Safety and efficacy of the use of lumen-apposing metal stents in the management of postoperative fluid collections: a large, international, multicenter study

Authors
Juliana Yang1, Jeremy H. Kaplan2, Amrita Sethi2, Enad Dawod3, Reem Z. Sharaiha3, Austin Chiang4, Thomas Kowalski4, Jose Nieto5, Ryan Law6, Hazem Hammad7, Sachin Wani7, Mihir S. Wagh7, Dennis Yang8, Peter V. Draganov8, Ahmed Messallam8, Qiang Cai9, Vladimir Kushnir10, Natalie Cosgrove10, Ali Mir Ahmed10, Andrea Anderloni12, Douglas G. Adler13, Nikhil A. Kumta14, Satish Nagula14, Frank P. Vleggaar15, Shayan Irani16, Carlos Robles-Medranda17, Abdul Hamid El Chafic18, Rishi Pawa17, Olaya Brewer1, Omid Sanaei1, Mohamad Dbouk1, Vivek Kumbhari1, Mouen A. Khashab1

Institutions
1 Division of Gastroenterology and Hepatology, Johns Hopkins Medical Institution, Baltimore, Maryland, USA
2 Division of Digestive and Liver Disease, Columbia University Medical Center, New York, New York, USA
3 Division of Gastroenterology and Hepatology, Weill Cornell Medical Center, New York, New York, USA
4 Division of Gastroenterology and Hepatology, Thomas Jefferson University, Philadelphia, Pennsylvania, USA
5 Division of Gastroenterology and Hepatology, Borland Groover Clinic, Jacksonville, Florida, USA
6 Division of Gastroenterology, University of Michigan, Ann Arbor, Michigan, USA
7 Division of Gastroenterology and Hepatology, University of Colorado Anschutz Medical Campus, Aurora, Colorado, USA
8 Division of Gastroenterology and Hepatology, University of Florida, Gainesville, Florida, USA
9 Division of Digestive Disease, Emory University School of Medicine, Atlanta, Georgia, USA
10 Division of Gastroenterology, Washington University in Saint Louis, St. Louis, Missouri, USA
11 Division of Gastroenterology and Hepatology, University of Alabama at Birmingham, Birmingham, Alabama, USA
12 Division of Gastroenterology, Digestive Endoscopy Unit, Humanitas Research Hospital, Rozzano, Milan, Italy
13 Division of Gastroenterology and Hepatology, University of Utah School of Medicine, Salt Lake City, Utah, USA
14 Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York, New York, USA
15 Division of Gastroenterology and Hepatology, University Medical Center Utrecht, Utrecht, The Netherlands
16 Division of Gastroenterology and Hepatology, Virginia Mason Medical Center, Seattle, Washington, USA
17 Gastroenterology and Endoscopy Division, Instituto Ecuatoriano de Enfermedades Digestivas, University Hospital OMNI, Guayaquil, Ecuador
18 Division of Gastroenterology, Ochsner Medical Center, New Orleans, Louisiana, USA
19 Division of Gastroenterology, Department of Internal Medicine, Wake Forest School of Medicine, Winston-Salem, North Carolina, USA

Submitted: 28.11.2018
Accepted after revision: 10.4.2019

Bibliography
DOI https://doi.org/10.1055/a-0924-5591
Published online: 13.6.2019 | Endoscopy 2019; 51: 715–721
© Georg Thieme Verlag KG Stuttgart · New York
ISSN 0013-726X

Corresponding author
Mouen Khashab, MD, Division of Gastroenterology and Hepatology, Johns Hopkins Medical Institutions, 1800 Orleans St, Sheikh Zayad 7E Rm 7125G, Baltimore, MD 21224, USA
mkhasha1@jhmi.edu

Table 1s

Online content viewable at:
https://doi.org/10.1055/a-0924-5591

ABSTRACT

Background Multiple studies have examined the use of lumen-apposing metal stents (LAMs) for the drainage of peripancreatic fluid collections. Data on the use of LAMs for postoperative fluid collections (POFCs) are scarce. POFCs may lead to severe complications without appropriate treatment. We aimed to study the outcomes (technical success, clinical success, rate/severity of adverse events, length of stay, recurrence) of the use of LAMs for the drainage of POFCs.

Methods This international, multicenter, retrospective study involved 19 centers between January 2012 and October 2017. The primary outcome was clinical success. Secondary outcomes included technical success and rate/
severity of adverse events using the ASGE lexicon.

