Chapter 10
Endoscopic Treatment of Gastrointestinal Leaks

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Introduction

Gastrointestinal fistulas are abnormal communications between two epithelialized surfaces, typically between the gastrointestinal tract and another organ, including skin, abdominal cavity, or another organ in the body. Gastrointestinal leaks are serious complications, mainly related to postoperative anastomotic defects with substantial morbidity and mortality. When they become chronic, leaks and postoperative collections can evolve into fistulas [1, 2].

When the fistula is communicating with the airways, tracheoesophageal, bronchoesophageal, or bronchogastric fistulas may be due to malignant diseases, prolonged use of mechanical ventilation, or chronic leak after sleeve gastrectomy, for example. Due to the risk of recurrent aspiration pneumonia infection, these fistulas should be closed. Other types of fistulas are gastroduodenal, gastrocutaneous (for example, after removal of an endoscopic gastrostomy tube), and colonic fistulas. The latter can communicate with the vagina, bladder, and skin due to inflammatory pathologies, trauma, or a previous radiotherapy history [3]. After esophageal surgery, an anastomotic leak is a severe complication with an incidence ranging from 3% to 25% after esophagectomy or proximal gastrectomy. It can develop severe mediastinitis and sepsis with a mortality rate of 3–10% [4].

The process of managing fistulas and leaks is to identify their location, drain excess luminal content, prevent further leakage by diverting the flow of secretions or closing the originated defect. Surgical interventions can be complicated with high morbidity and mortality. In cases of leakage and fistulas in the postoperative period of a Gastric Bypass and Sleeve Gastrectomy, measures include surgical or percutaneous drainage, antibiotic therapy, and nutritional support. Surgical drainage can be indicated when there is peritonitis or perigastric abscess. Conservative management can be an option in stable cases with functioning and correctly located drain. Abscesses can be drained percutaneously or endoscopically [5]. Endoscopic management aims to resolve the three main causes of leakage: distal gastric stenosis, increased intragastric pressure, and the persistence of the fistulous path. Specifically, there may be a deviation of the sleeve gastrectomy gastric axis with increased intragastric pressure [5, 6].

Endoscopy is becoming the first line in treating fistulas due to the endoscopic arsenal for closing and covering the leaks and draining collections; this arsenal includes clips and self-expanding metallic prostheses, tissue sealants, in addition to "pigtail" prostheses and negative pressure therapy [1]. Treatment requires an individualized and multidisciplinary approach. Patient clinical stability, defect chronicity, defect characteristics (location and size of the fistula), and resource availability are essential aspects to be considered before the treatment [2]. Endoscopy is a tool that allows direct analysis of the leak orifice and visualization of complications such as strictures.

Classification

Fistulas can be classified according to anatomy, output volume, and etiology. Anatomically they can be internal or external, the latter being communication with the skin. Internal fistulae communicate between the GI tract and another organ, peritoneal space, or thorax. As for the throughput, they can be of high or low output [7].

Diagnosis

Fistulas diagnosis must be made through a good clinical history, physical examination, radiological findings, and endoscopic examination. A thorough clinical history should include recent surgical history, history of radiation therapy, and clinical signs of obstruction, infection, or abscess. The clinical evolution can lead to diarrhea, dehydration, weight loss due to nutrient malabsorption, fever, hypotension, and sepsis with leukocytosis. Tachycardia is usually the first signal of the clinical significance of a fistula causing infection and sepsis.

A physical exam is particularly helpful for external fistulae. The external fistula manifests itself with the discharge of secretion through the skin, abdominal pain, fever, obstruction, and leukocytosis. Enterocutaneous fistulas have a cure rate after surgery of 75–85%, with a mortality rate of 5–20% [8]. Adequate evaluation is critical to study the feasibility of endoscopic treatment. The affected tissue characteristics should be analyzed—whether macroscopically healthy, inflamed, or with a chronic or ischemic aspect. Fistulae can be further assessed using a combination of radiologic contrast imaging and endoscopic examination [2]. The fistula's origin and path must be identified to adequately treat the problem. Simple abdominal radiography can identify the presence of surgical clips and drains. Although barium is a standard contrast, its leakage can induce inflammation in the thoracic or peritoneal cavity. Therefore, water-soluble contrast is preferred when esophageal, stomach, or intestinal perforation is suspected. Fistulography can be performed with the injection of contrast into the cutaneous orifice in cases of external fistulas [7].

