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NEW CONCEPT

EUS-Guided Endoscopic Gastrointestinal Anastomosis with Lumen-Apposing Metal Stent: Feasibility, Safety, and Efficacy

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Abstract

Traditionally, restoration of normal bowel continuity after resection and bypass of a diseased or obstructed gastrointestinal tract can only be achieved through surgery, which can be technically challenging and comes with a risk of adverse events. Here, we describe our institutions' experience with endoscopic-guided gastroenterostomy or enteroenterostomy with lumen-apposing metal stent (LAMS) from March 2015 to August 2016. Ten patients had gastrogastrostomy (gastric pouch to gastric remnant) and three patients had jejunogastrostomy (Roux limb to gastric remnant) for the reversal of Roux-en-Y bariatric surgery. One patient had gastroduodenostomy (stomach to duodenal bulb) post antrectomy and one patient had jejunojejunostomy for distal obstruction following Roux-en-Y reconstruction. Technical and clinical success were achieved in all patients, save for delayed anastomotic stenosis following stent removal in one patient, with a mean follow-up of 126 days (3–318 days) with minimal complications in two patients. Endoscopic gastrointestinal anastomosis therefore may be a safe and feasible technique to re-establish continuity of the digestive system following bypass in the short-term.

Keywords Digestive system abnormalities · Malabsorption syndromes · Intestines · Intestinal obstruction · Intestinal fistula

Introduction

In a world of increasingly complex surgical procedures, the boundaries of surgery are still limited by the body's protective mechanism of adhesion, scar, and fistula formation. These natural mechanisms cause each subsequent surgery to be increasingly complex, due to a loss of anatomical dissection planes and repositioning of vital structures. In the USA, there are over six million surgeries performed on the digestive system each year and 32% will need a subsequent abdominal procedure [1, 2]. In addition, procedural complications such as inadvertent trauma to surrounding organs or vital structures come with a major risk of morbidity (3–16%) and mortality (0.4–0.8%) [3]. Therefore, we must find suitable alternatives to traditional surgery both to minimize surgical complications and also to preserve anatomical dissection planes for future procedures.

In recent years, the field of endoscopy has expanded from simple white light intraluminal endoscopy to extraluminal endosonography. Endoscopic ultrasound has numerous diagnostic and interventional capabilities including endoscopic stent placement for extraluminal cancers. Recent advancements in the field have led to the concept of 'endoscopic gastrointestinal anastomoses' utilizing lumen-apposing metal stents (LAMS) deployed via endoscopic ultrasound. This technology has been reported in a porcine study and several human case reports to reverse the anatomical changes of Roux-en-Y gastric bypass (RYGB) surgeries, as well as to bypass anastomotic strictures or obstructing lesions by

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creating an alternative route for the flow of gastrointestinal contents [4–9].

The objective of this retrospective study is to describe a series of 15 consecutive bariatric patients who required re-routing of their bowel anatomy following a previous surgical procedure. These patients were offered an endoscopically placed lumen-apposing metal stent as an alternative to surgery and the technical and clinical successes as well as complications are reviewed including evaluation of feasibility, safety, and efficacy.

Material and Methods

We prospectively collected data on patients who previously underwent a bariatric or RY reconstruction procedure and were referred for restoration of anatomy from March 2015 to August 2016 at the University of Minnesota Medical Center. Fourteen patients had undergone RYGB and one patient had antrectomy with Roux-en-Y reconstruction. Their individual indications for reversal are described in Table 1. Eight patients required reversal of Roux-en-Y anatomy following their bariatric procedure due at least in part to malnutrition, as defined as progressive weight loss despite modified high protein diets. Three patients required access for endoscopic retrograde cholangiopancreatography (ERCP), two patients required re-routing of their gastrointestinal anatomy due iatrogenic obstruction or discontinuity and one primarily for a persistent symptomatic marginal ulcer. All procedures were reviewed and performed with the collaboration of advanced gastrointestinal endoscopists and bariatric surgeons who are familiar with post RYGB anatomy. Informed consent was obtained after a detailed discussion of risks and possible alternatives, including open or laparoscopic surgery. Prior to the procedure, we assessed the gastrointestinal anatomy using oral contrasted computed tomography (CT).

