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

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

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

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

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

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

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

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

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

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

OTSC® System

Lively interest in Hands-On Trainings with the OTSC System

The European Society of Gastrointestinal Endoscopy (ESGE) offered an ESGE Learning Area to all delegates of the UEGW to provide a platform for live encounter and interaction among aspiring endoscopists and renowned experts in the field.

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

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

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

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

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

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

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

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

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

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

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

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

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November 2018 | Conference Report DGVS / DGAV

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

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

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

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

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

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

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

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

S Gölder et al. presented a retrospective study comprising all patients with high-bleeding-risk ulcers (Forrest Ia-IIb), treated with OTSC at the Augsburg Hospital. A total of 100 patients with peptic ulcer, primarily or secondarily treated with OTSC, were included (n=25 with gastric ulcer, n=75 with duodenal ulcer, primary OTSC treatment n=66, secondary OTSC treatment n= 34). Primary hemostasis by OTSC without further endoscopic treatment was achieved in 92 patients (92 %, n=60 primary therapy, n=32 secondary therapy). In 8 cases hemostasis could not be achieved with one single OTSC clip. In 17 cases recurrent bleeding occurred 1-12 days after initially successful hemostasis (n=10 primary therapy, n=7 secondary therapy). The group of patients with unsuccessful OTSC treatment showed significantly larger ulcers (median size 3 cm, IQR 2 – 3, 13; p=0.03), more frequent bleeding in the duodenal bulb (22 vs. 2, p=0.033), more frequent negative H.p. status (p=0.045) and significantly higher number of transfused ECs (p=0.002). No significance was reached regarding the Rockall score (median 7.5, p=0.69) nor regarding the Glasgow-Blatchford score (median 15.5, p=0.15). Also, NSAID or anticoagulant treatment was not significantly different between the groups (p=0,53 and p=0,44, respectively). The authors concluded, that OTSC Clip application for peptic ulcer bleeding shows high clinical success rates as primary and secondary therapy. Possible risk factors for therapy failure are ulcer size, localization of the bleeding source in the duodenal bulb, negative H.p. status and increased demand for transfusion.

Over the Scope Clip (OTSC) bei Magen- und Duodenalulcera mit hohem Blutungsrisiko – One and

done? (Over-the-Scope Clip (OTSC) for gastric and duodenal ulcers with high bleeding risk – one and done?)
Gölder S, Neuhaus L, Stückle J, Ebigbo A, Braun G, Probst A, Weber T, Freuer D, Messmann H, Augsburg, Deutschland.

Analysis of the STING treatment cases: haemorrhage treatment with OTSC in comparison to standard therapy not only cost-effective, but cost-cutting
A Küllmer et al. presented results of a study based on data gathered during a prospective randomized study (STING), exploring whether OTSC treatment is more cost-effective than conventional clips due to the higher success rate, despite of the higher price per clip. Two parameters for cost effectivity were calculated: (1) ICER (Incremental Cost Effectiveness Ratio): defines additional expenses for additional clinical results, meaning ∆costs of both alternatives divided by ∆clinical effect. (2) ACER (Average Cost Effectiveness Ratio): costs arising from a specific clinical result. The clinical status that had to be achieved was similar to the primary outcome of the STING study: successful hemostasis without any recurrent bleeding. The parameters for the total procedure, including costs for accommodation etc. were calculated as well as the costs for the endoscopic treatment only. The overall costs of standard treatment approaches were 13,025.95 €, versus 12,776.19 € for OTSC treatment; costs for the endoscopic procedure alone were 2,100.03 € (standard therapy) versus 1,960.17 € (OTSC-therapy). The ICER regarding the overall treatment was -589.01 € and -329.86 € for the endoscopic treatment. The ACER for the overall costs was 30,721.58 € for standard therapy and 15,066.26 € for OTSC therapy. ACER for the endoscopic procedure showed 4,952.90 € and 2,311.52 € for standard and OTSC treatment respectively. As a conclusion, OTSC therapy of recurrent ulcer bleeding was rated cost-effective and cost-cutting when compared to standard approaches.
OTSC- versus Standard-Therapie der Rezidiv-Ulkusblutung: eine Kosteneffektivitätsanalyse (OTSC versus standard treatment of recurrent ulcer bleeding: an analysis of cost effectiveness).
Küllmer A, Behn J, Glaser N, Thimme R, Caca K, Schmidt A, Freiburg Ludwigsburg, Deutschland.

