Conference report

Clinical presentations at German Congress on Visceral Medicine confirm efficacy of OTSC clipping and show clinical data on novel Ovesco products FTRD and remOVE

Leipzig, September 17–20, 2014. The 69th annual congress of the German society for gastroenterology, digestive and metabolic diseases, DGVS, was held under the presidency of Prof. Dr. med. Peter R. Galle.

A significant number of presentations provided clinical data on OTSC clipping and confirmed clinical efficacy and safety in the primary indications of the product, hemostasis, closure of acute lesions/perforations and closure of chronic lesions/fistulae (source: www.viszeralmedizin.com).

Reports on Ovesco OTSC

OTSC proves to be preferable treatment option for several indications

Glitsch A, Schreiber A,Boldt J, Keßler W, and Mayerle J, Greifswald, reported about a cohort of 46 patients treated with OTCS clips. The indications include postoperative anastomotic insufficiency (n=13), bleeding (n=7), perforations (n=15), pancreatic fistulae in the colon (n=4), fistulae in patients with inflammatory bowel disease (n=5) and OTSC use after ESD (n=2). Successful closure and complete healing was achieved for all but one indication. In the case of postoperative anastomotic insufficiencies 3 out of 13 insufficiencies could not be closed successfully (76.93% success rate). These patients had to undergo further laparoscopic treatment. In all other cases (n=43), no complications were observed and thus no further treatment was necessary. The authors declare OTSC to be a procedure with significantly lower morbidity and mortality in comparison to conventional treatment options and emphasize that it spares patients elaborate and more complication-prone methods of treatment.
Retrospektive Auswertung der OTSC Anwendung an der Universitätsmedizin Greifswald
Glitsch A, Schreiber A, Boldt J, Keßler W, Mayerle J

OTSC for stopping acute bleeding in the gastrointestinal tract

Braun A, Freiburg, and Kirschniak A, Tübingen, presented data about a total of 16 patients (median age=75.5 years, R=61-92 years; m=9, f=7) over three years with acute bleeding, who were treated with OTSC application during emergency endoscopy. 8 procedures were performed in the upper and 8 in the lower gastrointestinal tract. Patients with upper GI bleeding were given a highly dosed proton pump inhibitor (80mg i.v. Bolus, 320mg i.v. / 24h). Hemorrhages were classified as follows: Forrest Ia (n=7), Forrest Ib (n=7), and Forrest IIa (n=2). All patients suffered an acute drop in hemoglobin and showed definite signs of bleeding. No further local therapies were administered. All OTSC applications were performed by the same clinician and took 20 minutes or less. OTSC application and thus primary hemostasis was successful in all cases. None of the patient suffered recurrent gastrointestinal bleeding. 6 patients (4 Fla, 1 Flb, 1 Fil a) had a follow-up endoscopy between day 1 and 7; all clips were in-situ with no signs of bleeding. The other 7 patients were not reexamined due to good response to treatment. The authors see OTSC as a safe and very effective treatment option in emergency endoscopy. Primary hemostasis is possible for a large percentage of patients, which improves lethality, and examination time is low.
Endoskopische Behandlung von akuten Blutungen mit einem Over-The-Scope Clip (OTSC)
Braun A, Kirschniak A
Interdisciplinary treatment regime for thoracic anastomosis insufficiencies

Pauthner M, May A, Lorenz D, and Ell C, Offenbach, introduced the complication management regime for thoracic anastomosis insufficiencies (AI) at HSK Wiesbaden hospital. From 07/2000 to 12/2013, they counted 632 cases of resections in the esophagus, 557 of which included transthoracic esophageal resections with intra-thoracic anastomosis of a gastric sleeve. 49 of these 557 patients (8.8%) suffered from confirmed AI. Of these cases, 13 (26.5%) were treated conservatively with a triple-lumen jejunal feeding and gastric decompression tube (TLT), 14 (28.6%) were treated with a primary stent, in 7 patients an OTSC clip was placed endoscopically (14.3%) and 2 (4.1%) received transluminal vacuum therapy. 12 patients (26.5%) had to undergo repeat thoracotomy, 7 of which had a stent placed during the procedure (14.3%). Hospital lethality after all esophageal resections was 3.6%, with only 2.3% in the last 4 years. If gastric sleeve shows good blood circulation and the AI is small, either a clip or a TLT is placed. Routine check after 36-48h. Larger AIs are treated with stents; routine check after 24 h and placement of TLT to protect stent from bile. If pleural empyema occurs, a repeat thoracotomy is performed, including decortication and sewing-over of the AI as well as stent placement; stent is fixated with an absorbable suture. The authors report that this indication-specific, standardized complication management regime reduced lethality after occurrence of thoracic AI from 14.3% to 3.1%.

