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10-16-2018

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#### Recommended Citation

Hallac, Alexander; Srikureja, Wichit; Liu, Eashen; Dhumal, Parag; Thatte, Ashish; and Puri, Nishant, "Economical effect of lumen apposing metal stents for treating benign foregut strictures." (2018). *Articles, Abstracts, and Reports*. 779.

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## Case Control Study

**Economical effect of lumen apposing metal stents for treating benign foregut strictures**

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**Author contributions:** Hallac A and Srikureja W designed research; Liu E, Dhumal P, Thatte A and Puri N performed research and contributed new reagents/analytic tools; all authors analyzed data and wrote the paper.

**Institutional review board statement:** Providence Health Care (Spokane) approves this study, and is part of the corresponding author home institution.

**Conflict-of-interest statement:** All authors have no conflicts of interest to report.

**STROBE statement:** The STROBE Statement has been adopted.

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**Manuscript source:** Unsolicited Manuscript

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Received: June 29, 2018  
Peer-review started: June 30, 2018  
First decision: July 19, 2018  
Revised: July 27, 2018  
Accepted: August 21, 2018  
Article in press: August 21, 2018  
Published online: October 16, 2018

**Abstract****AIM**

To evaluate the clinical and economical efficacy of lumen apposing metal stent (LAMS) in the treatment of benign foregut strictures.

**METHODS**

A single center retrospective database of patients who underwent endoscopic treatment of benign foregut strictures between January 2014 and May 2017 was analyzed. A control group of non-stented patients who underwent three endoscopic dilations was compared to patients who underwent LAMS placement. Statistical tests performed included independent *t*-tests and five-parameter regression analysis

**RESULTS**

Nine hundred and ninety-eight foregut endoscopic dilations were performed between January 2014 and May 2017. 15 patients underwent endoscopic LAMS placement for treatment of benign foregut stricture. Thirty-six patients with recurrent benign foregut strictures underwent three or more endoscopic dilations without stent placement. The cost ratio of endoscopic dilation to LAMS (stent, placement and retrieval) is 5.77. Cost effective analysis demonstrated LAMS to be economical after three endoscopic dilation overall.

LAMS was cost effective after two dilations in the Post-surgical stricture subgroup.

### CONCLUSION

Endoscopists should consider LAMS for the treatment of benign foregut strictures if symptoms persist past three endoscopic dilations. Post-surgical strictures may benefit from LAMS if symptoms persist after two dilations in a post-surgical. Early intervention with LAMS appears to be a clinically and economically viable option for durable symptomatic relief in patients with these strictures.

**Key words:** Benign esophageal stricture; Endoscopy economics; Stent economics; Self expandable metallic stents; Esophageal diseases

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**Core tip:** The findings of our study will be helpful with clinical decision making when treating benign strictures of the esophagus and foregut. The main finding of our study is that lumen apposing metal stents have the potential to have an economical advantage over repeated dilations in the treatment of recurrent benign foregut strictures. Reports of placing lumen apposing stents as an alternative to serial endoscopic dilation have been reported, however no economic analysis has been published.

Hallac A, Srikureja W, Liu E, Dhupal P, Thatte A, Puri N. Economical effect of lumen apposing metal stents for treating benign foregut strictures. *World J Gastrointest Endosc* 2018; 10(10): 294-300 Available from: URL: <http://www.wjgnet.com/1948-5190/full/v10/i10/294.htm> DOI: <http://dx.doi.org/10.4253/wjge.v10.i10.294>

## INTRODUCTION

Pathological or therapeutic disruption of the foregut tissue is common, yet diverse in both its etiology and severity. Surgical anastomosis, peptic injury, radiation, caustic ingestion, eosinophilic esophagitis, Schatzki rings and esophageal webs all disrupt the innate tissue and predispose to luminal stricture formation<sup>[1,2]</sup>. The mechanism by which esophageal strictures develop is hypothesized to be the result of fibrous tissue production and collagen deposition stimulated by deep ulceration or chronic inflammation<sup>[3,4]</sup>. The principle symptoms of foregut stricture disease include, dysphagia, early satiety, epigastric pain, heart burn, nausea and vomiting. The current gold standard treatment of foregut strictures is endoscopic dilation. It is not uncommon for patients to undergo multiple dilations to achieve remission, while some have persistent disease forcing clinicians to face challenging management decisions. Currently, there are no established reliable predictors to identify which strictures will respond optimally to dilation. Additionally,

there is no expert consensus regarding the frequency of dilations necessary to define a refractory structure<sup>[5]</sup>.

