



Effect of Early Use of Covered Self-Expandable Endoscopic Stent on the Treatment of Postoperative Stapler Line Leaks

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Abstract

Background Postoperative leaks are a dreaded complication after bariatric surgery (BS). Its treatment is based on nutritional support and sepsis control by antibiotics, collections drainage and/or prosthesis, and/or surgery.

Objectives The aim of this study is to report our experience with coated self-expandable endoscopic stents (SEES) for leaks treatment.

Setting This study was performed in a University Hospital, (censored).

Methods We performed a retrospective analysis of our BS database from January 2007 to December 2013. All patients with leak after BS treated with SEES were included.

Results We identified 29 patients; 17 (59 %) were women, with median age of 37 (19–65) years, and preoperative body mass index of 40 (28.7–56.6) kg/m². Nineteen (65.5 %) patients had a sleeve gastrectomy and 10 (34.5 %) a Roux-en-Y gastric bypass. All patients had a leak in the stapler line. Median time from surgery to leak diagnosis was 7 (1–51) days,

and SEES were installed 8 (0–104) days after diagnosis. Twenty-one (72 %) patients also had abdominal exploration. Median length of SEES use was 60 (1–299) days. Patients who had SEES as primary treatment (with or without simultaneous reoperation) had a shorter leak closure time (50 [6–112] vs 109 [60–352] days; $p=0.008$). Twenty-eight (96.5 %) patients successfully achieved leak closure with SEES. There were 16 migrations in 10 (34 %) patients, 1 (3 %) stent fracture, 1 opening of the blind end of alimentary limb (3 %), and 5 patients (17 %) required a second stent due to leak persistence.

Conclusions SEES is a feasible, safe, and effective management of post BS leaks, although patients may also require prosthesis revision and abdominal exploration. Primary SEES placement is associated with a shorter leak resolution time.

Keywords Bariatric surgery · Complications · Leaks · Endoscopic stents · Roux-en-Y gastric bypass · Sleeve gastrectomy

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Introduction

Obesity is an epidemic disease with several related comorbidities and entails a higher risk of mortality [1] than observed in general population. Nowadays, bariatric surgery (BS) is recognized as the most effective treatment against obesity due to its good long-term weight control and high rate of remission or amelioration of comorbid diseases [2–4]. There are several surgical alternatives in the field of BS; currently, laparoscopic sleeve gastrectomy (SG) and laparoscopic Roux-en-Y gastric bypass (LRYGB) are the most frequent procedures performed around the world [5]. One of the most feared and life-threatening complications in BS are the postoperative leaks (PL), which are reported in the order of 1 to 5 % of the

LRYGB and SG [6–8]. Leaks are a challenging problem because obese patients develop rapid and acute inflammatory response and they have diminished cardiopulmonary reserve. Moreover, diagnosis can be initially difficult and tachycardia may appear as the only early manifestation, thus surgeons must have a high index of suspicion for this complication [9]. Furthermore, there are no standardized protocols for leaks treatment, despite the fact that antibiotics, percutaneous drainages, or reoperation seems a reasonable approach to initially control intra-abdominal sepsis.

Coated self-expandable endoscopic stents (SEES) have been extensively used in general and oncologic surgery for treatment of esophageal obstructions, leaks, and fistulas [10–14], and its application in BS has been reported for the treatment of both acute and chronic leaks, as well as for anastomotic strictures with a high rate of success [8, 15]. Here, we report our experience with the use of coated SEES in the management of leaks after SG or LRYGB.

Materials and Methods

We performed a retrospective analysis of our prospectively collected electronic BS database from January 2007 to December 2013. All patients primarily operated in our center or referred, with a PL were included in the analysis. Demographic data, comorbid diseases, and type of BS were recorded. Leak location, determined by images as oral and iv contrast-enhanced computed tomography scan (CT) or upper gastrointestinal series (UGI), was detailed. Treatments were described in terms of the number of SEES used, need for SEES revision or replacement, and the need of surgical exploration. Only patients with an active stapler line leak demonstrated by radiological means were treated with SEES. All SEES were placed under radioscopy guidance in the operating room (OR) under general anesthesia, and an UGI series were performed one day after. If the leak was excluded, clear liquids were immediately started. All SEES were removed in the OR under sedation when the leak appeared to be healed according to surgeon's criteria. The day after removal, UGI series were performed and if normal, soft oral feeding was started; conversely, if leak persisted, a new SEES was placed.

Median times from BS to leak diagnosis, from leak diagnosis to SEES placement, and from leak diagnosis to complete resolution were retrieved. In order to elucidate the role of the early management with SEES, patients were also subdivided in two groups: (1) those who were treated only with SEES or SEES plus concurrent surgery (primary SEES), and (2) those who were treated initially by surgery, in whom SEES was placed later (secondary SEES). Median time of leak resolution (leak diagnosis – leak resolution) was calculated and compared between groups.

