

Report on the ESGE Days 2023

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ESGE President: **Professor Helmut Messmann**
 ESGE Days Scientific Committee Coordinator: **Professor Marianna Arvanitaki**

OTSC® System

Multicentric RCT shows higher efficacy of OTSC compared to TTS clip as first-line mechanical treatment in the specific setting of peptic ulcer bleeding

In the opening session with best abstracts (Plenary Session) Paola Soriani, Italy, presented the TOP study (“Higher efficacy of over-the-scope clips compared to through-the-scope clips for first-line endoscopic treatment of acute peptic ulcer bleeding”), which was awarded the 2019 ESGE research grant.

The international multicenter RCT study was conducted in five hospitals in Italy and Spain between October 2018 and October 2022. The aim of the head-to-head RCT was to compare OTSC vs TTSC as first-line mechanical treatment in the specific setting of peptic ulcer bleeding. The primary outcome was successful hemostasis (absence of bleeding upon at least one minute observation after the assigned endoscopic therapy). Secondary outcomes include 30-day bleeding, overall clinical success (combination of successful hemostasis and no evidence of 30-day rebleeding), need for blood transfusion and number of red blood cell units transfused, length of hospital stay and 30-day mortality.

In total, 251 patients with clinically suspected acute UGIB were screened. 112 patients with gastroduodenal peptic ulcer Forest Ia, Ib, Forest 2a or 2b were finally randomized to the OTSC (n=61) or TTSC (n=51) group. Between the two groups there were no meaningful differences in terms of demographic data, clinical data or lesion characteristics. OTSC showed significantly higher efficacy in achieving successful hemostasis than TTSC (98.4% (60/61) vs 78.4% (40/51); p=0.001). TTSC failure was related to fibrotic peptic ulcer (7/11), posterior duodenal wall location (3/11) and large-size visible bleeding vessel (1/11). When successful hemostasis was obtained, 30-day rebleeding occurred in 1.7% (1/60) and 5.0% (2/40) of OTSC- and TTSC-treated patients, respectively (p=0.562). Overall clinical success rate was 96.7% (59/61) in the OTSC group compared to 74.5% (38/51) in the TTSC group (p=0.0006). Relative risk (RR) analysis showed that treatment with OTSC has a 25% higher likelihood of obtaining successful hemostasis compared to TTSC (RR=1.25; 95%CI 1.08–1.45; p=0.003). The likelihood of achieving overall clinical success was significantly higher in the OTSC group as well (RR=1.30; 95%CI 1.10–1.53; p=0.002).

Soriani concluded that OTSC has a higher efficacy as first-line endoscopic treatment of acute peptic ulcer bleeding compared to TTSC, both in terms of technical and overall clinical success rates. The likelihood of achieving successful hemostasis is remarkably higher when using OTSC. The working group suggests that OTSC should acquire a central role as first-line mechanical endoscopic treatment option for peptic ulcer bleeding.

Soriani P, Gastroenterology and Digestive Endoscopy Unit, Azienda USL di Modena, Carpi, Italy. **Higher efficacy of over-the-scope clips compared to through-the-scope clips for first-line endoscopic treatment of acute peptic ulcer bleeding: results of an international, multi-center, randomized controlled trial.**

Prof. Götz recommends OTSC as part of the standard endoscopic toolbox and shows specific use cases of OTSC in the Postgraduate Course

Martin Götz, Germany, presented in his lecture "Endoscopic treatment: Needles, clips, powders" (Postgraduate Course, Session 2) the current tools for the treatment of non-variceal bleeding and recommended to have Ovesco's OTSC available in every Gastroenterologist's toolbox. According to him, OTSC should be used as first-line therapy in high-risk lesions and rebleeding.

Furthermore, Prof. Götz demonstrated in his presentation the benefit of using OTSC as first-line therapy for high-risk lesions in the duodenum (video case of large thrombus on an ulcer which is bleeding underneath) and showed the study data of STING and STING II. Another recommendation of Prof. Götz included the combination

of different techniques, e.g., in case of persistent Forrest Ia bleeding after use of OTSC; here he recommends either the use of another OTSC (positioning at 90° to the first clip) or to perform APC treatment in addition.

Götz M, Medical Clinic IV - Gastroenterology/Oncology, Böblingen Hospital, Böblingen, Germany. **Endoscopic treatment: Needles, clips, powders.**

Cohort study with 32 patients indicates that stentfix OTSC decreases migration rates and increases permanence time of FCMS in benign esophageal disease

A retrospective cohort study on the migration in fully covered metal stents (FCMS) was presented by D. Hernández Castillo. The aims of the study were (1) to compare the migration rates of FCMS against conventional endoclips (through-the-scope clips), and (2) to compare the FCMS permanence time between the groups and the technical success of application and removal of stentfix OTSC.