An evolving, but "off label" treatment for benign foregut strictures is placing stents for sustained esophageal patency. The use of self-expandable metal stents (SEMS) has the benefit of providing an ongoing radial force to suppress the stricture and maintain luminal patency. The SEMS design has been innovated upon, ultimately resulting in the creation of the lumen apposing metal stent (LAMS). LAMS are short, self-expanding, fully covered, metal stents with large flanges that anchor the stent at both ends.

Clinical guidelines, supported by large studies and systemic reviews have validated the use of stents as an acceptable salvage therapy in the treatment of refractory benign and malignant strictures; however, these studies did not include LAMS<sup>[5-10]</sup>.

The objective of this study is to examine the use of LAMS in the treatment of benign foregut strictures. Case series and case reports have documented the use of LAMS in benign strictures of various etiology at different locations in the foregut<sup>[11-17]</sup>. We aim to illustrate the clinical effectiveness and economics of LAMS.

## MATERIALS AND METHODS

Institutional review board approval was obtained for the development of a retrospective database to evaluate the efficacy of LAMS in the treatment of benign foregut strictures. The database used for this study included all patients who underwent endoscopic dilation or LAMS placement for treatment of benign foregut strictures at a single non-university tertiary care center. The database was constructed by manual review of the electronic health record (EHR) system of a large regional health system. This retrospective case-control study was reported in accordance with the STROBE statement<sup>[18]</sup>.

Current procedural terminology (CPT) codes were used to identify the most recent 1000 controlled radial balloon dilation (CRE) and Savary-Gilliard dilations of the foregut. All endoscopic procedures performed between January 2014 and May 2017 was reviewed, 998 procedures were identified. These procedures were reviewed to isolate all patients who underwent three or more CRE or Savary-Gilliard dilations during the 40-mo period, and 36 patients fit these criteria. Three or more dilations were selected as our inclusion criteria for recurrent strictures based on the fact that LAMS placement required a minimum of two endoscopies and LAMS placement is rarely first line therapy at our institution. The 36 patients' medical records were interrogated to establish a control group for the comparison of LAMS versus serial endoscopic dilation.

Fifteen patients underwent endoscopic LAMS placement for treatment of benign foregut stricture disease. The LAMS were placed without electrocautery or sutures with the intention of maintaining luminal patency for 90 d or until surgical revision. The LAMS utilized were 10 mm in length, fully covered, with bilateral 21 mm or 24

**Table 1** The mean time between dilations for all patients in the recurrent dilation group

	<i>n</i>	Mean time between dilations (d)	SD	<i>t</i>	<i>P</i>
Male	20	146.8	169.7	-0.01	0.9
Female	16	147.5	141.1		
Non-Surgical	31	137.6	159.9	-1.1	0.3
Surgical	5	205.7	121.4		

mm flanges. When deployed the stent self-expanded to a luminal diameter of 10 mm or 15 mm (Axios™ Stent, Boston Scientific®, Marlborough, MA, United States). The patients who underwent LAMS placement consented to undergoing treatment with a medical device in an “off label” non-United States Federal Drug Enforcement Agency (FDA) approved indication.

Clinical end points were the number of symptom free days and the number of days between endoscopic dilations. The number of symptom free days and days between each endoscopic procedure was determined by documentation in the EHR and reported as mean time between dilations (MTBD) and mean symptom free days (MSFD). The review of EHR documentations was performed by a physician who is not a gastroenterologist to prevent potential bias. Complications were defined as removal of the stent prior to the intended 90-d duration of placement or hospital admission for gastrointestinal symptoms. Endoscopies performed prior to this study’s 2014 start date were reviewed when available.

### Statistical analysis

All statistical analysis was performed by a biostatistician using IBM SPSS Statistics for Windows, Version 24 (IBM Corp., Armonk, NY, United States). Statistical tests performed included independent *t*-tests and five-parameter regression analysis with the independent variable being endoscopic dilations as pair indices and the dependent variable being time. All patients that lacked sufficient follow up to accurately characterize their post stent clinical course were included in the descriptive statistical analysis and excluded from the case control analysis. Statistical significance was determined using a threshold of *P* = 0.05.

