Conference Report United European Gastroenterology Week (UEGW) 2016

- HemoPill acute trial - non-invasive detection of upper GI bleeding feasible and safe
- Swiss FTRD trial - 94% R0-resection of colonic non-lifting polyps with the System
- STING trial – 96.8% primary hemostasis and 81.5% permanent hemostasis with OTSC versus 62.5% and 30.3% with standard therapy in patients with recurrent peptic ulcer bleeding

The 24th United European Gastroenterology Week (UEGW) was held on October 15-19, 2016, in Vienna, Austria. Several workshops, talks and posters presented original research with Ovesco technology and procedures. Hands-on training sessions in the ESGE learning area with the OTSC System attracted lively interest.

HemoPill acute

Clinical pilot study with the new telemetric sensor capsule: detection of upper GI bleeding correct and safe

A. Schmidt et al., Hospital of Ludwigsburg, University of Heidelberg, Germany, reported on a prospective cohort pilot study with Hemopill acute, the swallowable telemetric sensor capsule for detection of blood in the upper GI tract.

Between 04/2015 and 02/2016, 28 patients with symptoms of upper gastrointestinal bleeding (UGIB) without evidence of hemorrhagic shock swallowed the sensor capsule immediately after presentation in the emergency room. Independent of the HemoPill measurement values, all of the patients received esophagogastrroduodenoscopy (EGD) within 12 hours.

Ingestion of the capsule was feasible and without adverse events in all patients. EGD showed active bleeding in 3 patients and signs of recent bleeding in 10 patients. The capsule was able to correctly detect UGIB in 12 patients. In one case, bleeding was most likely generated during subsequent EGD and therefore not detected by the sensor. All 15 patients without endoscopic evidence of UGIB were correctly recognized as negative by the capsule. There were no adverse events related to the capsule. Normal capsule excretion could be documented in 25 patients; there was no evidence of capsule retention.

The authors concluded that non-invasive detection of UGIB with HemoPill acute is feasible and safe. Further studies are required to confirm the results of this pilot study.
**FTRD System**

**Workshops in the ESGE Learning Area comprising the FTRD System**

The European Society of Gastrointestinal Endoscopy (ESGE) offered an ESGE Learning Area to all delegates of the UEGW to provide a platform for live encounter and interaction among aspiring endoscopists and renowned experts in the field. The FTRD System was part of two workshops in the ESGE Learning Area. One workshop was held by A. Schmidt and K. Caca, Ludwigsburg, Germany on the topic “Submucosal vs full-thickness resection: what to use and when” and the second was held by K. Caca on “Full thickness resection methods”.

**New patient series with the FTRD System from Switzerland: EFTR efficacious and safe**

Clinical experience with the FTRD from two tertiary referral centers in Switzerland was presented in a poster by P. Aepli and colleagues, cantonal hospitals of Lucerne and St. Gallen, Switzerland. This poster received the UEGW Poster Champ Award.

Eighteen consecutive patients with colonic polyps were treated with the FTRD during a one-year period (05/15 - 04/16). Thirteen procedures were performed in the colon and five in the rectum. Indications were adenoma recurrence or residual adenoma with non-lifting sign after previous polypectomy (n=7), staging resection following presumed incomplete polypectomy of early carcinoma (n=5), treatment-naïve adenoma with non-lifting sign (n=5), and one adenoma located at the appendiceal orifice (n=1).

In only one case (polyp at appendiceal orifice) the lesion could not be reached due to diverticulous narrowing of the sigmoid. En-bloc and histologically complete (R0) resection was achieved in 16 of 17 cases (94.1 %), complete full-thickness resection was noted in 14 of 17 cases (82.4 %), i.e. 11/12 (91.7 %) in the colon and 3/5 (60.0 %) in the rectum. The mean diameter of resection specimen was 2.6 cm (range 1.8-3.2 cm). Two post-procedure minor bleedings were seen (one requiring re-colonoscopy and adrenalin injection). During a one-month follow-up no delayed complications were seen.

