Conference report

Clinical presentations at German Endoscopy Congress confirm efficacy of OTSC clipping in a range of indications

Munich, March 14–16, 2013. The 43rd German Endoscopy Congress, DGE-BV, was held under the presidency of Prof. Dr. Christoph F. Dietrich.

A significant number of presentations had clinical data of OTSC clipping as their topic and confirmed clinical efficacy and safety in the primary indications of the product, hemostasis, closure of acute lesions/perforations and closure of chronic lesions/fistula (source: www.dge-bv.de).

Reports on Ovesco OTSC

Large single center OTSC cohort with hemostatic and organ wall closure indications

Wedi E, Menke D, and Hochberger J, Strasbourg (France) reported about a cohort of 84 patients with OTSC clipping for GI bleeding, fistula and GI wall insufficiency. 101 OTSC clips have been used in this cohort, or 1.2 clips per patient. Indications included mainly severe upper GI peptic ulcer hemorrhage (n=38) and preventive clipping to avoid re-bleeding (n=12) or secondary perforation (n=18) after large area ESD. The clinical success rate in peptic ulcer bleeding was 79%, most patients had already been treated unsuccessfully with other hemostatic techniques before OTSC clipping or had been candidates for surgical hemostasis. 2 complications were encountered: 1 inadvertent clipping of an instrument with OTSC and fixation of the instrument to the tissue and one perforation of the sigmoid with the OTSC cap. The authors state that OTSC application is an effective procedure to deal with endoscopic situations that otherwise would require a surgical approach.

Der Einsatz des OTSC-Makroclips bei 84 Patienten mit schwerer GI-Blutung, Fisteln und Insuffizienzen – ein Résumé.
E. Wedi, D. Menke, and J. Hochberger, Strasbourg

Large single center cohort on OTSC hemostasis in severe GI bleeding

Kratt T, Stüker D, Gräpler F, Küper M, Wichmann D, Königsrainer A, Tübingen, showed data from their cohort on OTSC in endoscopic hemostasis (n=85). The bleeding location was in the upper GI tract in 63% (21% peptic gastric ulcers and 40% peptic duodenal ulcers) and in the lower GI tract in 37% (mostly bleeding after polypectomy in the rectum). The characteristics of the cohort underline the severity of bleeding: life-threatening bleeding (28.4%), patient in hemorrhagic shock (31.1%), immediate blood transfusion (33.8%), patient under anti-coagulation (21.6%), Forrest I bleeding (72.3%). OTSC placement was achieved with cap-suction in 72 cases and with an OTSC Anchor in 2 cases. Technically successful hemostasis for 72 hrs was achieved in 92.8% of cases, a persistent bleeding and an early relapse bleeding (<72 hrs) were seen in 3.6%, respectively. Late relapse
bleeding (>72 hrs) was observed in 3.6%. No severe complications were observed; in 3 cases mucosal esophageal lesions from device introduction were seen. In 14.5% OTSC clipping was done for recurrence of an initially successful other endoscopic therapy and in 13.3% for failure of other methods in the same treatment session. In 35.1% OTSC clipping was seen as an ultima ratio and as an alternative to surgical therapy otherwise becoming necessary. The summary of the authors is that the simple and easy to handle OTSC system is an effective treatment in severe GI bleeding and can avoid surgery in several cases.

Das OTSC-Clip-System: Klinische Erfahrungen zur Therapie der schweren GI-Blutung bei 85 Patienten
T. Kratt, D. Stüker, F. Gräpler, M. Küper, D. Wichmann, A. Königsrainer, Tübingen

**OTSC to prevent migration of covered self-expanding stents**

Fähndrich M, Pohl T, Rolffs S, Sandmann M, and Heike M, Dortmund, presented their technique of using OTSC to avoid migration of covered, self-expandable stents. Stent migration has an incidence of up to 30% and represents a significant clinical challenge. To prevent stent migration the authors used OTSC to fix the stent permanently to the neighboring GI wall. In 24 cases with benign indication for stent placement OTSC fixation was carried out in the following locations: esophagus, small bowel and colon. After 5–8 weeks the OTSC clips were removed by Nd:YAG laser cutting to intentionally remove the stent. In all 24 patients the procedure was technically successful. In 1 patient an undesired stent migration before intentional removal was observed. In another case the stent had to be removed after a few days due to intolerance by the patient in a location close to the upper esophageal sphincter. The authors conclude that OTSC clipping was found to be a safe and practical technique and has prevented stent migration in 96% of the cases studied.

