TITLE PAGE 1 Title: "Cut and Cover": A case series of dual modality treatment with stricturotomy and stenting for 2 3 inflammatory bowel disease related strictures 4 5 **Author Names:** Matthew J. Miller, mmillers@med.umich.edu 6 Abhishek Satishchandran, A.Satishchandran@UMHSparrow.org 7 Jeffrey Berinstein, jberinst@med.umich.edu 8 Peter D.R. Higgins, phiggins@med.umich.edu 9 George Philips, philipsg@med.umich.edu 10 Division of Gastroenterology, Department of Internal Medicine, University of Michigan Ann Arbor, MI, USA 11 12 Keywords: IBD, Crohn's, LAMS, dilation 13 14 **Contact Information:** 15 George M. Philips, MD, FASGE 16 **Assistant Professor of Medicine** 17 Division of Gastroenterology and Hepatology 18 University of Michigan 19 1500 E Medical Center Dr 20 Floor 3 Reception D 21 Ann Arbor, MI 48109 22 Email: philipsg@med.umich.edu 23 Phone:888-229-7408 24 Fax:734-936-5458 25 26 Acknowledgements 27 Samuel Tanner, tannesam@med.umich.edu – data visualization 28 29 30 31 32

33	STATEMENTS AND DECLARATIONS
34	Ethical considerations
35	Ethical approval to report this case series was obtained from The Institutional Review Board of the University
36	of Michigan (HUM00184362).
37	
38	Consent to participate
39	Patients in this study verbally consented to the novel therapeutic and were informed of and consented to
40	having their retrospective information used for research purposes.
41	
42	Consent for publication
43	To the extent reasonable, patient-related information was de-identified and data collection was covered by the
44	IRB. Verbal permission was given and documented in patient used for example endoscopic images.
45	
46	Declaration of conflicting interest
47	The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or
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53	Data availability
54	The datasets generated during and/or analyzed during the current study are available from the corresponding
55	author on reasonable request.
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ABSTRACT Background: Strictures are common in inflammatory bowel disease (IBD), and are managed medically and endoscopically, if feasible, due to a high rate of post-operative complications after surgery. Endoscopic balloon dilation (EBD) is often successful, but need for repeat dilation and subsequent surgery is common. Endoscopic stricturotomy (ESt) has gained popularity due to improved success but has been limited by frequent post-procedural bleeding. We hypothesized that lumen-apposing metal stent (LAMS) placement after ESt could prevent bleeding and re-stenosis. We aimed to evaluate the feasibility of this "cut and cover" technique. *Methods*: This is a retrospective study of adults with IBD who underwent endoscopic stricturotomy followed by LAMS placement at Michigan Medicine from July 1, 2023, to June 30, 2024. At the time of procedure, stricture type, location, and dimensions were noted, along with number of incisions required and the deployed LAMS dimensions. Adverse events and follow-up outcomes were recorded. Results: Five patients with Crohn's-related strictures underwent ESt with LAMS placement. Two had prior ulcerative colitis with ileal-pouch anal anastomosis with subsequent Crohn's of the pouch, and two had prior EBD. The mean patient age was 49 years. Strictures were short (<2 cm), and included anastomotic strictures. All patients had a stent in place for at least one month (median 54 days), with average endoscopic follow-up at 170 days post-ESt to assess stricture traversability. Immediate technical success was achieved in all cases, with no procedural complications such as bleeding or perforation, although stent migration was noted in 60% of cases by endoscopic follow-up. One patient was briefly hospitalized for post-procedure abdominal pain. Conclusions: In a small group of patients with IBD-related strictures, ESt followed by LAMS placement was technically feasible and demonstrates potential for high rates of clinical and technical success and few complications. Further multi-center studies are needed to confirm the technique's efficacy and safety.

INTRODUCTION

Strictures are commonly seen in inflammatory bowel diseases (IBD), especially Crohn's disease, with a 10-15% prevalence at diagnosis, increasing to 50% after ten years¹. Management of strictures is medical, endoscopic, and surgical. Due to characteristics of the stricture including length and refractoriness to medical and endoscopic balloon therapy, many patients will require surgical management of strictures¹. Post-operative complications, however, are frequently seen in IBD regardless of age, and have been estimated to occur in up to half of patients in some studies¹-³. Thus, optimizing endoscopic management of strictures has been a major focus in IBD care.

