December 2020 | Conference of UEGW 2020 Reporting 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. Friedrich, University of Tuebingen 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 ablation, or mechanical 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 34 % (Sung et al. 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 ProClip 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 %. 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 auxiliary 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. 33 OTSC, 33 standard endoscopic hemostosis. 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 rebleeding 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 ≥ 7 (STING II) is ongoing.

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

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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-hospital mortality (5.0% vs. 22.5% (p = 0.040)). A. Kümmerl et al., Medical Center University of Freiburg, Freiburg, Germany, presented a retrospective multicenter study comparing OTSC vs TAE (transarterial angiographic embolization) as salvage/balloon therapy for refractory peptic ulcer bleeding at this year’s virtual UEG Week. Results of the study were also presented at this year’s DGV/DGAV conference (conference of the German Society of Gastroenterology, and Digestive and Metabolic Diseases with Endoscopy Section (DGV) 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 (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 co-morbidity index, Rockall score, Helicobacter pylori status, ongoing anti-coagulation, 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 (66.7 % vs. 36 %, 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


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 therapy 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.

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 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 second strategy with ST followed by OTSC as first-line treatment was based on the cost of one hemoclip and a gold probe. The cost of an esophagegastrooduodenoscopy 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 0.0687 QALYs. The second strategy with ST followed by OTSC resulted in $ 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 ≥ 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 endoscopy/atherectomy treatment a repeat of standard therapy 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: A Cost-Effectiveness Compared to Standard Therapy: An Initial Assessment


OTSC Hemostasis Update 11

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

OTSC® Hemostasis Update | Research and clinical trials | Version 12 | 2020-12-14

OTSC® Hemostasis Update 10


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. Jensen et al. presented two randomized controlled trials (RCT) on the first-line treatment of UGIB where
OTSC® Hemostasis Update 12 | Research & clinical trials

Doppler probe assisted (DEP) or OTSC hemostasis is compared with standard endoscopic hemostasis. Individual data from the two successive RCTs 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). 29 patients were treated with DEP and 21 with OTSC and 101 with standard endoscopic treatment. All cases were randomized concerning the presence of stigmata of hemorrhage—major SRH (spurting arterial bleeding, nonbleeding visible vessel, or adherent clot) or lesser SRH (oozing bleeding or flat spot). The rates of 30-day rebleeding for DEP, 4.1% and more than double for DEP (P<0.14). 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 Jutabah, Kevin A. Ghassemi, MartiKaneshiro, Mary Ellen Jensen, Jeffrey Gombein

OTSC as first-line therapy for NVUGIH 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 NVUGIH 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). 93% of lesions included in the study were peptic ulcer disease (PUD) 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 as DEP, while DEP therapy ($1647) costs $18 less than OTSC ($1655). 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 NVUGIH, especially for high-risk stigmata. For lesser-risk stigmata, DEP is preferred as it has 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 inactivate 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 the first-line therapy group, 8 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 min 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 acutecare bleeding, especially as rescue treatment.

Note: Ulcer bleeding is contraindicated for the treatment of bleedings of esophageal varices.

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

Goklug Sinir, Ali Enkan Dumant, Hasan Yilmaz, Alayt Celebi, Sadechin 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 in which evaluated the use of OTSC with standard endoscopic treatment of severe nonvariceal upper gastrointestinal bleeding (NVUGIB) to patients treated with standard hemostasis RX methods (e.g. hemoclips or multiple probe with epinephrine injection or esophagogastrroduodenoscopy (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 First Endoscopic Treatment of Severe Non-Variceal Upper Gastrointestinal Bleed (NVUGIB)

Jensen DM 1, 2, Kovacs TG 2, 2, Ghassemi KA 1, 2, Kaneshiro M 1, 2, and Gombein, J 4