Ultrasonography and computed tomography with enterography can further evaluate the intestinal fistula and the presence of abscesses. Magnetic resonance cholangiopancreatography (MRCP) or endoscopic retrograde cholangiopancreatography (ERCP) is useful in biliopancreatic fistulas. Through ERCP, therapy can be performed—such as dilation of stenoses, sphincterotomy, or stent placement [8].

Endoscopic Treatment of Fistulae

Initially, clinical support is performed with venous hydration and control of hydroelectrolytic and acid-base disorders, antibiotic therapy, nutritional support, skin protection in enterocutaneous fistulas, and meeting each type's particularities of fistula [8]. It is critical to treat septic patients expediently, which may include surgical intervention in addition to endoscopic therapies as indicated.

Endoscopic treatment options for fistulae depend on the time of onset of the condition. For example, in cases of bariatric fistulas and leaks, chronicity is defined as:

– Acute phase: <7 days—stent or EVT
– Early phase: 1–6 weeks—stent + balloon dilation (rarely with associated septotomy) or EVT or PigTail drain
– Late phase: from 6 to 12 weeks: septotomy + balloon dilation and in some cases, stent placement or PigTail drain
– Chronic phase:> 12 weeks: septotomy + balloon dilation or Pigtail drain

There are several options for endoscopic treatment, which are outlined below.

Balloon Dilation

Distal obstruction is one factor that contributes to fistula formation. This is particularly true in cases of bariatric leaks. Distal obstruction increases luminal pressure, maintains patency of the fistula, and lengthens the time to healing. Thus, endoscopic dilation is a part of the therapeutic strategy. The dilations can be performed with hydrostatic or pneumatic balloons, the choice being dependent on the surgical technique that caused the intraluminal pressure change and the fistula. The dilations can be repeated until therapeutic success and must be individualized according to the patient's situation and the endoscopist experience.

Roux-En-Y Gastric Bypass (RYGB): Dilation with TTS-CRE balloons up to 15 mm for periods of 3 min [8]. Overdilation of a gastrojejunostomy can lead to weight gain, and so dilation past 15 mm is discouraged. For banded RYGB: If not previously removed, the narrowing caused by the external ring should be dilated with an achalasia balloon up to 30 mm because the CRE balloon is not strong enough

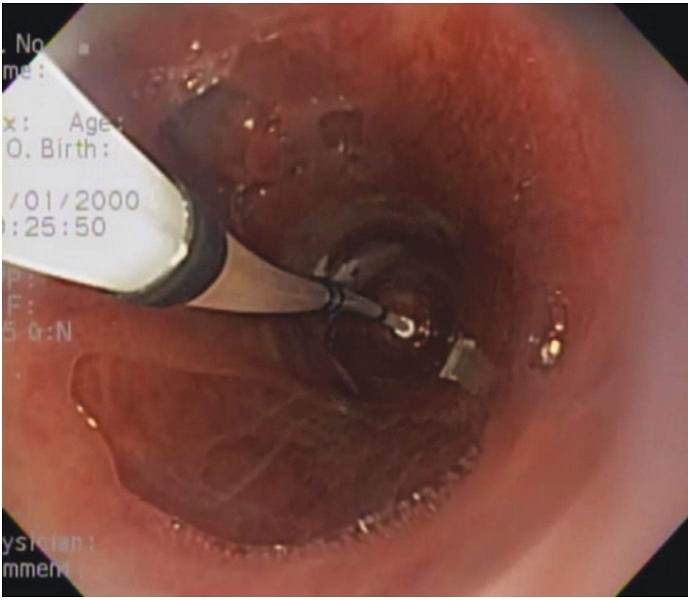

FIGURE 10.1 Endoscopic view with the achalasia balloon

to break the external ring or mesh. Endotracheal intubation and radiological guidance during dilation are advised [9]. Sleeve gastrectomy: the narrowing or corkscrew lumen should be dilated with a pneumatic achalasia balloon, beginning with 30 mm up to 35 mm. Endotracheal intubation and radiological guidance is advised [8] (Fig. 10.1).

