Original Article

Endoscopic Management of Post-Laparoscopic Sleeve Gastrectomy Leakage and Stenosis Using Fully Covered Stent

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Abstract

Background: Laparoscopic sleeve gastrectomy (LSG) is the most commonly performed surgery to treat morbid obesity. Post-LSG leak and stenosis are serious complications that can be associated with significant morbidity and mortality.

Objective: The objective was to report the efficacy and safety profile of using specifically designed fully covered self-expandable metallic stent for the treatment of post-LSG complications.

Methods: This retrospective study included adult patients who underwent placement of a fully covered esophagogastric, self-expandable metallic stent for post-LSG leak or stenosis. The procedure was carried out at King Abdulaziz University Hospital, Jeddah, Saudi Arabia, between September 2017 and May 2019. Data regarding demographics, indication for stenting, size of the stent, procedural success and poststenting adverse events were collected.

Results: A total of 14 patients met the inclusion criteria, with indication for endoscopic stenting being post-LSG leak in 11 patients and stenosis in 3 patients. The technical success rate of self-expandable metallic stent placement was 100%, and the clinical success was 85.7% (12 of 14 patients). Nausea (71.4%) and vomiting (85.7%) were the most frequent mild adverse events reported. Stent-induced esophageal stricture was the only major adverse event reported in two patients.

Conclusion: Placement of specifically designed self-expandable metallic stent for the treatment of post-LSG leak and stenosis is an effective and safe approach. Further studies with larger cohorts are needed to assess the optimal duration needed to treat such complications.

Keywords: Bariatric surgery, fully covered self-expandable metal stent, laparoscopic sleeve gastrectomy, leak, stenosis

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INTRODUCTION

Obesity is a global health problem that is associated with complications such as heart disease, stroke and diabetes mellitus, as well as increased risk of developing endometrial, breast and colon cancer. Such obesity-related complications result in >2.8 million adult deaths each year.[1] In Saudi Arabia, diet patterns have become Westernized, which, along with a sedentary lifestyle, has resulted in the prevalence of obesity to increase rapidly over the past decade.[2-4]

Bariatric surgeries, such as Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy (LSG), are considered as one of the most effective therapies for patients with morbid obesity. In addition to its effectiveness, LSG is a simple procedure, and thus has gained wide acceptance globally; however, it is not without risk of complications. Staple-line leakage is a serious postoperative complication, which can result in significant morbidity and mortality. Sleeve stenosis is another significant complication that occurs in up to 4% of patients undergoing LSG.[5,6]

Endoscopic stent placement is a minimally invasive approach in the management of post-LSG leak and stenosis with high clinical success rates. Multiple studies have described the efficacy and safety of using partially and fully covered (FC) esophageal self-expandable metallic stents (SEMSs) in the management of post-LSG leakage and stenosis.[6-9] However, only a few studies have reported the efficacy of specifically designed FC mega SEMS in the management of post-LSG leakage and stenosis.[10-12] Thus, the present study aimed to assess the efficacy and safety profile of using the mega stent in the management of post-LSG fistulas and stenosis in a single center. Previous studies in Saudi Arabia have only reported the use of partially covered SEMS in the management of post-LSG leak.[8]

METHODS

This retrospective chart review included all adult patients (aged >18 years) with post-LSG leakage or stenosis who underwent endoscopic FC-SEMS placement at King Abdulaziz University Hospital (KAUH), Jeddah, Saudi Arabia, between September 2017 and May 2019. The patients were either diagnosed at KAUH or referred from other hospitals. Patients treated with partially or uncovered SEMSs were excluded.

Electronic medical records were reviewed to collect the following data: age, gender, type of post-LSG complication (leak, stenosis or both), location of the leak and/or stenosis, type and sizes of used metallic stent, total days postsurgery before endoscopic stent insertion, poststent insertion pain, nausea or vomiting, distal end location of the placed stent (pre- or postpyloric), number of weeks before stent removal, early stent removal, stent-related complications (major complications: bleeding, esophageal stricture, perforation and migration; minor complications: poststent insertion onset pain, nausea or vomiting), outcome of endoscopic intervention and the need for any further management after stent removal, such as stent reinsertion or surgery.

