) or SGJ (36 patients). Primary endpoint occurred in 7.9% of patients who received EUS-GE and 38.9% in SGJ (risk difference −31.0%, 95% CI −47.6% to −11.4%, $p=0.002$). EUS-GE was associated with more rapid advancement to solid diet (median 2 days (P25–P75, 2–3) vs 5 days (P25–P75, 3.5–9)), shorter hospitalisation (median 3 days (P25–P75, 3–6) vs 9 days (P25–P75, 6–12.5)), better HRQoL for physical ($p=0.0016$) and social functioning ($p=0.011$) and lower treatment costs (US\$33 934 vs US\$51 437, difference −US\$17 503 (95% CI −US\$27 807 to −US\$7920)).

Conclusion In this randomised trial, EUS-GE was superior to SGJ with regards to oral intake, need for reinterventions or supplemental nutrition, length of hospitalisation, quality of life and treatment costs.

Trial registration number NCT05548114.

INTRODUCTION

Malignant gastric outlet obstruction (GOO) is caused by advanced pancreaticobiliary cancer in up to 85% of patients,^{1,2} and in others due to

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Although gaining in popularity, it is important to determine whether the novel, less invasive endoscopic approach—endoscopic ultrasound-guided gastroenterostomy is superior to the standard method—surgical gastrojejunostomy for treatment of patients with malignant gastric outlet obstruction.

WHAT THIS STUDY ADDS

⇒ In this multicentre randomised trial of 74 patients with malignant gastric outlet obstruction, it was observed that an endoscopic approach was superior to surgical gastrojejunostomy with regards to early resumption of oral intake, fewer need for reinterventions, shorter length of hospitalisation, early initiation or resumption of chemotherapy, better health-related quality of life and lower treatment costs.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ With the rising incidence of pancreatic cancer worldwide and approximately 20% of patients developing gastric outlet obstruction during illness, the study findings suggest that endoscopic ultrasound-guided gastroenterostomy should be the preferred treatment approach when the requisite expertise and resources are available.

gastric or duodenal neoplasia. Associated symptoms include early satiety, nausea, vomiting and abdominal discomfort, which, if untreated, could lead to poor nutritional status that negatively impacts quality of life with detrimental influence on tolerance and efficacy of oncological treatment.³ Rapid restoration of enteral nutrition through an effective intervention is therefore essential.

GOO has traditionally been treated by surgical gastrojejunostomy (SGJ), performed either through



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open or laparoscopic approaches, to bypass the obstruction. Although associated with durable symptom relief, given the invasiveness of the technique, longer recovery time is needed for gastrointestinal tract function, particularly motility, to adapt to the new anatomical milieu. This delays resumption of oral intake, hospital discharge, provision of chemotherapy and treatment of underlying cancer.^{4 5} In pursuit of less invasive alternatives that could offer comparable efficacy with more rapid recovery, endoscopic interventions have been developed. Since the late 1990s, endoscopic placement of metal endoprosthesis across the obstruction enabled early resumption of oral intake with fewer adverse events and shorter length of hospital stay. However, these therapeutic benefits were short-term due to recurrent obstructive symptoms from tissue ingrowth causing stent obstruction.^{5 6} More recently, this limitation has been overcome by creation of an internal gastroenterostomy under endoscopic ultrasound guidance (EUS-GE).⁷ By virtue of its minimally invasive ability to bypass the obstructing tumour, in retrospective, non-randomised studies, the newly proposed endoscopic approach has been reported to enable early oral intake, provide durable symptom relief and facilitate early hospital discharge.^{8 9}

Although gaining popularity, in a retrospective audit of the National Inpatient Sample database, it was observed that only about 20% of 20 930 hospitalisations for malignant GOO in the USA were being treated by EUS-GE, with a majority still managed surgically.¹⁰ With increasing incidence of pancreatic cancer worldwide, particularly in younger patients,¹¹ and growing need for more effective treatment options, it is unclear which palliative measure is preferable in patients presenting with GOO. We therefore performed a multicentre randomised trial to investigate whether EUS-GE is superior to SGJ as the first-line treatment in patients with malignant GOO.

METHODS

Study design

The GOOSE (Gastric Outlet Obstruction Surgery or Endoscopy) trial was an investigator-initiated, multicentre, randomised, superiority trial conducted at six centres in three countries (USA, Germany and India). A safety monitoring board reviewed all adverse events.

Patient and public involvement

Patients or public were not involved in design, or conduct, or reporting, or dissemination plans of our research. Patients were not invited to comment on study design and were not consulted to develop patient-relevant outcomes or interpret results. Patients were not invited to contribute to writing or editing of this document for readability or accuracy.

Study participants

Patients were eligible for inclusion in the trial if they were 18 years of age or older, had GOO Scoring System (GOOSS)¹² score of 0 or 1 (detailed description of GOOSS is provided below), had endoscopic or radiological findings of underlying unresectable malignancy with histological confirmation that were consistent with the clinical presentation and amenable to treatment by both methods. Exclusion criteria were altered anatomy due to prior gastric or duodenal surgery, presence of other adhesions or synchronous obstructive lesions in small bowel, prior endoscopic or surgical interventions to treat underlying clinical presentation, large volume malignant ascites and irreversible coagulopathy.

Randomisation and masking

Patients were enrolled by interventional endoscopists or surgeons in inpatient wards or outpatient consultation suites.

