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Outcomes of endoscopic ultrasound-guided gastro-enterostomy for gastric outlet obstruction in a two-centre Australian Cohort (with video)

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Abstract

Purpose: Endoscopic ultrasound-guided gastro-enterostomy (EUS-GE) is a relatively novel technique that has been shown to require less re-intervention than standard endoscopic enteral stenting for gastric outlet obstruction and is less invasive, quicker, and more cost-effective than surgery. This study evaluated the outcomes and safety of EUS-GE in patients treated for gastric outlet obstruction across two Australian centers.

Methods: Retrospective data on demographics, presenting symptoms, disease, endoscopic and clinical outcomes, and safety were collected on all patients who underwent EUS-GE from 2021 to 2022. Descriptive statistics were used to evaluate outcomes and safety and survival were calculated using Kaplan-Meier analysis.

Results: Eleven patients underwent EUS-GE during the defined period, 10 of whom had a malignant etiology (median age 73 years, interquartile range [IQR] 13; 63.6% male). Technical success was 90.9%. Of those patients, clinical success (the ability to tolerate at least a full liquid diet during follow-up) was 100%. The median length of hospital stay post-procedure was 6 days (IQR 14 days). No severe adverse events occurred, and one patient (10%) required a repeat endoscopy. Median survival post-EUS-GE was 298 days (95% confidence interval 0–730.1 days)

Conclusion: EUS-GE is an effective, safe, and durable therapy for patients with gastric outlet obstruction. This study presents Australian data on outcomes and safety that is comparable to international literature. EUS-GE should be considered for patients where local expertise allows.

KEYWORDS
endoscopic ultrasound-guided gastro-enterostomy, gastric outlet obstruction, gastroenterostomy, lumen-apposing metal stent, therapeutic endoscopic ultrasound

1 | INTRODUCTION

Gastric outlet obstruction (GOO) can be caused by both benign and malignant conditions. Symptoms of GOO may include nausea, vomiting, and reduced oral intake, which may lead to a significant reduction in quality of life. Computed tomography confirms the diagnosis (Figure 1A,B) and localizes the site of obstruction (Figure 1C). Traditionally, suitable patients would have required either open or laparoscopic surgical intervention as the primary treatment. Enteral stenting offers patients a minimally invasive endoscopic alternative, whereby self-expanding metallic stents (SEMS) can be placed directly across the site of obstruction and is ideal for patients with shorter prognoses or significant comorbidities. However, advances in chemotherapy can improve life expectancies, which is often associated with tumor ingrowth and overgrowth across duodenal SEMS resulting in reduced stent patency.[1] Furthermore, duodenal enteral stent placement may obstruct the ampulla resulting in secondary biliary obstruction. Therefore, alternative minimally invasive techniques are required for patients with GOO, especially those unsuitable for operative management. Moreover, surgical approaches are limited by prolonged recovery times, delayed gastric emptying and gastroparesis, risk of surgical complications, and high procedural costs.[2]

The technique of endoscopic ultrasound (EUS)-guided gastroenterostomy (EUS-GE) developed with the advent of lumen-apposing metal stents (LAMS) and has been used with increasing frequency over the past few years.[3–6] Internationally, reported rates of technical success are 92%–98.3%, clinical success of 88 to 98.3%, and adverse event (AE) rates of 6.8%–12%.[7–10] A systematic review comparing EUS-GE to enteral stenting for gastric outlet obstruction revealed similar rates of technical and clinical success as well as AEs, however, EUS-GE resulted in lower rates of re-intervention.[11] When compared to open gastroenterostomy, clinical success rates were similar as was a recurrence of obstructive symptoms, however, EUS-GE had lower associated costs and hospital length of stay.[12,13] When compared with laparoscopic gastroenterostomy, technical and clinical success rates were similar, however, AEs and costs were lower in the EUS-GE group.[14] Furthermore, Bronswijk et al[15] showed that EUS-GE patients had shorter time to oral intake, median hospital stay as well as lower rates of AEs when compared to laparoscopic GE. Hence, EUS-GE is a safe and effective minimally invasive therapeutic procedure.

Despite the international experience, there is limited Australian experience with EUS-GE and no data on the outcomes of patients who undergo this procedure. Only a few experienced interventional endosonographers have experience with this technique. We report outcomes of our patients who have undergone EUS-GE across two Australian hospitals in terms of technical and clinical success, AEs, and survival. We compared our experience in terms of success and AE rates to those in the literature.

