

Luminal-apposing stents for benign intraluminal strictures: a large United States multicenter study of clinical outcomes

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Abstract

Background The use of fully covered lumen-apposing metal stents (LAMS) for benign short gastrointestinal (GI) strictures has been reported. This study aimed to evaluate the safety and efficacy of LAMS for refractory GI strictures.

Methods A retrospective analysis was performed of patients who underwent LAMS placement for benign GI strictures in 8 United States centers. The primary outcomes were technical success and initial clinical response. Secondary outcomes were reintervention rate and adverse events.

Results A total of 51 patients underwent 61 LAMS placement procedures; 33 (64.7%) had failed previous treatments. The most common stricture location was the pylorus (n=17 patients). Various sizes of stents were used, with 15-mm LAMS placed in 45 procedures, 20-mm LAMS in 14 procedures, and 10-mm LAMS in 2 procedures. The overall technical success, short-term clinical response and reintervention rate after stent removal were 100%, 91.8% and 31.1%, respectively. Adverse events were reported in 17 (27.9%) procedures, with stent migration being the most common (13.1%). In subgroup analysis, both 15 mm and 20 mm stents had comparable short-term clinical response and adverse event rates. However, stent migration (15.6%) was the most common adverse event with 15-mm LAMS while pain (14.3%) was the most common with 20-mm LAMS. The reintervention rate was 80% at 200-day follow up after stent removal.

Conclusions Using LAMS for treatment of short benign GI strictures is safe and effective. Larger LAMS, such as the new 20 mm in diameter, may have a lower stent migration rate compared to smaller diameter LAMS.

Keywords Lumen-apposing metal stent, gastrointestinal stricture, stent migration

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Introduction

Benign gastrointestinal (GI) strictures can arise anywhere in the luminal GI tract as a result of a variety of causes, including inflammation, postoperative anastomosis, ulcer disease, and caustic ingestion [1]. Endoscopic therapy remains the mainstay management for the majority of these strictures, with several available modalities, including endoscopic dilatation, steroid injection, and fully covered self-expandable metal stent (FCSEMS) [2-4]. Although these modalities are relatively safe and effective, they are not without limitations. Endoscopic dilatation often requires multiple sessions, has a high rate of clinical recurrence, even with the addition of steroid injection, and entails a risk of perforation and bleeding [5]. FCSEMS are one option to overcome such limitations; however, these devices have a high rate of migration when placed in benign strictures [6]. This risk is the highest within the first month of stent placement, even if the stent is fixed with sutures or clips [6-8].

Lumen-apposing metal stents (LAMS) (Axios stent, Boston Scientific, Natick, Mass.) are fully covered stents with a 10-mm length and diameters of 10, 15 and 20 mm (in the USA), with a wide flange at each end. These stents were initially developed for drainage of pancreatic fluid collections; however, they have been increasingly used in other settings, such as endoscopic ultrasound-directed transgastric endoscopic retrograde cholangiopancreatography, gallbladder drainage, and to treat short-segment benign GI strictures [9-12]. The biflanged design along with the short saddle length make the risk of stent migration relatively low [13]. Therefore, LAMS have emerged as a novel modality for treating benign GI strictures. In this study, we report the feasibility, safety and efficacy of treating benign GI strictures with LAMS in different centers across the United States.

Patients and methods

Study population and data collection

This study was a retrospective, single-arm, multicenter study that included patients >18 years old with benign GI strictures at 8 large tertiary referral centers in the United States. The demographic data, location of stricture, duration of stricture before LAMS placement, previous endoscopic treatment for the strictures, LAMS lengths, adverse events, rate of reintervention, procedural information, and follow-up period for each patient were extracted. Informed procedural consent was obtained from all patients. The study was approved by the institutional review board for human research at each participating institution. Patients were excluded from the study if they were less than 18 years old or the LAMS was placed for malignant strictures.