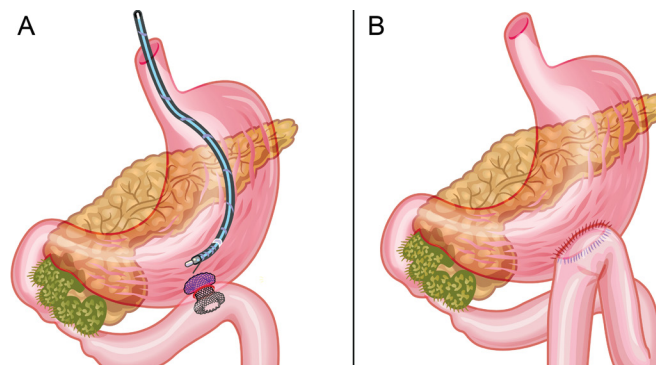


Figure 1 Methods of treatment for gastric outlet obstruction. Panel A shows the endoscopic ultrasound-guided gastroenterostomy approach, in which a lumen-apposing metal stent is placed into the jejunum from the gastric lumen. Panel B shows the surgical gastrojejunostomy approach.

Computer-generated randomisation assignments were provided by the statistician in the coordinating centre in randomly permuted blocks of 2 or 4 and stratified by study site. Randomisation assignments were placed in opaque sealed sequentially numbered envelopes at each site, which were opened by study investigators after consent for the study was obtained. Patients were randomly assigned in a 1:1 ratio to undergo either EUS-GE or SGJ. Assigned intervention was then performed within 7 days following randomisation. Given the differences in interventions performed, endoscopists and surgeons performing procedures and study participants were aware of treatment allocation. All surgeons and endoscopists participating in the clinical trial were experts, with endoscopists having performed at least 20 EUS-GE procedures. Patient-reported outcomes were assessed by telephone calls or follow-up appointments by dedicated study personnel who were aware of treatment assignment. Statisticians analysing data were blinded to treatment allocation, and data analysis was performed using anonymised group assignment codes.

Interventions

Surgical gastrojejunostomy

After administration of prophylactic intravenous antibiotics, under general anaesthesia, laparoscopic or robotic techniques were attempted based on tumour size, location and operator preference (figure 1). However, given the likely inclusion of patients with advanced pancreatic cancer that frequently precludes minimally invasive approaches due to bulky tumour size with mesenteric involvement and/or pre-existent unrelated surgical intervention with intra-abdominal adhesions, an open GJ could also be performed. Laparoscopic GJ was created with a four-trocar technique and carbon dioxide insufflation, creating a side-to-side antecolic anastomosis along anterior gastric wall with longitudinal 60 mm stapler. Closure of common channel enterotomy was performed with continuous absorbable suture.¹³ A similar technique was adopted for robotic procedures, with anterior or posterior antecolic anastomosis, that were performed using Da Vinci Xi platform.¹⁴ Open GJ was performed via supra-umbilical midline incision with antecolic side-to-side anastomosis on anterior gastric wall, using longitudinal 60 mm stapler. In patients with bulky obstructing tumours, the lesser sac was entered along the greater curvature of the stomach, and anastomosis was created on the posterior gastric wall, using retrocolic approach.¹⁵

EUS-guided gastroenterostomy

After administration of prophylactic intravenous antibiotics, under general anaesthesia, a catheter was advanced via nares or oral cavity and through gastric or duodenal stenosis into the jejunum. Water mixed with methylene blue and radiocontrast agent was infused into the jejunum. Distended jejunum was then visualised using a linear array echoendoscope positioned in the stomach. The jejunal loop was punctured freehand using electrocautery enhanced delivery system of a 20 mm diameter (with 10 mm saddle length) lumen-apposing metal stent platform (Hot AXIOS, Boston Scientific, Marlborough, Massachusetts, USA) and endoprosthesis was deployed with distal flange in the jejunum and proximal flange in the stomach (figure 1).⁸

Trial endpoints

Primary endpoint was composite binary measure of following parameters: (1) GOOSS score of 0 or 1 at time of hospital discharge, (2) need for additional endoscopic or surgical interventions or supplemental nutrition or (3) procedure-related adverse events (such as bleeding, perforation or infection) graded according to Clavien-Dindo classification (definition in online supplemental table S1).¹⁶ With the exception of differences in GOOSS score between treatment arms, which was assessed at hospital discharge, components of primary endpoint were measured between randomisation and 6-month follow-up or until death due to underlying disease. The GOOSS¹² is a validated scale that evaluates level of oral intake before and after an intervention. GOOSS score is assigned on a 4-point scale with 0 for no oral intake, 1 for liquids only, 2 for soft solids only and 3 for low-residue or full diet, with lower scores indicating more severe symptoms (online supplemental table S2). Determination of advancement of oral intake, need for additional endoscopic or surgical interventions and initiation of supplemental nutrition was made by consensus of the multidisciplinary study team at each participating institution.

