Surgical Endoscopy (2021) 35:2715–2723
https://doi.org/10.1007/s00464-020-07702-5

Endoscopic management of refractory leaks and fistulas after bariatric surgery with long-term follow-up

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Received: 16 March 2020 / Accepted: 9 June 2020 / Published online: 18 June 2020

Abstract

Background In selected cases of post-bariatric leaks and fistulas, endoscopy is an initial treatment modality. Management can be complex and require multiple endoscopic sessions with varying degrees of success. Our aim was to describe our tertiary care experience on endoscopy management of refractory post-bariatric leaks and fistulas.

Methods Patients with post-bariatric leaks and/or fistulas who failed an initial endoscopic intervention were included. Endoscopic treatments were classified into four strategies: (1) closure management, (2) active drainage, (3) passive drainage, and (4) plugging. Clinical success and adverse events were assessed.

Results A total of 25 patients (mean age = 45.3 ± 11.8 years and 56% female) were included. Clinical success was achieved in 20 patients (80%) with a mean of 3.0 ± 1.5 procedures and a median time to healing of 114.5 (53–210.3) days. Closure and plugging were the main successful strategies used for early and acute leaks/fistulas, while drainage was for late and chronic leaks/fistulas. Adverse events were observed in 13 patients (52%) with one serious adverse event. Patients with fistulas had a lower success rate (72.2% vs. 100%, $P = 0.052$). Of those with clinical failure ($n = 5$), four underwent reconstructive surgery, eventually led to success in 3 patients. The other one died of septic shock related to a complicated fistula.

Conclusions Complex multi-modality endoscopic management ultimately achieved clinical success in most cases of refractory leaks/fistulas post-bariatric with an acceptable safety profile. However, a close follow-up to detect the development of long-term failure is warranted. These patients should be referred to a specialized bariatric center with expertise in bariatric endoscopy and surgery.

Keywords Bariatric surgery · Fistula · Leaks · Roux-en-Y gastric bypass · Sleeve gastrectomy

In response to the obesity pandemic, bariatric surgery has been increasingly utilized as the gold standard therapy for weight loss. Sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB) are now the two most commonly performed procedures in the USA [1]. Although both offer not only excellent and durable weight loss but also the resolution of several obesity-related comorbidities, surgery-related adverse events are not uncommon and can be life-threatening [2, 3]. A post-surgical leak is one of the most serious adverse events after bariatric surgery. It is defined as a breach in the bowel wall, which is mostly located at the upper gastric staple line for SG and the gastrojejunal anastomotic line for RYGB [4–6]. The incidence of leak after SG and RYGB was 0.7% and 0.8%, respectively, based on a longitudinal cohort of 28,616 patients [7]. A leak can evolve into a fistula with an epithelized tract if it does not heal in a timely manner. Fistulas represent one of the most challenging conditions for endoscopic treatment [8–10]. Clinicians will increasingly encounter these adverse events despite advanced surgical techniques due to the rising number of bariatric surgical procedures.

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00464-020-07702-5) contains supplementary material, which is available to authorized users.

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The goal of achieving closure of the leaks/fistulas requires a multidisciplinary team approach with the use of multiple treatment modalities, including endoscopic, surgical, radiological, and medical management to control infection, improve nutrition, and enhance drainage [4, 11]. Due to technological advances, endoscopic treatment has become a common initial approach in stable patients [4]. Several endoscopic devices and techniques are available, for example, enteral stents, clips, endoscopic suturing, biologic glue/tissue sealants, drains, septotomy, and balloon dilation. These different modalities provide varying degrees of treatment success ranging from 63 to 100% [8, 9, 12–16]. Not all leaks/fistulas are created equal; however, there is no standard treatment algorithm given a lack of randomized controlled trials comparing these different modalities and the heterogeneity in patient populations and treatment modalities used in retrospective studies. The American Society for Metabolic and Bariatric Surgery position statement did not endorse one endoscopic modality over another [4]. Previous studies have proposed different management algorithms [11, 17, 18].

None of the studies have specifically addressed complex endoscopic management in refractory cases after failing an initial endoscopic effort. This study aimed to describe the efficacy, safety, and long-term outcomes of endoscopic management in patients with refractory post-bariatric leaks and fistulas in a single referral tertiary care center and treatment modalities used for success in each subtype of leaks/fistulas.