1CURE Digestive Diseases Research Center, Los Angeles, CA, United States. 2 David Geffen School of Medicine at UCLA and Ronald Reagan UCLA Medical Center, Los Angeles, CA, United States. 3 West Los Angeles Veterans Administration Medical Center, Los Angeles, CA, United States. 4 Department of Medicine – GI - 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 g/dL, who showed severe duodenitis. A side viewing duodenoscope showed a large, cratered duodenal bulb ulcer with a visible vessel. Epinephrine was injected and 5 hemorrhoids were placed. Despite this, there was still active oozing of blood. All the hemorrhoids 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. Patients were continued and follow up endoscopy at 1 month showed healed ulcer site with clip in place. While OTSC has been well established in leaks, perforations and fistulas, their role in UGI hemorrhage is evolving. Several randomized trials comparing OTSC with standard 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, 1, Meir Mizrahi, 2, Yazan Fahmawi, MD, 2, Meir Mizrahi, 1, 2

1University of South Alabama College of Medicine, Mobile, AL; 2University of South Alabama, Mobile, AL; 3University 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

Manima Arampat, 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 presented with 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 11/0-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 endoscopy, patient had multiple episodes of hematemesis 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 flow underneath SRH and thereby reduce lesion rebleeding. Randomized Controlled Trial (RCT) of Over-the-Scope Clip (OTSC) as First Endoscopic Treatment of Severe Non-Variceal Upper Gastrointestinal Bleed (NVUGIB)

Jensen DM 1, 2, Kovacs TG 2, 2, Ghassemi KA 1, 2, Kaneshiro M 1, 2, and Gombein, J 4

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that failed initial endoscopic and angiographic interventions. Over-the-Scope Clip as Salvage Therapy for Refractory Non-Veal hemorrhage after Failed Endoscopic Treatment: A Case Series

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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 over 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 86.8 % (95 % CI: 81.3 % – 91.3 %) for upper GI bleeding and 89.5 % (95 % CI: 85.2 % – 93.8 %) for lower GI bleeding. The technical success rate was 98.7 % (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 surgical intervention 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.

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


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 > 2 mm, and those with a fibrocellular base and high-risk endoscopic stigmata (Forest classification types I and II). 95 % confidence interval regarding demographic, risk factors, lesion type and stigmata of hemorrhage. During the 30 day follow up, rebleeding occurred in one patient in the OTSC group (124/4, 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 therapy group (relative risk 0.1, 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 (0/4, 0 %), but did occur in 4 patients in the standard treatment group (AGC 2019, Annual Scientific meeting & Postgraduate Course, Oct 25-30, 2019, San Antonio, TX, USA. D.-J. Jensen UCLA School of Medicine, Los Angeles, CA, USA, presented a RCT evaluating OTSC as first-line endoscopic treatment of severe non-vascular upper gastrointestinal bleeding (NVUGIB). The RCT was conducted at two academic centers. Patients with high-risk 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 ( visceral 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 balanced on case-matched variables.

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 workshops, workshops and hands-on training sessions. […]
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 endoclip 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 EGSE 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 therapeutic 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, staples (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 in the decision process. Herein, interdisciplinary peri-interventional patient care is of great importance. In cases of late diagnosis or not certain/ not employed for expertise, the different endoscopic closure techniques are lecture. Depending on defect size, localization and local sponge/drainage for endoscopic vacuum therapy.

The importance it is for therapeutical success, to keep the time acute perforation and criteria for decision making between the management of free abdominal air due to the paradigm change has taken place within the last years in the term perforation and differentiated it from EGSD to hemostasis and the cost of either 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 per patient with recurrent bleeding was $3886.56 using the over the scope clip and $10,528.55 using OTSC. 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 5 % 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.

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 system is a new device that can be used as a first line therapy for the management of rapid and effective hemostasis. 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 Medtronic device can be used for transferring the target tissue into the cap. For this maneuver, the OTSC Anchor is positioned and tissue is fixed 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 spines may remain external. In the next step, the clip is released. After clip application the OTSC Anchor is detached from the tissue. The OTSC trench data was collected on hemostasis (GIE 2012: 75-100). OTSC showed a persistent pressure and 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 diffus tumor bleeding, in such a case, spray injection and multiple conventional clips must be used. Different types of over-the-scope clips have been tested to assess OTSC efficiency, but in general, the OTSC provides compression plus anchoring. The OTSC has a round tooth, it provides mainly compression. The OTSC gc has prolonged teeth with spikes for gastric wall closure. There are three different hole sizes (8.5-11 mm, 10.5-12 mm, 11.5-14 mm) and 2 endoclip cap depths (3 mm and 6 mm) on the market. The OTSC (1 traumatic) is used for stomach and chronic duodenal ulcers at the level of the bulb. The OTSC (a traumatric) is used for the small intestine and colon parts with thin wall.