Cross-sector routine data from social health insurance confirms safety and efficacy of colonic OTSC
D Horenkamp-Sonntag et al., German Technicians' Health Insurance, Hamburg, presented a study based on cross-sector routine data gathered by social health insurance (>10 million insured parties), examining OTSC application in the colon. Indication, patient characteristics, outcome and complications were assessed in the actual care setting. 348 patients (median age 67 years, 60 % male) were subject to colonic OTSC (OPS-Code 5460s3). Using further codes from different performance sectors, suspected indications were identified: (iatrogenic) perforation (n=58), polypectomy (n=210), bleeding (n=34) and others (n=46). A total of 16 patients (4.6 %) underwent an additional endoscopic intervention within 10 days of the initial procedure, 43 patients (12.4 %) within 100 days of the initial procedure. 12 patients (3.4 %) received abdominal surgery within 10 days after OTSC procedure, 41 patients (11.8 %) within 100 days of the procedure. Surgery after more than 30 days after OTSC application was mostly due to treatment of the underlying disease (carcinoma, diverticulitis etc.). Overall 9 patients (2.6 %) deceased within 100 days after the intervention. The authors concluded that, in the actual care setting, OTSC is mostly applied for polypectomies and iatrogenic perforations. The presented data supports first findings indicating that OTSC application in the colon is safe and helps to prevent surgery due to iatrogenic complications.
Sind OTS-Clips am Kolon effektiv und sicher? Evidenz-Generierung von endoskopischen Innovationen durch GKV-Routinedaten (Are OTS-Clips in the colon effective and safe? Evidence generation of endoscopic innovations with health insurance routine data.
Horenkamp-Sonntag D, Liebentraut J, Engel S, Knoop H, Hamburg bzw. Berlin, Deutschland.

OTSC as part of combination therapy of esophageal perforations and anastomotic insufficiencies following oncological resections
C Jung et al. presented a retrospective evaluation of all patients, that had been treated since 2014 at the University Hospital 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, 1ICF, 1 FLOT+RTC, 2 FLOT, 1 RTC, 1 GASTRIPEC, 1 unknown). Overall 8 patients received a fully-covered esophagus stent as primary therapy whereas 13 patients received an EndoVac as primary therapy. Complementary therapy was necessary in 6 patients (28.6 %) (2 stent + EndoVac, 1 EndoVac + Stent, 1 EndoVac + stent + fibrin, 1 stent + EndoVac + OTSC, 1 stent + OTSC). In overall 16/21 patients (76.2 %) complete restoration of the anastomosis was achieved. In 5 cases, continuity could not be restored, 2 of the patients died, 3 patients received a cervical drainage. The authors concluded that the group of patients examined was heterogenic and showed complex disease courses. The concept of combination therapy using EndoVac, esophageal stent, OTSC and endoscopic debridement seems to be promising. Further large scale studies are necessary to reliably describe the efficacy of this approach.
Multimodale endoskopische Behandlung von Ösophagusperforationen und postoperativen Anastomoseninsuffizienzen nach onkologischen Resektionen. Was ist die richtige Strategie? (Multimodal endoscopic treatment of esophageal perforation and post-surgical anastomosis insufficiency following oncological resection. Which is the correct strategy?)
Jung C, Kunsch S, Müller-Domieden A, Gaedcke J, Schüler P, Seif Amir Hosseini A, Ghadimi M, Ellenrieder V, Wedi E, Göttingen, Deutschland.