Materials and methods

This was a retrospective descriptive study from Mayo Clinic Rochester (Minnesota, USA). This study was approved by the Mayo Clinic Institutional Review Board (IRB 19-005570).

Study population

Patients who developed refractory leaks and/or fistulas after bariatric surgery and failed an initial endoscopic intervention requiring further endoscopic treatment from January 2005 to June 2019 were included. Patients who were still undergoing endoscopic management of leaks/fistulas at the time of the study; had a gastro gastric fistula that was not consecutive to leak; had no follow-up data of more than 60 days after the last endoscopic intervention were excluded from the study. All patients were followed until the last clinic visit or death by chart review. Leaks and fistulas were diagnosed by upper gastrointestinal contrast (UGI) study, computed tomography (CT) with oral contrast, and/or endoscopy with fluoroscopy. Leaks were defined as a disruption of the surgical anastomosis or the surgical staple line. Fistulas were defined as communication between two epithelialized surfaces.

Data collection

- *Baseline and surgical characteristics* age, gender, race/ethnicity, body mass index (BMI), type of bariatric surgery, smoking, history of diabetes mellitus, and serum albumin
- *Characteristics of leaks/fistula* time from bariatric surgery to occurrence [Acute (postoperative 1–7 days), early (1 to 6 weeks), late (6 to 12 weeks), and chronic (> 12 weeks)] based on the International Sleeve Gastrectomy Expert Panel Consensus [19], site of leaks/fistulas (proximal stomach, distal stomach, and gastrojejunal anastomosis), types of fistulas, size of the fistula's orifice (< 1 cm or ≥ 1 cm), presence of intra-abdominal fluid collection (no collection, < 5 cm or ≥ 5 cm), and gastric stenosis. Of note, chronic leak/fistula in this manuscript are referred to as a chronic fistula.
- *Endoscopic management* number of endoscopies, endoscopic techniques and devices used, and adverse events from endoscopic procedures
- *Other treatment* total parenteral nutrition, enteral nutrition, surgical re-intervention before endoscopic treatment, and percutaneous drain
- *Outcomes* healing, recurrence, and mortality

Procedures

A multidisciplinary care team including specialists from gastroenterology, bariatric surgery, interventional radiology, thoracic surgery if indicated involved in treatment decisions. Endoscopic treatments were classified into four main strategies as follows: (1) closure and covering; (2) active internal drainage; (3) passive internal drainage; (4) plugging. Figure 1 shows the four treatment strategies. Figure 2 demonstrates the fistula plug. Patients could receive more than one treatment strategy per endoscopy session. Other endoscopic modalities used included septotomy and balloon dilation to enhance adequate drainage. All endoscopic procedures were performed under general anesthesia. As we are a tertiary care center, all patients were referred to our center, and some patients were referred after initial management in their local hospitals. Unstable patients required an early operative re-intervention to manage intra-abdominal sepsis.

The first strategy, "closure and covering" consisted of enteral stents, suture, and clips to either close or cover the defect; the stents could also treat the distal stenosis. Different types of stents and clips have been used during the period of the study. They were placed either through the scope or over-the-scope. The usual time of stenting