The authors concluded, that treatment of non-lifting polyps ≤ 30 mm with the FTRD device was efficacious and sufficiently safe. Full thickness resection was evaluated an adjunctive colonoscopic technique, which offers minimally invasive treatment to a group of patients that would otherwise undergo surgery.

**OTSC System**

**Lively interest in Hands-On Trainings with the OTSC System**

In the ESGE Learning Area, three 90-minute Hands-On Trainings with the OTSC System were offered. All Hands-On Trainings were fully booked.

**STING trial: OTSC treatment superior to standard therapy in terms of technical and clinical success in recurrent peptic ulcer bleeding**

Preliminary results of a prospective randomized controlled trial comparing over-the-scope clips versus standard endoscopic therapy in patients with recurrent peptic ulcer bleeding were presented by A. Schmidt and colleagues, Hospital of Ludwigsburg, Hospital of Augsburg, University of Tuebingen, University of Ulm, Technical University Munich, Robert Bosch Hospital Stuttgart, and Horst-Schmidt Hospital Wiesbaden, Germany, University of Hong Kong, and Hospital of Bern, Switzerland.

Patients with re-bleeding from peptic ulcer within 7 days after initial successful endoscopic
hemostasis were included in the study. Patients with bleeding sources other than peptic ulcer, such as variceal and tumor bleeding, as well as perforated ulcers with requirement of surgical therapy were excluded. In total, 65 patients were included. After endoscopic confirmation of recurrent bleeding from peptic ulcer, patients were randomized to either OTSC treatment (n=33, additional injection of diluted adrenaline allowed) or standard therapy (n=32, TTSC or thermal method plus injection of diluted adrenaline). Hemostasis was achieved in 20/32 (62.5%) patients with standard therapy, and in 31/33 (96.8%) of patients with OTSC therapy (p=0.002). In case of unsuccessful treatment with standard therapy (12 patients), crossover to OTSC treatment was possible. In 10 of these patients, successful hemostasis was achieved with OTSC, in 1 patient with other endoscopic treatment, and 1 patient underwent surgery due to persistent bleeding. Permanent hemostasis (successful primary hemostasis and no re-bleeding within 7 days) was achieved in 10 patients of the standard therapy group (30.3%) and 26 patients of the OTSC group (81.5%; p<0.001). No statistical difference between the groups could be shown in need for surgery and mortality.

The authors concluded that OTSC treatment was superior to standard treatment in terms of technical and clinical success in patients with recurrent peptic ulcer bleeding. A lack of difference in mortality and need for surgery is likely to be explained by the crossover design. Further studies may evaluate the role of OTSCs as primary therapy for patients at high risk for re-bleeding.

Perforation closure after EFTR for gastric SMT with OTSC time-saving, easier to perform and related to fewer complications when compared to endoloop and metal clips technique

C. Zhang et al., Zhongshan Hospital of Fudan University, Shanghai, China presented a single-center prospective comparison study evaluating safety and efficacy of the OTSC vs endoloop and metal clips for perforation closure after endoscopic full-thickness resection (EFTR) of gastric submucosal tumors (SMTs).

40 consecutive patients who underwent EFTR for gastric SMTs between 03/2014 and 06/2014 were included. 20 patients received an OTSC for perforation closure and in 20 patients the endoloop and metal clip technique was applied. There was no significant difference in patient age, sex, tumor size and perforation size between the two groups. EFTR and closure procedure were both performed successfully in all of the patients. The operation time, closure time, total complication rate and hospital stays in OTSC group were all shorter than those in the endoloop group, but statistical difference was not reached. The operation cost in OTSC group was significantly less than that in the endoloop group. Seroperitoneum or pleural effusion occurred in two patients treated with the OTSC and in four patients treated with endoloop and metal clips. Those complications all disappeared spontaneously. Delayed bleeding and perforation were detected in one case in the endoloop and metal clips group, and the patient suffered secondary surgery to stop bleeding and repair perforation. No other severe complications developed in the two groups.