Results A total of 62 patients were included during the study period. The most common etiology of the POFCs was distal pancreatectomy (46.8%). The mean (standard deviation) diameter was 84.5 mm (30.7 mm). The most common indication for drainage was infection (48.4%) and transgastric drainage was the most common approach (82.3%). Technical success was achieved in 60/62 patients (96.8%) and clinical success in 57/62 patients (91.9%) during a median (interquartile range) follow-up of 231 days (90–300 days). Percutaneous drainage was needed in 8.1% of patients. Adverse events occurred intraoperatively in 1/62 patients (1.6%) and postoperatively in 7/62 (11.3%). There was no procedure-related mortality.

Conclusion This is the largest study on the use of LAMs for POFCs. It suggests good clinical efficacy and safety of this approach. The use of LAMs in the management of POFCs is a feasible alternative to percutaneous and surgical drainage.

Introduction

Postoperative fluid collections (POFCs) are a recognized source of morbidity and mortality [1,2]. POFCs were historically managed with surgical re-exploration and drainage; however, this approach is invasive and results in significant morbidity [1,3]. Over the past decade, image-guided percutaneous drainage has been increasingly utilized and has proven to be a safe and effective treatment option, with success rates between 60% and 84% [1,2,4–7]. However, depending on the location of the POFC, percutaneous drainage may not always be feasible.

Several reports have described endoscopic ultrasound (EUS)-guided drainage techniques in the management of a variety of intra-abdominal POFCs using plastic and fully covered self-expanding metal stents (FCSEMs), with technical and clinical success rates of 96%–100% and 80%–100%, respectively [5,6,8–11]. However, plastic stents and FCSEMs are not designed for this indication and carry risks such as stent migration and bleeding. Recent literature has shown excellent safety and efficacy for EUS-guided drainage using lumen-apposing metal stents (LAMs) for the management of symptomatic peripancreatic fluid collections resulting from pancreatitis; however, data on the outcomes of this approach in the management of POFCs remain scarce [1,12].

The objective of this international, multicenter, retrospective study was to evaluate the clinical outcomes of EUS-guided transmural drainage of POFCs using LAMs.

Methods

This international, multicenter, retrospective study involved 19 tertiary hospitals: 16 from the USA, two from Europe, and one from South America. The study was approved by the institutional review boards (IRBs) of participating hospitals: 16 from the USA, two from Europe, and one hospital in South America. The study was approved by the individual Institutional Review Boards (IRBs). Patients who underwent EUS-guided POFC drainage using LAMs between January 2012 and October 2017 were included.

POFCs were defined as any collection in the chest, abdomen, or pelvis due to prior surgical intervention. The collections were identified on cross-sectional imaging prior to EUS intervention and those amenable to EUS-guided drainage were included. Patients were identified using center-specific endoscopic or billing databases. All patient information was de-identified and stored in a password-protected computer.

Electronic records were reviewed to capture the following variables: demographics, POFC location and size, etiology of the surgical intervention, presence of main pancreatic duct (MPD) disruption or leakage based on endoscopic retrograde cholangiopancreatography (ERCP) findings, indication for drainage, stent type, stent size, number of stents, drainage approach (i.e. transgastric, transduodenal, transesophageal), technical success, procedure time, percutaneous drain (PCD) insertion, size of PCD, clinical success, success of stent removal, ERCP performed post-index procedure, insertion of transpapillary pancreatic stent, POFC recurrence, need for surgery, adverse events graded according to the American Society for Gastrointestinal Endoscopy (ASGE) lexicon [13], length of hospital stay (LOS), and duration of follow-up. None of the patients in the current study have been included in any prior published studies.

Procedure technique

Preprocedure informed consent was obtained from all patients. Prophylactic and post-procedure antibiotics were given at the discretion of the endoscopist and/or per institutional protocol. All procedures were performed by interventional endoscopists using linear array echoendoscopes. The procedures were performed with the patient under monitored anesthesia care, general anesthesia, or moderate/deep sedation per endoscopist and institutional preference.