Verwendung des Ovesco-Clips zur Verhinderung der Migration bei vollgecoverten selbstexpandierenden Stents
M. Fähndrich, T. Pohl, S. Rolffs, M. Sandmann, and M. Heike

**Hospitalisation time and 30-days mortality in GI perforations after technically successful and unsuccessful OTSC closure**

Hagel A, Nägel A, Raithel S, Diebel H, Neurath M, and Raithel M, Erlangen, showed data on the management of GI perforations with OTSC clips. They studied 19 patients with apparent perforation of a digestive organ wall in various anatomical locations. In 13 patients the perforation could be closed with OTSC ("O+") to avoid emergency surgery. In 6 patients OTSC closure was technically unsuccessful and emergency surgery was needed ("O–"). In the O+ group the duration of hospitalisation was 10.7 +/- 10 days, no mortality. 2 patients in this group had comorbidities unrelated to clip closure, leading to a prolonged hospital stay; excluding these 2 patients, hospitalisation was 5.8 +/- 2 days. In the O- group hospital stay was 12.1 +/- 7 days, one patient with esophageal perforation died after emergency surgery was not able to prevent fatal mediastinitis. The authors draw the conclusion that OTSC treatment can significantly reduce morbidity and mortality in GI perforations.

OTSC-Anwendung bei manifester GI-Perforation: 30-Tages-Mortalität, Hospitalisierungsduer und Outcome nach endoskopisch erfolgreichem und nicht-erfolgreichem Perforationsverschluss
A. Hagel, A. Nägel, S. Raithel, H. Diebel, M. Neurath, and M. Raithel, Erlangen
Monocentric case experience with OTSC in a broad range of wall closure indication: safe transmural closure

Nietsch H, Hammelmann F, and Asperger W, Halle, summarized their initial experience with OTSC in endoscopic closure of the GI organ wall in 10 consecutive applications. Indications included: post-surgical rectal anastomotic leak (n=2), rectal ESD perforation (n=1), gastric ESD perforation (n=2), esophageal perforation after balloon dilation (n=1), Mallory-Weiss tear (n=1), perforated gastric ulcer (n=1), post-surgical duodenal leak (n=1) and post-surgical bariatric suture line leak. All cases were successful. The authors conclude: OTSC enables a safe transmural closure of spontaneous and iatrogenic perforations. In a majority of cases target tissue handling is possible with suction only and does not require additional instruments. In well-trained endoscopy centers the learning curve for OTSC is short.

Erfahrungsbericht der ersten 10 Anwendungen des endoskopischen OTSC-Clipeinstruments
H. Nietsch, F. Hammelmann, and W. Asperger, Halle

OTSC for closure of distal esophageal perforation

Braun A, Richter-Schrag H, Hopt U, Fischer A, Freiburg, showed data on OTSC in the treatment of distal esophageal perforation after vomiting (Boerhaave, n=1) and iatrogenic injury (n=1). Esophageal perforation is a life-threatening situation with a high complication and mortality rate. In both cases endoscopic closure of the esophagus was achieved within 12 hrs after the lesion. Both patients received bilateral thorax drainage and antibiotic therapy. No patient developed sepsis. Starting oral intake was without problems. Control endoscopy after 3 months revealed no stenosis and both clips were found in place. The authors summarize that the closure of esophageal perforations with OTSC is a safe and effective method and is significantly more economic than common surgical therapy requiring longer hospital stays.