In conclusion, closure of the artificial perforation after EFTR with the OTSC is easier to perform, time-saving and related to fewer complications when compared to a closure technique with endoloop combined with metal clips.
OTSC decreases surgery rate in the management of iatrogenic perforations

S. Khater and colleagues, European Hospital Georges Pompidou, Paris, France, reported on a monocentric retrospective study, which investigated the impact of OTSC use in the management of iatrogenic perforations occurring during diagnostic and therapeutic endoscopic procedures.

All iatrogenic gastrointestinal perforations occurring between 06/2007 and 06/2015 during an endoscopic procedure and detected during the procedure, irrespective of the location of the perforation, were included in the study. The study was divided in two equal periods of time: a period before the use of the OTSC (06/2007 - 06/2011), and a period during which the OTSC was available (06/2011 – 06/2015). During the first period, 24 perforations were recorded for 29203 endoscopies performed. 15 of the 24 perforations (62.5%) were referred for surgery, and the mortality rate during this period was 8.3% (2/24). During the second period, 16 perforations were reported for 35525 endoscopies performed. In eleven patients, an OTSC was used to close the perforation, with a technical success achieved in 100% since all patients had an adequate deployment of the OTSC and a complete sealing of the perforation without leakage. However two of these patients had to undergo surgery despite an adequate closure of the perforation: one because of a localized peritonitis and the other because the clip deployed in the sigmoid had accidentally captured the right ureter. The rate of surgery during this period was 12.5% (2/16) versus 62.5% (p=0.002), and the mortality rate was 0% versus 8.3% (p=0.23).

The authors concluded that the OTSC System is effective for endoluminal closure of acute iatrogenic perforations and results in a significant decrease in the surgery rate. They advise, that all endoscopy units should have a supply of OTSC, with a proper training for endoscopists and nurses on its use.

Effective closure of acute perforations in more than 75 % with OTSC

Another study on perforation closure with OTSC was presented by M. Raithel and colleagues, Wald-Hospital St. Marien, Erlangen, University of Erlangen-Nuremberg, Erlangen, Julius Hospital, Würzburg, and Hospital of Fuerth, Germany. The study was carried out in a consecutive patient cohort presenting with acute nonsurgical or postoperative perforations, who underwent attempted OTSC placement as primary closure method after interdisciplinary consensus.

In total, 34 patients (16 female, 18 male, 69.5 years) were included with 22 non-surgical perforations and 12 postoperative perforations. Definitive closure of perforation was achieved in 26/34 patients (76.5%). Successful endoscopic perforation closure resulted in a significantly shorter hospital stay (8 days vs 18 days, p=0.03). In the group with unsuccessful endoscopic perforation closure 6 of 8 patients (75%) required immediate surgery.

Three deaths occurred in the group with successful perforation closure due to comorbidity, while one death in the OTSC failure group was related to a refractory perforation.

In conclusion, the OTSC was effective for closure of acute perforations in more than 75% of all patients. Clinical success and short hospitalization were best achieved in patients without comorbidity, but perforation closure was found to be not the only parameter relevant for patient outcome and mortality.
Promising results in treatment of large endoluminal GI defects using a multi-modal approach using endosponge and OTSC clips

