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Outcomes of a novel bariatric stent in the management of sleeve gastrectomy leaks: A multicenter study

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Title page

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Short title: Novel stent in the management of sleeve gastrectomy leaks

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Author's contributions:

Moura performed cases, coordinate the study, and wrote the manuscript. Jirapinyo performed the statistical analysis. Thompson coordinate the study and

edited the manuscript. All of the other author's performed at least one included case. All author's reviewed the manuscript before submission.

DISCLOSURES

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ABSTRACT

Background

The management of laparoscopic sleeve gastrectomy (LSG) leaks remains a challenge. This can be treated with placement of self-expandable metal stents, which are most effective in the acute and early settings. However, migration is a frequent adverse event (AE). Novel fully covered stents with a larger proximal flare to limit migration designed specifically to treat post-sleeve leaks were recently introduced.

Aim

The aim of this study is to evaluate the safety and efficacy of a novel stent specifically designed for post-sleeve leaks treatment.

Methods

This is a multicenter retrospective study, including patients with acute and early post-LSG leaks, treated with a large bariatric stent. The outcomes include technical success, clinical success, and safety profile. A multivariable regression was performed to assess predictors of success.

Results

Thirty-seven patients were included (10 acute and 27 early leaks), with 30 stents in the post pyloric (POST) and 7 in the pre-pyloric (PRE) position. Technical success was 100%. Mean stent dwell time was 29.08 days. Clinical success was achieved in 78.37%. Leak duration, leak size and stent dwell time did not correlate with clinical

success. During follow-up, 8 patients had stent migration (21,62%) and all were in a POST position. AE post stent removal were also evaluated (PRE:57.14% vs POST:33.3%, *p*=0.45). There was no difference between PRE and POST position in the severe AE analysis.

Conclusions

This novel large-caliber fully-covered stent specifically designed for sleeve leaks appears to be effective at treating acute and early leaks. However, the large flanges and long stent length do not appear to reduce migration rate, and may be associated with higher overall severe adverse event rates. Avoiding placement in the post-pyloric position may help mitigate migration risk, however, due to the risk profile this stent should be used with caution.

Key words: bariatric surgery, obesity, sleeve, endoscopy, endoscopic treatment, leak, fistula, stent

INTRODUCTION

Obesity is a worldwide pandemic and bariatric surgery has been the most effective treatment modality for many years, achieving satisfactory long-term weight loss, reduction of cardiovascular risk factors, and improvement of obesity related comorbidities [(1-3)].

Laparoscopic sleeve gastrectomy (LSG), pioneered in 1999, has become a well-standardized therapeutic option for surgical treatment of different degrees of obesity

and obesity-related diseases [4-6]. Despite satisfactory clinical results associated with bariatric surgery, the number of complications has increased due to broad adoption of the procedure [7]. Leaks are one of the most common complication associated with bariatric surgery, with rates varying from 0.5% to 1.5% after LSG, with increasing rates following revision surgeries [8,9]. Leaks are often located at the superior staple line below the gastroesophageal junction (GEJ) and is defined as a communication between intra- and extra-luminal compartments due to a defect in the GI wall [7,10].

There are several methods to treat these leaks endoscopically with covered self-expandable metal stents (CSEMS) and endoscopic internal drainage (EID) techniques being associated with best outcomes [10-12]. The duration of leak, as classified in an international consensus is essential in choosing the appropriate treatment [13]. If the leak is acute (< 7 days) or early (<45 days) CSEMS are recommended. CSEMS work by covering the orifice of the leak and also shaping the stomach and treating distal stenosis [10]. A recent systematic review and meta-analysis showed an overall success rate of 72.8%, with a migration rate of 28.2% for CSEMS [11]. Due to the high rates of CSEMS migration, some novel stents specifically for post-LSG leak treatment (longer and with a larger diameter) have recently been introduced, including the Megastent™ (Taewoong Medical Industries, Kangseo-GuSongjung-Dong, South Korea), Niti-S Beta™ stent (Taewoong Medical Industries, Kangseo-GuSongjung-Dong, South Korea), and the Hanarostent ® (M.I.Tech, Seoul, South Korea) [5,14,15].

Unfortunately, all studies related to these novel stents included a heterogeneous population, including leaks after different types of surgery (Roux-en-Y Gastric bypass and LSG), different duration of leak (acute and chronic), previous endoscopic treatment, and combined techniques (CSEMS and over-the-scope-clips) [5,14-16]. In this study, we presented the largest series including just acute and early leaks post-LSG who were endoscopically treated with a novel large bariatric stent specifically designed for LSG leaks.

MATERIAL AND METHODS

Methods

This is a retrospective multicenter analysis of prospectively collected data from 15 centers (secondary and tertiary centers), including 37 consecutive patients undergoing endoscopic treatment with a novel large bariatric stent for acute and early post-sleeve gastrectomy leaks between June 2016 and November 2018. The inclusion criteria were patients with an acute or early leak according to the International Sleeve Gastrectomy Expert Panel Consensus (acute: < 7 days, early: 7-45 days, late: 45 days-3 months, and chronic: > 3 months) [13] diagnosed by clinical history and imaging exams such as computed tomography (CT) with contrast or upper GI studies including contrast swallow or upper GI endoscopy, who underwent a novel specific bariatric 24 cm in length stent treatment.