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

100 % primary hemostasis rate and improved management of rebleeding with OTSC used as first line therapy
Lamberts R and colleagues, HELIOS Park-Hospital, Department II for Internal Medicine, Leipzig, Germany, conducted a retrospective study examining success rates in hemostasis of acute upper and lower gastrointestinal bleeding with the OTSC System as first or second line therapy in patients taking different regimens of antithrombotic and/or anticoagulant therapy.
Overall 75 consecutive patients (mean age 71.7, 55 men, 20 women) with active gastrointestinal bleeding were analysed. 34 patients (45.3 %) were under antiplatelet monotherapy, 10 patients (13.3 %) under dual antiplatelet therapy, 13 patients (17.3 %) under inhibitors of plasmatic coagulation, and 18 patients (24.0 %) no antithrombotic/anticoagulant therapy. OTSC was the first-line treatment in 45 (60 %) patients, in 30 patients (40 %) it was used in second line after preceding hemostasis attempts with conventional clips, adrenalin injection, fibrin glue and/or APC therapy. Key outcomes measured were: success rate with the OTSC therapy, rebleeding episodes, their management and the influence of antithrombotic or anticoagulant therapy.
Application of the OTSC resulted in immediate hemostasis in all 75 patients (100 % primary success rate). In 26 patients (34.7 %) a rebleeding episode was noted. In the group of first-line OTSC treatment the rebleeding rate was 28.9 % (13/45) compared to 43.3 % (13/30) in the group of second line OTSC treatment. In 23 patients rebleeding could be treated by further endoscopic interventions. Only 3 patients had to undergo radiological or surgical treatment because of final failure of endoscopic therapy attempts. In the rebleeding group the use of antiplatelet therapies was higher (73.1 % vs 48.9 %).
The authors concluded that primary OTSC application should be the treatment of choice in this high-risk patient population. Repeated endoscopic treatments to achieve definitive hemostasis may be justified and show promising results.
Use of over-the-scope clips (OTSC) for hemostasis in gastro-intestinal bleeding in patients under antithrombotic therapy.
Lamberts R, Koch A, Binner C, Zachaeus M, Knigge I, Bernhardt M, Halm U (2017).
Endoscopy International Open 2017; 05: E324-E330.

OTSC® Hemostasis Update 3

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

Honegger C and colleagues, Division of Gastroenterology and Hepatology, University Hospital Zurich, Zurich, Switzerland, presented data on 262 OTSC placements in a total of 233 interventions. Since 2009, the placement of OTSC has been established at the University Hospital Zurich for the entire spectrum of indications. OTSC has become a device of daily practice. A retrospective study now presents data of all patients treated with the OTSC device at the institution, focussing on indications, anatomic site of OTSC deployment, complications, and immediate and 30-day success rates.
Patient age ranged from 14 to 93 years with a median of 61 years. 51.5 % were male. Immediate success of OTSC treatment was observed in 87.1 % of all sessions (203/233). The success rates per indication were as follows: spontaneous bleeding 84.8 % (28/33); iatrogenic bleeding 100 % (20/20); acute perforation 90.3 % (65/72); prophylaxis for perforation 100 % (24/24); anastomotic leakage 61.1 % (11/18); fistulae 80.7 % (46/57); diameter reduction of the gastro-jejunal anastomosis 100 % (6/6); and stent fixation 100 % (3/3).
At 30-day follow-up, the overall success rate was 67.4 % (157/233). The success rates per indication were as follows: spontaneous bleeding 69.7 % (23/33); iatrogenic bleeding 90 % (18/20); acute perforation 86.1 % (62/72); prophylaxis for perforation 100 % (24/24); anastomotic leakage 33.3 % (6/18); fistulae 29.8 % (17/57), diameter reduction of the gastro-jejunal anastomosis 83.3 % (5/6); and stent fixation 66 % (2/3).
The authors concluded that the treatment with an OTSC is safe and feasible in clinical routine, with high immediate success rates with sustained clinical success at 30-day follow-up.
Establishment of Over-The-Scope-Clips (OTSC) in daily endoscopic routine
Honegger C, Valli PV, Wiegand N, Bauerfeind P, Gubler C (2016)
United European Gastroenterol J. 2017 Mar;5(2):247-254.

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

OTSC has long been described in the scientific literature as a highly effective device for the treatment of upper GI hemorrhage. Now a randomized-controlled trial at 9 academic referral centers (in Germany, Switzerland, and Hong Kong) has proven OTSC to be superior to standard methods. The trial, published by Dr. Arthur Schmidt, Ludwigsburg, Germany, enrolled 66 patients with recurrent bleeding and randomized them to receive either OTSC therapy or standard techniques (a combination of 2 methods from through the scope clipping, injection or electrical coagulation).
Persistent bleeding after per-protocol hemostasis was observed in 42.4 % of patients in the standard therapy

group and 6.0 % in the OTSC group (P=.001). Further bleeding occurred in 57.6 % in the standard therapy group and 15.2 % in the OTSC group (absolute difference, 42.4 %; 95 % CI 21.6-63.2; P=.001).
Gastroenterology. 2018 May 24. pii: S0016-5085(18)34570-0. doi: 10.1053/j.gastro.2018.05.037. [Epub ahead of print]

