Short Benign Ileo-Colonic Anastomotic Strictures. Management with Bi-Flanged Metal Stents: Case Reports and Review the Literature

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Bi-flanged metal stent; Lumen-apposing metal stent; Anastomotic ileo-colonic stricture; Self-expanding metal stent; Endoscopic innovation; Case series

Abbreviations:

1. Abstract

1.1. Background: The endoscopic management of benign short post-anastomotic ileo-colonic strictures (PAICS), refractory to primary and secondary treatment modalities, remains challenging. The lumen-apposing metal stent (LAMS) is one of the novel devices recently developed for therapeutic Gastrointestinal (GI) endoscopy. LAMS demonstrated statistically significant better results in regards to stent migration when compared with fully covered self-expandable metal stents (FCSEMS).

1.2. Method and Results: This article presents 6 cases of symptomatic PAICS, treated successfully with LAMS and review of the literature. We report a life-saving technique not previously documented and the use of technology to improve patient outcomes. The six patients, median aged 75 years, suffered from vomiting, constipation and recurrent abdominal pain, with the symptoms starting 23-25 weeks post-surgery. The median length of strictures was 1.83 cm. All six patients had a successful and uneventful bi-flanged metal stent (BFMS-LAMS) treatment of benign PAICS. All patients remained asymptomatic during 3 months of stent sojourn and up to a median 7 months at follow up after stent removal. According to the literature, application of LAMS for PAICS is associated with a < 10% risk of migration and a < 5% risk of bleeding. Conversely, FCSEMS are burdened with a high rate (15%-50%) of migration.

1.3. Conclusions: The evolving role of interventional endoscopy and availability of LAMS gives patients minimally invasive options obviating more invasive surgical interventions. Because the BFMS (NAGI stent) is longer and larger than the prototype AXIOS -LAMS, this could be considered in the management of short ileo-colonic post-anastomotic strictures longer than 10mm and shorter than 30mm.

2. Introduction

Colonic post-operative anastomotic strictures occur in 3%-28% of patients following colorectal surgery [1-3]. The management of...
benign gastrointestinal (GI) strictures include incisional therapy, intra-lesion steroid injection, endoscopic balloon dilatation, deployment of self-expandable metal stents (SEMS) and biodegradable stents (BDS) [4,5]. However, these endoscopic management techniques are not always successful despite repeated interventions [5]. In particular, refractory post-anastomotic ileo-colonic strictures (PAICS) may require multiple dilatations [6]. For refractory cases, SEMS may be used. However, SEMSs are vulnerable to stent migration, with rates exceeding 15%-50% [3,7]. The underlying risk of perforation (12%-20%) increases with the deployment of pre or post balloon dilatations [8,9]. The fully covered SEMS (FCSEMS) are demonstrating migration of a high rate (40%-60%), with an overall incidence of 20% [6,8-10]. The lumeno-apposing metal stent (LAMS) is one of the novel devices recently developed for therapeutic GI endoscopy. LAMS were originally designed for pancreatic fluid collections drainage (PFC) but are currently also being used for many off-label indications [2,5,7,8]. The bi-flanged metal stent (BFMS), another type of LAMS, is a saddle-shaped metal (Nitinol) stent that achieves lumen apposition because of its bilateral anchoring flanges, thus decreasing the risk of stent migration [5,7,11]. Moreover, because of its larger intraluminal diameter, it is able to accomplish more efficient drainage and its silicone coating prevents tissue ingrowth and thus facilitates easy removal [7,12]. The BFMS (Nagi-LAMS stent) has flared ends giving the bi-flanged design, with a longer saddle up to 3 cm, compared with the 1 cm of the Axios-LAMS stent (Figure 1). Successful management of multiple types of GI stenoses (esophageal, gastric, colonic), with LAMS, have been reported in several studies [2,3,5,13]. However, limited data exists regarding the role of BFMS (Nagi-LAMS stent) in these scenarios. The objective of this study is to evaluate the efficacy, feasibility, indications, and safety of BFMS, as a new endoscopic management of symptomatic short benign PAICS. This report describes a life-saving technique not previously documented and provides a review of the literature.