Prior to puncture of the POFC, a linear echoendoscope was used to evaluate its size and location, along with the presence of debris and surrounding organs. Color-enhanced Doppler ultrasound was then used to exclude intervening vascular structures. After careful visualization of the POFC, the distance between the luminal wall and the POFC was carefully measured to ensure the intended target was within a distance of 1 cm. Two types of LAMS (AXIOS; Boston Scientific, Marlborough, Massachusetts, USA) were used: the electrocautery-enhanced (“hot”) or nonelectrocautery-enhanced (“cold”) versions. The stent diameters were 10 mm or 15 mm. The type of stent was chosen at the discretion of the endoscopist and on the basis of the type of stent available at the time of the procedures.

The electrocautery-enhanced LAMS was inserted with cautery assistance into the POFC cavity, followed by deployment of the distal flange and then the proximal flange under direct EUS and/or endoscopic guidance (Fig. 1). If a nonelectrocautery-enhanced LAMS was used, the POFC was first punctured with a 19-gauge needle, then coiling of 0.025– or 0.035-inch
guidewire within the POFC under fluoroscopic guidance, followed by tract dilation and LAMS insertion. Endoscopic debridement of necrotic material was performed as needed and at the discretion of the endoscopist.

Endpoints
The primary endpoint was clinical success, defined as successful drainage of the POFC using a LAMS with corresponding reduction in the POFC to \( \leq 3 \) cm on computed tomography (CT) or magnetic resonance imaging (MRI), with corresponding clinical symptom resolution within 3 months of stent insertion and without the need for percutaneous drainage or surgery. Secondary endpoints were: technical success rate, defined as successful stent deployment to the intended target; adverse events, with severity graded per the ASGE lexicon; rate of stent migration; re-interventions; POFC recurrence; and the need for surgery.

Statistical analysis
Dichotomous variables were reported as frequencies with percentages. Continuous variables were reported as mean and standard deviation (SD), or median and interquartile range (IQR), where appropriate. The analysis was performed using STATA software version 13 (Stata Corp LLC, College Station, Texas, USA).

Results
A total of 62 patients (45.2% women; mean age 59.3 years [SD 13.6 years]) with POFCs underwent EUS-guided drainage (Table 1, see online-only Supplementary material), with 60/62 patients recruited between 2015 and 2017. Eight patients (12.9%) had failed prior percutaneous drainage. The 10-mm LAMS was used in 32.3% (20/62) of patients and the 15-mm LAMS was used in 67.7% (42/62). Two technical failures occurred: one using a noncautery-enhanced 10-mm LAMS and one using a cautery-enhanced 10-mm LAMS.

The etiologies for the POFCs were: distal pancreatectomy 46.8% (29/62), Whipple procedure 9.7% (6/62), colectomy 8.1% (5/62), cholecystectomy 6.5% (4/62), splenectomy 4.8% (3/62), orthotopic liver transplant 3.2% (2/62), partial gastrectomy 3.2% (2/62), hiatal hernia repair 3.2% (2/62), thoracic endovascular repair 1.6% (1/62), retroperitoneum resection 1.6% (1/62), partial hepatectomy 1.6% (1/62), and others 9.7% (6/62). POFCs were intraperitoneal in 48.4% of patients (30/62), retroperitoneal in 40.3% (25/62), pelvic in 8.1% (5/62), and intrathoracic in 3.2% (2/62). The primary indications for drainage were infection in 30/62 (48.4%), pain in 26/62 (41.9%), early satiety in 4/62 (6.5%), gastric outlet obstruction (GOO) in 1/62 (1.6%), and others in 1/62 (1.6%) (Table 1). The mean diameter of the POFCs was 84.5 mm (SD 30.7 mm). ERCP was performed in 17 patients (27.4%). Pancreatic duct leakage was diagnosed in 12 patients, of whom two had discon-
nected pancreatic ducts that were managed with simultaneous transpapillary stent placement.

### Procedure characteristics

A total of 62 patients with POFCs underwent EUS-guided drainage with placement of a LAMS (54 cautery-enhanced, 8 noncautery-enhanced). The most common approach was transgastric in 82.3 % of patients (51/62), followed by transduodenal in 8.1 % (5/62), transrectal 8.1 % (5/62), and transesophageal 1.6 % (1/62) (Table 2). The mean procedure time was 30.4 minutes (SD 14.0 minutes). The median duration between surgery and the EUS-guided drainage procedure was 99 days (IQR 42–272), with 10 patients being treated < 30 days from surgery. The mean number of LAMSs placed was 1. A total of 10/62 patients (16.1%) required placement of double-pigtail plastic stents within the LAMS: 5 patients received 7-Fr stents and 5 patients received 10-Fr stents, with the mean diameter of the plastic stents being 8.5 Fr (SD 1.5 Fr).