Ethical concerns

An IRB approval for retrospective analysis was obtained for each center prior to collecting data for this study. Written informed consent from each center was obtained from all patients before the procedures.

Outcomes measures

The outcomes of this study were technical success, clinical success, and safety profile, including stent migration. Clinical success was defined as complete and permanent resolution of abdominal or thoracic drainage with imaging documentation of closure after at least 2 months. Adverse events were divided into early (initial seven-days after stent placement), during follow-up (between 7 days and stent removal), and post stent removal (diagnosed at scheduled stent removal). Severe adverse events were also analyzed. Severe adverse events were defined as per the ASGE guidelines [17], including: unplanned admission or prolongation for > 10 nights, ICU admission > 1 night, and surgery for adverse event. Additionally, we compared stent placement location (pre-pyloric and post-pyloric) related to outcomes.

Materials and procedures

For this retrospective observational study, all patients who underwent this novel large bariatric stent placement as a primary treatment of acute and early post LSG leaks were included. All patients underwent laparoscopic or radiological drainage before endoscopic stent placement. All endoscopic stent placements were performed with endotracheal intubation to protect the airway. First, an esophagogastroduodenoscopy (EGD) was performed to confirm the topography of the leak. After leak site identification,

the procedures begin with passage of a rigid guidewire (Savary-Gilliard guidewire, Cook Medical, Winston Salem, NC) placed in the second or third part of the duodenum under endoscopic and fluoroscopic guidance. Then, the stent catheter was inserted over the guidewire. The stent was positioned and slowly deployed under endoscopic and fluoroscopic guidance.

All the patients were treated with one of the two specific bariatric stents. Both stents have a length of 24 cm and a body diameter of 28 mm, with either 32 mm or 36 mm proximal and distal flanges (Hanaro® ECBB™ with a flange diameter of 28/32 mm and a lumen diameter of 24/28 mm (Model Number: ECBB-28-240-090); and Hanaro® Gastro-Seal™ with a flange diameter of 36 mm and a lumen diameter of 28 mm (Model number: ECBS-28-240-090), M.I.Tech, Seoul, South Korea). These are long flexible silicone-covered nitinol stents, designed with larger flanges to avoid migration, with narrow lumens, and drawstrings at both ends to reposition or remove the stents as needed (Figure 1).

After stent placement patients were kept NPO for 1 day, followed by liquid diet for 3 days and then soft foods until stent removal. No solid foods were allowed during this period. During stent use patients received PPIs and symptomatic medications for pain and nausea. Hospitalized patients also received intravenous medications. Stent removal was schedule for 4 to 6 weeks for all patients.

Figure 1. Novel large bariatric stent design for sleeve leaks. A. Hanaro® ECBB™ Stent; **B.** Hanaro® Gastro-Seal™ Stent

Statistical Analysis

For the qualitative analysis, technical success, clinical success, and adverse events were calculated. The averages and standard deviations were calculated using Microsoft Excel (https://products.office.com/pt-br/excel). In this analysis, only acute and early leaks were included, defined according to the International Sleeve Gastrectomy Expert Panel Consensus [13]. Success and adverse event rates between different groups were calculated with the Chi-squared test. *P* value < 0.05 was considered significant.

For the quantitative analysis, a Chi-squared test were used to find an association between successful fistula closure and several factors including period of the leak, size of the leak orifice, stent position, and stent dwell time. A multivariable logistic regression analysis was then performed to assess predictors of successful closure. Given the number of outcomes, three predictors were put into the model and these were chosen *a priori*. These predictors included duration of leak, stent position, and stent dwell time. Statistical analysis was performed using SAS version 9.2 software (SAS Institute, Cary, NC).

RESULTS

Thirty-seven patients treated with the 24 cm length bariatric stent for early and acute post-LSG leaks were included in the analysis, including 11 men (29.73%) and 26 women (70.27 %), with an average age of 35.95 (SD: 9.67) years. Of the 37 leaks, 34 were located at the angle of His, 2 in the proximal corpus, and 1 at the distal esophagus. The mean size was 11.91 mm (SD: 7.56) with 24 leaks (64.86%) smaller

than 10 mm and 12 larger than 10 mm. The mean time to leak was 16.94 days (SD: 10), including 10 acute (27.02%) and 27 early (72.98%) leaks (Table 1).