Prespecified key secondary endpoints included clinical measures regarding quality of life in patients with cancer as measured by European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ) 30-item core instrument (C30) (online supplemental figure S1),^{17 18} and treatment costs from intervention until hospital discharge (costs for procedure, hospital stay, medications, materials, imaging, facility charges). C30 includes five scales within functional domain, nine scales of multi-item and single-item within symptom domain, and one item for global health and quality of life. Functional domain includes physical, role, cognitive, emotional and social functioning scales. Symptom domain includes fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhoea and financial difficulties. The instrument is scored according to developer guidelines in which linear transformations are applied to generate scores ranging from 0 to 100. For functional scales, 0 represents poor function and 100 represents good function, whereas for symptom scales, higher scores represent higher symptom severity. C30 was administered before EUS or surgery, then at hospital discharge, 1, 3 and 6 months after intervention.

Other secondary endpoints included time to advancement of diet to liquids (GOOSS score 1) and to solid foods (GOOSS score ≥ 2), procedural duration, duration of hospitalisation (from day of assigned procedure until discharge), hospital readmissions, disease-related adverse events, mortality and time to provision of chemotherapy after intervention. Further details of these clinical measures are provided in online supplemental table S3.

Clinical data were collected at hospital discharge, 1, 3 and 6 months post-index procedure by dedicated trial personnel, who were aware of treatment group assignments, by means of telephone calls or follow-up appointments with treating physicians in outpatient clinics, using standard case report forms (CRFs). On-site data monitoring was coordinated by the Corporate Office of Research Operations at Orlando Health, whereby an independent monitor at participating institutions checked all endpoints and CRFs with onsite source data. The research manager audited data from all sites on a quarterly basis and any discrepancies were resolved by cross-referencing CRFs against onsite source data. A biannual audit was jointly performed by research staff and institutional review board. The primary endpoint was assessed jointly by the principal investigator (endoscopist) and designated surgeon at each participating site by evaluation of individual patients. Assessment of other outcomes was performed by an adjudication committee consisting of a gastroenterologist, surgeon and an expert statistician at the coordinating centre who reviewed all medical records, with arbitration and resolution of any discrepancies.

Statistical analysis

This was a superiority trial designed to have 80% power to detect the difference in primary composite outcome of 12% with EUS-GE and 43% with SGJ based on the available literature.^{7 19–22} Power calculation based on two-sided 0.05 alpha level χ^2 test resulted in sample size estimation of 32 patients per arm, and we required enrolling 36 patients per arm to account for a 10% dropout (PASS 15 Power Analysis and Sample Size Software, NCSS, Kaysville, Utah, USA).

For primary composite outcome comparison, a χ^2 test was used. We also compared individual components of the composite endpoint, separately for time to reintervention or need for supplemental nutrition (negative outcome) and for time to initiation of solid diet (GOOSS ≥ 2 , positive outcome). For these outcomes and other secondary time-to-event outcomes (such as time to chemotherapy), due to the number of deaths observed in each arm and deaths being a competing risk of each outcome, we used Fine-Gray subhazards competing risk regression model to compare cumulative incidence event.²³ Patient characteristics, features of underlying malignancy, symptoms, procedure details and outcome measures were summarised as means (with SD) or medians (with IQR) for continuous data (depending on distribution of data) and as frequencies and proportions for categorical data. For comparison of categorical data, χ^2 test or Fisher's exact test was used as indicated. For comparison of continuous data, a two-sample t-test was used and Wilcoxon rank-sum test was used when data showed skewness. Difference in proportions and 95% CIs were calculated using the Agresti-Caffo method²⁴ and difference in median and 95% CI were calculated using the Hodges-Lehmann method.²⁵

For EORTC QLQ-C30 scales, we used a mixed model to assess the effect of the trial treatments on patients' health-related quality of life (HRQoL) from discharge through month six. For each C30 scale evaluated, analysis included variables such as type of treatment, visits, how treatment effect changed over time, patients' baseline scores and differences between patients in change in their quality of life over the study duration. The model assessed changes in scores over visits with pairwise comparisons of mean scores between treatment arms for each visit with the visit variable treated as discrete so that treatment-by-visit interaction would allow the model to have

positive or negative effect time profiles without assuming a specific parametric form.²⁶ A 10-point difference in each subscale score at any specific time point was deemed clinically meaningful.²⁷

For all analyses, the analytical cohort was intention-to-treat. Two-sided *p* values were reported for comparison of all outcome measures with significance determined at 0.05, and no adjustments were made for multiple testing for secondary outcomes. All statistical analyses were performed using Stata V.17.0 (Stata Corp, College Station, Texas, USA).

Cost analysis

Trial centres reported billing data across spending categories from index procedure through hospital discharge. All relevant costs pertaining to treatment were taken into consideration: procedure costs, inpatient hospital stay from date of procedure to discharge, medications, materials, anaesthesia, pharmacy and imaging studies. All cost data were adjusted for inflation in local currency units using the country's respective consumer price index.^{28–30} Purchasing power parity exchange rates were then used to convert all currencies to US dollars with 2023 as the base year.³¹

Generalised linear models (GLM) were used to examine differences in cost between study groups. Before fitting the model, the skewness of cost data was assessed and determined to be highly positively skewed. The Modified Park test indicated that the GLM should be fitted to the study cost data using a log link and gamma distribution.^{32 33}

RESULTS

Between 16 September 2022 and 24 November 2024, a total of 116 patients with malignant GOO were screened for eligibility at six sites in the USA, India and Germany and 74 patients who met criteria were enrolled and randomised to EUS-GE arm (*n*=38) or SGJ arm (*n*=36) (figure 2). The distribution of patients across trial sites is provided in online supplemental table S4. As there were no exclusions or dropouts, all 74 patients were assessed for the primary endpoint. All patients underwent assigned treatment, and patients in the intention-to-treat cohort and per-protocol cohort were identical. All patients underwent intervention within 7 days of study enrolment, with mean time from enrolment to intervention of 1.2 days (SD 1.7).