Procedures were performed in the operating room under general anesthesia in the supine position. Each patient received intravenous prophylactic antibiotics as per hospital protocol. We began the procedure with white light and endosonographic examination of the gastrointestinal tract along the gastric pouch to the proximal portion of Roux limb with a linear echoendoscope (Olympus Endoscopy, Center Valley, PA) and adjunct fluoroscopy was utilized throughout. We then proceeded to identify the excluded gastric remnant or other target via endoscopic ultrasound. The gastric remnant has characteristics which make it sonographically identifiable as described in (Fig. 1a). We identified the position of both intervening walls lying in the closest proximity to each other. A distance no greater than 1.5 to 2 cm between the two

Table 1 Patient demographics

Patient	Age	Gender	BMI	Endoscopic procedure	Significant history	Indication
1	60	Female	25.5	Gastrogastrostomy	RYGB, MS, recurrent pancreatitis, and previous lap assisted ERCP	Access for ERCP
2	46	Female	30.0	Gastrogastrostomy	RYGB	Hyperinsulinemic hypoglycemia
3	67	Female	25.8	Gastrogastrostomy	RYGB, dilated cardiomyopathy, substance abuse, and GJ stricture	Malnutrition, intractable marginal ulcer
4	53	Female	27.0	Gastrogastrostomy	RYGB	Malnutrition
5	41	Female	20.7	Enteroenterostomy	RYGB, gastric remnant resection for bleeding ulcer, and complex enterocutaneous fistulas	Biliopancreatic limb obstruction
6	45	Male	24.2	Gastroduodenostomy	Antrectomy with Roux-en-Y gastrojejunostomy for perforated ulcer, GJ stricture secondary to marginal ulcer, and smoker	Intractable marginal ulcer with GJ stricture
7	57	Male	23.1	Gastrogastrostomy	RYGB for GERD, failed Nissen fundoplication	Malnutrition
8	50	Male	35.8	Gastrogastrostomy	RYGB, choledocholithiasis	Access for ERCP
9	67	Female	28.4	Jejunogastrostomy	RYGB, metastatic pancreatic cancer with biliary obstruction	Access for ERCP
10	43	Male	26.3	Gastrogastrostomy	RYGB, multi-visceral organ transplant for catastrophic vascular insufficiency	Re-establish foregut continuity
11	53	Female	23.7	Jejunogastrostomy	RYGB	Malnutrition
12	55	Female	18.1	Gastrogastrostomy	RYGB	Malnutrition
13	52	Female	25.9	Jejunogastrostomy	RYGB, multiple revision surgeries, and hemicolectomy complicated by enterocutaneous fistula	Malnutrition, short gut syndrome
14	65	Female	17.4	Gastrogastrostomy	RYGB, laparotomy for bowel obstruction, and anterior pelvic exenteration for bladder cancer	Malnutrition
15	46	Female	17.6	Gastrogastrostomy	RYGB	Malnutrition, intractable GJ ulcer

RYGB Roux-en-Y gastric bypass, *MS* multiple sclerosis, *ERCP* endoscopic retrograde cholangiopancreatography, *GJ* gastrojejunostomy, *GERD* gastroesophageal reflux disease

opposing walls is critical in the formation of the new gastrogastrostomy based on LAMS properties. At this position, intervening walls were accessed with a 19-gauge Flex needle (Boston Scientific, Marlborough, MA) (Fig. 1b). Contrast was injected into the remnant stomach and its position confirmed on fluoroscopy before a 0.025-in. Visiglide wire (Olympus, Center Valley, PA) was advanced (Fig. 1c) into the remnant stomach or other target, to serve as a guide for passing instrumentation. To create the enteroenterostomy tract, a 10- or 15-mm HOT Axios (Boston Scientific, Marlborough, MA) device was passed over the Visiglide wire using 100 W effect 5. This was followed by deployment of a lumen-apposing metal stent, such that the flare on both ends of the stent was fully open within each respective lumen (Fig. 1d). Prior to the end of the procedure, the stent itself was further dilated to between 10 to 13.5 mm (Figs. 2c and 4a).