Continuous variables are expressed as median (range), while categorical variables are expressed as number of cases

(percentage). Statistical analysis was performed with the Statistical Package for Social Science (SPSS 20.0, Chicago, IL, USA) using the Mann–Whitney test for non-parametric variables and Fisher's exact test for categorical ones. Statistical significance was considered when p value <0.05 .

Results

Of 4746 patients who underwent LRYGB or SG in our center, 20 (0.44 %) developed a postoperative leak, without differences between procedures rates (LRYGB: 0.54 % vs SG: 0.31 %, $p=0.31$). Of these patients, 17 received a covered SEES as part of leak treatment. There were also 12 referred patients who required SEES, totaling 29 cases. Demographic preoperative data is summarized in Table 1. Nineteen patients had a SG (including two conversions from lap banding) and 10 had a LRYGB. Leaks were diagnosed by UGI series or by an orally and intravenous contrast-enhanced abdominopelvic CT scan in 7 and 93 % of the cases, respectively. All leaks were located in the upper pole of the last stapler of both, LRYGB and SG.

According to the sleeve gastrectomy consensus for leak classification [16], we had 15 patients with acute leak, 13 with early leak, and only 1 patient with chronic leak.

Postoperative Leak Management

Besides the general medical management for sepsis control which included fluid resuscitation, iv wide spectrum antibiotics, intensive care unit management in some cases, and nutritional support, eight patients were treated only with SEES (5 SG and 3 LRYGB). Four patients had concurrent surgery with SEES placement (2 SG, 2 LRYGB), and 17 patients had at least one reoperation before the SEES placement (12 SG and 5 LRYGB, Table 1). Of note, no surgeries were required for collection drainage after SEES placement. In regards to stents type, all of them were fully covered. The length and diameter are detailed in Table 1.

Median time between BS and leak diagnosis was 7 (1–51) days, and median time between leak diagnosis and SEES placement was 8 (0–104) days. Median leak resolution time, measured from leak diagnosis to SEES removal, with normal UGI series confirming leak closure, was 82 (6–352) days. The median length of SEES use was 60 (1–299) days and 19 patients (65 %) had SEES in situ for more than 6 weeks, although 9 of them required prosthesis change during this period for reasons described below.

Regarding the timing of stent placement, when comparing the primary and secondary SEES installation, the primary SEES was associated with a significantly shorter leak resolution time as compared to the secondary SEES (primary: 50 [6–112] vs secondary: 109 [60–352] days, $p=0.008$, Fig. 1).

Table 1 Demographics, clinical data, leak treatment, and SEES complications

ID	Age	Gender	BMI	Surgery	Surgery–diagnosis	Stent-surgery	Reoperation	Length and diameter	Stent complication (management)	Diagnosis-resolution
1	28	M	42.8	LRYGB	3	After	Two laparotomies w/drains	160×22 mm	Two migrations (reposition and replacement)	240
2	23	M	54.7	LRYGB	5	After	One laparotomy w/drains	100×23 mm	–	352
3	19	F	39.7	SG	10	After	Two laparoscopies	100×23 mm	Two migrations (reposition and replacement)	109
4 ^a	45	M	40	SG	3	After	One laparotomy w/drains	160×22 mm	Three migrations, leak persistence (reposition and replacement)	306
5	30	F	40.2	LRYGB	19	After	One laparoscopy	160×22 mm	–	123
6 ^a	37	M	40	LRYGB	5	Only	–	160×22 mm	Stent fracture (laparoscopic removal)	112
7 ^a	43	F	38	SG	7	Only	–	100×23 mm	–	89
8	48	F	41	LRYGB	9	Concurrent	One laparoscopy	100×20 mm	One migration (reposition)	35
9	43	F	34	SG	8	Only	–	100×23 mm	–	–
10 ^a	34	F	32	SG	9	After	One laparoscopy	150×20 mm	One migration (replacement)	No resolution
11	23	F	38	SG	7	After	One laparoscopy	100×20 mm	Two migrations (reposition and replacement)	60
12 ^a	21	M	40	SG	(–)	After	Two laparotomies w/drains	125×20 mm	Leak persistence (replacement)	(–)
13	19	F	36.6	SG	51	Concurrent	One laparoscopy	100×20 mm	–	42
14	52	M	37.4	SG ^b	8	After	One laparoscopy	100×23 mm, 150×23 mm, 100×25 mm	Two migrations (reposition)	172
15	47	M	40.9	LRYGB	6	After	One laparoscopy	100×20 mm	–	65
16	36	F	41	SG	7	Concurrent	One laparoscopy	170×18 mm	One migration (retire)	6
17 ^a	29	M	35	SG	3	Only	–	100×20 mm	Leak persistence (replacement)	105
18 ^a	65	F	28.7	SG ^b	20	After	One laparotomy w/drains	100×20 mm	–	91
19	55	F	32.5	SG	8	Only	–	150×20 mm	–	50
20 ^a	19	F	32.5	SG	11	After	Three laparotomies w/drains	150×18 mm	–	86
21 ^a	38	M	35.4	SG	4	After	One laparoscopy	150×18 mm	–	62
22	47	F	33.5	LRYGB	9	Only	–	150×20 mm	Blind end alimentary limb opening (laparoscopic removal)	14
23	42	M	40	SG	1	After	One laparoscopy	150×20 mm	One migration (retire)	69
24 ^a	35	M	44.8	SG	31	After	Two laparoscopies	150×20 mm	–	68
25	30	M	55.4	LRYGB	4	After	One laparoscopy	125×20 mm	One migration (replacement)	131
26	42	F	56.6	LRYGB	6	Only	–	150×20 mm	–	29
27	37	F	47	LRYGB	15	Concurrent	One laparoscopy	150×20 mm	Leak persistence (replacement)	78
28 ^a	51	F	–	SG	2	After	Two laparotomies w/drains	150×20 mm	Leak persistence (replacement)	161
29 ^a	38	F	35	SG	4	Only	–	150×20 mm	–	75

