

## December 2020 | Conference of UEGW 2020 Report of the United European Gastroenterology Week (UEGW) 2020

The 28th United European Gastroenterology Week (UEGW) was taking place digitally on October 11-13, 2020. Ovesco technology and procedures were presented in talks, posters and a live-broadcasted endoscopy.

### The OTSC® is established as sole second line treatment for recurrent peptic ulcer bleeding

K. Caca, Hospital of Ludwigsburg and University Heidelberg, Germany, gave a lecture on new tools for the management of upper GI bleeding.

First-line endoscopic hemostatic therapy achieves very high success rates of about 90 %, independent from which hemostasis technique is used: injection techniques, thermal coagulation or conventional clips. However, the mortality rate of acute upper GI bleeding is 5.8 % (Lau et al. Lancet 2012). Predictors for adverse outcome are the patient's age and comorbidities, and especially re-bleeding (Chiu et al. Clin Gastroenterol Hepatol 2009). In case re-bleeding occurs, re-endoscopy is still superior to surgery concerning complications and associated with a success rate of about 75 % (Lau et al., NEJM 1999). But if re-endoscopy is not successful and surgical salvage therapy is necessary, the mortality rate is quite high, it rises to 29 % (Jairath et al. B J Surg 2012).

Over the past few years, new endoscopic hemostasis techniques have been developed to increase success rates of secondary endoscopic hemostasis. These are the so-called "topic substances" (Hemospray, EndoClot and PuraStat) and the OTSC.

There are no randomized studies evaluating topic substances; observational studies show that they can stop haemorrhage even in diffuse bleedings in nearly 95 %, but quite high rebleeding rates of about 30 – 40 % occur. So, these techniques are established as rescue therapy or "add-on" therapy especially for diffuse bleedings.

The OTSC however is established as the sole second line treatment for recurrent peptic ulcer bleeding. It overcomes typical problems of through-the-scope clips, which can hardly grasp a centric vessel in a large ulcer with fibrotic base and cannot be well applied in ulcers at the posterior duodenal wall or the duodenal knee because of the tangential position and the narrow distance. The OTSC allows a better visualization of the ulcer due to suction into the cap of the device and/or the possibility of grasping by an OTSC Anchor. Besides, OTSC has the advantage of higher compression force (as high as a surgical seal) and thereby better hold in fibrotic tissue.

The STING trial (Schmidt A et al. Gastroenterology 2018) is a randomized controlled trial in patients with recurrent peptic ulcer bleeding (n=66, 33 OTSC, 33 standard endoscopic hemostasis). It showed a relative risk-reduction of 73.6 % in the OTSC group compared to the group with standard endoscopic therapy. 14 patients crossed over to the OTSC group after failed standard endoscopy (10 patients) or rebleeding after primary successful standard therapy (4 patients), so no significant differences could be found in rates of angiographic embolization, surgery, transfusion requirements and mortality.

Regarding the role of OTSC in first line therapy, there are no prospective trials so far; a retrospective study (FLET Rock study, Wedi E et al., Surg Endosc 2018) evaluating OTSC "first line" vs. a matched control group, showed that observed mortality, re-bleeding, and mortality after re-bleeding were significantly lower with OTSC as first line therapy.

A study prospectively evaluating OTSC as first line therapy in 100 patients with acute NVUGIB and Rockall Score  $\geq 7$  (STING II) is ongoing.

### New tools for treatment of upper GI bleeding. Therapy update: Non-variceal upper GI bleeding

Caca K, Ludwigsburg, Heidelberg, Germany.

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## December 2020 | OTSC® superior to TAE in refractory peptic ulcer bleeding – study shows significantly lower in-hospital mortality and shorter ICU stay

Compared to patients treated with transcatheter arterial embolization (TAE) for refractory peptic ulcer bleedings, OTSC showed higher efficacy (72.5% vs. 62.5% (p = 0.474)) and significantly reduced length of stay in ICU (4.9 vs. 9.2 days p = 0.009) as well as a significantly reduced in-house mortality (5.0% vs. 22.5% (p = 0.048)).

A. Küllmer et al., Medical Center University of Freiburg, Freiburg, Germany, presented a retrospective multicenter study comparing OTSC vs TAE (transarterial angiographic embolization) as salvage/bailout therapy for refractory peptic ulcer bleeding at this year's virtual UEG Week. Results of the study were also presented at this year's DGVS/DGAV conference (conference of the German Society of Gastroenterology, and Digestive and Metabolic Diseases with Endoscopy Section (DGVS) and the German Society of General Surgery and Visceral Surgery (DGAV)).

Primary endpoint of the study was clinical success defined as the combined endpoint of successful hemostasis and no re-bleeding within 7 days. Secondary endpoints were adverse events, length of hospital stay, days on intensive care unit (ICU), number of blood transfusions and mortality. Statistical analysis was performed for the total cohort and a matched cohort after adjustment of differences in baseline characteristics with propensity score matching (PSM).

Overall, 128 patients with peptic ulcer bleeding refractory to standard endoscopic therapy were included in the study. 66 patients were treated with OTSC, 62 patients with TAE. Between the two comparison groups there were no significant differences regarding age, Charlson comorbidity index, Rockall score, Helicobacter pylori status, ongoing anticoagulation, NSAID intake, primary hemostasis rate in first line therapy and number of endoscopic treatment attempts before salvage therapy. Also, in both groups, the proportion of patients with ulcer size > 20mm was similar (27.3 % vs. 33.9 %, p = 0.48). Most ulcers were in the duodenal bulb (65 % in OTSC group; 85.5 % in the TAE group; p = 0.014). The OTSC group included significantly less Forrest Ia bleedings (19.7 % vs. 38.7 %, p = 0.02) and significantly more Forrest Ib bleedings (63.6 % vs. 43.5 %; p = 0.03). PSM was performed to control for these biases and resulting in treatment groups of n = 40 each, with no significant differences in ulcer localization and bleeding characteristics.

Clinical success was higher in the OTSC group but did not reach statistical significance (72.5 % vs. 62.5 %; p = 0.474) while TAE patients stayed significantly longer in ICU (4.9 vs. 9.2 days, p = 0.009) and in-hospital mortality was significantly higher in the TAE group (5.0 % vs. 22.5 %, p = 0.048). The 7-day rebleeding rate was higher in the TAE group (17.5 % vs. 32.5 %; p = 0.196). Also, severe adverse events occurred more often in the TAE group (3.0 % vs. 7.5 %, p = 0.308).

The authors concluded that OTSC treatment for refractory peptic ulcer bleeding shows at least similar efficacy compared to TAE, but significantly lower mortality rates and significantly shorter ICU stay.

### OTSC vs TAE as salvage therapy for refractory peptic ulcer bleeding

Kuellmer A, Mangold T, Bettinger D, Maruschke L, Wannhoff A, Caca K, Edris W, Jung C, Kleemann T, Schulz T, Thimme R, Schmidt A.

United European Gastroenterology Week Virtual 2020, Congress lecture, 2020 October 11

## OTSC® Hemostasis Update 11

### September 2020 | OTSC® clipping for recurrent peptic ulcer bleeding is cost-effective as compared to a repeat of standard treatment

A cost analysis based on mathematic modelling determined the average cost of repeating standard treatment in patients with persistent/recurrent peptic ulcer bleeding (\$ 6,578) and the average cost of second-line OTSC treatment after failed standard therapy, which was lower (at average \$ 6,298). The average cost of standard treatment was based on the cost of one hemoclip and a gold probe. However, many patients treated with standard endoscopy receive more than one hemoclip, which would make the cost of repeat standard treatment even higher.

J. X. Yu et al., Division of Gastroenterology and Hepatology, University of Michigan, Ann Arbor, Michigan, USA, evaluated by mathematic modelling the cost-effectiveness of OTSC clips for the treatment of peptic ulcer bleeding as first-line and second-line therapy. A decision tree was used to model the cost, effectiveness, and rates of persistent/recurrent bleeding of OTSC versus standard treatment (ST) for the management of peptic ulcer bleeding.

Three possible treatment strategies were modeled for a patient with peptic ulcer bleeding: OTSC clipping after first line standard therapy, a repeat of standard therapy after first-line standard therapy, and standard therapy after first-line OTSC clipping. It was assumed that if the second-line therapy remained unsuccessful, the patient would undergo interventional radiology or surgery.

The average cost of standard treatment was based on the cost of one hemoclip and a gold probe. The cost of an esophagogastroduodenoscopy and for hospitalization were estimated from Medicare and Medicaid data, the probability of persistent/recurrent bleeding with standard therapy and OTSC therapy was obtained through review of the literature.

Results showed that the first treatment strategy of first-line ST followed by OTSC was the most cost-effective strategy, costing \$ 6,298 per patient and resulting in 0.0686 QALYs. The second strategy with ST followed by ST cost \$ 6,576 and resulted in 0.0659 QALYs. The third strategy with OTSC as first-line treatment and second-line ST cost \$ 6,490 and resulted in 0.0687 QALYs. As the probability of persistent/recurrent bleeding following ST increases, OTSC treatment becomes preferred in more scenarios. Specifically, for medium- or high-risk ulcer with Rockall  $\geq 4$ , OTSC as first line therapy followed by ST is preferred.

The authors concluded that in patients with persistent/recurrent peptic ulcer bleeding after standard endoscopic treatment a repeat of the standard approach is not cost-effective. Instead, OTSC clipping should be used. For first-line therapy, OTSC clipping should be considered for patients with intermediate or high-risk ulcers as determined by the Rockall score.

### Clipping Over the Scope for Recurrent Peptic Ulcer Bleeding is Cost-Effective as Compared to Standard Therapy: An Initial Assessment

Yu JX, Russell WA, Asokkumar R, Kaltenbach T, Soetniko R

Gastrointest Endoscopy Clin N Am 30 (2020) 91-97. <https://doi.org/10.1016/j.giec.2019.09.004>

## OTSC® Hemostasis Update 10

### June 2020 | Conference Report of DDW 2020 Report of the Digestive Disease Week (DDW) 2020

### 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

The conference of the Digestive Disease Week (DDW) 2020 scheduled for May 2-5, 2020 in Chicago, had to be cancelled due to the current situation. However, many scientific publications on Ovesco products were submitted this year again. The most important abstracts on Ovesco products are summarized in the report attached below.

### 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. Jensenet 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 is a safe endoscopic method or hemostasis in acute variceal bleeding especially as a rescue treatment\***

G. Sirinet 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?**

Goklug Sirin, Ali Erkan Duman, Hasan Yilmaz, Altay Celebi, Sadettin Huelague

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## **OTSC® Hemostasis Update 9**

### **February 2020 | Conference Report of the American College of Gastroenterology 2019 Annual Scientific Meeting-ACG 2019**

#### **OTSC®: Besides a RCT showing OTSC's superiority in NVUGIB treatment, many case reports were presented documenting successful OTSC use in critical clinical cases**

The American College of Gastroenterology 2019 Annual Scientific Meeting (ACG) 2019 was held on October 25-30, 2019, in San Antonio, TX USA. Ovesco products were presented during various plenary and poster sessions throughout the conference. A summary of those presentations can be found below:

#### **OTSC System**

#### **Besides a RCT showing OTSC's superiority in NVUGIB treatment, many case reports were presented documenting successful OTSC use in critical clinical cases**

#### **OTSC treatment of NVUGIB is associated with 85 % lower rebleeding rate when compared to standard hemostasis methods**

Jensen DM et al., CURE Digestive Diseases Research Center, Los Angeles, CA, United States presented the results from their recent Randomized Controlled Trial (RCT) that was conducted at 2 academic medical centers which evaluated the outcomes of patients treated with OTSC for initial endoscopic treatment of severe non-variceal upper gastrointestinal bleeding (NVUGIB) to patients treated with standard hemostasis RX methods (e.g. hemoclips and/or multipolar probe with epinephrine pre-injection). 49 patients who met clinical and esophagogastroduodenoscopy (EGD) criteria for PUB's or UGI Dieulafoy's lesions (with major SRH or spots with arterial blood flow) were randomized in a 1:1 allocation to either standard RX (as described in above RCT) or OTSC. All patients received high dose PPI's after randomization and were followed prospectively for 30 days. The proportion of patients with 30-day rebleeding was significantly higher with standard RX – 28 % (7/25) – compared to OTSC RX – 4.2 % (1/24). The OTSC rebleeding rate was 85 % lower than standard group (relative risk 0.149 with 95 % confidence intervals of 0.006, 0.863). The number needed to treat (NNT) was 4.2. In patients with severe UGI bleeding from PUB's or Dieulafoy's lesions, primary endoscopic treatment with OTSC resulted in significantly lower rates of rebleeding and severe complications and fewer RBC transfusions than standard endoscopic hemostasis. Results appear to relate OTSC's superior ability to obliterate arterial blood flow underneath SRH and thereby reduce lesion rebleeding.

#### **Randomized Controlled Trial (RCT) of Over-the-Scope Clip (OTSC) as Initial Endoscopic Treatment of Severe Non-Variceal Upper Gastrointestinal Bleeding (NVUGIB)**

Jensen DM<sup>1,2,3</sup>, Kovacs TOG<sup>1,2</sup>, Ghassemi KA<sup>1,2</sup>, Kaneshiro M<sup>1,2</sup>, and Gornbein, J<sup>4</sup>

<sup>1</sup>CURE Digestive Diseases Research Center, Los Angeles,

CA, United States. <sup>2</sup>David Geffen School of Medicine at UCLA and Ronald Reagan UCLA Medical Center, Los Angeles, CA, United States. <sup>3</sup>West Los Angeles Veterans Administration Medical Center, Los Angeles, CA, United States. <sup>4</sup>Department of Medicine – GIM - DOMSTATS, UCLA, Los Angeles, CA, United States

#### **The OTSC as valuable tool for salvage hemostasis in duodenal ulcer**

Meir Mizrahi, MD et al, University of South Alabama College of Medicine, Mobile, AL, presented a case where traditional hemostasis methods failed, and an OTSC was used as salvage/rescue hemostasis therapy. The patient was a 45-year-old Asian male with a history of cirrhosis secondary to alcohol presented with jaundice and melena with a hemoglobin of 5.9 gm/dl. EGD showed severe duodenitis. A side viewing duodenoscope showed a large, cratered duodenal bulb ulcer with a visible vessel. Epinephrine was injected and 5 hemoclips were placed. Despite this, there was still active oozing of blood. All the hemoclips were removed with snare. OTSC System was loaded onto a standard gastroscope and advanced to the lesion. Target tissue was sucked into the cap and OTSC clip was released by turning the hand wheel. The clip closed itself and firmly anchored the tissue resulting in complete hemostasis. Proton pump inhibitors were continued and follow up endoscopy at 1 month showed healed ulcer site with clip in place. While OTSC have been well established in leaks, perforations and fistulas, their role in UGI hemorrhage is evolving. Several randomized trials comparing OTSC with conventional endoscopic hemostasis therapies are ongoing and results are awaiting, however our case reiterates that OTSC platform should be available and be part of endoscopic hemostasis armamentarium.