Baseline patient demographic characteristics, Karnofsky performance status (definition in online supplemental table S5), clinical features and HRQoL were similar between arms (table 1). 15 (39.5%) patients in the EUS-GE and 15 (41.7%) patients in the SGJ arm were female. Primary malignancy was pancreaticobiliary or gastroduodenal cancer in 29 (76.3%) in EUS-GE and 33 (91.7%) in SGJ arm. Distant metastases were observed in 20 (52.6%) patients in the EUS-GE and 20 (55.6%) patients in the SGJ arm.

Primary endpoint

The primary composite endpoint occurred in 7.9% of patients who received EUS-GE and 38.9% of patients who received SGJ (difference −31.0%, 95% CI −47.6% to −11.4%, *p*=0.002) (table 2).

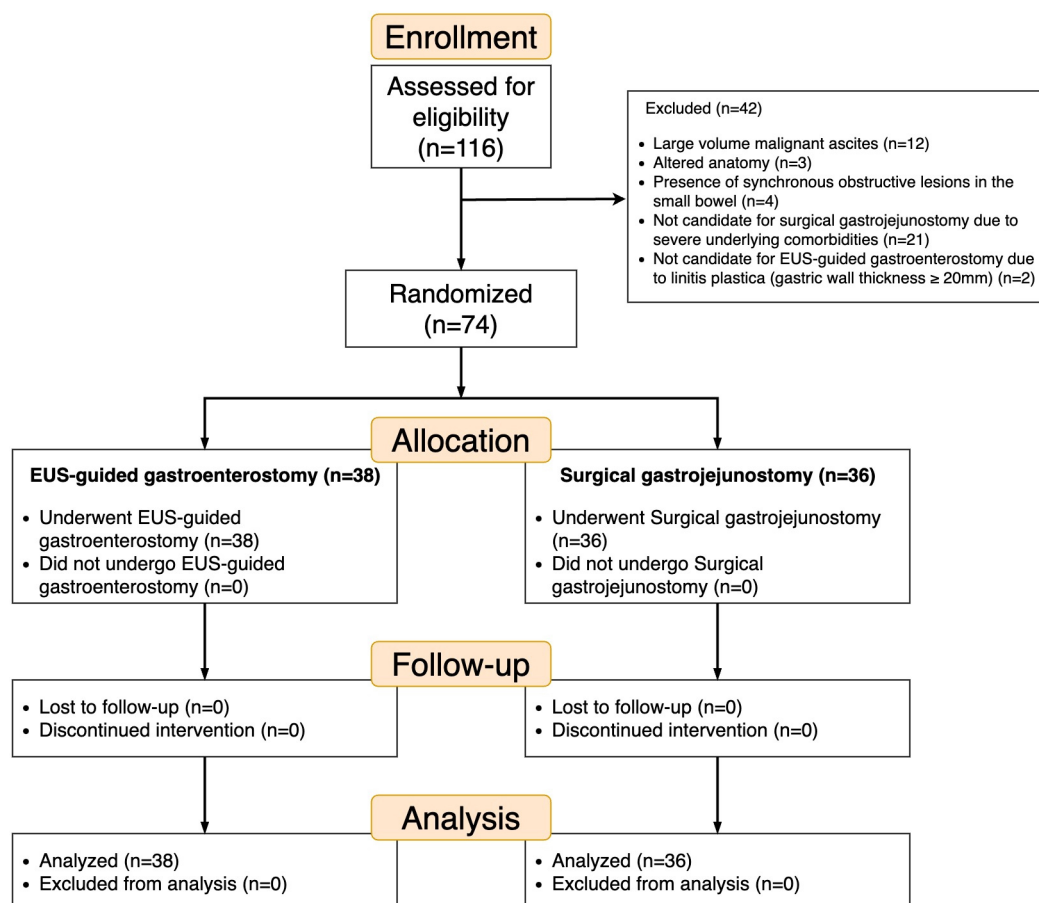


Figure 2 Consort flow diagram of study participants and follow-up. EUS, endoscopic ultrasound.