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

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

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

The 48th Conference of the German Society for Endoscopy and Imaging Procedures (Deutsche Gesellschaft für Endoskopie und Bildgebende Verfahren, DGE-BV) took place on March 15-17, 2018 in Munich, Germany. Dr. A. Braun, SRO Langenthal, Switzerland, presented personal data on OTSC application for emergency treatment of acute hemorrhage.
Between 2011 and 2017, 48 patients (29 female, median age 75.5 years (61-92)) each received one OTSC clip for first-line treatment of acute gastrointestinal hemorrhage. All patients had shown acute hemoglobin decrease and secure bleeding signs such as hematemesis, melena or hematochezia. Bleeding was located in the upper GI tract in 34 cases (14 Forrest Ia, 15 Forrest Ib, and 5 Forrest IIa) and in the lower GI tract in 14 cases (4 Forrest Ia, 7 Forrest Ib and 3 Forrest IIa). Patients with upper GI bleeding received peri-interventional PPI medication (80mg i.v. bolus, 320 mg i.v. / 24 h). For placement of the OTSC in some cases an endoscopic forceps was used to grasp tissue. No further local therapies were applied. All OTSC applications were performed by one single endoscopist.
OTSC application and primary hemostasis were successful in all cases. Maximal procedure time was 20 minutes. No relapse hemorrhage occurred. 26 patients (15 F Ia, 9 F Ib) received follow-up endoscopy on day 1 to 4, which showed the clip in situ and no bleeding stigmata. The other 22 patients received no follow-up examination. The clinical course was uneventful in all cases.
The author concludes that OTSC application for emergency endoscopic treatment of acute hemorrhage is safe and very effective. Primary hemostasis is achieved in a large fraction of patients, which makes reduction of the mortality rate of acute gastrointestinal hemorrhage possible. OTSC application is related to short procedural time.

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

Braun A (2018)

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

El Douaihy Y et al., Department of Internal Medicine, Staten Island University Hospital - Northwell Health System, Staten Island, New York, USA, reported on a case of active bleeding from a gastroduodenal artery pseudoaneurysm and simultaneous perforation, which was treated by deployment of a single OTSC-Clip.
The 61-year-old male patient with history of duodenal ulcer and angiographic embolization of a gastroduodenal artery pseudoaneurysm 6 months before presented to the emergency room for bright red blood per rectum with signs of upper GI bleed. In esophagogastroduodenoscopy two vessels were identified at the base of an ischemic ulcer correlating with the previous location. The endoscopist at the time elected to inject epinephrine and apply electrocautery which resulted in an arterial pulsatile bleed and a perforation. The field of vision was extremely compromised in addition to the difficult location. Mounting of a cap on the gastroscope to improve stability of the scope and applying point pressure to decrease bleeding, as well as vigorous water irrigation permitted the identification of the exact bleeding site. Then, an OTSC was deployed in a single attempt which resulted in immediate adequate hemostasis and closure of the perforation.
The authors emphasize that deployment of the OTSC requires pin-point precision to achieve satisfactory hemostasis. They rate the use of the over-the-scope clip simple yet very effective. The device was not only a rescue tool for hemostasis from a recurrent actively bleeding GDA pseudoaneurysm, but also for simultaneous perforation closure.
The video can be viewed directly from the GIE website or by using the QR code below.

Over-the-scope clip to the rescue of a bleeding gastroduodenal artery pseudoaneurysm
El Douaihy Y, Kesavan M, Deeb L, Abergel J, Andrawes S (2016)
Gastrointest Endosc. 2016 Jun 12. pii: S0016-5107(16)30236-X. doi: 10.1016/j.gie.2016.05.043.

OTSC® Hemostasis Update 2

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

J Brandler and colleagues, Department of Internal Medicine, Mayo Clinic, Rochester, Minnesota, USA, performed a study on 67 patients with gastrointestinal bleeding from high-risk lesions who were treated with the OTSC System.
The definition of high-risk lesions was lesions situated in the area of a major artery and larger than 2 mm in diameter and /or a deep penetrating, excavated fibrotic ulcer with high-risk stigmata, in which perforation could not be ruled out or thermal therapy would cause perforation, or lesions that could not be treated by standard endoscopy (epinephrine injections, hemoclips, coagulation). Between 12/2011 and 02/2015, data from 67 patients with high risk non-variceal gastrointestinal bleeding, of which 49 received OTSCs as primary and 18 as rescue therapy, was prospectively collected and retrospectively analysed. Clinical severity was determined based on the Rockall score and a modified Blatchford score.
Out of 67 patients, 47 (70.1 %) remained free of rebleeding at 30 days after OTSC placement. No difference was found in the proportion of patients with rebleeding who received primary or rescue therapy (hazard ratio .639; 95 %CI .084 – 4.860; P=.6653). Only 9 rebleeding events were linked clearly to OTSCs and required intervention, indicating an OTSC success rate of 81.3 %.
The authors concluded that OTSCs have a valuable role in managing and adverting high-risk radiologic or surgical interventions for non-variceal gastrointestinal bleeding, despite the presence of high risk of adverse outcome and severe prognostic scores.