#### **Dominant Claw Control: Role of OTSC Clip as Salvage Hemostasis Therapy**

Gilad Shapira, MD<sup>1</sup>, Manoj Kumar, MD<sup>2</sup>, Yazan Fahmawi, MD<sup>2</sup>, Meir Mizrahi, MD<sup>3</sup>

<sup>1</sup>University of South Alabama College of Medicine, Mobile, AL; <sup>2</sup>University of South Alabama, Mobile, AL; <sup>3</sup>University of South Alabama College of Medicine, Spanish Fort, AL

#### **Two patients, in which the OTSC System was successfully used as salvage therapy for refractory NVUGIB after failed conventional management**

Shivantha Amamath, MD et al, Staten Island University Hospital, Northwell Health, Staten Island, NY, presented a case series of OTSC as salvage therapy after failed conventional management.

85-year-old female with Pulmonary Hypertension and Atrial Fibrillation was admitted for hypovolemic shock from hematemesis. Endoscopy revealed a large posterior duodenal bulb ulcer with adherent clot for which epinephrine injection was used. The ulcer's size and location prompted angiography and coil embolization of the gastroduodenal artery (GDA). Patient was in hypovolemic shock again due to a massive bleed. She was high risk for surgical intervention due to pulmonary hypertension, and repeat endoscopy was performed for hemostasis. An 11/6t-type OTSC clip was successfully deployed at a large vessel oozing blood, after removal of a large adherent clot by snare. No further intervention was needed afterward. 76-year-old male with extensive cardiac history was admitted with burns and inhalation injury from a house fire, requiring tracheostomy and gastrostomy placement. During hospitalization, patient had multiple episodes of melena and required blood transfusion. Endoscopy revealed two large anterior and posterior duodenal bulb ulcers, with a visible vessel, managed by electrocautery. Due to persistent bleeding, he underwent coil embolization of the GDA. Two days later, patient had recurrent bleeding. Repeat endoscopy with OTSC was used for successful hemostasis of a large visible vessel in the posterior duodenal bulb. Traditional endoscopic management carries a 20 % rebleeding risk and successful secondary hemostasis drops from 90 % to 75 %. Anatomic variation in blood supply to the duodenal bulb, either from branches of celiac axis or superior mesenteric artery may be the reason why our patients failed angiographic coil embolization of the GDA. To our knowledge, we report the first two cases where OTSC was used for successful salvage of NVUGIB

that failed initial endoscopic and angiographic interventions.

#### Over-the-Scope Clip as Salvage Therapy for Refractory Non-Variceal Upper Gastrointestinal Hemorrhage After Failed Conventional Management: A Case Series

Shivantha Amamath, MD, BSc (Hons) Biology, MRSB<sup>1</sup>, Jobin Philipose, MD<sup>2</sup>, Jeffrey Abergel, MD<sup>1</sup>, Hafiz Khan, MD<sup>2</sup>

<sup>1</sup>Staten Island University Hospital, Northwell Health, Staten Island, NY; <sup>2</sup>Staten Island University Hospital, Staten Island, NY

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#### January 2020 | Systematic review and meta-analysis of OTSC® therapy for digestive bleeding, covering 851 cases shows consistently high rates of definitive hemostasis, technical and clinical success

In 851 patients from 21 studies, definitive hemostasis was reached in 87.8 %, technical success in 97.8 %, and primary clinical success in 96.6 %.

V.T. Chandrasekar et al., Department of Gastroenterology and Hepatology, University of Kansas School of Medicine, Kansas City, Kansas, United States, conducted a comprehensive electronic database search for articles using OTSC for hemostasis aiming to determine technical and clinical success rates in achieving hemostasis as well as the rate of re-bleeding. All articles describing the use of OTSC for GI bleeding were reviewed. Case reports and smaller case series of fewer than five patients were excluded. The primary outcome was the rate of definitive hemostasis after primary technical and clinical success and without re-bleeding during follow-up.

A total of 21 studies comprising overall 851 patients met the inclusion criteria. 62.2 % of patients were males, median patient age was 69.7 years. 687 patients (80.7 %) were treated for upper GI bleeding and the remaining 164 patients (19.3 %) were treated for lower GI bleeding. OTSC was utilized as first-line treatment in 645 patients (75.8 %) and as second-line treatment in 206 patients (24.2 %). The definitive hemostasis rate was 87.8 % (95 % CI: 83.7 % – 92 %) during a median follow-up of 56 days. The rate of definitive hemostasis was 86.6 % (95 % CI: 81.9 % – 91.3 %) for upper GI bleeding and 89.5 % (95 % CI: 85.2 % – 93.8 %) for lower GI bleeding. The technical success rate was 97.8 % (95 % CI: 96.7 % – 98.9 %) and the primary clinical success rate was 96.6 % (95 % CI: 95.1 % – 98.2 %). Re-bleeding occurred in 10.3 % of patients (95 % CI: 6.5 % – 14.1 %). The failure rate of OTSC as first-line treatment was 9 % (95 % CI: 5.2 % – 12.8 %) and 26 % (95 % CI: 16.1 % – 36.0 %) when used as second line treatment. Only two adverse events requiring intervention were reported in 851 patients. In one patient with bleeding duodenal ulcer perforation occurred during OTSC placement which required surgery and another patient developed duodenal obstruction 1.8 months after OTSC placement; the obstruction could be resolved by three balloon dilations.

The authors concluded that this systematic review evaluating OTSC treatment of gastrointestinal bleeding showed high rates of definitive hemostasis, technical success, and primary clinical success, along with low re-bleeding rates. More randomized-controlled trials were desirable.

#### Efficacy and safety of Over-The-Scope-Clips for gastrointestinal bleeding: a systematic review and meta-analysis.

Chandrasekar VT, Desai M, Aziz M, Patel HK, Gorrepati VS, Jegadeesan R, Rai T, Sathyamurthy A, Murino A, Hassan C, Repici A, Sharma P..

Endoscopy 2019; 51: 941-949. <https://doi.org/10.1055/a-0994-4361>

#### December 2019 | Conference Report: United European Gastroenterology Week (UEGW) 2019

##### OTSC® shows superiority over conventional therapy in high-risk ulcer bleeding and variceal bleeding

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 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.

#### OTSC® Hemostasis Update 8

December 2019 | New randomized-controlled trial: OTSC® in first line has superior ability to

#### reduce rebleeding in NVUGIB when compared to standard treatment

A randomized controlled trial presented at the American College of Gastroenterology (ACG) meeting shows the rebleeding rate after first-line OTSC treatment of NVUGIB to be 85 % lower than after standard treatment.

At this year's ACG Annual Scientific Meeting, taking place on October 25-30 in San Antonio, TX, USA, Dr. D. Jensen UCLA School of Medicine, Los Angeles, CA, presented a RCT evaluating OTSC as first-line endoscopic treatment of severe non-variceal upper gastrointestinal bleeding (NVUGIB). The RCT was conducted at two academic medical centers. Patients with peptic ulcer bleeding or Dieulafoy's lesions, who met emergency endoscopy criteria were included in the study and randomized in a 1:1 allocation to either standard treatment (conventional clips and/or multipolar electrical probe with epinephrine pre-injection) or OTSC. All patients received high dose PPIs after randomization and were followed for 30 days.

Overall 49 patients could be included in the study, 24 patients were allocated in the OTSC arm and 25 patients in the standard treatment arm. The two groups were well matched regarding demographics, risk factors, lesion type and stigmata of hemorrhage. During the 30 day follow up, rebleeding occurred in one patient in the OTSC group (1/24, 4.2 %) and 7 patients in the standard treatment group (7/25, 28 %; p=0.024). The rebleeding rate was 85 % lower in the OTSC group than in the Standard treatment group (relative risk 0.149, 95 % confidence intervals of 0.006 and 0.863). The number needed to treat (NNT) was 4.2. Severe complications did not occur in the OTSC group (0/24, 0 %), but did occur in 4 patients in the standard treatment group (4/25, 16 %, p=0.041). Angiographic embolization was not necessary in the OTSC group, but was necessary in 2 patients (8 %) of the standard treatment group (p=0.157). The mean number of red blood cell transfusions (± standard deviation) after randomization was 0.4 ± 0.2 in the OTSC group and 0.76 ± 1.64 in the standard treatment group, a Kruskal-Wallis test performed for statistical comparison.

In summary, patients with severe NVUGIB, who received primary endoscopic treatment with the OTSC, experienced significantly lower rates of rebleeding, significantly less severe complications, and needed fewer red blood cell transfusions than patients treated with standard endoscopic hemostasis. The authors concluded that the OTSC has a superior ability to obliterate arterial blood flow underneath stigmata of hemorrhage and thereby reduce lesion rebleeding.

##### Randomized Controlled Trial (RCT) of Over-the-Scope Clip (OTSC) as Initial Endoscopic Treatment of Severe Non-Variceal Upper Gastrointestinal Bleeding (NVUGIB).

Jensen DM, Kovacs TOG, Ghassemi KA, Kaneshiro M, Gornbein J. Los Angeles, CA, USA.

ACG 2019, Annual Scientific meeting & Postgraduate Course, Oct 25-30, 2019, San Antonio, TX, USA.

#### December 2019 | Conference Report of DGVS and DGAV 2019

The 74th annual conference of the German Society of Gastroenterology, and Digestive and Metabolic Diseases with Endoscopy Section (DGVS) took place together with the 13th autumn conference of the German Society of General Surgery and Visceral Surgery (DGAV) on October 2-5, 2019 in Wiesbaden, Germany. Ovesco products were presented in talks, posters, meetings, video forums, workshops and hands-on training sessions. [...]

##### OTSC® System

The clinical application of the OTSC System is trained in workshops and hands-on training sessions

Hands-on training of hemostasis techniques in small groups attracted lively interest

On Wednesday, hands-on trainings sessions of

endoscopic-interventional techniques took place. Training on two different topics was offered: first hemostasis and clips, and second stent placement. In the beginning, a short lecture gave an overview over the respective topic, then hands-on training of the respective procedures was performed in small groups. Within this part, also possible complications of the hemostasis procedures were presented and acceptable therapeutic solutions worked out. The mainly practical instruction in small groups on the basis of examples from everyday endoscopic practice found widespread appeal among the very interested endoscopists.

#### DEGEA offers instruction on leakage closure and variceal bleeding at the training model

The German Society for Endoscopy Professionals (Deutsche Gesellschaft für Endoskopiefachberufe – DEGEA) offered several workshops on Saturday, including one workshop with the topic: "What is when... difficult situations and prevention of complications". In the theoretical part, S. Loeffler, Ovesco Endoscopy AG, Tuebingen, spoke about perforation closure, foreign body removal and stent fixation. In the practical part, various techniques were trained under instruction by different tutors at the training model; besides others, the OTSC System and endoclips were employed for leakage closure and variceal bleeding. The program was well attended by experienced colleagues and beginners.

#### Endoscopic closure techniques are highly effective for the management of acute perforations

A. Schmidt, University Hospital Freiburg, reported on perforation management in endoscopy. First, he defined the term perforation and differentiated it from leakage/insufficiency and fistula development on the basis of clinical characteristics. Then he explained that a paradigm change has taken place within the last years in the management of free abdominal air due to the introduction of highly effective endoscopic closure techniques. The presence of extraluminal air does not automatically imply the need for surgical therapy any more. Based on the recommendations of the ESGE Position Statement 2014, he explained general measures in case of acute perforation and criteria for decision making between endoscopic and surgical treatment. He emphasized, how important it is for therapeutical success, to keep the time between discovery of the perforation and start of therapy as short as possible. After that, he presented common endoscopic closure techniques. These included through-the-scope clips, OTSC clips, stents (SEPS, SEMS) and sponge/drainage for endoscopic vacuum therapy. Endoscopic suturing techniques were not part of the lecture. Depending on defect size, localization and local expertise, the different endoscopic closure techniques are employed for perforation management. Herein, interdisciplinary peri-interventional patient care is of great importance. In cases of late diagnosis or not certain/ not possible closure, or clinical worsening, surgical therapy is still the treatment of choice.

#### Perforations in endoscopy – do I still need my surgeon? (Perforationen bei der Endoskopie – brauche ich meinen Chirurgen noch?)

Schmidt A, Freiburg.

For questions and further information:

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

## OTSC® Hemostasis Update 7 August 2019 | Conference Report of the Digestive Disease Week 2019

The 50th Digestive Disease Week (DDW) 2019 took place on May 18 – 21, 2019 in San Diego, CA, USA.

Ovesco products were presented in talks, posters, state-of-the-art-lectures and debates.

#### 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<sup>1</sup>, Kallenbach T R<sup>2</sup>, Keyes E<sup>2</sup>, Soetniko R M<sup>2</sup>  
<sup>1</sup>Ann Arbor, <sup>2</sup>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<sup>1</sup>, Wedi E<sup>2</sup>

<sup>1</sup>Berlin, <sup>2</sup>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-Medrande 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-Medrandia C<sup>1</sup>, Alcivar-Vasquez JM<sup>1</sup>, Baquerizo-Burgos ROJ<sup>1</sup>, Ignacio Olmos J<sup>1</sup>, Rubio-Cordova M<sup>1</sup>, Pitanga Lukashok H<sup>1</sup>

<sup>1</sup>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<sup>2,1,3</sup>, Kovacs TO<sup>2,1</sup>, Ghassemi KA<sup>2,1</sup>, Kaneshiro M<sup>2,1</sup>, Dulai G<sup>2,1</sup>, Machicado GA<sup>2,1</sup>

<sup>1</sup>Santa Monica, <sup>2</sup>Los Angeles, <sup>3</sup>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 rebleeding 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<sup>1</sup>, Behary J<sup>2</sup>, Koo JH<sup>1,3</sup>, Levy MT<sup>1,3</sup>, Abi-Hanna D<sup>1</sup>, Edwards PD<sup>1</sup>, Bassan MS<sup>1,3</sup>

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#### July 2019 | Meta-analysis comprising 475 patients demonstrates success of OTSC® as first and second line therapy for non-variceal gastrointestinal bleeding

93 % primary hemostasis was achieved with primary OTSC therapy (288 patients), 91 % with rescue OTSC therapy (187 patients)

Ofosu A et al., The Brooklyn Hospital Center, Clinical Affiliate of the Mount Sinai Hospital, Brooklyn, NY, USA, performed a systematic review and meta-analysis to evaluate primary hemostasis rates and re-bleeding rates of the OTSC for primary therapy and rescue endoscopic interventions in patients with non-variceal gastro-intestinal bleeding (NVGIB).

A total of 16 studies which involved 475 patients were included. 288 patients were treated with OTSC as primary therapy while 187 patients were treated with OTSC as rescue therapy. Primary hemostasis rate achieved with primary endoscopic therapy with OTSC was 0.93 (95 % CI: 0.89 – 0.96). Similarly, primary hemostasis rate achieved with rescue endoscopic therapy with OTSC was 0.91 (95 % CI: 0.84 – 0.95). Re-bleeding rates after primary endoscopic therapy with OTSC was 0.21 (95 % CI: 0.08 – 0.43) and 0.25 (95 % CI: 0.17 – 0.34) with rescue therapy. There was a decreased risk of re-bleeding in patients treated with OTSC as primary therapy versus rescue therapy RR = 0.52 (95 % CI: 0.31-0.89).

The authors concluded that this meta-analysis demonstrates success on the use of OTSC as primary and rescue therapy in the management of NVGIB. Further

studies are however needed.

#### Over-the-scope-clips as primary and rescue therapy for non-variceal gastrointestinal bleeding: a systematic review and meta-analysis

Ofosu A, Ramai D, John F, Barakat M, Sunkara T, Sharma S, Gaduputi V, Adler DG, Reddy M.

