

Conference Report

The American College of Gastroenterology 2019 Annual Scientific Meeting-ACG 2019

Oct 25-30, 2019

San Antonio, TX USA

Ovesco products were presented during various plenary and poster sessions throughout the conference. A summary of those presentations can be found below:

OTSC® System

Besides a RCT showing OTSC's superiority in NVUGIB treatment, many case reports were presented documenting successful OTSC use in critical clinical cases

OTSC treatment of NVUGIB is associated with 85 % lower rebleeding rate when compared to standard hemostasis methods

Jensen DM et al., CURE Digestive Diseases Research Center, Los Angeles, CA, United States presented the results from their recent Randomized Controlled Trial (RCT) that was conducted at 2 academic medical centers which evaluated the outcomes of patients treated with OTSC for initial endoscopic treatment of severe non-variceal upper gastrointestinal bleeding (NVUGIB) to patients treated with standard hemostasis RX methods (e.g. hemoclips and/or multipolar probe with epinephrine pre-injection). 49 patients who met clinical and esophagogastroduodenoscopy (EGD) criteria for PUB's or UGI Dieulafoy's lesions (with major SRH or spots with arterial blood flow) were randomized in a 1:1 allocation to either standard RX (as described in above RCT) or OTSC. All patients received high dose PPI's after randomization and were followed prospectively for 30 days. The proportion of patients with 30-day rebleeding was significantly higher with standard RX – 28 % (7/25) - compared to OTSC RX – 4.2 % (1/24). The OTSC rebleeding rate was 85 % lower than standard group (relative risk 0.149 with 95 % confidence intervals of 0.006, 0.863). The number needed to treat (NNT) was 4.2. In patients with severe UGI bleeding from PUB's or Dieulafoy's lesions, primary endoscopic treatment with OTSC resulted in significantly lower rates of rebleeding and severe complications and fewer RBC transfusions than standard endoscopic hemostasis. Results appear to relate OTSC's superior ability to obliterate arterial blood flow underneath SRH and thereby reduce lesion rebleeding.

Randomized Controlled Trial (RCT) of Over-the-Scope Clip (OTSC) as Initial Endoscopic Treatment of Severe Non-Variceal Upper Gastrointestinal Bleeding (NVUGIB)

Jensen DM ^{1,2,3}, Kovacs TOG ^{1,2}, Ghassemi KA ^{1,2}, Kaneshiro M ^{1,2}, and Gornbein, J ⁴

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The OTSC as valuable tool for salvage hemostasis in duodenal ulcer

Meir Mizrahi, MD et al, University of South Alabama College of Medicine, Mobile, AL, presented a case where traditional hemostasis methods failed, and an OTSC was used as salvage/rescue hemostasis therapy. The patient was a 45-year-old Asian male with a history of cirrhosis secondary to alcohol presented with jaundice and melena with a hemoglobin of 5.9 gm/dl. EGD showed severe duodenitis. A side viewing duodenoscope showed a large, cratered duodenal bulb ulcer with a visible vessel. Epinephrine was injected and 5 hemoclips were placed. Despite this, there was still active oozing of blood. All the hemoclips were removed with snare. OTSC System was loaded onto a standard gastroscope and advanced to the lesion. Target tissue was sucked into the cap and OTSC clip was released by turning the hand wheel. The clip closed itself and firmly anchored the tissue resulting in complete hemostasis. Proton pump inhibitors were continued and follow up endoscopy

at 1 month showed healed ulcer site with clip in place. While OTSC have been well established in leaks, perforations and fistulas, their role in UGI hemorrhage is evolving. Several randomized trials comparing OTSC with conventional endoscopic hemostasis therapies are ongoing and results are awaiting, however our case reiterates that OTSC platform should be available and be part of endoscopic hemostasis armamentarium.

Dominant Claw Control: Role of OTSC Clip as Salvage Hemostasis Therapy

Gilad Shapira, MD¹, Manoj Kumar, MD², Yazan Fahmawi, MD², Meir Mizrahi, MD³

¹University of South Alabama College of Medicine, Mobile, AL; ²University of South Alabama, Mobile, AL; ³University of South Alabama College of Medicine, Spanish Fort, AL

Clip retention time of OTSC is median 8.9 months, clip location and indication for placement are key factors in time to clip loss