2 | MATERIALS AND METHODS

A retrospective review of patients with gastric outlet obstruction who underwent EUS-GE over a 2-year period was performed across two centers—The Sydney Adventist Hospital (SAH) and Concord Repatriation General Hospital, (CRGH) in Sydney, from 2021 to 2022, with follow-up available until December 2022.

Consecutive adult patients who underwent direct EUS-GE for GOO were included in the analysis. All patients were discussed within a formal multidisciplinary team (MDT) setting, where EUS-GE was considered the most appropriate palliative treatment for gastric outlet obstruction. The SAH Upper Gastrointestinal Cancer MDT was the main referral pathway, however, later patients were referred to the author directly by surgeons, oncologists, and palliative care physicians, sometimes from other hospitals. These patients were also discussed at the MDT prior to proceeding with EUS-GE.

The procedure was performed by a single pancreato-biliary endoscopist (Saurabh Gupta) at both sites who is a highly experienced endosonographer and has previously published[16] on the use of LAMS in the gallbladder and biliary tract. He is an active member of the EUS

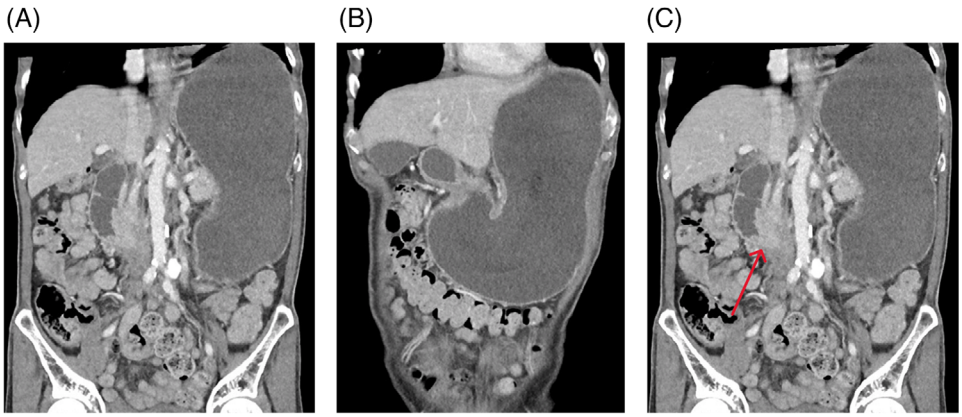

FIGURE 1 (A) (left) and (B) (center) show computed tomography images of gastric outlet obstruction (GOO) with an overly distended stomach and non-dilated bowel loops. (C) (right) shows one patient's GOO with the level of obstruction identified in the distal portion of the second part of the duodenum (red arrow).

special interest group within the Gastroenterology Society of Australia and runs EUS training workshops within Asia Pacific. All procedures were performed in an endoscopy unit, where patients underwent general anesthesia with endotracheal intubation to minimize the risk of aspiration, as has been done routinely for enteral stenting in the setting of gastric outlet obstruction. Most patients also had pre-procedure nasogastric tube drainage to decompress the stomach.

The Australian Register of Therapeutic Goods (ARTG) Certificate lists the intended use of the electrocautery enhances Axios LAMS (Hot AXIOS, Boston Scientific Corporation Inc.; ARTG Identifier 282177: start date 7/11/2016) for trans-gastric or trans-duodenal endoscopic drainage of a pancreatic pseudocyst, walled-off necrosis or biliary tract.[17] The LAMS device and technique used for EUS-gastro jejunostomy (EUS-GJ) is the same as for these uses, but as it isn't specifically listed it remains 'off-label'. The application of this technique was in compliance with the relevant NSW Framework for New Health Technologies and Specialised Services[18] and medical governance was sought from the local hospitals before implementation of this technique. Given the 'off-label' use of LAMS in EUS-GE, all patients were informed accordingly, and consent was obtained.