Table 1. Clinical and demographic features

Success rate

Technical success of stent placement (Figure 2) was achieved in all cases (100%) confirmed by endoscopic and fluoroscopic visualization or an oral water soluble contrast study, including 30 (81.9%) placements in the post pyloric (POST) and 7 (18.91%) in the pre-pyloric (PRE) position. For all stents, the proximal flange was positioned in the esophagus. The mean stent dwell time was 29.08 days (SD: 9.28). Of the 37 leaks, 29 (78.37%) resolved with stent placement (Figure 3), with no residual drainage, and eight had failed. The PRE position had a higher success rate (85.71 vs 76.66%, p=0.60) compared to the POST position, however, no statistical difference was found. After stent failure, use of other endoscopic techniques and conservative approach, increased the clinical success to 94.59%. In the 8 failed cases, 4 were treated with other endoscopic techniques (2 septotomies and 2 EID with pigtails), 2 with conservative approach, 1 patient was referred to surgery, and 1 patient died the 5th day after stent placement due sepsis.

In the quantitative analysis we tried to find an association between successful leak closure and several variables, including leak duration, size of leak, stent position, and stent dwell time. However, no statistical difference was found (Table 2).

Figure 2. Stent placement (step by step)

A. Leak in the staple line at the angle of His; **B.** Extensive leak after contrast study, fluoroscopic view; **C**. External marking of the gastric-esophageal junction, leak, incisura angularis, and pylorus for guidance during stent placement, fluoroscopic view; **D.** A 24-cm large bariatric stent inserted in the post-pyloric position, fluoroscopic view; **E.** Contrast study after stent placement with no signs of leakage, fluoroscopic view; **F.** CT scan 2 weeks after stent placement showing completely expanded stent

Figure 3. Endoscopic treatment of an acute bariatric leak

A. Leak in the staple line at the angle of His; **B.** Leak and external drainage after contrast study, fluoroscopy view; **C.** Stent placement, endoscopic view; **D.** Stent placement, fluoroscopic view; **E.** Complete healing of the leak; **F.** No signs of leakage after contrast study, fluoroscopic view.

Table 2. Stent clinical success based on several variables

In the multivariable logistic regression analysis, period of leak (acute/early), stent position, and stent dwell time did not correlate with clinical success after controlling for the other two confounders ($p>0.05$ for all three factors).

Adverse events rate

The adverse events (AE) (Figure 4) were analyzed into three groups including early, during follow-up, and post stent removal (Table 3). Then, the severe adverse events

(SAE) were analyzed separately. In all the analysis we performed an analysis associating the adverse event to the stent position (PRE or POST) (Table 4).

Early AEs, including abdominal pain, nausea, emesis and reflux, were reported in 33 (89.19%) patients with no statistical difference when comparing stent position (PRE: 57.14% vs POST: 83.33%, p=0.57). The majority of patients had moderate symptoms. Also, an individualized analysis was performed for each AE without statistical difference, however, there is a trend for more reflux in POST position (56.66% vs 14.28%, p=0.18). Additionally, one bronchial aspiration during anesthesia and one death, unrelated to the stent, due to sepsis were reported. The patient who died was diagnosed with septic shock three days after bariatric surgery and his clinical condition did not improve after laparoscopic lavage and external drainage. Stent placement appeared to resolve the leak, however, the sepsis persisted with ongoing clinical deterioration and the patient died on the 5th day after stent placement.

During follow-up, 28 (75.67%) patients reported AEs. One patient had an esophageal perforation diagnosed on the 10th day. The patient's perforation was initially treated by surgery to drain the mediastinum followed by endoscopic vacuum therapy. In this case the leak was treated with two septotomies sessions. Eight patients (21.62%) had stent migrations and all of these were placed in a POST position (p<0.001). In six of these cases the stent was repositioned and migrated a second time. Of these, five experienced complete leak resolution and one required further endoscopic intervention. The other two migrated stents were surgically removed. One patient developed melena,

without need of blood transfusion. In this case, an EGD was performed with no signs of bleeding. One patient had early stent removal due to intolerance resistant even to intravenous medication and required surgical revision, and another patient had a stent fracture and the stent was then replaced for a new one.

Post stent removal adverse events were reported in 11 patients (29.72%), including 10 ulcers at the distal edge of the stent. Of these, two gastric ulcers were associated with a contained perforation treated with a conservative approach, and one submucosal antral abscess treated with endoscopic ultrasound (EUS)-guided drainage. Also, an esophageal stenosis needing one endoscopic dilation with bougies was reported. In this analysis, we also compared the stent position related to AE, and no statistical difference between stent position was found (PRE: 57.14% vs POST: 33.3%, p=0.45).

SAE including two stent migrations and one esophageal perforation needing surgery were reported. All SAE are highlighted (bold) in Table 3. There was no difference between PRE (14.28%) and POST (6.66%) stent position in the SAE analysis (p=0.54).

Figure 4. Adverse events related to stent placement

A. Esophageal perforation with mediastinal drain visible; **B.** Stent migration, fluoroscopic view; **C.** Surgical removal of migrated stent; **D.** Contained gastric perforation after stent removal; **E.** Ulcer at the distal stent; **F.** Submucosal antral abscess

Table 3. Adverse events analysis

Table 4. Adverse events analyzing PRE and POST position

DISCUSSION

Post-bariatric surgery leaks remain a serious and challenging complication. Endoscopic approaches have been shown to be highly effective in reducing morbidity and mortality in the treatment of these conditions. Different endoscopic treatments including covering, closing, plugging and draining can be performed depending on the duration and location of the leak. However, at this time there is no concensus regarding the best approach for this condition [7,10].

