Conference Report

50th Digestive Disease Week – DDW 2019

May 18 – 21, 2019
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Ovesco products were presented in talks, posters, state-of-the-art-lectures and debates.

National and international multicenter studies confirm that the FTRD® allows for fast, safe, and effective resection of difficult colorectal and upper GI lesions

FTRD® System

U.S. multicenter FTRD study shows R0 resection rate of 79 % in patients with difficult colonic lesions

Y. Ichkhanian et al., Baltimore, Maryland, USA, performed a retrospective study at 26 U.S. tertiary-care centers assessing feasibility, efficacy and safety of the FTRD for the resection of colonic lesions. Patients who underwent EFTR using the FTRD for lower GI lesions between 10/17 and 01/19 were included. Outcomes were technical success (defined as en-bloc resection) and R0 histologic margin. Chi square test was used to assess the association between lesion type, size, and location with the two outcomes.
A total of 95 patients (mean age 65.5 years, 38.9 % female) underwent resection of colonic lesions using the FTRD. Inclusion criteria were the following lesions of the lower gastrointestinal tract: difficult adenomas (defined as non-lifting, recurrent, residual or involving appendiceal orifice/ diverticular opening) (n=63), low-risk adenocarcinomas (n=21), and sub-epithelial tumors (n=11). Lesion location was in the proximal colon in 58 (61 %) patients, followed by distal colon in 17 (18 %), and rectum in 20 (21 %). 65 patients (70 %) received propofol sedation, 21 patients (23 %) received general anesthesia. Prophylactic antibiotics were used in 32 patients (33.8 %). Mean pre-resection lesion diameter and total procedure time were 15.5 ± 6.4 mm (range 3-30 mm) and 59.7 ± 31.8 min, respectively. 71 patients (76.3 %) were discharged post-procedurally. Technical success was achieved in 80 (84.2 %) patients. R0 resection was achieved in 75 patients (79 %). A total of 5 (5.3 %) adverse events occurred, 3 AEs were mild (3.6 %) (1 minor bleeding and 2 iatrogenic strictures), and 2 AEs (2.1 %) were severe (1 appendicitis, 1 perforation).
The authors concluded that EFTR is a feasible, safe and effective technique for EFTR of difficult colonic lesions. Surgical management can be avoided in the vast majority of cases.

Non-exposure full-thickness resection of colonic lesions in the U.S.: The FTRD experience.
Ichkhanian Y[1], Vosoughi K[1], Sharaiha RZ[2], Hajifathalian K[2], Tokar JL[3], Templeton AW[4], James TW[5], Grimm IS[5], Mizrahi M[6], Samarasena JB[7], Chahade NEH[7], Lee J[7], Chang KJ[7], Barawi M[8], Irani SS[9], Friedland S[10], Korc P[11], Aziz AAdam A[12], Al-Haddad MA[13], Kowalski TE[14], Novikov AA[14], Diehl DL[15], Smallfield G[16], Ginsberg GG[17], Oza V[18], Pannu D[18], Fukami N[19], Pohl H[20], Lajin M[21], Kumta NA[22], Tang SJ[23], Amateau SK[24], Ngamruengphong S[1], Kumbhari V[1], Brewer Gutierrez OI[1], Khashab MA[1].
[1]Baltimore, [2]New York, [3]Philadelphia, [4]Seattle, [5]Chapel Hill, [6]South Alabama, [7]Orange, [8]Detroit, [9]Indianapolis, [10]Stanford, [11]Newport Beach, [12]Chicago, [13]Indianapolis, [14]Philadelphia, [15]Danville, [16]Richmond, [17]Philadelphia, [18]Florence, [19]Scottsdale, [20]New York, [21]Michigan, [22]New York, [23]Jckson, [24]Minneapolis

EFTR of colonic lesions with evidence of adenocarcinoma allows exact histological risk stratification and avoidance of surgery in low-risk lesions

A. Küllmer et al., University of Freiburg, Freiburg, Germany, presented a retrospective study at 96 German centers which evaluated EFTR with the FTRD for risk stratification of early colorectal cancer. 156 patients with evidence of adenocarcinoma were included. 64 patients underwent EFTR after incomplete resection of a malignant polyp (group 1) and 92 patients had non-lifting lesions.
Technical success was achieved in 144/156 (92.3 %), mean procedural time was 42 minutes. R0 resection was achieved in 112/156 (71,8 %). Subgroup analysis showed a R0 resection rate of 87.5 % in Group 1 and 60,9 % in

