Douglas G. Adler MD, FACG, AGAF, FASGE, Series Editor

Endoscopic Management of Laparoscopic Gastric Sleeve Leaks

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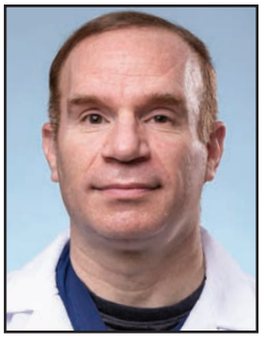

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INTRODUCTION

Bariatric surgery is a well-established option for patients with obesity, with over 200,000 procedures performed annually in the United States. Sleeve gastrectomy comprises 58% of these surgeries.[1] Gastric sleeve leaks (GSL) can occur in 1-2% of patients following laparoscopic sleeve gastrectomy.[2] Leaks occur when tissue breakdown, most commonly near the anastomosis and/or suture or staple lines and can evolve into a fistula with an epithelialized tract if they do not heal in a timely manner.[3] GSL are the second most common cause of mortality in patients undergoing sleeve gastrectomy, following pulmonary embolism.[4]

A multidisciplinary approach is important when managing these patients and should involve surgery, gastroenterology, and interventional radiology. Prompt diagnosis, classification, and treatment of GSL is essential. Techniques for managing GSL can vary based on the patient's clinical condition, leak classification, expert experience, and availability of resources. In the presence of hemodynamic compromise, septic shock or peritonitis, further surgical management is needed. Otherwise, endoscopic treatment is preferred, due to high perioperative morbidity with surgery.[5]

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Classification

Classification of GSL can guide management decisions. There are several proposed classification systems that are based on timing of presentation and findings on computed tomography (CT) scan.

The Rosenthal sleeve gastrectomy leak classification system organizes leaks based on timing of presentation.[6] Acute leaks are diagnosed and treated before 7 days from the operative procedure, early leaks between 1-6 weeks, late leaks between 6-12 weeks, and chronic leaks after 12 weeks.

Sleeve leaks can also be classified according to a CT scan classification system[7] which is organized by the type of collection on CT and leak visualization. (Table 1) Johari et al. proposed a validated classification system, based on CT imaging that predicts a stepwise increased risk of complication severity, increased hospital stay and salvage resection using a 2-phase modified Delphi process.[8] (Table 1)

Etiology

The etiologies of GSL can be due to mechanical/tissue causes or ischemic causes. It is related to an increase in intraluminal pressure which exceeds the strength of the tissue and/or staple line.[9] When creating a gastric sleeve, a long staple line anastomosis is created which extends from the antrum of the stomach to the gastroesophageal junction. Leaks can form anywhere along the staple line, although most leaks occur near the angle of His, where the gastric wall is susceptible to ischemia. Relative ischemia tends to occur in this area secondary to surgical ligation of gastric arteries, relative dysmotility and increased intragastric pressure. Distal obstructions, such as concomitant gastric sleeve stenosis, can further increase intraluminal pressure and contribute to the development of leaks.

Risk Factors

Surgical and nonsurgical risk factors contribute to the development of GSLs. Several studies have demonstrated that male gender and higher BMI, especially in super-obese patients (BMI >50 kg/m^2), increase the risk of developing a GSL.[2,10]

Surgical risk factors relate to stapling, ischemia, gastric stenosis, and the experience of the surgeon. Meticulous tissue handling, consideration of tissue thickness, conscious stapling, avoidance of inadvertent narrowing are methods to decrease surgical risk factors.[9] Additionally, surgeons performing >43 cases per year can achieve a <1% leak rate.[11]

Table 1. CT Classification of Laparoscopic GSLs

Csendes et al.		**Johari et al.**	
Type	**Collection on CT**	**Class 1**	Phlegmon associated with staple line
I	< 5cm in LUQ	**Class 1a**	Phlegmon
II	> 5cm in LUQ	**Class 1b**	Phlegmon with small localized locules of gas
III	Diffuse abdominal collections	**Class 2**	Fluid collection
IV	Pleural (thoracic) collections	**Class 2a**	Fluid collection with localized locules of gas
Type	**Staple line localization**	**Class 2b**	Extensive mixed fluid and gas collection
S	Superior part of sleeve	**Class 3**	Contrast leak
M	Middle part of sleeve	**Class 3a**	Contained contrast leak
I	Inferior part of sleeve	**Class 3b**	Free intraperitoneal contrast leak
	Leak Visualization	**Class 4**	Chronic fistula
a	No leak		
b	Positive leak		

