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BRIEF COMMUNICATION

Secured Lumen-Apposing Fully Covered Metallic Stents for Stenoses in Post-Bariatric Surgery Patients

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Abstract
New approaches for refractory stenosis in post-bariatric surgical patients include fully covered lumen-apposing metallic stents (LAMS); however, stent migration continues to be a problem. Endoscopic suture placement to LAMS can reduce the migration. Aiming to assess the feasibility and safety of the procedure, we evaluated nine consecutive patients with inability to tolerate a solid diet due to a benign gastrointestinal stricture recalcitrant to previous attempts at endoscopic therapy. All patients were symptom-free starting from 1-week follow-up. Median stent dwell time was nearly 3 months. During the removal procedures, three incidental foreign bodies were found and removed. No stent migration was observed in any patients. Suturing LAMS is a feasible technique allowing for prolonged stent dwell times; however, it requires a high level of expertise plus additional procedure time.

Keywords Self-expandable metallic stents · Lumen-apposing metallic stent · Stricture · Bariatric surgery · Obesity

Introduction

Gastric or luminal stenosis is an important post-bariatric surgical complication with a reported incidence of 1–27% [1, 2]. It is usually treated with an endoscopic approach including initial through-the-scope balloon dilation; however, that may require multiple procedures and also has a risk of perforation. In case of a recalcitrant stricture, the use of a fully covered

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self-expandable metallic stent (FCSEMS) has gained popularity. Nevertheless, this technique also has an important drawback which is its ability to slide across the mucosa and migrate longitudinally.

Recently, a newer lumen-apposing metallic stent (LAMS), originally developed to perform transmural drainage of pancreaticobiliary collections, has been shown to be effective in relieving luminal obstructions. The LAMS is a fully covered stent which prevents tissue ingrowth, but more importantly, it has two wide phalanges that enable firmer anchorage to the surrounding mucosa thus hindering its migration [3]. Even though LAMS does have a lower migration rate, the percentage is still reported to be nearly 10% [4].

The migration rate of stents can be halved with endoscopic suture placement to the surrounding mucosa [5]. Securing the LAMS on the other hand with sutures has never been reported that could potentially decrease its migration rate. The aim of our study was to demonstrate and assess the technical feasibility, tolerability, efficacy, and safety of sutured LAMS for patients with benign gastrointestinal strictures.

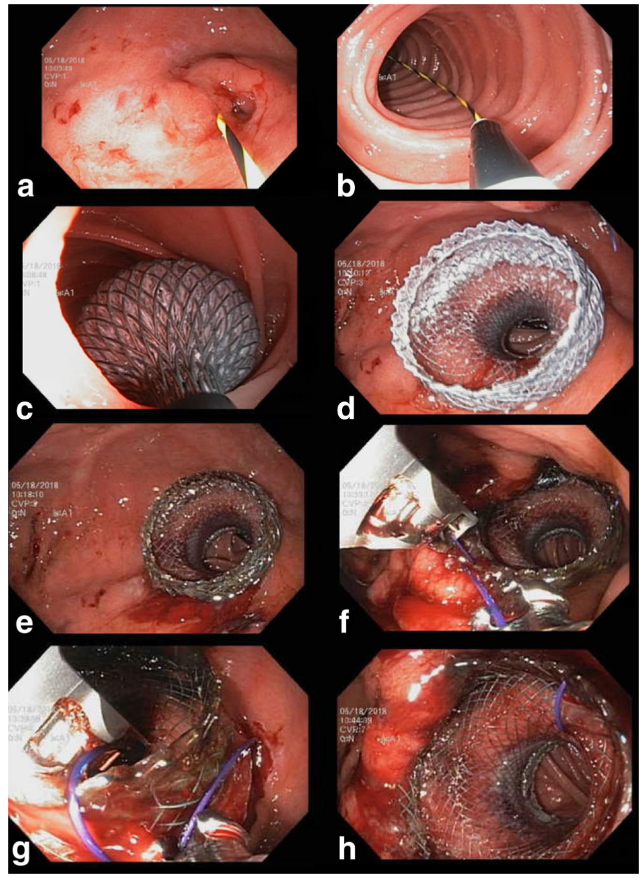

Fig. 1 Deployment and securing the lumen-apposing self-expandable metallic stent (LAMS) with endoscopic suturing (Axios 20 × 10 mm; Boston Scientific, Natick, MA). **a**, **b** Guidewire and LAMS catheter advancing through the stricture towards the efferent intestinal loop. **c** Deployment of first the distal and **d** then the proximal phalange through the stenotic area. **e** Deployed and positioned LAMS through the stricture. **f** Bite through the proximal gastric wall adjacent to the stent. **g** Bite through the proximal strut of the stent. This step is followed by a third bite through the gastric wall. **h** Final endoscopic appearance of the secured LAMS to the adjacent gastric wall after the suture had been placed

