

Endotherapy including temporary stenting of fistulas of the upper gastrointestinal tract after laparoscopic bariatric surgery

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Background: Reoperations for complications of bariatric surgery are associated with high morbidity and mortality. It is not known whether endoscopic treatment may reduce reoperation rates.

Methods: Twenty-one patients underwent endoscopic treatment for persisting large anastomotic leaks before considering redo surgery. Eight patients had a gastric bypass, eight had a sleeve gastrectomy combined with a duodenal switch (SDS), four had a sleeve gastrectomy alone, and one had a Scopinaro procedure (biliopancreatic diversion). Fistulas were gastrocutaneous in 15 patients, duodenocutaneous in 2, gastroperitoneal in 3, and gastrobronchial in 1. Partially covered self-expanding metal stents (SEMSs) were used, followed by additional endoscopic procedures if the SEMS failed. SEMSs were removed by traction alone or by insertion of a self-expanding plastic stent (SEPS) followed by extraction of both stents together.

Results: SEMS insertion led to 62% (13/21) primary closures. Complementary endoscopic treat-

ment led to 4 secondary closures. Total success rate was 81% (17/21). Three patients in whom SEMSs failed underwent reoperation but died during postoperative follow-up; one patient died from pulmonary embolism before SEMS extraction. The success rates of endotherapy were 100% (8/8) in the gastric bypass group, 62.5% (5/8) in the SDS group, 75% (3/4) in the sleeve gastrectomy group, and 100% (1/1) for the Scopinaro procedure. Gastrocutaneous fistulas on sleeve sutures were successfully treated in 60% of cases (6/10), while other anastomotic fistulas were successfully treated in 100% of cases (11/11) ($P = 0.0351$).

Conclusions: Endoscopic treatment using SEMSs for complications of bariatric surgery is feasible. Healing of severe leaks was obtained in 81% (17/21) of patients, avoiding high-risk reoperation. Gastrocutaneous fistulas on a sleeve suture are the most difficult condition to treat.

Introduction

The demand for bariatric surgery is dramatically increasing: about 140 000 procedures were performed in the United States in 2004 [1]. In consequence, surgical and medical gastroenterological teams are faced with an increase in the number of complications. These occur in about 20% of cases and are associated with high morbidity if surgery has to be repeated [1–3]. Anastomotic leaks are one of the most serious complications, leading to sepsis, abscess formation, and even death [4]. Classical management involves reoperation as early as possible in the case of clinically alarming symptoms such as severe tachycardia or respiratory distress. When detected, the leak should be repaired or patched with omentum and drains should be placed. These reinterven-

tions can be challenging and may lead to additional complications such as the development of long-standing cutaneous fistulas.

An alternative treatment modality for the anastomotic leaks could be to bypass the leak endoscopically. A stenting technique was previously described for the management of malignant fistulas or benign fistulas due to trauma or associated with Boerhaave's syndrome, esophagogastrectomy, or iatrogenic perforation [5–13]. It has been suggested from these reports that partially covered nitinol self-expanding metal stents (SEMSs) are most effective for closure of fistulas, especially in the absence of associated strictures. Anastomotic fistulas occurring after bariatric surgery are an example of such an indication. Nitinol SEMSs are soft. The covered versions provide a barrier to saliva and fluids. Development of tissue

hyperplasia at both ends minimizes the risk of migration and could increase watertightness. On the other hand, hyperplasia makes removal difficult and raises questions about the placement of SEMSs for a long period. It has been shown that placement of a self-expanding plastic stent (SEPS) inside the SEMS can induce pressure necrosis of this hyperplasia, allowing subsequent removal of the stent [14,15]. We have applied this and other techniques for the removal of SEMSs. This paper presents the results of endotherapy of 21 patients presenting with leaks after laparoscopic bariatric surgery.

