Conference Report

Digestive Disease Week – DDW 2021

May 21 – 23, 2021
Virtual Event

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

stentfix OTSC® System

Preventing migration of FCSEMS: stentfix OTSC shows advantages in comparison to no fixation and endoscopic suturing

D. Lew, et. al., Cedars-Sinai Medical Center, Los Angeles, California, US, presented findings from a retrospective cohort study conducted between January 2013 to October 2020 including 199 patients with FCSEMS placement in the GI tract. Multiple patients who required repeat procedures for stent adjustment and/or fixation, were counted as a separate event. The study included 438 procedures which were performed respectively in 60% (264) without fixation, 34% (150) with suturing, and 5% (23) with the recently available stentfix OTSC. Indications for stent placement included 44% benign stricture, 35% fistula/perforation, and 20% malignant stricture. Most stents (53%) were placed in the esophagus. In the stent migration rates at all weeks assessed, there was not a significant difference between stentfix OTSC and suturing ($p>0.05$). Better results regarding the migration rate was achieved when comparing both stentfix OTSC and suturing to no fixation up to 8 weeks ($p=0.02$). Beyond 8 weeks, there were no significant differences in all groups ($p>0.05$). Median time to stent migration for no fixation was 3 weeks compared to 5 weeks with stentfix OTSC and suturing ($p=0.005$).
Clinical success rate for the cohort occurred in 61% of the patients (n=121). The total median procedure time for a fixation with stentfix OTSC was, with a difference of 24 min, significantly shorter than suturing (44 vs 68 minutes, $p=0.002$). Rates of adverse events, including chest/abdominal pain and nausea/vomiting, were not significantly different but trended towards being lowest in the stentfix OTSC group at 9%, compared to 21% with no fixation, and 18% with suturing ($p>0.05$). No perforations occurred.
The authors found that stentfix OTSC and endoscopic suturing seem to be equally effective in preventing stent migration when compared to no fixation. However, stentfix OTSC showed advantages by a decreased overall procedure time, less adverse events, and especially lower costs. Therefore, it may be preferred over endoscopic suturing. Anyway, further studies with larger sample size are needed.

Comparison of no stent fixation, full-thickness endoscopic suturing, and over-the-scope-clip (OTSC) in preventing migration of fully covered self expanding metal stents (FCSEMS)
Lew D[1], Patel S[1], Liu Q[1], Gaddam S[1], Gupta K[1], Jamil LH[2], Lo SK[1], Park KH[1]
[1]Los Angeles, [2]Royal Oak

How to prevent migration of esophageal stents: efficacy and safety of endoscopic fixation with suturing, stentfix OTSC and hemostatic clips

M. Coronel, et. al., The University of Texas MD Anderson Cancer Center, Houston, Texas, US, presented a single-center retrospective study reviewing patients who underwent esophageal FCSEMS with endoscopic stent fixation (ESF), performed from 9/1/2017 to 9/1/2020. A patient cohort was identified (n=21) and matched (1:1 ratio) with a retrospective, consecutive patient cohort who underwent esophageal FCSEMS placement without ESF (n=21). The primary outcome was to identify early (<30 days) or late (>30 days) stent migration rates in these two groups.

In the ESF group, endoscopic suturing was used in 67% (14) of the patients, stentfix OTSC in 23% (5), and hemostatic clips in 10% (2). The FCSEMS with ESF group showed no early stent migration and delayed migration in 3 patients (14%). These 3 patients had successful stent removal and in 1 patient another stent was placed with endoscopic suturing. The FCSEMS without ESF group showed early migration in 1 patient and delayed migration in 6 patients (33%) (p=0.14). In 2 patients the stents could not be removed as they were noted to be impacted in the stomach.
While not statistically significant, migration rates were lower in the ESF group without causing additional complications when compared to the FCSEMS alone group. The authors concluded that endoscopic stent fixation appears to be safe and effective.

Efficacy and safety of endoscopic fixation to prevent migration of esophageal stents. A tertiary care center experience.