Clinical Manifestations

Clinical manifestation of GSL can range from asymptomatic leaks diagnosed with routine imaging to signs and symptoms of perforation, peritonitis, and septic shock. Fever and tachycardia are two of the most important clinical factors in the diagnosis of GSL.[5] Other clinical manifestations include abdominal pain, pain radiating to the left shoulder, vomiting and tachypnea.[12]

Diagnosis

Upper gastrointestinal (UGI) fluoroscopy and CT scan of the abdomen with oral contrast are the most common tests used to diagnose GSL. In a head-to-head study comparing UGI contrast studies and CT scan with oral contrast, CT was found to be superior to UGI series in the diagnosis of GSL with a sensitivity of 95% vs. 74.9% respectively.[13] Endoscopy is also useful when trying to establish the characteristics of the leak such as size of the orifice.[14]

Endoscopic Management

Endoscopic treatment is feasible in most patients with GSL and have been shown to facilitate healing of GSL in 74-81%[14,15] of patients, with early intervention increasing the likelihood of success.[15] Predictors of successful healing with endoscopic management include acute leaks that developed ≤ 3 days from the operative procedure, early endoscopic treatment < 21 days after leak diagnosis, leak size < 1 cm, and no prior history of banded gastroplasty.[15]

There are various treatment options for endoscopic management of GSL. Treatment strategy depends on the characteristics of the defect and center level of experience. The size, viability of surrounding tissue, and location of the defect can be defined endoscopically to determine which closure strategy might be best to perform. Additionally, treatment of distal stenoses and removal of foreign material is important for successful treatment of GSL.[16]

A retrospective review of 37 patients with GSL demonstrated that 30/37 (81%) were successfully managed endoscopically. Endoscopic techniques performed included: 44% fully covered bariatric gastric stents, 34% internal pigtail plastic stents, 11% septoplasty, 5% endoluminal vacuum therapy, and 3% over-the-scope clip (OTSC).[14] Other endoscopic approaches include use of tissue sealants, endoscopic suturing, and novel techniques such as use of cardiac septal occluders. Patients may require combined endoscopic modalities for successful closure, especially in patients with refractory leaks who failed initial endoscopic intervention.[17]

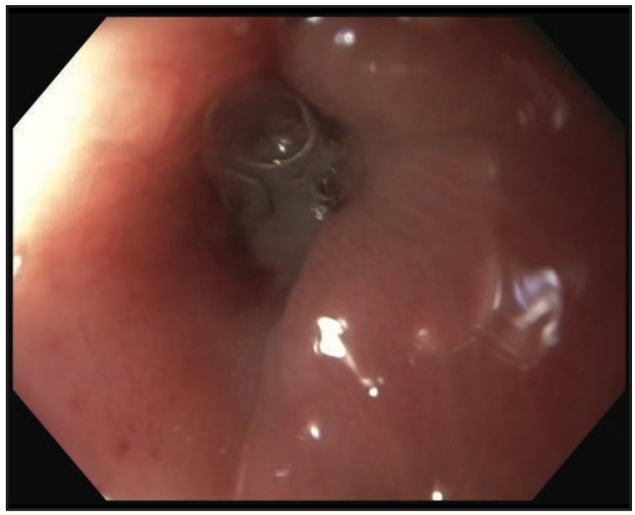

Figure 1a. A patient with a 1cm gastric sleeve leak. Note visible staples.