Patients and methods

Between May 2004 and January 2006, 21 patients (15 women) underwent endoscopic treatment for leakage after bariatric laparoscopic surgery. The patients were consecutive referrals to our endoscopy unit from other hospitals. Their demographic data and type of last bariatric surgical intervention are shown in **Table 1**. These procedures had all been performed by two surgeons with a very high level of experience in bariatric surgery (more than 250 operations per year). Twenty of the patients had developed a leak in the days following surgery. One patient developed gastric perforation after dilation of an anastomotic stenosis 2 months after bariatric surgery. The types of fistulas and surgical management before referral are summarized in **Table 2**. All patients were fasting and received parenteral nutrition after diagnosis of the fistula.

Because of the large size of the leak seen at endoscopy, all patients underwent placement of a SEMS across the fistula with the aim of avoiding the passage of gastric secretions through the fistula (**Fig. 1**). In some cases placement of a second SEMS was necessary because of liquid reflux from the distal end between the gastric and the stent wall, or because of lack of watertightness at the proximal end due to the angle between the proximal end of the stent and the esophagus. In other cases, relapse or persistence of leakage after SEMS extraction justified another SEMS implantation. Overall, 12 patients received only one SEMS, 5 received two SEMSs, 3 received three SEMSs, and 1 patient received four SEMSs for adequate occlusion of the fistula. Most of the SEMSs (28/35) were partially covered nitinol Ultraflex stents (Microvasive Endoscopy, Boston Scientific Corp, Natick, Massachusetts, USA) 15 cm in length and 18 mm in diameter. Four Ultraflex SEMSs of 12 cm length and one of 10 cm length, all 22 mm diameter, were used in five cases, mostly patients with sleeve gastrectomy (4/5). Two completely covered nitinol SEMSs (Silky Esophageal Stent; Stentech Company, Seoul, Korea) 14 or 18 cm in length and 18 mm in diameter were inserted in two cases.

Additional endoscopic treatment was proposed in cases of persistent leakage after stenting. This consisted of sealant insertion (biological fibrin glue, Tissucol; Baxter, Deerfield, Illinois, USA), surgical tissue adhesive (*N*-butyl-2-cyanoacrylate, Histoacryl; Braun Melsungen, Melsungen, Germany), or fistula bioprosthetic plug (Surgisis AFP; Cook Biothec Inc., West Lafayette, Indiana, USA) and clip placement after stent removal. Abscess drainage was also performed in association with stenting in two patients. Endotherapy was performed in all patients under general anesthesia with tracheal intubation and under fluoroscopic control. Treatment success was defined as complete and persistent closure of leakage after SEMS removal (primary closure) or after complementary endoscopic treatment (secondary closure).

Table 1 Patient demographic and surgical data

Age, median, years (range)	46 (30–59)
Sex ratio, women/men	15/6
BMI, median, kg/m ² (range)	41 (27–63)
Type of last surgery before endotherapy:	
Gastric bypass	8
Sleeve gastrectomy and duodenal switch	8
Sleeve gastrectomy alone	4
Scopinaro procedure	1
Previous bariatric operation:	
No	10
Yes	11*
Lap band	6
VBG (Mason procedure)	3
Bypass	2
Scopinaro procedure	1

BMI, body mass index; VBG, vertical banded gastroplasty.

* One patient had two previous bariatric operations.

Table 2 Types of fistulas and surgical management before referral

Type of fistula, patients, n:	
Gastrocutaneous	15
Duodenocutaneous	2
Gastrobronchial	1
Gastroperitoneal	3
Revision laparoscopies, patients, n:	
None	5
One	11
Two	5
Median delay between laparoscopic bariatric surgery and endotherapy, days (range)	31 (14–199)

At the beginning of our series, SEMS extraction was done in a single endoscopic session by pulling gently but firmly on the proximal end of the stent with a rat-tooth forceps. Occasionally argon plasma coagulation was used to help destroy hyperplasia that had developed between the SEMS meshes. These procedures were time-consuming and the extraction technique was usable mainly in patients who had only proximal and mild hyperplasia. For this reason we changed to another extraction technique, in which we inserted a 15-cm SEPS (Polyflex Stent, Rüschi, Kern, Germany; then Boston Scientific Corp.) into the SEMS in order to induce necrosis of the hyperplastic proliferation (**Fig. 2**). Extraction was then easily performed in a second endoscopic session.