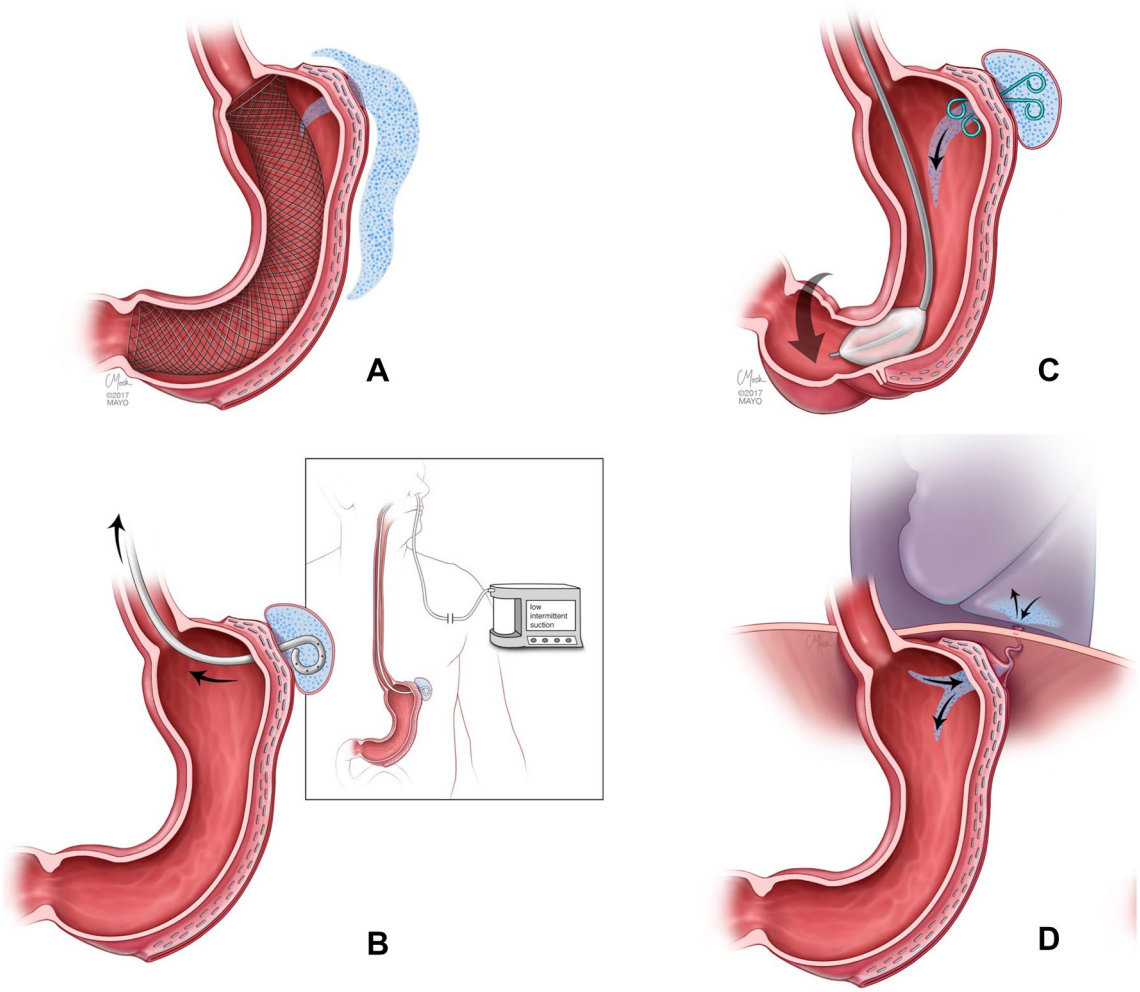

Fig. 1 **A** Closure management strategy with metallic stent in place. **B** Passive drainage strategy with 2 pigtail drains. **C** Active drainage strategy with nasocystic drain on low intermittent suction. **D** Plugging strategy of gastropleural fistula. Used with permission of Mayo Foundation for Medical Education and Research. All rights reserved