Recent studies with the OTSC are:

• A Meta-Analysis of 9 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., Seng 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 UG (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 patients with ulcers including e.g. patients with ulcers and hemoglobin < 10, for patients with cirrhosis and ulcer bleeding, for patients with a spurring 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 case of rebleeding, 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, Wedi E² Berlin, “Göttingen”

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

C. C. Madrida et al., Guayaquil, Guayas, Ecuador, reported on an analysis of data on consecutive patients who presented with high-risk ulcer GI bleeding between 2005/2014 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 round teeth, it provides mainly compression. Th
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 endoscopy, and one with an OTSC and one with APC. The median procedure time was 11 (10-15) min for OTSC and 20 (15-40) for combined therapy (p<0.001).

The authors concluded that the OTSC as first-line single therapy is more effective than standard visually guided 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 series by the study group to compare OTSC with standard hemostasis in patients with severe NVUGIB. Planned by the study group to compare OTSC with standard hemostasis in severe NVUGIB. 19 patients had bleeding peptic ulcers (12 duodenal, 7 gastric) and 1 Dieulafoy 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 ulcers before and after visually guided hemostasis (GIE 2016; 83: 129-30).

Residual arterial blood flow detection after OTSC and DEP guided complete hemostasis were similar (5 % (1-20 vs. 0-0 %) 0-0 (0.063) respectively) but were significantly lower than standard visually guided therapy – 24.2 % (23/95) in the DEP group and 30.8 % of 20 rebleeding rates were seen after OTSC or successful DEP hemostasis (5 % (1-20 vs. 0-0 %) 0-0 (0.063) 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 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 NVUGIB 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. What is the most effective method potentially more than standard endoscopic hemostasis as primary treatment of severe non-variceal upper gastrointestinal bleeding

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July 2019 | Meta-analysis including 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).

Otosu 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) (March 2019). 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) and primary hemostasis rate achieved with rescue 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: 0.12 – 0.26) and 0.25 (95 % CI: 0.17 – 0.34) with rescue therapy. The odds ratio (OR) for 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

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.


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, Rockall score patients (RS ≥ 4), 94% operated as first-line treatment in 10 (53%) and as second-line treatment in 9 (47%) cases. 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 ≥ 8) and intermediate-risk (RS = 4 – 7) patients as compared to historical controls 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 ≥ 4). There was no difference in mortality rates as compared to historical controls.

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

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

OTSC use decreased the rebleding rate in high-risk (RS ≥ 8) patients with statistical significance compared to the rates reported by the Rockall study (0% vs. 53%, p < 0.01) and reduced (0% vs. 24%, p = 0.08) the rebleding rate in high-risk (RS ≥ 8) and intermediate-risk (RS = 4 – 7) patients as compared to historical controls 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 ≥ 4). There was no difference in mortality rates as compared to historical controls.

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

Use of over-the-scope-clips (OTSC®) in non-variceal upper gastrointestinal bleeding in patients with severe cardiovascular comorbidities: a retrospective study

OTSC® Hemostasis Update 4

OTSC® Hemostasis Update 12 | Research & clinical trials

OTSC® Hemostasis Update 12 | Research & clinical trials

OTSC® Hemostasis Update 12 | Research & clinical trials
of the USEGW 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.