Several techniques for EUS-GE have been reported, including the direct puncture technique initially described by Khashab et al. in 2015.[3,19,20] All involve the use of a cautery-enhanced LAMS to create a gastrojejunostomy anastomosis. The direct technique was employed in all our patients (refer to video). An adult gastroscope was advanced to the level of luminal obstruction and, if possible, beyond the stenosis. Approximately 500 mL of fluid (methylene blue, sterile blue dye, and contrast) was instilled into the lumen distal to the obstruction. If this was not possible, then fluid was injected through the working channel of the gastroscope or via an endoscopic retrograde cholangiopancreatography stone retrieval balloon that was advanced past the obstruction under fluoroscopic guidance. Hyoscine butylbromide or glucagon was administered intravenously to minimize small bowel peristalsis. The gastroscope was then exchanged for the curvilinear array echoendoscope, and under EUS guidance, a distended small bowel loop adjected to the stomach was identified. A 19- or 22-gauge needle puncture into the small bowel was performed and blue fluid was aspirated to confirm a small bowel puncture. With continuous EUS visualization, the needle was withdrawn, and the electrocautery-enhanced LAMS was directly advanced into the same loop of the small bowel and deployed to create the gastroenterostomy. Balloon dilation of the waist of the stent was performed at the discretion of the endoscopist.

Research Ethics and Governance approval of the audit was granted by Adventist HealthCare Limited. Data from electronic medical records was used to determine baseline demographics, etiology and location of the obstruction, and diet tolerability according to the GOO scoring system (0 representing no oral intake, 1 for liquid diet only, 2 for soft solids, and 3 for low-residue or a full diet),[21] technical and clinical success, need for re-intervention, length of hospital stay, time to oral intake, last known to follow up, death and AEs as defined by the American Society of Gastroenterology.[22]

The primary outcomes were technical and clinical success. Technical success was defined as adequate positioning and deployment of the EUS-GE stent. Clinical success was defined as the ability to tolerate at least a full liquid diet during the follow-up period. Secondary outcomes included AEs, maximal size of LAMS, length of hospital stay, time to oral take, ability to tolerate solid diet (GOO scoring system score of 4), un-planned re-intervention, EUS-GE dysfunction (recurrence of obstructive symptoms confirmed endoscopically or on imaging), distal obstruction (mechanical obstructions located downstream to the EUS-GE site), need for decompression percutaneous endoscopic gastrostomy (PEG), and overall survival.

Descriptive statistics were used to characterize the demographics and outcomes of the cohort with categorical data summarised using counts and percentages and continuous data using medians and interquartile range (IQR). Survival was defined as the time from the procedure to the date of death. Patients who were still alive or those with unknown date of death were censored to the date of last known contact. Median survival was calculated using Kaplan-Meier survival analysis. All statistical analyses were performed using IBM SPSS Statistics Version 26.0 (2019).

3 | RESULTS

Eleven patients, seven of whom were male (63.6%) with a median age of 73 underwent EUS-GE during the defined period, all using the direct puncture approach described previously. Table 1 outlines the baseline patient characteristics.

Pancreatic cancer was the most common cause of obstruction ($n = 4$, 36.4%), followed by two patients with a primary duodenal malignancy (18.2%) and two with an unknown primary (18.2%). One patient (9.1%) had a benign etiology. Seven patients were obstructed in the second portion of the duodenum (63.6%) followed by the third portion of the duodenum in two (18.2%), and one patient had obstruction in each of; the pylorus (9.1%) and duodenal bulb (9.1%). Vomiting was the primary symptom in eight patients (72.7%), and abdominal pain in six (54.5%). One patient (9.1%) presented with a suspected gastrointestinal bleed, and another (9.1%) as an incidental imaging finding.

Prior to their procedure, six patients (54.5%) were unable to tolerate any oral intake, with a GOO score of 0, whilst four were able to tolerate only liquids, GOO score of 1 (36.4%). One patient had a GOO score of 3 following prior enteral stent placement, however developed features concerning impending obstruction, with recurrent intermittent vomiting and computed tomography demonstrating a markedly distended stomach proximal to the stent, and stent occlusion from tissue ingrowth was confirmed endoscopically.

Nine (81.8%) of the eleven patients had their procedures performed at the SAH, whilst the remaining two (18.2%) were performed at CRGH (Table 2). Technical success was achieved in ten of the eleven patients with a success rate of 90.9%. Four patients (40%) had a 20 mm LAMS inserted, and 6 patients (60%) had a 15 mm stent inserted (these were placed prior to the 20 mm stent being available for use in Australia). The median maximal dilation size was 15 mm, with a minimum dilation of 10 mm.

TABLE 1 Baseline demographics (EUS-GE—endoscopic ultrasound—gastro-enterostomy; IQR—interquartile range; GOO—gastric outlet obstruction).