Methods and Procedure Details

Patient Selection

We retrospectively evaluated our prospectively collected single-institutional experience with sutured LAMS for benign gastrointestinal strictures. The need for a LAMS and suture placement for each patient was agreed upon by a multidisciplinary bariatric care team. Conventional approach to such dilations is repeated through-the-scope balloon dilations before proceeding to stent placement. As such, patients included in this study were the ones referred for recalcitrant strictures after at least two through-the-scope balloon dilations, or that were unable to be traversed by a single-channel adult gastroscope. Since the LAMS' body has a length of 1 cm, any stricture longer than 1 cm was not deemed suitable. In those cases, we elected to use an esophageal FCSEMS that was also sutured if applicable. Other therapeutic options including revision surgery were also presented and comprehensively discussed with the patient.

Procedures

The procedures were performed by a single endoscopist under general anesthesia. In all cases, Axios (Boston Scientific, Natick, MA) 15- or 20-mm-diameter LAMS were utilized, with the latter being preferred if available. The Overstitch (Apollo Endosurgery, Austin, TX) suturing device loaded with 2.0 Prolene (non-absorbable) sutures and the Tissue-Helix device (Apollo Endosurgery, Austin, TX) were used for the placement of sutures (Fig. 1). Endoscopic scissors (Enzisor Endoscopic Scissors, Slater Endoscopy, Miami Lakes, FL) were used to remove the sutures. Thereafter, stents were removed utilizing raptor forceps (US Endoscopy, Mentor, OH), or polyp snares if needed. During the removal procedure, any other incidentally identified endoluminal foreign materials were also removed using the abovementioned devices (Fig. 2).

Definitions and Final Outcomes

We defined stenosis as an untraversable area with a standard adult gastroscope, therefore < 10 mm in diameter, or when the distal lumen could not be visualized, or significantly slower passage of radiographic contrast. Short segment stenosis was defined as a < 1-cm stricture length. The primary endpoint