For late and chronic fistulas, EID leads to satisfactory results, either with pig tails, endoscopic vacuum therapy or septotomy followed by achalasia balloon dilation. Additionally, EID allows the introduction of the endoscope into the contained cavity to wash the contents [7,10,12]. EID with pigtails has been used for treatment of leaks and fistulas, with efficacy up to 84% [18]. EVT is another effective modality in the treatment of wall defects, with success rates of up to 94.2%; however, this usually requires inpatient stays and multiple procedure, and deaths due to severe hemorrhage with this technique have been reported [19,20]. Additionally, the use of a cardiac septal defect occluder in the treatment of late and chronic fistula has been shown to be effective in a recent publication [7].

For acute and early leaks after LSG, stents, suturing, clips, and EID can be used. Endoscopic stenting appears effective and is being used with increased frequency [10,11]. Undrained collections should be drained radiologically, surgically or endoscopically before luminal stenting [10]. CSEMS provide a physical barrier between the leak and the luminal contents, allowing the leak to heal while providing enteral or oral diet [21]. A systematic review and meta-analysis including non-specific bariatric CSEMS reported a polled successful leak closure rate of 87.77%. However, stent migration was noted in

16.94% [21]. Other systematic review and meta-analysis recently published reported migration rate of 28.2% [11]. This AE most likely is associated with the use of esophageal CSEMS, which are placed too distally in the last portion of the esophagus or where proper fit is not possible due to small caliber of the stents. The partially CSEMS can be used to limit migration, however, stent removal is challenging due to tissue hyperplasia and in-growth at the proximal margin [22,23]. Some other techniques to avoid stent migration have been used, including nasal bridle technique and clips (both through-the-scope and over-the-scope) to fix the upper flared end of the stent, however, none has provided a definitive solution for stent migration [15,24]. Stent fixation with endoscopic suturing has shown satisfactory results in minimizing stent migration, however, due to extra costs, challenging nature of the procedure, and no randomized studies proving its efficacy, this technique is not widely adopted [24,25].

Recently a novel, fully CSEMS, specifically designed for post-LSG leak treatment, has been introduced, the Hanarostent ® (M.I.Tech, Seoul, South Korea). This long length stent has larger flanges to limit migration, flexible body structure to enable conformity to sleeve anatomy, and is able to be repositioned as needed. There is a paucity of literature regarding this stent, with just one study including 12 patients post LSG and RYGB leaks [15]. In this study [15] the clinical success was 75%, similar to the other stents, however, the dislocation or migration rate was higher, occurring in 66.7% [26].

Our study is the first to analyze this novel stent just in patients underwent LSG complicated with a leak. Also, for more accurate results, we included just patients with early and acute leaks, since the CSEMS are best used in these conditions. It is well known, for late and chronic leaks CSEMS have unsatisfactory results and other endoscopic approaches are preferred [7,10,11]. Additionally, this is the first study to analyze stent position and its impact on outcomes.

The clinical success rate of our study was 78.37%, similar to a recent systematic review and meta-analysis including different types of CSEMS [11]. When analyzing pre-pyloric and post-pyloric position, we found that pre-pyloric position is associated with better results (85.71% vs 76.66%), however, no statistical difference was found. In our series just one patient had stent replacement due to stent fracture. In cases where the leak did not heal after stent removal, a new stent was not placed due to the low success rate of CSEMS in late and chronic leaks [10,11,27]. In these cases, other endoscopic techniques, including septotomy and EID with pigtails, and conservative approach were performed, increasing the success rate of leak closure to 94.59%. From our cohort just one patient was referred to surgery. Also, one patient died due to sepsis on the 5th day after stent placement and did not complete the treatment, being considered as a fail in our rigorous analysis. These results confirm that endoscopic techniques should be considered the first line approach for leaks after bariatric surgery.

Despite these satisfactory results, our study revealed a high AE rate. First, we analyzed the AEs in the first seven-day post stent placement. In this analysis 89.19% of our patients reported symptoms, including abdominal pain, nausea, emesis and reflux. These symptoms are commonly mild with most esophageal stents and fairly well tolerated, usually resolved in few days [21]. However, probably due to the size (longer and larger) of this novel stent, most of the patients reported moderate symptoms, without complete resolution until stent removal at completion of therapy. Additionally, one patient had early stent removal due to intolerance secondary to abdominal pain,

reflux and emesis, refractory to intravenous medication, including PPI, anti-emetic and pain medications. We performed individual analysis of the symptoms comparing PRE and POST position and founded that POST is associated with more symptoms, mainly with reflux. However, no statistical difference was found in this analysis. We believe the higher rate of reflux in POST position may be due to pancreatobiliary fluid reflux into the esophagus.