Stricturotomy

This procedure is indicated for fistulas located at the angle of His. There is often a perigastric cavity with a septum and stenosis of the distal pouch. This cavity can contain pus and secretions and drains placed previously and must be washed and cleaned previously. The septum between the perigastric cavity and the proximal gastric pouch is then incised with a Needle Knife™ or similar or using argon plasma, then communicating the two cavities. In a gastric bypass, the gastrojejunal anastomosis stenosis is dilated with a hydrostatic balloon for about 3 min [9]. In sleeve gastrectomy cases in which the pouch's diameter is smaller than the esophagus and stenosis is present, a pneumatic dilation of up to 30 mm can be added [8].

Endoclips

Endoclips have been used effectively to close acute perforations, with a controversial role when it comes to closing fistulas/leaks. Over-the-scope (OTS) and Through-the-scope (TTS) clips are available on the market. The TTS clip has several sizes and models, inserted through the endoscope channel, and can be reloadable or single fire clips. The single-use allows reopening and repositioning several times before the final release. However, these clips limit the pressure applied to chronic wounds, so, in tissue with necrosis or inflammation, the closure may not be adequate [2].

The OTS, on the other hand, is a clip in the shape of a "bear trap" mounted on the endoscope tip, closing the defect thickness up to 2 cm. Some of those available are OTSC (Ovesco Endoscopy AG, Tuebingen, Germany) and Padlock (US Endoscopy/Steris, Mentor, Ohio). However, despite performing a mechanical compression with full-thickness closure, they pose a challenge in cases of removal in the event of a technical failure in placement, with a high recurrence rate of fistula—which could interfere in a future surgical procedure. Some professionals use argon in the edges of the fistula and the surrounding mucosa to ensure a more efficient grip of the clip [2].

Unfortunately, part of the studies showed a failure of the OTS clip system in treating fistulas in an average period of 2 weeks (ranging from 5 days to 4 weeks) after treatment. This fact may reflect the lesions' chronicity and suggest that merely closing the fistulous orifice without treating the underlying cause may not be sufficient for therapeutic success. Thus, the OTS proved to be promising in immediate closings of iatrogenic perforations, close larger defects of up to 3 cm, with a higher clinical success rate compared to closing the fistulas [3].

A systematic review of the OTS clip's use analyzed the effectiveness and safety of this method in closing fistulas and leaks after vertical gastrectomy. After selecting ten studies, 195 patients with fistula/leak after sleeve were included. 65.3% of patients needed a clip to close the lesion. From complications, leakage was reported in five patients (9.3%), and migration, stenosis, and loosening of the OTS clip in one patient. 86.3% of patients ($n = 63$) had successful wound closure, showing that the system is a promising treatment. Studies with a larger sample are necessary [10].

Self-Expanding Luminal Stent

The endoscopic stent comes as an alternative to occlude the defect and deflect the luminal content, aiding in the mucosa's healing, allowing an early oral diet, and reducing the risk of stenosis [2]. The use of the stent avoids the morbidity of reoperation and the need for long-term parenteral nutrition [11]. Before its use, it is necessary to drain collections for successful closure and avoid sepsis risk. Traditional esophageal stents are designed for esophageal strictures secondary to malignancy and are used off-label for bariatric leaks and stenoses. They have a diameter ranging from 16 to 23 mm and a length of 6–15 cm. New bariatric stents have been developed and customized for vertical gastrectomy, which can reach 240–280 mm in length, with a maximum diameter of 30 mm and promising results [6]. Stents can be plastic or metallic, fully or partially covered. Fully covered stents are removed easily but have more chance of migration, especially when there is no associated stenosis. Although more challenging to be removed, already partially covered stents have less chance of migration, with mucosal hyperplasia occurring in the uncovered extremities, which favors its fixation [2, 12]. This removal difficulty may be associated with complications such as perforation. The technique of placing a fully covered prosthesis on top of the partially covered one causes tissue necrosis, allowing its removal less traumatically 1 week later.