Coronel M[1], Ge PS[1], Kumar S[1], Lum P[1], Weston BR[1], Ross WA[1], Raju GS[1], Lee J[1], Coronel E[1]
[1]Houston

FTRD® System

Exploring the role of full-thickness resection with FTRD System in the management and staging of patients with suspected T1 colorectal carcinoma

A. Vareedayah, et. al, NYU Langone Health, New York, New York, USA, report on a single center retrospective study with prospectively collected data from patients who underwent FTR for colorectal lesions, focusing on those with histological evidence of carcinoma.
Of a total of 64 patients, a subgroup of 12 patients (50 % male) with a mean age of 71, showed suspected malignancy in the biopsies taken. 9 underwent FTR alone and 3 as part of a hybrid approach for large, laterally spreading lesions with a combination of EMR followed by FTR (mean lesion size was 23 mm). 3 patients had known carcinoma prior to resection. Primary outcomes of this study were: technical success and clinical success (defined as macroscopically complete resection). Technical success was achieved in 9/12 cases; 2 failures were due to malfunction of the snare and could be resolved by resection of the lesion above the inserted clip with a separate snare. One case was inadvertent snare excision prior to clip deployment with post resection perforation closed by subsequent clip release. Clinical success was achieved in 100% of cases; R0 resection in 11 of 12 patients (1 patient showed invasion into the muscularis propria with a positive vertical margin). Of 4 patients who underwent further surgery, surgical pathology revealed one T1 stage with lymphatic invasion, two T2 and one T3 stages. On the second postoperative day after resection of a T1 adenocarcinoma at the appendiceal orifice, one patient presented to the emergency department with nausea, vomiting and abdominal pain. CT showed peri-appendiceal inflammatory change that was resolved with IV antibiotics. No other adverse events were reported in this subgroup of patients. The authors conclude that these data suggest that FTR is technically feasible, effective, and safe for the removal of early-stage, low-risk colorectal cancer. No residual tumor was found in any of the patients who underwent surgery. Further studies and longer follow-up are needed to clarify the recurrence rates and long-term survival of these patients.

Final pathologic staging of patients with suspected T1 colorectal carcinoma with full thickness resection (FTR): A single center North American experience

Vareedayah AA[1], Yuen PYS[1], Ooka K[1], Morales SJ[1], Mahadev S[2], Haber GB[1]
[1]New York, [2]New York

An alternative to surgical resection: EFTR with FTRD System at an academic tertiary care cancer center setting

P. Ge, et. al, The University of Texas MD Anderson Cancer Center, Houston, US, Texas, presented on their initial clinical outcomes of EFTR at a major US-based academic cancer center. Demographics, procedural and technical characteristics, lesion characteristics, resection outcomes, and histopathologic diagnosis were recorded. Adverse events were recorded including perforation,

bleeding, pain/discomfort, intraluminal trauma during instrument insertion, and inadvertent injury to adjacent organs.
The EFTR was performed using the FTRD System for 3 gastric, 2 colonic, and 5 rectal lesions in a total of 10 patients (30 % female) with a mean age of 63.6 years. Indications included gastric neuroendocrine tumor (NET) (30 %), rectal NET (10 %), recurrent adenoma at EMR site (10 %), and prior polypectomy scars where the original pathology included adenocarcinoma or NET with positive margins (50 %). The gastroduodenal FTRD was utilized in all gastric cases and colonic FTRD was utilized in all colorectal cases. A 20 mm balloon was used to facilitate device passage through the upper esophageal sphincter in all 3 gastric cases and through the anal canal in 1 colorectal case. All 7 colorectal cases were notable for prior EMR scars and severe fibrosis. *En bloc* resection, R0 resection, and curative resection were achieved respectively in 100 %, 100 %, and 90 % cases. The lone non-curative resection was a rectal NET with negative resection margins but with lymphovascular invasion and perineural invasion on histopathology. Final pathology indicated NET in 4 patients, tubular adenoma in 1 patient, and clean polypectomy scar with no residual tumor in 5 patients. The mean specimen size was 26.5 mm (SD, 3.4 mm). Mean EFTR time was 9.9 min (SD, 6.6 min) and mean total procedure time was 51.4 min (SD, 16.0 min). Three minor adverse events were noted, including perineal pain, abdominal pain, and tenesmus, all of which were self-limited with spontaneous resolution within 1 day. No major adverse events occurred, and no patients required hospitalization. On short term follow-up (mean 1.7 months) no delayed adverse events could be noted.
The authors concluded that EFTR is an effective therapeutic option despite severe fibrosis and occupies a unique role in the endoscopic management of small fibrotic or subepithelial lesions which are otherwise unsuitable for conventional endoscopic resection techniques. Ongoing studies with long-term follow-up will seek to further validate these findings.