Minerva Gastroenterol Dietol. 2018 Nov 7. doi: 10.23736/S1121-421X.18.02513-8. [Epub ahead of print]

#### OTSC® Hemostasis Update 6

#### May 2019 | Systematic review and meta-analysis of OTSC® literature data covering 1868 patients confirms high technical and clinical success rates

Pooled durable clinical success proportions of OTSC use were 87.5 % in hemorrhage, 81.4 % in acute leaks/perforations and 63.0 % in chronic leaks/fistulae. Since its market launch in 2007, the OTSC System has been the object of intensive clinical research. Weiland T et al., Tuebingen, performed a systematic collection of all data for post-market clinical follow-up (PMCF) aiming to systematically assess efficacy and safety of the OTSC.

The PMCF database was systematically searched for clinical data on OTSC therapy of GI hemorrhage (H), acute leaks/perforations (AL) and chronic leaks/fistulae (CL). Major outcomes were successful clip application and durable hemostasis/closure of defects.

457 publications were reviewed. 58 articles comprising 1868 patients fulfilled criteria to be included in the analysis. These consisted of retrospective analyses, prospective observational trials, one randomized-controlled trial (STING) and one quasi-controlled study (FLETRock). The pooled proportion analysis revealed high overall proportions of technical success: H – mean 93.0 % [95 % CI 90.2 – 95.4], AL – mean 89.7 % [95 % CI 85.9 – 92.9] and CL – mean 83.8 % [95 % CI 76.9 – 89.7]. Pooled durable clinical success proportions were: H – mean 87.5 % [95 % CI 80.5 – 93.2], AL – mean 81.4 % [95 % CI 77.0 – 85.3] and CL – mean 63.0 % [95 % CI 53.0 – 72.3].

By pooling all clinical data gained, the authors concluded that OTSC application in GI hemorrhage and closure of GI lesions is safe and effective in real clinical use.

#### Efficacy of the OTSC System in the treatment of GI bleeding and wall defects: a PMCF meta-analysis.

Weiland T, Rohrer S, Schmidt A, Wedi E, Bauerfeind P, Caca K, Khashab MA, Hochberger J, Baur F, Gottwald T, Schurr MO.

Minimally Invasive Therapy & Allied Technologies, DOI: 10.1080/13645706.2019.1590418.

<https://doi.org/10.1080/13645706.2019.1590418>

#### OTSC® Hemostasis Update 5

#### March 2019 | Application of the FTRD® in duodenal lesions is feasible, efficacious and safe

EFTR of duodenal lesions in 20 patients showed technical success in 17/20 (85.0 %), a R0 resection rate of 12/17 (70.6 %) and only minor peri-procedural bleeding in 3/20 cases (15.0 %). No major bleedings or perforations occurred.

Bauder M et al., Department of Gastroenterology and Oncology, Ludwigsburg Hospital, Ludwigsburg, Germany, performed a study investigating the safety and efficacy of FTRD application in the duodenum. Between 03/2014 and 06/2017, a total of 20 patients underwent EFTR of a duodenal lesion. Indication for EFTR was: adenomas (n=13, seven treatments naïve, six pretreated), subepithelial tumors (n=5) and T1 adenocarcinoma (n=1). The FTRD could be advanced to the lesion in 19/20 cases (95 %). In one case advancing the FTRD through the pylorus was not possible despite balloon dilatation. Overall technical success was 17/20 (85.0 %). In two cases the FTRD clip was deployed correctly, but the integrated snare could not be closed because of device dysfunction. Both lesions were then resected with a standard snare above the FTRD clip after extraction of the device. In both cases there was no macroscopic evidence of residual adenoma.

However, R0 resection could not be confirmed in both cases. R0 resection rate in the technically successful FTRD applications was 12/17 (70.6%). Minor bleedings occurred at the first post-interventional day in 3/20 patients (15.0%). No major bleedings or perforations occurred. During follow-up after 3 and 12 months, there were two recurrent adenomas that were successfully re-resected by FTRD.

The authors concluded that the FTRD indicates good technical efficacy and safety for resection of duodenal non-ampullary adenomas and subepithelial tumors. It offers the possibility of re-resections at the same site. Especially in pretreated or difficult lesions, such as non-lifting adenomas, EFTR should be considered.

#### Endoscopic full-thickness resection of duodenal lesions—a retrospective analysis of 20 FTRD cases.

Bauder M, Schmidt A, Caca K.

United European Gastroenterology J 2018 Aug;6(7):1015-1021.

#### February 2019 | OTSC® is safe and effective in pediatric patients for acute GI bleeding throughout the GI tract

##### Case series of 11 OTSC applications in 10 pediatric patients shows 100% technical success with immediate hemostasis and no complications.

Tran P et al., UT Southwestern Medical Center, Children's Health – Children's Medical Center Dallas, TX, USA, published the center's experience utilizing OTSCs for non-variceal gastrointestinal bleeding in pediatric patients. Overall 10 patients (median age 14.7 years, range 3.9 – 16.8 years, median weight 39 kg, range 17.4 – 85.8 kg) underwent 11 endoscopic procedures utilizing the OTSC System for hemostasis. Upper GI bleeding due to stomach or duodenal ulcer was seen in 4 patients, 2 of these had ulcer disease of the stomach and duodenum, respectively, secondary to nonsteroidal anti-inflammatory drug use. 1 patient had peptic ulcer disease of unknown etiology and 1 had duodenal ulcers secondary to active *Helicobacter pylori* infection. Upper intestinal bleeding was found in 2 other patients, 1 with postpolypectomy bleeding in the stomach and 1 with biliary sphincterotomy. Lower intestinal bleeding was seen in the remaining 4 patients. 1 patient had an ulcer located in the sigmoid colon presumed to be secondary to intestinal ischemia, 1 had postpolypectomy bleeding in the sigmoid colon, and 2 patients had anastomotic ulcers, 1 at an ileoileal and 1 at an ileocolonic anastomosis. 4 patients (40%) had OTSC placed as first-line intervention.

Placement of the OTSC was technically successful in all patients resulting in immediate hemostasis. No complications occurred. The two patients with anastomotic ulcers have continued to have clinical bleeding resulting in chronic anemia. One of these patients continues to require monthly iron infusions and the other remains transfusion dependent. The remaining 8 patients have had no evidence of recurrent bleeding at follow-up (median follow-up time 32.9 months, range 21.2 – 39.4 months).

The authors concluded that the OTSC System is a reliable and effective tool for active GI bleeding or high-risk lesions and should be considered for high risk or urgent/emergent cases of bleeding in children.

##### Over the Scope Clips for Treatment of Acute Nonvariceal Gastrointestinal Bleeding in Children Are Safe and Effective.

Tran P, Carroll J, Barth BA, Channabasappa N, Troendle DM.

JPGN 2018;67: 458-463.

#### January 2019 | OTSC®: A meta-analysis of 1517 cases over 9 years confirms its outstanding clinical effects for rescue therapy

OTSC use in patients with refractory gastrointestinal diseases achieved an overall clinical success rate of 78%, 85% for bleeding, 85% for perforation, 52% for fistula, 66% for anastomotic dehiscence, and 95% for other conditions. Overall OTSC-associated complications were 1.7%, severe OTSC-associated

##### complications 0.59%.

Kobara H et al., Departments of Gastroenterology und Neurology, Faculty of Medicine, and Gastroenterological Surgery, Faculty of Medicine, Kagawa University, Takamatsu, Japan, published a meta-analysis clarifying the current status and limitations of OTSC according to different indications of GI refractory disease, including refractory bleeding, perforation, fistula, and anastomotic dehiscence. An extensive literature search identified studies reporting on 10 or more cases, in which the OTSC System was applied. A total of 1517 cases described in 30 articles were retrieved. The clinical success rates and complications were calculated overall and for each indication.

The average clinical success rate was 78.3% (n = 1517) overall, 84.6% for hemorrhage (n = 559), 84.6% (n = 351) for perforation, 51.5% (n = 388) for fistula, 66% (n = 97) for anastomotic dehiscence, and 95.1% (n = 122) for other conditions, respectively. The authors rated these results, despite the lower performance of the OTSC System for fistula, as more than satisfactory when considering that there are no other effective endoscopic methods currently available and these refractory conditions hitherto required surgical interventions. With respect to safety, the overall OTSC-related complication rate was 1.7% (26/1517 cases), the incidence rate of severe complications that required surgery was 0.59% (9/1517 cases).

The authors concluded that the OTSC system serves as a safe and effective device for GI refractory diseases, which hitherto required surgical interventions.

##### Over-the-scope clip system: A review of 1517 cases over 9 years.

Kobara H, Mori H, Nishiyama N, Fujihara S, Okano K, Suzuki Y, Masaki T.

J Gastroenterol Hepatol 2018 Aug 2 doi:10.1111/jgh.14402.

#### January 2019 | Multicentric analysis: OTSC® is highly effective as first- and second-line treatment for NVUGIB in high-risk patients with cardiovascular disease and complex, large ulcers.

##### In a multicentric cohort of 100 consecutive patients with mean age 72 y, 51% severe cardiovascular comorbidity, and 73% on antiplatelet or/and anticoagulation therapy presenting with non-variceal upper GI bleeding from ulcers with median size of 3 cm, OTSC therapy led to 94% primary hemostasis and 86% long-term clinical success.

Non-variceal upper gastrointestinal bleeding (NVUGIB) is a common clinical problem with high rates of morbidity and a mortality rate between 5-10%. An aging patient population with a high prevalence of cardiovascular comorbidity has led to increase in the incidence of NVUGIB in patients older than age 70 years. A high comorbidity rate has also been identified as an independent risk factor for complications and mortality after NVUGIB.

Wedi E et al., Department of Gastroenterology und GI Oncology, University Medical Centre Goettingen, Germany presented prospectively collected multicentric data from 02/2009 to 09/2015 from all patients who underwent emergency endoscopy for high-risk NVUGIB in two academic centers and were treated with OTSC as first-line (n=81) or second-line therapy (n=19). 100 consecutive patients (mean age 72 years, range 27-97) were included in the study. 51% had severe cardiovascular comorbidity (ischemic heart disease, congestive heart failure, hypertension, valvular heart disease, peripheral arterial occlusive disease and atrial fibrillation) and 73% were on antiplatelet or/and anticoagulation therapy, other comorbidities in the patient cohort included kidney disease (n=20), former or recent malignancy (n=23), respiratory disease (n=16), liver disease (n=6) and diabetes mellitus (n=26). The median size of the treated ulcers was 3 cm (range 1-5 cm), the patients in 85% of cases were classified as ASA 3 to 5 (ASA 3: 40%, ASA 4: 40%, and ASA 5: 5%). In 94% of patients (n=94) primary hemostasis with OTSC was achieved. The primary

endpoint with successful initial hemostasis and no early ( $\leq 24$  h) or delayed ( $\leq 30$  days) re-bleeding was achieved in 86% of patients. Mean number of OTSCs placed on the initial endoscopic exam was 1 (range 1-3). Long-term hemostasis (6 months) was achieved in 86%.

The authors concluded that in this cohort the OTSC System was demonstrated to be a safe and effective first- and second-line treatment for NVUGIB in high-risk patients with cardiovascular disease and complex, large ulcers.

**Use of the over-the-scope-clip (OTSC) in non-variceal upper gastrointestinal bleeding in patients with severe cardiovascular comorbidities: a retrospective study**  
Wedi E, von Renteln D, Gonzalez S, Tkachenko O, Jung C, Orkut S, Roth V, Tumay S, Hochberger J  
Endoscopy International Open 2017; 05: E875–E882 | <http://dx.doi.org/10.1055/s-0043-105496>

#### OTSC® Hemostasis Update 4

#### December 2018 | Significant reduction of rebleeding rates in patients with high-risk NVUGIB by OTSC®

OTSC use decreased the rebleeding rate in high-risk (RS  $\geq 8$ ) patients with statistical significance compared to the rates reported by the Rockall study (0% vs. 53%,  $p < 0.01$ ). Also in intermediate-risk (RS = 4 – 7) patients rebleeding was reduced (0% vs. 24%,  $p = 0.08$ ).

Asokkumar et al., Singapore General Hospital, Singapore, studied rebleeding and mortality rates of patients treated with OTSC for high-risk adverse outcome (HR-AO) non-variceal upper gastrointestinal bleeding (NVUGIB).

The Rockall data and a historic cohort of the same institution (52 patients with peptic bleeding) were used for comparison. 18 patients with 19 bleeding lesions were included: 9 (47%) duodenal ulcers, 4 (21%) Dieulafoy's lesions, 3 (16%) gastric ulcers, and 3 (16%) bleedings after gastric biopsy, gastric polypectomy and endoscopic ultrasound-guided fine-needle aspiration of peri-gastric mass. OTSC was applied as first-line treatment in 10 (53%) and as second-line treatment in 9 (47%) lesions. Complete hemostasis was achieved in all patients. There were no complications associated with OTSC placement. OTSC use significantly decreased (0% vs. 53%,  $p < 0.01$ ) and reduced (0% vs. 24%,  $p = 0.08$ ) the rebleeding rate in high-risk (RS  $\geq 8$ ) and intermediate-risk (RS = 4 – 7) Rockall score patients as compared to the rates reported by the Rockall study, respectively. When compared to the institution's prior study, a decrease in the rebleeding rate was found with OTSC (0% vs. 21%,  $p = 0.06$ ) in the intermediate-to-high risk Rockall score patients (RS  $\geq 4$ ). There was no difference in mortality rates as compared to both control studies.

The authors concluded that use of OTSC is safe, efficacious and appears superior to standard treatment for HR-AO NVUGIB. OTSC should be considered as first-line treatment for HR-AO bleeding.

##### Use of over-the-scope-clip (OTSC) improves outcomes of high-risk adverse outcome (HR-AO) non-variceal upper gastrointestinal bleeding (NVUGIB).

Asokkumar R, Soethniko R, Sanchez-Yague A, Wie LK, Salazar E, Ngu JH.

Endoscopy International Open 2018; 06: E789-E796 C.

#### December 2018 | Conference Report United European Gastroenterology Week (UEGW) 2018

The 26th United European Gastroenterology Week (UEGW) was held on October 20-24, 2018, in Vienna, Austria. Several workshops, talks and posters presented original research with Ovesco technology and procedures. Hands-on training sessions in the ESGE learning area with the OTSC System attracted lively interest.

##### OTSC® System

##### Lively interest in Hands-On Trainings with the OTSC System

The European Society of Gastrointestinal Endoscopy (ESGE) offered an ESGE Learning Area to all delegates

of the UEGW to provide a platform for live encounter and interaction among aspiring endoscopists and renowned experts in the field.

In the ESGE Learning Area, three 90-minute Hands-On Trainings with the OTSC System were offered. All Hands-On Trainings were fully booked.

Besides, a talk on the OTSC System was held in the ESGENA Lunch Session (A. Caputo: "Advantages of the OTSC System in the treatment of UGIB") and the exhibition of Ovesco products attracted lively interest.

#### Large systematic review shows 77-96 % clinical success of OTSC in various indications without the need for further intervention

N. Bartell et al., Department of Gastroenterology and Hepatology, University of Rochester, United States, reported on a systematic review with the OTSC System. The study evaluated a large body of literature to determine the overall efficacy and safety of OTSC. 81 case series/retrospective reviews/prospective studies (Group A with a total of 2285 patients) and 157 case reports (Group B with a total of 177 patients) were included.