### Clinical endpoints

Technical success was achieved in 96.8 % of patients (60/62), with a mean procedure time of 30.4 minutes (SD 14.0 minutes). The mean length of hospital stay following LAMS insertion was 7.4 days (SD 14 days). All stents were successfully removed following resolution of the POFC. The mean duration of LAMS placement was 46.8 ± 26.22 days.

Overall, clinical success was achieved in 91.9 % of patients (57/62). A total of five patients (8.1 %) required percutaneous drain placement. Clinical success based on POFC location was as follows: thoracic 50 % (1/2), pelvic 80 % (4/5), and abdominal 94.5 % (52/55) (Table 3). The mean number of endoscopic procedures needed to achieve clinical success was 1.6 (SD 1.2), with 69.4 % of patients (43/62) achieving clinical success with one endoscopy session, 17.7 % (11/62) with two sessions, 4.8 % (3/62) with three sessions, and 8.1 % (5/62) with four or more sessions. A total of 9 patients underwent necrosectomy with a mean of three sessions (SD 2.1 sessions), with 33.3 % (3/9) undergoing one necrosectomy session, 22.2 % (2/9) undergoing two sessions, and 44.4 % (4/9) requiring three or more sessions. Percutaneous drainage was needed in 8.1 % of patients (5/62).

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**Table 1** Baseline characteristics of the 62 patients and their postoperative fluid collections (POFCs) that were managed by placement of a lumen-apposing metal stent.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), years</td>
<td>59.3 (13.6)</td>
</tr>
<tr>
<td>Sex, female, %</td>
<td>45.2 %</td>
</tr>
<tr>
<td>Prior interventions, n (%)</td>
<td>8 (12.9 %)</td>
</tr>
<tr>
<td>Indication for POFC drainage, n (%)</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>30 (48.4 %)</td>
</tr>
<tr>
<td>Pain</td>
<td>26 (41.9 %)</td>
</tr>
<tr>
<td>Gastric outlet obstruction</td>
<td>1 (1.6 %)</td>
</tr>
<tr>
<td>Early satiety</td>
<td>4 (6.5 %)</td>
</tr>
<tr>
<td>Others</td>
<td>1 (1.6 %)</td>
</tr>
<tr>
<td>Location of POFC, n (%)</td>
<td></td>
</tr>
<tr>
<td>Intraperitoneal</td>
<td>30 (48.4 %)</td>
</tr>
<tr>
<td>Retroperitoneal</td>
<td>25 (40.3 %)</td>
</tr>
<tr>
<td>Intrathoracic</td>
<td>2 (3.2 %)</td>
</tr>
<tr>
<td>Pelvic</td>
<td>5 (8.1 %)</td>
</tr>
<tr>
<td>Longest diameter of POFC, mean (SD), mm</td>
<td>84.5 (30.7)</td>
</tr>
<tr>
<td>Size of POFC, n (%), mm</td>
<td></td>
</tr>
<tr>
<td>≤ 50</td>
<td>6 (9.7 %)</td>
</tr>
<tr>
<td>51–100</td>
<td>39 (62.9 %)</td>
</tr>
<tr>
<td>≥ 101</td>
<td>17 (27.4 %)</td>
</tr>
</tbody>
</table>