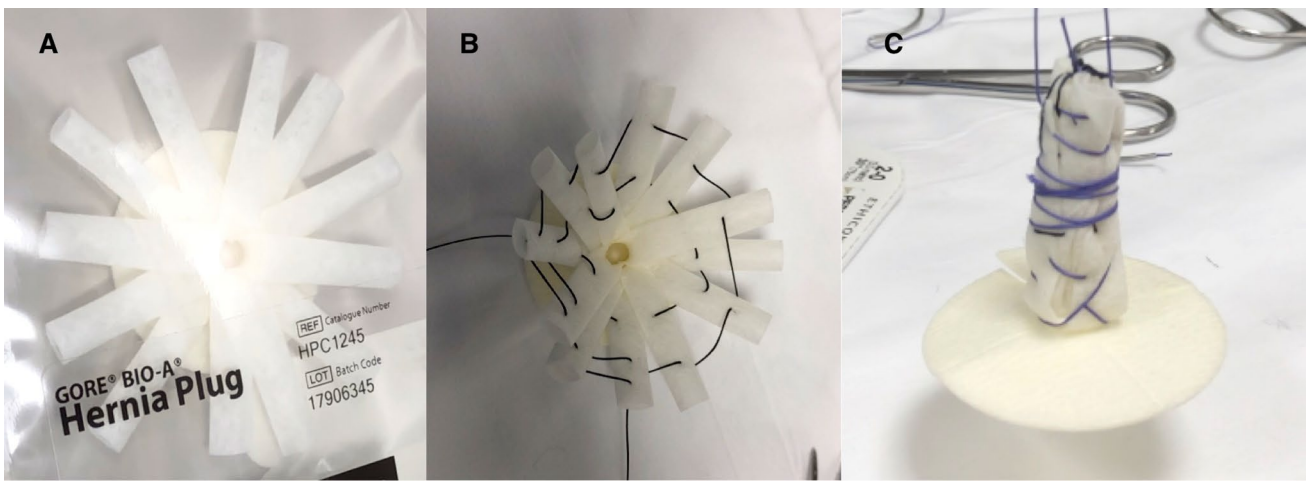

Fig. 2 Fistula plug before assembled (**A** and **B**) and after assembled (**C**)

was 4 to 6 weeks before removal and replacement if indicated. Suturing was performed using an endoscopic suturing device (Overstitch; Apollo Endosurgery, Austin, TX). The second strategy, "active drainage" consisted of nasocystic drainage and trans-prosthetic retrograde internal endoscopic drainage (TRIED). Nasocystic drainage is a short-term drain with active intermittent suction. The TRIED procedure is a full-length port with a locking loop drain that was placed in the fluid collection and was connected to a low intermittent suction drain via jejunostomy. The third strategy, "passive drainage" consisted of pigtail drains that were used for long-term drainage for several months. The aim of drains was to induce re-epithelialization, stimulate tissue ingrowth, and ultimately close the defect. The fourth strategy, "plugging" involved the use of biologic glue/tissue sealants and Amplatzer cardiac septal defect occluder to incorporate and fibrose a small residual collection, sinus tract, or fistula.

Patients usually underwent a UGI study the next day. If no leakage, patients then started on a liquid diet and slowly advanced. They were followed with clinical symptoms, UGI study, and/or CT at an interval based on the decision of the multidisciplinary care team to reassess the leaks/fistulas and fluid collection and helped guide treatment decisions.

Assessment of clinical outcomes

Clinical success was defined as a complete resolution of the leak or fistula on imaging (CT with oral contrast or UGI study) and/or endoscopy with the use of a guidewire and fluoroscopy. After the resolution of leaks/fistulas, patients were followed in our bariatric clinic as part of routine visits. Some patients were referred back to their local institutions. For patients with clinical failure, surgical revision was offered in those who had persistent symptoms. All procedure-related adverse events were recorded and graded based on the Cotton Lexicon for adverse events in gastrointestinal endoscopy [20]. Serious adverse events were defined as adverse events that resulted in surgical intervention, unplanned or prolonged hospitalization, intensive care admission > 1 night, or persistent disability. The duration of treatment was defined as the length of time from the first to the last endoscopic treatment. Time to healing was defined as the length of time from the first endoscopic treatment to healing. Time to recurrence was defined as the length of time from healing to recurrence. The duration of follow-up was defined as the length of time from the last endoscopy to the last clinic visit or death.

Statistical analysis

Data were expressed as mean and standard deviation for continuous variables with normal distribution or median and range for skewed data and proportions for categorical variables. Continuous data were compared using an unpaired Student t-test and nonparametric Mann–Whitney *U* test when appropriate. Categorical data were compared using a Chi-square test or Fisher's exact test when cells had expected counts of less than 5. *P*-value of less than 0.05 was considered significant. The analysis was performed using JMP Pro 14.1. (SAS Institute, Cary, NC).

Results

Baseline characteristics

From 2005 to 2019, a total of 25 patients with refractory leaks and/or fistulas were included with a mean age of 45.3 ± 11.8 years and 56% female. Thirteen patients (52%) had SG, 10 patients (40%) had RYGB, and 2 patients (8%) had biliopancreatic diversion with duodenal switch for obesity. All were primary bariatric operations. The majority were non-Hispanic whites (88%), non-diabetes (72%), and never smokers (60%). The baseline serum albumin was 3.1 ± 0.9 g/dl. Most patients received either enteral feeding (36%) or parenteral nutrition (40%) as part of their endoscopic management. Table 1 outlines the baseline patient and surgical characteristics.