### Economic analysis

The economic analysis was designed utilizing the recommendations of the International Association of Health Technology Agencies to increase generalizability to clinical gastroenterologists<sup>[19]</sup>. The 2016 Medicare National Average Payment fee schedule that was issued by Center for Medicare and Medicaid Services in January of 2016 was used to determine the cost of endoscopic interventions. A 2% reduction was calculated on all costs to reflect the sequestrations placed by the United States government on all Medicare rates. The cost we associated with each endoscopic dilation is the mean cost of a CRE and Savary-Gilliard dilations. The cost of the LAMS was the specific per unit cost at our institution. The breakeven number for using a stent is calculated by

dividing the delta between the MSFD and MTBD by the coefficient of the regression.

## RESULTS

### Recurrent dilation group

Strictures of non-anastomotic origin accounted for 86.1% (*n* = 31). Five post-surgical strictures located at anastomotic sites accounted for 13.9% of the recurrent dilation group (Table 1). Patients’ ages ranged from 26 to 90 years with a median of 66 years of age. The majority of patients were men (55.6%, *n* = 20). The MTBD was 147 ± 156 d.

The regression results demonstrate that after the initial endoscopic dilation, patients with recurrent benign esophageal strictures will have a decreased time between subsequent dilations that averages 28 d. The reduction of time between subsequent dilations was 20 d in non-surgical strictures and 64 d in postoperative strictures.

### LAMS group

The LAMS group consisted of 15 patients who underwent endoscopic LAMS placement as an adjunctive treatment for various benign strictures of the foregut (Table 2). Strictures occurred post surgically at locations including: Gastrojejunal anastomosis (GJ), Roux-en-Y gastric bypass (RYGB), vertical band gastroplasty (VBG), esophagogastric anastomosis (EG). The majority of the LAMS group were post-surgical strictures, of which 27% (*n* = 4) resulted from weight loss surgeries. Thirteen percent (*n* = 2) of patients had post procedural dysphagia and abdominal pain leading to elective premature LAMS removal (Table 2). Patient eight obtained partial relief of dysphagia on the initial LAMS which recurred promptly after LAMS removal prompting insertion of a second LAMS 21 d later intended to provide symptomatic relief prior to surgical intervention. Patient 14 underwent LAMS placement for a persistent peptic stricture of the duodenal bulb which initially relieved some symptoms, however; symptoms recurred and the LAMS was removed and replaced 74 d later for worsening symptoms.

The median length of follow up was 299 d (range, 7-628). The median duration of the endoscopic LAMS placement was 14.7 min (range, 3.3-68.3), LAMS removal had a median endoscopy duration of 14.7 min (range, 1.7-28.2).

Sixty percent (*n* = 8) of the LAMS group had sufficient follow up for inclusion in a multivariate regression

Table 2 Pre and post lumen apposing metal stent details for the all patients who underwent endoscopic treatment during a 40-mo period at a non-university tertiary care center

Patient	Age (yr)	Gender	Anastomotic Stricture (Yes/No)	Stricture location	Prior foregut surgery	EGD dilations prior to stenting	Duration of stent insertion (d)	Stent migration (Yes/No)	Adverse Events	Symptomatic relief	Post stent Interventions
1	59	M	Yes	GJ	RYGB	2	168	No	No	Yes	No
2	46	F	Yes	GJ	RYGB	3	91	No	No	Yes	No
3 <sup>1</sup>	62	F	Yes	GJ	Distal gastrectomy	3	90	No	No	Yes	Surgical Revision
4 <sup>1</sup>	86	M	No	Pyloric channel	Subtotal gastrectomy	3	138	No	No	Yes	No
5 <sup>1</sup>	90	M	No	Distal esophagus	Nissen fundoplication	3	91	No	No	Yes	No
6	78	F	No	Distal esophagus	Nissen fundoplication	4	31	No	No	Yes	No
7	65	F	No	Pyloric channel	No	2	< 159	Yes	No	Yes	No
8 <sup>1</sup>	65	F	No	Mid Gastric Body	VBG	1	Stent 1: 184, Stent 2: 162	No	No	Yes	Surgical VBG removal
9	73	F	No	Pyloric channel	No	2	98	No	No	Yes	No
10	78	F	No	Mid Gastric Body	VBG	3	-	-	No	Yes	-
11	72	M	Yes	EG	ILE	0	50	No	No	Yes	No
12 <sup>1</sup>	56	M	Yes	EG	ILE	4	15	No	Yes-Chest pain	No	Yes-EGD dilation
13 <sup>1</sup>	73	F	Yes	EG	Total gastrectomy	3	7	No	Yes-Abdominal Pain	No	Yes-EGD dilation
14	69	M	No	First duodenal segment	No	1	Stent 1: 116 Stent 2: 265	No	No	No	-
15	78	M	No	Duodenal bulb	No	3	20	No	Yes- Obstructive jaundice from stent pressure	No	-