Endoscopic Internal Drainage

The presence of an intra-abdominal collection (IAC) requires drainage as they tend to be the source of sepsis. Adequate drainage can be performed internally by endoscopy, via percutaneous drains, or, less frequently, via surgery.[18,19] The reported efficacy rate when EID is used as a primary intervention is 74-86%.[18-20]

Endoscopic internal drainage (EID) is accomplished under general anesthesia with fluoroscopy to identify the defect within the staple line.[18] One or more double pigtail stents (DPS) with a diameter of 7 or 10 French are left in place, with one end of the pigtail in the collection and the other end of the pigtail in the stomach, for several months.[18-20] Follow up endoscopy with fluoroscopy can be performed after one month for stent retrieval and to determine the presence of any residual leak. In patients with persistent leaks, stents are re-inserted.[18] Adverse events of EID include stent migration, seen in 46% of cases, minor gastric mucosal trauma, minor bleeding related to stent erosion, and major bleeding from nearby vessel

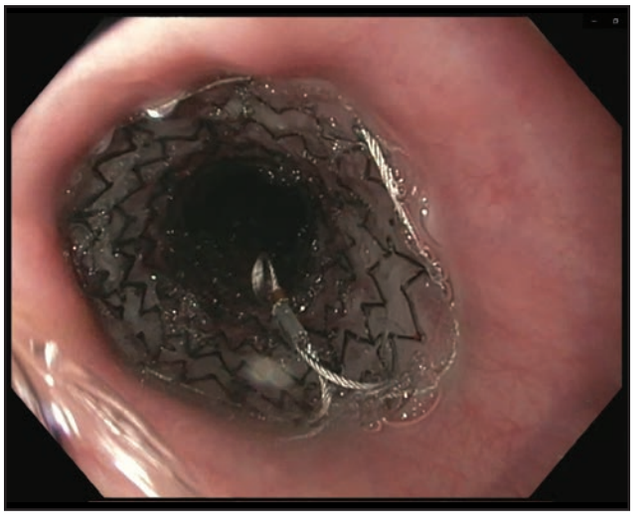

Figure 1b. Proximal end of a 19x100mm fully covered esophageal stent used to close the leak

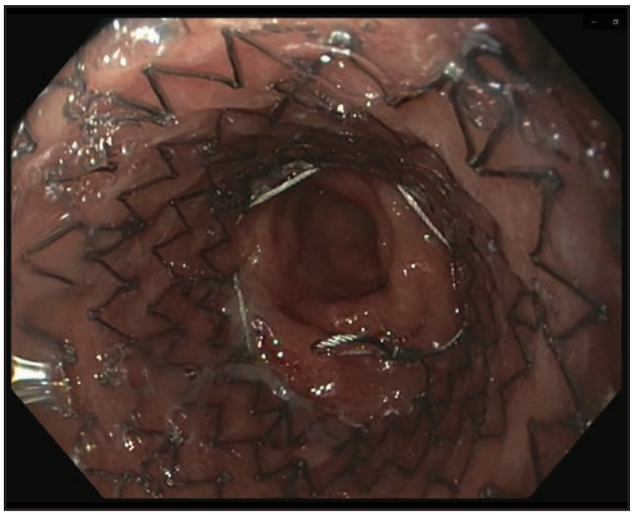

Figure 1c. Distal end of same stent, showing position within the sleeve itself

(i.e., splenic vessels).[18,20]

Endoscopic ultrasound (EUS) can also be utilized for endoscopic drainage of IAC. EUS allows determination of collection size, location, and avoidance of any intervening vessels. Drainage is accomplished by using a 19G needle, guidewire, over the wire puncture and deployment of multiple DPS or lumen-apposing metal stents (LAMS) or can simply be done via freehand technique.[21] LAMS can be exchanged at 1 month with DPS, if needed.[18]

Self-Expanding Metal Stents

SEMS placed is the most common endoscopic interventions used to manage GSL.[22] The objective of endoluminal stenting is to divert gastric contents from the leak site and to bypass any distal stenosis if present. The ideal stent should be long enough to cover the distal end of the sleeve, including the incisura. Predictors for success include male gender, higher pre-bariatric surgery BMI, and early stenting. (25 vs. 49 days).[23] (Figure 1)