Exploring the role of endoscopic full thickness resection at an academic tertiary care cancer center setting

Ge PS[1], Coronel M[1], Tillman MM[1], Badgwell B[1], Bednarski BK[1], Chang GJ[1], Katz M[1], Rodriguez-Bigas MA[1], You YN[1], Halperin DM[1], Casanova DN[1], Weston BR[1], Bhutani MS[1], Lee J[1], Ross WA[1], Coronel E[1]
[1]Houston

EFTR of upper gastrointestinal lesions with colonic FTRD - A retrospective observational of a 13 cases series

J. Nilsson, et. al, University of Alberta, Edmonton, Alberta, Canada presented outcomes from a retrospective observational case series consisting of 13 cases of duodenal (4) and gastric (9) lesion resections with the colonic FTRD System. Indications for EFTR were sub-epithelial tumor (n=8), polyp (n=2) and scar-resection (n=3). The colonic FTRD could pass the upper esophageal sphincter or pylorus without dilatation and could be advanced to the lesion in 13/13 cases (100 %). One sub-epithelial lesion was too big for the cap and one scar could not be sucked into the cap. R0-resection rate for deployed clips was 10/11 (91 %). Technical success was achieved in 11/13 (85 %) of procedures. There were two superficial esophageal tears from FTRD insertion that required no therapy. No bleeding occurred in the postoperative period. This study further confirms acceptable efficacy and safety of EFTR in the upper GI use.

Endoscopic Full-Thickness Resection of upper gastrointestinal lesions using a colonic FTRD- A retrospective observational case series of 13 FTRD cases

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FTR in the UGIT: efficacy and safety of diagnostic FTRD and gastroduodenal FTRD

S. Yuen, et. al, NYU Langone Health, New York, New York, US, presented their retrospective single center, single endoscopist analysis of prospectively collected data on lesions resected with the FTRD Systems in the UGIT. The study included 6 patients (3 male) with a mean age of 67 years. Indications for FTR were gastric subepithelial tumors (4) or duodenal polyps (2). Three patients had endoscopic ultrasound prior to FTR. Mean lesion size was 15.6 mm in 5 patients and 40 mm in 1. Four patients had no prior attempts at removal and two were referred for FTR for polyp recurrence after prior (partly

multiple) polypectomy. For the 4 cm polyp recurrence a hybrid resection comprising EMR of the periphery and FTR of the central non-lifting component was used. Primary outcomes included technical success, clinical success, and R0 resection rate. Resections were performed using either the diagnostic FTRD or gastroduodenal FTRD, both with cap diameter of 19.5 mm and depth of 23mm. 5/6 patients underwent pre-dilation (Savary 20 mm dilator and/or 20 mm balloon) prior to passage of the FTRD through the upper esophageal sphincter. The FTRD comprising cap, snare and sheath was inserted and advanced to the resection site. Additional dilation of the pyloric channel was performed for duodenal access. A grasping forceps was used to gently pull the lesion into the cap, with adjuvant use of suction as required. The FTRD clip was then deployed, immediately followed by snare closure and electrosurgical excision of the entrapped tissue with a pure cut current. FTRD was advanced without difficulty after appropriate dilation or advancement over a balloon, and deployment was successfully performed. Clinical success, defined as macroscopically complete lesion resection, was achieved in 5/6 cases. In one antral leiomyoma, the deep margin was positive. Adverse events, including bleeding and perforation, did not occur. The authors concluded that FTR in the upper gastrointestinal tract was technically successful in 100 % of the cases. Pre-dilation and balloon assist are critical elements in successful deployment but were necessary as the major concern with this device was the large outer diameter with possible perforation or inability to pass the sphincters. UGIT FTR provides a simple, quick, and effective alternative for deep resection of subepithelial lesions and duodenal lesions notorious for complications of bleeding and perforation.