Group 2 (p<0.001). Severe procedure-related adverse events were recorded in 3,9 %. Discrimination between high- vs. low-risk tumor was successful in 155/156 cases (99.3 %). 84,1 % of Group 1 were identified as low-risk lesions, whereas 16,3 % in group 2 had low-risk features. In total 53 patients (34 %) underwent oncologic resection due to high risk features whereas 98 patients (62 %) were followed endoscopically.
The authors concluded that EFTR in early colorectal cancer is technically feasible and safe. It allows exact histological risk stratification to avoid surgery for low-risk lesions.

Endoscopic full-thickness resection in colorectal cancer. experience.
Küllmer A[1], Mueller J[1], Caca K[2], Aepli P[3],Dakkak D[4], Schumacher B[4], Glitsch A[5], Schäfer C[6], Wallstabe I[7], Hofmann C[8], Erhardt A[9], Meier B[2], Bettinger D[1], Thimme R[1], Schmidt A[1]
[1]Freiburg, [2]Ludwigsburg, [3]Luzern, [4]Essen, [5]Greifswald, [6]Neumarkt, [7]Leipzig, [8]Mainz, [9]Wuppertal

EFTR with the FTRD is a fast, safe and effective option for rectal neuroendocrine tumors

B. Meier et al., Ludwigsburg hospital, Ludwigsburg, Germany, presented a study evaluating FTRD resection of rectal neuroendocrine tumors (NET). Rectal NET are subepithelial tumors with potential for malignancy. Prevalence is rare but increasing over the last decades.
Between 09/2015 and 05/2017, data of 40 cases of rectal NET were collected. Lesions were located in the lower (13/40), middle (24/40) and upper (3/40) rectum and had a median size of 8 mm (SD 4.43, range 3-25 mm). In 15 % (6/40) rectal NET were reported as recurrent NET.
All lesions could be reached and resected with FTRD. The median procedure time was 18.5 minutes (range 7-60 min). All lesions could be resected macroscopically and histologically complete. Histology after EFTR showed low-grade NET (G1) without lymphovascular infiltration (L0, V0) and without other risk factors in 70 % (28/40). In 30 % (12/40) histology revealed granulation tissue or scarring. Procedure-related adverse events were observed in 12.5 % (5/40). In four cases (10 %) minor periprocedural bleeding was observed and managed endoscopically (coagulation and/or injection). In one case (2.5 %) a technical problem was observed (rupture of the FTRD snare). Endoscopic follow-up was available in 80 % (32/40) and conducted after a median time of twelve weeks (range 1-49 weeks) after resection. In 72 % (23/32) the OTSC had spontaneously detached and in 28 % (9/32) the clip was still in situ. No evidence of a residual or recurrent lesion could be found.
The authors concluded that EFTR with the FTRD is a fast, safe and effective option for rectal NET < 20 mm. IT should be considered as first-line therapy for rectal NET < 20 mm without risk factors.

Full thickness resection of neuroendocrine tumors in the rectum.
Meier B[1], Albrecht H[2], Wiedbrauck TH[3], Schmidt A[4], Caca K[1]
[1]Ludwigsburg, [2]Neumarkt, [3]Duisburg, [4]Freiburg

86 % R0 resection rate achieved in large colorectal lesions resected with FTRD alone or hybrid technique

A. Vareedayah et al., NYU Langone Health, New York, New York, USA, performed a retrospective study on consecutive patients treated with the FTRD device at 9 North American centers. A total of 64 patients was included. The primary indication for EFTR was non-lifting adenoma (37 patients, 58 %). Other indications included suspected high-grade dysplasia/cancer, lesions in the appendiceal orifice and subepithelial lesions. The mean size of the resected lesions was 24 mm. The FTRD could not be advanced to the lesion in 4 patients. 56/60 lesions (93 %) were successfully removed by FTRD alone (when <2 cm) or a combination of FTRD and EMR (when >2 cm). R0 (including clear vertical margin for hybrid procedures) was achieved in 48/56 patients (86 %). Complications occurred in 3 patients. Perforation in one patient was treated endoscopically. Rectal bleeding in one patient did not require intervention. One patient required surgery for appendicitis 72 h after the procedure.
The authors concluded that EFTR is a safe and effective method for resection of large colorectal lesions.