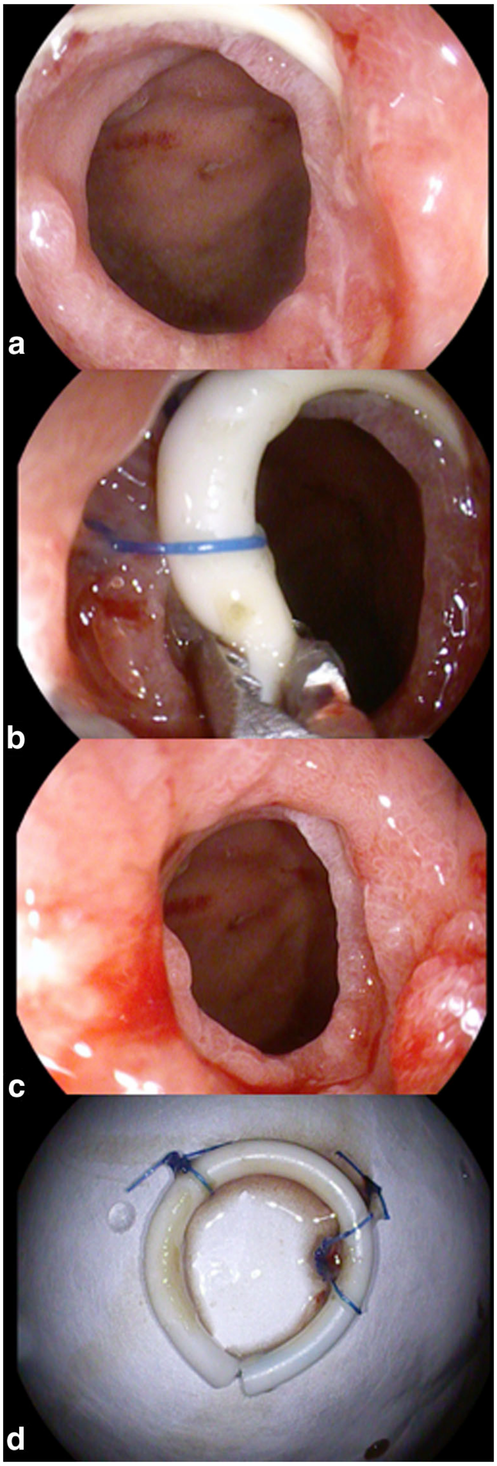

Fig. 2 Removal of a Fobi band which was incidentally found during a stent retrieval procedure. **a** Fobi band found to have eroded through the gastrojejunal anastomosis immediately upon removal of the lumen-apposing metallic stent. **b** Removal of the band utilizing Raptor forceps (US Endoscopy, Mentor, OH). **c** Large lumen opening noted after the removal of the band. **d** Retrieved Fobi band after the procedure

was the technical success which was defined as the successful placement of the stent along with securing the stent with sutures. Procedure time was recorded as room-in to room-out time and also includes time for anesthesia and preparation of the room. The short-term clinical efficacy was defined as the restoration of an unrestricted diet and symptomatic improvement of the gastric outlet obstruction 1 week after the stent insertion.

Results

Baseline Characteristics

Nine consecutive patients had undergone LAMS placements that were secured with sutures (Table 1). Patients had a median age of 47, and 78% were women. Eight patients were post-bariatric surgery including six post-Roux-n-Y gastric bypass (RYGB) and two post-vertical banded gastroplasty (VBG). One non-bariatric patient had a pyloric stricture which was presumed to be peptic. The width of strictures varied between 3 and 8 mm. Common to all patients was a history of a recalcitrant stricture, defined by at least two failed endoscopic therapy attempts. All patients were symptomatic at initial presentation with the inability to tolerate solid food.

Procedural and Clinical Features

Six of the nine patients' stents, which were inserted between April 2018 and January 2019, have been removed as of February 2019. The remaining three patients have still in situ stents with their follow-up times ranging from 0.6 to 2.4 months (median 1.1 months). The plan is to remove those stents after 6 to 9 months from the time of their placement. The overall short-term clinical success is 100%. All patients with in situ stents remain asymptomatic to date. Of the six patients who have had their stents removed, only one, a 45-year-old female with a 4-mm stricture following a RYGB surgery (patient 5), had symptomatic recurrence after the removal of the first stent and undergone a second stenting procedure. However, her symptoms recurred again and she proceeded to revision surgery. The other five of six patients with removed stents (patients 2, 3, 4, 6, and 7) have been followed up for 1 to 6 months after the removal, and remain asymptomatic.

The total procedure time, i.e., room-in to room-out time as mentioned previously, ranged between 24 and 69 min (median 52 min). Fifteen- and 20-mm-width stents were used in four and five cases respectively. The total number of sutures varied between 2 and 4, with a median of 3. Technical success was 100%. Procedures were well tolerated, with no adverse events except in one case (patient 7) with self-limited symptoms of regurgitation and pyrosis on post-procedure day 3 that were successfully medically managed.

In three post-bariatric cases, foreign material was incidentally identified and removed during the stent retrieval. The

Table 1 Demographical and procedural data

Patient	Age/sex	History/indication	Stricture diameter (mm)	Procedure time (min)	Number of sutures	Type/size of stent (mm)	Stent induration (months)	Follow-up time (months)	Stent removed	Clinical outcome
1	65/F	Peptic ulcer/pyloric stricture	5	69	4	Axios/15 × 10	2.4	2.4	No	Symptoms resolved
2	49/F	VBG/band stenosis	4	52	3	Axios/15 × 10	8.2	8.2	Yes	Symptoms resolved
3	72/M	VBG/band stenosis	8	62	3	Axios/15 × 10	6.0	7.1	Yes	Symptoms resolved
4	31/M	RYGB/GJ stenosis	8	59	3	Axios/20 × 10	8.3	8.3	Yes	Symptoms resolved
5	45/F	RYGB/GJ stenosis	3	47	2	Axios/20 × 10	1.1	9.4	Yes	Proceeded to revision surgery*
6	36/F	RYGB/GJ stenosis	7	24	2	Axios/15 × 10	2.2	5.7	Yes	Symptoms resolved
7	74/F	RYGB/GJ stenosis	4	60	3	Axios/20 × 10	3.4	8.6	Yes	Symptoms resolved
8	49/F	RYGB, gastro-gastric fistula/GJ stenosis	8	41	2	Axios/20 × 10	0.6	0.6	No	Symptoms resolved
9	45/F	RYGB/GJ stenosis	6	39	3	Axios/20 × 10	1.0	1.0	No	Symptoms resolved