Gastrointestinal Endoscopy System (GES) was held in the ESGENCA 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 fulla closure (30.6%), bleeding (28.9%), perforation closure (16.3%), leaks (15.1%), EFTR (6.4%) and stent fixation (0.7%). Complete luminal obstruction in 1177 patients and small bowel fixation with pancreatic in 1117 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 in 177 patients. Between 4/2014 and 03/2018, 100 patients with peptic ulcer bleeding ( Forrest Ia IIb), n=15, injection therapy (n=10) were treated with OTSC. The OTSC was used as first-line procedure in 66 patients. Successful primary hemostasis could be achieved in 89 patients (92% of all cases). In 75 patients (77%), OTSC failure resulted in recurrent bleeding. In 17 cases 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 further surgery was necessary after the first OTSC clip was placed 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 H.p. status (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, p=0.812) and for the Glasgow-Blatchford score (median 15.5, p=0.15). Also, NSAID or anticoagulant treatment was not associated with different bleeding times (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?)  

Analysis of the STING treatment cases: hemorrhage treatment with OTSC in comparison to standard therapy not only cost-effective, but cost-cutting  
A Külerner 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 expenditure for additional clinical results, meaning ΔCosts of both alternatives divided by Δclinical 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 amounted to €12,778.19 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 entire treatment 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 Kostenfunktionalitätsanalyse (OTSC versus standard treatment of recurrent ulcer bleeding: an analysis of cost effectiveness).


Cross-sector routine data from social health insurance confirms safety and efficacy of colonic OTSC.  
D. Horenkamp-Sonnag et al., German Technicians’ Health Insurance, Hamburg, presented a study based on cross-sector routine data collected by social health insurance (> 10 million insured parties), examining OTSC application and safety. 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 54603). Using further codes from different performance sectors, additional indications were identified (iatrogenic perforation (n=58), polypectomy (n=210), bleeding (n=34) and others (n=46). A total of 16 patients (4.5%) underwent 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=0.03), more frequent negative 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 associated with different bleeding times (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.

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November 2018 | Conference Report DGVS  
DGAV

The 17th 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 Vascular Surgery (DGAV) on September 12-15, 2018 in Munich, Germany.

Ovesco 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 Waldhaller presented retrospective data gathered in the University Hospital of Giessen and Marburg evaluating different endoscopic modes of therapy for non-variceal upper gastrointestinal 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.

OTSC placement were fistula closure (30.6%), bleeding (28.9%), perforation closure (16.3%), leaks (15.1%), EFTR (6.4%) and stent fixation (0.7%). Complete luminal obstruction in 1177 patients and small bowel fixation with pancreatic in 1117 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. Success without the need for further intervention.

For questions and further information:

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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 abdomin 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 not a true double 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-Cls in the colon effective and safe? Evidence generation of endoscopic innovations with health insurance routine data.


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 who had been treated since 2014 at the University Hospital Goettingen 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, 1 CF, 1 FLOT+R+T, 2 FLOT, 1 RT, 1 GASTRIP, 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 primary therapy in the first line was used in second line after preceding hemostasis attempts with conventional clips, adenalin 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 26.9 % (13/49) compared to 43.3 % (13/30) in the group of second line therapy. 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.


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 July 2018. In total of 233/262 (88.1 %) of all sessions 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, focusing 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 61.5 years. 51.5 % were male. Immediate success of OTSC treatment was observed in 98.5 % of all sessions (203/205). 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 % (40/49); diameter reduction of 86.1 % (61/72); 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 % (15/17); delayed perforation 90 % (18/20); 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). In the rebleeding group the use of OTSC was safe and feasible in clinical routine, with high immediate success rates with sustained clinical success at 30-day follow-up.


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 bleed. 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, Ludwigswig, Germany, enrolled 86 patients with ongoing bleeding and randomized them to receive either OTSC therapy or standard techniques (a combination of 2 methods from 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 6.3 % in the OTSC group (P=0.001). Further bleeding occurred in 57.6 % in the standard therapy group and 15.2 % in the OTSC group (absolute difference, 42.4 %; 95 % CI 21.8-63.2; P=0.001).

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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 the first time at the conference. 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 severe bleeding signs such as hematemesis, melena or hematochezia. Bleeding was located in the upper GI tract in 34 cases (4 Forrest la, 15 Forrest Ib, and 5 Forrest IIa) and in the lower GI tract in 14 cases (4 Forrest la, 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, 11 M) received follow-up endoscopy on day 1 to 4, which showed the clip in situ and no bleeding stigma. 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.