Endoscopic technique

The LAMS are commercially available in 3 different luminal diameters; 10 mm, 15 mm, and 20 mm. All stents have a saddle

length of 10 mm. The flange diameter increases in size with wider stents (21 mm, 24 mm and 29 mm). A forward-viewing therapeutic endoscope or an oblique-viewing therapeutic linear echoendoscope was used for stent deployment in all cases. If felt to be warranted, a guidewire was introduced across the stricture under fluoroscopic guidance. The stent was then positioned and deployed across the stricture under endoscopic guidance. Depending on the endoscopist's discretion, the LAMS was removed using rat-tooth, biopsy forceps, and/or snare.

Definitions

Technical success was defined as successful LAMS deployment across the stricture, verified on endoscopic and/or fluoroscopic views. Short-term clinical success was defined as resolution of symptoms with the indwelling LAMS in place. Long-term clinical success was defined as symptom resolution following LAMS removal and without reintervention. The last follow up was defined as the patient's last visit, whether in the clinic or via telecommunication.

Study outcomes

The primary outcomes in this study were to evaluate the overall technical success and short-term clinical success of LAMS placement for management of benign GI strictures and to compare the outcomes of the most widely used LAMS sizes, 15 mm and 20 mm. Secondary outcomes were stent migration, reintervention rate due to recurrence of symptoms, and adverse events.

Data analysis

A Kaplan-Meier analysis was performed to determine the need for reintervention due to recurrence of symptoms after LAMS removal. The Kaplan-Meier analysis starting time was the LAMS extraction, while the endpoint was the last follow up. To compare the outcomes of the 2 sizes (15 mm vs. 20 mm) of LAMS stents chi-squared analysis and/or Fischer's exact test were used for categorical variables, while a *t*-test was used to compare means of continuous variables. Frequencies and percentages were calculated using basic descriptive statistics.

Results

Patient characteristics

Fifty-one patients (20 male) with a mean age of 60.3 years underwent LAMS placement for 61 benign luminal strictures (Table 1): 10 mm × 10 mm LAMS were placed in 2 (3.2%) patients, 15 mm × 10 mm LAMS in 36 (70.6%), and 20 mm × 10 mm LAMS in 13 (25.5%) patients. The mean stricture length was 8.3 mm. Most strictures were located in the pylorus

Table 1 Baseline characteristics and previous treatments

Characteristics	All patients n=51	15 mm × 10 mm LAMS n=36	20 mm × 10 mm LAMS n=13	P-value
Age, mean, years	60.3	58.6	63	0.88
Men, n (%)	20 (39.2%)	12 (33.3%)	6 (46.2%)	0.54
Weight, kg	78.1	77.2	81.4	0.91
Number of strictures	61	45	14	
Stricture length, mean (SD), mm	8.3 (2.3)	7.4(2.3)	10 (2.3)	0.53
Duration of the stricture prior to LAMS, mean (SD), months	17.3 (20.9)	17.5 (20.9)	19.8 (21.1)	0.9421
Location of stricture				
Esophagogastric anastomoses	10 (19.6%)	5 (13.9%)	4 (30.8%)	0.48
gastro-Jejunal anastomosis	11 (21.6%)	9 (25%)	2 (15.4%)	>0.99
Pylorus	17 (33.3%)	13 (36.1%)	4 (30.8%)	>0.99
Ileo-colonic	2 (3.9%)	2 (5.6%)	0	>0.99
Duodenum	4 (7.8%)	4 (11.1%)	0	>0.99
Esophagus	2 (3.9%)	1 (2.8%)	0	>0.99
Gastric body	1 (2%)	1 (2.8%)	0	>0.99
Sigmoid	1 (2%)	1 (2.8%)	0	>0.99
Other	3 (5.9%)	0 (0%)	3 (23%)	0.015
Previous treatment				
Previous balloon dilation, n (%)	27 (52.9%)	17 (47.2%)	8 (57.1%)	0.53
Previous balloon dilation plus steroid injection, n (%)	14 (27.4%)	8 (15.7%)	5 (38.5%)	0.29
Previous needle-knife, n (%)	2 (3.9%)	2 (5.6%)	0	>0.99
Previous traditional FCSEMS, n (%)	6 (11.8%)	4 (7.8%)	2 (15.4%)	0.65

LAMS, lumen-apposing metal stent; FCSEMS, fully covered self-expandable metal stent; SD, standard deviation