Between 2019 and 2022, 32 consecutive patients (median age 65 years) received FCMS therapy for the indication of benign esophageal disease. Overall, 40 FCMS were applied: 31 FCMS in the conventional endoclips group and 9 in the stentfix OTSC group. Main indication was stenosis (16/32; 50%) followed by perforation (9/32; 28.1%). The migration rate in the conventional endoclip group was higher than in the stentfix OTSC group (41.9% (13/31 stents) vs 22.2% (2/9); $p=0.494$ NS). Permanence time before removal or migration of FCMS was significantly longer in the stentfix group compared to the endoclips group (57 vs 24 days; $p=0.01$). In univariate analysis the fixation with conventional endoclips was the main variable for migration (HR 2.83 CI95% 0.105 - 1.19; $p=0.092$ NS), not confirmed in multivariate analysis. Stentfix OTSC application and removal was possible in all cases. There were no related complications.

The authors concluded that FCMS fixation with the stentfix OTSC System might decrease the migration rates and increase stent permanence time in benign esophageal disease. Application and removal of stentfix OTSC is safe. Randomized controlled trials with larger number of patients are required to confirm these results.

D. Hernández Castillo, Hospital General Universitario Gregorio Marañón, Madrid. **Usefulness of the OTSC Stentfix clip in preventing migration of fully covered metal stents in benign esophageal disease**

Stentfix OTSC was also recommended for stent fixation in the Postgraduate Course by Prof. Siersema, Radboud-Universiteit Nijmegen, Netherlands. In his opinion stentfix OTSC is particularly useful when there is a risk of stent migration. He described the novel system as a "very elegant way to fix the stent to the wall of the esophagus" (Management of strictures and leaks in the upper GI tract; Postgraduate Course, Session 3).

HemoPill®

Case report: HemoPill acute confirms GI blood loss in obscure bleeding and helped to guide timing for device assisted enteroscopy

Joachim Rainer, Italy, reported on the application of the HemoPill acute in a patient with obscure-occult gastrointestinal (GI) bleeding. The 71-year-old patient was admitted to the hospital due to severe iron deficiency anaemia without any visible signs of overt GI bleeding (blood loss). He had several comorbidities, such as ischemic heart disease with previous stent placements, COPD and peripheral artery disease. Due to his cardiac condition, he was on long term dual anti-platelet therapy.

After blood transfusion, upper and lower GI endoscopy were performed and did not show any bleeding sites. Subsequent video capsule enteroscopy (VCE) revealed angiodysplastic lesions (1b according to Yano-Yamamoto classification) of the proximal jejunum. Device assisted enteroscopy (DAE) was planned to treat the bleeding lesions; but due to the patient's contraction to SARS-CoV-2 infection the procedure was delayed. The patient's recovery took several weeks. In the absence of clinical signs of bleeding, HemoPill acute was used to re-assure the indication for VCE.

HemoPill acute is a novel swallowable telemetric device from Ovesco for real time luminal blood detection. The capsule (of smaller size than a video capsule) measures the photometric characteristics of the material that passes the sensor gap and calculates a numeric value, which has good specificity and sensibility for intraluminal blood (HI value ≥ 1.0). Rainer sees a great advantage of this technology in the fact that it provides instant information by its real time measurement and that it requires neither fasting nor bowel preparation before its application.

In this case, blood was detected approximately 60 minutes after application (presumably after pylorus passage, at the small bowel level) confirming the need for DAE. Angiodysplasia was treated using argon plasma coagulation and a spiral enteroscope.

Rainer concluded that HemoPill acute was able to confirm the GI blood loss even in obscure bleeding and helped to guide timing for DAE. According to him, future research is necessary on the potential of such real time intraluminal blood detection in suspected small bowel bleeding.

Rainer J, Azienda Unità Sanitaria Locale di Modena, Carpi, Italy. **Application of a novel swallowable telemetric device for real time luminal blood detection to guide timing of enteroscopy in a patient with obscure-occult gastrointestinal bleeding. A case report.**

FTRD® System

Case report: Hybrid-FTRD rescues patient with a recurrent fibrotic adenoma

The group of Tribonias et al., Greece, presented a case of a recurrent fibrotic adenoma of the ascending colon that was removed endoscopically combining ESD and FTRD. Initially, the 20 mm 0-IIa adenoma with an obvious scar (NICE:2) from the previous resection attempt (EMR) was removed using ESD and a needle-type knife. Due to the presence of severe fibrosis and difficulty in approaching the lesion, the ESD procedure was interrupted and a Hybrid-ESD-FTRD was chosen. Histological results confirmed R0 and full-thickness resection and showed a tubular adenoma with high-grade dysplasia. 6 months follow-up endoscopy showed no recurrence of the resected adenoma. Tribonias et al. consider the combined ESD-FTRD technique as a salvage resection technique in difficult scarred and fibrotic lesions. Larger lesions (> 25 mm) could be effectively resected by first reducing their size with ESD and removing them with subsequent FTRD application.