Before the procedure, all patients were admitted under the care of the bariatric team and underwent comprehensive assessment. If a patient had clinical symptoms such as fever and pain, computed tomography (CT) was performed to confirm the existence of intra-abdominal collection or fistula. Percutaneous drainage under ultrasound or CT guidance with a pigtail catheter placement was performed in case intra-abdominal fluid collection was found on imaging. Patients were kept NPO, and were prescribed intravenous (IV) broad-spectrum antibiotics.

Diagnosis and procedure

The diagnosis of both leakage and stenosis was confirmed through imaging (upper gastrointestinal series with water-soluble contrast media or CT imaging) and/or endoscopic evaluation. All cases in this study were discussed at multidisciplinary meetings before proceeding with stent placement. Endoscopic FC-SEMS placement was performed by an experienced interventional endoscopist either under conscious sedation or general anesthesia. FC metallic Niti-S MEGA (Taewoong Medical, South Korea) [Figure 1] and Hanaro (M. I. Tech, Pyeongtaek, Korea) [Figure 2] esophageal stents were used in all patients. The size of the used stents was not consistent and based on stock availability. The stent was kept for a minimum of 4 weeks, unless early removal was necessary, and a maximum of 8 weeks. The patients were followed up in the outpatient clinic for at least 3 months poststent removal.

Under the guidance of fluoroscopy, an endoscopic clip was placed as a radiopaque marker to outline the distal extent of the stent. A guidewire was placed into the duodenum, after which the endoscope was removed, but the guidewire was kept in place. The stent was then advanced over the guidewire until it reached the radiopaque marker. The gastroscope was reintroduced into the esophagus, and the stent was

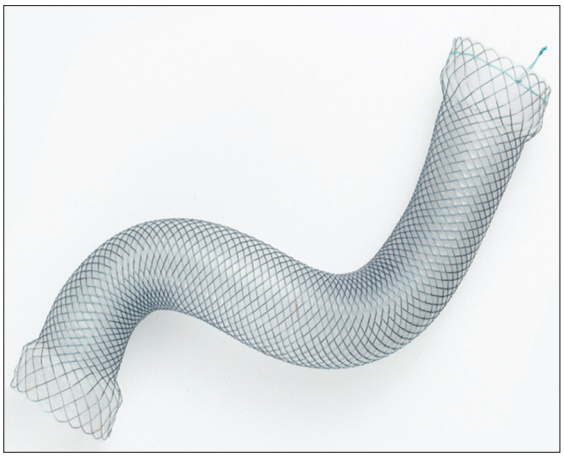

Figure 1: Niti-S MEGA fully covered esophageal metallic stent

Figure 2: Hanaro fully covered esophageal metallic stent

deployed over the guidewire under direct endoscopic and fluoroscopic guidance between the radiopaque marker and mid-esophagus. Choosing the location of the stents' distal end deployment was mainly based on the ability of the endoscopist to advance the tip of the stent delivery catheter to either the prepyloric or postpyloric area.

Definitions

Technical success was defined as the ability to place the stent across the area of leakage or stenosis with proximal end in the esophagus and distal end either in the prepyloric region or in the duodenum. Clinical success was defined as complete resolution of sleeve leakage or stenosis, confirmed with endoscopic evaluation at the time of stent removal and by radiologic imaging within 48 h after the removal. Using the Rosenthal classification,[13] post-LSG leak was defined as acute leak (within 7 days), early leak (8–42 days) and late leak (>42 days postsurgery). A chronic leak was defined as a leak that lasted >90 days, and early stent removal was defined as removal of the stent before 4 weeks.

Statistical analysis

Data analysis was conducted using SPSS version 23 (SPSS Inc., Chicago, IL, USA) where descriptive statistics and chi-square test of difference were used. Descriptive statistics was conducted to determine the distribution of the variables. chi-square test of independence was conducted to determine if there is a significant association between the outcome of the sleeve operation and other variables. The mean and standard deviation and/or the median with range were used for continuous variables, as appropriate. The percentage and count were used for categorical variables.

Ethical approval was obtained from the Unit of Biomedical Ethics at KAUH, Jeddah, Saudi Arabia.

RESULTS

A total of 14 patients met the inclusion criteria of this study, of which 9 were women. All the patients were of Saudi nationality. The mean age of the patients was 43.8 (±11.2) years (median: 42.5) [Figure 3]. All cases, except one, were referred to our center from other hospitals with post-LSG leak or stenosis.