On occasion, the stomach pouch was not suitable for use such as with a pouch with a capacity of less than 1 oz or if the gastric wall was beyond 2.0 cm from the remnant stomach at its closest point. In some cases, a loop of bowel was found to be interposing between the two stomach walls and in other a large blood vessel was within the typical window. In these cases, we instead attempted to use the proximal Roux limb as a proxy for the gastric pouch to create the anastomosis in the same manner as described above.

In one patient, there was a point of obstruction occurring proximal to the jejunojejunostomy, between the Roux limb and the biliopancreatic limb. In this instance, an endoscopic jejunojejunostomy proximal to the obstruction was needed to drain the biliopancreatic limb. Therefore, a variation of the procedure placement of a radiologist guided percutaneous gastrostomy into the remnant stomach, which allowed a second operator with a pediatric gastroscope (GIF-XP160; Olympus) to access the biliopancreatic limb. In this case, rather than using endosonography a dual-channel gastroscope (GIF-2TH180; Olympus, Center Valley, PA, USA) was placed to access the Roux limb via the stomach pouch. Both scopes were advanced simultaneously until the second operator visualized the light source from the counterpart scopes (Fig. 3a). At this point, the new jejunojejunostomy was created in a similar manner as described previously [5].

Post-operatively, outpatients were discharged on the same day on liquid diet and advanced as tolerated. If patients had percutaneous gastrostomy, tube feeds could be resumed immediately. Patients routinely followed up with a gastroenterologist or bariatric surgeon in 1 to 2 weeks to evaluate for complications and plan for subsequent stent removal or exchange as indicated.

Results

Fifteen patients underwent uncomplicated and technically successful endoscopic gastrointestinal anastomosis at the University of Minnesota Medical Center from March 2015 to August 2016. There were no unsuccessful attempts at endoscopic reversal during this time frame. Ten patients had gastrogastrostomy (gastric pouch to gastric remnant) for reversal of Roux-en-Y anatomy. Three patients had jejunogastrostomy (Roux limb to gastric remnant) for the reversal of Roux-en-Y anatomy. One patient had

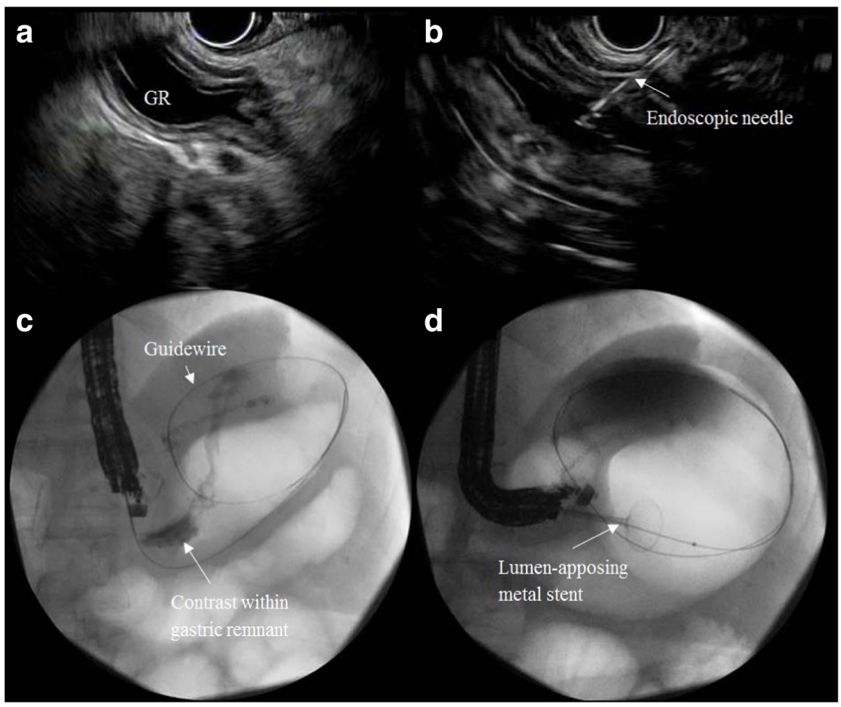

Fig. 1 Gastrogastrostomy. Sonographic characteristics of gastric remnant (GR) (**a**). Gastric remnant is punctured with a 19-gauge Flex endoscopic needle (**b**). Contrast was injected into the remnant stomach and its position confirmed on fluoroscopy (**c**) and LAMS deployed under fluoroscopic guidance (**d**)