Results

All 21 patients were initially treated with SEMS insertion, and in 62% (13/21) this led to primary closure as confirmed by the absence of residual fistula after stent extraction. Complementary endoscopic treatments were used to treat residual fistula that persisted despite stenting, and this led to four secondary closures, giving an overall success rate of 81% (17/21) (**Table 3**). Failures were recorded in four patients, all with fistula after sleeve gastrectomy (3 with SDS, 1 with sleeve gastrectomy alone). One woman with SDS developed an upper digestive bleed 4 days after SEMS deployment. After urgent stent extraction, laparotomy revealed bleeding from the splenic branch artery. Hemostasis was obtained after major abdominal surgery. The patient died 2 months later. The second failure in a case of SDS

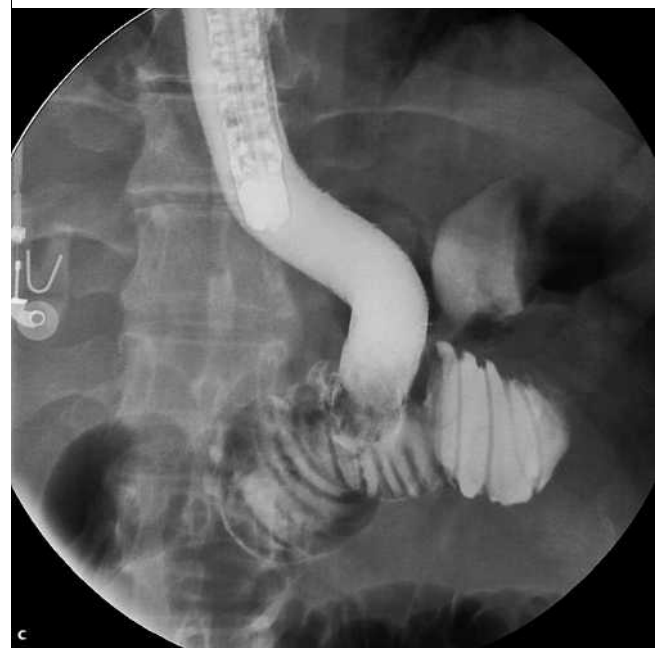
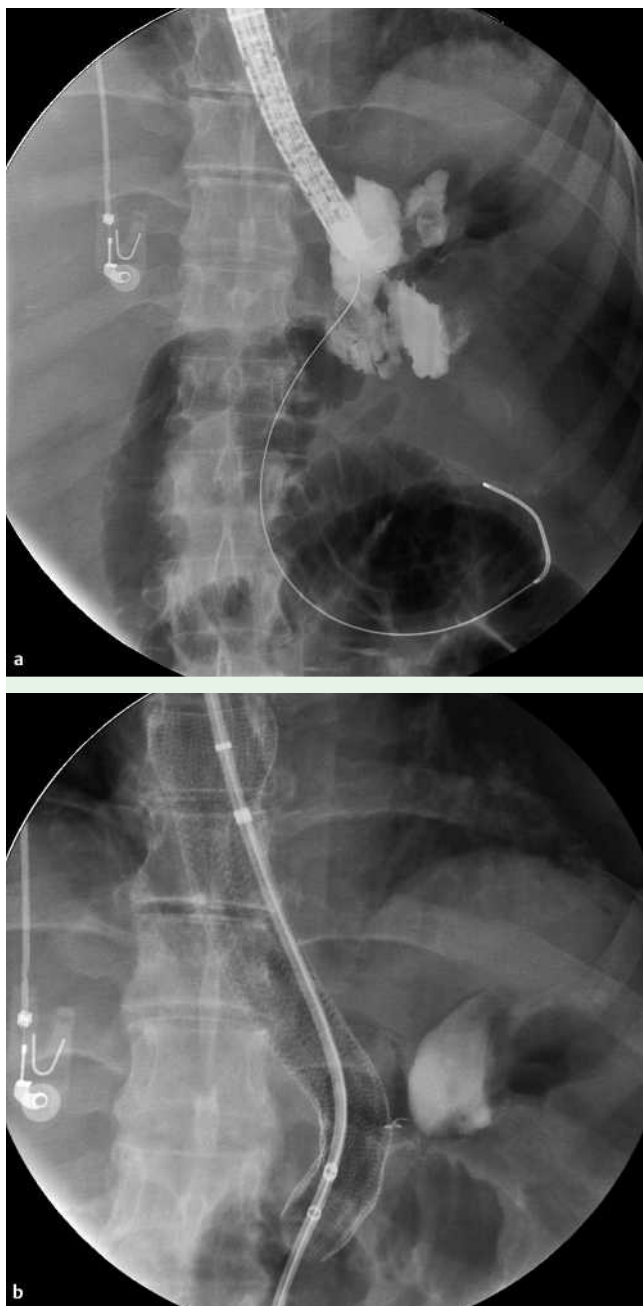