**Table 2** Procedural characteristics for the placement of the 62 lumen-apposing metal stents (LAMSS).

<table>
<thead>
<tr>
<th>LAMS type, n (%)</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cautery-enhanced</td>
<td>54 (87.1 %)</td>
</tr>
<tr>
<td>Noncautery-enhanced</td>
<td>8 (12.9 %)</td>
</tr>
<tr>
<td>Stent diameter, n (%)</td>
<td></td>
</tr>
<tr>
<td>10 mm</td>
<td>20 (32.3 %)</td>
</tr>
<tr>
<td>15 mm</td>
<td>42 (67.7 %)</td>
</tr>
<tr>
<td>Drainage approach, n (%)</td>
<td></td>
</tr>
<tr>
<td>Transgastric</td>
<td>51 (82.3 %)</td>
</tr>
<tr>
<td>Transduodenal</td>
<td>5 (8.1 %)</td>
</tr>
<tr>
<td>Transrectal</td>
<td>5 (8.1 %)</td>
</tr>
<tr>
<td>Transesophageal</td>
<td>1 (1.6 %)</td>
</tr>
<tr>
<td>Time from surgery to endoscopic drainage, median (IQR), days</td>
<td>99 (42–272)</td>
</tr>
<tr>
<td>&lt; 30 postoperative days until endoscopic drainage, n (%)</td>
<td>10 (16.1 %)</td>
</tr>
<tr>
<td>Stents per patient, mean (SD)</td>
<td>1.2 (0.07)</td>
</tr>
<tr>
<td>Endoscopic interventions per patient, mean (SD)</td>
<td>1.6 (1.2)</td>
</tr>
<tr>
<td>Tract dilation performed prior to stenting, n (%)</td>
<td>28 (45.2 %)</td>
</tr>
<tr>
<td>Tract dilation size, mean (SD), mm</td>
<td>13.3 (0.5)</td>
</tr>
<tr>
<td>Number of patients undergoing necrosectomy, n (%)</td>
<td>9 (14.5 %)</td>
</tr>
<tr>
<td>Necrosectomy sessions, mean (SD)</td>
<td>3.0 (2.1)</td>
</tr>
<tr>
<td>Successful LAMS removal, n (%)</td>
<td>62 (100 %)</td>
</tr>
<tr>
<td>Stent duration, mean (SD), days</td>
<td>46.8 (26.22)</td>
</tr>
<tr>
<td>Procedure time, mean (SD), minutes</td>
<td>30.4 (14.0)</td>
</tr>
</tbody>
</table>

SD, standard deviation; IQR, interquartile range.
A total of eight adverse events occurred, with an overall adverse event rate of 12.9% (Table 4). Adverse events included bleeding episodes (n=3), pain (n=2), infection (n=2), and stent dislodgement (n=1). None of the bleeding episodes were due to pseudoaneurysm. Bleeding episodes included: one mild intraoperative bleed on insertion of the stent, which subsequently resolved without intervention; one severe bleed on post-procedure day 4, for which the source was not identified; and one moderate bleed on post-procedure day 1, which was managed with repeat endoscopy and proton pump inhibitors, with no endoscopic intervention being performed and the source of bleeding remaining unclear. Postoperative adverse events requiring intervention occurred in seven patients: stent occlusion (n=3); infection (n=1); stent dislodgement (n=1); and one POFC recurrence 5 days following LAMS removal, which was managed with stent re-insertion. In terms of severity, three events (37.5%) were mild, three (37.5%) were moderate, and two (25.0%) were severe. There was no procedure-related mortality. The median length of follow-up was 231 days (IQR 90–300).

**Discussion**

The development of a POFC following intra-abdominal surgery is not a rare occurrence, particularly following pancreatic surgical resections [1, 14]. POFCs may be asymptomatic and may resolve with conservative management; however, symptoms such as GOO, pain, infection, and sepsis may develop when they are left untreated [6, 7, 15, 16]. POFCs were traditionally managed surgically, but this carries non-trivial morbidity and mortality; percutaneous drainage has therefore become a common treatment modality, with success rates varying between 60% and 84% and mortality rates between 1.4% and 15% [1, 6, 17, 18]. However, there are several disadvantages to the use of percutaneous drainage catheters, including decreased quality of life, increased risk of infection, electrolyte loss, and the development of fistulas, which can become chronic and difficult to resolve [1, 2, 4–6].

Since the first description of EUS-guided drainage of a pelvic abscess using plastic stents by Giovannini et al. in 2003 [19], interventional EUS has expanded to include a wide range of indications, such as EUS-guided drainage of peripancreatic fluid collections using both plastic stents and FCSEMs [8, 20–22]. These techniques have more recently been used for drainage of POFCs, with clinical success rates of 80%–100% and technical success rates of 96%–100% [1, 5, 7, 8, 11, 18, 23–26].

There are several disadvantages to the use of double-pigtail plastic stents, including their small lumen diameter, which necessitates placement of multiple stents to obtain adequate drainage. In addition, stent occlusion and other stent-related adverse events occur in up to 18% of patients [27].
FCSEMSs are larger in caliber, they do not provide lumen apposition and are prone to migration in upwards of 15% of patients [28]. Furthermore, necrosectomy cannot be performed through FCSEMSs. Lastly, FCSEMSs are relatively long and the length of stent within the cavity of the POFC means it can abut against the wall of the cavity after its partial collapse, resulting in bleeding [1, 29, 30].