Efficacy and Safety of Full Thickness Resection (FTR) in the Upper Gastrointestinal Tract (UGIT): A Single Center North American Experience

Yuen PYS[1], Vareedayah AA[1], Morales SJ[1], Ooka K[1], Haber GB[1]
[1]New York

OTSC® System

Presentation of comparative data regarding OTSC vs standard therapy for the prevention of rebleeding in peptic ulcers

S. M. Chan, et. al, Chinese University of Hong Kong, Hong Kong, performed a multicenter randomized controlled trial from July 2017 till Oct 2020. Aim of the study was to compare the efficacy of the OTSC to standard endoscopic therapy in primary treatment of patients with peptic ulcer bleeding in peptic ulcers ≥ 1.5cm.

Inclusion criteria was a Forest Ia-IIb bleeding. The primary outcome was a clinical rebleeding within 30 days. 100 patients were enrolled and a crossover between the methods was allowed in case of failure. There were two cases of successful crossover from failed standard therapy to OTSC and four unsuccessful crossovers after failed OTSC placement to the standard treatment. The overall rebleeding within 30 days was calculated as 14 % (7/50) in the OTSC arm and 16 % in the standard arm. The all-cause mortality was 4% (2/50) with OTSC vs 8% (4/50) in the standard arm (p=0.68). None of the patients required surgical intervention.

The authors state that, for large ulcers ≥ 1.5cm, OTSC as primary hemostasis did not confer to an improvement in clinical outcomes in this study.

Several aspects of the study design remained unclear in the abstract presented such as the high percentage of patients (approx. 80 %) without active bleeding in the study population, also in reference to the primary endpoint being the re-bleeding rate at 30 days.

The Use of Over-the-scope-clip (OTSC) Versus Standard Therapy for the Prevention of Rebleeding in High Risk Peptic Ulcers: A Randomized Controlled Trial

Chan SM[1], Pittayanon R[2], Wang H[3], Chen J[4], Kuo Y[3], Teoh AY[1], Yip H[1], Tang RS[1], Ng S[1], Wong SH[1], Mak JW[1], Chan H[1], Lau L[1], Lui RN[1], Wong M[1], Rerknimitr R[2], Chiu PW[1], Ng EK[1]
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A Purely Endoscopic Management Approach for Type V Mirizzi Syndromes

S. Al Ghamdi, et. al, The Johns Hopkins Hospital, Baltimore, MD, present a case of a 94-year-old female who was transferred to their hospital with Type V Mirizzi Syndrome with many large stones in the cystic duct and gallbladder. In the first session stones were removed endoscopically.
Colonoscopy was performed one week later to evaluate the fistula. Several small gallstones were seen in the colon, along with a small fistula with intermittent extrusion of microvilli at the hepatic flexure. Contrast was injected into the defect, confirming the correct location of the CCF. The fistula tract was deepithelialized using argon plasma coagulation and a hemoclip was placed to mark the area. An OTSC clip (14/6 t) was successful deployed over the fistula and completely closed it, as later confirmed by a contrast injection. After the procedure, the patient's abdominal pain resolved completely. She returned five months later to undergo her final ERCP. Cholangioscopy revealed a residual stone at the CD takeoff that was successfully treated with EHL. An occlusion cholangiogram confirmed complete stone clearance.
This case demonstrates the use of ERCP and EHL for successful management of a large, impacted CD stone resulting in biliary obstruction and acute cholangitis. Endoscopic management of a concomitant CCF using an OTSC clip was also successful. This suggests the feasibility of a purely endoscopic management approach for Type V Mirizzi Syndrome.
A Purely Endoscopic Management Approach for Type V Mirizzi Syndromes
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Endoscopically Directed Single Port Intragastric Fundoplication, Sleeve, and Myotomy: A Preclinical Study

H. Hernandez-Lara, et. al, Mayo Clinic Rochester, Rochester, MN, presented a video demonstrating the safety and feasibility of various peroral endoscope directed stapling procedures using a novel percutaneous endoscopic trocar and a laparoscopic stapler in 2 domestic pigs. OTSC clips were used to close the trocar insertion and the intragastric port site with no adverse events. The authors concluded that single port, endoscopically directed intragastric procedures such as fundoplication, sleeve, and myotomy using laparoscopic staplers are now feasible.
Endoscopically Directed Single Port Intragastric Fundoplication, Sleeve, and Myotomy: A Preclinical Study
Hernandez-Lara H, Abu Dayyeh BK, Garcia Garcia de Paredes A, Rajan E, Storm AC.
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