Leaks and fistulas

A majority of the leaks/fistulas were chronic (48%). They were most commonly localized in the proximal stomach (72%). They were divided into acute ($n = 8$), early ($n = 3$), late ($n = 2$), and chronic ($n = 12$). Fistulas were present in 18 patients (72%). Gastrocutaneous fistula ($n = 9$, 36%) was the most common type, followed by gastrobronchial fistula ($n = 4$, 16%), gastrocolonic fistula ($n = 2$, 8%), and gastropleural fistula ($n = 2$, 8%). Fluid collection and distal stenosis were present in 68% and 48% of patients, respectively. Characteristics of leaks and fistulas are described in Table 2.

Treatment outcomes and adverse events

The median time from bariatric surgery to leaks/fistulas was 58 days (5–465.5 days). Preceding endoscopic intervention at our institution, 14 patients (56%) had early abdominal exploration, 21 patients (84%) had percutaneous drain placement for infectious control and management of leaks and 6 patients (24%) had single or multiple endoscopic interventions at outside institutions while the remaining 19 patients (76%) had their first failed intervention at the study institution. Clinical success from a combination of different strategies was achieved in 20 patients (80%) with the mean number of endoscopic procedures per patient of 3.0 ± 1.5

Table 1 Baseline characteristics

Characteristics ($n=25$)	Mean ± SD or n (%)
Female	14 (56%)
Age	45.3 ± 11.8 (Range 26–71)
BMI at baseline (kg/m^2)	46.7 ± 9.9
BMI at complication (kg/m^2)	35.1 ± 12.6
Race	
Non-Hispanic white	22 (88%)
Hispanic white	3 (12%)
Type of bariatric surgery	
SG	13 (52%)
RYGB	10 (40%)
BPD-DS	2 (8%)
Smoking	
Never smoker	15 (60%)
Former smoker	7 (28%)
Active smoker	3 (12%)
Serum albumin (g/dL)	3.1 ± 0.9
Diabetes	7 (28%)
Nutrition	
Enteral nutrition (oral intake)	6 (24%)
Nutritional support	19 (76%)
Enteral feeding	9 (36%)
Parenteral nutrition	10 (40%)
Parenteral nutrition > 90 days (of 10 patients)	4 (40%)

BMI body mass index, *BPD-DS* biliopancreatic diversion with duodenal switch, *RYGB* Roux-en-Y gastric bypass, *SG* sleeve gastrectomy

Table 2 Characteristics of leaks and fistulas

Characteristics ($n=25$)	N (%)
Leak/fistula classification	
Acute (< 7 days)	8 (32%)
Early (1–6 weeks)	3 (12%)
Late (6–12 weeks)	2 (8%)
Chronic (> 12 weeks)	12 (48%)
Location of leaks/fistula	
Proximal stomach	18 (72%)
Distal stomach	2 (8%)
Gastrojejunal anastomosis	4 (16%)
More than one location	1 (4%)
Presence of fistula	18 (72%)
Type of fistula	
Gastropleural	2 (8%)
Gastrobronchial	4 (16%)
Gastrocutaneous	9 (36%)
Gastrocolonic	2 (8%)
Gastrogastric	1 (4%)
Fistula size	
< 1 cm	13 (72.2%)
≥ 1 cm	5 (27.8%)
Fluid collection	
< 5 cm	10 (40%)
≥ 5 cm	7 (28%)
No walled-off collection	8 (32%)
Distal stenosis	12 (48%)

and the median duration of treatment of 60 days. Most patients required at least two strategies (76%). Other endoscopic modalities used included balloon dilation (36%) and septotomy (8%) to facilitate internal drainage. The median time to healing was 115 days. Of patients with clinical success, 4 patients (19%) had recurrent leaks/fistulas with the median time to recurrence of 484 days. Of these with recurrence, two achieved healing with percutaneous drain, and the other two achieved healing with endoscopic treatment. The median duration of follow-up was 437 days. Table 3 outlines interventions and treatment outcomes.

