Conference Report United European Gastroenterology Week (UEGW) 2020

- **HemoPill® acute detects small bowel bleeding rapidly and reliably**
- **OTSC® superior over TAE as salvage therapy in refractory peptic ulcer bleeding in terms of ICU stay and in-hospital mortality**
- **EFTR with the FTRD® is a safe and effective method for treating malignant or difficult colonic lesions**

The 28th United European Gastroenterology Week (UEGW) was taking place digitally on October 11-13, 2020. Ovesco technology and procedures were presented in talks, posters and a live-broadcasted endoscopy.

HemoPill® acute

First application experience with the telemetric capsule HemoPill acute shows fast and reliable haemorrhage proof

T. Brunk et al., Vivantes Hospital in the Friedrichshain, Berlin, Germany, presented a study on the application of the HemoPill acute in case of suspected small bowel bleeding. 13 patients (5 female, 8 male, age 28 – 84 years, Glasgow-Blatchford-Score 6 – 12 (median 10, SD 2)) with acute GI bleeding and without findings in esophagogastroduodenoscopy (EGD) were included in the study.

The HemoPill acute is a sensor-based telemetric capsule for detection of haemorrhage in the upper gastrointestinal tract. It determines photometrically an intensity ratio of violet and red light and calculates the so-called HemoPill indicator (HI). The measurement is independent from food components. It is visualized in real time via radio on a mobile HemoPill Receiver. HI of 1.0 – 1.5 indicates fresh blood/ haematin, other gastrointestinal content inclusively bilirubin leads to HI of 0.5 – 0.9.

Application of the HemoPill acute was performed via swallowing in 9 cases and via endoscopic placement into the duodenum in 4 cases. The application was technically successful in all cases, no complications occurred. In 7/13 cases the HI was ≥ 1.0 (median 1.4; SD 0.7) and indicated bleeding of the small bowel. In these patients double-balloon-enteroscopy was performed within 24 h (median 22 h). Angiodysplasia was detected as probable bleeding source and treated with Argon-Plasma-coagulation. In all other 6 cases with HI < 1 standard elective evaluation of the colon and small intestine was performed. Signs of active bleeding were not found. In 1 case video-capsule-enteroscopy provided evidence of a not-bleeding jejunal ulcer.

The authors concluded that based on this preliminary data the HemoPill acute rapidly and reliably detected active small bowel bleeding in patients with suspected acute GI bleeding and negative EGD. Further comparative investigation is needed to better define the value of this promising new system.

HemoPill acute: preliminary results using a sensor based telemetric capsule system in patients with EGD negative acute mid GI-bleeding
Brunk T, Tauchmann C, Berger AW, Hochberger J, Berlin, Germany.

OTSC® System

OTSC superior to TAE in refractory peptic ulcer bleeding – study shows significantly lower in-hospital mortality and shorter ICU stay

A. Kuellmer et al., Medical Center University of Freiburg, Freiburg, Germany, presented a retrospective multicenter study comparing OTSC vs TAE (transarterial angiographic embolization) as salvage therapy for refractory peptic ulcer bleeding.

Primary endpoint of the study was clinical success defined as the combined endpoint of successful hemostasis and no re-bleeding within 7 days. Secondary endpoints were adverse events, length of hospital stay, days on intensive care unit (ICU), number of blood transfusions and mortality. Statistical analysis was performed for the total cohort and a matched cohort after adjustment of differences in baseline characteristics with propensity score matching (PSM).

Overall, 128 patients with peptic ulcer bleeding refractory to standard endoscopic therapy were included in the study. 66 patients were treated with OTSC, 62 patients with TAE.

Between the two comparison groups there were no significant differences regarding age, Charlson comorbidity index, Rockall score, Helicobacter pylori status, ongoing anticoagulation, NSAID intake, primary hemostasis rate in first line therapy and number of endoscopic treatment attempts before salvage therapy. Also, in both groups, the proportion of patients with ulcer size > 20mm was similar (27.3 % vs. 33.9 %, p = 0.48). Most ulcers were in the duodenal bulb (65 % in OTSC group; 85.5 % in the TAE group; p = 0.014). The OTSC group included significantly less Forrest Ia bleedings (19.7 % vs. 38.7 %, p = 0.02) and significantly more Forrest Ib bleedings (63.6 % vs. 43.5 %; p = 0.03). PSM was performed to control for these biases and resulting in treatment groups of n= 40 each, with no significant differences in ulcer localization and bleeding characteristics.

Clinical success was higher in the OTSC group but did not reach statistical significance (72.5 % vs. 62.5 %; p = 0.474) while TAE patients stayed significantly longer in ICU (4.9 vs. 9.2 days, p = 0.009) and inhospital mortality was significantly higher in the TAE group (5.0 % vs. 22.5 %, p = 0.048). The 7-day re-bleeding rate was higher in the TAE group (17.5 % vs. 32.5 %; p = 0.196). Also, severe adverse events occurred more often in the TAE group (3.0 % vs. 7.5 %, p = 0.308).