	EUS-GE Patients $n = 11$
Age (years), Median (IQR)	73 (13)
Male, *n* (%)	7 (63.6)
Presenting Symptom(s), *n* (%)	
Vomiting	8 (72.7)
Abdominal pain	6 (54.5)
Imaging finding	1 (9.1)
Gastrointestinal bleeding	1 (9.1)
Primary Disease, *n* (%)	
Pancreatic cancer	4 (36.4)
Duodenal cancer	2 (18.2)
Unknown primary	2 (18.2)
Colorectal cancer	1 (9.1)
Breast cancer	1 (9.1)
Benign disease	1 (9.1)
Disease Extent, *n* (%)	
Local invasion	4 (36.4)
Liver metastases	2 (18.2)
Peritoneal metastases	1 (9.1)
Diffuse metastatic	3 (27.3)
Unknown	1 (9.1)
Site of Obstruction, *n* (%)	
Pylorus	1 (9.1)
Duodenal bulb	1 (9.1)
Second portion of the duodenum	7 (63.6)
Third portion of the duodenum	2 (18.2%)
Pre-procedural GOO Score, *n* (%)	
0	6 (54.5)
1	4 (36.4)
2	0 (0)
3	1 (9.1)
Procedure Location	
SAH	9 (81.8)
CRGH	2 (18.2)

TABLE 2 Outcomes of EUS-GE (EUS-GE—endoscopic ultrasound—gastro-enterostomy; SAH—Sydney Adventist Hospital; CRGH—Concord Repatriation General Hospital; IQR—interquartile range).

	EUS-GE Patients $n = 11$
Technical Success, *n* (%)	10 (90.9)
Procedure Location	
SAH	9 (81.8)
CRGH	2 (18.2)
	Technically Successful EUS-GE $n = 10$
Stent Size, mm (%)	
15	4 (40)
20	6(60)
Median dilation Size of LAMS, mm (IQR)	15, (8)
Clinical Success, *n* (%)	10 (100)
Time to Clinical Success, days (IQR)	2 (3)
Oral Intake Day of Procedure, *n* (%)	10 (100%)
Median length of Hospital Stay, days (IQR)	6 (14)
Median length of follow-up, days (IQR)	169 (287)

TABLE 3 Safety of EUS-GE (EUS-GE—endoscopic ultrasound—gastro-enterostomy; CI—confidence interval).

	Technically Successful EUS-GE $n = 10$
Adverse Events, *n* (%)	
None	8 (80)
Mild	1 (10)
Moderate	1 (10)
Total	2 (20)
Unplanned Repeat Endoscopy, *n* (%)	1 (10)
EUS-GE Dysfunction, *n* (%)	1 (10)
Median survival post EUS-GE, days (95% CI)	298 (0–730.1)

Of the ten patients with technical success, all ten (100%) achieved clinical success during the follow-up period. The median time to achieve clinical success was 2 days (IQR 3 days). These patients were all able to commence oral intake (fluids) immediately post-procedure. The median length of stay post-procedurally was six days (IQR 14 days).

There were two AEs in total (20%), Table 3. One patient (10%) experienced a mild AE post-procedure (fever), and one (10%) experienced a moderate AE whereby the patient vomited following a meal. The same patient required an unplanned repeat endoscopy for EUS-GE dysfunction and food debris was found to be blocking the LAMS necessitating successful endoscopic clearance. No patients experienced a severe AE, and there were no procedure-related deaths.

During the follow-up period, one patient (9.1%) developed a second obstruction distal to the site of the EUS-GJ, thought to be secondary to small bowel adhesions, and a PEG was inserted for decompression to facilitate early discharge to return interstate where she resided. Eight patients (72.7%) died during the follow-up period, whilst the remaining three patients were censored to their last known follow-up date. Of those patients where technical success was achieved, median survival was 298 days (95% confidence Interval [CI]: 0–730.1 days), displayed in Figure 2.