Since the first clinical experience using the unique dumbbell-shaped fully covered metal stent in 2012 reported by Itoi et al., there has been increasing preference among endoscopists for the use of LAMSs for cystgastrostomy and management of pancreatic necrosis [31, 32]. Data on the use of LAMSs for peripancreatic fluid collections have been encouraging with overall technical success rates exceeding 95%, clinical success rates of 85%–91%, a migration rate of 5%, and adverse event rates of 10%–15% [33, 34]. The larger lumen diameter allows for easy access into the cavities for necrosectomy, whenever needed.

There is however scarce literature reporting on the use of LAMSs in the management of POFCs. A recently published study by Mudireddy et al. included 47 patients with POFCs that were managed using LAMSs and showed a clinical success rate of 89.3%, technical success rate of 89.3%, and an adverse event rate of 6.4% [1].

Our current report is the largest study evaluating the outcome of LAMS use for the drainage of POFCs, with technical and clinical success rates of 96.8% and 91.9%, respectively. Adverse events occurred in 12.9% of patients (8/62), of which 11.3% were postoperative and 1.6% intraoperative. There have been recent discussions about an increased risk of bleeding with the use of LAMSs owing to concerns about erosion or direct impingement of LAMSs into vessels following cavity collapse, leading to pseudoaneurysmal formation and hemorrhage; however, this was not reflected in our study.

The present study also included 27 (43.5%) nonpancreatic surgery POFCs. The clinical and technical success rates for these POFCs were 88.9% (24/27) and 92.6% (25/27), respectively. These findings are comparable to the currently available literature with clinical outcomes and treatment success between 86% and 100% [10, 19, 25, 26, 35–37]. Our study also showed that drainage of POFCs within <30 days may be safely performed without increased risk of recurrence or adverse events. These are important findings illustrating the expanding use of EUS-guided fluid collection drainage beyond that of pancreatic collections.

There are several limitations to this study. Firstly, this is a retrospective study, which carries inherent limitations including variable follow-up, heterogeneity between centers, and no standardized algorithm of stent management across the multiple centers. The number of patients contributed from some of the centers was small. In addition, only tertiary referral centers were involved, which would limit its generalizability to other centers with less experience. This study specifically applies to the use of the AXIOStent and cannot be generalized to other LAMSs such as the NAGI and SPAXUS stents (both Taewoong Medical Co. Ltd., Seoul, South Korea). Finally, we did not account for the cost-effectiveness of using LAMSs.

In conclusion, in this large, international, multicenter study, our data suggest that LAMSs are safe and effective in the management of patients with POFCs.

Competing interests

Dr. Amrita Sethi is a Consultant for Olympus and Boston Scientific. Dr. Reem Z. Sharaiha is a consultant for Boston Scientific and Apollo Endosurgery. Dr. Thomas Kowalski is a consultant for Boston Scientific and Medtronic. Dr. Jose Nieto is a consultant for Boston Scientific. Dr. Sachin Wani is a consultant for and received grant support from Boston Scientific and Medtronic, and grant support from Cook. Dr. Mihir S. Wagh has served as a consultant for Boston Scientific and Medtronic. Dr. Ali Mir Ahmed is a consultant for Boston Scientific and Cook Medical. Dr. Andrea Anderloni is a consultant for Boston Scientific. Dr. Douglas G. Adler is a consultant for Boston Scientific. Dr. Nikhil A. Kunta is a consultant for Apollo Endosurgery, Boston Scientific and Olympus. Dr. Frank P. Vleegaa is a consultant for Boston Scientific Dr. Isaac Rajiman is a consultant for Boston Scientific. Dr. Shayan Irani is a consultant for Boston Scientific. Dr. Vivek Kumbhari is a consultant for ReShape Lifesciences, Apollo Endosurgery, Boston Scientific and Medtronic. Dr. Vikesh Singh is consultant for Abbvie, Novo Nordisk, and Ariel and advisory board participant for Nordmark. Dr. Douglas Pleskow is a consultant for Boston Scientific, Olympus, Nine Point and CSA. Dr. Mouen A. Khashab is a consultant for Boston Scientific, Olympus and Medtronic and is on the medical advisory board for Boston Scientific and Olympus.

References