Initial north American experience with endoscopic full-thickness resection of colorectal lesions: a multicenter retrospective cohort study.
Vareedayah A[1], Yuen PYS[1], Skinner M[1], Koller K[1], Alkaade S[2], Diehl DL[3], Al-Haddad MA[4], Templeton AW[5], Hwang JH[6], Stavropoulos SN[1], Cohen J[1], Mendoza Ladd AH[7], Grajales-Figueroa G[8], Mahadev S[9], Haber GB[1]
[1]New York, [2]St. Louis, [3]Danville, [4]Indianapolis, [5]Seattle, [6]Redwood City, [7]El Paso, [8]Mexico City, [9]New York

First international experience of FTRD application in the upper GI tract shows high technical and clinical success rates

K. Hajifathalian et al., Cornell, NYC, New York, United States, presented an international multicenter retrospective study including patients who had an endoscopic resection of an upper GI tract lesion using the FTRD System between 08/2017 and 11/2018. 54 patients from 11 centers with endoscopic resection of an upper GI tract lesion using FTRD were included. The most common lesions were mesenchymal neoplasms (n=22), followed by ectopic pancreas or scar tissue (n=12), adenomatous polyps (n=7), hamartomatous polyps (n=6), adenoma with high-grade dysplasia or adenocarcinoma (n=3), carcinoid tumor (n=3), and hyperplastic polyp (n=1). 1 lesion was located in the esophagus, 10 in the cardia/fundus, 15 in the stomach body, 20 in the antrum, and 8 in the duodenum. The average size of lesions was 14 mm (SD 8 mm). Deployment of FTRD was technically successful in 92 % of the patients (n=50) leading to complete and partial resection of the target lesion in 41 (76 %) and 9 (16 %) patients, respectively. Histological margin of resection was reported in 47 patients, and in these FTRD led to R0 resection in 74 %(n=35), R1 resection in 21 % (n=10), and Rx in 4 % (n=2). Thus a R0 resection could be achieved in 35 patients (65 %) out of the 54 patients the procedure was attempted. Out of 4 patients with adenoma with high-grade dysplasia or adenocarcinoma, 3 had an R0 resection. FTRD was complicated by intra-procedural minor bleeding in 5 patients (11 %) and major bleeding in 4 patients (9 %), all of which were controlled endoscopically. 9 patients (17 %) were taking antithrombotic medication at the time of the procedure. Previous biopsy or attempted resection by hot snare, EMR or ESD had been performed in 32 patients (59 %).
The authors concluded that these results suggest a high technical and clinical success rate with low risk of early recurrence and an acceptable complication rate for FTRD in the upper GI tract.

Full-thickness resection device (FTRD) for treatment of upper gastrointestinal tract lesions: the first international experience.
Hajifathalian K[1], Dawod QM[1], Issa D[1], Meining A[3], Schmidt A[4], Vosoughi K[2], Ichkhanian Y[2], Ngamruengphong S[2], Kumbhari V[2], Samarasena JB[5], El Hage Chehade N[5], Tang SJ[6], Kasmin F[7], Templeton AW[8], Fukami N[9], Goetz M[10], Sampath K[1], Glaser N[4], Mahadev SH[1], Mukewar S[1], Call-Locke DL[1], Hwang JH[11], Sharaiha RZ[1], Khashab MA[2]
[1]New York City, [2]Baltimore, [3]Ulm, [4]Freiburg, [5]Irvine, [6]Jackson, [7]New York City, [8]Seattle, [9]Scottsdale, [10]Tuebingen, [11]Stanford

Hybrid EMR-EFTR is associated with 76 % negative vertical margins and low complication rate

P.Y.S. Yuen et al. presented a comparative study, comparing consecutive patients treated with hybrid EMR-EFTR due to large colorectal lesions (n=17) with patients who underwent EFTR alone due to colorectal lesions (n=14). Mean lesion size in the EFTR group was 16.8 mm, mean lesion size in the hybrid group was 33.6 mm. Mean procedure time was 67 minutes in the EFTR group and 100 minutes in the hybrid group. Histology confirmed R0 resection in 93 % (13/14 patients) in the EFTR group and negative vertical margins in 76 % (13/17 patients) of lesions in the hybrid group. Two of four in the hybrid group with positive vertical margins were due to technical difficulty (snare malfunction and lesion not entrapped by snare) and subsequently removed with EMR. Complications were relatively scarce. In one patient the snare was inadvertently closed, with tissue resection prior to clip deployment resulting in a wall defect. One patient, who did not take the antibiotic medication as prescribed, developed appendicitis, which required surgery 72 hours after the procedure. The authors concluded that Hybrid EMR-EFTR for colorectal lesions is a safe and effective method for resection of lesions that are otherwise too large for EFTR alone. There were no adverse events related to deployment of the clip into tissue with EMR defect. This approach is an alternative to ESD or surgery.