Xiao Jing Wang, MD et al, Mayo Clinic, Rochester, MN presented their findings from a retrospective review of OTSC usage from 1/1/2011 to 1/1/2019. The primary endpoint was clip retention time (time when the clip was placed to time the clip was last seen or was physically removed). Secondary endpoints were rate of complications and factors that influence clip retention time and clinical success. A total of 358 OTSC were placed in 299 patients (55.8 % male, n = 184) with mean age 64 + 15.3 years. Clip placement was clinically successful in 81 % of cases (n = 265). Median time to clip loss as assessed by Kaplan-Meier curve was 267 days (95 % CI 196 - 406). Adverse events occurred in 34 clip placements (10.7 %) and included bleeding (n = 8, 24.2 %), perforation (n = 5, 15.2 %), ulceration (n = 3, 9.1 %), migration (n = 15, 45.5 %), and infection (n = 1, 3.0 %). Univariate analysis revealed that age, gender, type of OTSC clip used, and performing endoscopist did not impact clip retention rate. A size 14 clip had marginally higher rates of retention compared to others. Clips placed in the rectum or esophagus were lost earlier compared to those in the small/large intestine and stomach. Clips placed for fistulas and those associated with adverse event were associated with earlier clip loss. In evaluation of clinical success, clips placed for fistulas had a relative risk of clinical failure of 2.08 (95 % CI 1.29 - 3.36) compared to all other indications. OTSC are retained for a median of 8.9 months with clip location and indication for placement being key factors in time to clip loss.

Clip It and Forget It? A Natural History of 358 Over-the-Scope Clips

Xiao Jing Wang, MD¹, Daniel Gonzalez Izundegui, MD¹, Sneha Singh, MBBS¹, Gerardo Calderon, MD², Oscar Garcia Valencia, MD³, Andrew C. Storm, MD⁴

¹Mayo Clinic, Rochester, MN; ²Indiana University Hospital, Rochester, MN; ³University of Miami, Rochester, MN; ⁴Mayo Clinic College of Medicine and Science, Rochester, MN

Post-operative duodenal-enteric fistula in patient with multiple gunshot wounds successfully closed with OTSC

David H. Kruchko, et al, Advocate Lutheran General Hospital, Chicago, IL presented a case where an OTSC was used successfully for immediate closure of a duodenal-enteric fistula caused by a gunshot wound, which saved the patient from undergoing additional surgery. A 41-year-old man presented with multiple gunshot wounds to the abdomen. An emergent exploratory laparotomy was performed, with partial small bowel resection for gunshot wounds to the jejunum and ileum. His postoperative course was complicated by an intra-abdominal abscess. A sinogram revealed a duodenal-enteric fistula with a fluid collection, requiring Jackson Pratt drain placement and antibiotic therapy. Given the lack of improvement, the patient was taken for EGD. A 10 mm fistulous tract was identified at the junction of the 2nd and 3rd portion of the duodenum. A 12/6t OTSC was deployed over a pediatric colonoscope. The scope was passed to the level of the fistula, with fluoroscopy for localization. Using suction, the fistula was pulled into the cap of the OTSC device and the clip was successfully deployed, closing the fistula. Clip placement was confirmed via fluoroscopy. The next day, upper gastrointestinal stomach X-Ray was completed and did not show extravasation to suggest a leak at the duodenum. His diet was advanced and after a prolonged hospital course, he was discharged.

Endoscopic Closure of Post-Operative Duodenal-Enteric Fistula Following Repair of Abdominal Gunshot Wound

David H. Kruchko, DO¹, Natasha Shah, MD², Ryan T. Hoff, DO², Asif Lakha, MD²

¹Advocate Lutheran General Hospital, Chicago, IL; ²Advocate Lutheran General, Hospital, Park Ridge, IL

Boerhaave’s Syndrome successfully repaired by placement of 2 OTSC clips and esophageal stent

Eric Then, MD et al, St. Barnabas Hospital, Bronx, NY, presented a case of Boerhaave’s Syndrome successfully repaired by using 2 OTSC clips and placement of an esophageal stent. Patient is a 65-year-old male with a

medical history of chronic obstructive pulmonary disease who presented the emergency department with chest pain, shortness of breath and productive cough after an episode of retching 2 days prior. Notable workup in the emergency department included a chest x-ray which showed left lower lobe pneumonia, pneumothorax, and a left pleural effusion. A chest tube was then placed and a computed tomography angiography of the chest was also done. This showed pneumomediastinum with air around the mid to distal esophagus. A barium esophagram was subsequently done which showed contrast leak at the distal esophagus. An upper endoscopy was then performed and showed a large linear perforation near the gastroesophageal junction. This was closed with 2 OTSC clips in addition to placement of an overlapping partially covered stent. In order to ensure complete closure an esophagram was done with radioisotope. This showed complete closure of the perforation, with no evidence of leakage of the radiotracer. After the procedure the patient was able to tolerate oral feedings with no clinical sequelae. During his hospital stay the patient completed treatment with antibiotics, his chest tube was successfully removed and he was subsequently discharged home. Surgical repair is currently the treatment of choice in BS. Present day, endoscopic measures are challenging this consensus. More recently cases of BS have been successfully treated with the use of endoscopic suturing with esophageal stent placement. Our case was successfully treated by using 2 OTSC and placement of an esophageal stent.