For decades, endoscopic management of strictures has been accomplished primarily via endoscopic ballon dilation (EBD). EBD has a high technical success rate (>90%) and short-term clinical efficacy (>80%), but nearly half of patients have symptom recurrence with frequent need for repeat dilation and future surgery^{1,4}. Complications of EBD include perforation and bleeding in approximately 5% of patients⁴. Endoscopic lumenapposing metal stent (LAMS) placement has been previously explored for primary management of Crohn's strictures, but its utility has been dismissed due to lower efficacy and high rate of complications, especially early distal stent migration (reported >50% in some studies)^{5,6}. More recently, endoscopic stricturotomy (ESt) has emerged as an alternative, which utilizes an endoscopic knife to mechanically open the stenotic segment of bowel. ESt is theoretically more durable in alleviating luminal fibrotic narrowing, similar to surgical stricturoplasty. Meta-analysis has shown similar technical success and superior clinical success compared with EBD⁷. While rates of perforation are like EBD, an ongoing challenge has been bleeding, complicating at least 10% of ESt in a meta-analysis⁷.

Given the prior reported success in using self-expanding metal stents for treatment of bleeding after use of endoscopic cutting tools⁸, we were interested in technical and clinical success as well as complication rates when LAMS are used after ESt. We hypothesize that placement of LAMS may serve to tamponade the site of stricturotomy to prevent delayed bleeding complications and help prevent re-stenosis during the healing process post-ESt. We aimed to evaluate the feasibility of managing IBD-related strictures with a dual modality of endoscopic stricturotomy and LAMS placement, a so-called "cut and cover" technique.

METHODS

Study Population

- 71 This is a retrospective study of adults (≥18 years) seen at a single academic tertiary referral center (Michigan
- 72 Medicine). We identified all patients with history of inflammatory bowel disease and endoluminal strictures
- 73 who underwent endoscopic stricturotomy with subsequent LAMS placement from July 1, 2023 through June
- 74 30, 2024.
- 75 The Institutional Review Board of the University of Michigan approved this study.

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Data Collection

- All data was collected retrospectively from a prospectively collected endoscopy database. Baseline
- 79 characteristics included patient demographics, previous therapy (e.g., endoscopic balloon dilation), and
- specific IBD treatment at time of stricturotomy with LAMS placement. Procedure-related data included the
- 81 type of stricture (anastomotic or non-anastomotic), location of the stricture, stricture length and diameter,
- number of incisions made, and diameter of LAMS used. All procedure-related adverse events were recorded
- and evaluated. Follow-up data included duration of follow-up, treatment outcomes (i.e. stricture improvement,
 - resolution, recurrence), and need for additional interventions. We used the CARE checklist when writing our
- 85 report9.

Definitions

- 88 Immediate technical success was defined as conversion of a non-traversable stricture (by single channel
 - therapeutic gastroscope) to a traversable stricture after stricturotomy and LAMS placement. Long-term
- 90 *technical success* was defined by a traversable stricture ≥3 months after stent removal. *Short-term clinical*
- 91 success was defined as improvement or resolution of obstructive symptoms including postprandial fullness,
- bloating and/or hospitalizations at initial follow-up clinic visit or endoscopy for stent removal. Short-term
- 93 follow-up was the stent indwell time (eg, the time between stent deployment and follow-up endoscopy for
- 94 removal). Long-term follow-up was the time between stent removal and follow-up endoscopy to assess patency
- 95 (≥3 months after removal).

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RESULTS

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Patient Characteristics

Table 1 shows baseline and procedure characteristics for the total of five patients who underwent stricturotomy with LAMS placement during the study period. All patients had Crohn's disease, with two of five (40%) with prior diagnosis of ulcerative colitis with subsequent Crohn's of the pouch. All patients returned for endoscopic removal of LAMS, with all but one (4/5) returning ≥3 months after LAMS removal to assess luminal traversability. The mean age was 49 years (range 33 to 68). Two of five patients (40%) were male. Two of five (40%) had anastomotic strictures after ileocolonic resection, two of five (40%) had strictures within an ileal pouch anastomosis, and one (20%) was surgery naïve with stricturing at the ileocecal valve. Two of five (40%) had previous EBD to attempt dilation of their strictures. All strictures were less than 2 cm. One of five (20%) patients was actively using tobacco at the time of the intervention.

