

## Abstract Collection of the Digestive Disease Week (DDW) 2020

- **FTRD® System: EFTR enables new therapeutic options for the treatment of lesions and is a feasible and safe modality, which leads to a high R0 resection rate**
- **First clinical cases with LiftUp® reveal promising results, proving it as valuable, safe and fast**
- **OTSC® shows superiority & cost-effectiveness over standard therapy for first-line UGIB and shows high success rates in the management of non-acute, full-thickness gastrointestinal defects**

DDW 2020 and all associated events, scheduled for May 2-5, 2020, in Chicago, have been cancelled. A summary of the most important abstracts on Ovesco products can be found below:

### FTRD System

**The FTRD System is a safe and useful method for resection of colonic lesions including the appendix**

Y. Ichkhanian et al. presented the first multicenter international study assessing the outcome of using FTRD for endoscopic full-thickness resection of appendiceal lesions. To study the rate of appendicitis after lesion resection, 56 consecutive patients between 11/2016 and 11/2019 underwent resection of colonic lesions involving the appendix. Most lesions were of Is 25 (45 %) and IIa 20 (36 %) Paris class and had a mean circumferential appendiceal orifice involvement of 66 ±29 %. The technical success rate was 95 % (53 patients) and in 47 cases successful EFTR was achieved. R0 resection was achieved in 92 % (49/53), antibiotics were administered in 81% (43/53) for a median of 5 days. Follow-up colonoscopy showed no residual lesions in 19/53 patients. In 9 (19 %) out of 47 successful EFTR cases appendicitis was diagnosed. Three patients were treated with antibiotics alone, 6 underwent appendectomy..

The authors concluded that the FTRD is safe and feasible for the resection of appendiceal lesions, with appendicitis occurring in about 20 % of cases.

**Endoscopic full-thickness resection of polyps involving the appendiceal orifice: first multicenter international study**

*Yervant Ichkhanian, Mohammed Barawi, Bachir Ghandour, Talal Seoud, Shyam Thakkar, Truptesh H. Kothari, Krystle Bittner, Asad Ullah, Vivek Kaul, Shivangi Kothari, Edris Wedi, Patrick Aepli, Thomas E. Kowalski, Brianna Shinn, Reem Z. Sharaiha, Qais M. Dawod, SriHari Mahadev, Kaveh Hajifathalian, Gianluca Andrisani, Heinz Albrecht, Andrew Q. Giap, Shou J. Tang, Yehia M. Naga, Ayla S. Turan, Shai Friedland, Benjamin Tharian, Shayan S. Irani, Andrew S. Ross, Laith H. Jamil, Daniel Lew, Andrew Nett, Omid Sanaei, Nasim Parsa, Jad Farha, Manol Jovani, Vivek Kumbhari, Anthony N. Kalloo, Mouen A. Khashab*

**EFTR with the FTRD in the colorectum is safe and more efficient when compared to conventional endoscopic resection**

B. Meier et al. report from the German colonic FTRD registry in which the use of the FTRD for resection of colorectal lesions is analysed. Data from 1178 FTRD procedures provided by various German endoscopy centers were collected between 09/2015 and 10/2019. Whereas the R0 resection rate (overall 80 %) was higher in the rectum (83.6 %) than in the colon, the full-thickness resection rate (overall 89.9 %) in the rectum (83.3 %) was lower when compared to the colon. In 92 % of cases (1086/1178) follow-up data

were available, endoscopic follow-up in 58 % (683/1178) with a mean follow-up time of 22 weeks (median 14 weeks, range 1-202 weeks). Dislocation of the FTRD Clip appeared in 69 % and in 31 % it was still in situ. Procedure-related adverse events were reported in 12.1 %, of which 2 % required surgical treatment .

The authors summarized that FTRD shows safe, effective, and fast results in endoscopic full-thickness resection of colorectal lesions.