Serious adverse events occurred in one patient who developed peri-procedural cardiac arrest, which was successfully resuscitated. Other adverse events were mainly related to enteral stenting. Of all 41 endoscopic stenting procedures, there were 9 events (22%) of stent-induced ulceration, 6 events (14.6%) of stent migration, and 1 event (2.4%) of esophageal tear during stent removal. Stent migration was more common in non-sutured stents (3/15, 20%) than sutured stents (3/26, 11.5%) with the OverStitch device. For adverse events not related to enteral stents, one patient had an esophageal tear during the withdrawal of the Overstitch device. None of the patients required endoscopic or surgical interventions for their adverse events.

Endoscopic treatment strategies

In patients with early and acute leaks/fistulas (< 6 weeks, $n=11$), clinical success was achieved in 100%. The main strategies that led to treatment success were closure management, followed by plugging ($n=6$) and closure management ($n=4$). In patients with late and chronic leaks/fistulas, clinical success was achieved in 71.4% (10/14 patients). The common themes of treatment strategies used for this group were passive drainage and active drainage (Fig. 3).

Endoscopic treatment failure

Of those 5 patients who failed to achieve healing endoscopically, all had fistulas. Further treatments are detailed in Supplementary file 1. Four of them underwent reconstructive surgery as follows: two patients had takedown of the fistula followed by bypass surgery leading to resolution

Table 3 Interventions and patient outcomes

Interventions	*N* (%), median (IQR) or mean ± SD
Reoperation prior to endoscopic treatment	14 (56%)
Percutaneous drain	21 (84%)
Outside endoscopy	6 (24%)
Closure management	5 (20%)
Internal drainage	1 (4%)
Number of endoscopic procedures	2 (2–3) 3.1 ± 1.6
Duration of treatment (days)	60 (33–188)
Total number of treatment modalities used	
1	6 (24%)
2	14 (56%)
3	3 (12%)
4	2 (8%)
Number of stenting procedure	41
Sutured	26
Not sutured	15
Other endoscopic modalities used	
Dilation	9 (36%)
Septotomy	2 (8%)
Clinical success	20 (80%)
Time from treatment to healing (days)	114.5 (53–210.3)
Recurrence after healing	4 (19%)
Time from healing to recurrence (days)	484 (224–763)
Duration of follow-up (days)	437 (276–1070)
Mortality	1 (4%)

of the fistula. One patient had fistula takedown with primary closure but had a persistent fistula that was successfully treated with a subsequent surgery with fistula takedown and bypass surgery. The fourth patient died of septic shock related to their fistula and overwhelming sepsis. The fifth patient was treated conservatively with medications for symptomatic control.

Leaks with versus without fistulas

Eighteen patients were classified as refractory leaks with fistulas, while 7 patients had leaks without fistulas. Both groups had comparable baseline characteristics but patients with fistulas had a higher rate of diabetes (38.9% versus 0%, $P = 0.13$) and lower BMI (33.9 versus 39.1 kg/m^2, $P = 0.10$). The treatment success was lower in those with fistulas (72.2% versus 100%, $P = 0.052$). The duration of treatment (106 days versus 38 days, $P = 0.84$) and time to healing (136 days versus 69 days, $P = 0.23$) were numerically longer in those with fistulas (Supplementary file 2).

Discussion

With a rise in the number of bariatric procedures performed, post-bariatric leaks and fistulas will continue to increase, which incur significant morbidity and non-negligible mortality. Endoscopy is often a preferred approach in stable patients with a leak or fistula not readily amenable for surgical repair. The treatment has remained a challenge with no standardized algorithm. Our study aimed at providing more insight into treatment efficacy and outcomes of refractory cases and treatment modalities used for success in each subtype of leaks/fistulas.

Our study demonstrated a treatment success rate of 80%, which is in line with previous studies despite enrolling only refractory cases [8, 9, 12–16]. The use of combined endoscopic modalities in our cohort could contribute to this favorable outcome. Most of our patients required at least two modalities (74%). Previous studies also supported the use of combined rather than a single modality to enhance clinical success [16, 21]. Given the heterogeneity in number, techniques, and sequence of endoscopic modalities used in each patient, a direct comparison between different strategies cannot be made. However, the most common strategies used in patients with early and acute leaks/fistulas were closure and plugging strategies, and a common theme of treatment in patients with late or chronic leaks/fistulas involved passive and active drainage strategies. These are consistent with our previous proposed physiologic-based management algorithm for post-bariatric leaks/fistulas that supported the use of a closure and covering strategy for acute leaks as a supplement to surgical washout or percutaneous drain prior to the formation of an organized collection and the use of internal drainage strategy for chronic leaks with an organized collection [11].