Fig. 1 Placement of a covered Ultraflex stent in order to cover a large anastomotic fistula in a case of gastric bypass: **a** opacification of the fistula and placement of Savary guide; **b** stent deployment; **c** checking that the orifice is adequately covered.



Fig. 2 Insertion of a Polyflex stent into a self-expandable metallic stent in order to induce pressure necrosis of the hyperplasia, thus allowing both stents to be subsequently removed.

occurred in a woman with gastrocutaneous and transdiaphragmatic fistulas. A 22-mm-diameter Ultraflex stent was inserted at the level of the fistulas. Because of persistent active fistulas at the level of the sleeve despite the insertion of the Ultraflex, the latter was removed by inserting a SEPS and a complementary treatment with fibrin glue was performed. After a transient amelioration the patient decided to be transferred back to the referring hospital. She died in a septic condition 3 months after the initial surgery. The third failure occurred in a drug- and alcohol-dependent woman, who decided to be treated in another hospital after one endoscopic procedure with placement of a stent. She was reoperated on and died 5 months after initial surgery. One patient with sleeve gastrectomy died from massive pulmonary embolism 4 weeks after stent insertion when the fistula was closed and sepsis resolved, and stent extraction was already being planned. In the last three of these four patients, information on the degree of fistula closure after stent removal was in-

complete at the time of the patients' deaths. These cases were therefore considered to represent failure of endotherapy in an intent-to-treat analysis, although to our knowledge none of these deaths were related to the stents.

The endotherapy success rates (intent-to-treat analysis) are presented in relation to each type of surgery in **Table 4**. Regarding the type of fistula, the gastrocutaneous fistulas originating from a sleeve suture after SDS or sleeve gastrectomy were

Table 3 Treatment results: primary and secondary closures

	Patients, n	No. of SEMSs used, median (range)	Duration of stenting, median, days (range)	No. of endoscopies for treatment, median (range)	Type of complementary treatment (n)
Primary success*	13	1 (1–3)	62 (35–214)	2 (1–3)	–
Secondary success†	4	3 (1–4)	176 (61–206)	4 (3–6)	Histoacryl (1) Fistulaplug (2) Clips and Tissucol (1)
Failure	4	1 (1–2)	n. a.	1 (1–3)	Tissucol (1)

SEMS, self-expanding metal stent.

*Primary success: fistula closure achieved by SEMS insertion only.

†Secondary success: fistula closure achieved after stent insertion and complementary treatment.