In Group A, technical success of OTSC placement was 95.3 %, with a clinical success of 77.2 %. Indications for OTSC placement were fistula closure (30.6 %), bleeding (28.9 %), perforation closure (16.3 %), leaks (15.1 %), EFTR (8.4 %) and stent fixation (0.7 %). Complete luminal obstruction (n=1) was the only reported adverse event across all studies. 24/81 papers reported the need for surgery despite OTSC placement (90/673 patients, 13.4 %).

Indications for OTSC placement in Group B were fistula closure (37.9 %), perforation closure (33.9 %), bleeding (14.1 %), EFTR (7.9 %) and leaks (6.2 %). Pooled technical success in this group was 99 % and clinical success was 96.0 %. 7/177 (4 %) patients required surgical intervention despite OTSC placement. Complete luminal obstruction in 1/177 patients and small bowel fixation with pneumoperitoneum in 1/177 patients were the only OTSC related adverse events reported.

The authors concluded that the OTSC is a safe and effective, surgery-sparing endoscopic tool in today's GI practice with 77-96 % of patients achieving clinical success without the need for further intervention. Technical success of > 95 % has been reported across all indications.

#### OTSC for high-risk peptic ulcer bleeding: one and done in 75 %

S. Gölder et al., Department of Internal Medicine III, Klinikum Augsburg, Germany, presented a study evaluating the use of OTSC for the treatment of high-risk peptic ulcer bleeding (HRUB).

Between 4/2014 and 03/2018, 100 patients with peptic ulcer bleeding (Forrest Ia-Ib), in the stomach of the duodenum were treated with OTSC. The OTSC was used as first-line procedure in 66 patients. Successful primary hemostasis could be achieved in 89.4 %. The OTSC was used as secondary treatment after failure of an initial endoscopic treatment in 34 patients. OTSC clipping led to successful primary hemostasis in 94.1 %. Recurrent bleeding occurred in n=9 for primary OTSC (15.3 %) and in n=7 patients with secondary OTSC (21.9 %) (p=0.812). No treatment beside the single OTSC clip was necessary in 75.8 % (n=50) in the primary-OTSC arm and in 73.5 % (n=25) in the secondary-OTSC arm, respectively.

OTSC failure occurred more often in large ulcers (> 3 cm, p=0.03), in the duodenal bulb (p=0.03) and in ulcers with negative helicobacter test (p=0.045). The patients with OTSC failure received more blood transfusions (p=0.002). No statistical difference was found for the Rockall score (median 7.5), the Glasgow Blatchford score (median 15.5), NSAID use or anticoagulation.

The authors concluded that the OTSC has a high rate of bleeding control in first- and second line treatment of peptic ulcer bleeding. Potential risk factors for treatment failure are location in the duodenal bulb, longer ICU stay, higher amount of transfusions and a higher reimbursement per case.

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#### November 2018 | Conference Report DGVS / DGAV

The 73th annual conference of the German Society of Gastroenterology, and Digestive and Metabolic Diseases with Endoscopy Section (DGVS) took place together with the 12th autumn conference of the German Society of General Surgery and Visceral Surgery (DGAV) on September 12-15, 2018 in Munich, Germany.

Ovesco products were presented in talks, posters, research, innovation and video forums and hands-on training sessions. Dr med. Edris Wedi (University Hospital Goettingen) received the DGVS endoscopy research award and the award of the Olympus Europe foundation 2018 for his work.

#### OTSC® System – presented studies confirm superiority of the OTSC in acute gastrointestinal haemorrhage

##### Marburg: OTSC highly effective for the treatment of acute ulcer bleeding

A Waldthaler presented retrospective data gathered in the University Hospital of Giessen and Marburg evaluating different endoscopic modes of therapy for non-variceal upper gastro-intestinal bleeding (NV-UGIB). Between 09/2016 and 1/2018, 131 patients (median age 68 years, 77 male) with NV-UGIB were treated. In 68 patients, the bleeding required intervention at the time of examination. Cause of hemorrhage was a peptic ulcer in 47 cases (69.1 %; 31 duodenum, 13 stomach, 1 cardia, 2 anastomosis), a Mallory-Weiss syndrome in 7 cases (10.3 %), tumor bleeding in 6 cases (8.8 %), angiodysplasia in 5 cases (7.4 %), and other causes in 3 cases (4.4 %). Primary endoscopic therapy consisted of a combination approach using injections and hemoclipping (n=15), injections (n=10), hemoclipping (n=9), OTSC (n=12, thereof 8 for duodenal ulcer) and thermal coagulation (n=1). 9 of the 68 treated patients suffered from recurrent ulcer bleeding (6 from a duodenal ulcer, 2 from anastomosis, 1 patient with Mallory-Weiss syndrome), none of these had received OTSC as primary therapy (rebleeding rate primary OTSC vs primary other treatment 0 % vs 8 %; p=0.001). 4 of the 6 patients suffering rebleeding from duodenal ulcer were treated with OTSC. The two remaining patients received a combination therapy consisting of injection and hemoclipping, both patients developed a second rebleeding which in turn was treated using an OTSC Clip. The authors concluded that therapy of acute ulcer bleeding with the OTSC proves to be highly efficient as primary and secondary therapy. They enhanced the fact that none of the patients included in the present study, which received an OTSC, developed recurrent bleeding. Advantages of OTSC treatment especially arose in the therapy of duodenal ulcer not only in cases of recurrent bleeding but also as primary therapy.

##### OTSC Therapie der nicht varikösen oberen gastrointestinalen Blutung im Klinikalltag – eine retrospektive Analyse (OTSC treatment of non-variceal upper gastrointestinal bleeding in hospital routine – a retrospective analysis).

Lerner C, Waldthaler A, WilBniowski TT, Bauer C, Grote T, Gallmeier E, Gress TM, Denzer U, Marburg.

##### Augsburg: closure of ulcer bleedings with high risk of recurrence: one and done in 75 %

S Gölder et al. presented a retrospective study comprising all patients with high-bleeding-risk ulcers (Forrest Ia-Ib), treated with OTSC at the Augsburg Hospital. A total of 100 patients with peptic ulcer, primarily or secondarily treated with OTSC, were included (n=25 with gastric ulcer, n=75 with duodenal ulcer, primary OTSC treatment n=66, secondary OTSC treatment n=34). Primary hemostasis by OTSC without further endoscopic treatment was achieved in 92 patients (92 %, n=60 primary therapy, n=32 secondary therapy). In 8 cases hemostasis could not be achieved with one single OTSC clip. In 17 cases recurrent

bleeding occurred 1-12 days after initially successful hemostasis (n=10 primary therapy, n=7 secondary therapy). The group of patients with unsuccessful OTSC treatment showed significantly larger ulcers (median size 3 cm, IQR 2 – 3, 13; p=0.03), more frequent bleeding in the duodenal bulb (22 vs. 2, p=0.033), more frequent negative H.p. status (p=0.045) and significantly higher number of transfused ECs (p=0.002). No significance was reached regarding the Rockall score (median 7.5, p=0.69) nor regarding the Glasgow-Blatchford score (median 15.5, p=0.15). Also, NSAID or anticoagulant treatment was not significantly different between the groups (p=0.53 and p=0.44, respectively). The authors concluded, that OTSC Clip application for peptic ulcer bleeding shows high clinical success rates as primary and secondary therapy. Possible risk factors for therapy failure are ulcer size, localization of the bleeding source in the duodenal bulb, negative H.p. status and increased demand for transfusion.

##### Over the Scope Clip (OTSC) bei Magen- und Duodenalulcera mit hohem Blutungsrisiko – One and done? (Over-the-Scope Clip (OTSC) for gastric and duodenal ulcers with high bleeding risk – one and done?)

Gölder S, Neuhaus L, Stücker J, Ebigo A, Braun G, Probst A, Weber T, Freuer D, Messmann H, Augsburg, Deutschland.

##### Analysis of the STING treatment cases: haemorrhage treatment with OTSC in comparison to standard therapy not only cost-effective, but cost-cutting

A Küllmer et al. presented results of a study based on data gathered during a prospective randomized study (STING), exploring whether OTSC treatment is more cost-effective than conventional clips due to the higher success rate, despite of the higher price per clip. Two parameters for cost effectiveness were calculated: (1) ICER (Incremental Cost Effectiveness Ratio): defines additional expenses for additional clinical results, meaning  $\Delta$ costs of both alternatives divided by  $\Delta$ clinical effect. (2) ACER (Average Cost Effectiveness Ratio): costs arising from a specific clinical result. The clinical status that had to be achieved was similar to the primary outcome of the STING study: successful hemostasis without any recurrent bleeding. The parameters for the total procedure, including costs for accommodation etc. were calculated as well as the costs for the endoscopic treatment only. The overall costs of standard treatment approaches were 13,025.95 €, versus 12,776.19 € for OTSC treatment; costs for the endoscopic procedure alone were 2,100.03 € (standard therapy) versus 1,960.17 € (OTSC-therapy). The ICER regarding the overall treatment was -589.01 € and -329.86 € for the endoscopic treatment. The ACER for the overall costs was 30,721.58 € for standard therapy and 15,066.26 € for OTSC therapy. ACER for the endoscopic procedure showed 4,952.90 € and 2,311.52 € for standard and OTSC treatment respectively. As a conclusion, OTSC therapy of recurrent ulcer bleeding was rated cost-effective and cost-cutting when compared to standard approaches.

##### OTSC- versus Standard-Therapie der Rezidiv-Ulkusblutung: eine Kosteneffektivitätsanalyse (OTSC versus standard treatment of recurrent ulcer bleeding: an analysis of cost effectiveness).

Küllmer A, Behn J, Glaser N, Thimme R, Caca K, Schmidt A, Freiburg Ludwigsburg, Deutschland.

##### Cross-sector routine data from social health insurance confirms safety and efficacy of colonic OTSC

D Horenkamp-Sonntag et al., German Technicians' Health Insurance, Hamburg, presented a study based on cross-sector routine data gathered by social health insurance (>10 million insured parties), examining OTSC application in the colon. Indication, patient characteristics, outcome and complications were assessed in the actual care setting. 348 patients (median age 67 years, 60 % male) were subject to colonic OTSC (OPS-Code 5460s3). Using further codes from different performance sectors, suspected indications were identified: (iatrogenic) perforation (n=58), polypectomy (n=210), bleeding (n=34) and others (n=46). A total of 16 patients (4.6 %) underwent

an additional endoscopic intervention within 10 days of the initial procedure, 43 patients (12.4 %) within 100 days of the initial procedure. 12 patients (3.4 %) received abdominal surgery within 10 days after OTSC procedure, 41 patients (11.8 %) within 100 days of the procedure. Surgery after more than 30 days after OTSC application was mostly due to treatment of the underlying disease (carcinoma, diverticulitis etc.). Overall 9 patients (2.6 %) deceased within 100 days after the intervention. The authors concluded that, in the actual care setting, OTSC is mostly applied for polypectomies and iatrogenic perforations. The presented data supports first findings indicating that OTSC application in the colon is safe and helps to prevent surgery due to iatrogenic complications.

**Sind OTS-Clips am Kolon effektiv und sicher? Evidenz-Generierung von endoskopischen Innovationen durch GKV-Routinedaten (Are OTS-Clips in the colon effective and safe? Evidence generation of endoscopic innovations with health insurance routine data.**

Horenkamp-Sonntag D, Liebentraut J, Engel S, Knoop H, Hamburg bzw. Berlin, Deutschland.

**OTSC as part of combination therapy of esophageal perforations and anastomotic insufficiencies following oncological resections**

C Jung et al. presented a retrospective evaluation of all patients, that had been treated since 2014 at the University Hospital Göttingen for iatrogenic esophageal perforation (IEP) or post-surgical anastomotic insufficiency (PAI) with the EndoVac system, with esophageal stents and OTSCs. A total of 21 patients were recorded, 4 out of these with iatrogenic esophageal perforation and 17 with PAI. 12/17 PAI patients had received a preoperative radio/chemotherapy (5 CROSS, 1ICF, 1 FLOT+RTC, 2 FLOT, 1 RTC, 1 GASTRIPEC, 1 unknown). Overall 8 patients received a fully-covered esophagus stent as primary therapy whereas 13 patients received an EndoVac as primary therapy. Complementary therapy was necessary in 6 patients (28.6 %) (2 stent + EndoVac, 1 EndoVac + Stent, 1 EndoVac + stent + fibrin, 1 stent + EndoVac + OTSC, 1 stent + OTSC). In overall 16/21 patients (76.2 %) complete restoration of the anastomosis was achieved. In 5 cases, continuity could not be restored, 2 of the patients died, 3 patients received a cervical drainage. The authors concluded that the group of patients examined was heterogenic and showed complex disease courses. The concept of combination therapy using EndoVac, esophageal stent, OTSC and endoscopic debridement seems to be promising. Further large scale studies are necessary to reliably describe the efficacy of this approach.

**Multimodale endoskopische Behandlung von Ösophagusperforationen und postoperativen Anastomoseninsuffizienzen nach onkologischen Resektionen. Was ist die richtige Strategie? (Multimodal endoscopic treatment of esophageal perforation and post-surgical anastomosis insufficiency following oncological resection. Which is the correct strategy?)**

Jung C, Kunsch S, Müller-Domieden A, Gaedcke J, Schüler P, Seif Amir Hosseini A, Ghadimi M, Ellenrieder V, Wedi E, Göttingen, Deutschland.

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**October 2018 | Successful application of OTSC® in GI bleeding under antithrombotic/anticoagulant therapy**

100 % primary hemostasis rate and improved management of rebleeding with OTSC used as first line therapy

Lamberts R and colleagues, HELIOS Park-Hospital, Department II for Internal Medicine, Leipzig, Germany, conducted a retrospective study examining success rates in hemostasis of acute upper and lower gastrointestinal

bleeding with the OTSC System as first or second line therapy in patients taking different regimens of antithrombotic and/or anticoagulant therapy.

Overall 75 consecutive patients (mean age 71.7, 55 men, 20 women) with active gastrointestinal bleeding were analysed. 34 patients (45.3 %) were under antiplatelet monotherapy, 10 patients (13.3 %) under dual antiplatelet therapy, 13 patients (17.3 %) under inhibitors of plasmatic coagulation, and 18 patients (24.0 %) no antithrombotic/anticoagulant therapy. OTSC was the first-line treatment in 45 (60 %) patients, in 30 patients (40 %) it was used in second line after preceding hemostasis attempts with conventional clips, adrenalin injection, fibrin glue and/or APC therapy. Key outcomes measured were: success rate with the OTSC therapy, rebleeding episodes, their management and the influence of antithrombotic or anticoagulant therapy.

Application of the OTSC resulted in immediate hemostasis in all 75 patients (100 % primary success rate). In 26 patients (34.7 %) a rebleeding episode was noted. In the group of first-line OTSC treatment the rebleeding rate was 28.9 % (13/45) compared to 43.3 % (13/30) in the group of second line OTSC treatment. In 23 patients rebleeding could be treated by further endoscopic interventions. Only 3 patients had to undergo radiological or surgical treatment because of final failure of endoscopic therapy attempts. In the rebleeding group the use of antiplatelet therapies was higher (73.1 % vs 48.9 %).

The authors concluded that primary OTSC application should be the treatment of choice in this high-risk patient population. Repeated endoscopic treatments to achieve definitive hemostasis may be justified and show promising results.

**Use of over-the-scope clips (OTSC) for hemostasis in gastro-intestinal bleeding in patients under antithrombotic therapy.**

Lamberts R, Koch A, Binner C, Zachaeus M, Knigge I, Bernhardt M, Halm U (2017).