Efficacy of Over-the-Scope Clips in Management of High-Risk Gastrointestinal Bleeding
Brandler J, Baruah A, Zeb M, Mehfooz A, Pophali P, Wong Kee Song L, AbuDayyeh B, Gostout C, Mara K, Dierkhising R, Buttar N (2017)
Clin Gastroenterol Hepatol. 2017 Jul 26. pii: S1542-3565(17)30857-1. doi: 10.1016/j.cgh.2017.07.020.

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

Mangiafico S et al., Azienda Ospedaliero, University of Modena, Italy, presented at the 25th UEG week (October 28 – November 1, 2017, Barcelona) data from 9 Italian tertiary referral centers comprising a large series of patients with non-variceal upper and lower gastrointestinal bleeding lesions in whom OTSC was used as first-line endoscopic treatment.
Over a period of three years (01/2014 - 01/2017), data on 201 consecutive patients (mean age 68 years, range 28-89 years), who underwent emergency endoscopy for severe acute nonvariceal gastrointestinal bleeding and were treated with OTSC as primary first-line therapy, was prospectively collected and analyzed.
106/201 patients were treated with the a version of the OTSC system while in 95/201 patients the t clip was preferred. Indications for OTSC treatment included duodeno-jejunal ulcer Forrest 1a (n=29) and Forrest 1 b (n=35), gastric ulcer Forrest 1a (n=19) and Forrest 1b (n=28), Mallory Weiss (n=19), Dieulafoy's lesion (n=9), post gastric- ESD bleeding (n=14), post EMR bleeding (n=15), post ESD bleeding (n=12), traumatic rectal ulcer (n=2), colonic diverticulum (n=4), and surgical anastomosis bleeding (n=15).
Technical success was achieved in all cases (100 %). Primary hemostasis was achieved in 193/201 patients (96 %). In the remaining 8 patients hemostasis was obtained with radiological vascular embolization (n=5) or surgery (n=3).
Early rebleeding (within the first 24 hours) occurred in 9/201 patients (4 %) and it was treated with epinephrine injection with or without use of through the scope clips or radiological vascular embolization. No late rebleeding was observed in the series.
The authors concluded that the use of OTSC as first-line therapy in acute high-risk gastrointestinal bleeding is safe and highly effective.

High efficacy of OTSC as first-line endoscopic treatment in patients with gastrointestinal bleeding: an italian multicentric experience in a large cohort of patients.
Mangiafico S, Russo S, Lupo M, Caruso A, Grande G, Zito F, Bertani H, Conigliaro R, Pisani A, Germaná B, Galloro G, Pasquale L, Mangiavillano B, Bassotti G, Mutignani M, Manta R (2017)

November 2017 | Recommendation for OTSC® as first-line therapy in non-variceal upper gastrointestinal bleeding

Chan SM and Lau JYW, Prince of Wales Hospital, The Chinese University of Hong Kong, Hong Kong, China, published an editorial in Endoscopy International Open on the question: "Can we recommend OTSC as first-line therapy in case of non-variceal upper gastrointestinal bleeding?"
The authors explicate that 8 to 15 % of patients with non-variceal upper GI bleeding (NVUGIB) continue to bleed after endoscopic hemostasis and acid suppression therapy. Further bleeding remains one of the most important predictors of mortality. These facts make research on methods to improve endoscopic hemostasis so important.
The authors list several limitations to conventional hemostatic methods such as the impossibility to consistently seal larger vessels with thermocoagulation,

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

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

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

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

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

Chan SM, Lau JYW

Endoscopy International Open 2017; 05: E883–E885

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

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

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

Patient two was a 76 year old man presenting with fresh melena and a haemoglobin of 7.5 g/dl. He reported on a history of recurrent bleeding from a chronic gastric ulcer. Additionally, he had previously been on warfarin therapy for the treatment of deep vein thrombosis complicated by pulmonary embolism. Endoscopy revealed bleeding from a chronic ulcer at the ankle incisura of the stomach. The first attempt to stop the bleeding with heaterprobe and hemoclips failed. Then an OTSC anchor device was used to target the ulcer base and deploy an OTSC clip without suction. Complete hemostasis was achieved and the patient had an uneventful recovery.