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 by using the QR code below.


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 analyzed. 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. 0.84 – 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 adviring high-risk radiologic or surgical interventions for non-variceal gastrointestinal bleeding, despite the presence of high risk of adverse outcome and severe prognostic scores.


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 centers on over-the-scope clip therapy in 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. 196/201 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 duodenal-jejunal ulcer Forrest 1a (n=29) and Forrest 1 b (n=3), gastric ulcer Forrest 1a (n=19) and Forrest 1b (n=28), Mallory-Weiss (n=9), non variceal GI bleeding (n=14), 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 or 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 nonvariceal 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 201 patients

November 2017 | Recommendation for OTSC® as first-line therapy in non-variceal upper gastrointestinal bleeding
Kesavan M, Deeb L, Abergel J, Andrawes S, 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 of the Chinese University of Hong Kong, published an article 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 4.5g/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 and a 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 incisure of the stomach. The first attempt to stop the bleeding with heaterprobe and hemoclip failed. Then an OTSC anchor device was used to tampon the ulcer base and deploy an OTSC clip without success. 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 management of refractory peptic ulcer bleeding**

Xiao X, Lau JY (2016)


https://www.youtube.com/watch?v=Guu_szn_YqC8fe

June 2016 | 80% success in endoscopic closure of post-surgical gastrointestinal leaks

R Manta et al., Niguarda Ca’ Granda Hospital, Milan, Nucaro S, Agostino Hospital, Modena, Nuoco Regnina Margherita Hospital, Rome, Baggiovara 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 its first line 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 adjunctive treatment to close the gap between two OTSCs where needed. A covered self-expanding metal stent (cSEMS) was applied when the closure was considered incomplete at endoscopy. When dehiscence characteristics were not fitting for OTSC positioning, a SEMS was directly used. Endoscopy was the first line therapy, when an ascitic cavity was present beyond the anastomotic leak. Leak closure was successful in 39 patients with upper GI leaks (83.3%) and 22 patients with lower GI leaks (75.9%). A covered stent (5 mm) was used as the primary 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.


United European Gastroenterology Journal 0(0) 1–8

DOI: 10.1177/2050640615626051

**OTSC® Hemostasis Update 12**

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, SLIT) of upper and lower gastrointestinal bleeding (GIB).

All patients with upper and lower GIB who underwent FLET and SLIT 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 GI blebs fulfilled the inclusion criteria. One patient had 3 OTSC applications, another one had 12 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 19.3 days (range 1-79). Primary success was achieved in 78 out of 78 (100%). Technical failure was significantly lower when OTSCs were used as FLET compared to SLIT (4.9 vs 23%, P = 0.0008). Patients with Rockall scores ≥ 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 or ≥ 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 OTSCs were 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 rate of severe hemorrhage: A single-center experience with 100 cases


World J Gastroenterol 2015 Nov 7;21(41): 0000-0000. ISSN 1007-9272 (print) ISSN 2219-2340 (online)

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

Wedl E and colleagues, Strassburg University Hospitals, Strasbourg, France and Strasbourg University Teaching Hospital, Hildesheim, Germany, and Iahn 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 perforation 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 (85.3%) patients with upper GI bleeding and in 33/32 patients with lower GI bleeding. Technical success of perforation closure was 100% when clinical success was seen in 4/7 cases (57.14 %) due to attendant circumstances unrelated to the OTSC. Technical and clinical success was achieved in 18/18 (100%) patients for the prevention of bleeding or perforation after endoscopic mucosal resection and ESD and 20/20 in 3 cases of fistula closure. Two application-relevant 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 clips for severe gastrointestinal bleeding, leaks and fistulas


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. Famik, university hospital Frankfurt am Main, and colleagues in four German tertiary endoscopic centers (Frankfurt, Töbingen, 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 ± 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 %) for cSEMS vs. OTS (p<0.001). The authors suggest, that, due to its lower complication profile and high efficiency 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 perforation, the cSEMS should 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


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 ulcersations 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 in some patients, your 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, 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 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