Second, we analyzed the AEs during follow-up. An esophageal perforation was reported in our series. The patient was referred to surgery for mediastinum drainage and esophageal repair. Then, a complete dehiscence of the esophageal closure was diagnosed and treated by endoscopic vacuum therapy. This case has been published as a video case report [19]. Another study using this stent in both LSG and RYGB leaks also reported two perforations [15]. The causes of the perforation are unclear, and two hypotheses were made. First, the large proximal flange of the stent could cause esophageal wall ischemia; second, the angle of the sleeve could cause a kinking of the stent and thereby applied an additional pressure against the wall causing rupture. These factors also raise concern for the potential of esophageal-aortic fistula. However, no cases have been reported at this time. One patient also reported melena without need of blood transfusion. However, on EGD no active bleeding or signs of recent bleeding were found.

Despite the large stent flanges, specifically designed to prevent migration, stent migration was the most common AE of this series, occurring in 21.62% (8/37) of cases. This rate is higher than the 16.94% (CI, 9.32% - 26.27%) rate published in a meta-

analysis including standard esophageal stents [21]. Although this larger stent was designed to prevent migration, the long length and the larger diameter may paradoxically contribute to stent migration as this may cause more friction between the GI wall and the stent, making it more susceptible to peristaltic movements [28]. In most cases, migration required endoscopic repositioning, rather than removal. In 6 of 8 patients, the stent migrated more than one time requiring repositioning on both occasions. In two cases, the stent migrated to the jejunum. An enteroscopy was performed, however, due to the stent size, endoscopic removal was unsuccessful. In these cases, both patients were referred to surgery. One of these cases has been published as a case report [29]. In one of these cases, the stent had required previous repositioning. Due to the risk of recurrent migration, we recommend stent fixation after first episode. In the literature, there are some reports of stent migration that passed the rectum, however, probably due to the size of this stent, we did not experience any stent elimination through the rectum [30]. Additionally, we compared the PRE and POST-pylorus stent position and founded that all the migrations occurred in POST position. As a result, we strongly recommend PRE position placement. Additionally, close clinical follow-up, including patient symptoms and a low threshold to obtain imaging exams is recommended.

Sleeve stenosis is also an important factor to consider in leaks and their treatment. Stent placement in the PRE position should still be effective in addressing stenosis in the majority of patients. Additionally, patients with stenosis may be at lower risk of stent migration, allowing POST positioning without increased risk of migration. However, this study can not be performed with our current population due to a low number of events.

Third, we analyzed the adverse events diagnosed post stent removal. The most common diagnosis was ulceration, and two of these were associated with a contained perforation effectively treated with a conservative approach. Also, one submucosal abscess was reported and drained by EUS. We believe that ulcerations are caused due to the long and large design of the stent causing pressure in both the gastric and duodenal wall. In the comparison between stent position, the PRE position was related to more AEs, however, no statistical difference was found. This may be related to the pressure of the peristaltic movements trying to push the stent downwards. Additionally, the long stent length (24 cm) may increase pressure and tissue trauma in the gastric antrum. We believe that 18 cm or 21 cm length stents may have lower rates of adverse events after stent removal, however, this could not be analyzed in the current study. Also, an esophageal stenosis treated by one session of endoscopic dilation with bougies was reported. The stenosis is likely related to scar formation caused by the large proximal flange of the stent.

Finally, although the rate of adverse events appears to be fairly similar between this and conventional stents, the rate of SAE may be considerable higher, although this is not able to be statistically assessed without a control group. In this study, similar to other studies regarding various large bariatric stents [14-16], the rate of SAE (8.10%) was relatively high in light of previous publications regarding conventional esophageal stents used for this application [11,30]. In one series including[16] 62 patients who received large bariatric stents, there were 4 small bowel perforations, 11 migrations, and one death due to severe hemorrhage. In another series[15] of 12 patients, there were 8 stent

migrations or dislocations (66.7%). Additionally, a study[14] including 38 patients who received large bariatric stents, had one case of hemorrhage due to an aorto-esophageal fistula caused by mechanical pressure of the stent. In our study, there were 8 migrations (out of 37 patients) and two of these patients needed surgery for stent removal. Additionally, we report one esophageal perforation needing surgical treatment. There was no difference between PRE and POST position in the SAE analysis for the current study. The SAE seen for these large bariatric stents appear to be substantially higher than those seen for conventional stents when used for this application. In fact, a large meta-analysis including 24 studies using conventional stents for sleeve leaks identified no perforations or stent related deaths.

The main limitation of this study is the retrospective design, which can lead to selection bias. The multicenter design with a few numbers of case performed at each center is also a limitation. However, all the authors have experience with CSEMS and with endoscopic management of leaks after bariatric surgery.

In summary, this novel large-caliber fully-covered stent specifically designed for LSG leaks appears to be effective in the treatment of acute and early leaks, with similar results compared to conventional esophageal stents. However, the large flanges and long stent length, do not appear to reduce migration rate, and may contribute to other adverse events. Additionally, post-pyloric position is associated with a higher incidence of migration and should be likely avoided. Given these results, suggesting similar

benefit with an increased risk profile, this stent should be used with caution and design modification should be considered.