A novel hybrid technique using endoscopic mucosal resection (EMR) and endoscopic full-thickness resection (EFTR) for large colorectal neoplasms unresectable by EMR alone
Yuen PYS1, Vareedayah AA[1], Skinner M[1], Hoerter NA[1], Koller K[1], Mahadev SH[2], Haber GB[1]
[1,2]New York City

OTSC treatment of high-risk peptic ulcer bleeding is proven to be safe, effective and cost-effective when compared to standard treatment

OTSC® System

Treatment of recurrent peptic ulcer bleeding with the OTSC is associated with on average $2160 savings per patient when compared to standard TTS clipping

J. X. Yu et al., University of Michigan, Ann Arbor, Michigan, USA, presented a study evaluating the cost-effectiveness of OTSC clips as compared to through-the-scope clips. A decision tree was used to model the costs, effectiveness (quality-adjusted life years) and rates of persistent/recurrent bleeding were compared in OTSC versus standard therapy for the treatment of peptic ulcer bleeding. The costs were estimated based on 2016 CMS reimbursement rates. Cost-effectiveness of the modalities was determined by the incremental cost-effectiveness ratio. The initial procedure cost was estimated to be the cost of an EGD with hemostasis and the cost of either an OTSC or 2 TTS was estimated using actual costs from a large health care system in the US. The authors assumed that the patients who were successfully treated incurred the cost of an admission for gastrointestinal bleeding with less than major comorbidity or complication. Patients who did not have clinical success with either the OTSC or standard therapy would incur the cost of an admission for gastrointestinal bleeding with major comorbidity or complication. The primary outcome of interest was the total cost. Sensitivity analyses were performed to ensure the robustness of the results.
The total cost to treat a patient with recurrent bleeding was $8368.56 using the over the scope clip and $10,528.55 using TTS. Thus, the use of OTSC clips, on average, resulted in $2160.00 savings per patient. The findings can be regarded as robust as sensitivity analyses showed that OTSC remains cost effective if the rate of further bleeding after OTSC remains lower than 55 % or remains higher than 17 % with standard therapy using TTS clips.
The authors concluded that a strategy to treat recurrent peptic ulcer bleeding using the OTSC is associated with both a higher efficacy and a lower cost. Gastroenterologists should consider using the over the scope clip rather than standard therapy when the risk of rebleeding after standard therapy is higher than 55 %.

Over the scope clips for recurrent peptic ulcer bleeding is cost effective as compared to the through the scope clips

Yu J X[1], Kaltenbach T R[2], Keyes E[2], Soetniko R M[2]
[1]Ann Arbor, [2]San Francisco

State-of-the-art lecture on the OTSC for severe upper GI bleeding

J. Hochberger, Vivantes hospital Friedrichshain, Academic Teaching Hospital of Humboldt University Charité, Berlin, Germany, held a state-of-the-art lecture on the OTSC treatment of severe upper GI bleeding. The OTSC is a Nitinol macro clip which provides controlled mechanical tissue compression. It has the working principle of a surgical stapler, therefore, tissue perfusion is preserved after clip application. The application of the clip is easy and similar to a band ligation device. The lesion is targeted, the OTSC cap is brought in connection to the tissue, the target tissue is suctioned into the cap and the OTSC clip is released by turning the hand wheel. In acute bleeding, suction is often enough to pull the target tissue into the application cap. For fibrotic tissue or tangential application, a forceps or OTSC Anchor can be used for transferring the target tissue into the cap. For this maneuver, the OTSC Anchor is positioned and tissue is fixated with the anchor, the OTSC cap is aligned to the lesion by pulling the Anchor and advancing the endoscope. Thereby, the tip of the OTSC Anchor can be mobilized into the cap, the anchor spikes may remain external. In the next step, the clip is released. After clip application the OTSC Anchor is detached from the tissue. The OTSC bench data was collected on hemostasis (GIE 2012; 75: 152-9). OTSC showed a persistent pressure increase after application in comparison to the sloping pressure curve achieved with conventional clips. With OTSCs, a significantly lower number of clips was needed for effective hemostasis and a significantly shorter time to effective hemostasis was needed with OTSC vs 2 TTS clips. In summary, the OTSC is easy to apply, application is fast, one single OTSC is sufficient in most cases. The OTSC provides a strong and reliable mechanical closure with maintained tissue perfusion. Early clip loss is rare with OTSC. Its special clinical strength are chronic peptic ulcers with fibrotic base. Limitations for the OTSC are rare, application is limited when access to the bleeding vessel with the OTSC and clip housing is insufficient. This can be the case when there is a stenosis between endoscope and target area, then prior dilation is necessary. Another reason for insufficient access is a lateral position of the bleeding source, in this case, traction into the housing is