**Efficacy and safety of endoscopic full-thickness resection with the FTRD in the colorectum: evaluation of a large PMCF analysis**

*Benjamin Meier, Arthur Schmidt, Armin Kuellmer, Julius Mueller, Andreas Wannhoff, Klaus Weiss, Georg Huebner, Michael Repp, Alexander Meining, Benjamin Walter, Karel Caca.*

**EFTR is a more reliable in the therapy of colorectal neoplasia with high risk of incomplete removal when compared to endoscopic submucosal dissection (ESD)**

S. Suchanek et al. compared endoscopic full-thickness resection (EFTR) with the endoscopic submucosal dissection (ESD) in colorectal neoplasia (size ≤ 3 cm) therapy and primarily assessed R0 resection. The Bicentric prospective randomized study included 35 patients (71 % men, mean age 66 years) with T1 cancers (46 %), non-lifting adenomas (29 %) and local residual neoplasia (23 %). The 19 lesions (54 %) treated by EFTR were mostly localized in the right colon, while the 16 lesions treated by ESD were mostly localized in rectum. Technical success in the EFTR group was achieved in 90 % and in the ESD group in 94 % (p-value 0.999). R0 resection was successful in 17 patients (90 %) treated with EFTR and in 13 (81 %) patients treated with ESD. In 5/11 patients (46 %; EFTR) and in 6/10 patients (60 %; ESD) curative resection of malignant lesions was

performed. Perforation occurred in 4 cases (11 %; all in ESD) of which 2 (6 %) needed surgical therapy and 2 (6 %) were treated endoscopically.

The authors concluded that both EFTR and ESD are technically effective methods for the treatment of colorectal neoplasia with high risk of incomplete removal, but EFTR seems to be the more safe method comparing to ESD.

**Endoscopic full thickness resection versus endoscopic submucosal dissection in colorectal neoplasia therapy – bicentric prospective randomized study**

*Stepan Suchanek, Premysl Falt, Ondrej Ngo, Nagyija Brogyuk, Renata Chloupkova, Ondrej Urban, Ondrej Majek, Miroslav Zavoral*

**EFTR + EMR as hybrid technique enables new possibilities in resection of large colorectal lesions**

W. Yuen et al. reported on the comparison of using the FTRD alone and using a hybrid EFTR + EMR technique in consecutive patients with lesions unresectable by conventional EMR alone. Many large colorectal lesions can be targeted by combining full-thickness resection (FTR) and endoscopic mucosal resection (EMR) by treating the laterally spreading components with EMR and invasive, non-lifting portions with FTR. Out of the 62 patients (total) 33 were treated with FTR alone and 29 were treated with hybrid EMR + FTR. The mean lesion size for the hybrid group was 36 mm (15-60 mm) and 19 mm (7-40 mm) for the FTR group. Technical success for FTR was achieved in 55 out of 62 patients (89 %), of which 53 (96 %) had R0 resection margins. No difference in R0 resection rate appeared when comparing hybrid FTR + EMR (23/24, 96 %) to FTR (30/31, 97 %) alone. In 2 cases adverse events occurred: one patient developed acute appendicitis and one patient suffered an inadvertent perforation.

The authors concluded that FTRD is a safe and effective method to resect large and complex colorectal lesions with high technical and clinical success rates. A hybrid EMR + FTR technique can expand the pool of resectable lesions.

**Hybrid technique using endoscopic mucosal resection and endoscopic full-thickness resection for large colorectal lesions: initial north American experience**

*William Yuen, SriHari Mahadev, Poi Yu Sofia Yuen, Kristen Koller, Ashley A. Vareedayah, Gregory B. Haber*

