

Conference Report United European Gastroenterology Week (UEGW) 2019

- **OTSC[®] shows superiority over conventional therapy in high-risk ulcer bleeding and variceal bleeding**
- **First clinical cases with stentfix OTSC[®] yield promising results, proving the tools as valuable, safe and effective**
- **EFTR is a feasible and safe treatment of T1 colorectal cancer, which delivers optimal histology for risk assessment and leads to a high R0 resection rate**

The 27th United European Gastroenterology Week (UEGW) was held on October 19-23, 2019, in Barcelona, Spain. Several workshops, talks and posters presented original research with Ovesco technology and procedures.

OTSC System

OTSC as first-line therapy for high-risk GI ulcer bleeding is associated with shorter procedure time and less rebleeding when compared to case-match controls with conventional therapy

R. Oleas et al., Instituto Ecuatoriano de Enfermedades Digestivas (IECED), Guayaquil, Ecuador, presented a case-match control study assessing the OTSC as first-line therapy in comparison to a combined therapy with conventional hemoclips and adrenaline injection in the management of high-risk bleeding peptic ulcers. The following bleeding ulcers were considered as high-risk ulcers: those located in a major arterial territory, those having an endoscopically visible large-caliber artery > 2mm, and those with a fibrotic ulcer base and high-risk endoscopic stigmata (Forrest classification types I and II). 95 consecutive patients (mean age 60.9 ± 19.1, 32.6 % female) presenting with high-risk ulcer GI-bleeding between 05/2014 and 09/2018 were included, 46 received an OTSC as primary therapy and 49 matched cases received the combined conventional therapy. Most lesions were gastric ulcers (71.6 %). 6 cases of rebleeding occurred: 2 in the OTSC group and 4 in the combined therapy group (p=0.444). The median

procedure time was 11 min (10-15) for OTSC and 20 min (15-40) for combined therapy (p<0.001).

The authors concluded that the OTSC is safe and effective for first line single therapy of high-risk bleeding peptic ulcers. It should be considered the treatment of choice in patients with high-risk bleeding peptic ulcers.

Over-the-scope clip as first-line therapy in the management of high-risk bleeding peptic ulcers: a case-match control study

Robles-Medranda C, Alcivar-Vasquez J, Oleas R, Baquerizo-Burgos J, Olmos JI, Rubio-Cordova M, Puga-Tejada M, Pitanga-Lukashok H, Guayaquil, Ecuador.

OTSC is a safe and effective alternative to sclerotherapy in the management of actively bleeding fibrotic esophageal varices

R. Oleas et al., Instituto Ecuatoriano de Enfermedades Digestivas (IECED), Guayaquil, Ecuador, reported on the use of the OTSC in the management of actively bleeding fibrotic esophageal varices. Repetitive endoscopic band ligations are associated with fibrosis of the esophageal wall. Fibrosis of the esophageal wall, however, impairs band ligation in case of rebleeding. Out of 95 patients presenting with

actively bleeding esophageal varices between 09/2016 and 01/2019, 5 patients could not be treated with band ligation due to fibrosis of the esophageal wall. Thus, the OTSC was deployed over the bleeding fibrotic varix as rescue therapy. The cirrhosis etiology was alcohol in one patient and NASH in 4 patients. 2 patients had received 2 previous band ligations, 2 patients had received 3 previous band ligations and 1 patient had received a single previous band ligation. 4 patients were staged as Child-Pugh B and 1 patient as Child-Pugh C. During follow-up endoscopy, 2 patients were submitted to further band ligation for variceal eradication. Neither re-bleeding nor mortality did occur. The authors concluded that the OTSC is a safe and effective alternative in the management of fibrotic esophageal varices. Randomized controlled trials are required to validate these data.

Over-the-scope clip as a rescue therapy for fibrotic bleeding esophageal varices: A single-center experience

Oleas R, Alcivar-Vasquez J, Alvarado-Escobar H, Puga-Tejada M, Robles-Medranda C, Guayaquil, Ecuador.