necessary, use with a side viewing endoscope is not possible. Another limitation for OTSC application is diffuse tumor bleeding, in such a case, spray, injection and multiple conventional clips must be used.

Different types of over-the-scope clips have been developed. The OTSC t has teeth with small spikes, it provides compression plus anchoring. The OTSC a has round teeth, it provides mainly compression. The OTSC gc has prolonged teeth with spikes for gastric wall closure. There are three different hood sizes (8,5-11 mm, 10,5-12 mm, 11.5--14 mm) and 2 different cap depths (3 mm and 6 mm) on the market. The OTSC t (traumatic) is used for stomach and chronic duodenal ulcers at the level of the bulb. The OTSC a (atraumatic) is used for the small intestine and colon parts with thin wall.

Recent studies with the OTSC are

- A Meta-Analysis of 20 studies (n = 510 patients) regarding OTSC hemostasis showing a high technical and clinical success rate of 93.0 % and 87.5 % (Weiland T et al., MinInvTh 2019)
- The multicenter FLETRock trial (n=118) of the OTSC as first line therapy revealing a total success rate of 92.5 %. The re-bleeding rate and re-bleeding associated mortality determined in comparison to the prognostic Rockal score was significantly reduced (Wedi E et al., Surg.End. 2018)
- The randomized controlled STING trial (n=66) proving that OTSC clipping is significantly superior to former standard therapy techniques in the treatment of severe recurrent UGIB (Schmidt A et al., Gastro 2018)
- A large multicenter cohort study (n=286) on OTSC first-line treatment revealing superior technical and clinical success rates of 97.9 % and 96.4 % (Manta R et al., End Int open 2018).

In conclusion, the OTSC should be used as primary tool in all high-risk patients (Rockal 7 +), high-risk defined e.g. for patients under anticoagulation, for patients with hemoglobin < 10, for patients with cirrhosis and ulcer bleeding, for patients with a spurting ulcer that can easily be faced with an OTSC, and for patients with ulcers with sclerosed ulcer base. Besides, the OTSC should be used in all re-bleeders, if the lesion can be reached with OTSC and clip housing.

Over-the-scope clip for severe upper GI-bleeding – Time for a change in practice?

Hochberger J[1], Wedi E[2]
[1]Berlin, [2]Göttingen

The OTSC as first-line single therapy is as safe and effective as combined therapy for the management of high-risk bleeding peptic ulcers

C. Robles-Medranda et al., Guayaquil, Guayas, Ecuador, reported on an analysis of data on consecutive patients who presented with high-risk ulcer GI bleeding between 05/2014 and 09/2018. High-risk upper GI bleeding was considered as those ulcers located in a major arterial territory, if the lesion had an endoscopically visible large-caliber artery (>2 mm), if there was a fibrotic ulcer with high-risk endoscopic stigmata (Forrest classification types I and II).
95 patients were included, 46 received an OTSC as primary therapy for HR bleeding ulcers and 49 matched cases received TTS hemostatic clips in combination with epinephrine injection (combined therapy). The mean age was 60.9 ± 19.1, 32.6 % female. Most lesions were gastric ulcers (71.6 %). The median number of OTSC used was 1 (1-3), whereas for combined therapy was 2 (1-8) TTS clips. Six cases of rebleeding (6.3 %) were observed: two in the OTSC group and four in the combined therapy group (p=0.444). Two cases of the OTSC group (4.3 %) had rebleeding after 48 hours of the procedure; meanwhile, one case of rebleeding was observed in the combined therapy group at the same period and was treated with APC (p=0.520). Three cases in the combined therapy group had rebleeding in less than 48 hours after the procedure (p=0.088), two treated with an OTSC and one with APC. The median procedure time was 11 (10-15) mins for OTSC and 20 (15-40) for combined therapy (p<.001).
The authors concluded that the OTSC as first-line single therapy is as safe and effective as combined therapy for the management of high-risk bleeding peptic ulcers; improving the procedure time.