Our adverse events were predominantly from enteral stent placement as also seen in previous studies [8, 9]. Stent migration was one of the most common complications, which can embed into the wall and result in obstruction and ulceration. A previous meta-analysis reported the pooled rates of stent migration of 28.2% in SG patients and 30.5% in RYGB patients [22]. Our study found that stent fixation using the OverStitch suturing systems mitigated the risk of stent migration from 20 to 11.5%. No adverse events were specifically associated with the use of this suturing device. The reduced migration rate from suturing stent fixation was also observed in previous studies in non-bariatric populations [23–25]. Our findings supported the role of endoscopic stent suture fixation in complicated bariatric patients. Moreover, all adverse events in our cohort were managed conservatively without the need for endoscopic or surgical intervention.

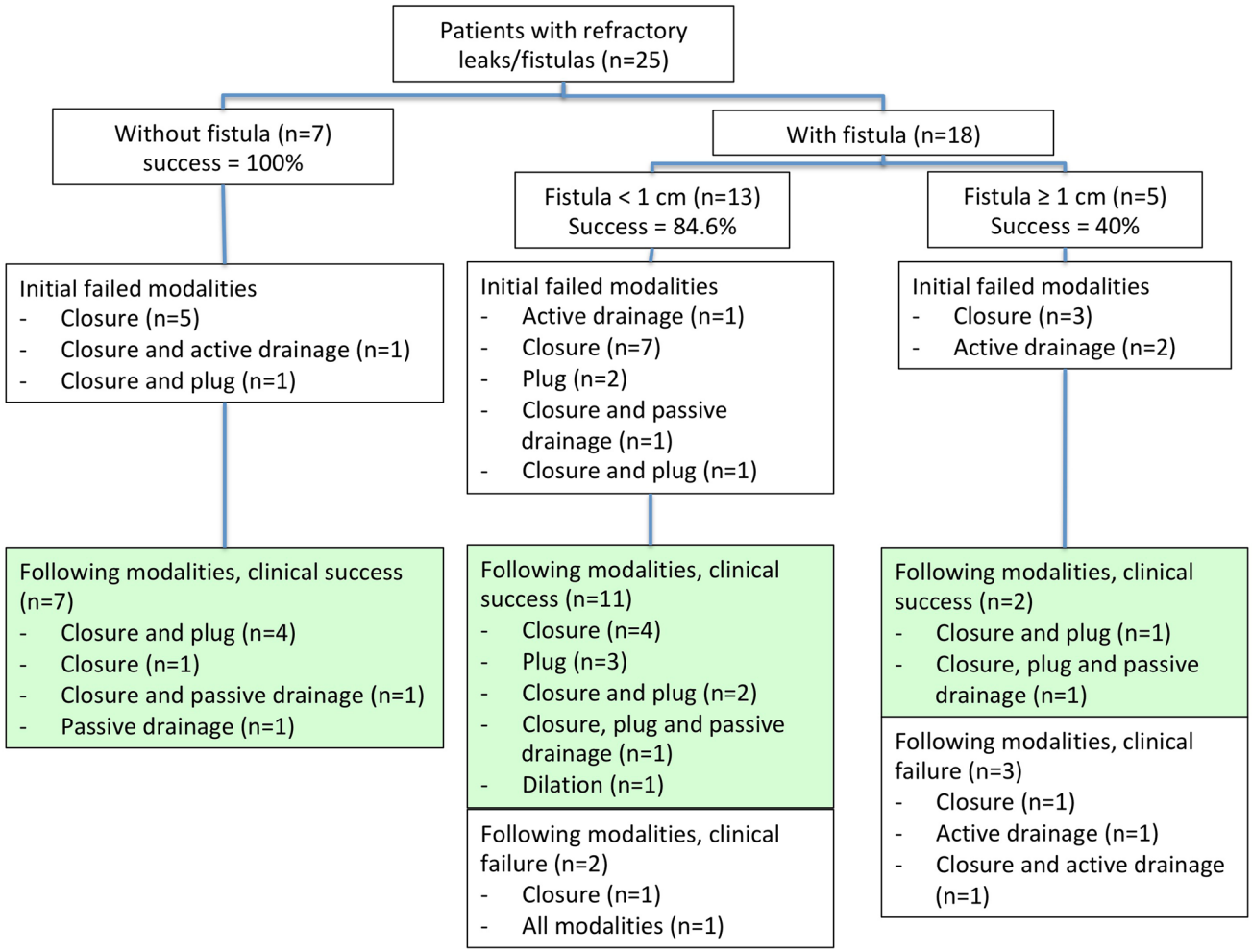

Fig. 3 Treatment outcomes of endoscopic strategies used in acute/early and late/chronic leaks and fistulas

The management of patients who failed endoscopic management becomes much more challenging. Surgery is not generally the first-line treatment due to associated morbidity and mortality [26–28]. However, it is ultimately required in some cases, especially in those with chronic fistulas. Of our cohort, all failed cases had a fistula, with the endoscopic failure rate in patients with fistula of 27.8% (5/18 patients). The presence of these fibrotic epithelialized tracts is the most difficult situation to be successfully managed endoscopically. Four patients in our cohort underwent salvage reconstructive surgery as a last resort. The clinical resolution was achieved after surgery in two patients, but those two developed post-surgical esophageal anastomotic leaks requiring further endoscopic management; one patient required a subsequent surgery to close the fistula. The fourth patient subsequently developed septic shock, multiple organ failure, and expired. These complex situations are best taken care of in a tertiary bariatric center by a collaborative effort from experienced endoscopists and bariatric surgeons as a multidisciplinary care approach.