Successful Endoscopic Repair of Boerhaave's Syndrome: Changing the Narrative

Eric O. Then, MD¹, Michell Lopez, MD¹, Andrew Ofosu, MD², Vijay Gayam, MD³, Vijay S. Are, MD⁴, Vinaya Gaduputi, MD, FAGC⁵

¹St. Barnabas Hospital, Bronx, NY; ²Brooklyn Hospital Center, Brooklyn, NY; ³Interfaith Medical Center, Brooklyn, NY; ⁴Stormont Vail Health System, Topeka, KS; ⁵SBH Health System, Bronx, NY

Staple-Line Leak Following Sleeve Gastrectomy successfully closed with OTSC

Augustine Tawadros, MD et al, Robert Wood Johnson Medical School, Rutgers University, New Brunswick, NJ, presented a case of endoscopic management with an OTSC for a staple-line leak following gastrectomy. A 38-year-old woman, with limited past medical history, presented 6 weeks after SG with a staple-line leak. Her immediate post-op period had been complicated by a peri-splenic abscess, which was managed with IV antibiotics (ABX) and percutaneous drainage (PD). Upper GI series (UGIS) at this time did not reveal a SLL. After clinical and radiographic resolution, the drain was removed. Several days later, the patient presented with nausea, vomiting, and non-bloody watery diarrhea. She was found to be febrile and tachycardic; labs, including a test for Clostridium difficile, were negative. A repeat CT scan confirmed an upper abdominal fluid collection. Subsequent UGIS revealed a SLL in the proximal stomach with a suture line fistula. After several weeks of NPO status, ABX and PD failed to lead to leak closure, the patient underwent endoscopy with successful placement of an gastric OTSC clip. Repeat UGIS confirmed fistula closure. After several weeks of additional conservative management, the PD was removed. Several months later, the patient remains stable.

Endoscopic Management With an Over-the-Scope Gastric Clip of a Staple-Line Leak Following Sleeve Gastrectomy

Augustine Tawadros, MD¹, Kevin Skole, MD², Wai Y. Chau, MD³

¹Robert Wood Johnson Medical School, Rutgers University, New Brunswick, NJ; ²University Medical Center of Princeton at Plainsboro, Plainsboro Township, NJ; ³University Medical Center of Princeton at Plainsboro, Plainsboro, NJ

Successful closure of Boerhaave with use of OTSC alone

Muaataz Azawi, MD et al, Elmherst Medical Center, Astoria, NY, reported a case of a 57-year-old male who presented with trauma in setting of alcohol intoxication. In the ED patient was found to have a left hemopneumothorax found in CT scan. The patient was admitted for lactatemia and chest tube management. Afterwards patient developed sepsis due to empyema which prompted him to undergo for VATs procedure. Patient remained septic and CT with contrast revealed an esophageal leak and Boerhaave's syndrome was suspected. GI was consulted and patient underwent EGD. A 8 mm perforation was found in the left latero-posterior portion of the esophagus consistent with Boerhaave syndrome. To repair the defect, the tissue edges were approximated using suction and one 11 mm OTSC was successfully placed (Bear claw). Thereafter patient underwent g-tube and j-tube placement. Next, the patient was discharged home and was seen in the clinic, where the g-tube and j-tube was removed.

The current management of BS includes conservative, endoscopic, and surgical treatments. The survival rates for each treatment are 75 %, 100 %, and 81 %, respectively. The estimated mortality rate of patients with BS is 20 % – 40 %. Endoscopy can be utilized to confirm the diagnosis of BS, particularly in equivocal cases.

Endoscopic treatment with stenting can be effective and less invasive. In a systematic review that, endoscopic stenting had a success rate of 81 % but endoscopic intervention was required in 17 % and surgical reintervention in 10 % patients. More recently, the use of OTSC has been reported in treatment of boerhaave's alone or in combination with local therapies or esophageal stent. These endoscopic interventions are typically performed within several days of the perforation. Here we report successful closure of boerhaave with use of OTSC alone after 14 days from perforation.

Boerhaave's Syndrome Was Treated With Over-the-Scope Clip OTSC Closure (Bear Claw Closure): A Rare Case Report

Muaataz Azawi, MD¹, Soohwan Chun, MD², Raghav Bansal, MD³

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Gastric perforation by foreign body successfully managed by removal of foreign body with endoscopic forceps and perforation closure with OTSC