A retrospective, observational cohort study, evaluating the success, safety and complications rates of a multi-modal endoscopic approach using sponge and OTSC clips to close large endoluminal GI defects was presented by J. P. Gutierrez et al., Basil I. Hirschowitz Endoscopic Center of Excellence, Birmingham, USA, and University Hospital Erlangen, Germany. During an 18-months period, 11 patients (8 male, 3 female, mean age 57.2 years; range 38 to 73) with large fistulae or perforations were treated. The mean ASA score was 3.5 (range 3–4). Seven patients were critically ill at the time of consultation, with large perforation or intra-abdominal abscess. The etiology of the GI defects were Boerhaave’s syndrome (n=2), leak after gastric sleeve surgery (n=2), colorectal anastomotic leak (n=2), lung abscess with tracheoesophageal fistula (n=1), combined retroperitoneal and pleural abscess (n=1), entero-cutaneous fistula in Crohn’s (n=1), radiation-induced rectovesical fistula (n=1). The defects were treated sequentially by endoscopic lavage and debridement, followed by insertion of sponge. Once the cavity decreased in size the sponge was exchanged or removed and the smaller diameter defect was closed using one or more over-the-scope clips. In defects larger than 5 cm a stent was also inserted to bridge the lumen. Five patients also underwent placement of a direct endoscopic jejunalostomy using balloon-assisted enteroscopy technique. The mean number of procedures was 3 (range 2–5). Successful closure of the GI defect and resolution of the abscess was achieved in six patients (54.4%). In three patients closure failed and they underwent surgery. Two patients died from underlying sepsis without improvement of their fistula. There were no adverse events related to the multi-modal endoscopic therapy.

In summary, the use of multi-modal endoscopic therapy based on endo-sponge and over-the-scope clip appears promising for the treatment of complex GI endoluminal defects, especially when patients are poor surgical candidates and are critically ill. In up to 50% of patients the therapy was successful, in other patients the endoscopic therapy served as bridge to surgery, thus decreasing the size of GI defect and improving the patient’s general status.

OTSC for enterocutaneous fistulae and peristomal leakage

M. Bukhari et al., John Hopkins University, Baltimore, USA, reported on a single-center retrospective study of patients with persistent enterocutaneous fistula (ECF) following gastrostomy or jejunostomy tube removal who underwent OTSC closure. Persistent ECF was defined as persistent leakage for more than 1 week after removing the feeding tube. A total of 16 patients (mean age 54, 69% female) were included in the analysis. Fourteen patients had a PEG tube and two had a jejunostomy tube placement with a median time of percutaneous tube dwell of 22 months (range 1–48). The median duration of persistent ECF was 21 days (range 8–60). The median size of the fistula was 10mm (range 5–15). ECF orifice was ablated with argon plasma coagulation (APC) prior to OTSC placement in 87.5% of patients. Technical success (satisfactory application of the OTSC resulting in immediate fistula closure) was achieved in all patients (100%). The median follow up post OTSC placement was 30 days (range 3–120). Overall clinical success (resolution of leakage after placement of the OTSC at last available follow-up) was accomplished in 62.5% of cases (10/16 patients) without any adverse events. Two patients who failed OTSC were managed successfully with alternative endoscopic
therapies, 3 were managed surgically and 1 died of unrelated causes.

In summary, endoscopic closure of ECF using the OTSC led to permanent resolution of leakage in over 60% of cases. No adverse events occurred.

**OTSC can replace or supplement traditional surgical approach in 75% in the treatment of fistula, perforation or anastomotic leak**

A retrospective analysis of prospectively collected data in cases of restitution of the digestive tract integrity with OTSC System in two Lithuanian hospitals was presented by I. Kildusiene and G. Radziunas, Oncosurgery, National Cancer Institute, Vilnius, Lithuania.

Between 2013 and 2016, 20 patients (8 female, 12 male, mean age 65 years) were treated in 24 procedures applying 27 OTSC clips. Indications were: anastomotic leak and fistula (n=13), iatrogenic lesion of the colon (n=4), perforation due to necrotic pancreatitis after multiple operations (n=2), leak of the esophageal suture after perforation with a foreign body (n=1). Mean size of the fistula/leak was 1.2 cm (range 0.2–4.0 cm). Complete defect closure at initial procedure was achieved in 15/20 cases (75%). In 13/20 patients (65%) fistulae remained permanently closed.

The authors discussed, that unsuccessful clinical outcome is affected not only by technical details, but also by severe general patient condition (for example caused by sepsis or poor nutritional status).

The authors concluded, that the OTSC System can replace or supplement traditional surgical approach in 75% in the treatment of fistula, perforation or anastomotic leak. Therefore, the OTSC System should be available in all endoscopy units where interventional procedures are carried out.