Endoscopic clipping is a therapeutical option for complications after esophago-gastric surgery

A. Meining, University Hospital Wuerzburg, Germany, held a talk on therapeutic options for complications after esophago-gastric surgery. When diagnosis of complications is made early and perforation/leakage is small, endoscopic clipping can be a valuable treatment option. The ESGE Guidelines recommend the following endoscopic treatment options for early diagnosed gastric perforations, as long as the patient shows no signs of sepsis: Endoclips for small defects, OTSC for large defects if available, when OTSC is not available, endoloop in combination with clips is recommended. If endoscopic treatment fails or the patient develops signs of sepsis/peritonitis, surgical management is recommended. A. Meining presented a clinical case of a patient with leak after oesophagectomy, closure of the leak

was attempted with stents, hemoclips, glueing, and OTSC. Mucosal incision prior to placing another OTSC was performed. This led to a successful treatment as it reduced the tension on the tissue and therefore closed the leak.

Crash Course: Complications after oesophago-gastric surgery: What to do? Endoscopic clipping is still an option

Meining A, Wuerzburg, Germany.

OTSC for prophylactic closure of the mucosal defect after ESD for SNADET-treatment is associated with higher rates of complete closure, lower rates of delayed adverse events and shorter procedure time when compared to conventional clips and laparoscopic hand-suturing

O. Dohi et al., Kyoto Prefectural University of Medicine, Kyoto, Japan, presented a study comprising consecutive patients with superficial non-ampullary duodenal epithelial tumor (SNADET), who were treated by Endoscopic submucosal dissection (ESD) and prophylactic defect closure using conventional clips, laparoscopic hand-saw suturing, or OTSC. Inclusion criteria were SNADETs larger than 10 mm without submucosal invasion with clinically low risk for lymph node metastasis. ESD was performed using a needle-type knife (Flush Knife) or a scissor-type knife (Clutch Cutter). The primary end point was to evaluate the en-bloc resection rate and intraoperative complication rate (perforation and bleeding) for comparison of Flush Knife and Clutch Cutter. The secondary endpoint was to evaluate the rate of delayed complications for comparison of the three prophylactic closure techniques.

A total of 77 lesions in 75 patients (male/female 54/23; median age 67 years) were resected by ESD. 37 ESD procedures were performed using the Flush Knife and 40 procedures using the Clutch Cutter. There were 14, 13, and 50 cases using conventional clip, laparoscopic hand-sewn suturing and OTSC for prophylactic closure of the

mucosal defect after ESD, respectively. R0-resection rate was 83,8 % using the Flush Knife and 97,5 % using the Clutch Cutter, the difference did not reach statistical significance. The rates of complete closure were 78.6 % with conventional clip, 92.3 % with hand-sewn laparoscopic suture and 98.0 % with OTSC (p=0.13). The procedure time with OTSC was significantly shorter than that with the conventional clip and the laparoscopic suturing (p<0.01). Adverse events such as delayed bleeding and delayed perforation occurred in 15.4 % and 7.7 % with conventional clip, in 2.3 % and 0 % with laparoscopic suturing, and in 0 % and 2.3 % with OTSC, respectively (p=0.56 and p=1). The authors concluded that ESD using Clutch Cutter and prophylactic defect closure with OTSC seems to be the best alternative for minimally invasive treatment of SNADET.

Clinical impact of endoscopic submucosal dissection using clutch cutter with over-the-scope clip closure for superficial non-ampullary duodenal epithelial tumor

Dohi O, Yoshida N, Ishida T, Takayama S, Nakano T, Majima A, Inoue K, Kamada K, Takagi T, Konishi H, Naito Y, Itoh Y, Kyoto, Japan.

100 % technical and clinical success rate with OTSC for EUS related iatrogenic duodenal perforation

H. El Bacha et al., Ibn Sina Hospital, University Mohamed V, Rabat, Morocco, presented a retrospective study of patients with EUS related iatrogenic perforation. The study included all consecutive patients with EUS related perforation observed in the gastroenterology and hepatology unit between 2011 and 08/2018, who were diagnosed immediately and received conservative endoscopic management. Endoscopic management consisted of immediate OTSC-clipping. Patients with primary surgical management and conservative non-interventional management, as well as perforation resulting from an endoscopic intervention were excluded. 13 perforations in 8504 EUS procedures had occurred

(0.15 %). One was a large duodenal tear requiring immediate surgery, one other was misdiagnosed and early discharged, but readmitted 24 h later with peritonitis which lead to emergency surgery. These two patients were excluded from the study. A total of 11 patients were included (all women, mean age 75, range 68-88). Perforations were located in the superior flexure of the duodenum in 9/11 cases (81 %), in the descending part of the duodenum in 1/11 cases (9 %), and in the inferior duodenal flexure in 1/11 cases (9 %). Defect size ranged from 10-15 mm. OTSC clipping was technically and clinically successful in all cases. 3/11 patients (27 %) had a stay in the intensive care unit for less than 72 h, total hospital stay ranged from 3- 22 days.