Table 4 Endotherapy success rates (intent-to-treat analysis) in relation to type of surgery and fistula

Type of surgery and fistula	Patients, n	Endotherapy successful, n	Endotherapy failed, n	Success rate, %
Gastric by-pass (8 patients)				100
Gastrocutaneous	4	4	0	
Gastroperitoneal	3	3	0	
Gastrobronchial	1	1	0	
Sleeve gastrectomy + duodenal switch (8 patients)				63
Duodenocutaneous	2	2	0	
Gastrocutaneous	6	3	3	
Sleeve gastrectomy (4 patients)				75
Gastrocutaneous	4	3	1	
Scopinaro procedure (1 patient)				100
Gastrocutaneous	1	1	0	
Total	21	17	4	81

Table 5 Status of the 21 SEMSs at the end of the study

SEMS follow-up	No. of patients
Endoscopic extraction:	18
By traction	(5)
By traction after APC	(2)
By Polyflex insertion	(11)
Self migration	1
Patient died with SEMS in place	2
Total	21

APC, argon plasma coagulation.

the most difficult to treat, with a success rate of only 60% (6/10), compared with 100% (11/11) for all other cases ($P=0.0351$).

Information on the end-of-study status of the SEMSs is summarized in **Table 5**. Where a SEPS was used, the median interval between SEPS insertion and extraction was 22 days (range 13–34 days). There was one spontaneous migration with an Ultraflex stent of 22 mm diameter inserted in a patient with SDS. The SEMS was found on X-ray at the level of the ileocecal valve. The patient had no symptoms and was discharged. He never came back, but was reported as well after 6 months by his general practitioner. We believed that the SEMS was naturally expelled. The median clinical follow-up after SEMS extraction for the 17 healed patients is 221 days (range 61–544). There were no immediate complications after placement or extraction of stents. The source of bleeding in the patient who needed an urgent laparotomy 4 days after SEMS placement was considered to be too far from the anastomosis to be directly related to the stent deployment. A frequent side effect of this treatment, reported by

approximately 30% of patients, is transient thoracic pain, probably related to an inflammatory reaction due to expansion of the stent. Transient pain and inflammation were also reported after a SEPS was inserted to aid subsequent removal of a SEMS. This pain was attributed to necrosis of hyperplastic tissue. Dysphagia requiring endoscopic treatment was observed in two patients. Balloon dilation was performed on a hyperplastic stricture in two patients with a SEMS after indwell times of 32 and 102 days respectively. Two patients, including one of the two patients who had already undergone dilation once before SEMS extraction, needed a last dilation session 31 days and 40 days respectively after stent extraction because of a short fibrotic stricture present at the level corresponding to the proximal part of the previously inserted SEMS. These two patients had SEMS indwell times of 61 and 202 days respectively.

Discussion



This is the first series demonstrating the feasibility of endotherapy for the healing of suture leaks and fistulas occurring after laparoscopic bariatric surgery. Anastomotic leaks, although rare when the surgeon is experienced (they have been reported at rates between 1% and 12.5% after gastric bypass) [16–18], represent major complications in these highly debilitated patients who often have multiple comorbid conditions. Surgical repair of leakage after bariatric surgery is always hazardous. In these difficult situations we have demonstrated that endotherapy, mainly based on SEMS placement, is an effective therapeutic option, with an overall success rate of 81% (17/21). This success rate

may be an underestimate because two of the four patients whose endotherapy was counted as failed in the intent-to-treat analysis were in fact not evaluable for efficacy of the stent treatment: one patient died of a pulmonary embolism and one patient decided to be reoperated on in another hospital while the SEMS treatment was ongoing. The relatively high success rate observed in this series, and the possibility of removing the SEMS in all cases – especially by the use of SEPS to induce pressure necrosis of hyperplasia might justify the use of endotherapy, in combination with laparoscopic drainage of fluid collection, even earlier in the management of those patients, when the first reintervention is planned.

Four patients died during follow-up. To our knowledge, none of these deaths were stent related: one pulmonary embolism while the SEMS was still in place, one reoperation while SEMS treatment was still ongoing, and two deaths 2 months and 5 months respectively after SEMS extraction. On the other hand, these figures do illustrate the risk of reoperation in these patients: two patients died after reintervention.