Endoscopic Technique

In all cases, a therapeutic gastroscope (GIF-1TH190; Olympus America, Center Valley, PA) was used to perform the stricturotomy and subsequent LAMS stent placement (AXIOS; Boston Scientific Corp., Marlborough, Massachusetts, USA). Fluoroscopy was not used in any case. The gastroscope was advanced and the stricture(s) were assessed and dimensions measured. If the target stenosis walls were less distinct, the endoscopic ultrasound 20 mHz miniature probe (UM-3R-3; Olympus America, Center Valley, PA) was advanced through the endoscopic channel to estimate the depth of the electrosurgical incision (ESi). In three of five patients, this added modality was utilized to safely optimize the depth of the electrosurgical incision. The ESi was performed at preset sphincterotomy settings (Endocut I mode: effect 2, duration 3, interval 2) with an IT-2 endoscopy knife (Olympus America, Center Valley, PA) in 2 or 3 quadrants at the discretion of the endoscopist based on the endoscopic appearance. After the ESi the endoscope was advanced across the stenosis to test patency. After stricturotomy, a 15 mm (diameter) by 10 mm (length) or 20 mm by 10 mm stent was advanced freehand through the stricture and the stent was deployed at the discretion of the endoscopist. Intraprocedural balloon dilation occurred after stent placement in two of five patients at the discretion of the endoscopist. Patients were instructed to follow a modified "stent diet" while the stent was in place (handout on 'Easy to Chew and Swallow Diet (IDDSI 7EC)' created by University of Virginia Health System)¹⁰. All patients had a stent indwell time of at least 36 days (Figure 1, mean 64.6 days [range 36-99]), with removal subject to scheduling and at the discretion of the patient. A follow up endoscopy was performed at least 3 months after stent extraction (4/5 patients completed; mean 170 days [range 97-239] post stent removal) and 6-9 months after the index stricturotomy. Example endoscopic images are provided in Figure 1.

Technical Success

Six stents were placed in five patients (Table 1). Stricturotomy was performed in all patients, with most (3/5) patients undergoing ESi in three quadrants. Only one of five patients required the larger diameter 20 mm by 10 mm LAMS placed. Five of five (100%) patients had endoscopies with immediate technical success. There was no evidence of intraprocedural or post-procedural bleeding or perforation in any patient. While stent migration was common by the time of follow-up endoscopy for stent removal (60% of patients), this was not associated with any complications or need for emergent endoscopy, and all stents were removed at a scheduled follow-up endoscopy. At long-term follow-up endoscopy (completed at a mean of 5.6 months post-stricturotomy [Table 2]), long-term technical success (traversability) was reported in all patients who returned for follow-up.

Clinical Success

Immediately post-procedure, one out of five (20%) patients was hospitalized post-procedure for undefined abdominal pain. There was no evidence of perforation, bleeding, stent migration, or other complication with a one-night observation stay and imaging. Otherwise, there were no adverse events that required surgery or endoscopic reintervention. All patients reported symptomatic improvement at short-term follow-up despite frequent stent migration. Among the five patients, they had cumulatively undergone seven endoscopic procedures in the prior year to treat or investigate obstructive symptoms; none required endoscopic treatment for obstructive symptoms in the year following ESt and LAMS placement (swimmer plot, Figure 2).

DISCUSSION

Among five patients undergoing endoscopic stricturotomy with subsequent LAMS placement, the procedure was technically and clinically successful in all patients. To our knowledge, this is the first study to examine the use of LAMS post-stricturotomy in a series of patients and demonstrate longer term outcomes. Previous studies have examined the use of LAMS for treatment of stricturing in Crohn's disease. In one study⁵, stent migration was reported in 80% of patients with only one of ten patients returning for scheduled endoscopic extraction and others requiring sooner re-intervention or treatment for complications. Despite stent migration in 60% of patients at the time of follow-up endoscopy in our study group, there were no patients who required repeat endoscopy at sooner than 1 month due to stent intolerance, bleeding, or other issues. By performing stricturotomy first, LAMS placement may be safer and more effective in the treatment of Crohn's strictures.

The patients evaluated in our study were successfully treated with varying states of disease activity and medical therapy. All patients were on advanced IBD therapies at the time of the procedure, with one patient who benefited by way of reduction of obstructive symptoms despite active disease at long-term follow-up endoscopy. Patients with severe ulceration at the site of stricture could not be treated in all quadrants with stricturotomy. Further study is needed to determine if the efficacy of ESt is reduced by decreased number of incisions. Strictures >4 cm usually require surgery¹, but the strictures managed in our study were all short (<2 cm); thus, the feasibility of managing longer strictures with this technique requires further evaluation and longer LAMS. Patients in our study experienced no complications aside from one patient briefly hospitalized for post-procedural pain, but this did not require stent removal or re-intervention. Notably, previous studies demonstrated a 10% bleeding rate when stricturotomy was performed alone?; however there were no bleeding-related complications in our small cohort.