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[1], Alcivar-Vasquez JM[1], Baquerizo-Burgos ROJ[1], Ignacio Olmos J[1], Rubio-Cordova M[1], Pitanga Lukashok H[1]
[1]Guayaquil, Guayas, Ecuador

The OTSC is more effective in obliterating arterial blood flow in severe NVUGIB than standard visually guided endoscopic hemostasis

D.M. Jensen et al., David Geffen School of Medicine at UCLA, Santa Monica, California, USA, held a state-of-the-art lecture on the treatment of patients with severe non-variceal upper gastrointestinal bleeding (NVUGIB). Recurrent NVUGIB after standard visually guided endoscopic hemostasis is common in high-risk patients. A recent randomized controlled trial (Gastro 2017; 152:1310-18) found the 30-day rebleeding rate to be 26.3 % (20/76) with visually applied MPEC and/or standard hemoclips with or without epinephrine. The rebleeding rate was reduced to 11.1 % (8/72) when blood flow was monitored with Doppler endoscopic probe (DEP) and used as a guide for hemostasis. However, when residual arterial blood flow was not obliterated, the rebleeding rate was very high – 88.8 % (8/9 patients). D.M. Jensen et al performed a prospective cohort study with OTSC in 20 patients with severe NVUGIB as primary hemostasis with DEP monitoring before and after hemostasis. 19 patients had bleeding peptic ulcers (12 duodenal, 7 gastric) and 1 Dieulafoys lesion. Results were compared to previously studied patients from the Gastro RCT and to results of a cohort study of DEP in patients with peptic ulcer bleeding before and after visually guided hemostasis (GIE 2016; 83: 129-36).

Residual arterial blood flow detection after OTSC and DEP guided complete hemostasis were similar (5 % - 1/20 vs. 0 % - 0/63 respectively) but were significantly lower than standard visually guided therapy – 24.2 % (23/95) in the cohort study. Low 30 day rebleeding rates were seen after OTSC or successful DEP hemostasis (5 % - 1/20 vs. 0 % - 0/63 respectively) which were significantly lower than standard visually guided hemostasis – 26.3 % (20/76) in the Gastro RCT. Compared to standard through the scope hemoclips, the OTSC was able to imbed in fibrotic based chronic ulcers, grasp a greater volume of tissue with the stigmata of hemorrhage in the center, and more effectively obliterate blood flow underneath NVUGI lesions.

The authors concluded that OTSC was more effective in obliterating arterial blood flow in severe NVUGIB lesions than standard visually guided endoscopic hemostasis. Residual arterial blood flow highly correlated with lesion rebleeding rates. The OTSC as primary treatment of NVUGIB lesions has the potential of significantly reducing rebleeding rates compared to other, standard visually guided hemostasis techniques. A new RCT has been planned by the study group to compare OTSC with standard hemostasis in patients with severe NVUGIB.

Why over-the-scope clip is potentially more effective than standard endoscopic hemostasis as primary treatment of severe non-variceal upper gastrointestinal bleeding

Jensen DM[2,1,3], Kovacs TO[2,1], Ghassemi KA[2,1], Kaneshiro M[2,1], Dulai G[2,1], Machicado GA[2,1]
[1]Santa Monica, [2]Los Angeles, [3]Los Angeles, CA, USA

Case control study shows decreased rebleeding rates with OTSC in high-risk peptic ulcer bleeding when compared to conventional endoscopic treatment