<sup>1</sup>Indicates patients included in the multivariate regression analysis. M: Male; F: Female; GJ: Gastro-jejunal anastomosis; RYGB: Roux-en-Y gastric bypass; VBG: Vertical band gastroplasty; EG: Esophago-gastric anastomosis; D1: Duodenal segment 1; D2: Duodenal segment 2.

analysis (Table 3). Of the eight patients in the LAMS group included in the multivariate analysis, 63% ( $n = 5$ ) had benign esophageal strictures, and 25% ( $n = 2$ ) had pyloric stenosis. No difference was seen when performing an independent  $t$  test comparing patient gender and MSFD ( $t = -0.014$ ,  $P = 0.95$ ) in patients treated with LAMS. Similarly, surgical versus non-surgical stricture etiology did not demonstrate a difference in MSFD ( $t = 0.72$ ,  $P = 0.511$ ).

### Clinical comparison

Comparing the MTBD of the 36 patients in the dilation group with that of the LAMS group showed a higher number of symptom free days in each analyzed subcategory (Table 4). Significant differences in the MTBD are demonstrated when comparing all patients in the LAMS group versus their recurrent dilation counterpart ( $P = 0.011$ ). Sub-analysis dividing the patients by gender and surgical setting (if the stricture was post-surgical) showed that males who underwent LAMS placement reported significantly more symptom free days than their recurrent dilation group counterpart ( $P = 0.013$ ) (Table 4).



**Table 3** Regression analysis of the time between dilation (d) for patients who underwent lumen apposing metal stent placement

	R <sup>2</sup>	Intercept	Coefficient	F	P
Mean overall	68.3%	220.3	-27.8	8.6	0.04
Mean female	16.9%	192	-17.4	0.8	0.41
Mean male	96.1%	250	-39.3	99.3	0.001
Mean surgical	62.2%	96.2	-63.3	6.5	0.06
Mean nonsurgical	62.8%	188.3	-19.4	6.7	0.06

**Table 4** The comparison of clinical outcomes in the lumen apposing metal stent and recurrent dilation groups

	Group	n	Mean symptom free days	SD	t	P (two tail)
Overall	Dilation	36	153	153.7	2.9	0.01
	LAMS	8	327	156.9		
Male	Dilation	20	147	169.04	3.5	0.01
	LAMS	3	347	73.7		
Female	Dilation	16	160	137.2	2.1	0.09
	LAMS	5	353	190.9		
Nonsurgical	Dilation	31	144	158.7	1.5	0.26
	LAMS	3	298	165.6		
Surgical	Dilation	5	209	114.08	2.06	0.07
	LAMS	5	382	148.8		

LAMS: Lumen apposing metal stent.

**Table 5** The economic analysis for lumen apposing metal stent utilization

	MSFD	MSFD/Cost Ratio	MTBD	Coefficient from Regression	Breakeven n
Overall	327	56.7	153	27.8	3.4
Male	347	60.1	147	39.3	2.2
Surgical	382	66.2	209	63.3	2.2

MSFD: Mean symptom free days; MTBD: Mean time between dilations (d).