Tribonias G, Aravantinou-Koutsouvi A, Bellou G, Zacharopoulou E, Palatianou M, Leontidis N, Internos I, Penesis G, Vamvakousis V, Tzouvala M, General State Hospital of Nikaia "Saint Panteleimon", Nikea, Greece. eP583V. **Hybrid rescue resection of a recurrent fibrotic adenoma in the ascending colon by combining Endoscopic Submucosal Dissection (ESD) and Full Thickness Resection Device (FTRD)**

EFTR as first-line treatment for colorectal lesions highly suspicious of invasive adenocarcinoma

The study of Terán et al. examined the oncological outcomes of EFTR in small colorectal lesions highly suspicious of invasive adenocarcinoma (HSoIA).

In this descriptive study, all patients with HSoIA colorectal lesions (0-IIc or 0-III Paris morphology and/or NICE 3) suitable for the full-thickness resection device (FTRD) (≤ 30 mm) were included at a tertiary hospital between May 2018 and October 2022. Demographic, clinical, technical, oncological and pathological data were retrospectively analyzed.

A total of 20 lesions were resected in 20 patients (80% male, 70.1 ± 9.49 years). Most patients had significant comorbidities (Charlson's comorbidity index 6.55 ± 2.83 ; 80% of ASA III-IV patients). Lesion size was $17.9 \pm 4.24 \times 13.7 \pm 3.53$ mm on average; 75% of lesions had Paris morphology 0-IIc and 15% 0-III; 70% of cases were NICE 3. Technical success rate was 100% with R0 resection in 95% of cases and only one (5%) adverse event (delayed bleeding). Pathological results revealed invasive adenocarcinoma in 60% (12/20), all well or moderately differentiated. Lympho/vascular invasion was seen in 75% and budding in 12.3%. All adenocarcinoma patients had NOM0 disease on CT scan and/or MRI. EFTR was the only treatment for 70% of patients: 8 adenomas, 2 low-risk adenocarcinomas with lymph node involvement and 4 high-risk adenocarcinomas in patients not suitable for surgery. Only 50% of patients with high-risk adenocarcinomas received oncologic surgery.

The authors concluded that EFTR is safe and has a high R0 resection rate for HSoIC colorectal lesions. EFTR could be considered as a first-line treatment because these cases represent a wide spectrum of conditions, from adenomas to invasive adenocarcinomas, both in patients who are suitable for surgery and in those who are not.

Terán Á, Fraile-Lopez M, Moris M, Pascual M, López Arias MJ, Crespo J, Marqués de Valdecilla University Hospital, Santander, Spain. eP622. **Endoscopic full-thickness resection as the first line treatment for small but highly-suspicious of invasive adenocarcinoma colorectal lesions**

remOVE System

Case report: Use of OTSG Xcavator® for necrosectomy of a walled-off necrosis makes procedure more effective and faster

F. Pereira Correia, Portugal, reported on the use of the OTSG Xcavator in a 34-year-old man, who was admitted to the emergency department due to acute biliary pancreatitis (BISAP 2). The patient had a severe clinical evolution with acute necrotic and organized collections (walled-off necrosis, WON). In addition, a rupture of a

pseudoaneurysm occurred inside the WON, which was treated with arterial embolization. Due to a suspected infection of the WON, broad-spectrum antibiotic therapy was started, and endoscopy was planned for drainage. One week later, endoscopic necrosectomy was performed. After transgastric drainage with LAMS, necrosectomy was performed using the OTSG Xcavator from Ovesco. The device is specifically designed for large volume grasping and therefore effectively removed the necrotic tissue. As the OTSG Xcavator allows the introduction of liquids or the simultaneous use of other devices, Correia perceives the free working channel as a great benefit of the device. In this case, the OTSG Xcavator optimized the necrosectomy by making the procedure more effective and faster.

Correia F, Gastroenterology Department, Hospital Professor Doutor Fernando Fonseca, Amadora, Portugal. eP056V. **Endoscopic necrosectomy of extensive WON with solid debris using OTSG: Once you dig, you`ve got to clean it.**

Further lectures involving Ovesco products

Ovesco products and their use were mentioned in various presentations at the ESGE Days 2023. The stentfix OTSC System and OTSC System was mentioned in 4 further presentations and presented in 4 further ePosters. The FTRD System was presented in 4 further ePosters.

Contact us with any questions or for more information:

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