Andy Tien, MD et al, Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA, presented a case of non-surgical endoscopic management of a sealed nail perforation in the gastric antrum. A 48-year-old homeless male with a history of multiple abdominal surgeries due to gunshots and stab wounds complicated by abdominal hernias presented with 1 week of abdominal pain after drinking an open bottle of soda. Vital signs were stable on presentation. Labs were unremarkable. Computed tomography (CT) revealed a needle-like foreign body in the antrum of the stomach that appeared to project beyond the lumen without signs of pneumoperitoneum free perforation or fluid. An upper endoscopy was performed to further characterize the foreign body. Upon entering the stomach, a 2 mm round metallic circular object was visualized along the lesser curvature of the antrum, suggestive of a nail embedded into the gastric antrum. General surgery was consulted given concern for perforation, however, the patient was deemed a high-risk surgical candidate due to hostile abdominal scarring. The decision was made for endoscopic repair of the nail perforation. On repeat endoscopy, the nail was again visualized in the lesser curve of the antrum; rat-tooth forceps were used to remove a 2.8 cm rusty nail which was safely pulled through an overtube. The scope was reinserted with an OTSC attached, which was then successfully deployed at the site of perforation. Patient tolerated the procedure well with no signs of peritonitis and follow-up CT four days post-procedure showed the clip in place. There are limited cases in the literature of endoscopic intervention in a sealed nail perforation in the stomach in an adult. We found that an OTSC clip was effective in sealing a small perforation without evidence of peritonitis on follow-up examinations. Coordination with the surgical service is important in endoscopic repair of perforations. Overall, endoscopic removal of a sealed nail perforation is a viable option for high-risk patients.

Non-Surgical Endoscopic Management of a Sealed Nail Perforation in the Gastric Antrum

Andy Tien, MD, MS, Elizabeth Dong, MD, Marianne Fahmy, MD

Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA

Successful endoscopic closure of pyelo-duodenal fistula using the OTSC System

Erica Duh, MD et al, University of California Irvine Medical Center, Orange, CA, presented a case of successful endoscopic closure of a pyelo-duodenal fistula using the OTSC System. A 62-year-old female presented with sharp, severe abdominal pain. She denied back pain, hematuria, fever, and dysuria. She had no significant past medical history and did not take any medications. CT abdomen and pelvis demonstrated a large right-sided staghorn calculus extending into the renal pelvis. The patient underwent percutaneous nephrolithotomy, which was complicated by perforation of the renal pelvis and abdominal compartment syndrome. Subsequently, a proximal ureteral stricture was refractory to stenting and balloon dilation. CT urography demonstrated a PDF. After placement of a metallic ureteral stent and nephrostomy tube, a nephrostogram was negative for extravasation, so the patient underwent EGD to evaluate for the resolution of the PDF. During the procedure, iohexol contrast and methylene blue were inserted via nephrostomy tube, and fluoroscopic imaging showed contrast in the right kidney and bladder without extravasation. However, on endoscopy, methylene blue extravasation led to identification of two mucosal defects in the anterior duodenal sweep. The larger defect was closed using the helix tissue retractor and OTSC System (12/6 t-type). The smaller defect was closed with 2 hemostasis clips. Follow-up

renal scan and CT imaging showed no evidence of contrast extravasation. The OTSC is an innovative endoscopic technique most often used for hemostasis and for treatment of endoscopic or surgical complications (e.g., fistula, leakage, or perforation). Most reports document successful OTSC use for fistula closure including gastrocutaneous and esophageal fistulas. Our case is, to our knowledge, the second ever documented PDF closure using the OTSC System.

Successful Endoscopic Closure of a Pyeloduodenal Fistula Using the Over-the-Scope Clip System

Erica Duh, MD¹, Meredith Clary, MD², Jason Samarasena, MD, FACG¹, Ralph Clayman, MD³, Kenneth J. Chang, MD, FACG²

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Duodeno-pleural fistula secondary to transarterial chemoembolization successfully treated with OTSC

Peter Natov, BSc et al, Center and Tufts University School of Medicine, Boston, MA presented a case of endoscopic closure of a duodeno-pleural fistula secondary to transarterial chemoembolization, A 49-year-old woman with a history of chronic hepatitis B cirrhosis and HCC presented to the emergency room with right-sided chest pain. She was diagnosed with HCC 16 years ago in China and underwent partial hepatectomy and chemotherapy. Two years prior to current presentation, MRI demonstrated a 2.0 x 2.7 x 3.3 cm liver lesion consistent with recurrent HCC. TACE was performed. She subsequently reported abdominal pain. Endoscopy discovered a duodenal ulcer, and imaging noted a developing phlegmon and free air. Management with bowel rest and parenteral nutrition led to clinical improvement without the need for surgery. On this presentation, she described new onset pleuritic chest pain and dyspnea. Imaging revealed a large loculated right pleural effusion with gas foci and visible extraluminal enteric contrast surrounding the duodenal bulb, suggestive of an empyema secondary to a duodeno-pleural fistula. Pleural fluid analysis showed a pH < 6.8, high amylase and lipase levels, and cultures of multiple enteric organisms. Fistula closure was attempted endoscopically. A 4 mm opening was found in the duodenal bulb. The mucosa was denuded with argon beam plasma coagulation and an 11/6t OTSC successfully closed the defect. Extravasated contrast was not seen on imaging two days later.