Table 1 (continued)

ID	Age	Gender	BMI	Surgery	Surgery-diagnosis	Stent-surgery	Reoperation	Length and diameter	Stent complication (management)	Diagnosis-resolution
Summary values	37 19–65	17 F 58.6 %	40 28.7–56.6	19 SG 65.5 %	7 1–51	17 after 58.6 %		150 (100–160) × 20 (18–24)		82 3–352

Summary values are expressed as median (range) or number of cases (percentage from total). *ID* identification number, *BMI* body mass index; surgery-diagnosis: time from primary surgery to leak diagnosis in days; stent-surgery: relation between stent installation and reoperation; diagnosis-resolution: time from leak diagnosis to stent retrieval with leak resolution expressed in days. *M* male, *F* female, *RYGB* laparoscopic Roux-en-Y gastric bypass, *SG* sleeve gastrectomy

^a Referred patients

^b Conversion from adjustable gastric banding to sleeve gastrectomy

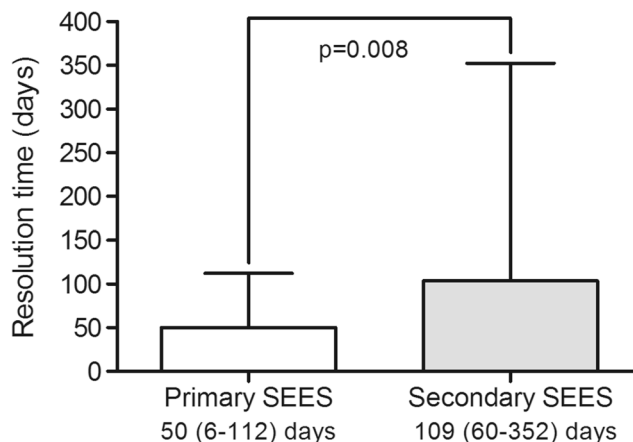


Fig. 1 Comparison of resolution time between primary and secondary SEES. SEES self-expandable endoscopic stent. Primary SEES: installed concurrently with reoperation or without it. Secondary SEES: installed after reoperation. Resolution time is expressed in median (range) of days. *P* value was obtained by Mann–Whitney test

Despite a long period for leak resolution in the secondary SEES group, the overall rate of resolution was 96 % for the entire series (28/29 patients). The only patient who did not resolve with SEES placement was a SG patient who initially received a SEES and healed her leak, but reopened 8 months later. She was treated with a second SEES successfully. Nevertheless, 3 years after surgery, the leak reopened again. A laparoscopic jejunostomy was performed for nutritional support and after sepsis management; a laparoscopic proximal gastrectomy with hand-sewn Roux-en-Y esophagojejunostomy was performed, with no further complications.

Self-Expandable Endoscopic Stent Performance

In this series, SEES achieved a high rate of leak resolution. Nevertheless, SEES were not exempt of complications. In fact, 16 patients required additional procedures besides SEES placing during their evolution. There were 16 migrations in 10 patients (34 %), 7 of which were treated with repositioning, 5 with installation of a second SEES and in 4 cases, prosthesis were removed without repositioning or replacement due to leak closure. There were five additional SEES replacement due to leak persistence after removal. Two patients required reoperation exclusively due to SEES complications: one SG patient had a prosthesis fracture and required a laparoscopic removal of the distal segment of the prosthesis that migrated to the jejunum, and one RYGB patient in whom the distal edge of the prosthesis opened the stapler line of the blind end of the alimentary limb. Prosthesis was removed by laparoscopy, the open limb was closed using silk stitches, and drains were placed near the leak and the alimentary blind end. Complications associated with SEES in each patient are detailed in Table 1.