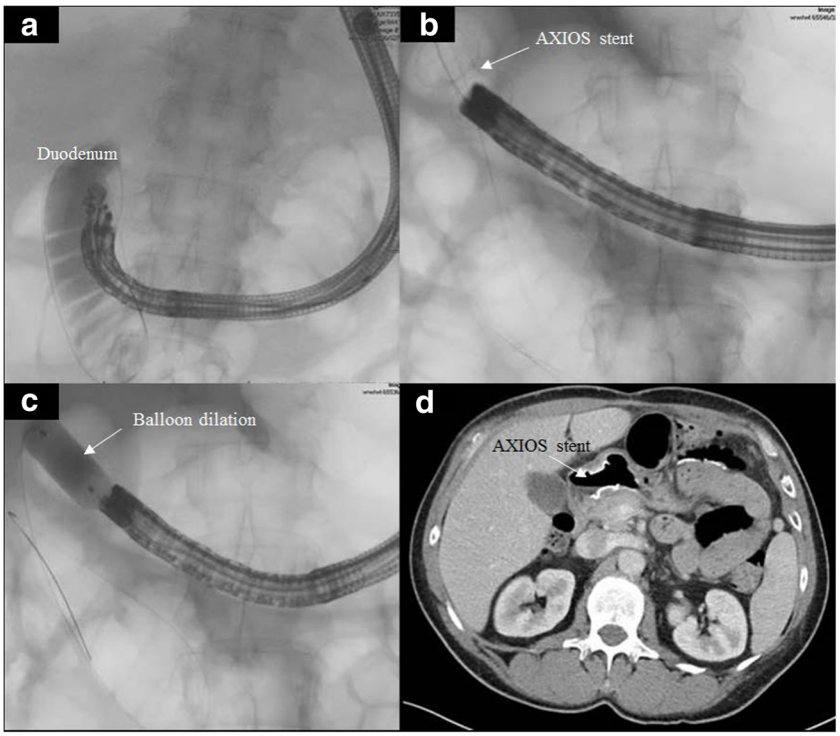

Fig. 2 Gastroduodenostomy. Contrast injected into the excluded duodenum and its position confirmed on fluoroscopy (**a**). LAMS deployed and balloon dilated under fluoroscopic guidance (**b**, **c**). Computed tomography showed gastroduodenostomy with LAMS (**d**)

gastroduodenostomy (stomach to duodenal bulb) and one patient had jejunojejunostomy for distal obstruction following RYGB (Fig. 3).

Mean procedural length was 54 min from scope insertion to withdrawal (range 24–96 min). No immediate procedural related adverse events occurred. All patients were discharged on