Endoscopic Closure of a Duodeno-Pleural Fistula Secondary to Transarterial Chemoembolization

Peter S. Natov, BSc¹, Sukeerti Kesar, MD², Robert F. Yacavone, MD³

¹Tufts Medical Center and Tufts University School of Medicine, Boston, MA; ²Tufts Medical Center, Boston, MA; ³Tufts University Medical Center, Boston, MA

Gastro-colo-cutaneous fistula with OTSC closed with hemoclips and OTSC

Hassaan Zia, MD et al, University of Oklahoma Health Sciences Center, Oklahoma City, OK, presented a case of endoscopic closure of a gastro-colo-cutaneous fistula with an OTSC System. A 55-year-old male with Stage IV gastroesophageal junction neuroendocrine carcinoma with ongoing chemoradiotherapy had a PEG tube placed for dysphagia. There were no post procedural complications. Two months post procedure, patient presented with pancytopenia and a two-week history of persistent diarrhea, malodorous peristomal drainage and weight loss. Computerized tomography (CT) imaging with intravenous (IV) contrast confirmed the presence of a gastro-colo-cutaneous fistula with internal bolster located in the transverse colon. Due to immunocompromised status, endoscopic closure was pursued with a colonoscopy and esophagogastroduodenoscopy (EGD). A pediatric colonoscope with distal cap attachment was used, an internal bolster with colo-cutaneous fistula with no cologastric fistula was seen. The site was tattooed with 6 mL of spot (carbon black). The gastrostomy tube was removed, and three hemostatic clips were used for closure. No air leak was noted over the exterior abdominal wall. This was followed by EGD, the residual gastrocolic fistula was closed by a OTSC 10/3t. A CT scan with oral contrast demonstrated no residual leak/fistula. Total parenteral nutrition (TPN) was initiated. Patient continued to do well, and post-procedural hospital stay was uneventful.

Endoscopic Closure of GastroColoCutaneous Fistula: A Rare Complication of Percutaneous Endoscopic Gastrostomy Tube Placement

Hassaan Zia, MD, Maham Hayat, MD, Ralph Guild, MD

University of Oklahoma Health Sciences Center, Oklahoma City, OK

Two patients, in which the OTSC System was successfully used as salvage therapy for refractory NVUGIB after failed conventional management

Shivantha Amarnath, MD et al, Staten Island University Hospital, Northwell Health, Staten Island, NY, presented a case series of OTSC as salvage therapy after failed conventional management.

85-year-old female with Pulmonary Hypertension and Atrial Fibrillation was admitted for hypovolemic shock from hematemesis. Endoscopy revealed a large posterior duodenal bulb ulcer with adherent clot for which epinephrine injection was used. The ulcer's size and location prompted angiography and coil embolization of the gastroduodenal artery (GDA). Patient was in hypovolemic shock again due to a massive bleed. She was high risk for surgical intervention due to pulmonary hypertension, and repeat endoscopy was performed for hemostasis. An 11/6t-type OTSC clip was successfully deployed at a large vessel oozing blood, after removal of a large adherent clot by snare. No further intervention was needed afterward. 76-year-old male with extensive cardiac history was admitted with burns and inhalation injury from a house fire, requiring tracheostomy and gastrostomy placement. During hospitalization, patient had multiple episodes of melena and required blood transfusion. Endoscopy revealed two large anterior and posterior duodenal bulb ulcers, with a visible vessel, managed by electrocautery. Due to persistent bleeding, he underwent coil embolization of the GDA. Two days later, patient had recurrent bleeding. Repeat endoscopy with OTSC was used for successful hemostasis of a large visible vessel in the posterior duodenal bulb. Traditional endoscopic management carries a 20 % rebleeding risk and successful secondary hemostasis drops from 90 % to 75 %. Anatomic variation in blood supply to the duodenal bulb, either from branches of celiac axis or superior mesenteric artery may be the reason why our patients failed angiographic coil embolization of the GDA. To our knowledge, we report the first two cases where OTSC was used for successful salvage of NVUGIH that failed initial endoscopic and angiographic interventions.

Over-the-Scope Clip as Salvage Therapy for Refractory Non-Variceal Upper Gastrointestinal Hemorrhage After Failed Conventional Management: A Case Series
 Shivantha Amarnath, MD, BSc (Hons) Biology, MRSB¹, Jobin Philipose, MD², Jeffrey Abergel, MD¹, Hafiz Khan, MD²
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FTRD® System

Successful R0 resection of difficult adenomas, subepithelial lesions and early carcinomas located in the upper and lower GI tract by EFTR with the FTRD System

Esophagus dilation was performed to enable insertion of colonic FTRD in the stomach for resection of suspected GIST

