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ORIGINAL CONTRIBUTIONS

Endoscopic Closure of Gastro-gastric Fistula After Gastric Bypass: a Technically Feasible Procedure but Associated with Low Success Rate

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Abstract

Background Gastro-gastric fistulas (GGF) are reported to be as high as 12% after gastric bypass for treatment of morbid obesity. While different endoscopic methods are described, the management traditionally consists of surgical revision with high associated morbidity. The aim of the study was to assess feasibility, safety and success rate of endoscopic closure using an endoscopic suturing device.

Methods From January 2016 to March 2018, we reviewed the electronic records of all patients undergoing endoscopic closure of a GGF with the Apollo Overstitch system (Apollo Endosurgery, Austin, Texas, USA). Demographic details, procedure details, and outcome variables were recorded.

Results A total of six patients (M:F = 5:1) underwent endoscopic fistula closure. Five patients (83.3%) had a prior banded gastric bypass (with subsequent band removal). The median number of prior abdominal surgeries was 3, the mean time from bypass to endoscopic fistula closure was 5 years (range 1.1–10.4). While immediate complete endoscopic fistula closure was possible in 10 of 12 attempts in those six patients (83%), all patients had recurrent (persistent) fistulas at follow-up. After a mean follow-up time of 12 months, 83.3% had further laparoscopic converted to open ($n = 2$) or laparoscopic ($n = 3$) revisions with complete fistula closure. One patient is refusing further intervention.

Conclusion Endoscopic gastro-gastric fistula closure with an endoscopic suturing device is feasible and safe. Unfortunately, due to the nature of gastro-gastric fistulas, permanent successful closure is rare. Therefore, the approach should be reserved for patients in whom a laparoscopic or open surgical attempt is impossible due to prior abdominal revisions.

Keywords Gastro-gastric fistula · Endosurgery · Endoscopic suturing · Bypass

Introduction

Roux-en-Y gastric bypass (RYGB) is the most commonly performed surgical procedure worldwide for the long-term treatment of morbid obesity [1, 2]. While post-operative complication rates have decreased over time with experience and improved techniques, there are important complications such as gastro-gastric fistulas (GGF) that must be recognized [3]. GGF are a well-known complication after RYGB and have a reported incidence of up to 12% [4–6]. An abnormal communication between the gastric pouch and the excluded stomach can lead to pain, stricture formation, ulceration, bleeding, weight regain, dysphagia, or nausea [5].

While asymptomatic patients can be treated conservatively initially and definitive treatment can be deferred, patients with severe symptoms require revisional surgical procedures that are usually technically challenging and with high associated morbidity and mortality [7, 8]. Over the past decade, several endoscopic techniques have been described, including the use of clips, plugs, fibrin glue, stents, or coagulation. The results of these techniques, however, have varying levels of success [8–12]. Thus, optimal management of GGF after RYGB has yet to be determined. The Apollo OverStitch device is a newly

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developed flexible endoscopic surgical device with promising early results in the treatment of various gastrointestinal pathologies [13, 14].

The aim of this study was to assess the feasibility, safety, and success rate of an endoscopic suturing device for closure of GGF.

Materials and Methods

Patient Selection

We performed a retrospective chart review of all patients undergoing endoscopic closure of a GGF with the Apollo OverStitch suturing device (Apollo Endosurgery, Austin, Texas, USA) at a single bariatric surgery center in Berne, Switzerland. From January 2016 to March 2018, we reviewed their electronic medical records for demographic details, procedure details, and outcome variables. The study was approved by the local ethics review board.

Patients who were over the age of 18, had a prior RYGB for weight loss, and had a documented GGF that underwent endoscopic closure were included. Demographic data recorded included age at time of procedure, gender, and BMI. Patient comorbidities, medications, and prior surgical history were recorded. Details of the GGF were recorded, including time from RYGB to diagnosis of GGF, mode of diagnosis, and presenting symptoms.