Endoscopy International Open 2017; 05: E324-E330.

### OTSC® Hemostasis Update 3

**July 2018 | Large single center experience presented: Establishment of the OTSC® clip in daily endoscopic routine**

Honegger C and colleagues, Division of Gastroenterology and Hepatology, University Hospital Zurich, Zurich, Switzerland, presented data on 262 OTSC placements in a total of 233 interventions. Since 2009, the placement of OTSC has been established at the University Hospital Zurich for the entire spectrum of indications. OTSC has become a device of daily practice. A retrospective study now presents data of all patients treated with the OTSC device at the institution, focussing on indications, anatomic site of OTSC deployment, complications, and immediate and 30-day success rates.

Patient age ranged from 14 to 93 years with a median of 61 years. 51.5 % were male. Immediate success of OTSC treatment was observed in 87.1 % of all sessions (203/233). The success rates per indication were as follows: spontaneous bleeding 84.8 % (28/33); iatrogenic bleeding 100 % (20/20); acute perforation 90.3 % (65/72); prophylaxis for perforation 100 % (24/24); anastomotic leakage 61.1 % (11/18); fistulae 80.7 % (46/57); diameter reduction of the gastro-jejunal anastomosis 100 % (6/6); and stent fixation 100 % (3/3).

At 30-day follow-up, the overall success rate was 67.4 % (157/233). The success rates per indication were as follows: spontaneous bleeding 69.7 % (23/33); iatrogenic bleeding 90 % (18/20); acute perforation 86.1 % (62/72); prophylaxis for perforation 100 % (24/24); anastomotic leakage 33.3 % (6/18); fistulae 29.8 % (17/57), diameter reduction of the gastro-jejunal anastomosis 83.3 % (5/6); and stent fixation 66 % (2/3).

The authors concluded that the treatment with an OTSC is safe and feasible in clinical routine, with high immediate success rates with sustained clinical success at 30-day follow-up.

**Establishment of Over-The-Scope-Clips (OTSC) in daily endoscopic routine**

Honegger C, Valli PV, Wiegand N, Bauerfeind P, Gubler C

(2016)

United European Gastroenterol J. 2017 Mar;5(2):247-254.

**June 2018 | Breaking news: Ovesco OTSC® clip superior to standard hemostatic therapy in randomized-controlled trial**

OTSC has long been described in the scientific literature as a highly effective device for the treatment of upper GI hemorrhage. Now a randomized-controlled trial at 9 academic referral centers (in Germany, Switzerland, and Hong Kong) has proven OTSC to be superior to standard methods. The trial, published by Dr. Arthur Schmidt, Ludwigsburg, Germany, enrolled 66 patients with recurrent bleeding and randomized them to receive either OTSC therapy or standard techniques (a combination of 2 methods from through the scope clipping, injection or electrical coagulation).

Persistent bleeding after per-protocol hemostasis was observed in 42.4 % of patients in the standard therapy group and 6.0 % in the OTSC group (P=.001). Further bleeding occurred in 57.6 % in the standard therapy group and 15.2 % in the OTSC group (absolute difference, 42.4 %; 95 % CI 21.6-63.2; P=.001).

Gastroenterology. 2018 May 24. pii: S0016-5085(18)34570-0. doi: 10.1053/j.gastro.2018.05.037. [Epub ahead of print]

**Over the Scope Clips are More Effective Than Standard Endoscopic Therapy for Patients With Recurrent Bleeding of Peptic Ulcers.**

Schmidt A<sup>1</sup>, Gölder S<sup>2</sup>, Goetz M<sup>3</sup>, Meining A<sup>4</sup>, Lau J<sup>5</sup>, von Delius S<sup>6</sup>, Escher M<sup>7</sup>, Hoffmann A<sup>8</sup>, Wiest R<sup>9</sup>, Messmann H<sup>2</sup>, Kratt T<sup>2</sup>, Walter B<sup>4</sup>, Bettinger D<sup>10</sup>, Caca K<sup>11</sup>.

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**April 2018 | 100 % hemostasis with OTSC® reported for first-line emergency treatment of acute hemorrhage**

The 48th Conference of the German Society for Endoscopy and Imaging Procedures (Deutsche Gesellschaft für Endoskopie und Bildgebende Verfahren, DGE-BV) took place on March 15-17, 2018 in Munich, Germany. Dr. A. Braun, SRO Langenthal, Switzerland, presented personal data on OTSC application for emergency treatment of acute hemorrhage.

Between 2011 and 2017, 48 patients (29 female, median age 75.5 years (61-92)) each received one OTSC clip for first-line treatment of acute gastrointestinal hemorrhage. All patients had shown acute hemoglobin decrease and secure bleeding signs such as hematemesis, melena or hematochezia. Bleeding was located in the upper GI tract in 34 cases (14 Forrest Ia, 15 Forrest Ib, and 5 Forrest IIa) and in the lower GI tract in 14 cases (4 Forrest Ia, 7 Forrest Ib and 3 Forrest IIa). Patients with upper GI bleeding received peri-interventional PPI medication (80mg i.v. bolus, 320 mg i.v. / 24 h). For placement of the OTSC in



some cases an endoscopic forceps was used to grasp tissue. No further local therapies were applied. All OTSC applications were performed by one single endoscopist. OTSC application and primary hemostasis were successful in all cases. Maximal procedure time was 20 minutes. No relapse hemorrhage occurred. 26 patients (15 F 1a, 9 F 1b) received follow-up endoscopy on day 1 to 4, which showed the clip in situ and no bleeding stigmata. The other 22 patients received no follow-up examination. The clinical course was uneventful in all cases.

The author concludes that OTSC application for emergency endoscopic treatment of acute hemorrhage is safe and very effective. Primary hemostasis is achieved in a large fraction of patients, which makes reduction of the mortality rate of acute gastrointestinal hemorrhage possible. OTSC application is related to short procedural time.

#### Endoskopische Behandlung von akuten Blutungen mit einem over-the-scope clip (OTSC)

Braun A (2018)

### March 2018 | One step application of OTSC® for salvage hemostasis and simultaneous perforation closure

El Douaihy Y et al., Department of Internal Medicine, Staten Island University Hospital - Northwell Health System, Staten Island, New York, USA, reported on a case of active bleeding from a gastroduodenal artery pseudoaneurysm and simultaneous perforation, which was treated by deployment of a single OTSC-Clip.

The 61-year-old male patient with history of duodenal ulcer and angiographic embolization of a gastroduodenal artery pseudoaneurysm 6 months before presented to the emergency room for bright red blood per rectum with signs of upper GI bleed. In esophagogastroduodenoscopy two vessels were identified at the base of an ischemic ulcer correlating with the previous location. The endoscopist at the time elected to inject epinephrine and apply electrocautery which resulted in an arterial pulsatile bleed and a perforation. The field of vision was extremely compromised in addition to the difficult location. Mounting of a cap on the gastroscope to improve stability of the scope and applying point pressure to decrease bleeding, as well as vigorous water irrigation permitted the identification of the exact bleeding site. Then, an OTSC was deployed in a single attempt which resulted in immediate adequate hemostasis and closure of the perforation.

The authors emphasize that deployment of the OTSC requires pin-point precision to achieve satisfactory hemostasis. They rate the use of the over-the-scope clip simple yet very effective. The device was not only a rescue tool for hemostasis from a recurrent actively bleeding GDA pseudoaneurysm, but also for simultaneous perforation closure.

The video can be viewed directly from the GIE website or by using the QR code below.



#### Over-the-scope clip to the rescue of a bleeding gastroduodenal artery pseudoaneurysm

El Douaihy Y, Kesavan M, Deeb L, Abergel J, Andrawes S (2016)

Gastrointest Endosc. 2016 Jun 12. pii: S0016-5107(16)30236-X. doi: 10.1016/j.gie.2016.05.043.

### OTSC® Hemostasis Update 2

#### February 2018 | OTSC® prevents rebleeding in over 70 % of high-risk GI bleeding cases

J Brandler and colleagues, Department of Internal Medicine, Mayo Clinic, Rochester, Minnesota, USA, performed a study on 67 patients with gastrointestinal bleeding from high-risk lesions who were treated with the OTSC System.

The definition of high-risk lesions was lesions situated in the area of a major artery and larger than 2 mm in diameter and/or a deep penetrating, excavated fibrotic ulcer with high-risk stigmata, in which perforation could not be ruled

out or thermal therapy would cause perforation, or lesions that could not be treated by standard endoscopy (epinephrine injections, hemoclips, coagulation). Between 12/2011 and 02/2015, data from 67 patients with high risk non-variceal gastrointestinal bleeding, of which 49 received OTSCs as primary and 18 as rescue therapy, was prospectively collected and retrospectively analysed. Clinical severity was determined based on the Rockall score and a modified Blatchford score.

Out of 67 patients, 47 (70.1 %) remained free of rebleeding at 30 days after OTSC placement. No difference was found in the proportion of patients with rebleeding who received primary or rescue therapy (hazard ratio .639; 95 %CI .084 – 4.860; P=.6653). Only 9 rebleeding events were linked clearly to OTSCs and required intervention, indicating an OTSC success rate of 81.3 %.

The authors concluded that OTSCs have a valuable role in managing and averting high-risk radiologic or surgical interventions for non-variceal gastrointestinal bleeding, despite the presence of high risk of adverse outcome and severe prognostic scores.

#### Efficacy of Over-the-Scope Clips in Management of High-Risk Gastrointestinal Bleeding

Brandler J, Baruah A, Zeb M, Mehfooz A, Pophali P, Wong Kee Song L, AbuDayyeh B, Gostout C, Mara K, Dierkhising R, Buttari N (2017)

Clin Gastroenterol Hepatol. 2017 Jul 26. pii: S1542-3565(17)30857-1. doi: 10.1016/j.cgh.2017.07.020.

### November 2017 | 96 % hemostasis with OTSC® as first-line treatment in patients with gastrointestinal bleeding: an Italian multicentric study comprising 201 consecutive patients

Mangiafico S et al., Azienda Ospedaliero, University of Modena, Italy, presented at the 25th UEG week (October 28 – November 1, 2017, Barcelona) data from 9 Italian tertiary referral centers comprising a large series of patients with non-variceal upper and lower gastrointestinal bleeding lesions in whom OTSC was used as first-line endoscopic treatment.

Over a period of three years (01/2014 - 01/2017), data on 201 consecutive patients (mean age 68 years, range 28-89 years), who underwent emergency endoscopy for severe acute nonvariceal gastrointestinal bleeding and were treated with OTSC as primary first-line therapy, was prospectively collected and analyzed.

106/201 patients were treated with the a version of the OTSC system while in 95/201 patients the t clip was preferred. Indications for OTSC treatment included duodeno-jejunal ulcer Forrest 1a (n=29) and Forrest 1b (n=35), gastric ulcer Forrest 1a (n=19) and Forrest 1b (n=28), Mallory Weiss (n=19), Dieulafoy's lesion (n=9), post gastric- ESD bleeding (n=14), post EMR bleeding (n=15), post ESD bleeding (n=12), traumatic rectal ulcer (n=2), colonic diverticulum (n=4), and surgical anastomosis bleeding (n=15).

Technical success was achieved in all cases (100 %). Primary hemostasis was achieved in 193/201 patients (96 %). In the remaining 8 patients hemostasis was obtained with radiological vascular embolization (n=5) or surgery (n=3).

Early rebleeding (within the first 24 hours) occurred in 9/201 patients (4 %) and it was treated with epinephrine injection with or without use of through the scope clips or radiological vascular embolization. No late rebleeding was observed in the series.

The authors concluded that the use of OTSC as first-line therapy in acute high-risk gastrointestinal bleeding is safe and highly effective.

#### High efficacy of OTSC as first-line endoscopic treatment in patients with gastrointestinal bleeding: an Italian multicentric experience in a large cohort of patients.

Mangiafico S, Russo S, Lupo M, Caruso A, Grande G, Zito F, Bertani H, Conigliaro R, Pisani A, Germanà B, Galloro G, Pasquale L, Mangiavillano B, Bassotti G, Mutignani M, Manta R (2017)

### November 2017 | Recommendation for OTSC®

#### as first-line therapy in non-variceal upper gastrointestinal bleeding

Chan SM and Lau JYW, Prince of Wales Hospital, The Chinese University of Hong Kong, Hong Kong, China, published an editorial in Endoscopy International Open on the question: "Can we recommend OTSC as first-line therapy in case of non-variceal upper gastrointestinal bleeding?"

The authors explicate that 8 to 15 % of patients with non-variceal upper GI bleeding (NVUGIB) continue to bleed after endoscopic hemostasis and acid suppression therapy. Further bleeding remains one of the most important predictors of mortality. These facts make research on methods to improve endoscopic hemostasis so important.

The authors list several limitations to conventional hemostatic methods such as the impossibility to consistently seal larger vessels with thermocoagulation, the difficulty of tangential application of hemostatic clips, the frequent dislodgement of the clips and the difficulty of clip application in chronic ulcers with a fibrotic base. The authors argue that the Over-the-Scope-Clip, with a wider jaw and greater strength, has the advantages of a firm grip over a larger amount of tissue. Clip retention is almost universal. The editorial names the study from Wedi et al with 100 patients with NVUGIB and first-line OTSC management and a reported 94 % success rate for primary hemostasis. Besides, the study of Richter-Schrag et al is cited, including 100 patients with both NVUGIB and lower GI bleeding and showing similar results.

However, the paper also names problems that can lower the success of OTSC hemostasis, namely tangential application or OTSC deployment with scope in retroflexion (when ulcers are located in the lesser curve or the posterior wall of the duodenal bulb). The text offers a solution to this problem: usage of a smaller OTSC and an anchoring device to puncture near the bleeding site to guide the OTSC. Second, pretreatment with adrenaline injection is recommended to improve visualization in case of actively bleeding ulcers.

The authors narrate to eagerly await the publication of the STING trial, which randomized patients with refractory bleeding to OTSC or conventional treatment. They propose an RCT comparing OTSC as primary treatment to current standards.

In summary, the editorial recommends the application of OTSC in patients with hemodynamic instability, comorbid illness, with active bleeding ulcers, large ulcers and ulcers at posterior duodenum and lesser curve. The authors speculate that the added cost in managing further bleeding after standard treatment likely outweighs the cost of OTSC.

#### Can we now recommend OTSC as first-line therapy in case of non-variceal upper gastrointestinal bleeding?

Chan SM, Lau JYW

Endoscopy International Open 2017; 05: E883–E885

### July 2017 | Video case report: OTSC® hemostasis in patients with refractory bleeding due to chronic peptic ulcer

Xiao X and Lau JY, Department of Surgery, Chinese University of Hong Kong, Hong Kong, published an article on VideoGIE, the official video journal of the American Society of Gastrointestinal Endoscopy, showing OTSC treatment in two patients with refractory peptic ulcer bleeding.

The first patient was an 89-year-old woman admitted with fresh hematemesis and a haemoglobin of 4.8g/dl. Endoscopy revealed bleeding from a 2-cm chronic bulbar ulcer. She was treated by angiographic embolization to her right gastroduodenal artery (GDA). Three days later, she again experienced massive bleeding. A pulsatile vessel at the ulcer base was discovered and treatment with an OTSC clip induced. The cap was adjusted to encompass the vessel, and a trip string was pulled to deploy the OTSC. The patient was discharged 4 days later without further bleeding.