In all patients the treatment consisted initially in the placement of a SEMS at the level of the leakage in order to cover the fistula. Often a leak-proof situation is achieved after a few days when hyperplasia develops at noncovered extremities of the stent, that is, either at both ends or at just the upper one. But since the lumen is often larger on the distal side of the anastomosis, a second or even a third stent had to be placed in 48% of the patients (10/21). When the stented segment has been demonstrated clinically or by contrast study to be leak-proof, the SEMS is left in place for an additional period of approximately 2 months, with duration of indwell adjusted for different situations. Large fistulas, especially when associated with an abscess, should probably be covered for longer until sepsis and inflammation have resolved. Some previous studies have suggested removing the SEMS no later than 6 weeks after placement because that is when it is easiest to extract them, followed by renewed SEMS placement where there is persistent fistulizing disease [19]. We think that in the particular case of bariatric surgery, the fistulas are so large that extracting a SEMS after 4 or 6 weeks will force a further SEMS placement session in the majority of the patients. In these circumstances, the use of SEPS in cases where there is significant hyperplasia is probably cost-effective.

One reason for the lower success rate of fistula closure associated with sleeve gastrectomy could be that it is more difficult to achieve watertight closure of the fistula by the stent in these situations, since the gastric side to be covered by the stent is usually larger in diameter and distal hyperplasia rarely develops. At all events, persistent leakage due to reflux between the distal part of the first stent and the gastric wall was often the reason for a second SEMS insertion. The second SEMS was inserted into the lower part of the first SEMS in order to extend the distal cover, which was sometimes transpyloric.

Endoscopic options for treatment of upper digestive fistula were reviewed in a recent technical paper on esophageal leakage [20]. Basically, treatment options are divided into repair techniques, which use clips, suturing devices, or sealant for small and recent fistulas, and diversion techniques, which employ stent placement for larger or chronic leakages. The published literature on SEMSs used for benign leakage has previously been quite limited because of concerns about acute complications and long-term sequelae. It consists mainly of three case reports of treatment of Boerhaave's syndrome in the 1990s [4–6]. Since 2000, the number of reported cases describing expandable stent use for fistula

occlusion has dramatically increased. This is due to the development of the SEPS, which is effective when fistulas are associated with a stricture, and also to increased use of SEMSs for traumatic nonmalignant perforation [9] or for anastomotic leaks [10]. The latter paper describes the use of SEMSs in 18 anastomotic leakages after resection for cancer and in three other situations. Complete healing was achieved in 80% of the cases. Only 56% of the SEMSs were removed, underlining the persisting concern about removability and long-term consequences. One recent series of 12 patients demonstrated that SEPS placement could also be a successful minimally invasive treatment option for intrathoracic esophageal anastomotic leaks [21]. After a median SEPS indwell time of 4 weeks the authors achieved complete closure of the leaks in 11 patients after stent removal, even in cases of extensive anastomotic dehiscence. In another retrospective study of 15 patients with malignant or benign esophageal leakage, successful sealing was seen in 73% of patients using SEPSs [22]. We have also reported the use of SEPSs for treatment of anastomotic leakage after esophagogastrectomy [13]. In that paper and in the report on management of complications after treatment for Zenker's diverticulum [12], we described the concept of sequential implantation of SEMSs and SEPSs to combine the benefits of initial leak-proofing using partially covered stents while avoiding the concern about removability. This is an ideal technique to apply to the treatment of fistulas occurring in the setting of bariatric surgery, since very few were associated with a stenosis, making early migration of a plastic stent highly probable [23]. In such cases, Ultraflex stents are particularly useful because of both their softness, which allows close adaptation to tortuous anatomy, and their very low risk of migration [24]. Combining these advantages with removability without major technical difficulties might make this technique an ideal treatment modality for any leakage occurring in the absence of stenosis, particularly when, as in our cases, the need to maintain the SEMS for more than 6 weeks is predictable on the basis of the longstanding fistulas associated with sepsis. In the setting of bariatric surgery, further comparative studies might evaluate whether endotherapy could be performed prior to any surgical attempt to close leaks or fistulas, and whether this approach could lead to a lower complication rate and represent a lower-cost alternative to a surgical redo.

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