**FTRD is an effective and safe method for lesions in the GI tract not amenable to traditional endoscopic resection**

A. Agnihotri et al. published a systematic review and meta-analysis to assess the efficacy and safety of the endoscopic full-thickness resection device (FTRD). Only studies with more than 9 patients were searched in bibliographic databases (PubMed, Ovid, Scopus, EMBASE, Web of Science, Cochrane and Google scholar) and abstracts published in major gastroenterology conferences within the last two years were evaluated. Overall, 15 studies with 1752 patients (mean age ranged from 59.7 to 70 years; 60 % male) with the following indications were included: recurrence or incomplete resection after prior polypectomy (50.7 %), primary non-lifting adenoma (17.8 %), known intramucosal cancer (9.9 %), submucosal lesions (9.2 %) and lesions involving appendicular orifice (6.6 %). Pooled technical success was achieved in 88.3 % of cases (95 % CI: 0.86-0.89,  $I^2=0$  %) and most adverse events (overall pooled rate 12.3 %) were minor.

The authors confirmed previous study results by classifying the FTRD as effective and overall safe modality for endoscopic full-thickness resection.

**Safety and efficacy of endoscopic full-thickness resection device (FTRD) in the gastrointestinal tract: a systematic review and meta-analysis**

*Abhishek Agnihotri, Mohammad Bilal, Shailendra Singh, Laura C. Horton, Corey S. Miller, Brian Chan, Douglas K. Pleskow, Mandeep Sawhney, Tyler M. Berzin, Jonah Cohen*

**FTRD in therapy for lesions in the upper GI tract is associated with a high clinical success rate and low risk of recurrence**

K. Hajifathalian et al. presented an international multi-center retrospective study in which 56 patients from 13 centers (average age  $61 \pm 14$  years) with mesenchymal neoplasms including gastrointestinal stromal tumour (n=23, 41 %), adenomas (n=7, 13 %), and hamartomas (n=6, 11 %) were included. The average lesion size was 14 mm (range 3 to 33 mm), of which 47 (84 %) were localized in the stomach, and 8 (14 %) in the duodenum. The technical success rate with the FTRD was 93 %. In 43 patients (77 %) complete resection and in 9 patients (16 %) partial resection was achieved. R0 resection was successfully performed in 38 (68 %) cases and 12 (21 %) cases of adverse events were reported. Follow-up endoscopy of 31 cases (55 %) showed no residual or recurrent lesion in 30 patients (97 %), in one patient (3 %) residual adenoma was found.

Based on the results, the authors concluded that FTRD in the upper GI tract shows high technical success rates, as well as an acceptable risk of complication and histologically complete resection.

**Full-thickness resection device (FTRD) for treatment of upper gastrointestinal tract lesions: the first international experience**

*Kaveh Hajifathalian, Yervant Ichkhanian, Qais M. Dawod, Alexander Meining, Arthur Schmidt, nicolas glaser, Kia Vosoughi, David L. Diehl, Ian S. Grimm, Theodore W. James, Adam W. Templeton, Jason B.*

*Samarasena, Nabil E. Chehade, John Lee, Kenneth J. Chang, Meir Mizrahi, Mohammed Barawi, Shayan S. Irani, Shai Friedland, Mohammad A. Al-Haddad, Thomas E. Kowalski, George Smallfield, Gregory G. Ginsberg, Norio Fukami, Shou J. Tang, Franklin Kasmin, Martin Goetz, Stefan Seewald, Vivek Kumbhari, Saowanee Ngamruengphong, Saurabh Mukewar, Kartik Sampath, SriHari Mahadev, David L. Carr-Locke, Mouen A. Khashab, Reem Z. Sharaiha*

## **RESECT+**

### **First case-series to use LiftUp for human in-vivo study**

M. Schaefer et al. reported on the first experience with the novel agent LiftUp for submucosal injection. 10 consecutive patients (median age 74.5 years; 6 male, 4 female) with colorectal polyps  $\geq 15$  mm were included. Lesions were localized in the rectum (n=5), caecum (n=2), sigmoid (n=1), transverse colon (n=1), and ascending colon (n=1) and the median lesion size was 20.5 mm (range: 15-30 mm). To assess endoscopic resection after LiftUp injection, EMR (8 patients) or ESD (2 patients) were performed. Median volume of LiftUp was 5.25 ml (range 2-12 ml) and median procedure time was 2.25 minutes for EMR and 5.5 minutes for ESD. In all 10 cases macroscopic complete resection was achieved and the R0 resection rate was 78 % (7/9). No adverse events occurred.