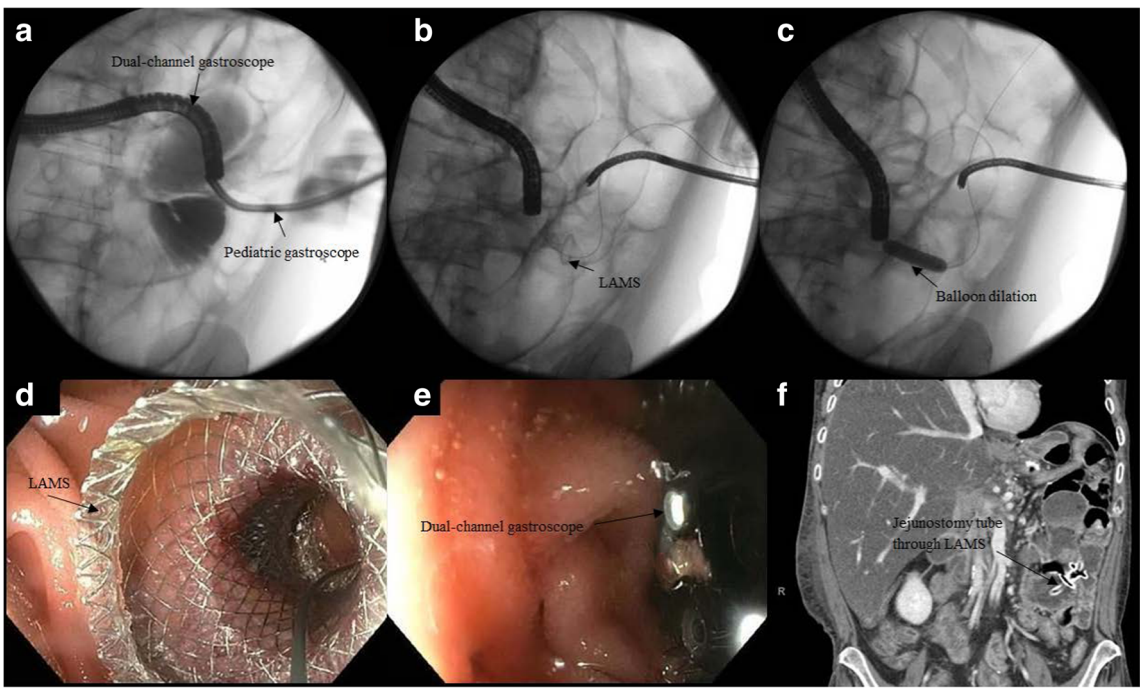

Fig. 3 Jejunojejunostomy. Fluoroscopy showed the dual-channel gastroscope and pediatric gastroscope approach each other head-on (**a**). LAMS deployed and dilated using a CRE balloon dilator (**b**, **c**). Flare on both ends of the stent is fully open within each respective lumen (**d**) and Dual-channel gastroscope visualized with pediatric gastroscope (**e**). Computed tomography showed LAMS connecting the Roux limb and pancreaticobiliary limb (**f**)

the same day as their procedure except for three patients who were already admitted as inpatients prior to the procedure. Time of stent removal was variable with many still in situ at the time of this presentation; however, complications related to prolonged stent placement were not found (Table 2). One patient had stent removal at 2 months and subsequently developed spontaneous closure of the tract; however, the majority of patients that had subsequent endoscopy following stent removal demonstrated patent endoscopically created anastomoses (Fig. 4). One patient declined stent removal and their stent has remained patent after 318 days.

In terms of short-term complications, we had two acute stent-related complications. The first was the single patient who had their stent removed at 2 months after reversal of the RYGB. She developed a narrowing of her gastrogastrostomy following removal of the stent and presented with progressive recurrent dysphagia and vomiting. This was managed with balloon dilation and subsequent endoscopic-guided transgastric-stapled stricturoplasty. [9] A second patient had inadvertent stent migration during a repeat ERCP for recurrent pancreatitis 6 months following the initial procedure. No adverse outcome occurred in this patient. Two patients died due to unrelated baseline comorbidities with the stents in situ at 97 and 102 days post-procedure. The first patient died due to progression of a newly diagnosed metastatic pancreatic cancer and the second patient died from a ruptured aortic graft pseudo-aneurysm. Mean follow-up was 126 days (range 3–318 days). At the time of this manuscript, 6/15 patients had their stents removed, two of which were mentioned above. Repeat endoscopy was performed in two of these other four cases for various indications and the endoscopic anastomoses remained patent for at least three months in each of these cases. We did not have any patients with anastomotic leaks in our series.