OTSC Hemostasis Update | Research and clinical trials | Version 12 | 2020-12-14
January 2016 | OTSC® as successful treatment of massively bleeding jejunal varix, which had resisted previous interventions

S Kothar, T Kothar 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 jejunal varical bleeding (hemorrhage) 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. The patient suffered for 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 bleeding source was a jejunal varix on the anterior wall of the small bowel after a previous endoluminal resection. 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 massive bleeding, e.g. in patients with severe anticoagulative therapy. The authors conclude that OTSC is an asset in such indication and there is limited experience with such application. The Over-The-Scope-Clip Device: An Indispensable Tool in Interventional Endoscopy: A Case Series. Kothar S, Granato CM, Sharma S, Kothari T, Fagan N, Adamcik-Mwang M, Wang G, Ullah A, Kaul V. Program No. P234. ACG 2015 Annual Scientific Meeting Abstracts. Honolulu, HI: American College of Gastroenterology December 2015.

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 Gastro Clip® OTSC endoluminal resection device. 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. 75 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 more expansive 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 massive bleeding, e.g. in patients with severe anticoagulative therapy. The authors conclude that the OTSC System provides tissue apposition far superior to traditional clips and can function as a "rescue therapy" in patients with severe non-variceal upper gastrointestinal bleeding in whom prior endo-scopy therapies have failed, avoiding more invasive proce-dures 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 endo-scopes and endoscopic devices.

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

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 Basile I. Hirschowitz Endoscopic Center of Excellence, Department of Gastroenterology, University of Alabama, Bir- mingham, 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 123 patients (58 male, 4 female), mean age of 59 (range: 29–86) with ongoing upper gastrointestinal bleeding despite two or three previous sessions of endoscopic thera-py. 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 cases of complications associated with OTSC application. The OTSC System was loaded onto a standard gastro-scope and introduced into the upper gastrointestinal tract under standard direct visualization. The bleeding lesion was located and the gastroscopy 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 endo-scopy therapies have failed, avoiding more invasive proce-dures 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 endo-scopes and endoscopic devices.

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

Paris, March 19–22: The JFHOD congress – Joumées Francophones d’Hépato-Gastroenterologie et d’Endoscopie 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 use in 55 patients with 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 <7 g/dl upon admission. Median age 73 years (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 used as a second option after failure of other ineffective methods of others. 12.7 % (7=7) had to undergo surgical treatment. Out of these 7 patients died, giving a total mortality rate of 7.2 % in this highly challenging case series.

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

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 Basile I. Hirschowitz Endoscopic Center of Excellence, Department of Gastroenterology, University of Alabama, Bir- mingham, 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 123 patients (58 male, 4 female), mean age of 59 (range: 29–86) with ongoing upper gastrointestinal bleeding despite two or three previous sessions of endoscopic thera-py. 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
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), postoperative bleeding (n=2), pre-endoscopic 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 Gaster and OTSC Andro) or nondonated devices (rat tooth/alligator forceps or suction alone) in 15. Median follow-up time was 2.9 months; mean defect size 10 mm (range 5.2–9.5 mm). The overall success rate was 51 %. 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

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

Three different case reports recently 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 nonvisible 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

April 2014 | Conference report | 44° DGE-BV Congress, Hamburg
The 44° DGE-BV Congress of the German Society for Endoscopy, Gastroscopy/Diagnostic Endoscopy 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, the registry of bleeding (R20) and pre-endoscopic indications with the OTSC System in all main indications. In addition our products were featured in several hands-on courses alongside the conference (Chairs: Hochberg J., Maiss J., Kraus F.). Ovesco presented their new products, the DC Clip Cutter and the IFTR device which are both due to be launched late this year. The reaction of the medical world was more than promising.

• New Clips for Blutung und Verschluss Techniken
Caca K, Ludwigswind, 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 Top papers
Häther M, Vienna, Austria
M. Häther updated the plenary session on important recent papers on GI PPI medication simultaneously. Manta et al. 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
DOI:10.1007/s00464-013-2816-9

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

• Clip-Karussell
Groth S, Hamburg, Germany
S. Groth elaborated on the endoscopists’ 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.