### Economic analysis results

The average cost of an endoscopic dilation is \$1282, whereas the cost of a LAMS is \$4060, endoscopic insertion and endoscopic removal cost \$2399 and \$937 respectively. The total cost for the LAMS and endoscopic insertion and removal is \$7396; thus, a cost ratio is 5.7. Dividing the overall MSFD for the LAMS group and the recurrent dilation group by the cost ratio demonstrates that LAMS placement only became economical when the time between dilation is less than or equal to 57 d (Table 5). The overall MTBD for the recurrent dilation and LAMS group is 152 d. The overall breakeven number for using LAMS is 3.5 dilations, thus endoscopic LAMS placement is economical after the three dilations.

## DISCUSSION

The use of esophageal prosthesis began over a century ago and progressed into commercially available applications in the 1970s. The current generation of SEMS were initially used in the biliary tree before being developed into esophageal specific applications in the 1990's<sup>[20]</sup>. The recommended use of SEMS is most clearly defined in the malignant stricture population; however, ambiguity exists in the use of SEMS in benign strictures of the gastrointestinal tract. Complications of

stent migration and variability in efficacy of SEMS have limited their use in benign strictures.

The FDA approved the first LAMS in 2012 for the endoscopic treatment of pancreatic pseudocysts<sup>[21]</sup>. There is a paucity of published experience using LAMS in the treatment of benign foregut strictures, with only three studies, including ours, containing 15 or more patients<sup>[11,12]</sup>. The limited number of studies utilizing LAMS in benign stricture disease is primarily due to the low use of "off label" non-FDA approved devices. As such, we believe our results along with Irani *et al*<sup>[12]</sup> and Yang *et al*<sup>[11]</sup>'s showcase the utility of LAMS in the treatment of benign foregut strictures.

### Clinical outcomes

Our results are most similar to the prospective multi-center trial performed by Yang *et al*<sup>[11]</sup>. Yang *et al*<sup>[11]</sup>'s cohort included 23 patients who underwent an average of 3.7 endoscopic dilations prior to LAMS placement. As such, this demonstrated the generalizability of our control group, which included individuals who underwent three or more endoscopic dilations. In addition to the 23 foregut LAMS placements, Yang *et al*<sup>[11]</sup>'s cohort included four colonic stricture stent placements with 60 d (IQR, 40-90 d) median duration of LAMS placement compared to our median of 96 d (IQR, 41-161 d). Both our cohort

and Yang *et al*<sup>[11]</sup>s did not experience any tissue overgrowth or technical difficulties with LAMS removal; yet, these issues were encountered in Irani *et al*<sup>[12]</sup>'s series. The adverse events related to LAMS extraction could be more prevalent in Irani *et al*<sup>[12]</sup>'s series due to their 300 d median follow up time post LAMS insertion, which is slightly larger than both Yang *et al*<sup>[11]</sup>s and our own cohort, which had median follow up times of 100 and 299 d respectively. Yang *et al*<sup>[11]</sup>, Irani *et al*<sup>[12]</sup> and our own cohort all reported encountering patients with pain following LAMS insertion that was severe enough to prompt premature LAMS removal, the mean incidence of premature LAMS removal due to pain was 6% (range, 4.3%-7%). Our study included a unique adverse event after LAMS was placed across a duodenal bulb stricture (Table 2, Patient 15), in which the distal flange of the stent created backpressure on the intraduodenal segment of the common bile duct leading to abdominal pain and obstructive jaundice resulting in stent removal 20 d after placement.

### Stent migration

In 2015, Fuccio *et al*<sup>[9]</sup> performed a meta-analysis of SEMS use in refractory benign esophageal stricture. Fuccio *et al*<sup>[9]</sup>'s meta-analysis reported a stent migration rate of 36% in fully covered self-expanding metal stents (FCSEMS)<sup>[9]</sup>. Twenty-two percent of the patients in Fuccio *et al*<sup>[9]</sup>'s analysis who underwent FCSEMS placement met the Kochman *et al*<sup>[22]</sup>'s criteria for refractory benign esophageal stricture meaning they underwent at least five dilation sessions and/or cycles with dilation to at least 14 mm.

LAMS migration was confirmed in one of 15 patients in this study although a second stent migration could have occurred in the single patient lost to follow up (Table 2, Patient 11). Our reported LAMS migration rate of 6.7%-13.3% of patients is consistent with the two largest studies of LAMS that collectively had a migration rate of 7.5% in their 58 cases<sup>[12,13]</sup>.