GJ gastrojejunal, *RYGB* Roux-n-Y gastric bypass, *LAMS* lumen-apposing metallic stent, *VBG* vertical banded gastroplasty

*This patient had undergone two LAMS procedures; however, her symptoms recurred and a revision surgery was eventually required

first patient was post-RYGB (patient 7) who had an eroding mesh at the previously strictured site which was relieved with Raptor forceps (US Endoscopy, Mentor, OH) and then completely dissected out with a stag-beetle knife (Sumitomo Bakelite, Tokyo, Japan). An expected 15-mm full-thickness defect was closed with four bites of single running suture. The second and third patients had histories of RYGB and VBG, (patients 5 and 6) in both cases; exposed Fobi gastric bands were visualized at the previously stenotic areas, they were captured with Raptor forceps and easily removed without any following luminal defect.

Discussion

The recommended endoscopic management in post-bariatric strictures is initially balloon dilation that could be followed by other therapies such as incision, incision plus intra-lesional steroids, or stent placement [6]. Fully and partially covered stents have been used; however, they have certain drawbacks that could be overcome by LAMS [3].

The use of LAMS in gastrointestinal strictures has certain nuances. An initial point is to select the stent with the widest befitting diameter in order to generate a greater radial force opposing the visceral wall, thus facilitating dilation. To the best of our knowledge, this is the first experience with 20-mm diameter LAMS in gastrointestinal strictures. Nevertheless, LAMS must be used with caution in this context, as it requires expertise and meticulous placement to avoid misdeployment and complications such as perforation [7].

Suturing LAMS is more challenging compared to other stents. Its two narrow-angled phalanges need precise targeting, which is already difficult with the stiffer and bulkier endoscope with a mounted stitching device. The phalanges also hinder the stents' longitudinal movement and interfere its appropriate positioning. This technical challenge is also reflected by its approximately twofold procedure time when compared to unsecured LAMS placement [4].

The experience regarding LAMS in benign gastrointestinal stenosis is limited to a total of 70 reported cases to date that are mainly post-bariatric, short segment, and recalcitrant strictures. Its reported clinical efficacy is appreciable with 64 to 100% success rates [4]. However, 8% migration is still a principal concern, despite being lower than FCSEMS. The reported migrations of LAMS were in first 70 days and mostly symptomatic [4].

The optimal time to remove LAMS is not known yet. The reported risks of 7% bleeding and 25% migration with prolonged dwell when used in the treatment of peripancreatic fluid collections necessitate their removal after 3–6 weeks in [8]. However, these risks may not be applicable for gastrointestinal strictures as reported bleeding and migration rates were as low as 2.9% and 7.1% respectively [4]. Thus, we argue that LAMS may be left in place for a longer time to achieve a more durable response, so we have increased the dwell time to 6 months.

Another potential use of LAMS in post-bariatric surgery population is to remove the surgical prosthetic bands. The underlying mechanism is presumably the mucosal hypoxia and subsequent erosion caused by the transmural pressure. A similar technique was previously used to remove surgical band remnants [9]. We think that LAMS, in particular, can have an advantage in this area and can be used for the removal of a previously placed bands/mesh as well.

In summary, LAMS has become an attractive option for post-bariatric surgery patients with short and refractory strictures. This is especially true with the addition of sutures which may virtually eliminate the risk of migration and thus permit a longer stent dwell time and a more durable dilation. However, there are important caveats of sutured LAMS to consider including the cost, the need for general anesthesia, and the associated technical difficulty.

Compliance with Ethical Standards

Conflict of Interest Mouen A Khashab is on the medical advisory board for Boston Scientific and Olympus America and is a consultant for Boston Scientific, Olympus America, and Medtronic.

Anthony N Kalloo is a founding member, equity holder, and consultant for Apollo Endosurgery.

Vivek Kumbhari is a consultant for Medtronic, Reshape Lifesciences, Boston Scientific, and Apollo Endosurgery. He has received research support from ERBE USA and Apollo Endosurgery. The other authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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