The success of endoluminal stenting for GSL is between 70%-88%.[22,24,25] Additionally, successful treatment of GSL with SEMS can occur in 50% of patients after a single endoscopic session.[22] The most undesired adverse effect of SEMS for treatment of GSL is migration which has been demonstrated in 30-47% cases.[22,24] Anti-migratory mechanisms that can be utilized include endoscopic suturing of stents, longer stent length, and the use of endoscopic clips.[22] Other adverse events include stent intolerance, bleeding, foreign body obstruction, strictures, and mucosal hypertrophy. According to one group, the optimal time for stent removal is after six to eight weeks, and they proposed that shorter intervals may lead to incomplete leak closure and longer intervals may result in stent migration or mucosal hypertrophy leading to difficulty with stent extraction.[25] Still, in practice many different physicians have different opinions on the optimal stent indwell time and most patients receive individualized care.

Fully covered self-expanding metal stents (fcSEMS) have the advantage of being easily removable compared to partially covered self-expanding metal stents (pcSEMS).[26] However, fcSEMS have a high migration rate, reaching up to 26-67%.[27,28] The Mega stent (Taewoong Medical, Seoul, Korea) was designed as a proposed solution to overcome the problem of migration.[28] It is an ultra-large fully covered stent with braided mesh and increased flexibility which allows it to conform to post-bariatric anatomy. Its design can increase compression and coaptation against the luminal wall. Shehab et. al has demonstrated the success rate of Mega stents to be 82% with a migration rate of 18%.[28] Stenting can be combined with other treatment modalities, such as over-the-scope clips, which can directly close the wall defect.[29]

Through-the-Scope-Clips

Through the scope clips (TTSC) were initially designed for the treatment of gastrointestinal

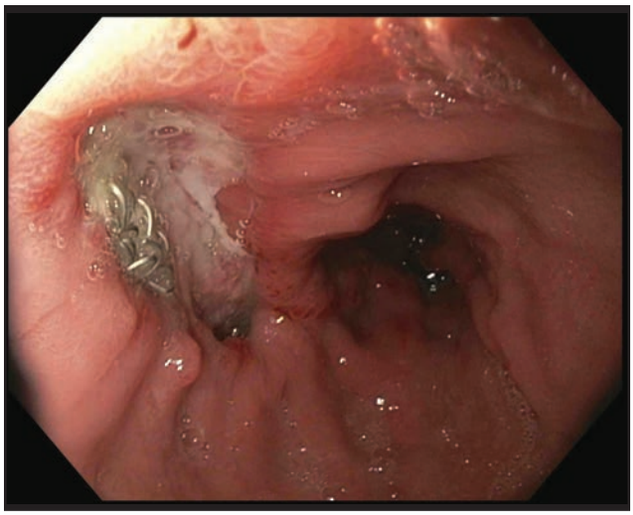

Figure 2a. Medium sized gastric sleeve leak along the suture line

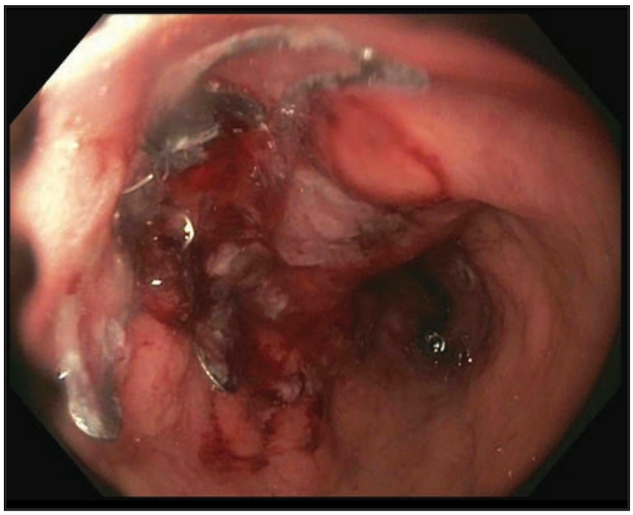

Figure 2b. Same gastric sleeve leak after closure via two adjacent over-the-scope-clips

bleeding. These clips can approximate the edges of a lesion and produce mechanical compression/hemostasis without creating tissue injury seen with thermal hemostatic devices.[30] TTSC have been reported as a modality for management of GSL.[31,32] Once the edges of the defect are approximated, one or more clips are deployed to close the defect. In a meta-analysis of 17 studies including a total of 98 patients treated with clips for GSL, 4 studies (13 patients) utilized TTSC and successful treatment was reported in 9 of 13 patients (69.2%).[32] This study is limited by the inclusion of very small number of patients. The use of TTSC can be considered in stable patients with small leaks, if the leak has failed endoscopic stenting, or is not amenable to stent placement.[31]