After the initial leak control, the stent is removed in post-bariatric complications even if complete orifice closure is not achieved. When necessary, endoscopic treatment continues through septotomy, stenotomy, and balloon dilations, which will lead to complete closure of the fistula. Internal drainage with pigtail drains has been successfully described in some initial cases, especially in smaller leaks (<10 mm) with associated perigastric abscess [5]. Most post-bariatric studies have a success rate of 70–85%, in many cases, part of a strategy that is not limited to the placement of a single stent [12].

In a multicenter study by Neto et al. [6] in which 87 patients in the postoperative period of bariatric surgery underwent stent implantation, only 19.5% of patients had stent migration, mainly in the vertical gastrectomy, and these were repositioned or replaced; only 3.4% ($n = 3$) of the patients had their stents removed due to intolerance. 80.5% of the cases were resolved without additional procedure, demonstrating the usefulness of stents in post-bariatric complications [13]. Another study of luminal stenting after bariatric leak evaluated 58 patients (50 with leak and 8 with stenosis and obstruction after bariatric surgery). They found success in treating 72% with failure in 16 patients, 14 of which were treated endoscopically with other procedures and two with surgery. Stent migration occurred in 19% of cases. Luminal self-expanding stenting is one of the early treatment options of post-bariatric fistulas, leaks, and strictures [14] (Figs. 10.2, 10.3, 10.4, 10.5, 10.6 and 10.7).

In parallel, another promise in the treatment using prostheses is the cardiac septal defect occluder (CSOs)—

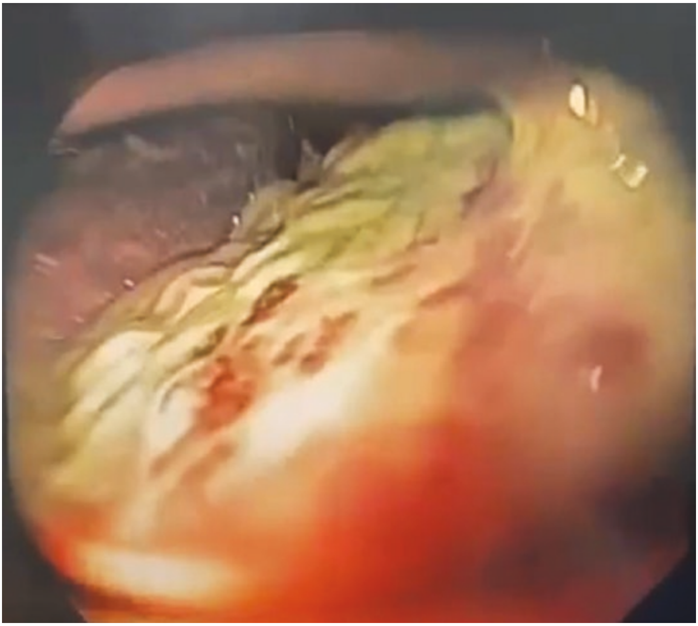

Figure 10.2 Endoscopic image in the abdominal cavity

Amplatzer™—a double disk-shaped prosthesis that promotes occlusion of the fistulous orifice and tissue growth, which can be recaptured and repositioned during its placement. The device allows addressing irregular fistulas with edema, less susceptible to suture or cut. The disk has a variable diameter (9–54 mm), a variable waist (4–38 mm), and close ventricular septal defects and other defects such as aortic pseudoaneurysms. Reports demonstrate its use in closing bronchopleural and gastrointestinal fistulas [1]. There are two types of CSOs, both of which can be used in gastrointestinal defects. However, the system has a maximum length of 80 cm, which cannot be used by most endo-

FIGURE 10.3 Fistulae orifice

scopes. One possible technique is to separate the CSO from its delivery system and use it with an adapted bile catheter long enough to be used through a therapeutic endoscope with a pediatric biopsy forceps aid [1]. In a systematic review by De Moura et al. [1], out of 19 selected studies, technical success was achieved in all cases. The authors considered the closure successful in 77.27% of the fistulas, with disagreement in two cases considered successful by the authors of the selected articles [1]. Due to the scarce literature composed of case reports, this review draws attention to the potential use of these CSO devices successfully in gastrointestinal fistulas.