Patient two was a 76 year old man presenting with fresh melena and a haemoglobin of 7.5 g/dl. He reported on a history of recurrent bleeding from a chronic gastric ulcer.

Additionally, he had previously been on warfarin therapy for the treatment of deep vein thrombosis complicated by pulmonary embolism. Endoscopy revealed bleeding from a chronic ulcer at the ankle incisura of the stomach. The first attempt to stop the bleeding with heaterprobe and hemoclips failed. Then an OTSC anchor device was used to target the ulcer base and deploy an OTSC clip without suction. Complete hemostasis was achieved and the patient had an uneventful recovery.

The authors concluded that OTSC is useful in the treatment of chronic peptic ulcerations with refractory bleeding. The anchor device was rated a helpful tool, which allows accurate targeting of the bleeding artery.

#### Over-the-scope clip treatment of refractory peptic ulcer bleeding

Xiao X, Lau JY (2016)

Gastrointest Endosc. 2016 Feb;83(2):458-9. doi: 10.1016/j.gie.2015.05.040.

[https://www.youtube.com/watch?v=G6u\\_szn\\_Yqc&feature=youtu.be](https://www.youtube.com/watch?v=G6u_szn_Yqc&feature=youtu.be) 309

#### June 2017 | 80 % success in endoscopic closure of post-surgical gastrointestinal leaks

R Manta et al., Niguarda-Ca Granda Hospital, Milan, Nuovo S. Agostino Hospital, Modena, Nuovo Regina Margherita Hospital, Rome, Baggiovana Hospital Modena and Federico II University of Naples, Naples, all Italy, published a large case series on patients with post-surgical gastrointestinal leaks managed with endoscopy as initial approach.

A total of 76 patients underwent endoscopic treatment for a leak either in the upper (47 cases) or lower (29 cases) gastrointestinal tract. The first attempt for leak closure was the application of one or more OTSC clips. Fibrin glue was used as an adjuvant treatment to close the gap between two OTSCs where needed. A covered self-expanding metal-stent (SEMS) was applied when the closure was considered incomplete at endoscopy. When dehiscence characteristics were not fitting for OTSC positioning, a SEMS was directly used. Endosponge was the first line therapy, when an abscess cavity was present beyond the anastomotic leak.

Leak closure was successful in 39 patients with upper GI-leaks (83 %) and 22 patients with lower GI leaks (75.9 %), accounting for an overall 80.3 % success rate. Leak closure failed in 15 (19.7 %) patients, and the surgical approach was successful in all 14 patients who underwent re-intervention, whilst one patient died due to sepsis at day 7 post-op.

The authors conclude that an endoscopic approach is successful and safe in the majority of patients with anastomotic gastrointestinal leaks. Therefore, endoscopic treatment should be attempted before resorting to more invasive, costly and risky re-interventions.

#### Endoscopic management of patients with post-surgical leaks involving the gastrointestinal tract: A large case series.

Manta R, Caruso A, Cellini C, Sica M, Zullo A, Mirante VG, Bertani H, Frazzoni M, Mutignani M, Galloro G, Conigliaro R (2015)

United European Gastroenterology Journal 0(0) 1–8 DOI: 10.1177/2050640615626051

#### OTSC® Hemostasis Update 1

#### March 2017 | High-risk GI bleeding: primary hemostasis in first-line OTSC® treatment in 95 %

HJ Richter-Schrag and colleagues, Center of Interdisciplinary Gastrointestinal Endoscopy and Department of General and Visceral Surgery, University of Freiburg, Germany, performed a retrospective study evaluating rebleeding, primary failure and mortality of patients, in whom OTSCs were used as first-line and second-line endoscopic treatment (FLET, SLET) of upper and lower gastrointestinal bleeding (GIB).

All patients with upper and lower GIB who underwent FLET and SLET with OTSCs between 04/2012 and 05/2016 were included. In addition, patients with upper

GIB were categorized by complete Rockall risk score, and the data were used to calculate predictors of OTSC success and mortality.

A total of 93 patients (58 males, median age 72, range 19-98) with altogether 100 severe acute GIB lesions fulfilled the inclusion criteria. One patient had 3 OTSC applications, and five other patients had 2 OTSCs on different lesions. First-line OTSC treatment was performed in 61 cases and second line OTSC treatment in 42 cases. The mean hospital stay was 19.8 d (range 1-79). Primary hemostasis was achieved in 88 % of cases (88/100). Clinical success (no in-hospital rebleeding) was achieved in 78 % of cases (78/100). Primary failure was significantly lower when OTSCs were applied as FLET compared to SLET (4.9 % vs 23 %, P=0.0008). Patients with Rockall scores  $\geq 7$  had a significantly higher in-hospital mortality compared to those with scores  $<7$  (35 % vs 10 %, P=0.034). No significant differences were observed in patients with scores  $<7$  in rebleeding and rebleeding-associated mortality. The authors concluded that the reduction of primary failure in endoscopic treatment of severe acute gastrointestinal bleeding was best achieved when OTSC was used for first line treatment. In this series, first line OTSC treatment seemed to be a predictor of successful reduction of rebleeding rates. **First-line endoscopic treatment with over-the-scope clips significantly improves the primary failure and rebleeding rates in high risk gastrointestinal bleeding: A single-center experience with 100 cases**

Richter-Schrag HJ, Glatz T, Walker C, Fischer A, Thimme R (2016)

World J Gastroenterol 2016 Nov 7; 22(41): 0000-0000. ISSN 1007-9327 (print) ISSN 2219-2840 (online)

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#### November 2016 | Large single-center experience with 101 OTSC® applications in patients with severe hemorrhage, perforations and fistulae: 89 % overall primary clinical success

Wedi E and colleagues, Strasbourg University Hospitals, Strasbourg, France and St. Bernward Academic Teaching Hospital, Hildesheim, Germany, and Icahn School of Medicine at Mount Sinai, New York, United States, and Boston Children's Hospital, Boston, United States, conducted a retrospective study to investigate efficacy and clinical outcome of patients treated with an OTSC clip for gastrointestinal (GI) emergencies and complications. From 02/2009 to 10/2012, 84 patients were treated with 101 OTSC clips. 41 patients (48.8 %) presented with severe upper-GI bleeding, 3 (3.6 %) patients with lower-GI bleeding, 7 patients (8.3 %) underwent perforation closure, 18 patients (21.4 %) had prevention of secondary perforation, 12 patients (14.3 %) had control of secondary bleeding after endoscopic mucosal resection or endoscopic submucosal dissection (ESD) and 3 patients (3.6 %) had an intervention on a chronic fistula. In 78/84 patients (92.8 %), primary treatment with the OTSC was technically successful. Clinical primary success was achieved in 75/84 patients (89.28 %). In detail OTSC application lead to a clinical success in 35/41 (85.36 %) patients with upper GI bleeding and in 3/3 patients with lower GI bleeding. Technical success of perforation closure was 100 % while clinical success was seen in 4/7 cases (57.14 %) due to attendant circumstances unrelated to the OTSC. Technical and clinic success was achieved in 18/18 (100 %) patients for the prevention of bleeding or perforation after endoscopic mucosal resection and ESD and in 3/3 cases of fistula closure. Two application-related complications were seen (2 %). In conclusion, this study confirms the high value of the OTSC for the treatment of severe gastrointestinal bleeding, fistula closure and the non-surgical management of perforations. **One hundred and one over-the-scope-clip applications for severe gastrointestinal bleeding, leaks and fistulas**

Wedi E, Gonzalez S, Menke D, Kruse E, Matthes K, Hochberger J (2016)

World J Gastroenterol. 2016 Feb 7; 22(5): 1844-1853.

#### June 2016 | OTSC® vs. cSEMS for intestinal

#### leakage: clipping associated with significantly higher clinical success rates

A retrospective study comparing over-the-scope clips (OTSC) and covered self-expanding metal stents (cSEMS) for upper gastrointestinal perforation or leakage was conducted by Prof. Dr. med. H. Farnik, university hospital Frankfurt am Main, and colleagues in four German tertiary endoscopic centers (Frankfurt, Tübingen, Jena, Dortmund).

Technical success, outcome (e.g. duration of hospitalization, in-hospital mortality), and complications were assessed and analyzed with respect to etiology, size and location of leakage.

Between 2006 and 2013, overall 106 patients underwent endoscopic treatment for postoperative leakage, endoscopic perforation or spontaneous rupture of the upper gastrointestinal tract. Of these, 72 (69 %) were treated by cSEMS and 34 (31 %) by OTSC. OTSC was preferred in small-sized lesions and in perforation caused by endoscopic interventions, cSEMS in patients with concomitant local infection or abscess. For cSEMS vs. OTSC, mean treatment duration was 41.1 vs. 25 days (p<0.001), median leakage size was 10 mm (range 1-50 mm) vs. 5 mm (range 1-30 mm), and complications were observed in 68 % vs. 8.8 % (p<0.001), respectively.

Clinical success for primary interventional treatment was observed in 29/72 (40 %) vs. 24/34 (70 %, p = 0.006), and clinical success at the end of follow-up was 46/72 (64 %) vs. 29/34 (85 %) for patients treated by cSEMS vs. OTSC; p = 0.04.

In conclusion, cSEMS and OTSC are rather complementary means than to be mutually exchangeable.

The authors suggest that, due to its low complication profile and high effectivity rates, the OTSC should be the first choice in all cases when it is technically feasible and the diameter of the lesion is not too large. In patients with larger defects and already infection accompanying the leak, cSEMS placement might be preferred.

#### Indication for 'Over the Scope' (OTS)-Clip vs. Covered Self-Expanding Metal Stent (cSEMS) Is Unequal in Upper Gastrointestinal Leakage: Results from a Retrospective Head-to-Head Comparison

Farnik H, Driller M, Kratt T, Schmidt C, Fährdrich M, Filmann N, Königsrainer A, Stallmach A, Heike M, Bechstein WO, Zeuzem S, Albert JG (2015)

PLoS One. 2015 Jan 28;10(1):e0117483. doi: 10.1371/journal.pone.0117483. eCollection 2015.

#### February 2016 | OTSC® as successful last resort before surgery for challenging bleeding lesions

Endoscopy, the official blog of "GIE: Gastrointestinal Endoscopy" recently published a video on OTSC use by Dr. James Y. W. Lau. The video, called "Over-the-scope clip treatment of refractory peptic ulcer bleeding", presented two cases in which OTSC was used to treat chronic peptic ulcerations with refractory bleeding after failed angiographic embolization and endoscopic treatment respectively.

Dr. Lau concluded that, "Endoscopists should consider the use of OTSC when tackling challenging bleeding lesions especially when other standard treatments have failed and certainly before referring your patients to surgery."

#### February 2016 | Use of Over-The-Scope Clip for treatment of refractory upper gastrointestinal bleeding: high technical and clinical success rates reported

Chan SM, Chiu PWY, Teoh YB and Lau JYW from the Department of Surgery, Institute of Digestive Disease, Prince of Wales Hospital, Chinese University of Hong Kong, China, reported about a prospective case series to evaluate the safety and efficacy of the Over-The-Scope Clip in patients with refractory GI bleeding. The case series from included nine patients (4 men, 5 women) with a median age of 72.5 years (range 39 - 91 years), suffering from bleeding gastric ulcers (n=2), bleeding duodenal ulcers (n=5), bleeding gastrointestinal

stromal tumor in the stomach (n=1), and bleeding from ulcerative carcinoma of the pancreas (n=1). Median diameter of the ulcers was 2.5 cm (1-4 cm). Six of the nine patients underwent previous endoscopic hemostasis attempts.

A total of 10 OTSCs were applied in the nine patients. The technical success rate of OTSC was 100 % (10/10). Endoscopic hemostasis was achieved in all patients. No local complications occurred. The clinical effectiveness was 77.8 % (7/9), while two patients with specific conditions developed rebleeding after OTSC application due to chronically fibrotic ulcers because of residual tumor infiltration and previous radiotherapy.

Chan and colleagues discuss that in 8/10 patients, the bleeding was located in difficult positions, where application of conventional clips would have been complicated as the endoscope approach to the ulcer would have been at a steep angle. The OTSCs allowed a larger amount of tissue to be captured for compression compared to common clips while avoiding the possibility of thermal injury with its high risk of perforation, as can happen with thermal hemostasis methods.

As numerous methods of endoscopic hemostasis have been developed, the authors recommend considering the OTSC System in refractory gastrointestinal bleeding before conventional clips, surgery or angiographic embolization.

**Use of Over-The-Scope Clip for treatment of refractory upper gastrointestinal bleeding: a case series**  
Chan SM, Chiu PWY, Teoh YB, Lau JYW  
Endoscopy. 2014 May;46(5):428-31. doi: 10.1055/s-0034-1364932. Epub 2014 Feb 6.

### January 2016 | OTSC® as successful treatment of massively bleeding jejunal varix, which had resisted previous interventions

S Kothari, T Kothari and V Kaul of the Center for Advanced Therapeutic Endoscopy, Division of Gastroenterology and Hepatology at the University of Rochester/Strong Memorial Hospital in Rochester, NY, USA presented a case of successful treatment of massive gastrointestinal bleeding from a jejunal varix with OTSC after several other treatment options had failed. The 67-year old male patient had a medical history of coronary artery disease, chronic renal insufficiency and Laennec's cirrhosis before he was admitted for a laparoscopic left radical nephrectomy for renal cell carcinoma. Afterwards, the patient suffered from several complications, including superior mesenteric vein thrombosis, melena with a significant drop in hematocrit and clinical signs of bleeding, which led to identification and unsuccessful treatment of several possible bleeding sites. The patient underwent anticoagulation, a tagged red blood cell scan, angiography, coil-embolization, repeat mesenteric angiography and repeat (push) enteroscopy. The patient also received a total of 38 units of packed red cells, 13 units of thawed plasma, 9 units of fresh frozen plasma, 3 units of platelets and 2 units of cryoprecipitate. Due to multiple comorbidities, he was deemed as a high-risk patient unfit for surgery. Finally, a tortuous, varix-like, prominent blood vessel with a central small ulceration, bleeding actively, was identified in the proximal jejunum. Ethanolamine injection into the varix did not achieve hemostasis. Finally, a size 12/6t OTSC clip was applied over the actively bleeding jejunal varix using a pediatric colonoscope. Instant and complete hemostasis was achieved with this single clip. No additional transfusions were required and his hematocrit stabilized over the next few days. Due to his overall poor prognosis and multiple comorbidities, the patient's family opted for "comfort measures only" and he passed away several days later. The authors emphasize the fact that they were able to quickly and effectively treat a massively bleeding jejunal varix, which had resisted multiple evaluations and courses of treatment. They deem the OTSC device a major advance in endoscopic management of high-risk patients in a variety of challenging clinical settings, especially in case of poor candidates for surgical intervention. They also note that endoscopic perforation management with the OTSC clip may avoid the cost and morbidity of surgery and other interventions. Statement by Ovesco Endoscopy: the treatment of jejunal varix hemorrhage is not a common indication for the use of OTSC and there is limited

experience with such application.  
**The Over-The-Scope-Clip Device: An Indispensable Tool in Interventional Endoscopy: A Case Series.**  
Kothari S, Granato CM; Sharma S, Kothari T, Fagan N, Adamcewicz M, Wang G, Ullah A, Kaul V. Program No. P234. ACG 2015 Annual Scientific Meeting Abstracts. Honolulu, HI: American College of Gastroenterology.