The authors concluded that OTSC treatment for refractory peptic ulcer bleeding shows at least similar efficacy compared to TAE, but significantly lower mortality rates and significantly shorter ICU stay.

OTSC vs TAE as salvage therapy for refractory peptic ulcer bleeding

Kuellmer A[1], Mangold T[1], Bettinger D[1], Maruschke L[1], Wannhoff A[2], Caca K[2], Edris W[3], Jung C[4], Kleemann T[5], Schulz T[5], Thimme R[1], Schmidt A[1]. [1]Freiburg, Ludwigsburg[2], Offenbach[3], Goettingen[4], Cottbus[5], Germany.

The OTSC is established as sole second line treatment for recurrent peptic ulcer bleeding

K. Caca, Hospital of Ludwigsburg and University Heidelberg, Germany, gave a lecture on new tools for the management of upper GI bleeding.

First-line endoscopic hemostatic therapy achieves very high success rates of about 90 %, independent from which hemostasis technique is used: injection techniques, thermal coagulation or conventional clips. However, the mortality rate of acute upper GI bleeding is 5.8 % (Lau et al. Lancet 2012). Predictors for adverse outcome are the patient's age and comorbidities, and especially re-bleeding (Chiu et al. Clin Gastroenterol Hepatol 2009). In case re-bleeding occurs, re-endoscopy is still superior to surgery concerning complications and associated with a success rate of about 75 % (Lau et al., NEJM 1999). But if re-endoscopy is not successful and surgical salvage therapy is necessary, the mortality rate is quite high, it rises to 29 % (Jairath et al. B J Surg 2012).

Over the past few years, new endoscopic hemostasis techniques have been developed to increase success rates of secondary endoscopic hemostasis. These are the so-called "topic

substances" (Hemospray, EndoClot and PuraStat) and the OTSC.
There are no randomized studies evaluating topic substances; observational studies show that they can stop haemorrhage even in diffuse bleedings in nearly 95 %, but quite high rebleeding rates of about 30 – 40 % occur. So, these techniques are established as rescue therapy or "add- on" therapy especially for diffuse bleedings.
The OTSC however is established as the sole second line treatment for recurrent peptic ulcer bleeding. It overcomes typical problems of through-the-scope clips, which can hardly grasp a centric vessel in a large ulcer with fibrotic base and cannot be well applied in ulcers at the posterior duodenal wall or the duodenal knee because of the tangential position and the narrow distance. The OTSC allows a better visualization of the ulcer due to suction into the cap of the device and/or the possibility of grasping by an OTSC Anchor. Besides, OTSC has the advantage of higher compression force (as high as a surgical seal) and thereby better hold in fibrotic tissue.
The STING trial (Schmidt A et al. Gastroenterology 2018) is a randomized controlled trial in patients with recurrent peptic ulcer bleeding (n=66, 33 OTSC, 33 standard endoscopic hemostasis). It showed a relative risk-reduction of 73.6 % in the OTSC group compared to the group with standard endoscopic therapy. 14 patients crossed over to the OTSC group after failed standard endoscopy (10 patients) or rebleeding after primary successful standard therapy (4 patients), so no significant differences could be found in rates of angiographic embolization, surgery, transfusion requirements and mortality.
Regarding the role of OTSC in first line therapy, there are no prospective trials so far; a retrospective study (FLET Rock study, Wedi E et al., Surg Endosc 2018) evaluating OTSC "first line" vs. a matched control group, showed that observed mortality, re-bleeding, and mortality after re-bleeding were significantly lower with OTSC as first line therapy.
A study prospectively evaluating OTSC as first line therapy in 100 patients with acute NVUGIB and Rockall Score ≥ 7 (STING II) is ongoing.

New tools for treatment of upper GI bleeding. Therapy update: Non-variceal upper GI bleeding

Caca K, Ludwigsburg, Heidelberg, Germany.