Over-the-Scope Clips

The over-the-scope clip (OTSC) is a mechanical clipping device designed to encircle, lift, and close endoscopic defects. These clips can achieve full thickness closure of luminal defects.[29] Suction or grasping can be utilized to help ensure proper placement over the entire defect. OTSC is a wall defect closure strategy for the management of GSL. A meta-analysis reported the use of OTSC in 85 patients across seventeen papers (98 patients) with a successful closure rate of 67.1%.[32] The use of OTSC is more efficient if IAC are drained prior.[33] OTSC-related adverse events occur in approximately 1.7% of cases.[34] These include jejunal stenosis, clip mis-deployment, and micro-perforation or free perforation if there is an underlying ulcer.[33,34]

As most GSL are located at the proximal end of the staple line, using an OTSC and its mounting system to maneuver and position the clip may be difficult, due to limited space. Successful deployment of an OTSC depends on the working space, size, orientation of the defect and surrounding tissue quality.[35] Using OTSC as a closure device to treat GSL should be considered for small- to medium-sized defects that can easily be accessed endoscopically. (Figure 2)

Tissue Sealants

Tissue sealants are adhesives that can be used to treat gastrointestinal leaks with initial data arising predominantly from use in Roux-en-Y gastric bypass (RYGB) patients. Such products are not readily available for endoscopists, which limit its use. The most commonly used sealant used for GSL closure is fibrin glue.[32] Fibrin glue mechanically occludes the stomach wall defect and aids in wound healing. It induces a cellular response to tissue damage by forming matrix-building strands which promotes neovascularization and fibroblast proliferation.[36] In a 2021 systematic review and meta-analysis, 10 case series comprising 63 patients with GSL were treated with fibrin glue. In 25 patients, the sealant was delivered endoscopically with a 100% success rate. The amount of glue ranged from 2-10 cc (median 4cc). Adverse events were reported in one study and included pain and fever in 3/24 patients.[32]

Another example of a tissue sealant glue is cyanoacrylate. Cyanoacrylate is a highly adhesive synthetic glue with antibacterial properties that can be utilized as a tissue sealant for GSL closure.[37] Only a small amount (0.5-4cc) is needed and it can be utilized in a wet environment. Despite its advantages, it's rapid polymerization results in poor mechanical properties such as low tensile strength and brittle nature, as well as risking damage to the endoscope.[37]

SurgiSIS (Cook Biotech Inc., West Lafayette, IA) is an acellular matrix biomaterial comprising porcine small intestine submucosa. It stimulates proliferation and formation of fibroblasts in the regions of wounds.[38] Strips of soaked SurgiSIS material are captured within a specially designed polypectomy snare and loaded into the endoscope outside of the patient. The scope is re-inserted after which the snare is used to place the material on the defect.[38] In a 2009 clinical trial, the rate of closure of 5 to 10mm wide fistulas in patients who had undergone prior gastric bypass was achieved in 20/25 patients (80%) after 3 sessions.[38] Further studies are necessary to determine the efficacy of SurgiSIS in patients with leaks from sleeve gastrectomy.