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

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

Xiao X, Lau JY (2016)

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

https://www.youtube.com/watch?v=G6u_szn_Yqc&feature=youtu.be 309

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

R Manta et al., Niguarda-Ca Granda Hospital, Milan, Nuovo S. Agostino Hospital, Modena, Nuovo Regina Margherita Hospital, Rome, 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 initial approach.

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

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

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

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

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

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

OTSC® Hemostasis Update 1

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

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

All patients with upper and lower GIB who underwent FLET and SLET with OTSCs between 04/2012 and 05/2016 were included. In addition, patients with upper GIB were categorized by complete Rockall risk score, and the data were used to calculate predictors of OTSC success and mortality.

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

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

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

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

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

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

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

June 2016 | OTSC® vs. cSEMS for intestinal leakage: clipping associated with significantly higher clinical success rates

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

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

Between 2006 and 2013, overall 106 patients underwent endoscopic treatment for postoperative leakage, endoscopic perforation or spontaneous rupture of the upper gastrointestinal tract. Of these, 72 (69 %) were

treated by cSEMS and 34 (31 %) by OTSC. OTSC was preferred in small-sized lesions and in perforation caused by endoscopic interventions, cSEMS in patients with concomitant local infection or abscess. For cSEMS vs. OTSC, mean treatment duration was 41.1 vs. 25 days (p<0.001), median leakage size was 10 mm (range 1-50 mm) vs. 5 mm (range 1-30 mm), and complications were observed in 68 % vs. 8.8 % (p<0.001), respectively.

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

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

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

Farnik H, Driller M, Kratt T, Schmidt C, Fähndrich M, Filmann N, Königsrainer A, Stallmach A, Heike M, Bechstein WO, Zeuzem S, Albert JG (2015)
PLoS One. 2015 Jan 28;10(1):e0117483. doi: 10.1371/journal.pone.0117483. eCollection 2015.

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

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

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

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

Chan SM, Chiu PWY, Teoh YB and Lau JYW from the Department of Surgery, Institute of Digestive Disease, Prince of Wales Hospital, Chinese University of Hong Kong, China, reported about a prospective case series to evaluate the safety and efficacy of the Over-The-Scope Clip in patients with refractory GI bleeding.

The case series from included nine patients (4 men, 5 women) with a median age of 72.5 years (range 39 - 91 years), suffering from bleeding gastric ulcers (n=2), bleeding duodenal ulcers (n=5), bleeding gastrointestinal stromal tumor in the stomach (n=1), and bleeding from ulcerative carcinoma of the pancreas (n=1). Median diameter of the ulcers was 2.5 cm (1-4 cm). Six of the nine patients underwent previous endoscopic hemostasis attempts.

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

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

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

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

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

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

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

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

E. Wedi and J. Hochberger of the Department of Hepato-Gastroenterology at the University Hospital of Strasbourg, France, reported on clinical experiences with the over-the-scope clip system and its application aids such as the OTSC Twin Grasper and OTSC anchor for coarse tissue.

They present a review of 14 clinical studies on OTSC use and add their own experiences with 84 patients (101 OTSC applications). All Strasbourg patients suffered from recurrent bleeding/lesions of perforations and fistulae or post-operative leakage. 78 out of 84 cases (92.85 %) could be treated successfully.