Therapie der Anastomoseninsuffizienz nach Ösophagusresektion – die viszeralmedizinische Herausforderung

Pauthner M, May A, Lorenz D, Ell C

New treatment option for chronic, therapy-resistant esophageal-bronchial fistulae

Wedi E, Sportes A, and Hochberger J, Strasbourg, France, presented the case of a 68-year-old patient with a chronic esophageal-bronchial fistula. In early 2010 he presented with haemoptysis and an unidentified pulmonary lesion. Examination of the mediastinum and subsequent exploratory thoracotomy showed giant-cell granuloma with no indication of malignancy. In December 2011 patient reported repeated incidents of coughing during food intake with recurrent bronchio-pulmonary infections, and an esophageal-bronchial fistula was diagnosed. Initial treatment included a fully covered Nitinol stent (23/18 mm wide, 12 cm long), which dislocated two days after food was reintroduced. In the following 1.5 years, a variety of endoscopic treatment options were explored (partially covered stent, fibrin glue, standard hemoclips, etc.), but all proved unsuccessful while a 5-7 mm wide fistula tract had formed. In collaboration with pulmonologists and thoracic surgeons, an experimental course of treatment was employed. Deep tissue in the fistula tract was excised using endoscopic submucosal dissection (ESD). Then a flexible bronchoscopy with APC and chafing of the fistula tract with a brush was performed. Finally, the fistula tract was closed with a 17.5 mm OTSC macro clip. Preliminary endoscopic-radiological follow-up over a 4 month period has shown no recurrence. The authors conclude that excision of the fistula and subsequent closure with an OTSC macro clip is a promising new treatment option, which should be further evaluated.

Therapie-refraktäre ösophago-bronchiale Fistel – Was tun, wenn alle Therapieoptionen versagen?

Wedi E, Sportes A, Hochberger J
Report on Ovesco FTRD (Full-Thickness Resection Device), newly launched by Ovesco

Preliminary clinical experience with the FTRD system in the lower gastrointestinal tract

Schmidt A, Damm M and Caca K, Ludwigsburg, together with Gubler C and Bauerfeind P, Zurich, Switzerland, reported their experience with endoscopic full-thickness resection in the lower GI tract of 21 patients from July 2012 to March 2014. Resection was always performed using the FTRD system mounted onto a standard endoscope. Indications included recurrent or incompletely resected adenoma with non-lifting sign (n=9), adenoma with high-grade prostate intraepithelial neoplasia (HG-PIN) (n=1), adenoma on base of appendix (n=3), broad-based adenoma in patient with coagulation disorder (n=1), diagnostic (re-)resection in patients with T1 carcinoma (n=3), adenoma on diverticulum (n=1), a submucosal tumor (n=2), a diagnostic FTR for a patient with suspected Hirschsprung’s disease (n=1). Lesions were located in the cecum (3), ascending colon (4), transverse colon (2), descending colon (4), sigma (2), recto-sigmoid (3), and rectum (3). Navigation to target lesion with FTRD mounted onto endoscope was possible in all but one case (95.2% success rate). Once lesion war reached, resection was technically successful in all cases and macroscopically complete in 19 out of 20. Histological findings confirmed complete full-thickness resection in 17/20 cases (85%). No perforations or relevant bleeding occurred. Two patients developed postpolypectomy syndrome (PPCS) after resection in the cecum, which was treated conservatively and with success. The authors conclude that endoscopic full-thickness resection in the lower GI tract with the FTRD System is technically feasible, effective and safe. Larger studies are necessary for further evaluation of this technique.

Endoskopische Vollwandresektion im unteren GI-Trakt mit dem FTRD-System: eine retrospektive Studie

Schmidt A, Damm M, Gubler C, Caca K, Bauerfeind P

Report on OTSC Proctology

Prosst R presented the experiences of a prospective pilot study at St. Anna hospital, Stuttgart, and edz center of excellence in proctology, Mannheim, regarding the use of OTSC Proctology. The study included 20 patients (14 male, 6 female), aged 56.1 years on average (R 25-73 years). There were 14 transsphincteric and 6 suprasphincteric anorectal fistulae. Average procedure time for clipping of fistulae was 32 minutes (R 17 to 66 minutes). There were no intraoperative complications. Follow-up endoscopy after six months or more showed proper healing in 18 of 20 cases (90% success rate). The clip had remained in-situ in 13 patients. Clips fell off spontaneously (10 to 4 days post-op) in three patients. Clip was surgically removed in two patients (clip dislocation, severely impaired wound healing). The fistula persisted/recurred in two of 20 cases (10%). Reasons were spontaneous clip displacement on day 3 post-op and failure to heal. In the second case, the clip was removed and another loop was placed. The author pointed out that, since this is a new method, clinical experience is limited and efficiency with regards to ano-/recto-vaginal fistulae is unclear. The report claimed OTSC Proctology to be a very promising new treatment option with lower morbidity and fewer complications than established methods. It prevents traumatizing the sphincter, eliminates the risk of postoperative incontinence, and does not impede further treatment options. Additionally, patient satisfaction is high and the instrument is easy to use.

OTSC ohne Endoskop: Anorektaler Fistelverschluss mittels OTSC Proctology

Prosst R

Report on remOVE System (product approval in Europe pending)

Early clinical data on new bipolar DC cutting instrument for OTSC clips show efficacy and safety

Rische S, Schmidt A, Damm M, Cahyadi O, Bauder M, and Caca K, Ludwigsburg, summarized a retrospective study of compassionate use cases, which used a prototype of the remOVE System to remove OTSC clips in 13 patients. Clips remained in the upper and lower gastrointestinal tract for an average of 70 days (R 7-469 days). Fragmentation of clip was successful in all cases. Mean procedure time was 45 minutes (R 35-75 minutes). Endoscopic removal of clip fragments was possible in all but one case (92.31% success rate). No serious complications were observed. The authors conclude that OTSC clip removal with the remOVE system prototype is easy, fast and safe, and is thus suited for elective procedures as well as endoscopic emergencies.

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