DISCLOSURES

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Author 3: reports grants and personal fees from Fractyl Labs, GI dynamics, GI windows, Appolo Endosurgery, Olympus, Medtronic, and M.I. Tech.

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Table 1. Clinical and demographic features

Population and leak characteristics	Results n (%)
Gender	Female: 22 (70.2%) Male: 11 (29.73%)
Age	mean 35.95 (SD: 9.6)
Location	34 angle of His (91.9%) 2 proximal corpus (5.4%) 1 distal esophagus (2.7%)
Leak size	mean 11.91 mm (SD: 7.5) < 10 mm: 24 (64.8%) > 10 mm: 13 (35.1%)
Time to leak	mean: 16 days (SD: 10) acute: 10 (27%) early: 27 (72.9%)

Table 2. Stent clinical success based on several variables

Variables	Results (%)	Statistical significant (p<0.05)
Technical success	All cases: 37/37 (100%)	-
Clinical success	YES: 29 (78.3%) NO: 8 (21.6%)	-
Clinical success based on time of leak	Acute (7/10) – 70% Early (22/27) – 81.4%	p= 0.78
Clinical success based on size	≤ 10 mm (18/23) – 78.2% > 10 mm (10/14) – 71.4%	p= 0.86
Clinical success based on stent position	Pre-pyloric (6/7) – 85.7% Post pyloric (23/30) – 76.6%	p= 0.85
Clinical success based on stent dwell	≤ 30 days (19/25) – 76% > 30 days (10/12) – 83.3%	p= 0.86

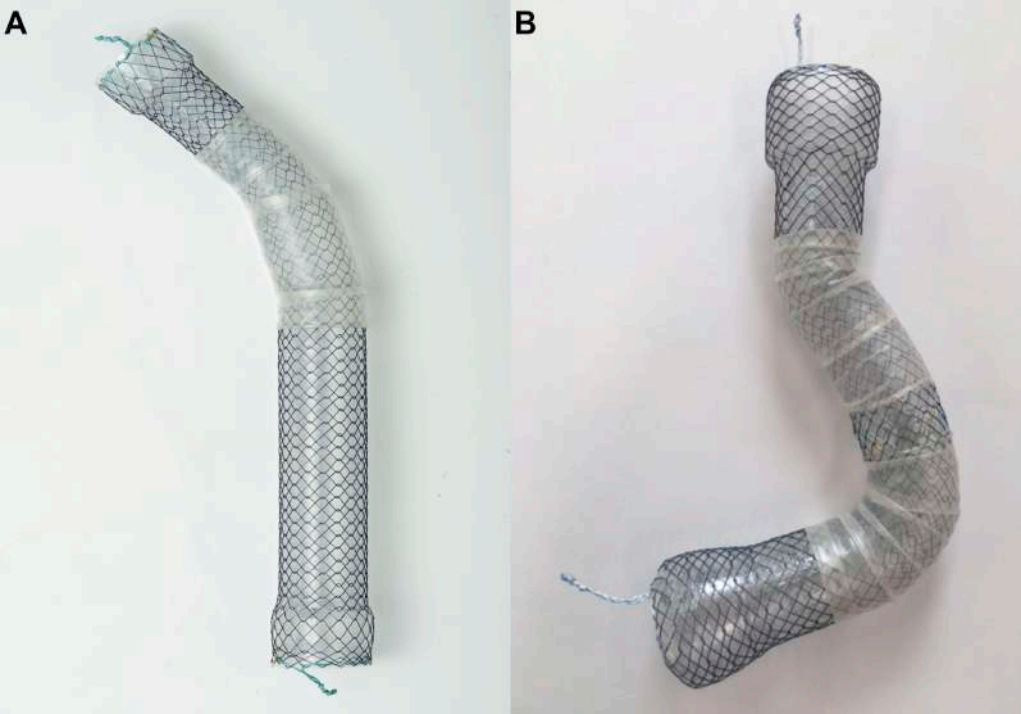
Table 3. Adverse events analysis

Variables	Results
Adverse events – Early	YES: 89.1% NO: 10.8% 28 abdominal pain (9 mild, 14 moderate, 5 severe) 23 nausea (5 mild, 16 moderate, 2 severe) 22 emesis (6 mild, 14 moderate, 2 severe) 18 reflux (5 mild, 11 moderate, 2 severe) 1 bronchial aspiration (during anesthesia ET tube placement) 1 death (unrelated to stent)
Adverse events – During follow-up	YES: 75.6% NO: 24.3% 11 abdominal pain (2 mild, 4 moderate, 4 severe) 10 nausea (2 mild, 4 moderate, 4 intense)