Discussion

Endoscopic ultrasound (EUS) has grown from being a niche tool in the 1980s to its current use as an interventional tool, intersecting traditional boundaries between interventional radiology, advanced endoscopy, and minimally invasive surgery. EUS combines real-time imaging with interventional endoscopy, particularly with the advent of the curved linear echoendoscope making passage of devices for the creation of the enteric-enteric anastomosis possible. The idea of non-surgical options for the creation of an enteric anastomoses is enticing, particularly in complex patients who have had multiple surgeries and in patients unsuitable for lengthy surgical procedures. In particular, endoscopic entero-enteric anastomosis is a creative solution in patients who have undergone bariatric surgery and in the treatment of intestinal obstruction secondary to other causes. As the anastomosis is created by direct lumen to lumen access and without incisions, morbidity is decreased and recovery time is minimal. In fact, we did not experience any short or long procedure-related complications such as leaks or hemorrhage and the majority of our patients had the procedure as an outpatient and were discharged the same day. These data compare favorably to those of the few published case reports and small series [4–7] Limited midterm

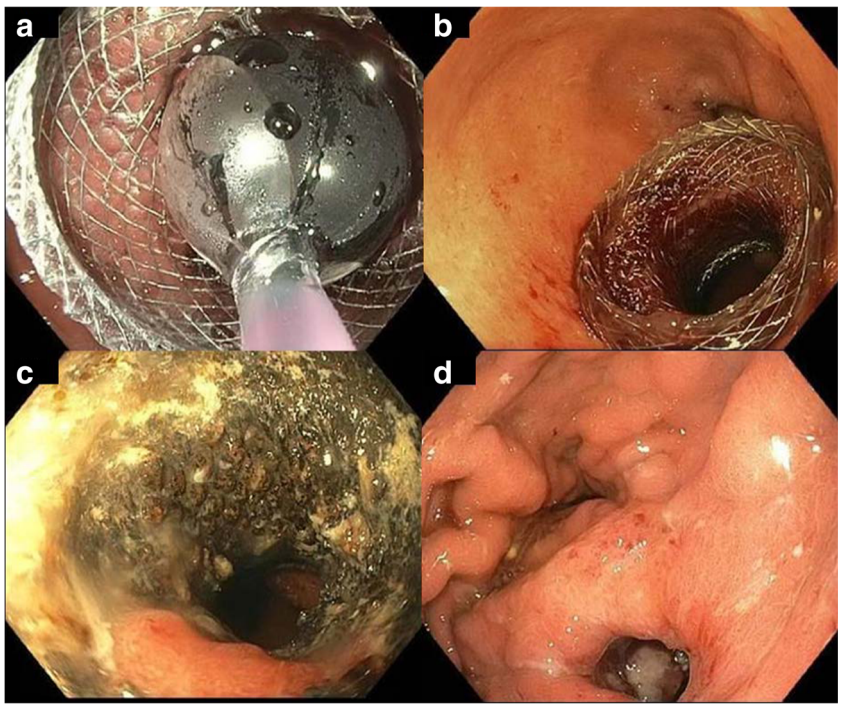

Fig. 4 LAMS within gastric remnant post balloon dilation (**a**, **b**). Patent stent after 10 months (**c**) and patent anastomosis 3 months following stent removal (**d**)

Table 2 Outcomes and complications of endoscopic gastrointestinal anastomosis

Patient	Technical success	Clinical success	Procedure duration (min)	Complications	Stent removal	Stent duration in situ (days)
1	Yes	Yes	59	Stent dislodged during repeated ERCP	Yes	180
2	Yes	Yes	38	Gastrogastrostomy stricture	Yes	66
3	Yes	Yes	74	None	Yes	316
4	Yes	Yes	64	None	No	318
5	Yes	Yes	96	None	No	241
6	Yes	Yes	41	None	No	134
7	Yes	Yes	56	None	Yes	55
8	Yes	Yes	24	None	Yes	76
9	Yes	Yes	78	None	No	106
10	Yes	Yes	59	None	No	101
11	Yes	Yes	82	None	No	94
12	Yes	Yes	46	None	No	76
13	Yes	TBD	29	None	No	22
14	Yes	TBD	32	None	No	7
15	Yes	TBD	33	None	No	3

TBD to be determined as duration of evaluation was too brief to common on clinical success

data on the complications of surgical reversal in those with RYGB suggest the possibility of severe complications in upwards of a 1/3 of this patient population. [10]

