CASE STUDY

Use of sleeve-customized self-expandable metal stents for the treatment of staple-line leakage after laparoscopic sleeve gastrectomy

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Bariatric procedures have emerged as a leading therapeutic approach in morbidly obese patients. Laparoscopic sleeve gastrectomy (LSG) was originally introduced as a bridge procedure before Roux-en-Y gastric bypass (RYGB) but has subsequently become a definitive procedure after demonstrating similar efficacy to that of RYGB for inducing weight loss.[1] Moreover, LSG has demonstrated a good safety profile and is less technically demanding than RYGB.[2,3] However, LSG is prone to some adverse events because of the long staple line and elevated intragastric pressure.[4] These include staple-line leakage, bleeding, and sleeve stricture.[4] The prevalence of staple-line leaks has been as high as 20% in some reports, but a more traditional estimate is 1% to 9%.[5,6] The onset of leaks is defined as acute, early, late, or chronic depending on the time interval since surgery: up to 1 week, 1 to 6 weeks, 6 to 12 weeks, and more than 12 weeks, respectively.[6]

Immediate treatment usually includes surgical or percutaneous drainage, antibiotics, and nutritional support.[7-9] After primary control of the leakage, further specific therapeutic approaches have been described: surgical repair, over-the-scope clip system, fibrin glue, and covered or partially covered self-expandable metal stents (SEMSs).[10-13] These stents can reduce intragastric pressure and leakage and thus expedite healing.[7,14] Sleeve-customized SEMSs (S-SEMSs) are specifically designed for sleeve leakage because they are longer than the standard available esophageal stent. These longer stents have the potential to better reduce intrasleeve pressure and may have lower migration rates. Endoscopic placement of SEMSs is increasingly used; however, this practice is currently based on small case series that showed promising results. In this study we report our recent experience in the treatment of this dreaded adverse event with S-SEMSs.

METHODS

We reviewed the medical records of consecutive patients diagnosed with staple-line leakage and referred to our department between June 2012 and December 2013 for treatment with S-SEMSs. The patients were managed by a multidisciplinary team that included bariatric surgeons, gastroenterologists from the bariatric endoscopy service, invasive radiologists, and nutritionists.

Endoscopic evaluation of the leak location and of the presence of sleeve stricture was performed. An S-SEMS was then placed with the patient under conscious sedation and with fluoroscopic guidance (Fig. 1). The proximal third of the stent was located above the gastroesophageal junction. Hanaro stents (MI-Tech, Seoul, Korea) with a length of 18 to 24 cm and a diameter of 18 to 22 mm were used in 5 patients and the Niti-S megastents (Taewoong, Seoul, Korea) with a length of 18 or 23 cm and a diameter of 22 to 24 mm were used in 21 patients. These stents have the CE mark. In some of the patients a stricture was diagnosed in the middle of the sleeve. In those patients the longer 23cm stent was chosen and the distal tip was inserted to the first part of the duodenum. This way the whole sleeve is covered and dilated by the stent. As we explain in the discussion we believe this achieves better pressure reduction by dilating the stricture. We used a stiff guidewire, the .38-inch Amplatz Super Stiff

Abbreviations: LSG, laparoscopic sleeve gastrectomy; RYGB, Roux-en-Y gastric bypass; SEMS, self-expandable metal stent; S-SEMS, sleeve-customized self-expandable metallic stent.