Table 1 Baseline characteristics of patients and underlying malignancy

	EUS (n=38)	Surgery (n=36)
Age (years):		
Mean (SD)	65.3 (15.1)	61.5 (12.3)
Median (P25–P75)*	68.5 (57–76)	61 (51.5–72)
Gender: n (%)		
Female	15 (39.5)	15 (41.7)
Male	23 (60.5)	21 (58.3)
Race: n (%)		
Asian	15 (39.5)	18 (50.0)
Black	4 (10.5)	4 (11.1)
Hispanic	4 (10.5)	0
White	15 (39.5)	14 (38.9)
Primary malignancy: n (%)†		
Pancreaticobiliary	22 (57.9)	20 (55.6)
Gastroduodenal	7 (18.4)	13 (36.1)
Other‡	9 (23.7)	3 (8.3)
Site of obstruction: n (%)		
Distal stomach to duodenal bulb	13 (34.2)	14 (38.9)
Second to fourth portion of duodenum	25 (65.8)	22 (61.1)
Metastatic disease: n (%)	20 (52.6)	20 (55.6)
Peritoneal carcinomatosis present: n (%)	7 (18.4)	4 (11.1)
Duration of symptoms (days):		
Mean (SD)	20.0 (16.1)	21.1 (13.3)
Median (P25–P75)*	14.5 (12–22)	17.5 (11–31.5)
Body mass index (kg/m ²):		
Mean (SD)	24.0 (5.4)	23.4 (5.2)
Median (P25–P75)*	22.9 (20.4–27.2)	22.4 (21–25.0)
Serum albumin (g/dL):		
Mean (SD)	3.0 (0.75)	3.3 (0.66)
Median (P25–P75)*	3.0 (2.5–3.6)	3.2 (2.9–3.6)
ASA class: n (%)		
II	17 (44.7)	16 (44.4)
III	19 (50.0)	17 (47.2)
IV	2 (5.3)	3 (8.3)
Karnofsky performance status: n (%)		
20–40	6 (15.8)	5 (13.9)
50–70	23 (60.5)	20 (55.6)
80–90	9 (23.7)	11 (30.6)

*IQR is expressed as 25th percentile to 75th percentile.

†Patients undergoing chemotherapy prior to study enrolment: EUS 15 (39.5%) and Surgery 13 (36.1%).

‡Other types of primary malignancy: EUS group: colorectal cancer (n=4), breast cancer (n=1), lung cancer (n=1), lymphoma (n=1), renal cell cancer (n=2). Surgery group: colorectal cancer (n=1), lung cancer (n=1), urothelial cancer (n=1).

ASA, American Society of Anesthesiologists; EUS, endoscopic ultrasound; P25, 25th percentile; P75, 75th percentile.

There was no mortality during index hospitalisation in both groups. On comparison of individual components of the composite endpoint, at time of discharge, all patients in the EUS-GE arm were on solid diet with GOOSS score of at least 2, compared with 80.6% in the SGJ arm (difference 19.4%, 95%CI 4.7% to 32.4%). A greater proportion of patients in the SGJ arm (n=12, 33.3%) also required more reinterventions or supplemental nutrition compared with EUS-GE (n=2, 5.3%) (difference –28.1% (95% CI –43.9% to –9.6%)). Of 12 SGJ arm patients requiring reinterventions or supplemental

nutrition, all 12 patients required supplemental enteral nutrition via temporary percutaneous gastrojejunal feeding tubes due to persistence of GOO symptoms and inability to tolerate solid diet. Two patients in the EUS-GE arm required reinterventions for recurrence of symptoms: one patient underwent duodenal stent placement and one patient underwent placement of a fully covered metal stent inside pre-existing endoprosthesis for stent occlusion. Cumulative incidence analysis with death as a competing risk showed that cumulative incidence of the need for reinterventions or supplemental nutrition (negative outcome) was greater for the SGJ arm (p=0.006) and for initiation of solid diet (positive outcome) was greater for the EUS-GE arm (p<0.001) (online supplemental figures S2 and S3). Procedure-related adverse events graded according to Clavien-Dindo classification were similar between two arms (2.6% in EUS-GE vs 2.8% in SGJ, difference –1.5% (95% CI –10.1% to 9.5%), p=0.999) (table 3).

Key secondary endpoints

Health-related quality of life

No significant differences between the arms in overall (global) quality of life, functional scales and symptom scales were observed at baseline. At discharge, significantly better outcomes were seen in the EUS arm for two function and two symptoms scales. Significantly higher function scales in favour of EUS were observed for physical functioning (difference 11.61, 95%CI 2.15 to 21.07, p=0.016) and social functioning (difference 15.73, 95%CI 3.58 to 27.88, p=0.011). Significantly lower symptom scales in favour of EUS were also observed at discharge for dyspnoea (difference –9.53, 95%CI –18.00 to –1.07, p=0.027) and pain (difference –12.38, 95%CI –24.32 to –0.45, p=0.042). All of the aforementioned differences were deemed clinically meaningful based on at least a 10-point difference at any time point. All EORTC QLQ-C30 scale results are reported in online supplemental tables S6 and S7 and online supplemental figures S4 and S5.

Costs

Mean total costs per patient from admission through discharge were US\$33 934 for EUS and US\$51 437 for surgery, with mean difference of US\$–17 503 per patient (95%CI US\$–27 807 to US\$–7920, p<0.001). Significantly lower costs for EUS were observed for admission, professional, pharmacy and anaesthesia costs. However, there were no significant differences between the groups for procedure, radiology, laboratory and miscellaneous cost categories (online supplemental table S8).