Our study provides a novel approach to address refractory strictures in the IBD population by combining stricturotomy with luminal stenting. While stricturotomy has demonstrated greater effectiveness than balloon dilation⁷, it has been associated with significant complications. This pilot study demonstrates that endoscopists can utilize a tandem approach of stricturotomy followed by LAMS stenting to address the luminal stricture with a sustained response endoscopically and clinically while averting significant immediate procedural complications. Interestingly, there was a 60% migration rate when the stents were used in tandem. It is unknown as to the optimal duration of stent indwell time since all patients with stent migration had it noted incidentally at the follow up endoscopy for stent extraction. It is also unknown if stricturotomy increases the risk of stent migration; however, in our series there was no clear association between the number of incisions and stent migration. Of note, the smaller 15 mm LAMS stent was chosen in most cases, but it is possible that opting for a larger diameter stent, if the proximal small bowel can accommodate it, may reduce the likelihood

of stent migration. While our cohort was too small to fully explore this, the one patient with larger 20 mm stent deployed did not experience stent migration. Overall, our stent migration rate was similar to previous studies but associated with no need for urgent or emergent repeat endoscopy. A second novel concept that was explored in this pilot study was the utilization of the endoscopic miniature ultrasound probe to estimate the safe depth of the ESi. This added modality conceptually provided a more objective assessment and safe stricturotomy.

Limitations of our study include the small sample size and the lack of delineation in the type of stricture (anastomotic vs non-anastomotic). One clear limitation with this endoscopic technique is the need for a therapeutic gastroscope (Olympus GIF-1T was utilized) for LAMS stent placement. For patients with prior surgical resection, reaching the site of small bowel stricture is not a major concern, but in patients with native anatomy and small bowel stricturing, reaching the site of stricture may not be feasible. However, this is the first pilot study to demonstrate the technical feasibility of this approach and provide prolonged clinical follow-up data.

In summary, in a retrospective study of five patients with IBD strictures treated with a dual modal treatment of ESt with LAMS placement, the procedure did not result in any complications of bleeding or perforation and was technically and clinically successful. The case series demonstrates that this is a feasible endoscopic approach but will need more rigorous evaluation in multiple centers and larger sample sizes.

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Figure 1. *Endoscopic images.* An example patient is provided, with images *A)* pre-stricturotomy, *B)* post-stricturotomy, *C)* post-stent placement, *D)* post-stent removal (at first follow-up endoscopy), and at *E)* patency re-assessment endoscopy.

ID	Age (yrs)	Sex	use	Prior bowel surgeries	Active IBD meds	Location of stricture	Prior endoscopic interventions	Stricture dimensions	Travers -able	Incisions	LAMS size used	Dilation post- LAMS
1	68	F	No	Colectomy with IPAA	Vedolizumab	Pouch	EBD to max 18 mm	8 x 10 mm	No	2	15 x 10 mm	No
2	43	M	Yes	ICR	Upadacitinib	End-to-side ileocolonic anastomosis	None	7 x 8 mm	No	2	15 x 10 mm	No
3	36	F	No	Naïve	Infliximab + azathioprine	Ileocecal valve	None	8 x 10 mm	No	3	15 x 10 mm	Yes
4	65	F	No	Colectomy with IPAA	Infliximab + azathioprine	2; pouch inlet and 30cm proximal in neo-TI	EBD to max 8 mm	10 x 10 mm proximally, unmeasured distally	Proximal no; distal (pouch) yes	3 (each)	15 x 10 mm (x2)	No
5	33	M	No	ICR	Risankizumab	Side-to-side ileocolonic anastomosis	None	8 x 10 mm	No	3	20 x 10 mm	Yes

Table 1. Baseline patient and procedural characteristics. Dimensions given are inner diameter by length. EBD, endoscopic balloon dilation. IBD, inflammatory bowel disease. ICR, ileocolonic resection. IPAA, ileal pouch anal anastomosis. LAMS, lumen-apposing metal stent. TI, terminal ileum.

ID	Short-term follow-up (days)	Short-term clinical success	Stent migration	Long-term follow-up (days)	Long-term technical success	Complications
1	99	Yes	Distal	97	Yes	None
2	36	Yes	None	239	Yes (despite active disease)	Hospitalization-pain
3	54	Yes	Distal	None	N/A	None
4	63	Yes	Proximal migrated distally, distal migrated proximally	140	Yes	None
5	71	Yes	None	204	Yes	None

Table 2. *Short-term success, long-term success, and complications.* Short-term follow-up to stent removal was mean 64.6 days. Long-term follow-up between stent removal and assessment for luminal patency was mean 170.0 days.