Endoscopic Technique

Informed consent was obtained in the clinic before the procedure. All procedures were performed by the same team (surgeon J.Z. and gastroenterologist H.M.) at the same bariatric surgery center. All procedures were performed under general anesthesia and patient stayed overnight for surveillance and due to hospital policy. An upper endoscopy was performed using a standard flexible gastroscope. The esophagus, gastric pouch, and proximal jejunum were visualized and inspected. The anastomosis and GGF were measured by visual estimation against a premeasured endoscopic tool. If the GGF was large enough, an endoscopic exploration of the excluded stomach was performed and the stomach and duodenum were inspected. After insertion of an overtube to protect the larynx, pharynx, and proximal esophagus, the GGF was primed circumferentially with argon plasma coagulation. The Apollo OverStitch device was then introduced with a pre-charged needle and suture (2-0 prolene), and closure of the GGF was performed using 1–3 sutures, each suture with 4–8 stitches. A final inspection of the patency of the closure of the fistula was performed prior to removal of the overtube. Size of the GGF, size of the pouch, duration of operation, and number of sutures as well as number of stitches per suture were recorded.

Follow-up Evaluation

The patients had routine follow-up appointments at a comprehensive bariatric surgery center at 1 month, 3 months, 6 months, and 1 year after the procedure, with more frequent consultations as indicated by patient symptoms. Patient weight and vitals were taken using the same equipment. Routine post-operative video-esophagram to assess objective result of gastro-gastric fistula closure was usually performed immediately before the 3 months follow-up appointment or earlier if symptoms reappeared or persisted. Any post-operative imaging or procedures were recorded.

Outcome Measures

Technical feasibility was defined as successful closure of the gastro-gastric fistula at the time of the procedure based on immediate visual inspection. Safety of the procedure was defined as the absence of complications intra-operatively and within 30 days of the procedure, including infection, bleeding, return to the operating room, or death. Long-term success was defined as symptomatic control without repeat interventions in the follow-up period. An unsuccessful attempt was defined as recurrent symptoms or fistulas requiring a repeat endoscopic or surgical procedure during the follow-up period.

Results

A total of six patients (five females and one male) underwent endoscopic gastro-gastric fistula closure (EGC) with the endoscopic suturing device (Apollo OverStitch device). Baseline patient characteristics are summarized in Table 1.

Table 1 Baseline patient characteristics

Number of patients ($n = 6$)	
Female/Male	5/1 (83.3%/16.7%)
Mean age (years)	51 (26.2–76.5)
Mean initial BMI kg/m^2	49.0 (42.6–56.9)
Mean BMI at time of EGC (kg/m^2)	38.6 (31.5–46.5)
EWL at time of EGC (%)	41.2 (8.2–59.6)
Median no. of prior abdominal surgeries	3 (3–5)
Prior silastic ring/band	5 (83.3%)
Time from RYGB to EGC (years)	5.0 (1.1–10.4)
Duration of GGF, months	16.0 (3.5–38.5)
Size of GGF, mm	12 (6–20)
Mean follow-up time (months)	12.3 (5.1–15.3)

EGC endoscopic gastro-gastric fistula closure

The mean age was 51 years (range 26–76). Body mass index (BMI) at the time of the procedure was a mean of 39 kg/m^2 (range 31–46). Two patients (33.3%) had diabetes, two patients had hypertension (33.3%), and one patient had obstructive sleep apnea (16.7%). The patients had a median of 3 (range 3–5) prior abdominal surgeries. Five patients (83.3%) had a prior banded gastric bypass. Four of these patients had the silastic ring or silastic band removed. One patient had her silastic band removed and then a second band placed at a later time, which was also subsequently removed. The mean time from RYGB to the first diagnosis of GGF was 3.7 years (range 2.4–9.3). The mean time from RYGB to time of endoscopic repair of the GGF was 5 years (range 3.2–10.4). The presenting symptoms were weight regain in five patients, and dysphagia and nausea in one patient. The mean follow-up time was 12.3 months (range 5.1–15.3).

The mean pre-operative GGF size was 12 mm (6–20), and the intra-operatively measured size was a mean of 16.5 mm (range 6–20) by a 9.7 mm (range 4–20). Mean duration of initial endoscopic suturing procedure was 22.5 min (range 12–30). The six patients had a total of 12 endoscopic suturing procedures performed for closure of the GGF; 10 (83.3%) were technically successful upon immediate intra-operative assessment. A median of 1 suture (range 1–2) was used during the procedure, and a median of 5 stitches (range 4–8) per suture were placed. No procedure-related morbidity or mortality occurred.