(33.3%), followed by gastrojejunal anastomoses (21.6%), esophagogastric anastomoses (19.6%), duodenum (7.8%), other (5.9%), ileocolonic (3.9%), esophagus (3.9%), gastric body (2%), and sigmoid colon (2%). Eighteen (35.3%) patients had had no previous stricture treatments, 27 (52.9%) had previously undergone endoscopic dilation alone, 14 (27.5%) had previously undergone endoscopic balloon dilation combined with steroid injection, 2 (3.9%) had undergone prior needle-knife strictureplasty, and 6 (11.8%) had received previous FCSEMS. Clinical symptoms had been present for a mean of 17.3 months.

Procedural and clinical outcomes

Table 2 shows the procedure and clinical outcomes. LAMS were deployed across strictures successfully in all procedures; the technical success rate was 100%, regardless of the stent size. Short-term clinical success was achieved in 56/61 (91.8%) procedures. The median procedure time was 17.5 min (range 5-38). Among the 61 LAMS placed, 44 (72%) were either removed endoscopically or passed spontaneously, and 13 (21.3%) were still in place during the follow-up period. The fate of the remaining 4 stents was unknown, as patients either died or went to a hospice during the follow-up period with the stent *in situ*. Mean stent indwell time was 71.7 days. Long-term clinical success was achieved in 18/61 (29.5%).

Adverse events were reported in 17 (27.9%) patients after LAMS placement. Stent migration was the most common adverse event (13.1%), followed by pain (6.6%), occlusion

(4.9%), bleeding (1.6%), and the formation of a proximal or distal stricture (1.6%). Reintervention after stent removal was performed in 19 (31.1%) cases. The reintervention rate after stent removal was almost 80% at 200 days of follow up (Fig. 1). Balloon dilation after stent removal and surgical intervention were performed in 9 (14.7%) and 5 (8.2%) cases, respectively. A new LAMS was placed (similar size or different size) because of recurrence of symptoms in 11 (18%) cases. The mean time to reintervention was 73.3 days. All patients had at least one follow-up visit and the mean follow-up period was 173.8 days.

15- vs. 20-mm LAMS

Tables 1 and 2 show the basic characteristics and procedural outcomes based on LAMS size. No statistical differences between the 2 groups were noted in the baseline characteristics. Twenty-two (61.1%) patients who received 15-mm LAMS had undergone at least one previous intervention, while 10 patients (76.9.1%) with 20-mm LAMS had undergone at least one previous intervention. The most common prior intervention in both groups was balloon dilation, at 47.2% and 57.1% for the 15- and 20-mm LAMS groups, respectively. However, these differences were not statistically significant.

Regarding the procedural and clinical outcomes, the 15-mm LAMS and the 20-mm LAMS had comparable short-term clinical success, 91.1% and 92.9%, respectively. Both sizes of stent had essentially the same adverse event rate: 28.9% for the 15-mm LAMS and 28.6% for the 20-mm LAMS. However, the

Table 2 Procedure and outcome variables

Etiology	All procedures	15 mm (n=45)	20 mm (n=14)	P-value
Procedure time, median (range), min	17.5 (5-138)	21 (5-138)	21 (8-78)	0.83
Technical success, n (%)	61 (100%)	45 (100%)	14 (100%)	>0.99
Short-term clinical success, n (%)	56 (91.8%)	41 (91.1%)	13 (92.9%)	>0.99
Stent indwell time, mean (SD), days	71.7 (106.7)	72.0 (104.2)	71.2 (106.7)	>0.99
Stent removed	36 (59%)	28 (62.2%)	6 (42.9%)	0.23
Adverse events	17 (27.9%)	13 (28.9%)	4 (28.6%)	>0.99
Stent migration	8 (13.1%)	7 (15.6%)	1 (7.1%)	0.67
Pain	4 (6.6%)	2 (4.4%)	2 (14.3%)	0.24
Bleeding	1 (1.6%)	1 (2.2%)	0 (0%)	>0.99
Perforation	0 (0%)	0 (0%)	0 (0%)	>0.99
Occlusion	3 (4.9%)	2 (4.4%)	1 (7.1%)	0.56
Adjacent stricture	1 (1.6%)	1 (2.2%)	0	>0.99
Re-intervention after stent removal	19 (31.1%)	13 (28.9%)	4 (28.6%)	0.7
Balloon dilation	9 (14.7%)	6 (13.3%)	3 (21.4%)	0.4
Surgical resection	5 (8.2%)	4 (8.9%)	0 (0%)	0.25
Stent replacement	11 (18%)	8 (17.8%)	1 (7.1%)	0.33
Time for reintervention, mean (SD), weeks	23.8 (23.5)	24.7 (23.5)	34 (24.2)	0.54
Follow up, mean (SD), days	173.8 (260.1)	179.3 (263.5)	107.7 (262.2)	0.38