Our study has some limitations. First, this is a retrospective analysis. There is no predefined endoscopic treatment protocol for post-bariatric leaks/fistulas in our hospital. The treatment decision was determined among multidisciplinary care team members. Second, the sample size is small, and there is heterogeneity in patient populations and treatment strategies used. The comparison among different endoscopic treatment strategies could not be made, and our ability to best define the most successful strategy in each subtype of leaks/fistulas is limited. Third, given the nature of studies in tertiary referral centers, there are patients that lost to follow up, which were excluded from this study. This could give rise to study bias. Finally, our hospital is a tertiary care center, which subjects to referral bias, potentially limiting the generalizability of this study, and some patients had undergone endoscopic management at another facility prior to referral.

In summary, complex endoscopic management ultimately succeeded in most cases with acceptable adverse events. Closure and plugging were the main successful strategies for early/acute leaks/fistulas, while drainage was the main successful strategy for late/chronic leaks/fistulas. Consideration should be given to patients who had fistulas as the treatment success rate was lower, and subsequent reconstructive surgery may not provide favorable outcomes. These patients should be referred to a specialized tertiary bariatric center.

Author contributions BA conceived and designed the study and critically revised the manuscript. VJ and EV designed the study, collected, analyzed, and interpreted the data and drafted the manuscript. DM and RM collected the data and drafted the manuscript. ACS interpreted the data, drafted, and critically revised the manuscript. All authors read and approved the final manuscript.

Funding None.

Compliance with ethical standards

Conflict of interests Dr. Abu Dayyeh is a consultant for Metamodix, BFKW, DyaMx, Boston Scientific, USGI medical, and Endo-TAGSS. He received research support from Apollo Endosurgery, USGI, Spatz Medical, Boston Scientific, GI Dynamics, Cairn Diagnostics, Aspire Bariatrics, and Medtronic. He served as a speaker for Johnson and Johnson, Endogastric Solutions, and Olympus. Dr. Storm is a consultant for Apollo Endosurgery, ERBE, GI Dynamics, and Endo-TAGSS. He received research support from Boston Scientific and Apollo Endosurgery. Dr. Jaruvongvanich, Reem Matar, Dr. Azilzullah, Dr. Malandris, Dr. Maselli, Dr. Vargas, Dr. Kellogg, Dr. Buttar, and Dr. McKenzie have no financial disclosures or conflicts of interest relevant to this study.

Ethical approval Our study was approved by the Ethics Committee of the Mayo Clinic Rochester.

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