2.1. Literature Search

These case reports adhere to the SAGE criteria [14]. The narrative review follows the PRISMA guidelines [15]. Included were all original studies and case reports concerning symptomatic benign GI strictures treated endoscopically with LAMS, BFMS and FCSEMS. We performed an electronic literature search in PubMed, Cochrane Library and Embase for articles published between March 2010 and June 2021.

3. Case Presentations

3.1. Chief Complaints: Patients [1-5], suffered from constipation and abdominal pain. Patient 6, suffered from recurrent symptomatic small-bowel obstruction with nausea, vomiting, abdominal pain and flatulence.

3.2. History of Present Illness: Patients [1-5], the symptoms starting [23-25] weeks post-surgery. Patient 6, necessitating hospitalization, the 28th week postoperatively. All included patients underwent ileocecal resection and one-stage, end-to-end anastomosis without diverging ileostomy, for adenocarcinoma in the right colon with an average age of 75 years (range: 68-82). None of the 6 patients did receive adjuvant chemotherapy, because the tumor staging was < T3N0M0. Surgery and diagnosis of stenosis had a median time span of 206.33 days (range: 167-257). The number of patients, etiology, complaints, therapy and other characteristics of the luminal anastomotic benign strictures, in patients who had BFMS placed, are summarized in Table 1. History of past illness: Patients 2 and 4 and 5, had hypertension. Patient 6, had obesity, osteoporosis, cataract, hypertension and type 2 diabetes mellitus. Patients 1 and 3, had a free previous medical history.

3.4. Personal and Family History: No family history of GI tumors.

Physical examination upon admission: Patients 1 – 5, had tenderness in the right upper quadrant of the abdomen. Temperature, blood pressure and pulse rate were normal. Patient 6, at admission, had persistent periumbilical pain was pale but alert with blood pressure 90/60 mmHg and a heart rate 98 beats/min.

3.4. Laboratory Examination: Patients 1 - 6, had normal serum carcinoembryonic antigen (reference range, 0-5.0 ng/mL) and hemoglobin levels, for men an average of 12.0 g/dL, for women, 10.2 g/dL. Normal hemoglobin levels for men are 13.0-17.5 g/dL, for women 11.6-16 gm/dL. The hospitalized patient (patient 6) had white blood cells 12,000 cells per microliter, normal range 4,500–11,000 cells per microliter (4.5 × 109/L).

3.5. Imaging Examinations: Patient 6, the computed tomography (CT) revealed partial small-bowel obstruction at the level of the ileo-colonic anastomosis and anastomotic stricture for patients 1 – 5. Colonoscopies demonstrated tight benign anastomotic stenoses that were not traversable with the pediatric colonoscope. Preoperative evaluation by CT scan and intra-procedural evaluation was performed to access the length and degree of all strictures.

Figure 1: Three types of metal stents (LAMS) with 10 mm diameters. The NAGI-LAMS stent is a bi-flanged metal stent (BFMS) that has flared ends giving the bi-flanged design, with a longer saddle up to 3 cm, compared with the 1 cm of the AXIOS-LAMS stent.