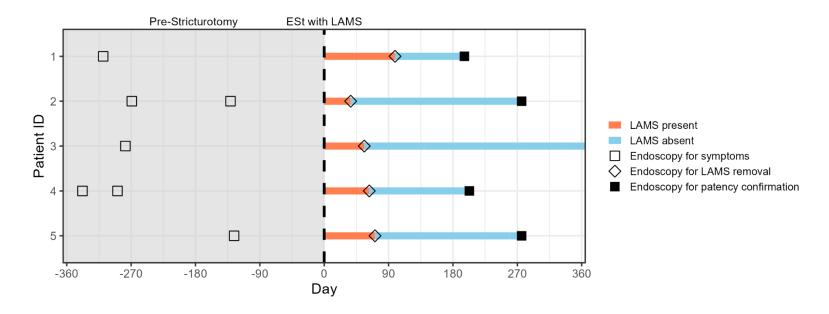
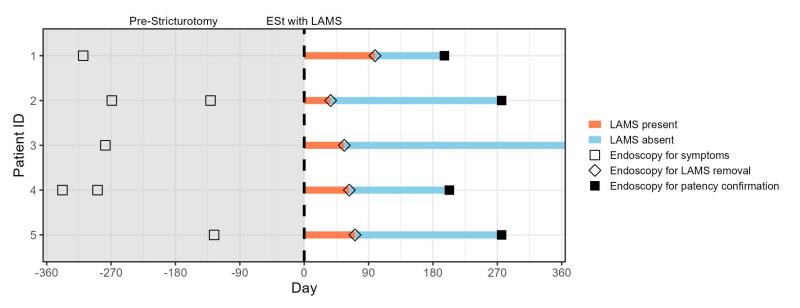


Figure 2. *Timeline of endoscopic stricturotomy, LAMS placement, stent removal, and reassessment.* Endoscopic procedures for symptoms up to one year prior to definitive ESt with LAMS placement (Day = 0) were reviewed. No endoscopies were performed for symptoms after ESt with LAMS placement. ESt, endoscopic stricturotomy. LAMS, lumen-apposing metal stent.





Reporting checklist for case report or case series.

Based on the CARE guidelines.

Instructions to authors

Introduction

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the CAREreporting guidelines, and cite them as:

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		Reporting Item	Page Number
Title			
	<u>#1</u>	The area of focus and "case report" should appear in the title	1
Keywords			
	<u>#2</u>	Two to five key words that identify topics in this case report	1
Abstract			
Introduction	<u>#3a</u>	What is unique and why is it important?	3
	<u>#3b</u>	The patient's main concerns and important clinical findings.	3
	<u>#3c</u>	The main diagnoses, interventions, and outcomes.	3
Conclusion	<u>#3d</u>	What are one or more "take-away" lessons?	3

	<u>#4</u>	Briefly summarize why this case is unique with medical literature references.	4
Patient information			
	<u>#5a</u>	De-identified demographic and other patient information.	5, Table 1
	<u>#5b</u>	Main concerns and symptoms of the patient.	5, Table 1
	<u>#5c</u>	Medical, family, and psychosocial history including genetic information.	Table 1
	<u>#5d</u>	Relevant past interventions and their outcomes.	5
Clinical findings			
	<u>#6</u>	Relevant physical examination (PE) and other clinical findings.	Table 1
Timeline			
	<u>#7</u>	Relevant data from this episode of care organized as a timeline (figure or table).	Figure 2
Diagnostic assessment			
	<u>#8a</u>	Diagnostic methods (PE, laboratory testing, imaging, surveys).	N/A, patients presented with strictures
	<u>#8b</u>	Diagnostic challenges.	N/A, see above
	<u>#8c</u>	Diagnostic reasoning including differential diagnosis	N/A, see above
	<u>#8d</u>	Prognostic characteristics when applicable	Table 1
Therapeutic Intervention			
	<u>#9a</u>	Types of intervention (pharmacologic, surgical, preventive).	6
	<u>#9b</u>	Administration of intervention (dosage,	N/A

strength, duration) #9c Changes in the interventions with 6 explanations. Follow up and outcomes #10a Clinician and patient-assessed outcomes 7, Table 2 when appropriate #10b Important follow-up diagnostic and other test 7, Table 2 results. #10c Intervention adherence and tolerability (how 7, Figure 2 was this assessed)? #10d Adverse and unanticipated events. Table 2 Discussion #11a Strengths and limitations in your approach to 8-9 this case. #11b Discussion of the relevant medical literature. 8-9 #11c The rationale for your conclusions. 8-9 #11d The primary "take-away" lessons from this 8-9 case report. **Patient** perspective #12 The patient can share their perspective on N/A, patient reported outcomes not included their case

Notes:

Informed consent

#13

10c: 7, Figure 2 The CARE checklist is distributed under the terms of the Creative Commons
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The patient should give informed consent.