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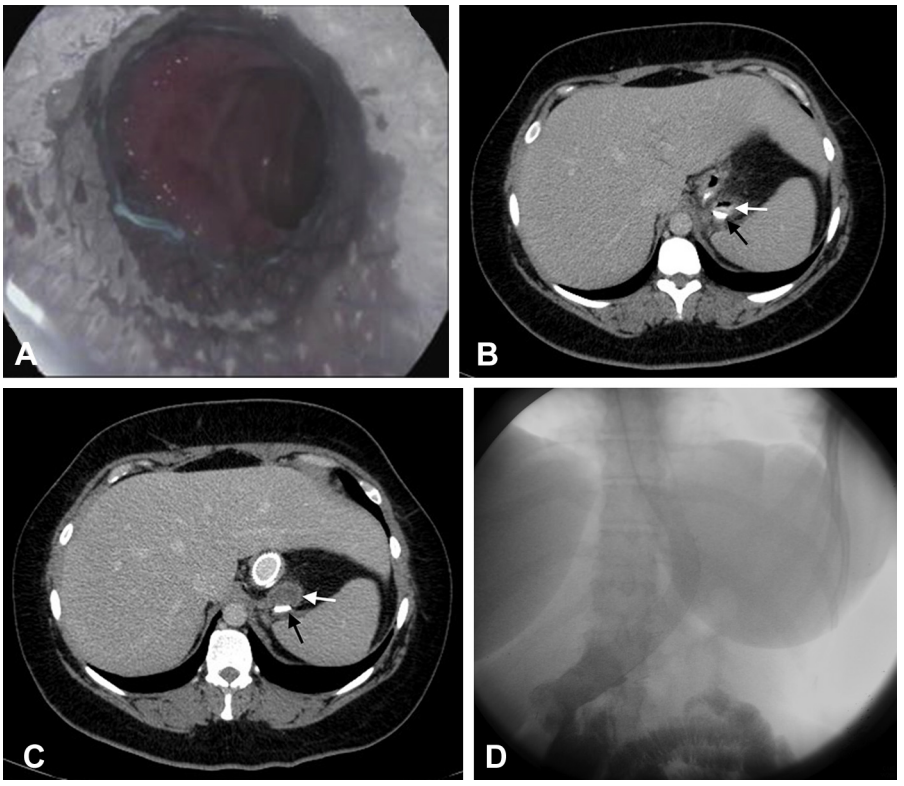

Figure 1. A representative case for staple-line leak treatment by S-SEMSs. **A,** Endoscopic view after deployment of S-SEMSs with the distal tip extending to the duodenal bulb. **B,** CT scan before stent insertion. Note air and extravasation of contrast material into the collection (*white arrow*) adjacent to the staple line (*black arrow*). **C,** CT scan after stent insertion; the leak is controlled. Contrast material is visible in the sleeve with no extravasation to the collection (*white arrow*). *Black arrow* denotes the staple line. **D,** Fluoroscopy demonstrating the stent that controls the leak.

(Boston Scientific, Marlborough, Mass, USA), which enabled us to deploy the long stents distally.

Confirmatory fluoroscopy or radiograph was performed 1 day after the procedure, after which patients gradually resumed a soft oral diet. Our target length of treatment was between a minimum of 2 weeks and a maximum of 6 weeks. The exact length of treatment was individualized by the drainage output, the nature of the fluid, and the patient's tolerance to the stent.

We considered the treatment as technically successful if stents remained in place for at least 2 weeks because we estimated this period as the minimum duration for stents to be potentially therapeutic. The primary endpoint was clinical resolution, defined as weaning from total parenteral nutrition, resuming oral diet, removal of intra-abdominal draining tubes, and avoidance of further surgical intervention. Secondary endpoints were fistula orifice closure and adverse outcomes, including stent migration, severe bleeding, ulceration, and intolerance.

RESULTS

Twenty-six consecutive patients with staple-line leak confirmed by CT scan were treated with S-SEMSs. Patients' characteristics stratified by the timing of the leak are depicted in Table 1. Eighty percent of patients (21/26) were women with an average age of 42 and body mass index of 41 before surgery. The average time between surgery and clinical presentation was 40 ± 31 days.

TABLE 1. Patients' demographic data distribution according to leak timing

	Acute	Early	Late	Chronic
Number of patients	1	17	5	3
Mean age, y	25	41.3	45	52
Body mass index	40	39.8	41.2	36.3
Sex (male %)	0	23.5	25	0

Surgical and nutritional treatment is summarized in Table 2. One patient (4%) presented with an acute leak, 17 (65%) with early leaks, 5 (19%) with late leaks, and 3 (12%) with chronic leaks. In 1 case the stent was used as a second-line treatment after failure of an over-the-scope clip system treatment.

The presence of a mid-sleeve stricture and intervention details are summarized in Table 3 and stratified according to outcome. Proximal leaks, below the gastroesophageal