http://www.acmcasereport.com/
Table 1: The number of patients, etiology, therapy and others characteristics of the luminal anastomotic benign strictures, in patients who had BFMS (NAGI-LAMS) stent placed.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Patient 1</th>
<th>Patient 2</th>
<th>Patient 3</th>
<th>Patient 4</th>
<th>Patient 5</th>
<th>Patient 6</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Sex</td>
<td>M</td>
<td>M</td>
<td>F</td>
<td>M</td>
<td>F</td>
<td>F</td>
<td></td>
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<tr>
<td>• Age (yrs)</td>
<td>82</td>
<td>79</td>
<td>70</td>
<td>76</td>
<td>68</td>
<td>75</td>
<td>75</td>
</tr>
<tr>
<td>• Surgical procedure (end-to-end, anastomosis)</td>
<td>ICA</td>
<td>ICA</td>
<td>ICA</td>
<td>ICA</td>
<td>ICA</td>
<td>ICA</td>
<td>ICA</td>
</tr>
<tr>
<td>• Length stricture (cm)</td>
<td>1.5</td>
<td>2.0</td>
<td>1.5</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
<td>1.83</td>
</tr>
<tr>
<td>• Duration of procedure (min)</td>
<td>19</td>
<td>23</td>
<td>26</td>
<td>12</td>
<td>14</td>
<td>15</td>
<td>18.16</td>
</tr>
<tr>
<td>• Technical success (%)</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>• Clinical success, short-term/long-term</td>
<td>Yes/Yes</td>
<td>Yes/Yes</td>
<td>Yes/Yes</td>
<td>Yes/Yes</td>
<td>Yes/Yes</td>
<td>Yes/Yes</td>
<td></td>
</tr>
<tr>
<td>• BFMS stents specifics</td>
<td>L=30mm</td>
<td>L=30mm</td>
<td>L=30mm</td>
<td>L=30mm</td>
<td>L=30mm</td>
<td>L=30mm</td>
<td></td>
</tr>
<tr>
<td>• Stenting dwell (days)</td>
<td>85</td>
<td>89</td>
<td>94</td>
<td>90</td>
<td>91</td>
<td>92</td>
<td>90.16</td>
</tr>
<tr>
<td>• Complications</td>
<td>Non</td>
<td>Mild abdominal pain, lasted 2 days</td>
<td>Mild abdominal pain, lasted 2 days</td>
<td>Mild abdominal pain, lasted 2 days</td>
<td>Mild abdominal pain, lasted 2 days</td>
<td>Mild abdominal pain, lasted 2 days</td>
<td></td>
</tr>
<tr>
<td>• Follow-up (days)</td>
<td>241</td>
<td>237</td>
<td>190</td>
<td>188</td>
<td>218</td>
<td>214</td>
<td>214.6</td>
</tr>
<tr>
<td>• Colonoscopy 4-5 weeks, after stent deployment</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>• Time span between, surgery and diagnosis of stenosis (days)</td>
<td>167</td>
<td>193</td>
<td>204</td>
<td>257</td>
<td>222</td>
<td>195</td>
<td>206.33</td>
</tr>
</tbody>
</table>

Technical success was defined as successful placement of BFMS across the stricture. Short-term clinical success was defined as symptoms resolution with indwelling stent (3 months). Long-term clinical success was defined as symptoms resolution after stent removal, for 7 months.

BFMS: Bi-flanged metal stent; ICA: Ileo-colonic anastomosis; L: Length; D: Diameter.

4. Final Diagnosis
All patients had a high-grade stricture (residual lumen, d < 7 mm). The median length of strictures was 1.83 cm (range 1.5-2.0). Malignancy was ruled out, in all patients, with biopsies for histological examination.

5. Treatment
Endoscopic procedure – stenting: Midazolam was used for conscious sedation or Propofol for deeper sedation. Fluoroscopic and direct endoscopic guidance, the latter with a flexible colonoscope, EC-590WM (Fujifilm, Tokyo, Japan) length 1330mm and broad working channel with a diameter of 3.8mm to reach the stricture site in the transverse colon, were used for all the procedures. We were able to deliver the BFMS via colonoscopy, because NAGI-LAMS stent usable length was longer than the colonoscope’s working length (1800mm vs 1330mm). The risk of intra-procedural perforation and stent migration was reduced with the avoidance of balloon dilatation either before or after BFMS deployment [8,9]. Access across the stricture was acquired using a 0.035 inch, 450cm long guide-wire (Jagwire, Boston Scientific, Natick, MA, USA). The deployed BFMSs were the NAGI-LAMS stent (Tae-woong Medical, Gyeonggido, South Korea) with 30mm length, 16mm lumen diameter, 10Fr delivery catheter, and flange diameter of 20mm (Figure 2). Subsequently, over the guide wire, through-the-scope (TTS), a stent was inserted and contrast injection revealed a stricture in the anastomotic area (Figure 3) and this was stented with a BFMS under fluoroscopic guidance (Figure 4). The distal (downstream) flange of the BFMS was deployed under fluoroscopic guidance and the proximal (upstream) end of the stent under direct endoscopic visualization. Clinical success was described in terms of the alleviation of GI obstructive symptoms, such as nausea, vomiting, constipation, abdominal distention and/or pain and occlusive ileus. Major adverse events were the tissue perforation and stent migration. Minor adverse events were considered transient fever, vomiting, nausea, abdominal pain and self-limited hemorrhage. Any different endoscopic technique or urgent surgery was considered as a procedural failure. Written informed consent forms, as well as authorization of use of personal information forms, were signed by all the patients before the procedure and the off-label use of BFMS. Furthermore, the six patients provided written informed consent for publication. Ethics approval is not required for case series at our institution.
6. Outcome and Follow-Up