SD, standard deviation

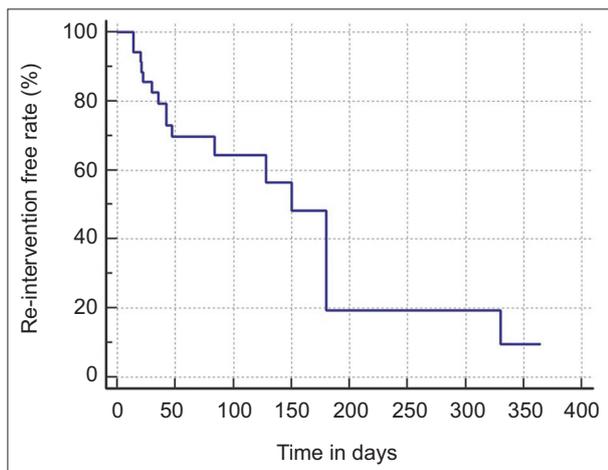


Figure 1 Rate of reintervention after lumen-apposing metal stent removal. In this figure, the starting point is the date of stent removal, while the endpoint is the last follow up

most common complication in the 15-mm LAMS group was stent migration which occurred in 7 patients (15.6%), whereas the most common complication in the 20-mm LAMS group was postprocedural pain, reported in 2 cases (14.3%). Other reported complications for the 15-mm LAMS group were postprocedural pain (4.4%), occlusion (4.4%), bleeding (2.2%), and adjacent stricture (2.2%). For the 20-mm LAMS group, one case of stent migration (7.1%) and one case of stent occlusion (7.1%) were reported. No statistically significant differences were found between the adverse events in the 2 groups (Table 2).

The reintervention rate after stent removal was comparable in the 20-mm LAMS and the 15-mm LAMS groups: 28.6% and 28.9%, respectively ($P=0.7$). The rate of reintervention with

balloon dilation after stent removal was higher (21.4%) in the 20-mm LAMS compared to the 15-mm LAMS group (13.3%), but the difference was not statistically significant ($P=0.4$). Surgical resection was performed in 5 cases (8.2%) of the 15-mm LAMS group, whereas none was performed in the 20-mm group. One stent (7.1%) was replaced with another LAMS in the 20-mm LAMS, whereas 8 stents (17.8%) were replaced with another LAMS in the 15-mm LAMS group, with no statistically significant difference between the 2 groups ($P=0.33$).

Discussion

In this multicenter study, we demonstrated that LAMS are feasible, effective and safe for the endoscopic management of benign GI strictures. Given their unique design and shape, LAMS are widely used for a variety of clinical indications beyond pancreatic fluid drainage. However, data are emerging about the use of LAMS in the treatment of benign GI strictures. Benign GI strictures can be difficult to manage by conventional endoscopic methods, such as balloon dilatation, steroid injection or by stenting using FCSEMS. In the present study, 61% of the patients had failed previous treatment.

In this study, technical success of LAMS placement was achieved in all patients (100%), regardless of the stricture etiology, the site or the size of stent. The median procedure time was 17.5 min (range 5-138) and the procedure was well-tolerated by all patients. Previous studies have also reported similar feasibility of LAMS placement [9,14,15]. The short-term clinical response was 91.8%, regardless of stent size, comparable to the short-term clinical response reported in other studies (90% and 90.5%) [9,13]. However, it is slightly

lower than the short-term clinical response reported by Bazerbachi *et al* (96.4%) [14]. This small difference might be due to the stricture characteristics and/or stent sizes used in the 2 studies. To our knowledge, this study is the first to compare 2 LAMS sizes, 15 mm and 20 mm. The short-term clinical success for the 15-mm LAMS group was comparable to that of the 20-mm LAMS (91.1% vs. 92.9%, respectively).