The authors concluded that duodenal perforation is a potentially serious adverse event of diagnostic EUS, but conservative endoscopic treatment with OTSC represents a feasible, efficient and safe treatment that can prevent surgery in most instances.

Over the scope clips for EUS duodenal perforation

El Bacha H, Rabat, Morocco, Prat H, Paris, France.

stentfix OTSC

The stentfix OTSC System is a viable approach to avoid migration of a fully covered self-expandable metallic stent in the treatment of trachea-esophageal fistula

M. Conio et al., General Hospital, Sanremo (IM), Italy, presented a clinical case, where the stentfix OTSC System was used. In the treatment of tracheoesophageal fistulas, the placement of fully covered self-expandable metallic stents (FC-SEMS) is currently one of the most commonly used strategies. The main limitation of FC-SEMS is migration, occurring in at least one-third of patients and requiring further endoscopic interventions. For the anchorage of esophageal stents, external or internal fixation by clips is

employed. The stentfix OTSC is a new designed version of the OTSC with a rounded clip preloaded on an applicator cap especially designed for stent fixation. It is intended for use in the gastrointestinal tract for the fixation of metallic stents.

A 53-year old man with locally advanced pharyngeal squamous cell carcinoma was treated with pharyngolaryngectomy and adjuvant radiotherapy and received endoscopic percutaneous gastrostomy (PEG) and tracheostomy. One year thereafter, he developed complex hypopharyngeal stricture with severe dysphagia. Multiple mechanical and pneumatic dilatation sessions led to the occurrence of a trachea-esophageal fistula. For fistula treatment, a 16 mm FC-SEMS was placed. Two weeks later, dysphagia occurred due to stent migration. The migrated stent was removed and another stent was placed and anchored with the stentfix OTSC System to treat the fistula. For treating the hypopharyngeal stenosis a similar second stent was placed. No adverse events occurred. Three months later, the patient can swallow a semiliquid diet.

The authors concluded, that the stentfix OTSC System is a viable approach to avoid stent migration. Its efficacy needs to be fully explored.

A new endoscopic device to prevent fully covered metal stent migration

Conio M, Savarese MF, Crespi M, De Ceglie A, Sanremo, Italy.

OTSC Proctology

The OTSC Proctology is a valuable tool within the great variety of approaches for the treatment of cryptoglandular fistulas

J. Warusavitarne, St. Mark's Hospital Harrow, London, UK, held a talk about the treatment of cryptoglandular fistulas. There is a whole toolbox

of endoscopic and surgical approaches and even stem cell therapy available for the treatment of cryptoglandular fistulas. The different techniques are used to either lay open the track, disconnect the track from the gut, excise or obliterate the track, fill the track, or correct the immunopathology. Important factors to consider when treating a fistula are the questions, whether the fistula is intersphincteric or transphincteric, how many tracts the fistula does have, the size of the internal opening, the degree of muscle damage from repeated sepsis, if there is faeces or air coming from the opening and the amount of discharge. The approach has to be tailored to the patient after careful consideration of all influencing details. The OTSC Proctology was presented as valuable tool within the great variety of approaches for the treatment of cryptoglandular fistulas with high success rates reported in clinical case series.

Cryptoglandular fistula: What is new?

Warusavitarne J

FTRD System

Dutch nationwide prospective cohort study shows 88.8 % R0 resection rate and 2.4 % major adverse events in EFTR of T1 colorectal cancer

L. Zwager, Amsterdam UMC, University of Amsterdam, Amsterdam, the Netherlands, presented a prospective multicenter cohort study evaluating technical and clinical success rates and safety of EFTR for T1 colorectal cancers (T1 CRC). Consecutive patients of 21 Dutch hospitals were included between 09/2015 and 04/2019. Inclusion comprised all scheduled T1 related procedures, both, primary treatment for lesions with optical diagnosis of T1 CRC and secondary treatment after previous (potentially) incomplete resection of T1 CRC. Technical success was defined as en-bloc resection with no macroscopic evidence of residual lesion judged by the endoscopist. Clinical success was defined as R0 resection with tumor-

free lateral and deep resection margins and possibility of discrimination between high-risk vs. low-risk T1 CRC. A lesion was defined as high-risk if one of the following risk-factors was present: poor differentiation, lymphatic or vascular invasion, deep submucosal invasion ($\geq 1000 \mu\text{m}$) or incomplete resection (R1/Rx resection). Besides, adverse events were evaluated.