The endoscopic BFMS placement, including scope insertion to reach the stricture site (Figure 5, right), had a median procedural duration 18.16 min (range: 12-26). There were constant stool and gas flow after BFMS deployment. No immediate adverse events occurred. Patient 6, complained of mild postprocedural discomfort that lasted 3 days and patient 2, complained of mild postprocedural abdominal pain that lasted 2 days. Both of them responded to analgesics (Paracetamol 1000mg/24h, for two days). All patients underwent colonoscopy 4-5 weeks after stent deployment. Three months later, median 90 days (range: 85-94), the stents (Figure 5, left) were removed, without any adverse events. No patients required additional interventions at a median follow-up of 214.6 days (range: 188-241). The patients had at least two follow-up visits for the next 7 months. The first and the second visit took place on the 3rd and 6th month respectively.
7. Discussion

GI luminal stents represent an appealing endoscopic option to manage selected colonic disorders, particularly post-anastomotic strictures. Strictures longer than 2 cm require multiple sessions of balloon dilatations, with limited long-term potency, perhaps due to lack of stricture remodeling and scaffolding [8,15,16]. A strong proposition for the management of benign anastomotic colon strictures are the metal stents (SEMS, FCSEMS, LAMS-BFMS). This proposition is based in the constant radial force to the stricture for an extended period of time, compared with balloon dilatation, thus inducing a remodeling of these recalcitrant fibrotic strictures [10,13,17-19]. The major adverse event of SEMS and FCSEMS is stent migration, which can occur in 15%-50% of patients, after a mean period of one month [4,8,14,20]. FCSEMS, in patients with post-surgical colorectal diseases, is burdened with a high rate (40%-60%) of migration [6,8]. In a review of 8 studies, with 192 patients, evaluating LAMS for benign GI strictures, LAMS demonstrated statistically significant better results in regards to stent migration and post procedure pain when compared with FCSEMS and BDS stents [5,17]. Endoscopic placement of LAMS and BFMS with fluoroscopic guidance is generally successful, with only a minority of cases requiring endoscopic ultrasound guidance where the lumen is completely obscured [7,12,17] Early LAMS placement is the proposed and viable option for long-term symptomatic relief, concerning patients with short ileo-colonic or colo-colonic anastomotic strictures [3,6,18]. Post-surgical ileo-colonic anastomotic strictures may profit from LAMS, if symptoms remain after two dilatations in patients with benign refractory stenosis [2-4,18,21]. LAMS has the potential to delay or ultimately prevent the necessity for consecutive dilations or surgical intervention [3,18]. Furthermore the underlying risk of perforation (12%-20%) and migration (>20%) increases with the deployment of pre or post balloon dilatations [8,9,18]. Due to the reasons mentioned above, a NAGI-LAMS stent was chosen and non pre balloon dilatations were performed in these six patients. In the reviewed literature, the rate of successful LAMS deployment, for ileo-colonic anastomosis, was 89%-98%.3,7 The overall stent migration reported only in 7%-9% of patients. 3,18 Proximal stent migration occurred, during the first 3 weeks, in 6% of patients [1,3,4,7,13]. One patient (4.5%) had self-limiting bleeding and this complication was associated with LAMS migration after one week of its placement [5,7]. No perforation and mortality were attributable to LAMS placement [1,3,4,13]. Our results, of NAGI-LAMS success in management of PAICSs, are in line with the two largest studies of LAMS showing its utility in the management of benign short PAICSs [3,16]. Our clinical success rate for treatment-naive patients was 100% (6/6). All patients in our cases tolerated NAGI-LAMS deployment and sojourn for the entire therapy duration without severe postprocedural pain or stent migration. This is in concordance with the literature, LAMS (Nagi, Axios) intolerance