### Clinical success

Eighty-one percent of patients in our study had symptomatic relief. Repeat endoscopic procedures after LAMS placement was limited to stent exchanges in two patients and a non-therapeutic endoscopy in one patient. LAMS successfully controlled symptoms in two patients prior to undergoing revision gastric surgery. Approximately 83% of patients were symptom free at 100 d after LAMS removal in Yang *et al*<sup>[11]</sup>'s study, and the clinical success rate at 6 mo follow up was 61% in Irani *et al*<sup>[12]</sup>'s study.

### Economic analysis

The cost breakeven point of the overall group is 3.5 and 2.2 dilations in the post-surgical group, which shows that stent placement may have an economical advantage over recurrent dilation after the third dilation. The male subgroup demonstrated a cost breakeven point after the second dilation; however, this finding is limited by a lack of sufficient number of subjects to provide a fe-

male subgroup analysis. Although our study did not utilize Kochman *et al*<sup>[22]</sup>'s criteria for refractory benign esophageal strictures as an inclusion requirement, applying our breakeven point for LAMS placement would demonstrate LAMS to be cost effective in all benign recurrent esophageal strictures as defined by Kochman *et al*<sup>[22]</sup>.

Endoscopists should welcome LAMS as a second line therapy for benign foregut strictures, as it has shown to be a clinically and economically effective treatment modality for managing the devastating symptoms of benign foregut strictures.

An interesting secondary finding from the analysis of the control group was the time between dilations was decreasing by 28 d between each dilation. This surprising finding should be expanded on in further studies that aim to elucidate the pathogenesis of benign foregut stricture formation.

The most significant limitation of our study beyond those inherent to retrospective analysis is the low sample size; however, this is to be expected in the study of a non-FDA approved use of a medical device. The absence of a formal symptom scoring system at post procedure clinic visits and the inability to follow all subjects long term makes our data mildly vulnerable to subject reporting and selection bias. More prospective trials are needed to develop a professional consensus on the role of LAMS in the treatment of benign foregut strictures.

## ARTICLE HIGHLIGHTS

### Research background

The use of lumen apposing metal stents (LAMS) began in 2012 as a treatment modality for pancreatic pseudocysts. Currently, LAMS are being used in various endoscopic procedures such as pancreatic pseudocyst drainage.

### Research motivation

The key question of our study is How effective and economical is the use of LAMS in the treatment of benign foregut strictures.

### Research objectives

The main objective of this study was to determine how to appropriately utilize LAMS in the treatment of benign foregut strictures. Benign foregut strictures frequently recur therefore this study will contribute to the literature used to determine treatment strategies for these difficult recurrent strictures.

### Research methods

The research methods that were adopted to realize our objective was a single center retrospective case-control study. The case-control study was complemented by a cost effectiveness analysis.

### Research results

The cost breakeven point of using a LAMS compared to repeat endoscopic dilation was 3.5 and 2.2 dilations in patients with benign foregut strictures and post-surgical strictures, respectively. Our results demonstrate that stent placement may have an economical advantage over recurrent dilation once a patient has undergone three endoscopic dilations. The optimal duration of stent placement to provide maximum efficacy and minimum adverse events remains unknown, further prospective multicenter studies are needed.

### Research conclusions

This study presents the novel finding that inserting a LAMS instead of serial



dilations can be a cost-effective treatment. We believe our results demonstrate that recurrent endoscopic dilation of benign foregut strictures can be optimally treated by LAMS in well selected patients. In summary, this study demonstrates that the interval between endoscopic dilations decreases overtime after each subsequent dilation. The use of LAMS for benign foregut strictures has been reported however we utilized an economic analysis to prove our hypothesis that there is a potential cost savings.

### Research perspectives

This study has important clinical implications particularly in the United States where the placement of a LAMS for any reason other than evacuating a pancreatic pseudocyst is not Federal Drug Enforcement Agency approved. Endoscopists can incorporate the findings of this study into their clinical practice when treating patients whose benign foregut strictures continue to require endoscopic dilations.

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**P- Reviewer:** Bilir C, Chow WK, Fiori E, Fogli L, Giannopoulos G, Goral V, Lee CL, Zhu YL **S- Editor:** Ma YJ

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