Despite the advanced endoscopic capabilities, a careful review of pre-procedural radiological imaging and careful planning of the procedure is vital for achieving optimal outcomes. First and foremost, this ensures consideration of appropriate indication which includes postoperative endoscopic access to the pancreaticobiliary systems, for ERCP, malnutrition with or without dumping syndrome and hyperinsulinemic hypoglycemia, restoration of iatrogenic discontinuity, and intractable marginal ulcer. Moreover, this will allow the proceduralist the opportunity to foresee anatomic relationships and develop a strategy for reversal. This may involve transjejunal access to the remnant rather than the desired transgastric (pouch) access. We did not, however, demonstrate increase risk or complication, such as ulceration or leak, or decreased efficacy, when utilizing transjejunal access. The operator will need to be acutely aware of the measurement between the two viscera which are to be connected. Given the properties and dimensions of the currently available lumen-apposing metal stents, a distance of < 15 mm is desired though slightly greater lengths have been accomplished successfully. Moreover, risk of leak drops considerably in scenarios where the pouch was created during RYGB without excision following stapling as the viscera are therefore essentially adherent. Another important consideration is the appreciation of regional vasculature, not only in the direct path of the enteroenterostomy but with the subsequent course of the expanding stent saddle. While we did not experience any issues with hemorrhage during this study, these have been recognized when using these stents for management of necrotizing pancreatitis [11].

Collaboration utilizing the unique skillsets of an advanced endoscopist and an experienced gastrointestinal surgeon is frequently necessary for creating the endoscopic enteroenteric anastomosis. We have taken the technology of lumen-apposing metal stents designed for the endoscopic treatment of pancreatic pseudocysts and walled-off necrosis [12] and brought it into the operating room. This stent has a "dumbbell" configuration with two large flanges, which are at least twice the diameter of the "saddle" section allowing for apposition of the tissue layers. The stent itself is made of nitinol wire, and fully covered to reduce intra-stent leakage and makes subsequent stent removal technically easier. The design of the stent distributes pressure evenly against the luminal wall and additional intra-stent balloon dilatation ensures a snug fit throughout the enterostomy. The more recently released electrocautery-tipped (HOT) delivery system enables a single-step puncture and stent deployment therefore decreasing the need for multiple exchanges of instrumentation during the procedure and reduces the risk of losing view and control over the enterotomy. While not formally studied, in all likelihood, this HOT technology reduces procedural time and complications.

Conclusion

EUS-guided gastrointestinal anastomosis with a lumen-apposing metal stent is an attractive and technically feasible

technique to re-establish gastrointestinal continuity in patients with RYGB and other selective altered anatomy. We demonstrate success with the creation of an entero-enteric anastomosis with this technology, particularly in the non-ideal surgical candidate and without significant complication to date. We do not yet know, however, the ideal length of time a stent used for this purpose should remain in situ to achieve durable patency, nor are we certain of all potential downstream effects of the stent in long term. However, endoscopic enteroenterostomy provides an alternative to conventional surgical approaches in comorbid patients where invasive procedures should be limited.

Compliance with Ethical Standards

Conflict of Interest Dr. Amateau serves as a consultant for Boston Scientific Corporation, the current manufacturer of the lumen-apposing metal stent used in this study. It is the only one currently available in the USA and they have no influence on his scientific endeavors.

Dr. Lim has nothing to disclose.

Dr. McDonald has nothing to disclose.

Dr. Arain received personal fees from Boston Scientific during the conduct of the study.

Dr. Ikramuddin serves as an advisory board member for Novo Nordisk, USGI, and Medica; consults for Medamodix; receives grant support from Medtronic, Enteromedics, and ReShape Medical; and receives consulting income from Enteromedics. The relationship has been reviewed and managed by the University of Minnesota in accordance with its conflict of interest policies.

Dr. Leslie serves as a consultant for Medtronic unrelated to the submitted work.

Ethical Concerns and Informed Consent Two of the authors are consultants for multiple device companies including Boston Scientific who produce the lumen apposing metal stent utilized in these procedures. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent for the procedure was obtained after a detailed discussion of risks and possible alternatives, including open or laparoscopic surgery. For this type of study, formal consent for data collection is not required.

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