• Over-The-Scope Clip System (OTSC) – One Therapy for Safety Closure
Leonhardt K, Ohse A, Bauer B, Reep 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 y). Three patients received two or more clips. 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=m, F=f) with OTSC for upper and lower GI bleeding (8 each). Patients with upper-GI bleeding received higher numbers of OTSC clips. 7 patients were classified F Ia, 7 F Ib, and 2 F IIa. All patients presented with an acute decrease of hemoglobin, with hematemesis, melena, and hematochecia. The clip was applied using a standard forceps. Technical success was achieved in 88 % (4 patients) 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 required 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 Verblutung 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 GI perforations, 70 % to 100 % for closure of gastrojejunoanastomotic/duodenal ulcers, 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 diastasis 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 patients.

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

February 2014 | New case series on use of OTSC for treatment of refractory upper GI bleed

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 20–91) 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 was defined as 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 controlled trials when OTSC may be superior to injection alone, and as effective as heater probe treatment. The overall rate of rebleeding in those conventionally treated patients ranged between 71 % and 9.5 % though since rebleeding correlates with the adverse outcome, this indicator alone probably that duodenal 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 clips is difficult and the 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 for 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 trial in 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 Id: nct01636900)


February 2014 | Retrospective study on efficacy and safety of the OTSC® System in the treatment of Dieulafoy’s 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 led to 64 patients. 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 System). 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.


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 group of patients with 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 94 patients suffered from bleeding lesions ranging from 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=8), 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 %). Reasons for failure 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 emergencys.


October 2013 | Efficacious OTSC® hemostasis in Dieulafoy’s gastric lesion resistant to conventional endoscopic treatment Dr. B. Mangiavillano and colleagues. Gastroenterology, 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.


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=44), 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 years) presented with hemorrhagic shock and hemoglobin of 5.9 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 regrettably and rapidly.


July 2013 | Recommendation of OTSC® System in complex GI bleeding The following article is 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 for a successful hemostasis is the straining of a jaw 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 seems to be recommended and can be applied for 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 (Kraft T et al., Poster DGE-BV meeting Munich 2012).


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/fistulae (source: www.dge-bv.de).

Large single center OTSC cohort with hemostatic and organ wall closure indications Wieß 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. Only 2 patients per indication. 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 in peptic ulcer bleeding was 78 %, most patients had already been treated unsuccessfully with other hemostatic techniques before OTSC clipping or had been candidates for surgical treatment.

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.

The Einzelschlag des OTSC-Klipsclips bei 84 Patienten mit schwerer GBlstützung, Fisteln und Inzisuren – ein Ressumé E. Wieß, D. Menke, and J. Hochberger, Strasbourg

Large single center cohort on OTSC hemostasis in severe GI bleeding Kraft T, Stüber K, Gräfner F, Küper M, Wichmann D, Kopf T, Wehner 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

OTSC® Hemostasis Update 12 | Research & clinical trials | Version 12 | 2020-12-14
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% of cases. Hemostasis 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. Hemostasis complications were observed; in 35.1% OTSC clipping was seen as an ultimate 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, Khiabanchian M, and Trabant 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. Khiabanchian, and I. Trabandt, Neubrandenburg

OTSC for stopping gastroduodenal artery bleeding in duodenal ulcer

Kratt T, Stüker D, Kirschniaik A, Heininger A, Wietek B, Königsrainer A, Tübingen, showed a case series (n=7) in which OTSC was applied in upper GI emergency hemorrhage 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 hemorrhage 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 Thrombomodulierung der lebensbedrohlichen A. gastroduodenalis Ulkus-Arrosionsblutung: alleinige endoskopische Therapie oder „bridge-to-surgery“


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 hemorrhosis (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 removal by means of APC-cutting of a clip hinge was 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-vascular bleeding.

Use of an over-the-scope clipping device: multicentric 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).

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.


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 vessel 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 ulcer 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, Mönkenmüller K

Gastrointest Endosc. 2012 Oct;76(4):971-8