247 procedures were included. Indications for EFTR were primary resection for suspected T1 in 81 cases and re-resection after previous incomplete resection of T1 CRC in 166 cases. Technical success was achieved in 211/247 cases (85.4 %), histopathology could not be obtained in 15/247 cases (6.1 %) because the lesion could either not be reached or not be retracted into the cap. In the remaining 232 cases amenable to EFTR, the R0 resection rate was 88.8 % (206/232). Final histopathology confirmed residual adenocarcinoma in 33.2 % (n=77/232). Discrimination between high-risk and low-risk carcinoma was achieved in 97.4 % (75/77). Low-risk T1 CRC was identified in 22.1 % (n=17/77) and high-risk T1 CRC in 75.3 % (n=58/77). Additional surgery was performed in 41.4 % (24/58) of the high-risk cases, of which 21/24 (87.5 %) had no residual cancer or lymph node metastasis. Endoscopic surveillance strategy was initiated in 46.6 % (27/58). The overall adverse event rate was 8.5 % (n=21/247), with emergency surgery in 2.4 % (6/247) for 2 immediate and 4 delayed perforations.

In conclusion, the authors rated EFTR a feasible and safe treatment for T1 CRC, both as primary treatment and secondary treatment after previous incomplete resection. EFTR delivers optimal histology for risk assessment and leads to a high R0 resection rate, avoiding surgery in most cases.

Endoscopic full-thickness resection is feasible for T1 colorectal cancers – a Dutch nationwide prospective cohort study

Zwager L, Amsterdam, Bastiaansen BAJ, Amsterdam, van der Spek BW, Alkmaar, Heine GDH, Alkmaar, Bronzwaer MES, Amsterdam, Haasnoot KJC, Alkmaar, van der Sluis H, Zwolle, Perk L, the Hague, Boonstra JJ,

Leiden, Rietdijk ST, Amsterdam, Schwartz MP, Amersfoort, Wolters HJ, Groningen, Weusten BLAM, Nieuwegein, Gilissen LPL, Eindhoven, ten Hove WR, Leiden, Nagengast WB, Groningen, Bekkering FC, Capelle aan den IJssel, Terhaar sive Droste JS, Hertogenbosch, Fockens P, Amsterdam, Dekker E, Amsterdam, the Netherlands.

EFTR of adenomas involving the appendiceal orifice is associated with an intermediate risk for developing appendicitis and consecutive risk for appendectomy

B. Walter et al., University Hospital Ulm, Ulm, Germany, presented the results of a retrospective analysis of 38 patients from 2 centers with adenomas involving the appendiceal orifice treated with the colonic FTRD. Objective of the study was to evaluate post treatment complications in acute and long term follow up (appendicitis, mucocele). All patients had received prophylactic antibiotic treatment for an average of 3.7 days in a row started preinterventionally. No acute severe events were reported for the EFTR procedure. Within follow-up, symptoms of appendicitis occurred in 9 patients (23.7 %). In 3 cases, conservative treatment was sufficient, 5 patients were transferred to appendectomy. No development of a mucocele was reported during long term follow-up (median follow-up time 11 months, range 6-32 months).

The authors concluded that EFTR of adenomas involving the appendiceal orifice is associated with an intermediate risk for developing appendicitis and consecutive risk for appendectomy. Patients must be thoroughly informed about the risks.

Intermediate risk of appendicitis following full-thickness resection of adenomas arising from the appendiceal orifice – a retrospective analysis

Walter B, Ulm, Germany, Wannhoff A, Ludwigsburg, Germany, Schmidbaur S, Ulm, Germany, Meier B, Ludwigsburg, Germany, Meining A, Würzburg, Germany, Caca K, Ludwigsburg, Germany.