G. Ermerak et al., Liverpool Hospital, Sydney, Australia, presented a case control study comparing patient outcomes including risk of re-bleeding and mortality in patients with bleeding peptic ulcer disease (PUD) undergoing conventional endoscopic intervention versus OTSC application at initial endoscopy.
16 cases of bleeding PUD managed with primary OTSC application over a period of 2 years were identified from a prospectively maintained database of GI bleeding at a large tertiary center. Age and sex matched controls undergoing endoscopic intervention with conventional hemostatic treatment were used from the same database. Indications for primary OTSC use included a bleeding vessel >4mm (n=12), concurrent dual antiplatelet or anticoagulant use (n=3), likely concurrent perforation (n=2), difficult access to the bleeding site (n=1) or failure of other interventions at the initial endoscopy (n=1). Cases treated with OTSC were more likely to be hospital inpatients (12 vs 4, P=0.005), hypotensive (Median SBP 100 vs 118, P=0.04), tachycardic (Median HR 101 vs 95, P=0.02) and have a greater proportion of Forrest I lesions (12 vs 4). There was a trend towards decreased re-bleeding within 30 days in the OTSC group (1 vs 5, P=0.07). The OTSC rebleed case required angioembolisation. All control rebleeds were managed endoscopically. 1 had OTSC salvage therapy. 30-day readmission, angioembolisation or mortality were not significantly different between the two groups.

The authors concluded that despite the presence of more high risk features the patients treated with primary OTSC application in this series had a trend towards reduced rebleeding rates and similar other outcomes when compared to conventional endoscopic therapy.

Over the Scope Clips for primary therapy of bleeding upper gastrointestinal ulcers: a retrospective case control study

Ermerak GG[1], Behary J[2], Koo JH[1,3], Levy MT[1,3], Abi-Hanna D[1], Edwards PD[1], Bassan MS[1,3]
[1,2,3] Sydney, Australia

After OTSC closure of iatrogenic colonic perforations only 7.5 % of patients required surgical intervention

D. Horenkamp-Sonntag et al., Technicians' Health Insurance, Hamburg, Germany, performed a nationwide evaluation of the use of OTSC in the colon in hospital reality using administrative codes in a large health insurance data base with about 10 Mio insured patients. OTSC in the colon was administered in 500 patients (mean age 66 years, 61 % males) in 212 hospitals. Application in combination with polypectomy was the predominant indication (62.2 %) whereas perforation during colonoscopy (16.0 %) and colonic bleeding (9.8 %) were less common indications. Various clinical settings (e. g. closure of anastomotic leaks, fistulas etc.) were applied in 12.0 % of patients. After closure of iatrogenic perforations by OTSC, only 7.5 % of cases required early surgical intervention. Operative procedures beyond 30 days after OTSC application were predominantly due to underlying diseases (colorectal cancer, diverticulitis etc.).

The authors concluded that OTSC application in the colon is predominantly employed in the context of polypectomy and iatrogenic perforations. OTSC use seems to be safe also in the colon, and in the case of iatrogenic perforation, use of OTSC is an attractive alternative to surgical closure.

Efficacy and safety of over-the-scope clips (OTSC) application in the colon: evidence generated from administrative data for an innovative endoscopic procedure
Horenkamp-Sonntag D[1], Liebentraut J[1], Engel S[1], Koop H[2]
[1]Hamburg, [2]Berlin

Successful closure of PEG-related fistula achieved with OTSC

M. A. Al Samman et al., Alpert Medical School of Brown University, Providence, Rhode Island, United States, presented a case of an elderly patient with a non-healing draining fistula from previous feeding tube placement. The 86-year-old female patient was a high-risk surgical candidate, therefore, endoscopic closure of the fistula using an OTSC was planned. OTSC placement was performed uneventful and resulted in immediate closure of the fistula. Follow-up for several months did not reveal any further leak.

A new scope for the management of gastrocutaneous fistulas using over the scope clips
Al Samman MA[1], Gao T[1], Feller E[1], Shah SA[1]
[1]Providence, Rhode Island, USA

Experimental study suggests that the OTSC is feasible for duodenal C-SEMS fixation