Overall, adverse events were reported in 17 procedures (27.9%), comparable to the overall adverse events reported in a meta-analysis of 8 studies (29.9%) [16]. Although the 2 stent sizes had the same rate of adverse events (28.9% for 15-mm LAMS and 28.6% for 20-mm LAMS), stent migration was the most common adverse event in the 15-mm LAMS group (15.6%) whereas postprocedural pain was the most common adverse event in the 20-mm LAMS group (14.3%).

Stent migration has been a well-recognized limitation of FCSEMS for the management of benign GI stricture, with a rate of 31.1% [2]. In our study, the overall stent migration rate was 13.1%. This lower migration rate of LAMS as compared to FCSEMS may be attributed to the LAMS stent design with the 2 flanges that distribute pressure across the stricture evenly, providing anchorage and reducing the risk of stent migration [13]. This effect was more pronounced with 20-mm LAMS: there was only one case of stent migration in this group, suggesting that the use of larger diameter LAMS may prolong the stent indwell time and may potentially lead to an increase in therapeutic yield.

Although LAMS has a good short-term clinical response, the reintervention rate is still high, as was demonstrated in this study, in which 80% of cases required reintervention at 200 days of follow up. Bazerbachi *et al* also reported a high reintervention rate, with 75% of cases requiring reintervention at 300 days of follow up [14]. In the current study, both stent sizes had the same reintervention rate after being removed. Although the difference was not statistically significant, surgical reintervention was required only in one case in the 20-mm LAMS group compared to 6 cases in the 15-mm LAMS group. The high reintervention rate raises concern about the cost-effectiveness of LAMS in the management of benign GI strictures, given the fact that LAMS placement is an expensive procedure. In a study evaluating the economical efficacy of LAMS in the management of benign GI strictures, Hallac *et al* found that LAMS placement may have an economic advantage over recurrent dilation after the third dilation [17]. In the present study, most of the strictures had already failed previous treatments. Therefore, given its tolerability and safety, LAMS might be considered as a destination therapy, especially in poor surgical candidates.

This study had several limitations that included its retrospective design, variations in the stricture characteristics and causes, different procedure techniques, as well as the lack of a control arm.

In conclusion, this study demonstrated that LAMS are feasible and safe, and have good short-term effectiveness for use in short, benign luminal GI strictures. Both LAMS sizes (15 mm and 20 mm) have comparable efficacy and safety profiles. However, the large diameter stent (20 mm) has a lower stent migration rate compared to the small diameter stent (15 mm). Therefore, larger prospective trials comparing different stent types and sizes are warranted.

Summary Box

What is already known:

- The management of benign gastrointestinal (GI) strictures has been challenging with the available endoscopic modalities (endoscopic balloon dilation, intralesional steroid injection, and fully covered self-expanding metal stents)
- Lumen-apposing metal stents (LAMS) were originally developed for endoscopic ultrasound-guided drainage of pancreatic fluid collections
- Given its unique design and shape, LAMS have emerged as a novel modality for management of refractory benign GI strictures

What the new findings are:

- Overall technical, short-term and long-term success rates were 100%, 91.8% and 24.6%. The overall rate of adverse events was 27.9%, with stent migration being the most common (13.1%)
- LAMS of 15 mm and 20 mm in diameter had comparable short-term clinical success: 91.1% and 92.9%, respectively; their adverse events rates were also the same: 28.6% for 15-mm LAMS and 28.9% for 20-mm LAMS
- The most common complication in the 15-mm LAMS group was stent migration (15.6%), while postprocedural abdominal pain was the most common complication (14.3%) in the 20-mm LAMS group
- Both stent sizes had comparable reintervention rate after stent removal: 28.9% and 28.6%, respectively

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