Meir Mizrahi, MD et al, University of South Alabama College of Medicine, Mobile, AL, presented a case of endoscopic full-thickness resection (EFTR) of stomach lesion using colonic FTRD using a novel technique for upper esophagus dilation to assist in the insertion of colonic FTRD through the mouth. A 49-year-old female was referred for endoscopic resection of submucosal lesion suspected for gastric stromal tumor (GIST) prior to bariatric gastric bypass surgery. EGD revealed the lesion in the gastric body. Endoscopic ultrasound (EUS) confirmed it as well demarcated hypoechoic lesion measuring 0.8 cm x 0.8 cm arising from the intersection of submucosal layer and muscularis layer without adjacent lymphadenopathy. FTRD under general anesthesia was planned. EFTR technique: To assist the insertion of colonic FTRD, upper esophagus was dilated with savory dilator size 51 French for 1 minute, then with 55 French for 1 minute and then with 60 French for 5 minutes. Pediatric colonoscope installed with FTRD was gently advanced into the stomach lumen. Circumferential marking of the lesion was done using FTRD marking probe. Favorable positioning was achieved. FTRD grasper was used to grasp and mobilize the tissue into the cap. Clip was applied and snare was hooked to high frequency generator performing high frequency snare resection. Endoscope was removed along with resection specimen. Histopathology revealed fibrotic nodule with complete resection (R0). Endoscopy at 3-month revealed no recurrence.

Overcoming the Challenge of Full Thickness Resection of Gastric Lesions Using Colonic Full Thickness Resection Device (FTRD): Novel Technique
 Yazan Fahmawi, MD¹, Manoj Kumar, MD¹, Meir Mizrahi, MD²
¹University of South Alabama, Mobile, AL; ²University of South Alabama College of Medicine, Spanish Fort, AL

Meta-analysis including 480 patients with FTRD treatment demonstrates pooled R0 resection rate of 81.12 % and technical success rate of 90.39 %

Meir Mizrahi, MD et al, University of South Alabama College of Medicine, Mobile, AL, presented a meta-analysis findings from a study conducted to confirm efficacy and safety of the FTRD System. A comprehensive literature review was performed. Studies with < 5 cases were excluded. Rates of histologic complete resection (R0), technical success, and complications were extracted. Pooled estimates and the 95 % CI were calculated depending on heterogeneity. Heterogeneity was assessed using I2 statistics. Nine studies (5 retrospective and 4 prospective) including 480 patients with 489 lesions were included. Indications were difficult adenomas (355), early carcinoma (82), and subepithelial lesions (SEL) (47). Locations of the lesions: stomach (5), duodenum (20), proximal colon (220), distal colon (98), and rectum (141). 57 % of patients were male with median of age 66.5 years (range 20 - 92). Mean size of the lesions was 15.36 mm (range 1 - 40). Median procedure time was 46.56 minutes (range 3 - 190). Mean hospital stay was 3.23 days (range 0 - 11). Pooled overall R0 resection rate and technical success rate were 81.12 % (95 % CI: 77.63 - 84.6; I 56.7 %) and 90.39 % (95 % CI: 87.76 - 93.00; I 10.2 %), respectively. The pooled R0 resection rate was 81.59 % (95 % CI: 76.96 - 85.63) for difficult adenomas, 83.47 % (95 % CI: 73.19 - 91.00) for early carcinomas, and 81.59 % (95 % CI: 68.25 - 91.05) for SELs. For locations, R0 resection rate were 78.42 % (95 % CI: 72.17 - 85.50), 76.97 % (95 % CI: 62.56 - 87.88), and 80.59 % (95 % CI: 67.56 - 90.09) for proximal, distal colon, and rectum, respectively. The complications were as follows: minor bleeding 2.89 (95 % CI: 1.60 - 4.76), major bleeding 0.88 (95 % CI: 0.26 - 2.15), perforation 2.23 % (95 % CI: 1.12 - 3.95), postpolypectomy syndrome 1.26 % (95 % CI: 0.48 - 2.68), local trauma 0.9 % (95 % CI: 0.27 - 2.19), and other complications 1.91 % (95 % CI: 0.90 - 3.54). Of 50 patients with peri-appendicular lesion, the rate of appendicitis was 14.29 % (95 % CI: 6.38 - 26.23). The rate of complications that required surgery was 1.55 (95 % CI: 0.66 - 3.06). No procedural death related was found. There was no correlation between mean lesion's size and complications rates.

Efficacy and Safety of Endoscopic Full-Thickness Resection Device (FTRD) for Gastrointestinal Lesions Full-Thickness Resection: A Meta-Analysis Study

Yazan Fahmawi, MD¹, Manoj Kumar, MD¹, Gilad Shapira, MD², Nicholas Ludvik, MD², Meir Mizrahi, MD³

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Single Center Experience with FTRD System shows difficulties in endoscope advance / suction of fibrotic lesions, but high R0 resection rate