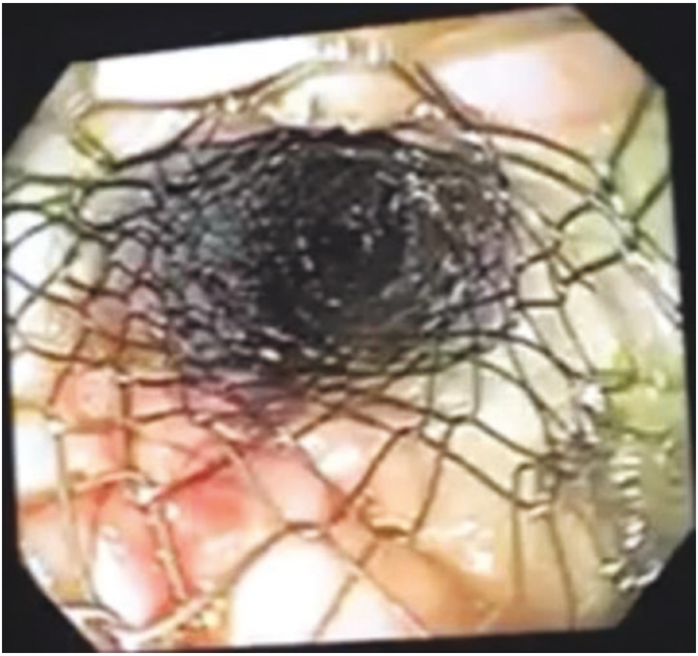

FIGURE 10.4 Stent placement

Figure 10.5 Leak healing after mega stent removal

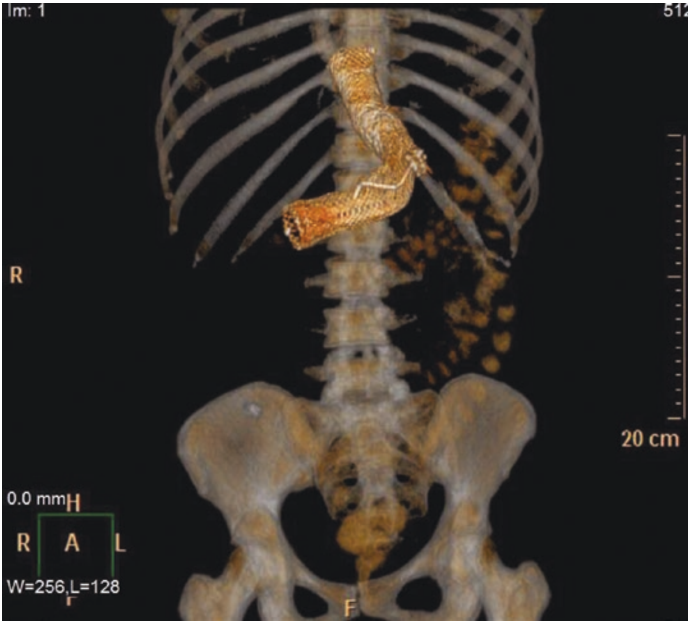

FIGURE 10.6 Mega stent in CT 3D view

Figure 10.7 Mega stent after endoscopic removal

Endoscopic Internal Drainage

Internal endoscopic drainage is performed with the implantation of one or more pigtail plastic stents placed through the leak orifice to drain collections and occlude the leak orifice, thus draining the collection internally and allowing an early oral diet with subsequent re-epithelialization of the fistula. It is essential in deciding the size and model of the stent to evaluate with a study of contrast and orifice and the cavity, including with endoscopic exploration [2]. This type of treatment is useful in late fistulas and can be a bridge to other endoscopic treatments and a unique modality [12] (Fig. 10.8).

Figure 10.8 Pigtail drainage

Endoscopic Suture

The OverStitch endoscopic suturing system (Apollo Endosurgery, USA) is an endoscopic suture platform that performs full-thickness closure of gastrointestinal tract defects with non-absorbable or resorbable sutures. It requires technical experience and specific training. It has been used for defect closure in acute and chronic leaks, as well as stent fixation to prevent migration [2]. It allows the closing of larger defects as a compared endoscopic clip (more than 2 cm). The device allows the performance of continuous or intermittent suture patterns without the need to remove the endoscope between sutures. In a series of post-bariatric fistulas, 9% of cases were total closure using the technique; however, reopening has been observed in up to 65% of cases [15]. Its usefulness in perforations and fistulas still needs further studies.