Endoscopic Suturing

Endoscopic suturing may be considered for closure of GSL when the defect size is large and other methods are less likely successful or have failed.[39] The OverStitch (Apollo Endosurgery Inc., Austin, TX) is an endoscopic suturing system, mounted over the scope, that places full-thickness sutures endoscopically. Choosing to perform endoscopic suturing for gastrointestinal leaks depends on the condition/viability/friability/etc. of the target tissue, the feasibility of placing the suture according to the shape of the defect, distance of the margins, and absence of IAC.[40]

The success of closing gastrointestinal leaks with endoscopic sutures was initially reported among RYGB patients.[41] Mukewar et al. reported 100% immediate clinical success rate for gastrointestinal fistula closure with endoscopic suturing, however only 40% sustained clinical success at 4 weeks after the index procedure.[39] There has been limited data which observed the use of endoscopic suturing in the management of GSL. Granata et al. reported 100% clinical success rate for gastric sleeve leak patients treated with OverStitch™ endoscopic suturing (6/6 patients).[40] In a 2022 randomized controlled trial, 5/15 patients with gastric sleeve leaks were managed with endoscopic suturing alone with 100% clinical success and no cases of recurrent gastric fistula during the 18 month follow up period.[3]

Septotomy

Septotomy is a relatively new procedure which allows for fluid drainage from an abscess cavity, formed secondary to a leak, into the stomach by dividing the septum that separates the abscess from the gastric lumen.[42] This division equalizes the intraluminal pressures by addressing the pressure gradient that drives gastric contents from the gastric lumen into the peri gastric collection.[43] These changes can result in abscess cavity collapse and healing can occur through secondary intention and epithelialization.[42,43]

This procedure is performed with a forward viewing gastroscope and the leak orifice is identified. If feasible, the abscess cavity is inspected and entered for irrigation.[42] Division of the septum can be performed using a needle knife, cutting knife, or other endoscopic tools.[43-45] Division of the septum is complete when the entire abscess cavity communicates with the gastric lumen, allowing drainage into the lumen of the stomach. In a small multicenter study of 9 patients with GSL treated via septotomy, the peri-gastric collections ranged in size from 3-10cm. The mean procedure time was 87 minutes and a mean of 2.3 procedures were required to achieve radiologic resolution.[43] Bleeding occurred in 3 patients and was managed successfully with TTSC. All patients achieved radiologic resolution. Diaz et al. demonstrated 5 patients with GSL who were treated with septotomy combined with sleeve dilation. Clinical success was achieved in 80% of patients (4/5), and no adverse events to the procedure were identified.[42]

Endoscopic Vacuum Assisted Closure

Endoscopic vacuum assisted closure (EVAC) is a negative pressure closure technique involving the placement of a porous polyurethane sponge in the abscess cavity at the leak site. In addition to drainage, it also increases local blood flow and

promotes granulation tissue formation.[46,47] The Endo-SPONGE system (B. Braun, Melsungen, Germany) allows for the insertion of an open-pored sponge into the leakage cavity using an endoscope. A drainage tube is connected to the sponge and suction is applied between 75 - 120 mm Hg depending on the size of the leak.[48] The sponge can be inserted in cavities from leaks with large openings (≥ 9mm). The sponge can be exchanged every 3 days via endoscopy.[48]

Studies have demonstrated 85-100% success with use of EVAC for treatment of GSL.[47-49] Markus et al. demonstrated a 90% healing rate with Endo-SPONGE with a mean treatment time of 17 days. GSL healing with use of a sponge was defined as wound cavity size smaller than 1 cm in radius and 2 cm in depth, after which EVAC was terminated.[48]

Cardiac Septal Occluders

Cardiac septal occluder devices (CSDO) are a novel, off-label, treatment option for the management of GSL. CSDO Amplatzer™ (St. Jude Medical, Plymouth, Minn) is a self-expandable double disk (double umbrella) closure device, made of nitinol and interwoven polyester, which promotes tissue in-growth while sealing fistulous tracts.[50] In a 2020 systematic review of 22 patients with GI fistulas, in 2 patients with GSL, technical success was 100% and clinical success (after one year of follow-up) was seen in 77%. Adverse events were reported in 5 patients and included migration and fistula enlargement. Further studies are needed prior to consideration of CSDO as the first line for treatment of GSL.[50]

CONCLUSION

Gastric sleeve leaks are common adverse events following sleeve gastrectomy. Management of these leaks should ideally occur in a multidisciplinary setting. An endoscopic approach should be considered as a less invasive option to surgery in patients without hemodynamic compromise, septic shock or peritonitis. The endoscopic armamentarium currently provides various options, and continues to expand, serving as a minimally invasive treatment avenue for the management of GSL. ■

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