Meir Mizrahi, MD et al, University of South Alabama College of Medicine, Mobile, AL, presented data from a retrospective case series of 17 patients who underwent EFTR with FTRD their institution. Complete resection (R0), technical success, and clinical outcomes were reviewed. The indications for EFTR were recurrent/residual adenoma (12 cases), primary non-lifting adenoma (2 cases), submucosal lesions resection (2 cases), and early carcinoma (1 case). Eleven patients were males and six were females. The median age was 60 years (range 32 - 84). Locations of the lesions were: (3) in the cecum, (8) in the ascending colon, (2) in the transverse colon, (2) in the hepatic flexure, (1) in the rectum, and (1) in the stomach. Technical success rate was 13/17 (76 %). Three of the unsuccessful attempts were due to inability to advance the endoscope to the cecum in one case and inability to pull up fibrotic lesions in the other two cases. The fourth unsuccessful case was due to device malfunction as the lesion was snared but the clip was not deployed. The mean maximum diameter of lesions after resection was 18.3 mm (range 13 - 22). R0 resection rate was 14/14 (100 %). Microscopic full-thickness resection was achieved in 43 % (6/14). The median procedure time was 67 minutes (range 31 - 140).

Endoscopic Full-Thickness Resection of Gastrointestinal Lesions With the Over-The-Scope Device: A Single Center Experience

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Successful R0 resection of residual sigmoid carcinoid tumor by FTRD

Pratik Patel, MD et al, East Carolina University - Vidant Medical Center, Greenville, North Carolina presented a technically and histologically successful full-thickness resection (FTR) of a sigmoid goblet cell carcinoid tumor. A 61-year-old male presents for screening colonoscopy and was found to have an 8 mm submucosal mass in the distal sigmoid. Pathology of biopsies showed hyperplastic colonic mucosa with marked reparative stromal and epithelial changes and mixed features of prolapse. He was referred for EUS of the submucosal lesion,

which revealed hypoechoic submucosal lesion in distal sigmoid measuring 7.4 x 4.7 mm. FNA was attempted but unsuccessful as the mass was small and mobile. Therefore, decision was made to perform endoscopic mucosal resection (EMR). Pathology on EMR of sigmoid lesion revealed goblet cell carcinoma. Deep and lateral margins were positive. Chromogranin A level was mildly elevated. He was referred to surgical oncology who recommended 3-month surveillance colonoscopy given low Ki index. CT Scan of Abdomen and Pelvis as well as Octreotide scan were both negative for distant metastases. At 3-month follow up colonoscopy, the decision was made to use Full-Thickness-Resection-Device (FTRD) of the sigmoid lesion given positive margins. Pathology of FTRD was consistent with neural sheath tumor and deep and lateral margins were negative. Repeat colonoscopy revealed well healed scar at site of FTRD and cold biopsies around the scar were benign. He will follow up in 3 years for repeat colonoscopy.

Full-Thickness-Resection-Device for the Removal of a Submucosal Sigmoid Carcinoid Tumor

Pratik Patel, MD¹, Ethan Phan, MD¹, Narasimha Swamy Gollol Raju, MD¹, Prashant Mudireddy, MD²
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Successful R0 resection of duodenal neuroendocrine tumor using the FTRD Device

Andrew Groff, BS et al, Penn State University Milton S. Hershey Medical Center, Hershey, PA, presented a successful R0 resection of a T2, grade 2 neuroendocrine tumor using the FTRD. A 68-year-old-male with history of Barrett’s esophagus was found to have a low-grade neuroendocrine tumor of the duodenal bulb on surveillance upper endoscopic screening. Computed tomography (CT) imaging of the abdomen revealed a hypervascular duodenal bulb mass, without obvious extension to the wall, lymphadenopathy, or evidence of metastasis. Endoscopic ultrasound (EUS) with fine needle aspiration (FNA), revealed a 1.2 cm mass arising from the submucosal layer with pathology indicating a low-grade neuroendocrine tumor. Due to the small tumor size, EFTR by FTRD was planned. Upon advancing the endoscope with the FTRD System attached, a non-bleeding neuroendocrine tumor was visualized. The mass was carefully pulled into the cap and after banding, ligation and cutting; there was a full-thickness en-bloc resection with all layers of the duodenum apparent. Pathology of the specimen documented a grade 2 neuroendocrine tumor with clean margins, confirming R0 resection. The patient was discharged the same day without associated complications. The FTRD System offers a novel endoscopic treatment approach to tumors extending beyond the submucosa that require full-thickness resection and would otherwise require higher risk surgical intervention. The technology allows for safe tissue closure, valid histologic evaluation of the en-bloc specimen, and minimal thermal injury, thus reducing the morbidity and cost otherwise associated with surgery.