was <5% post deployment [22-26]. LAMS demonstrated less stent migration (9% vs 40%) and post procedure pain when compared with FCSEMS and BDS [24,27-30]. The overall rate of successful LAMS (Nagi, Axios) deployment (98%), the lower migration (7%-9%), the lower bleeding (4.5%) without perforation, in the treatment of luminal colonic strictures, are all encouraging to consider LAMS in the treatment algorithm of benign short ileo-colonic post-surgical stenosis, in a multidisciplinary discussion [3,6,13,22,23]. Evidence for the usefulness of NAGI-LAMS for ileo-colonic or colo-colonic anastomotic strictures is presented in few case reports [25,28] Only 20 cases have been announced, in the literature, concerning the use of LAMS (Axios, Nagi) for the endoscopic management of colonic strictures [4]. The maximum efficacy and minimum adverse events regarding the optimal duration of LAMS placement remains undetermined. Many authors suggest limiting the sojourn period of LAMS (Nagi,Axios) to three months [5,6,12,18,22]. The novel design of these stents permits longer dwell time, which induces to better clinical results and low rates of recurrence [3,4,18,19]. In the reviewed literature, concerning the NAGI-AXIOS-LAMS stent, the mean stent indwell time was 3.56 months [4,5,11,13]. For these reasons we decided to remove the NAGI-LAMS stents after a sojourn of 3 months, and our patients were followed clinically, without the need for additional interventions due to major or minor adverse events, at a median follow-up of 7 months. The optimal period of stent sojourn remains to be evaluated in future studies. One of the originalities of our study is that we evaluate the efficacy,
feasibility and safety of the NAGI-LAMS stent, in the endoscopic management of symptomatic short benign PAICSs. We report a life-saving technique not previously documented, the unlabeled use of NAGI-LAMS stent and the use of technology to improve patient outcomes. The saddle length of this NAGI stent is longer than AXIOS stent, (30mm vs 10mm), and it may therefore be more optimal for longer (>1cm) luminal GI strictures [5,10,12]. Another difference between the NAGI-LAMS and the AXIOS-LAMS is the different size of stent diameter (D = 10, 12, 14, 16mm vs 10, 15mm) [10,12] Stent diameter and length selection are crucial for the clinical success of the procedure (Figure 1). Given these parameters (length and diameter) of LAMS, the NAGI-LAMS stent would be effective for strictures < 30mm in length and AXIOS-LAMS stent for strictures < 10mm in length [5,11,13] The anchoring effect of the NAGI stent stems from the bi-flanged design rather than exerting lumen-apposition [12]. Importantly the NAGI stent delivery catheter can be introduced via colonoscope, while the AXIOS stent shorter delivery catheter can only be delivered either via a therapeutic forward-viewing gastroscope or echoendoscope [4,5,12,17]. The low sample size in our study and the absence of comparative groups are important limitations that should be acknowledged. Although our results are concordant with the current literature, there are limitations considering the 3 months of stents sojourn and the short duration (7 months) of their follow-up time. More prospective multicenter trials are required to develop guidelines for the utility of NAGI-LAMS in the endoscopic management of benign ileo-colonic strictures. Further data are needed to validate the long-term safety and efficacy of BFMS (NAGI-LAMS) in the treatment of luminal GI stenosis.

8. Conclusion
In conclusion the length and wide flanges, of BFMS (NAGI-LAMS), may reduce migration rates and improve the patient tolerance. BFMS placement is a minimally invasive endoscopic procedure that may be beneficial as bridging to surgery or definitive therapy, when approaching patients with refractory short benign post-anastomotic ileo-colonic strictures. BFMS could represent an important alternative to traditional endoscopic options with better long-term results in the management of luminal GI strictures, longer than 10mm and shorter than 30mm.

References