Discussion

Currently, BS is recognized as the most effective treatment against obesity and its related comorbidities. Nevertheless, BS is not exempt of postoperative problems and leaks are one of the most feared and life-threatening complications. Despite the improvement in surgical devices such as laparoscopic staplers to perform safer BS and despite the experience gained through years, no surgeon is free of having a leak [17]. Probably the most important step in leak management is its early recognition and treatment, in order to prevent severe systemic inflammation [17, 18]. As mentioned above, there are no standardized protocols to treat this complication; therefore, besides the medical control of sepsis and the nutritional support, treatments are usually performed according to local experiences and what seems to be reasonable for each patient. This includes the non-surgical management, percutaneous image-guided drainage [19], endoscopic stents, reoperations, drains placement for collections management [20], and different combinations of them.

In our center, we do not routinely perform intraoperative nor postoperative leak assessment, since no study has demonstrated the usefulness of this practice [17, 21]. As widely known, leak diagnosis is based primarily on clinical signs as tachycardia, abdominal pain, and fever [22]. In these cases, we perform an orally and intravenous contrast-enhanced abdominopelvic CT scan, which has proven to be a very useful test for leak diagnosis [9], since besides demonstrating the leak itself, also can show the presence of intra-abdominal collections, which are generally indirect sign of leaks. We reserve UGI series, which sensitivity has been reported to vary between 22 and 75 % [23, 24], to patients with high suspicion of leak and a negative CT scan. It must be noted that both UGI and CT may be limited by patient positioning and inability to ingest oral contrast, and could result in false-negative results in one third of cases [17, 23]; therefore, high suspicion is the cornerstone when diagnosing this complication.

Endoscopic stents have been largely used in general and oncologic surgery for treatment of leaks and strictures [12, 13, 20, 25] and recently, SEES are also being increasingly used for treatment of post BS leaks [10, 11, 18, 26] with good results in terms of leak resolution. Here, we show our experience in the use of coated SEES in leaks treatment after SG and LRYGB. Nevertheless, the major flaw of our study is the absence of defined length of time for SEES use. In our series, each surgeon according to personal clinical judgment decided when to remove the prosthesis. Therefore, we are not able to make a recommendation regarding how long the prosthesis should be in situ. Fortunately, we had a high rate of leak resolution after SEES placement, without mortality related to leak per se or prosthesis complication. Notably, there was a significant shorter time of leak resolution when SEES was placed as the first choice of treatment (primary group).

As described above, endoscopic stents together with the simultaneous treatment of sepsis are becoming an attractive option in the management of post BS leaks due to its minimally invasive placement, low injury to patient, and early restoration of oral feeding. In our series, we observed 6 out of 29 patients who required a second SEES, 5 of them immediately after SEES removal, due to leak persistence, and 1 patient because of leak recurrence 8 months after SEES removal. Here, we show that placing a second SEES when leak persistence is found after removal is effective to achieve leak closure.

The main flaw of SEES is its high migration rate and need of prosthesis revision. Large series of leaks management with prosthesis after bariatric surgery have shown migration rates from 11 to 58 % [15, 27, 28], and other complications such as bleeding and prosthesis kinking. Here, we show a rate of 34 % of prosthesis migration, which is similar to previously reported data [9]. Recently, endoscopic stent anchoring with stitches or clips have been employed resulting in lesser migration rates [27, 29]. We have not anchored any SEES but certainly, it seems a promising alternative to prevent stent migration. Finally, adding two patients who required reoperation (stent fracture and opening of the blind end of the alimentary limb), we had a 41 % of total complications, a rate that is similar to others described in literature [15, 27, 28]. Regarding how long SEES must be in situ, several studies have suggested that they should not be placed longer than 6 weeks [9]. However, despite a long SEES use time in some cases (68 % of patients had the stent more than 6 weeks), we had no long-term esophageal strictures, and endoscopic removal was successfully achieved in all cases.

Conclusions

In summary, here, we show a large series of coated SEES for acute and early leak treatment after BS with good results in terms of leak resolution and morbidity rate similar to previously reported by other groups. Notably, the primary use of SEES was associated with a shorter length of leak resolution. Therefore, after prompt leak recognition in association with appropriate sepsis treatment with antibiotics, nutritional support, and collection drain, early SEES placement should be considered as a useful treatment for this complication.

Conflict of Interest The authors declare that they have no conflict of interest. For this type of study, formal consent is not required.

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