### August 2015 | Clinical experience with OTSC® shows high success rate for recurrent bleeding and complex resections

E. Wedi and J. Hochberger of the Department of Hepato-Gastroenterology at the University Hospital of Strasbourg, France, reported on clinical experiences with the over-the-scope clip system and its application aids such as the OTSC Twin Grasper and OTSC anchor for coarse tissue. They present a review of 14 clinical studies on OTSC use and add their own experiences with 84 patients (101 OTSC applications). All Strasbourg patients suffered from recurrent bleeding/lesions of perforations and fistulae or post-operative leakage. 78 out of 84 cases (92.85 %) could be treated successfully.

The report notes that misapplication and complications are rare (<3 % according to the literature) when using OTSC. If they occur, they include narrowing of the organ lumen in case of small passageways and comprehensive aspiration of tissue. The authors remark that this should be kept in mind, especially in narrow sections of the esophagus or bowel.

They also maintain, however, that OTSC is often a good option for achieving quick closure in case of acute perforation or severe bleeding. Possible complications might then be compensated in a subsequent procedure, e.g. through dilation of a stenosis. They also report isolated cases of a grasper getting caught in the OTSC clip. However, if the clip is deployed before the grasper is pulled back fully into the cylinder, this complication is extremely unlikely in clinical practice.

The authors report that a device for cutting the clip for later removal as well as other instruments based on the OTSC concept show promising results in experiments.

The paper concludes that OTSC is an asset in interventional endoscopy, especially in case of complex endoluminal resections. According to the literature, OTSC is especially useful for closure of perforations of up to 1.3 cm (and much larger in individual cases) and bleeding lesions with a high risk of recessive bleeding, e.g. in anti-coagulated patients or treatment of acute Forrest la/b hemorrhage.

Chronic fistulae, which have limited chances of successful treatment, regardless of treatment method, due to insufficient circulation in scarred and calloused tissue, remain a challenge, even with OTSC. Caution is also in order when closing no longer fresh postoperative leakage or perforations since these may require sufficient external drainage.

### Klinische Erfahrungen mit dem Over-the-Scope Clip (OTSC)

Wedi E, Hochberger J (2014)

Endo-Praxis, 30.1, 14-17

dx.doi.org/10.1055/s-0034-1370894

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### April 2015 | Study identifies OTSC® as effective and safe endoscopic therapy for acute gastrointestinal bleeding

In an observational retrospective case series, Dr. Matthew Skinner, Dr. Juan P. Gutierrez, Dr. Helmut Neumann, Dr. C. Mel Wilcox, Dr. Chad Burski and Dr. Klaus Mönkemüller of the Basil I. Hirschowitz Endoscopic Center of Excellence, Department of Gastroenterology, University of Alabama, Birmingham, USA, evaluated the efficacy and safety of OTSC clip placement in patients with upper gastrointestinal bleeding after traditional endoscopic methods had failed.

The study was conducted at a large tertiary care hospital, comprising 12 patients (8 male, 4 female), mean age of 59 (range: 29-86) with ongoing upper gastrointestinal bleeding despite two or three previous sessions of endoscopic therapy. Patients had a mean ASA score of 3 (range: 2-4), mean hemoglobin of 7.2 g/dL (range: 5.2-9.1), and shock was present in 75 % of patients. They had

all received packed red blood cells (mean 5.1 units, range 2-12). Bleeding was due to duodenal ulcer (6), gastric ulcer (2), Dieulafoy lesion (2), anastomotic ulceration (1) and Mallory-Weiss tear (1). Hemostasis was achieved in all patients, but rebleeding occurred in two patients 1 day and 7 days\* after OTSC placement. There were no complications associated with OTSC application.

The OTSC System was loaded onto a standard gastroscope and introduced into the upper gastrointestinal tract under standard direct visualization. The bleeding lesion was located and the gastroscope was maneuvered towards it. Once the OTSC cap was positioned on top of the lesion, full suction was applied to tissue, so that the lesion was fully engulfed inside the transparent cap before the clip was released. In two patients with post-bulbar ulcers, a wire or a wire placed inside a feeding tube was advanced into the distal duodenum and the scope advanced alongside the wire. This measure helped to prevent small-bowel luminal occlusion, which has previously been reported as a major adverse event.

The authors conclude that the OTSC System provides tissue apposition far superior to traditional clipping and can function as a "rescue therapy" in patients with severe non-variceal upper gastrointestinal bleeding in whom prior endoscopic therapies have failed, avoiding more invasive procedures such as embolization or surgery. They point out that the OTSC System appears promising for the treatment of bleeding lesions with large-diameter visible vessels or those located in awkward positions, such as the greater curvature of the stomach or the posterior duodenal wall, which may not always be amenable to treatment with standard endoscopes and endoscopic devices.

\*Any bleeding occurring more than 72 hours after therapy is usually regarded as a new incident.

### Over-the-scope clip placement is effective rescue therapy for severe acute upper gastrointestinal bleeding

Skinner M, Gutierrez JP, Neumann H, Wilcox C, Burski C, Mönkemüller K

Endoscopy International Open 2014; 02: E37-E40 171

### March 2015 | JFHOD Congress, France: OTSC® in hemostasis – high success rate in anti-coagulated patients

Paris, March 19-22: The JFHOD congress – Journées Francophones d'Hépatogastroentérologie et d'Oncologie Digestive 2015 – the major French clinical congress on gastroenterology, hepatology and GI oncology was held under the presidency of Prof. Jean-Christophe SAURIN.

The group around Prof. J. Hochberger presented their data on OTSC in the treatment of severe gastrointestinal hemorrhage.

Dr. E. Wedi, Dept. Of Gastroenterology and Digestive Endoscopy, University Hospital, Strasbourg, France summarized cases admitted to emergency care due to severe GI bleeding. All patients had Hb <7g/dl upon admission. Median age 73 yrs (29-97). 80 % were under concomitant anti-coagulation or antiplatelet therapy. In 87.2 % (48/55) bleeding was from a gastroduodenal peptic ulcer, and the remaining from various other causes.

OTSC clips were placed. The overall clinical success rate without recurrence was 83.6 % (46/55). In 32.7 % OTSC was placed as a salvage treatment due to prior ineffectiveness of other techniques. 12.7 % (n=7) had to undergo surgical treatment. Out of these 7 patients 4 died, giving a total mortality rate of 7.2 % in this highly challenging case series.

The report by Wedi et al. underlines that patients with a high Rockall score can profit from OTSC treatment, especially patients with anticoagulative or antiplatelet therapy.

### July 2014 | Retrospective study confirms safety and effectiveness of OTSC® in the endoscopic treatment of GI bleeding, perforation and fistula

Dr. Vijay Jayaraman and colleagues, Cedars Sinai Medical Center, Los Angeles, recently presented a retrospective study on their experience with the OTSC System in the treatment of GI bleeding, fistula and perforation. Their case series consisted of 24 consecutive patients treated

between January 2011 and April 2012 (mean age 70 years) included the following indications for OTSC placement (28 clips): postsurgical enterocutaneous fistula (n=10), spontaneous perforation (n=1), anastomotic leak (n=4), perforation after mucosal resection (n=3), prophylactic closure of mucosal defect after EMR (n=1), postpolypectomy bleeding (n=2), postendoscopic perforation (n=2), tracheoesophageal fistula (n=1) and leakage from a percutaneous jejunostomy site (n=1). Instruments or modalities used to grasp the tissue were dedicated devices (OTSC Twin Grasper and OTSC Anchor) in 16 and nondedicated devices (rat tooth/alligator forceps or suction alone) in 15.

Median follow-up time was 2.9 months; mean defect size 10 mm (range 5–2 mm). The overall success rate was 61%. In their experience the success rate of closure of an acute defect is higher compared to chronic fistula. 9 out of 24 lesions were chronic (>1 month) in this series which might explain the lower overall success rate in comparison to the literature (72–100%).

Furthermore, a trend towards higher success rate was noted in defects <10 mm compared to defects >10 mm. No patient reported any complications associated with OTSC placement.

Endoscopic therapy is still the initial choice before any surgical intervention to manage GI bleedings, fistulae, perforations and leaks. As through the scope clips are limited by their smaller wing span and low force of closure leading to suboptimal results, the OTSC clip provides a safe and effective endoscopic alternative.

#### Clinical Application and Outcomes of Over the Scope Clip Device: Initial US Experience in Humans

Jayaraman V, Hammerle C, Lo SK, Jamil L, Gupta K  
Diagn Ther Endosc. 2013;2013:381873 137

#### June 2014 | Three case reports on surgery-sparing uses of the OTSC® clip in multiple indications

Three different case reports lately published by Dr. V. Gómez et al., Dept. of Gastroenterology and Hepatology, Mayo Clinic, Jacksonville, USA, Dr. S. Singhal et al., Div. of Gastroenterology, The Brooklyn Hospital Center, New York, USA and Dr. J. Albert, Center of Internal Medicine, Johann Wolfgang Goethe University Hospital, Frankfurt/Main, Germany illustrate the broad spectrum of indications for which placement of OTSC clips can be useful.

**The first case report describes the use of the OTSC System in the management of a Dieulafoy lesion. A 74-year old man suffered from a recurrent, obscure, life-threatening gastrointestinal bleeding. EGD revealed a non-bleeding Dieulafoy lesion at the lesser gastric curvature. Due to the large size and difficult position of the lesion, conventional through-the-scope clips were not used, but an OTSC clip was successfully deployed. Novel treatment of a gastric Dieulafoy lesion with an over-the-scope clip**

Gómez V, Kyanam Kabir Baig KR, Lukens FJ, Woodward T  
Endoscopy. 2013;45 Suppl 2 UCTN:E71. 129

#### April 2014 | Conference report | 44<sup>th</sup> DGE-BV Congress, Hamburg

The 44<sup>th</sup> DGE-BV Congress of the German Society for Endoscopy and Imaging Procedures/Diagnostics was held in Hamburg, April 3–5, 2014 under the presidency of Prof. Dr. Thomas Rösch.

Again a significant number of both oral presentations and posters have been featured at this year's event. In summary they all reported their mostly positive experiences with the OTSC System in all main indications. In addition our products were featured in several hands-on courses alongside the conference (Chairs: Hochberger J., Maiss J., Kraus F.). Ovesco presented their new products, the DC Clip Cutter and the FTRD device which are both due to be launched later this year. The reaction of the medical world was more than promising.

• **Neue Clips für Blutung und Verschlusstechniken**  
Caca K, Ludwigsburg, Germany  
K. Caca gave a talk on "New tools for the treatment of GI-

hemorrhage and perforation". Even though also mentioning other devices he mainly elaborated on the OTSC System. In his summary of clinical cases his take home message was: "the OTSC device achieves hemostasis more quickly than all other devices and is more effective particularly regarding acute, difficult and heavy bleedings." For the treatment of perforation OTSC was the standard choice. Also, he showed first experiences with the all new DC Clip Cutter device as an important tool for removing the OTSC which will be launched later this year.

#### • Update Endoskopie – meine Toppapers

Häfner M, Vienna, Austria

M. Häfner updated the plenary session on important recent papers on GI hemorrhage. There he cited two papers by Manta et al. (2013) and Chan et al. (2014) where OTSC had proven to be safe, effective and efficient also in severe bleeding when other procedures had already failed.

#### Over-the-scope clip (OTSC®) represents an effective endoscopic treatment for acute GI bleeding after failure of conventional techniques

Manta R, Galloro G, Mangiavillano B, Conigliaro R, Pasquale L, Arezzo A, Masci E, Bassotti G, Frazzoni M  
Surg Endosc. 2013 Sep;27(9):3162-4 114  
doi: 10.1007/s00464-013-2871-1 [Epub 2013 Feb 23]

#### Use of Over-The-Scope Clip for treatment of refractory upper gastrointestinal bleeding: a case series

Chan SM, Chiu PW, Teoh AY, Lau JY  
Endoscopy. 2014 May;46(5):428-31  
doi: 10.1055/s-0034-1364932 [Epub 2014 Feb 6] 162

#### • Clip-Karussell

Groth S, Hamburg, Germany

S. Groth elaborated on the endoscopist's option once it comes to use clips. Interesting enough he exempted the OTSC from the rest of all products stating that OTSC is playing in a different league.

(Comment by Ovesco: **the comparator of OTSC is surgery!**)

Altogether five posters were dealing with OTSC:

#### • Over-the-Scope Clip System (OTSC) – OneTherapy for Safety Closure

Leonhardt K, Ohse A, Bauer B, Repp M, Altenburg, Germany report their 3.5-year experience with our system regarding the three major indications: hemorrhage, acute perforation, and chronic fistula/anastomotic leakage where they achieved a 85.7%, 84.6%, and 60% success rate. 33 patients were included in this retrospective analysis. Average age was 69 years (41–92 ys). Three patients received two clips at once. Across the GI tract the number of patients was equally distributed, except for Jejunum and Ileum with only one patient each. The authors conclude that OTSC is a useful and effective tool for the endoscopist sparing the surgeon in many cases.

#### • Endoscopic treatment of acute bleedings with an Over-The-Scope Clip (OTSC)

A. Braun et al. investigated the role of OTSC in the treatment of acute GI hemorrhage in an emergency. Between 2011 and 2013 they treated 16 patients (median 75.5 y/o (61–92), m=9, f=7) with OTSC for upper and lower-GI bleeding (8 each). Patients with upper-GI bleeding received high PPI-medication simultaneously. 7 patients were classified F la, 7 F lb, and 2 F lla. All patients presented with an acute decrease of hemoglobin, with hematemesis, melena, and hematochezia. The clip was applied by using a standard forceps. Technical success was achieved in all 16 patients (100%) with immediate primary hemostasis. None of the interventions took longer than 20 minutes. Only 6 patients underwent follow-up endoscopy between day 1 and 7 after clip application. All control endoscopies were uneventful and showed clinical success. 9 patients did not need any further endoscopy. None of the patients needed any further therapy for bleeding. All patients started normal oral intake from day 2. The authors conclude that OTSC is safe and effective for the treatment of hemorrhage which reduces mortality, with short intervention times.

#### Endoskopische Behandlung von akuten Blutungen mit einem Over-The-Scope Clip (OTSC)

Braun A, Richter-Schrag HJ, Fischer A, Freiburg, Germany

#### March 2014 | OTSC®: easy to use with good results, decreasing morbidity and mortality in diagnostic and therapeutic endoscopy

In the quest to describe the use and the clinical applications of OTSC System in an environment where endoscopic and surgical techniques are increasingly more complex and frequent Singhal et al. have searched and analysed the literature using the key words „endoscopy“ and „over-the-scope clip“ in order to identify human studies evaluating the application of OTSC from January 2001 to August 2012.

The indication, efficacy, complications, and limitations were recorded. The overall success rates of OTSC based on the current literature are in the range of 75% to 100% for closure of iatrogenic gastrointestinal perforations, 38% to 100% for closure of gastrointestinal fistulas, 50% to 100% for anastomotic leaks, and 71% to 100% for bleeding lesions. OTSC has shown 100% success rates in managing postbariatric surgery weight gain secondary to dilation of the gastro-jejunostomy.

The authors conclude that OTSC is easy to use with good results, thus decreasing the morbidity and mortality associated with complications secondary to both diagnostic and therapeutic endoscopy and avoiding surgery in many situations.