Details of repeat intervention during the follow-up period are visualized in Fig. 1. All six patients (100%) required either repeat endoscopic, surgical intervention or both for persistent symptoms and recurrent GGF during the follow-up period. Repeat endoscopic suturing was performed in five patients and one (20%) received a total of three endoscopic suturing procedures. Five patients (83.3%) required surgical intervention; two patients (33.3%) underwent laparoscopic pouch revision with partial gastrectomy, and three patients (50%) had a laparoscopic converted to open pouch revision with partial gastrectomy for excessive adhesions. The mean time from initial EGC procedure to the endoscopic or surgical revision procedure was 4.5 months (range 1.5–7).

Discussion

This is the first study to evaluate the utility of a novel endoscopic suturing device (Apollo OverStitch suturing device) for GGF closure after RYGB. While this technique is feasible and safe, long-term success rate is currently unknown. Despite high intra-operative success rate of 83.3%, all patients had recurrent or persistent GGF within a mean 12 months follow-up period, even after several EGC attempts.

The incidence of gastro-gastric fistulas reported in the literature is extremely wide, ranging from 0 to 46%, highlighting the number of factors that may influence their formation [4, 15].

There are multiple reasons for GGF formation: One reason is incomplete division of the remnant stomach from the pouch intra-operatively; another one is mucosal damage (ulcer formation) through acid over-production of the gastric pouch. Other causes may be biliary reflux, staple line dehiscence, marginal ulceration, abscess formation (possibly from an infected hematoma) with subsequent drainage into the stomach, leak or perforation, mucosal erosion from a foreign body (like a silastic ring in banded gastric bypass), and anastomotic stricture leading to pouch distension. Further, as a known factor for marginal ulceration, smoking might be another factor promoting fistula formation.

In most cases, the causes of fistula formation are a combination of the above but cannot always be determined. When diagnosed by either on endoscopy or on a swallow study (video-esophagram), initial conservative management should be attempted (see below). If the patient remains asymptomatic and no ulcerations are seen on endoscopy, there is no urgency to perform a revisional surgery, and definitive endoscopic or

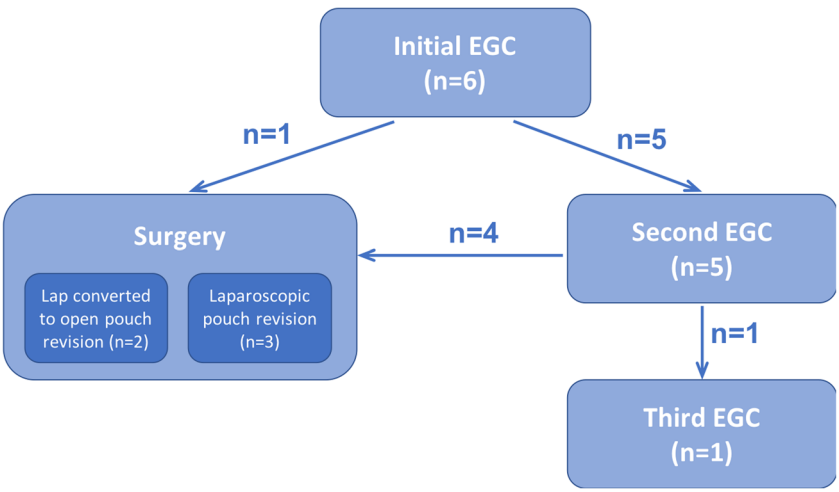

Fig. 1 Flow-charts of patients undergoing endoscopic gastro-gastric fistula closure (EGC), $n = 6$

surgical treatment can be deferred. Aside from weight regain, the main indications for revisional surgery are refractory ulcers and pain, followed by repetitive nausea and vomiting.