	10 emesis (1 mild, 5 moderate, 2 intense) 8 stent migrations (in 6 of these cases the stent was repositioned and migrated a second time - **2 needed surgery for removal**) 6 reflux (2 mild, 4 moderate) **1 esophageal perforation** 1 stent removal due intolerance 1 stent fracture (requiring stent exchange) 1 melena (no bleeding during upper GI endoscopy)
Adverse events – Post stent removal	YES (29.7%) NO (70.2%) 10 ulcers 2 contained perforation (conservative treatment) 1 submucosal antral abscess (EUS-guided drainage) 1 esophageal stenosis (one session endoscopic dilation)

Table 4. Adverse events analyzing PRE and POST position

Adverse events	**PRE-pylorus position (n, %)**	**POST-pylorus position (n, %)**	**Statistical significant (*p*<0.05)**
Early AE **Abdominal pain**	(4/7) 57.1%	(25/30) 83.3%	*p*= 0.57
Early AE **Nausea**	(4/7) 57.1%	(19/30) 63.3%	*p*= 0.88
Early AE **Emesis**	(4/7) 57.1%	(18/30) 60%	*p*= 0.94
Early AE **Reflux**	(1/7) 14.2%	(17/30) 56.6%	*p*= 0.18
AE during follow-up **Stent migration**	0	(8/30) 26.6%	***p*<0.001**