Spanish multicenter study proves EFTR as safe and feasible for various colorectal lesions

Uchima H et al., University Hospital Doctor Josep Trueta de Girona, Girona, Spain, from the Endoscopic Resection Working Group of the Spanish Society of Digestive Endoscopy, presented a multicenter study evaluating efficacy and safety of the FTRD System in colorectal lesions. Consecutive patients of 10 Spanish endoscopy centers treated with the colonic FTRD were assessed. 71 EFTR were scheduled. Indications for EFTR were: recurrent lesions with non-lifting sign (46.47 %), not pretreated lesions with non-lifting sign (23.94 %), residual lesions with non-lifting sign (11.26 %), appendicular lesions (2.8 %), suspected T1 lesions (7 %), suspicious scar (4.2 %) and subepithelial lesion (4.2 %). In 3 patients passage of the sigmoid was not possible with the FTRD cap. In the other 68 patients, technical success rate was 85.2 %, the en-bloc resection rate was 83.8 %. Final histology revealed LGD adenoma (40 %), HGD adenoma (23 %), intramucosal adenocarcinoma (4.47 %), SSP (5.87 %), T1sm1 (2.9 %), advanced adenocarcinoma < sm2 (13 %), scar tissue (6 %) and others (2.8 %). In one case, the OTSC clip was not deployed resulting in an intraprocedural perforation. There were 2 cases of delayed perforation and 1 case of delayed bleeding. 10 patients underwent surgery: 3 for perforation, 1 for intraappendicular lesion and 6 for advanced adenocarcinoma. During follow-up, 3 residual/recurrent adenomas were treated endoscopically, all of which showed benign histology.

The authors concluded that EFTR is a safe and feasible technique for colorectal lesions. Evaluation of the insertion with a long cap (e.g. “proVE” cap) and traction of the lesion prior to EFTR is highly recommended.

Safety and feasibility of endoscopic full-thickness resection in colorectum using over the scope clip. A multicenter Spanish experience

Uchima H, Girona, Barcelona and Badalona, Barquero D, Barcelona, Esteban Lopez-Jamar JM,

Madrid, Espinos JC, Terrassa, Marin-Gabriel J, Madrid, Roson P, Malaga, Fernandez Cadenas F, Oviedo, Palacio Galan MA, Oviedo, Puig I, Manresa, Rodriguez Sanchez J, Ciudad Real, Fraile Lopez M, Oviedo, Ortega Alonso A, Malaga, Arribas-Anta J, Madrid, Mel L, Madrid, Sabado F, Madrid, Garcia Lledo, Madrid, Fernandez-Simon A, Barcelona, Mata A, Barcelona, Albeniz E, Pamplona, Spain.

Cases of intended EFTR, where part of the lesion was trapped inside the OTSC, are evaluated

H. Uchima et al., University Hospital Doctor Josep Trueta de Girona, Girona, Spain, reported on 10 EFTR cases, where the lesion was trapped in the OTSC clip and could not be resected properly. Locations of EFTR were appendix (n=1), stump (n=1), right colon (n=1), transverse colon (n=2), left colon (n=2), sigma (n=2), and rectosigmoid junction (n=1). Mean diameter of the lesions was 19 mm. Indications for EFTR were: recurrent lesion with non-lifting sign (6 cases), native lesion with non-lifting sign (n=1), residual lesion with non-lifting sign (n=2), and appendicular lesion (n=1). In 8 cases, partial resection of the lesion was performed, in 2 cases only biopsies were taken. Final histology revealed LGD in 4 cases, HGD in 2 cases, intramucosal adenocarcinoma in 1 case, SSP in 2 cases and advanced adenocarcinoma > sm2 in 2 cases. 3 patients underwent surgery (appendicular lesion and advanced adenocarcinomas), 3 residual lesions were treated endoscopically and in 4 cases the scar showed no residual tissue.

The authors concluded that in some cases of intended EFTR, where part of the lesion was trapped inside the OTSC, residual lesion may be easily treated endoscopically or must not be treated at all when histology shows scar without residual dysplasia.

EFTR with OTSC in colorectum: what happens when the lesion is trapped in the over-the-scope-clip and is not resected

Uchima H, Girona and Barcelona, Barquero D, Barcelona, Esteban Lopez-Jamar JM, Madrid, Espinos J, Terrassa, Marin-Gabriel J, Madrid, Roson P, Malaga, Fernandez Cadenas F, Oviedo, Palacio Galan MA, Oviedo, Puig I, Manresa, Rodriguez Sanchez J, Ciudad Real, Fraile Lopez M, Oviedo, Ortega Alonso A, Malaga, Arribas-Anta J, Madrid, Mel L, Madrid, Sabado F, Madrid, Garcia Lledo J, Madrid, Fernandez-Simon A, Barcelona, Mata A, Barcelona, Eduardo A, Pamplona, Spain.

For questions and further information:

Ovesco Endoscopy AG
Scientific Information Service
Friedrich-Miescher-Straße 9
D-72076 Tübingen
science@ovesco.com