Conservative Treatment of GGF

Very small GGF may resolve with proton pump inhibitor treatment or proton pump inhibitor therapy plus endoscopic injection of fibrin sealant [16]. In cases in which a silastic ring or band is still in place and has caused perforation leading to fistula formation, the silastic ring or band will have to be removed endoscopically; otherwise, a spontaneous closure will not be possible. Conservative management consists of eradication of *Helicobacter pylori* if present, sucralfate, and high-dose proton pump inhibitors (40 mg twice daily), as well as analgesics in addition to avoiding NSAIDs and smoking cessation.

Surgical Treatment of GGF

In a study on surgical management of GGF performed by Chahine et al., GGF after RYGB were classified based on the location of appearance [17]. Type 1 GGF are more than 1 cm above the anastomosis while type 2 are less than 1 cm from the anastomosis. All patients required revisional surgery either because of refractory symptoms or because of weight regain. In this series, there were no conversions to laparotomy. Their recommendation for treatment of type 1 GGF is the excision of the fistula with preservation of the gastro-jejunal anastomosis, with or without calibration according to the size of the gastric pouch [16]. For type 2 GGF, which are usually associated with persistent marginal ulcer or anastomotic stenosis, complete revision of the gastro-jejunal anastomosis with fistula excision is usually recommended [8].

A described laparoscopic technique of GGF closure (removal) includes gastric pouch revision often in combination with remnant gastrectomy (fundectomy) [6]. Revisional surgery after RYGB is technically very challenging and can be associated with a high morbidity and mortality [7]. Therefore our rationale for an initial endoscopic treatment of GGF was based on no prior reports of associated morbidity with endoscopic closure intents.

Endoscopic Treatment of GGF

Papavramidis et al. published a report on endoscopic management of gastro-cutaneous fistula after bariatric surgery by using a fibrin sealant [9]. Endoscopic closure of gastro-cutaneous fistula with human fibrin tissue sealant is simple, safe, and effective and, in some cases, can be life-saving. Endoscopic application of fibrin sealant should be considered a therapeutic option for treatment of gastro-cutaneous fistula that develops after bariatric surgery. While this might be a viable option for gastro-cutaneous fistulas, GGF are completely different in their nature and therefore glue and fibrin sealant have not been shown to be successful as a single therapeutic treatment. The reason is that there is an acid pocket in the gastric pouch as well as on the other side of the fistula in the normally excluded stomach, thus keeping the fistula open from both sides. Additionally, liquids and food passing into the excluded stomach provides an additional stimulus to keep the fistula open.

Prior reports on endoscopic GGF repair involve a combination of devices, including the EndoCinch suturing system (CR Bard, Murray Hill, NJ), hemoclips, and Tisseel fibrin glue (Baxter, Deerfield, IL). In most cases, argon plasma coagulation is applied to the mucosa surrounding the rim of the fistula to ablate the mucosa before tissue approximation. This is thought to promote fusion of the opposed tissue [18]. In a study done by Fernandez-Esparrach et al., the most frequent GGF location is in the proximal pouch (49%), with 23% in the mid-pouch, 18% in the distal pouch, and 10% at the gastro-jejunal anastomosis. Similar to our initial approach, their study promotes an endoscopic repair of GGF after RYGB as a less-invasive approach [19]. Bhardwaj et al. published a series of eight patients who underwent endoscopic repair of small symptomatic GGF, using multiple endoclips [20]. Similar to our technique, they primed the entire circumference of the GGF with argon plasma coagulation. While all their repairs were successful on intraoperative inspection, 50% required revisional surgery. They describe further that the downside of the clip use is that such clips can only close smaller fistulas up to 8 mm due to the clip formation.

The strengths of this study are that we have 100% follow-up of the patients due to our dedicated bariatric center with post-operative video-esophagram studies to assess closure of the GGF. Limitations of this retrospective study are the small number of patients in a single-center setting.

Conclusion

Endoscopic GGF closure with an endoscopic suturing device is feasible and safe. Due to the nature of fistulas, especially gastro-gastric fistulas, permanent successful closure is rare. Therefore, this approach should be reserved for patients in whom a laparoscopic or open surgical attempt is impossible or associated with severe risk for complications due to prior abdominal revisions.

Compliance with Ethical Standards

The study was approved by the local ethics review board.

Conflict of Interest The authors declare that they have no conflict of interest.

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