Migration of duodenal covered self-expandable metallic stents (C-SEMS) is the main cause of stent dysfunction in patients with malignant gastric outlet obstruction. The ideal method to prevent migration has not been clarified. Y. Hori et al., Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan, evaluated over-the-scope clip, suture and clip methods for fixation of duodenal C-SEMS based on pathological findings. Gripping force of each device and invasion depth were assessed. The OTSC and suturing systems had a significantly higher mean gripping force compared with the clipping system (OTSC vs clip: 13.2 vs 1.0 N, $p < 0.001$; suture vs clip: 8.5 vs 1.0 N, $p < 0.001$). OTSC compression was stronger when compared with suturing (OTSC vs suture: 13.2 vs 8.5 N, $p= 0.006$). The submucosal layer, but not the muscle layer, was compressed more widely and deeply by OTSC compared with clips based on pathological findings by hematoxylin and eosin staining. The authors concluded that both OTSC and suturing methods used for duodenal C-SEMS fixation were feasible compared with the clipping method. The pathological evaluation of invasion depth indicated that OTSC may be safe even for preventive use. The study suggests that these methods can be applied clinically for duodenal C-SEMS fixation.

Feasibility and safety of duodenal covered self-expandable metallic stent fixation
Hori Y[1], Hayashi K[1], Naitoh I[1]
[1]Nagoya, Japan

New demilune shaped device (Coag Dissector) for ESD allows for rapid and safe dissection

H. Neumann et al., University Medical Center Mainz, Mainz, Germany, presented a study evaluating the efficacy and learning curve of a newly developed demilune shaped device for endoscopic submucosal dissection (ESD). The demilune device allows for fast submucosal cutting due to its special design which allows rapid movements above the muscle layer. In addition, the device allows for selective grasping of the vessels thereby enabling ad hoc hemostasis. Ex vivo porcine models were utilized in an advanced endoscopic simulator of interventional endoscopy. Artificial lesions, each 2x2 cm, were created at the fundus, corpus and antrum. ESD was performed after marking of the lesions with the ESD instrument, followed by lifting of the mucosa with submucosal injection of colored saline. Afterwards, circular incision of the lesions was performed with the new ESD instrument. For resection, the submucosa was lifted with a distal clear cap and cut with the new Demilune device. Resection specimens were retrieved to evaluate if all marks were included (R0). Average size of the removed lesions was 30 mm. En-bloc resection rate was 100 % and R0 resection rate was 95 %. Mean total procedure time was 25 minutes and not dependent on the location. No perforations occurred despite the rapid dissection speed through the submucosa. Satisfaction of the endoscopist and the supporting nurse staff was high through all cases.
The authors concluded that the new demilune shaped device for ESD allows for rapid and safe dissection of the submucosa due to its inherent design. Further studies are now focusing on in vivo studies to confirm these initial results.

Evaluation of a new demilune shaped device for endoscopic submucosal dissection
Neumann H[1], Grimminger PP[2], Zimmermann T[1], Thieringer F[1], Rahman KF[1], Galle PR[1], Kneist W[2]
[1,2]Mainz, Germany

EMR+ allows for fast enbloc resection of lesions up to 30 mm

B. Meier and K. Caca, Ludwigsburg Hospital, Ludwigsburg, Germany, reported on the ex-vivo and later in-vivo evaluation of the EMR+ technique in pigs' stomachs. The stomachs were adjusted in a special simulation model (EASIE R) to be accessible to endoscopy. Imaginary lesions were created with a template (circular, 30 mm) by coagulation. An additional working channel (AWC) was mounted on a gastroscope and used for a resection snare. The conventional working channel of the scope was used for an anchor device. For submucosal injection the LiftUp agent was used. After injection, the anchor device was used simultaneously with the snare to facilitate resection. 22 resections were performed and evaluated ex vivo, 13 resections were performed in vivo. Ex-vivo results were the following: Median size of enbloc resection specimen was 30 x 26 x 11 mm. Median procedure time (time from injection to extraction of the resection specimen) was 7 minutes. No perforations occurred. In-vivo results were the following: Median size of enbloc resection specimen was 35 x 35 x 11 mm. Median procedure time was 5 minutes. 92.3 % (12/13) of lesions could be resected macroscopically complete. No major adverse events were observed. In one case (7.3 %) a minor periinterventional bleeding occurred and was managed by coagulation. The authors concluded that EMR+ allows for fast enbloc resection of lesions up to 30 mm. The technique needs to be further evaluated in vivo and in actual mucosal neoplasia.

A novel technique for endoscopic enbloc resection for lesions up to 30 mm (EMR+)
Meier B[1], Caca K[1]
[1]Ludwigsburg, Germany

For further information: ovesco Endoscopy AG
Friedrich-Miescher-Strasse 9
72076 Tuebingen
Germany
science@ovesco.com