The authors concluded that endoscopic resection with LiftUp is feasible, safe, and fast. However, larger studies are needed for better evaluation of efficacy and safety.

### **First human in-vivo experience with novel agent for submucosal injection (LiftUp)**

*Moritz Schaefer, Benjamin Meier, Andreas Wannhoff, Karel Caca*

## **OTSC System**

**OTSC as first-line therapy for severe non-variceal UGI hemorrhage is recommended as the treatment of choice when compared to standard endoscopic hemostasis**

D. Jensen et al. presented two randomized controlled trials (RCT) on the first-line treatment of UGIB where Doppler probe assisted (DEP) or OTSC hemostasis is compared with STANDARD endoscopic hemostasis. Individual data from the two successive RCT's were used to analyze the rates of recurrent bleeding and severe complications for patients with bleeding peptic ulcers (PUB's) or Dieulafoy's lesions (DL). 69 patients were treated with DEP, 24 with OTSC and 101 with STANDARD endoscopic treatment. All cases were randomized concerning the presence of stigmata of hemorrhage – major SRH (spurting arterial bleeding, non-bleeding visible vessel, or adherent clot) or lesser SRH (oozing bleeding or flat spot). The rates of 30-day rebleeding for OTSC were 4.17% and more than double for DEP in 10.14%. STANDARD endoscopic hemostasis had a rebleeding rate of 25.7%, which undermines the significant superiority of DEP/OTSC.

The authors concluded that regarding the higher rates of rebleeding and severe complications for the STANDARD treatment group, the DEP or OTSC are the new initial treatments of choice for severe NVUGIH from PUB's or DL's.

**What treatment to use for severe non-variceal UGI hemorrhage: STANDARD endoscopic hemostasis, Doppler guided hemostasis, or over-the-scope-clip (OTSC)?**

*Dennis M. Jensen, Thomas O. Kovacs, Rome Jutabha, Kevin A. Ghassemi, Marc Kaneshiro, Mary Ellen Jensen, Jeffrey Gornbein*

**OTSC as first-line therapy for NVUGIB is associated with lower costs and higher effectiveness in QALY when compared to standard therapy**

J. Yu et al. evaluated costs and effectiveness in quality adjusted life years (QALY) for first-line therapy of severe NVUGIB with the OTSC System, the doppler probe assisted hemostasis (DEP) and standard therapy based on two randomized controlled trials (RCT). The three therapies were compared for lesions with major SRH (spurting bleeding, visible vessel, adherent clot) and lesser SRH (oozing bleeding, flat spot). 98 % of lesions included in the study were peptic ulcer disease (PUB) or Dieulafoy’s (DL), while 2 % were Mallory Weiss tears. Cost research included procedure and hospitalization costs, as well as equipment costs. QALY was evaluated based on literature review. Analysis revealed that for high risk-stigmata OTSC costs less and shows better effectiveness in QALY results. Main reason for this is, that due to low rebleeding rates, fewer reinterventions are necessary. For lesser risk stigmata, DEP and OTSC showed same effectiveness in QALY, while DEP therapy (\$6147) costs \$18 less than OTSC (\$6165). Standard therapy had higher costs and lower QALY rates when compared to OTSC/DEP for both stigmata.

The authors concluded that the OTSC System is the therapy of choice for severe NVUGIB, especially for high-risk stigmata. For lesser-risk stigmata, DEP is preferred as it has a small advantage in cost-effectiveness.