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

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

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

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

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

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

Wedi E, Hochberger J (2014)
Endo-Praxis, 30.1, 14–17
dx.doi.org/10.1055/s-0034-1370894 **179**

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

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

The study was conducted at a large tertiary care hospital, comprising 12 patients (8 male, 4 female), mean age of 59 (range: 29–86) with ongoing upper gastrointestinal bleeding despite two or three previous sessions of endoscopic 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 oc- curred in two patients 1 day and 7 days* after OTSC place- ment. There were no 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 gastroscope was maneuvered towards it. Once the OTSC cap was positioned on top of the lesion, full suction was applied to tissue, so that the lesion was ful-ly 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- scopic 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.
**Any bleeding occurring more than 72 hours after therapy is usually regarded as a new incident.*
Over-the-scope clip placement is effective rescue therapy for severe acute upper gastrointestinal bleeding
Skinner M, Gutierrez JP, Neumann H, Wilcox C, Burski C, Mönkemüller K
Endoscopy International Open 2014; 02: E37–E40 **171**

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

Paris, March 19–22: The JFHOD congress – Journées Francophones d'Hépato-Gastroenterologie et d'Oncologie Digestive 2015 – the major French clinical congress on gastroenterology, hepatology and GI oncology was held under the presidency of Prof. Jean-Christophe SAURIN.
The group around Prof. J. Hochberger presented their data on OTSC in the treatment of severe gastrointestinal hemorrhage.
Dr. E. Wedi, Dept. Of Gastroenterology and Digestive Endoscopy, University Hospital, Strasbourg, France summarized cases admitted to emergency care due to severe GI bleeding. All patients had Hb <7g/dl upon admission. Median age 73 yrs (29–97). 80 % were under concomitant anti-coagulation or antiplatelet therapy. In 87.2 % (48/55) bleeding was from a gastroduodenal peptic ulcer, and the remaining from various other causes.
OTSC clips were placed. The overall clinical success rate without recurrence was 83.6 % (46/55). In 32.7 % OTSC was placed as a salvage treatment due to prior ineffectiveness of other techniques. 12.7 % (n=7) had to undergo surgical treatment. Out of these 7 patients 4 died, giving a total mortality rate of 7.2 % in this highly challenging case series.
The report by Wedi et al. underlines that patients with a high Rockall score can profit from OTSC treatment, especially patients with anticoagulative or antiplatelet therapy.

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

Dr. Vijay Jayaraman and colleagues, Cedars Sinai Medical Center, Los Angeles, recently presented a retrospective study on their experience with the OTSC System in the treatment of GI bleeding, fistula and perforation. Their case series consisted of 24 consecutive patients treated between January 2011 and April 2012 (mean age 70 years) included the following indications for OTSC placement (28 clips): postsurgical enterocutaneous fistula (n=10), spontaneous perforation (n=1), anastomotic leak (n=4), perforation after mucosal resection (n=3), prophylactic closure of mucosal defect after EMR (n=1), postpolypectomy bleeding (n=2), postendoscopic perforation (n=2), tracheoesophageal fistula (n=1) and leakage from a percutaneous jejunostomy site (n=1). Instruments or modalities used to grasp the tissue were dedicated devices (OTSC Twin Grasper and OTSC Anchor) in 16 and nondedicated devices (rat tooth/alligator forceps or suction alone) in 15.
Median follow-up time was 2.9 months; mean defect size 10 mm (range 5–2 mm). The overall success rate was 61 %. In their experience the success rate of closure of an acute defect is higher compared to chronic fistula. 9 out of 24 lesions were chronic (>1 month) in this series which might explain the lower overall success rate in comparison to the literature (72–100 %).
Furthermore, a trend towards higher success rate was noted in defects <10 mm compared to defects >10 mm. No patient reported any complications associated with OTSC placement.
Endoscopic therapy is still the initial choice before any surgical intervention to manage GI bleedings, fistulae, perforations and leaks. As through the scope clips are limited by their smaller wing span and low force of closure leading to suboptimal results, the OTSC clip provides a safe and effective endoscopic alternative.
Clinical Application and Outcomes of Over the Scope Clip Device: Initial US Experience in Humans
Jayaraman V, Hammerle C, Lo SK, Jamil L, Gupta K
Diagn Ther Endosc. 2013;2013:381873 **137**

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

Three different case reports lately published by Dr. V. Gómez et al., Dept. of Gastroenterology and Hepatology, Mayo Clinic, Jacksonville, USA, Dr. S. Singhal et al., Div. of Gastroenterology, The Brooklyn Hospital Center, New York, USA and Dr. J. Albert, Center of Internal Medicine, Johann Wolfgang Goethe University Hospital, Frankfurt/Main, Germany illustrate the broad spectrum of indications for which placement of OTSC clips can be useful.
The first case report describes the use of the OTSC System in the management of a Dieulafoy lesion. A 74-year old man suffered from a recurrent, obscure, life-threatening gastrointestinal bleeding. EGD revealed a non-bleeding Dieulafoy lesion at the lesser gastric curvature. Due to the large size and difficult position of the lesion, conventional through-the-scope clips were not used, but an OTSC clip was successfully deployed. Novel treatment of a gastric Dieulafoy lesion with an over-the-scope clip
Gómez V, Kyanam Kabir Baig KR, Lukens FJ, Woodward T
Endoscopy. 2013;45 Suppl 2 UCTN:E71. **129**