Other secondary endpoints

The procedural duration (median 25.5 mins (P25–P75, 21–40) vs 111.5 mins (P25–P75, 89–141), difference –78 (95%CI –95 to –65), p<0.001) was significantly shorter for EUS-GE as compared with SGJ (table 2). In the surgical cohort, 10 (27.8%) patients underwent laparoscopic, 5 (13.9%) underwent robotic and 21 (58.3%) underwent open SGJ, with no significant difference between approaches, as shown in online supplemental table S9. Time to advance to a liquid diet (GOOSS score 1) and to a solid diet (GOOSS score ≥2) was significantly shorter for EUS-GE as compared with SGJ. This was associated with shorter hospital stay (median 3 days (P25–P75, 3–6) vs 9 days (P25–P75, 6–12.5), difference –5 (95%CI –7 to –3), p<0.001) and earlier initiation of chemotherapy following index procedure (median 21.5 days (P25–P75, 10.5–26.5) vs 35 days (P25–P75, 22–50)) for EUS-GE as

Table 2 Primary and secondary endpoints

	EUS (n=38)	Surgery (n=36)	Difference (95% CI)	P value*
Primary endpoint				
Composite endpoint: n (%)†	3 (7.9)	14 (38.9)	−31.0 (−47.6 to −11.4)	0.002
Components of composite endpoint				
Liquid diet only at discharge (GOOSS=1): n (%)	0	7 (19.4)	−19.4 (−32.4 to −4.7)	0.005
Need for reintervention or supplemental nutrition: n (%)‡§	2 (5.3)	12 (33.3)	−28.1 (−43.9 to −9.6)	0.006
Procedure-related adverse events: n (%)‡	1 (2.6)	1 (2.8)	−1.5 (−10.1 to 9.5)	0.999
Key secondary endpoints				
HRQoL (EORTC QLQ-C30) at discharge: (adjusted means)				
Physical	69.69	58.09	11.61 (2.15 to 21.07)	0.016
Social	57.09	41.35	15.73 (3.58 to 27.88)	0.011
Mean total costs (US dollars):	33,934	51,437	−17 503 (−27 807 to −7920)	<0.001
Other secondary endpoints				
Procedure duration (mins):				
Median (P25–P75)¶	25.5 (21–40)	111.5 (89–141)	−78 (−95 to −65)	<0.001
Time to start liquid diet (GOOSS=1) (days):				
Median (P25–P75)¶	1 (0–1)	1 (1–2)	−1 (−1 to 0)	<0.001
Time to start solid diet (GOOSS≥2) (days):				
Median (P25–P75)¶	2 (2–3)	5 (3.5–9)	−3 (−4 to −2)	<0.001
Solid diet at discharge (GOOSS≥2): n (%)	38 (100)	29 (80.6)	19.4 (4.7 to 32.4)	0.005
Disease-related adverse events: n (%)‡‡	28 (73.7)	26 (72.2)	−1.5 (−18.5 to 21.4)	0.887
Duration of hospital stay (days):**				
Median (P25–P75)¶	3 (3–6)	9 (6–12.5)	−5 (−7 to −3)	<0.001
Readmissions: n (%)‡‡‡‡	20 (52.6)	18 (50.0)	2.6 (−19.7 to 24.7)	0.821
Chemotherapy post-procedure: n (%)‡	16 (42.1)	22 (61.1)	−19.0 (−39.8 to 3.8)	0.102
Time to initiation of chemotherapy (days):				
Median (P25–P75)¶	21.5 (10.5–26.5)	35 (22–50)	−14.5 (−26 to −3)	0.301
Mortality: n (%)‡‡‡	22 (57.9)	15 (41.7)	16.2 (−6.5 to 37.3)	0.163
Time to death (days):				
Median (P25–P75)¶	59.5 (37–93)	65 (30–93)	−1 (−28 to 27)	0.172

Surgery: nausea/vomiting and abdominal pain from underlying malignancy (n=5), fatigue, lethargy and failure to thrive from underlying malignancy (n=4), urinary tract infection (n=2), pneumonia (n=3), acute gastroenteritis (n=1), sepsis with no clear source (n=4), hepatic abscess (n=1), small bowel obstruction managed conservatively (n=1), jaundice from malignant biliary obstruction (n=7) managed with endoscopic biliary decompression in six and managed conservatively in one, bilio-cutaneous fistula managed with percutaneous biliary decompression and percutaneous drain placement (n=1).

*For between-arm comparisons: χ^2 test or Fisher's exact test used for binary outcomes, mixed model for HRQoL, generalised linear model with log link for cost analysis, Wilcoxon test for continuous outcomes, competing risk model for time-to-event outcomes with death as a competing risk, log-rank test for time to death.

†Multiple events in a single patient were counted as a single event for comparison.

‡From index intervention to 6-month follow-up.

§Need for reintervention: EUS 2 (5.3%) and Surgery 7 (19.4%). Need for supplemental nutrition: EUS 0 and Surgery 10 (27.8%).

¶IQR is expressed as 25th percentile to 75th percentile.

**From index intervention to hospital discharge.

‡‡Reasons for readmission: EUS: nausea/vomiting and abdominal pain from underlying malignancy (n=9; GOO excluded by endoscopic examination), fatigue, lethargy and failure to thrive from underlying malignancy (n=8), fever and chills with no clear source (n=2), urinary tract infection (n=2), pneumonia (n=2), spontaneous bacterial peritonitis (n=1), anaemia requiring blood transfusions (n=4), cardiac arrhythmia treated with amiodarone (n=1), jaundice from malignant biliary obstruction managed with endoscopic or percutaneous biliary decompression (n=7), acute thromboembolism managed with anticoagulation (n=1), acute renal failure managed conservatively (n=1), melena managed conservatively (n=1), following a mechanical fall for management of facial trauma (n=1).

‡‡Cause of death: EUS: septic shock with organ failure due to immunocompromised state in 2 and progression of underlying malignancy in 20. Surgery: septic shock with organ failure due to immunocompromised state in 5 and progression of underlying malignancy in 10.

EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; EUS, endoscopic ultrasound; GOOSS, Gastric Outlet Obstruction Scoring System; HRQoL, health-related quality of life; mins, minutes; P25, 25th percentile; P75, 75th percentile.

compared with SGJ (although this difference was not statistically significant on competing risk regression, $p=0.30$). There was no significant difference in the proportion of hospital readmissions or disease-related adverse events between treatment arms (table 2). 6-month mortality did not differ between the arms, with mortality of 57.9% in EUS-GE and 41.7% in SGJ ($p=0.163$; χ^2 test) with no between-arm difference in risk of death ($p=0.172$; log-rank test).

DISCUSSION

This multicentre, randomised trial showed that in patients with malignant GOO, EUS-GE was superior to SGJ as resumption and advancement of oral intake was sooner, need for reinterventions was fewer, HRQoL was better and treatment costs were lower. Patients assigned to EUS-GE also had shorter lengths of hospital stay and received earlier oncological care at 6-month follow-up.

Table 3 Summary of procedure-related and disease-related adverse events from randomisation until 6-month follow-up or death

	EUS (n=38)	Surgery (n=36)	Difference (95% CI)	P value
Procedure-related adverse events: n (%) ^{*†}	1 (2.6)	1 (2.8)	−1.5 (−10.1 to 9.5)	0.999
Clavien-Dindo classification:				
Grade III	1	1	–	–
Disease-related adverse events: n (%) ^{*‡}				
Overall adverse events	28 (73.7)	26 (72.2)	−1.5 (−18.5 to 21.4)	0.887
Adverse events at 30 days	12 (31.6)	10 (27.8)	3.8 (−16.9 to 24.0)	0.721
Overall mortality	22 (57.9)	15 (41.7)	16.2 (−6.5 to 37.3)	0.163
Mortality at 30 days	5 (13.2)	4 (11.1)	2.0 (−13.6 to 17.3)	0.999
Pancreaticobiliary§	8	8		
Haematological/haemorrhagic¶	7	4		
Infection**	11	12		
Luminal††	8	11		
Cardiopulmonary‡‡	1	1		
Other§§	5	3		

*Multiple events in a single patient were counted as a single event for comparison.

†Procedure-related adverse events: EUS: gastric perforation occurred during deployment of the lumen-apposing metal stent. The stent was removed, and the area of perforation was successfully closed using two over-the-scope clips. EUS-guided gastrojejunostomy was then completed during the same session. Surgery: EGD performed for persistent nausea and vomiting showed ulceration at the surgical gastrojejunal anastomosis with a visible vessel. Endoscopic clips were placed at the visible vessel and a percutaneous gastrojejunostomy tube was placed for enteral nutrition.

‡Overall, 20 of 28 patients with adverse events in the EUS group and 18 of 26 patients with adverse events in the Surgery group warranted readmissions; others were managed as outpatients.

§Pancreaticobiliary adverse events: EUS: malignant obstructive jaundice (n=7) managed with endoscopic or percutaneous biliary decompression, elevated liver tests managed conservatively (n=1). Surgery: malignant obstructive jaundice (n=7) managed with endoscopic biliary decompression in six and managed conservatively with antibiotics in one, bilio-cutaneous fistula managed with percutaneous biliary decompression and percutaneous drain placement (n=1).

¶Haematological adverse events: EUS: thromboembolism managed with anticoagulation (n=4), embolic stroke managed with anticoagulation (n=1), anaemia managed with blood transfusions (n=2). Surgery: thromboembolism managed with anticoagulation (n=2), anaemia due to chemotherapy managed with blood transfusions (n=1), neutropenia due to chemotherapy (n=1).

**Infection-related adverse events: EUS: urinary tract infection (n=3), pneumonia (n=1), spontaneous bacterial peritonitis (n=1), sepsis with no clear source (n=3), fever and chills following chemotherapy (n=1), leucocytosis with no clear aetiology (n=1), acute gastroenteritis (n=1). Surgery: urinary tract infection (n=2), pneumonia (n=5), hepatic abscess (n=1), neutropenic sepsis (n=1), sepsis with no clear source (n=2), acute gastroenteritis (n=1).

††Luminal adverse events: EUS: dysphagia due to pancreatic mass causing extrinsic compression of the distal oesophagus managed conservatively (n=1), nausea/vomiting and abdominal pain due to underlying malignancy managed conservatively (n=3), diarrhoea managed conservatively (n=1), melena with normal EGD, managed conservatively (n=3). Surgery: dysphagia managed conservatively (n=1), nausea/vomiting and abdominal pain due to underlying malignancy (n=4) requiring PEGJ tube placement in one and managed conservatively in three, small bowel obstruction due to disease progression (n=1), ileus managed conservatively (n=1), melena/haematochezia managed with blood transfusions (n=2), diarrhoea managed conservatively (n=2).

‡‡Cardiopulmonary adverse events: EUS: atrial flutter treated with amiodarone (n=1). Surgery: hypoxia resolved with medical management (n=1).

§§Other types of adverse events: EUS: fatigue/lethargy and failure to thrive (n=3), acute renal failure (n=1), dehydration requiring intravenous fluids (n=1). Surgery: tachycardia and hypotension following percutaneous liver biopsy managed conservatively (n=1), anasarca managed with diuretics (n=1), hypophosphataemia managed medically (n=1). EUS, endoscopic ultrasound; PEGJ, percutaneous gastrojejunostomy.