FTRD® System

EFTR is a safe and effective method for treating malignant or difficult colonic lesions

S. Sferrazza et al., Santa Chiara Hospital, Trento, Italy, presented a prospective cohort study evaluating endoscopic full-thickness resection with the FTRD System for colorectal lesions unsuitable or difficult to remove both with standard and advanced endoscopic resection techniques.
20 subsequent patients of two tertiary referral centers were included in the study. 70 % of patients were male, median age of the patients was 71.5 years. Indications for EFTR were malignant features (40 %), recurrence or non-lifting sign (50 %) and intra-diverticular or intra-appendicular location (10 %). 16 % of procedures were performed in an outpatient setting. No differences were found in patient or procedural characteristics between inpatient or outpatient settings. 25 % of lesions were located in the rectum, 15 % in the sigmoid, 15 % in the descending colon, 20 % in the ascending colon, 20 % in the cecum and 5 % in a surgical anastomosis. Technical success was achieved in 95 % of the lesions. Median procedural time was 15 minutes (IQR 15 – 20). Mean lesion size was 19 mm (9 – 40 mm). No immediate peri-procedural complications occurred. One patient developed acute appendicitis requiring surgery. Median follow-up was 5 months (IQR 0-17 months). During follow-up, 2 recurrences were found, both were < 10 mm in size and removed endoscopically.
The authors concluded that endoscopic full-thickness resection is a safe and effective method

for treating malignant or difficult colonic lesions. The procedure is not time-consuming and can be performed by expert endoscopists with minimal prior experience with the device.

Endoscopic full-thickness resection for the management of difficult colorectal lesions: a prospective cohort study

Sferrazza S[1], Vieceli F[1], Maida MF[2], Michielan A[1], Conte E[3], Di Mitri R[3], de Pretis G[1], [1]Trento, [2]Caltanissetta, [3]Palermo, Italy.

Appendicitis as a delayed complication after EFTR

M. Raithel et al., Maltese Wood Hospital, Erlangen, Germany, presented a case report of perforated appendicitis as a delayed complication 3 months after successful EFTR.

A 71-year-old woman with family history positive for colorectal carcinoma and > 20 mm hyperplastic polyp at the appendix opted for EFTR for resection after careful clarification and discussion of endoscopic or surgical resection. The endoscopic resection was performed with the FTRD after chromo-endoscopic visualization, magnification with near focus view and marking of the lesion. The lesion was mobile, could be well grasped and the clip safely placed around it. However, because of incomplete EFTR, further polyp tissue had to be removed with a standard polypectomy snare to achieve complete resection. At the end of the procedure the lesion was macroscopically completely resected and a clear coagulation zone present. The histological preparation showed a R0 resection of a sessile serrated adenoma at and into the appendiceal orifice, which was completely resected. The patient recovered quickly without systemic signs of inflammation and was discharged from hospital 4 days later.

At day 92 after EFTR the patient presented with right sided abdominal discomfort, fever, nausea and vomiting. Also, laboratory and sonographic examinations were consistent with acute appendicitis. Emergency laparoscopic appendectomy had to be performed, showing a perforated appendix, local hemorrhagic peritonitis with complete adhesion and scarring of the appendix and the cecum. The postop course was uneventful, the patient left the hospital at day 4 and is doing well.

Perforated appendicitis as a delayed complication 3 months after successful endoscopic full-thickness resection (EFTR) with the over-the-scope clip device (OTSC): Case report and assessment of recent studies involving the appendix

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Live EFTR of a cecal non-lifting lesion

E. Dekker, Academic Medical Center, Amsterdam, the Netherlands, moderated the UEG Live Demo II Session with I.M. Gralnek, Afula, Israel, and R. Bisschops, Leuven, Belgium.

The case presented was a 75-year-old female patient with a small non-lifting lesion in the cecum detected during screening colonoscopy. The lesion was suspected for early cancer. The colonoscopy images presented showed a small sessile polyp with non-lifting sign 1 cm in size. For this type of lesion endoscopic full-thickness resection is a very suitable therapeutic option.

The procedure was performed by B. A. Bastiaansen, P. Fockens and team in Amsterdam (NL) and broadcasted live. The lesion presented itself as very vulnerable and irregular lesion with partly granular structure and in other parts complete loss of mucosal structure. The endoscopist estimated a deep submucosal invasion and stated that ESD in this case would be impossible, because the risk of adverse events would be very high, and it would not be radical enough while EFTR would yield a safe full-thickness specimen with good assessability by the pathologist.

Advancement of the endoscope with mounted FTRD to the lesion was successful, the grasper was used to grasp as much tissue as possible, gentle

suction was applied and the lesion was pulled slowly into the cap. The endoscopist emphasized the importance of having a good visualization of the white ring and watching the white ring moving forward when setting the clip application mechanism in motion to ensure that the clip has been deployed and no perforation is caused by the subsequent resection. After attainment of a good imaging, the clip was released, the lesion resected, and the endoscope was pulled out.
The specimen was about 3.5 cm with a lesion a bit larger than expected, the lateral margin was nice and clear at the ventral side and quite tight but sufficient at the dorsal side.
Evaluating the final endoscopic result, all four edges of the clip were clearly visible, tissue assessment of the margins was difficult but did not hint any conspicuities. Histology of the specimen showed a resection in R0.

UEG Live Demo Live Endoscopy II
Dekker E, Amsterdam, the Netherlands

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