Eleven patients had post-LSG leak, of which only one had a mid-sleeve leak, while the remaining had leaks at the gastroesophageal junction (GEJ). Two patients had acute sleeve leaks, eight had early leaks and one had chronic leak. The actual size of the leak opening could not be measured in most of the patients. However, in all patients, the proximal fistulae were <10 mm in size. In patients with mid-sleeve leak, the defect was approximately 10–12 mm in size. Three patients had post-LSG stenosis. All three patients with stenosis had been referred from other hospitals and had previously undergone unsuccessful endoscopic balloon dilations at the referring hospital.

The mean duration between LSG surgery and endoscopic FC-SEMS placement was about 32 days [Figure 4]. Eleven (78.57%) patients had prepyloric stent distal end placement, and three (21.43%) had postpyloric distal end placement. The mean diameter of the placed stents was 25.45 mm (range: 22–28 mm), and the mean length was 180 mm (range: 80–240 mm). The mean duration of stent removal was 5.71 weeks (±3.58) [Figure 5]. In one patient, the stent was removed 16 weeks after placement. She had undergone stent placement and removal at another hospital, and was referred to our center for the management of stent-induced esophageal stricture.

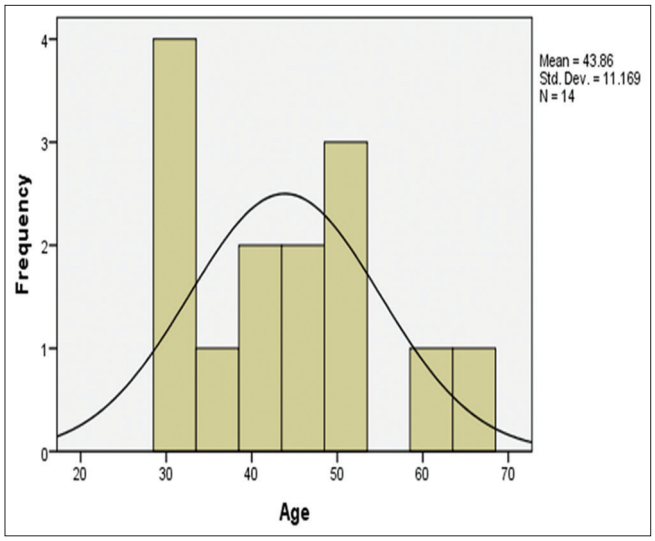

Figure 3: Distribution of patients by age

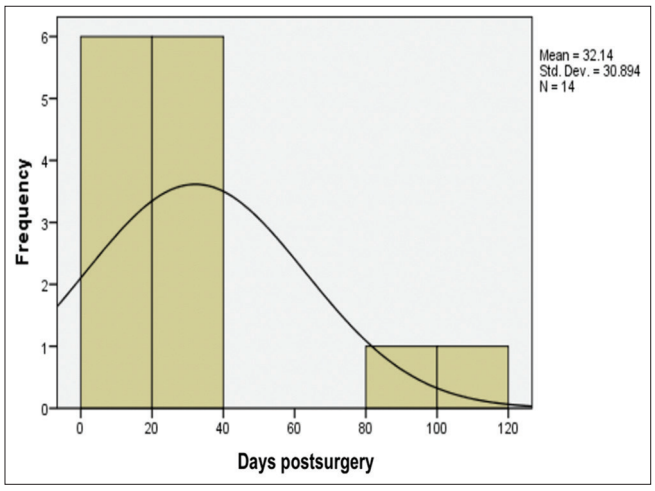

Figure 4: Duration between laparoscopic sleeve gastrectomy surgery and endoscopic fully covered self-expandable metallic stent placement