Endoskopischer Verschluss von distalen Ösophagusperforationen mit einem Over-The-Scope Clip (OTSC)
A. Braun, H. Richter-Schrag, U. Hopt, A. Fischer, Freiburg

Consecutive case series of OTSC application in the endoscopic management of complications and emergencies

Thomsen T, Berthold B, Khiabanchain M, and Trabandt I, Neubrandenburg, presented data of a case series (n=11). Indications included upper and lower GI bleeding, PEG-fistula closure, rectal-pelvic fistula closure, sigmoid anastomosis leak, bleeding from diverticulum (Hartmann situation), arterial bleeding from colon anastomosis. The overall clinical success rate in the mixed case series was 82%. No procedure took more than 30 min. As complications 1 fistula recurrence (required second OTSC procedure), 1 re-bleeding and 1 remaining perforation were seen. The authors summarize that OTSC clipping is a fast procedure with a high primary success rate and is quick to learn.

Endoskopische Interventionen mit dem OTSC-System am Klinikum Neubrandenburg
T. Thomsen, B. Berthold, M. Khiabanchain, and I. Trabandt, Neubrandenburg
**OTSC for stopping gastroduodenal artery bleeding in duodenal ulcer**

Kratt T, Stüker D, Kirschniak A, Heining er A, Wietek B, Königsrainer A, Tübingen, showed a case series (n=7) in which OTSC was applied in upper GI emergency hemostasis to stop bleeding from the gastroduodenal artery. Gastroduodenal artery bleeding is besides aortoduodenal fistula considered the most severe bleeding complication in the digestive tract, associated with high morbidity and mortality. In many cases surgical emergency hemostasis is inevitable. In all cases reported here the gastroduodenal artery was verified as the bleeding source by angiography after successful endoscopic treatment. In all 7 patients the acute bleeding from an ulcer at the posterior duodenal wall was successfully controlled with OTSC, in 4 cases fibrin glue was additionally applied. After the initial 72 hrs, 3 patients suffered from re-bleeding, which was then controlled surgically. No mortality was encountered in this case series. **The authors draw the conclusion that OTSC is effective in emergency management of gastroduodenal artery bleeding. In more than half of the cases endoscopic management was the only therapy. In the other patients OTSC was a successful “bridge to surgery” and allowed stabilizing the patient before the operation.**

OTSC-basierte Notfall-Hämostase der lebensbedrohlichen A. gastroduodenalis Ulkus-Arrosionsblutung: alleinige endoskopische Therapie oder „bridge-to-surgery”


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**Report on Ovesco FTRD (pre-commercial device)**

Kratt T, Stüker D, Gräpler F, Schnek M, Adam P, and Königsrainer A, Tübingen, presented data of their first 8 cases with FTRD, a device of Ovesco Endoscopy, not yet commercially available. It combines modified OTSC clipping with tissue resection. In 7 of the 8 cases the procedure was technically feasible; in 1 case the target lesion could not be reached. The cases treated included various indications in which FTRD was used as a device for full-thickness tissue retrieval with the primary purpose of enhanced histological examination of an in-toto full thickness specimen. The target lesions were in the upper GI tract, melanoma metastasis (n=3), GIST (n=1) or in the lower GI tract (adenoma or early colorectal cancer, low risk histology; n=4). The presentation gave a detailed case history of an elderly patient with recurrent adenoma (high grade dysplasia, partially adenocarcinoma) of the rectum. The patient had full thickness resection with FTRD under single-shot antibiotics and was discharged the following day. As histology demonstrated complete removal of the lesion, no further therapy was done. Follow-up was uncomplicated. After 14 weeks control endoscopy revealed that the clip had detached from the tissue, normal scar formation was seen at the resection site and no signs of residual lesion or new recurrence were found.

Klinische Evaluation eines neuen endoskopischen GI-Trakt-Vollwandresektionssystems: das OTSC-basierte „full thickness resection device” (FTRD)


**FTRD is not yet commercially available.**

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**For further information:**

Ovesco Endoscopy AG
Dorfackerstr. 26
72074 Tübingen, Germany
science@ovesco.com