A systematic review using endoscopic suturing in different contexts evaluated the use in 24 patients with fistulas or leaks, most of them female patients and without risk factors for poor wound healing. All defects were less than 5 cm in diameter. There was a technical failure in closing the coloanal fistula, and most of the closures were fistulas in endoscopic revisions of gastric anastomosis, with moderately high clinical success. Failures occurred in fistulas with cutaneous or bladder involvement, and all esophageal closures were successful. When compared to other studies, slightly lower success rates may be due to the complexity of some treated fistulas, such as enterocutaneous fistulas [16].

Endoscopic Vacuum Therapy (EVT)

It is a minimally invasive technique and can be used in rectal and esophageal surgery, such as anastomotic defects. It consists of polyurethane foam that can drain secretions when connected to a suction system, producing a continuous vacuum therapy. With continuous drainage, granulation tissue is formed and re-epithelialization with consequent closure by the second intention. Mechanical cleaning of the site occurs through the effect caused by negative pressure, reducing microorganisms and interstitial edema, with improved microcirculation. In the colon and rectum, it may favor early closure. Other uses include leaks in bariatric, pancreatic, and duodenal perforations after retrograde cholangiopancreatography (ERCP) [2]. Foam replacement is performed every 2–4 days, with promising results in major gastroesophageal surgeries, requiring further studies in cases of post-bariatric complications [12].

To assemble the device for placement, a nasogastric tube is inserted through the nose and removed through the mouth. Then, the distal end with holes is trimmed. The polyurethane sponge is sutured in the remaining tube, made slightly smaller than the fistulous orifice, promoting collapse and closure of the fistula. After its placement, continuous negative pressure of 100–180 mmHg is performed with a vacuum pump aid. The sponge is changed every 3–4 days, depending on the injury. Some authors suggest exchanges every 1–2 weeks, and further studies should be carried out to define the ideal time interval between exchanges [17].

Endoscopic negative pressure therapy can be performed in two ways: intracavitary and intraluminal. If it is intracavitary, the sponge is inserted through the defect into the extraluminal wound's cavity. This cavity is emptied continuously and drained under negative pressure. If it is intraluminal, the sponge is placed directly over the lumen [18].

Leeds et al., in a study with E-Vac therapy performed in nine patients with leaks after sleeve gastrectomy, found a success rate of 89%. The listed limitations of therapy included the need for multiple interventions to change the vacuum sponge (10.5 procedures on average) and the use of jejunostomy or total parenteral nutrition during treatment. E-Vac is an option in severe ICU or defects with no possibility of stent placement or internal drainage [11, 19].

A retrospective study by Min et al. [17] analyzed 20 patients with esophageal leak after esophagectomy treated with EVAC. Treatment failure was defined as no improvement of the anastomotic defect after treatment with EVAC, requiring additional therapeutic modalities, or death due to the leak. Overall there was a 95% success rate. There was a 35% rate of stenosis of successful treatments, with associated dysphagia and treated with dilation. There was an average of 5 interventions per patient. Limitations include small sample size and no comparison with other therapeutic modalities [17].

Tissue Sealant

Glues have been used successfully in low-flow leaks and fistulas. The most common are fibrin and cyanoacrylate. The fibrin glue is utilized in a double-lumen catheter and forms a flexible and absorbable tissue, simulating an initial stage of blood clotting and healing, acting better in dry areas. In that case, it is recommended to eliminate purulent material or perform mucosal ablation before use. On the other hand, cyanoacrylate is a synthetic glue that polymerizes after contact with moisture, necrosing the tissue and causing an inflammatory reaction, thus acting as a foreign body, helping in the healing of the tissue [2].

De-epithelialization of the tissue around the fistula should be performed before applying the sealant. This can be done using a biliary cytology brush or through low potency argon plasma coagulation. To apply the sealant, a double-lumen catheter is inserted to avoid the adhesion of the sealant to the endoscope [15].

Conclusion

Endoscopic treatment for leaks and fistulas is safe and efficacious. It is commonly the first line of treatment in post-bariatric surgeries when a bariatric endoscopist is available.

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