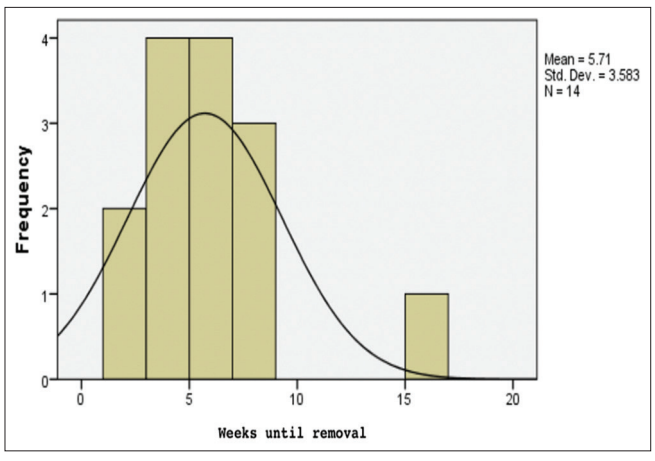

Figure 5: Duration for stent removal

Complications

In terms of minor complications, poststent insertion pain was reported in 8 patients (57.1%), nausea in 10 patients (71.4%) and vomiting in 12 patients (85.7%). Regarding major complications, stent migration was reported in three patients (21.4%), all of whom had distal migration of the device [Table 1]; in two cases, the stents were placed in the prepyloric area. The diameters of these migrated stents were 22 mm, 24 mm and 28 mm with variable lengths (100 mm–240 mm). All patients with migrated stents were diagnosed at the time of endoscopy for stent removal, and they were successfully retrieved endoscopically. The healing process was not affected, as the stent body still covered the site of the gastric leak and stenosis, and all these patients had an uneventful follow-up clinical course. Stent-induced esophageal stricture was reported in two patients (14.29%). None of the patients in this study developed stent-related perforation or bleeding. Early stent removal was reported in three patients (21.4%): one with leak and the other two with sleeve stenosis. None of these patients underwent stent reinsertion.

Clinical success

Endoscopic stent therapy was clinically successful in 12 patients (85.71%). All the patients were followed up for 6 months after therapy, and no recurrence was reported. In terms of stenosis, all three patients were treated successfully. Both cases of the intervention being unsuccessful was in post-LSG leakage patients.

DISCUSSION

In the present study, we reported on 14 patients with post-LSG leakage or stenosis. The technical success was 100% using variable diameters and lengths of FC-SEMSs. Further, this intervention was clinically successful in managing post-LSG leakage and stenosis in 12 of the 14 patients (85.7%). The clinical success rate in this study was similar to that reported by Manos *et al*.,[6] wherein the clinical success rate of stents placed for 4 weeks in 18 patients with post-LSG stenosis was 94.4%.

Table 1: Poststent complications, migration and need for surgical intervention

Complication	Frequency (%)
Poststent insertion pain	8 (57.1)
Postinsertion nausea	10 (71.4)
Poststent insertion vomiting	12 (85.7)
Stent migration	3 (27.2)
Stent reinsertion required	0 (0)
Need for surgical intervention	1 (7.2)

All three patients with post-LSG stenosis in our study were treated successfully using FC-SEMS, but two had early stent removal because of refractory nausea and vomiting and their inability to tolerate oral intake. Notably, the vast majority of patients in the current study had nausea and vomiting and more than half experienced pain. These minor adverse events have been similarly reported in previous studies. In the study by Garofalo *et al*.,[14] which evaluated the management of post-LSG using endoscopic placement of partially covered and long FC metallic stents, all 11 patients suffered the initial poststent placement retrosternal/epigastric pain and were treated with IV analgesics. Further, nausea and vomiting were present universally in their study group. In contrast, in a study by Senousy *et al*.,[15] in which 28 stents were successfully placed in 14 patients and the technical success in placement and removal, efficacy and complications of FC metal stent was evaluated in the management of benign esophageal diseases, poststent insertion nausea and vomiting were only reported in 3 (11%) cases and pain in 2 (7%) cases.

Safety is mainly related to major adverse events such as bleeding, perforation, stent migration and esophageal obstruction due to stent-induced stricture formation. In the present study, two patients (14.3%) developed stent-induced esophageal stricture causing severe dysphagia within 2 weeks after stent removal. Both patients underwent successful endoscopic management using multiple sessions of needle-knife stricturotomy through the scope balloon dilation.