A major reason for superior outcomes in the EUS-GE arm was due to the ability to initiate a liquid diet on the day of the procedure and rapid advancement thereafter to a solid diet, usually within 2–3 days. On the contrary, initiation of liquid intake was delayed by at least 24 hours in the surgical arm due to inherent differences in postprocedural treatment pathways. The ability to subsequently advance to a solid diet was also slower due to poor tolerance, which is attributed to delayed gastric emptying in patients undergoing SGJ.³⁴ Consequently, several patients required temporary percutaneous gastrojejunostomy tubes that resulted in prolonged hospitalisation, poor quality of life at discharge, higher treatment costs and delay in initiation or resumption of chemotherapy.

Although regarded as the treatment standard, surgical approach has several inherent shortcomings. Despite significant advancements in laparoscopic and robotic techniques, in the setting of advanced malignancy, mesenteric involvement by the tumour and presence of a bulky mass precludes adequate mobilisation of small bowel, thereby limiting technical success. Our study findings are consistent with recent reports that demonstrate higher technical success for minimally invasive methods in patients

with gastric or duodenal cancer, with open gastrojejunostomy being more commonly practiced in pancreatic cancer (online supplemental table S10). Also, while the presence of peritoneal carcinomatosis, malignant ascites, poor nutritional status with severe hypoalbuminaemia and prior upper abdominal surgery with adhesions are relative contraindications for minimally invasive SGJ, several of these patients may actually be amenable to less invasive endoscopic treatment. In the present study, of 42 patients who failed inclusion criteria, 36 were treated outside of the trial by EUS-GE. In six others, presence of tense ascites, extensive peritoneal carcinomatosis or thick gastric wall from tumour infiltration precluded performance of EUS-GE, thereby warranting duodenal stent placement.

The incidence of pancreatic cancer is rising,¹¹ with approximately 20% of patients developing GOO during the course of illness.⁶ Overall mortality at 6 months in our study cohort was 50%, with a short median survival time of only 60 days, consistent with published data.³⁵ Given the poor prognosis, emphasis on early resumption of oral intake is important to improve patient quality of life and receive timely oncological care. The study findings suggest that the novel EUS-GE treatment approach

could fulfil this unmet need and will be even more relevant with improved palliative oncologic treatments prolonging patients' life span.

There are several limitations to our study. One, patients and trial personnel were aware of the treatment-group assignments because feasibility and maintenance of blinding was not possible. Although statisticians were blinded to treatment assignments, lack of blinding of patients and outcomes assessors may have contributed to biased treatment effects and skewed results. Two, 58% of patients in the surgery arm were unable to undergo laparoscopic or robotic approaches and required open surgery. However, we did not find clinically meaningful differences in primary and secondary endpoints between treatment methods, as reported by other investigators³⁶ and consistent with published literature (online supplemental table S10). Moreover, we regard this to be a major strength of our study as all eligible patients, irrespective of disease stage, were allocated to treatment groups without selection bias. As a significant proportion of patients with malignant GOO present with advanced disease, findings of the present study are truly reflective of treatment challenges encountered in real life in this complex patient cohort. Three, the sample size calculation for this trial was based on a relatively large effect size between the two arms, which may increase risk of type I error. However, we believe that the risk is minimal as observed difference in the primary endpoint closely matched the assumed difference used in the sample size calculation, thus supporting the robustness and validity of the study results. Also, although the fragility index of the study is 4, validity and robustness of study results are strongly supported by use of a composite measure for the primary endpoint and several outcome measures favoured EUS-GE over surgical gastrojejunostomy. Four, the mortality rate was 57.9% for EUS-GE as compared with 41.7% for SGJ. While this was not statistically significant, the study was not powered for outcomes in mortality. Given low overall survival rates, it is possible that some patients could have had similar outcomes even with other minimally invasive endoscopic alternatives such as duodenal stent placement.^{5,6} With advancements in precision medicine, it is expected that survival time in pancreatic cancer will improve and, as shown in a recent study, state-of-the-art treatment such as EUS-GE may be of greater benefit as compared with duodenal stenting.³⁷ Conversely, in patients with very limited life expectancy or those not electing to receive palliative chemotherapy, duodenal stenting may be an equally effective endoscopic treatment alternative. Finally, more than 50% of study subjects in this trial were enrolled from two of six participating centres, highlighting the challenges with patient recruitment for a multidisciplinary randomised trial evaluating a complex terminal illness (online supplemental table S11).

In conclusion, in this multicentre randomised trial, an endoscopic approach was found to be superior to surgery in palliating malignant GOO, from both clinical and economic points of view. Therefore, endoscopic ultrasound-guided gastroenterostomy should be the preferred treatment approach when the requisite expertise and resources are available for the management of patients with malignant GOO.

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Ethics approval Study protocol was approved by institutional review board (IRB) of Orlando Health (IRB approval number 1929501) and by all other participating sites. Written informed consent was obtained from each patient or their legal representatives prior to randomisation. The trial was conducted in accordance with the principles of the Declaration of Helsinki. The trial was registered with ClinicalTrials.gov (NCT05548114). All authors vouch for completeness and accuracy of data and have reviewed and approved the final manuscript.

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