**Clipping over the-scope is cost effective for first line therapy of severe non-variceal UGI bleeding lesions with major stigmata**

*Jessica X. Yu, W A. Russell, Dennis M. Jensen, Roy M. Soetikno*

**OTSC application is a valuable tool as part of combination of endoscopic and cystoscopic treatment for closure of colovesicular fistula**

S. Siegal et al. reported on a male patient with diverticulitis presented with fecaluria, pneumaturia and urine per rectum and who was unable to undergo surgery. The workup revealed a colovesicular fistula which was treated with a combined approach of endoscopic and cystoscopic closure. For an easier fistula tract identification, initial cystoscopy was performed. Wire access through the bladder was placed to guide the therapeutic endoscope to the fistula in an endoscopic rendezvous maneuver. After successful deployment of the over-the-scope clip, the bladder mucosa was ablated by cystoscopic laser. Fluoroscopy showed that complete closure of the fistula was achieved.

The authors summarized that combined endoscopic and cystoscopic maneuvers are safe and reliable and are useful for patients to avoid surgical procedures.

**Combined endoscopic and cystoscopic closure of colovesicular fistula**

*Steve R. Siegal, John Knoedler, Jeffrey S. Scow, Eric Pauli*

**OTSC is an effective alternative with high success rates to surgical intervention for the management of non-acute, full-thickness gastrointestinal defects**

D. Morrell et al. published a systematic review and meta-analysis to investigate the use of OTSC for non-acute full-thickness gastrointestinal defects (FTGID). Databank research including MEDLINE and the Cochrane Library was performed for 43 studies in which the OTSC system was the primary treatment modality. These data were analyzed using a general variance-based approach and successful management was defined as radiologic

or clinical evidence of complete defect closure after conclusion of the follow-up period. 691 patients, of which most had gastrocutaneous fistulae (74), enterocutaneous fistulae (45), gastrogastic fistulae (39), and gastric sleeve leaks (29) were evaluated. The pooled success rate for OTSC treated full-thickness GI defects was 67 % (95 % CI: 59-75 %). Analysis of subgroup studies of fistulas (n=410) and leaks (n=210) showed 52 % and 77 % pooled success.

As conclusion, the authors see the OTSC as promising endoscopic treatment modality for non-acute GI defects. High rates of successful management as well as high effectiveness is expected when using the OTSC for defects usually treated with potentially morbid surgical interventions.

**Over-the-scope clip management of non-acute, full-thickness gastrointestinal defects: a systematic review and meta-analysis**

*David Morrell, Christopher Hollenbeak, Eric Pauli*

**OTSC is a safe endoscopic method for hemostasis in acute variceal bleeding especially as a rescue treatment\***

G. Sirin et al. presented a study to evaluate the use of the OTSC System as first-line treatment or rescue therapy for endoscopic hemostasis in patients with severe variceal bleeding. Out of 21 consecutive patients (14 male) with a mean age of 38, 14 patients (rescue treatment group) had previously been treated unsuccessfully with conventional endoscopic methods and 7 patients (first-line therapy group) have not had endoscopic treatment before. In the rescue treatment group, 5 patients had anastomotic varices, 5 had fibrotic esophageal varices, and 4 had fundal varices. In first-line therapy group, 2 patients had anastomotic varices, 2 had fibrotic esophageal

varices and 3 had fundal varices. Immediate hemostasis was achieved in all patients. Three patients with fundal varices suffered rebleeding, 2 in primary hemostasis group, and 1 in rescue therapy group, which could be treated successfully with synthetic glue injection. No adverse events related to OTSC application occurred.

The authors concluded that the OTSC seems to be a safe and useful method for hemostasis in acute variceal bleeding, especially as rescue treatment.

*\*Note: Usage of the OTSC System Set is contraindicated for the treatment of bleedings of esophageal varices.*

**Is over-the-scope-clip an effective rescue therapy for serious variceal bleeding?**

*Goktug Sirin, Ali Erkan Duman, Hasan Yilmaz, Altay Celebi, Sadettin Huelague*

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