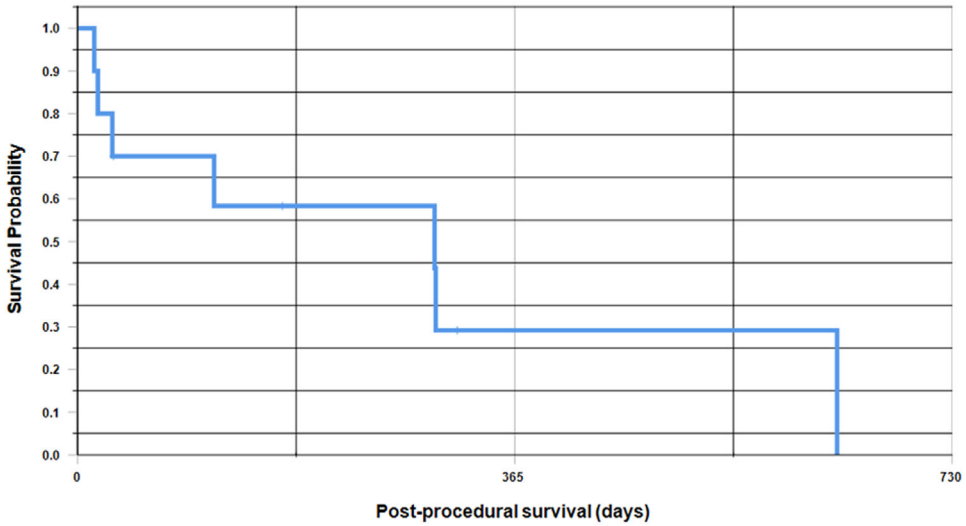

FIGURE 2 Survival of patients post-endoscopic ultrasound-guided gastro-enterostomy (EUS-GE) over the follow-up period.

4 | DISCUSSION

To our knowledge, this study is the first and largest Australian cohort study of EUS-GE and affirms that is a safe and effective treatment option for the management of GOO. We describe success rates and AEs comparable to the international experience.

Further adding to the strength of this study include the robust length of follow-up and the range of data that was able to be collected for most patients. We showed that EUS-GE stents are durable with a median survival of 298 days, and one patient with malignant GOO has a censored survival of 655 days. This is due to the rarely observed complications of stent ingrowth and overgrowth (particularly when compared to duodenal stents). It has been suggested that for benign conditions, an EUS-GE may last up to 7 years with membrane breakdown occurring at 3 years.[23] Occlusion was also uncommon, and this may be attributable to both the size of the stent and the prescription of an ongoing low-residue diet. Although we could not observe a difference between the 15 and 20-mm LAMS, it has previously been shown that the latter is superior in terms of tolerability of oral intake.[15]

In terms of safety, although infection and bleeding have been described as possible AEs in < 5% of patients,[8] we did not experience any of these and this may be attributable to our smaller cohort size. Furthermore, the patient where technical success was not achieved had metastatic pancreatic carcinoma, with both a previously inserted metallic biliary stent and a LAMS EUS-guided cholecystoduodenostomy placed for cholecystitis. Inadequate small bowel luminal distension occurred following fluid instillation, and the small bowel loop collapsed during LAMS advancement. A salvage enteral stent was placed instead.

Whilst EUS-GE is a promising technique, there is room for ongoing refinement of the procedure with the development of specific accessories to improve safety and efficiency. Moreover, whilst we report on the direct puncture approach, there are no randomized control trials comparing this method to balloon-assisted approaches, hence it remains unclear which of these methods is optimal.[5,24–26] However, a recent systematic review of 863 patients who underwent EUS-GE suggests that the direct approach has lower rates of AEs and hospital length of stay when compared to balloon-assisted techniques. This is noteworthy, as the direct approach is quicker (mean duration of 48.2 min vs. 64.7 min) and requires less resources and hence may be an easier technique to adopt.[10]

There were several limitations to this study notably due to its retrospective methodology. Of note, there is selection bias as most patients came from one of the two centers. Furthermore, the results may also be confounded by the fact that all procedures were performed by a single, highly experienced interventional endosonographer (Saurabh Gupta), which may affect the generalisability of these results across other non-tertiary centers without specific expertise. However, when compared to international data, our results remained consistent. The cohort size did not allow for subgroup comparison or predictors of success, however, previous studies have shown that large-volume ascites and increased distance between the stomach and small bowel increase the risk of technical failure.[27]

5 | CONCLUSION

In conclusion, we have shown that EUS-GE is a safe, effective, and durable therapy for patients with gastric outlet obstruction. Referral for EUS-GE should be considered in all patients with malignant GOO, as it enables a rapid return to oral intake, facilitates early discharge, and is more cost-effective when compared with surgery.

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CONFLICT OF INTEREST STATEMENT

Saurabh Gupta provides paid consultancy services for Apollo Endosurgery and Olympus. The rest of the authors declare no conflict of interest.

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