With partially covered SEMS, the reported incidence of esophageal strictures is approximately 5% and almost never with conventional FC SEMS.[16] Guzaiz *et al*.[17] retrospectively evaluated the effectiveness of gastroesophageal stenting in six patients with post-LSG leak using removable SEMS and found that one patient developed esophageal stricture at the proximal stent margin 6 months after stent removal and was treated endoscopically with four quadrant incisions and balloon dilation. In a study by Shehab *et al*.,[18] where 62 patients with post-bariatric surgical leaks (of which 46 [73%] were post-LSG leaks) were treated with endoscopic placement of mega stent and/or over-the-scope clips, 8 patients (12.9%) developed stent-induced esophageal strictures, and all were successfully treated with endoscopic balloon dilation. In the present study, the stent diameter and length did not appear to be related to the development of esophageal stricture and neither patient had known underlying esophageal disorders. The proximal flare of the placed stent and bile reflux could have contributed to the development of esophageal strictures.[18] In addition, the lengthened exposure of the esophageal wall to the proximal end of the stent could have resulted in mucosal inflammation and then granulation tissue formation, leading to the development of esophageal stricture.

Stent migration was reported in about 21% of the patients in this study. This is relatively low compared with that of studies on safety and efficacy of partially covered stents, which, hypothetically, can increase the rate of migration.[7,8] Another possible reason is that leaving the stent for a shorter time (<6 weeks) in most patients could have contributed to the lower rate of stent migration. Therefore, there is a need for larger cohort studies using FC stents to evaluate the risk of migration. The incidence of stent migration in our study was similar to those described in previous studies.[18,19] None of the patients in the current study developed stent-related perforation or bleeding; in one case, massive bleeding occurred, but it was from a bleeding duodenal ulcer. The distal end of the stent in this patient was placed in the prepyloric area, which is proximal to the ulcer location, making it less likely to be related.

In terms of clinical success, the endoscopic stent therapy was unsuccessful in two patients. One of these had undergone LSG revision, which was complicated with post-resleeve gastrectomy leakage. The patient was unable to tolerate the stent for more than 2 weeks because of refractory symptoms of pain, nausea and vomiting. The short duration of the stent therapy appears to have played a significant role in the failure of the stent therapy. It should also be noted that it remains unclear whether LSG revision leaks have lower success rates to endoscopic management in general, and SEMSs in particular, than patients with native LSG leaks. The second patient in whom the therapy was unsuccessful had undergone FC-SEMS placement for post-LSG leakage 90 days after surgery. On endoscopic evaluation, she had two large staple-line fistulae identified, one of which was located at the GEJ and the other at the mid-sleeve. Although the stent had been in place for more than 6 weeks, the two staple-line defects remained patent. Multiple factors could have contributed to the failure of stent therapy in this patient, such as the wall defect location, the number and size of the wall defects and the duration between surgery and stent placement. Tsai *et al*.[19] reported treating five patients with post-LSG leaks, two of whom had mid-sleeve leaks. All patients received covered SEMSs, and both patients with mid-sleeve leaks achieved leak closure. The interval between the development of LSG fistula and endoscopic intervention has been reported to influence the outcome. Bège *et al*.[20] indicated that patients who underwent endoscopic intervention early (<30 days) healed more rapidly and required fewer endoscopic

procedures than patients who were referred after 30 days. Therefore, in the second unsuccessful case of this study, the long interval between the LSG fistula and the endoscopic intervention (90 days) may likely have been cause of failure.

The major limitations of the current study include the small number of patients and the retrospective design. Therefore, to validate the findings of this study, a study with a larger sample size is needed to examine the efficacy and safety of using SEMSs in managing leak and stricture after LSG and to evaluate the relationship between the duration of stent placement and the risk of developing esophageal stricture.

CONCLUSION

The present study is the first study that addresses the effectiveness and safety of using a mega stent in the management of post-LSG-leak or stenosis in Saudi Arabia. FC-SEMS placement was found to be an effective and safe modality in treating post-LSG leak or stenosis. Nausea and vomiting were the most frequent mild adverse events, and esophageal stricture was the only major adverse event, seen in patients with extended stent placement (>6 weeks). As reasons for the development of stent-induced esophageal stricture in sleeve patients are not well understood, additional studies with larger cohorts are needed to assess the predictors associated with the development of these strictures.

Ethical considerations

This study was retrospectively approved by the Unit of Biomedical Ethics at King Abdulaziz University Hospital (Reference No. 424-20), Jeddah, Saudi Arabia, on August 18, 2020.

Peer review

This article was peer-reviewed by four independent and anonymous reviewers.

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Conflicts of interest

There are no conflicts of interest.

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