#### Over-the-Scope Clip: Technique and Expanding Clinical Applications

Singhal S, Changela K, Papafragkakis H, Anand S, Krishnaiah M, Duddempudi S  
J Clin Gastroenterol. 2013 Oct;47(9):749-56 128

#### February 2014 | New case series on use of OTSC® for treatment of refractory upper GI bleeding

Apart from using the OTSC System in acute and chronic perforations (i.e. perforations, anastomotic leakage, fistulae) the authors of the renowned Institute of Digestive Disease, Department of Surgery, Chinese University of Hong Kong are reporting of patients in whom OTSC was used for endoscopic control of refractory or major upper gastrointestinal bleeding from lesions in the gastroduodenal tract between 1 July and 31 December 2012. Nine patients were included (median age 72.5 years, range 39–91) with bleeding gastric ulcers (n=2), bleeding duodenal ulcers (n=5), bleeding gastrointestinal stromal tumor in the stomach (n=1), and bleeding from ulcerative carcinoma of the pancreas (n=1). The median size of the ulcers was 2.5 cm (range 1–4). Six of the nine patients had undergone previous endoscopic hemostasis. Technical success (defined as hemostasis achieved at index endoscopy) was achieved in all patients and the clinical effectiveness was 77.8% (defined as technical success with no rebleeding). All procedures were carried out by two experienced endoscopists. Those two patients that experienced rebleeding suffered from complex duodenal ulcer. One of them had been treated with radiotherapy for residual disease after resection of common bile duct cholangiocarcinoma. After several additional EGDs, transarterial embolization, and one surgical intervention which all failed to stop the bleeding, the patient died eventually. The second patient bled from the inferior pancreaticoduodenal artery and needed arterial embolization as well.

The authors discuss a meta-analysis of 1156 patients in 15 randomized trials where endoclips were shown to be superior to injection alone, and as effective as heater probe treatment. The overall rate of rebleeding in those conventionally treated patients ranged between 7.1% and 9.5% though. Since rebleeding correlates with the adverse outcome of this indication they speculate that control of bleeding would have a positive impact on patient outcome. Even though the study was carried out in patients with complex duodenal ulcer and underlying malignancies the technical success rate of OTSC was 100%. They also point out that usually in cases like these the application of conventional clips is difficult; the repeated application of heater probe being associated with a higher risk of perforation. Whereas the application of OTSC allows for larger amounts of tissue and constitutes a quite durable treatment (OTSC in situ after a median of 28 days in this study). The authors conclude that the use of OTSC is a safe

and effective method of endoscopic hemostasis for major bleeding from miscellaneous upper gastrointestinal causes and should be considered in refractory bleeding after conventional endoscopic hemostasis, before surgery or angiographic embolization.

**Comment by Ovesco:** a prospective controlled randomized multicenter trial with 64 patients with recurrent upper GI bleeding is recruiting in Germany (Endoscopic Treatment of Recurrent Upper GI Bleeding: OTSC [Over the Scope Clip] Versus Standard Therapy (STING). ClinicalTrials.gov Iden-tifier: NCT01836900)

**Use of Over-The-Scope Clip for treatment of refractory upper gastrointestinal bleeding: a case series**

Chan SM, Chiu PW, Teoh AY, Lau JY

Endoscopy. 2014 Feb 6.

[Epub ahead of print]

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**February 2014 | Retrospective study on efficacy and safety of the OTSC® System in the treatment of GI bleeding, fistula and perforation: primary technical success rate 91.3 %, durable clinical success rate 82.6 %**

Dr. Noriko Nishiyama and colleagues, Dept. of Gastroenterology and Neurology, Kagawa University, Japan, recently presented their retrospective study on efficacy and safety of the OTSC System in endoscopic closure of gastrointestinal bleeding, fistulas and perforations, concluding that the OTSC System is a highly useful device that can safely be utilized for these indications.

Their case series consisted of 23 consecutive patients treated between November 2011 and September 2012 (mean age 77 years) included the following indications for OTSC placement: stopping GI bleeding (n=9), closing perforation (n=10), closing chronic fistula (n=4) and prevention of post endoscopic submucosal dissection (ESD) duodenal artificial ulcer perforation (n=1). One patient had a perforation that formed a fistula. Lesions were located in the esophagus (n=1), the stomach (n=10), the duodenum (n=5), the sigmoid colon (n=3) and in the rectum (n=4). In 8 patients other therapies preceded OTSC application (e.g. conventional hemostatic clips, local injections, hemostatic coagulation forceps). Median follow-up time was 67 days. The primary technical success rate was 91.3 % (21/23). In two cases application of the OTSC clip was not possible due to stiff, fibrotic lesion edges. The overall clinical success rate (complete closure by using only OTSC clips) was 82.6 %. Major contributing factors for OTSC failure were a large lesion size (greater than 20 mm) and a delayed diagnosis (more than 1 week). No patient reported any complications associated with OTSC placement. In conclusion, the OTSC is an interesting and novel device that enhances the armamentarium of therapeutic gastroenterologists.

**Efficacy and safety of over-the-scope clip: including complications after endoscopic submucosal dissection**

Nishiyama N, Mori H, Kobara H, Rafiq K, Fujihara S, Kobayashi M, Oryu M, Masaki T

World J Gastroenterol. 2013 May 14;19(18):2752-60

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**November 2013 | OTSC® in endoscopic treatment of acute GI bleeding after failure of conventional techniques: primary hemostasis of 97 %**

The OTSC System can overcome the limitations of conventional clips in the treatment of patients with acute GI bleeding by providing compression of large amounts of tissue, leading to a more efficient hemostasis. Dr. R. Manta and colleagues, Gastroenterology and Endoscopy Unit, New S. Agostino Hospital, Modena, Italy draw this conclusion on the basis of a retrospective analysis of a consecutive case series of 30 patients with severe acute GI bleeding treated with the OTSC System after failure of conventional techniques.

Data were collected from six high-volume endoscopy units in a period between December 2011 and September 2012. All 30 patients suffered from bleeding lesions unresponsive to saline/adrenaline injection and through-the-scope clipping located in the upper and lower GI tract in 23 and 7 cases, respectively. Bleeding lesions included duodenal

ulcer (n=12), gastric ulcer (n=6), Mallory-Weiss (n=2), Dieulafoy (n=2) and surgical anastomosis (n=1) in the upper GI tract and endoscopic mucosal resection (n=5), endoscopic submucosal dissection (n=1) and colonic diverticulum (n=1) in the lower GI tract.

Primary hemostasis with OTSC was achieved in 29 of 30 cases (97 %). Rebleeding in two cases was successfully treated with injection of saline and adrenaline. Endoscopic follow-up after 2–4 days and after 1 month revealed correct placement of the OTSC clip and no procedure-related complications. Thus, the OTSC is an effective and safe device for treatment of acute GI bleeding and represents a useful adjunct to the therapeutic armamentarium in endoscopic emergencies.

**Over-the-scope clip (OTSC) represents an effective endoscopic treatment for acute GI bleeding after failure of conventional techniques**

Manta R, Galloro G, Mangiavillano B, Conigliaro R, Pasquale L, Arezzo A, Masci E, Bassotti G, Frazzoni M

Surg Endosc. 2013 Sep;27(9):3162-4

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**October 2013 | Efficacious OTSC® hemostasis in Dieulafoy's gastric lesion resistant to conventional endoscopic treatment**

Dr. B. Mangiavillano and colleagues, Gastrointestinal Endoscopy, Azienda Ospedaliera San Paolo University, Hospital-University of Milan, Italy, present a case study of a 69-year old woman with an episode of melena. EGD showed a Dieulafoy's bleeding lesion in the proximal third of the posterior wall of the stomach. The lesion was treated with an epinephrine injection and application of two conventional working-channel delivered metallic clips and the patient was discharged two days later. After three days the patient again presented with melena. Blood transfusions were necessary. An EGD was performed, showing no sign of an actively bleeding ulcer. The patient was admitted to hospital and suffered from another episode of melena with hemorrhagic shock. The now actively bleeding Dieulafoy's lesion was then treated with an OTSC clip, stopping the hemorrhage completely and persistently. Endoscopic follow-up after 30 days displayed correct placement to the OTSC and no signs of further bleeding.

**Successful treatment with an over-the-scope clip of Dieulafoy's gastric lesion resistant to conventional endoscopic treatment**

Mangiavillano B, Arena M, Morandi E, Viaggi P, Masci E

Endoscopy. 2012;44 Suppl 2 UCTN:E387

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**October 2013 | OTSC® successful in providing hemostasis in posterior duodenal ulcer bleeding after failure of conventional clips**

Ulcer bleeding is one of the key indications for the OTSC System. In a recently published case series (n=4), Prof. Klaus Mönkemüller and colleagues, Dept. of Internal Medicine, Gastroenterology and Infectious Diseases, Marienhospital Bottrop, Germany add to the growing clinical experience in using the OTSC System to control massive gastrointestinal bleedings and achieve life-saving hemostasis. All four patients (mean age 84.5) presented with hypotension and mean hemoglobin of 9 g/dL. After initial fluid resuscitation an emergent EGD displayed actively oozing ulcers in the posterior duodenum. As an initial therapy with injection of epinephrine-saline solution and standard clip placement failed and all patients suffered from rebleeding, the decision to apply the OTSC System was made. Hemostasis was attained successfully and all patients discharged in stable conditions. Even in difficult located ulcers in the posterior duodenum the placement of the OTSC is easy and effective to obliterate bleeding vessels resulting in life-saving hemostasis.

**Utility of the „bear claw“, or over-the-scope clip (OTSC) system, to provide endoscopic hemostasis for bleeding posterior duodenal ulcers**

Mönkemüller K, Toshiwaji J, Zabielski M, Vormbrock K, Neumann H

Endoscopy. 2012;44 Suppl 2 UCTN:E412-3.

[Epub 2012 Nov 20]

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**July 2013 | Recommendation of OTSC® System in complex GI bleeding**

In an overview article the authors are referring to the current guideline therapies available and new developments. They report that other new three-dimensional clips seem to be even less efficacious than normal hemoclips. Thus, the authors conclude that obviously one of the key elements to successful hemostasis is the strength of the jaws of a clip and the amount of tissue captured. They state that this is obviously fulfilled by the design of the OTSC System which allows for the capture of a large amount of tissue and is more secure than other clips in the experimental setting. Thus the OTSC System is being recommended and used in complex GI bleeding. According to Leung & Lau a single clip suffices for most circumstances and therefore the procedure is shorter when compared to multiple applications of hemoclips.

**Comment by Ovesco:** In a recently published series of 83 patients with severe and complicated GI bleedings (e.g. relapses after conventional endoscopic hemostasis or indication for a surgical intervention) the success rate was close to 93 % with OTSC (Kratt T et al., Poster DGE-BV meeting, Munich 3/2013)

**New endoscopic hemostasis methods**

Leung Ki EL, Lau JY

Clin Endosc. 2012 Sep;45(3):224-9 | Epub 2012 Aug 22

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**April 2013 | Conference report | OTSC® at German Endoscopy Conference (DGE-BV 2013 in Munich)**

OTSC was well-covered in the scientific programme of this year's German Endoscopy Conference in Munich.

**Clinical presentations 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).

**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 rebleeding (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 et al., Tübingen*

**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 rebleeding 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 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 rebleeding, 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“**

*T. Kratt, D. Stüker, A. Kirschniak, A. Heining, B. Wietek, A. Königsrainer, Tübingen*

**February 2013 | Retrospective multicentric review of early OTSC® patients in the US: overall clinical success rate of 71 %**

Dr. Todd H. Baron and colleagues, Division of Gastroenterology & Hepatology, Mayo Clinic, Rochester MN, USA report about their experience with 45 patients and 48 OTSC clip placements from March 2011 to January 2012. Median follow-up time in this mixed cohort was 77

days (30–330 days). Indication break-down included hemostasis (n=7), closure of chronic fistula (n=28), closure of iatrogenic perforations (n=5), closure of post-esophagectomy anastomotic leakage (n=3) and miscellaneous (n=2).

Before OTSC placement 49% of the patients had undergone other therapies for their condition that had failed. The overall clinical success rate was 71%. Hemostasis was achieved in 100% of cases. Anastomotic leakage and fistula was closed in 65%. Also one case of OTSC clip removal by means of APC-cutting of a clip hinge is described.

The authors conclude that the OTSC clip appears clinically effective and is a welcome addition to the therapeutic armamentarium in the closure of leaks, fistula, perforations and non-variceal bleeding.

**Use of an over-the-scope clipping device: multicenter retrospective results of the first U.S. experience**

*Baron TH, Song LM, Ross A, Tokar JL, Irani S, Kozarek RA*  
*Gastrointest Endosc. 2012 Jul;76(1):202-8*

**October 2012 | The success rates for hemostasis in severe GI bleeding, perforation closure and chronic fistula closure are 88 %, 79 % and 73 %, respectively**

The OTSC System has been described in more than 40 clinical papers in the scientific literature covering a range of indications. In order to summarize the clinical data published so far and to evaluate the overall clinical efficacy, Ovesco Endoscopy has commissioned systematic literature research on the OTSC System.

The study was limited to clinical publications and covered the key applications of the OTSC System, hemostasis, closure of acute GI lesions (perforations) and chronic GI lesions (fistula). Only clinical reports with >4 patients were included into the survey, that was carried out by Dr. Timo Weiland, novineon CRO, a specialized contract research organization for the medical device industry ([www.novineon.com](http://www.novineon.com)).

The success rates defined as permanent achievement of the therapeutic goal for hemostasis in severe GI bleeding, perforation closure (including acute anastomotic suture line failure) and chronic fistula closure are 88%, 79% and 73%, respectively. The OTSC System compares to the effectiveness of a surgical intervention in the respective indications or offers a new therapeutic option in situations where surgery is not feasible.

[http://www.ovesco.com/fileadmin/Downloads/OTSC\\_System\\_clinical\\_data\\_eng\\_Rev01\\_2012-10-22.pdf](http://www.ovesco.com/fileadmin/Downloads/OTSC_System_clinical_data_eng_Rev01_2012-10-22.pdf)

(English)

[http://www.ovesco.com/fileadmin/Downloads/OTSC\\_System\\_KlinischeDaten\\_deu\\_Rev01\\_2012-10-22.pdf](http://www.ovesco.com/fileadmin/Downloads/OTSC_System_KlinischeDaten_deu_Rev01_2012-10-22.pdf)

(German)

**October 2012 | Hemostasis in large gastric ulcer with the OTSC® System**

Vormbrock et al. report a successful treatment of gastric ulcer bleeding with the OTSC System.

In an emergency EGD removal of clots and fresh blood revealed an ulcer with a 2-mm thick pulsating vessel. Injection therapy was difficult due to the fibrotic tissue. Thus OTSC placement was decided. To mobilize the target tissue into the cap, two edges of the ulcer were grasped by each of the two jaws of the OTSC Twin Grasper. After retraction of the grasper and additional suction the OTSC was applied and immediate hemostasis achieved.

The authors conclude that the OTSC was effective for hemostasis in this fibrotic ulcer which was very hard to treat with other endoscopic methods. They state that the placement of OTSC was quick and easy resulting in potentially life-saving hemostasis.

**Use of the "bear claw" (over-the-scope clip) to achieve hemostasis of a large gastric ulcer with bleeding visible vessel**

*Vormbrock K, Zabielski M, Mönkemüller K*  
*Gastrointest Endosc. 2012 Oct;76(4):917-8*