AE post stent removal	(4/7) 57.1%	(7/30) 23.3%	*p*= 0.22
Severe adverse events	(1/7) 14.2%	(2/30) 6.6%	*p*= 0.54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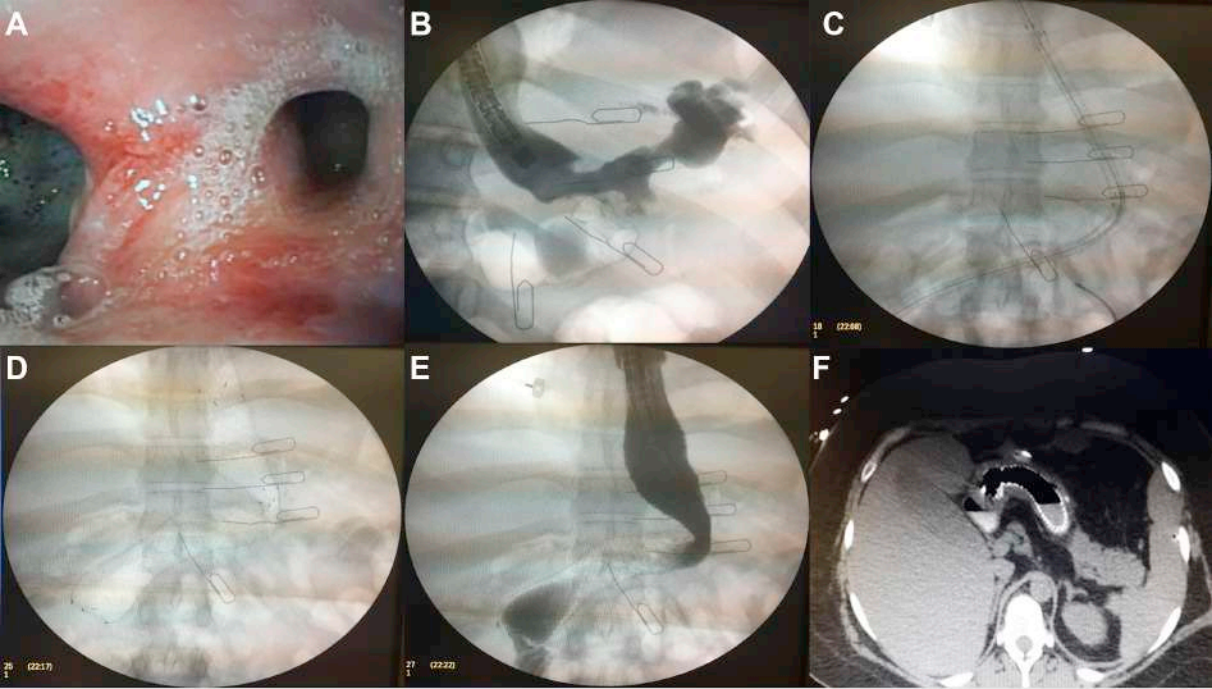
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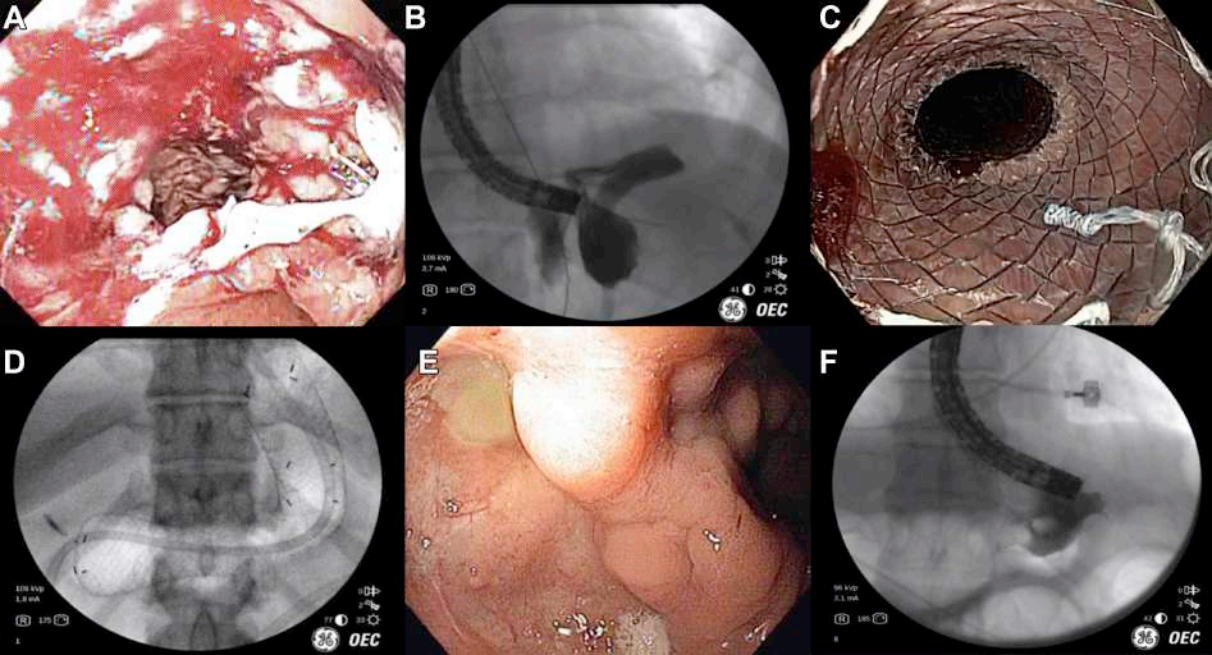
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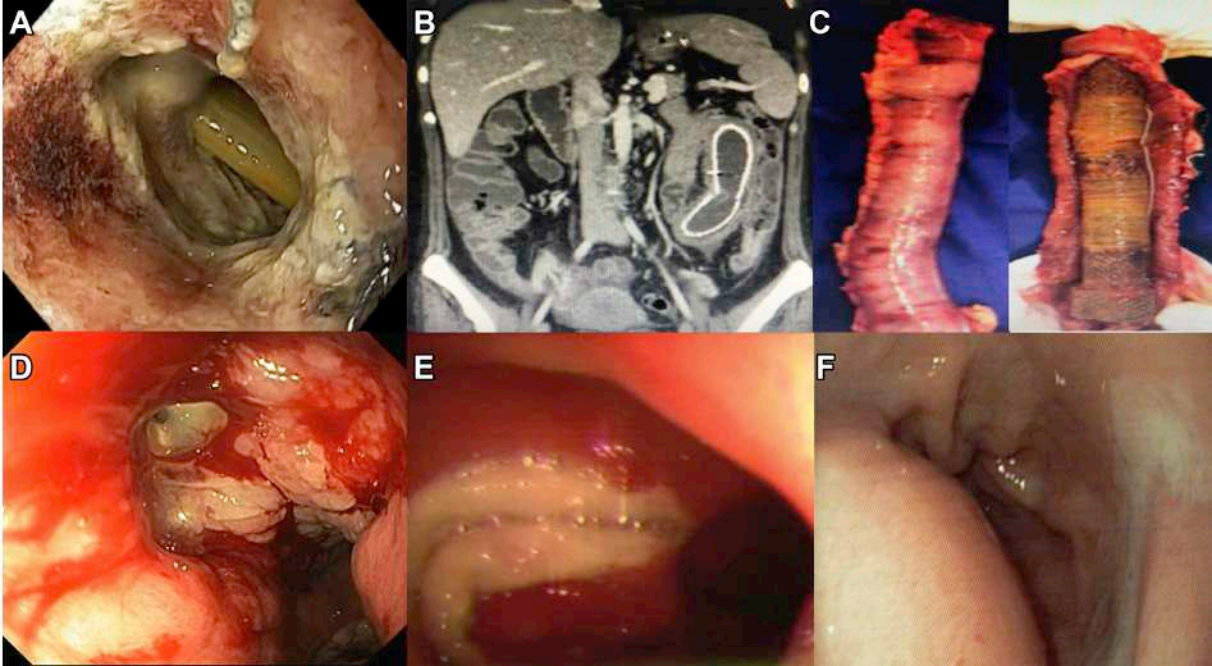
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Highlights

- Despite satisfactory clinical results associated with bariatric surgery in the treatment of obesity, the number of complications has increased due to broad adoption of the procedure

- A novel large-caliber fully-covered stent specifically designed for sleeve leaks appears to be effective at treating acute and early leaks

- The large flanges and long stent length of this novel large-caliber fully-covered stent specifically designed for sleeve leaks do not appear to reduce migration rate

- Post-pyloric POST position is associated with a higher incidence of migration and should be avoided.