A Minimally Invasive Approach to Resection of a Duodenal Neuroendocrine Tumor Using the Full-Thickness-Resection-Device

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Successful full-thickness resection of a recurrent colonic adenoma using the FTRD

Pradeep Yarra, MD et al, University of Kentucky, Lexington, KY presented a case of complete adenoma resection using the FTRD System. A 66-year-old male with a past medical history of CAD s/p CABG, hypertension, hyperlipidemia, liver cirrhosis and diabetes mellitus presented for surveillance colonoscopy. Three months prior to this he had a piece meal EMR of a 22 mm flat Tubulo-villous Adenoma in the proximal ascending colon. After this, a colonoscope was passed under direct vision. EFTR device was passed and when it reached the proximal ascending colon, the previously placed tattoo was seen. A postpolypectomy scar was found between the tattoos. This was a non-lifting lesion and was granular lateral spreading and 22 mm in size. Thermal marking was placed and the FTRD clip was now passed. FTRD clip was deployed and using a snare within cap technique a full-thickness resection of 22 mm was performed.

EFTR as a Means for Complete Resection for Adenomas

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Meta-analysis including 559 patients with colorectal lesions resected by EFTR shows R0-resection rate of 81 % and overall combined rate of any complication of 9.2 %

Chandra S. Dasari, MD et al, Kansas City VA Medical Center, Kansas City, KS presented findings from their FTRD meta-analysis. An electronic database search was conducted in PubMed/MEDLINE, Embase, Google Scholar and Cochrane databases to identify studies that used EFTR for colorectal lesions using the Full-Thickness-Resection-Device (FTRD). The primary outcome was the rate of technical success and R0 resection. Secondary outcomes included complications (bleeding, perforation and post polypectomy syndrome) and the total procedure time. Pooled rates were reported with 95 % Confidence Interval (CI) with heterogeneity (I²). We used a random effects model to calculate pooled rates and used the I-square statistic to quantify heterogeneity. A total of 7 studies were included in the final analysis - 559 patients with 563 lesions removed using FTRD; mean age 67 years, males 59.3 % and mean lesion size of 15.7 mm. Mean follow up of the studies was 4.0 months. The colorectal lesions resected by EFTR included: 32 % cancers, 0.01 % neuroendocrine tumors and 67 % adenomas. The pooled overall technical success was 91 % (95 % CI 88 % - 93 %, I² = 0 %) with a R0 resection rate of 81 % (95 % CI 74 % - 86 %, I² = 62 %). The pooled rates of immediate bleeding, perforation, and post polypectomy syndrome were 5 %, 3 % and 2 % respectively. The overall combined rate of any complication (bleeding, perforation and post polypectomy syndrome) was 9.2 % (6.1 % - 13.5 %). The mean total procedure time was 47.76 min (95 % CI 40 - 55, I² = 84 %). EFTR using FTRD System appears to be an effective and safe technique for the resection of non-lifting colorectal lesions, with a > 90 % technical success rate, R0 resection rate of > 80 % and an overall complication rate of < 10 %.

Efficacy and Safety of Endoscopic Full-Thickness Resection (EFTR) of Colorectal Neoplasms Using the Full-Thickness-Resection-Device (FTRD): A Systematic Review and Pooled Analysis

Chandra S. Dasari, MD¹, Venkat Nutalapati, MD¹, Abhiram Duvvuri, MD², Viveksandeep Thoguluva Chandrasekar, MD³, Afeerah Malik³, Divyanshoo Kohli, MD³, Prateek Sharma, MD, FACP⁴

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BougieCap

The BougieCap allows for direct visual control and optical feedback during bougienage procedures

Patient with prolonged history of esophageal stricture and complicated treatment experienced significant improvement of symptoms and no complications with BougieCap treatment

George Triadafilopoulos, MD, FACP et al, Stanford University School of Medicine, Mountain View, CA presented a case successful esophageal stricture dilation using the BougieCap. A 62-year-old male presented with dysphagia. He had a prior history of peptic stricture at the gastroesophageal junction, treated with multiple balloon dilations that was complicated by an esophageal perforation. Patient underwent an emergent thoracotomy, esophagectomy, and gastric pull-up with placement of a feeding jejunostomy. Four months after surgery, he noted recurrence of dysphagia, with food getting lodged in the area below his throat and upper chest. Barium swallow revealed a tight stricture at the anastomosis that narrowed the lumen down to 5 mm in size. Upper endoscopy confirmed a stricture located 18 cm from the incisors. Using an endoscopic BougieCap the stricture was dilated serially from 7 to 12 mm in size with good results. Expected mucosal disruption was identified at the end of the procedure. On follow up, patient reported significant improvement in his symptoms without any complications. Use of Savary-Gilliard Dilators for stricture dilation provides only haptic control and often requires the use of fluoroscopic guidance. Our case highlights the use of a novel device - the BougieCap - for treatment of esophageal strictures which allows for direct visual control and optical feedback during the procedure. Ability to visualize the tension on the tissue while passing the stricture with the cap avoids overstretching and may help reduce the risk of complications, allowing for a more effective procedure. Moreover, by eliminating the need to switch instruments, the use of BougieCap can reduce procedure times.

The Bougie Cap: A Novel Device for Treatment of Esophageal Strictures

Hannah Ramrakhiani, George Triadafilopoulos, MD, FACP



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