April 2014 | Conference report | 44th DGE-BV Congress, Hamburg

The 44th DGE-BV Congress of the German Society for Endoscopy and Imaging Procedures/Diagnostics was held in Hamburg, April 3–5, 2014 under the presidency of Prof. Dr. Thomas Rösch.
Again a significant number of both oral presentations and posters have been featured at this year's event. In summary they all reported their mostly positive experiences with the OTSC System in all main indications. In addition our products were featured in several hands-on courses alongside the conference (Chairs: Hochberger J., Maiss J., Kraus F.). Ovesco presented their new products, the DC Clip Cutter and the FTRD device which are both due to be launched later this year. The reaction of the medical world was more than promising.

- **Neue Clips für Blutung und Verschlusstechniken**

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

- **Update Endoskopie – meine Top papers**

Häfner M, Vienna, Austria
M. Häfner updated the plenary session on important recent papers on GI hemorrhage. There he cited two papers by Manta et al. (2013) and Chan et al. (2014) where OTSC had proven to be safe, effective and efficient also in severe bleeding when other procedures had already failed.
Over-the-scope clip (OTSC®) represents an effective endoscopic treatment for acute GI bleeding after failure of conventional techniques
Manta R, Galloro G, Mangiavillano B, Conigliaro R, Pasquale L, Arezzo A, Masci E, Bassotti G, Frazzoni M
Surg Endosc. 2013 Sep;27(9):3162-4 **114**
doi: 10.1007/s00464-013-2871-1 [Epub 2013 Feb 23]
Use of Over-The-Scope Clip for treatment of refractory upper gastrointestinal bleeding: a case series
Chan SM, Chiu PW, Teoh AY, Lau JY
Endoscopy. 2014 May;46(5):428-31
doi: 10.1055/s-0034-1364932 [Epub 2014 Feb 6] **162**

- **Clip-Karussell**

Groth S, Hamburg, Germany
S. Groth elaborated on the endoscopist's option once it comes to use clips. Interesting enough he exempted the OTSC from the rest of all products stating that OTSC is playing in a different league.
(Comment by Ovesco: **the comparator of OTSC is surgery!)**
Altogether five posters were dealing with OTSC:

- **Over-the-Scope Clip System (OTSC) – One Therapy for Safety Closure**

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

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

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

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

In the quest to describe the use and the clinical applications of OTSC System in an environment where endocopic and surgical techniques are increasingly more complex and frequent Singhal et al. have searched and analysed the literature using the key words „endoscopy" and „over-the-scope clip" in order to identify human studies evaluating the application of OTSC from January 2001 to August 2012.
The indication, efficacy, complications, and limitations were recorded. The overall success rates of OTSC based on the current literature are in the range of 75 % to 100 % for closure of iatrogenic gastrointestinal perforations, 38 % to 100 % for closure of gastrointestinal fistulas, 50 % to 100 % for anastomotic leaks, and 71 % to 100 % for bleeding

lesions. OTSC has shown 100 % success rates in managing postbariatric surgery weight gain secondary to dilation of the gastro-jejunostomy.
The authors conclude that OTSC is easy to use with good results, thus decreasing the morbidity and mortality associated with complications secondary to both diagnostic and therapeutic endoscopy and avoiding surgery in many situations.

Over-the-Scope Clip: Technique and Expanding Clinical Applications
Singhal S, Changela K, Papafragkakis H, Anand S, Krishnaiah M, Duddempudi S
J Clin Gastroenterol. 2013 Oct;47(9):749-56 **128**

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

Apart from using the OSTC System in acute and chronic perforations (i.e. perforations, anastomotic leakage, fistulae) the authors of the renowned Institute of Digestive Disease, Department of Surgery, Chinese University of Hong Kong are reporting of patients in whom OTSC was used for endoscopic control of refractory or major upper gastrointestinal bleeding from lesions in the gastroduodenal tract between 1 July and 31 December 2012. Nine patients were included (median age 72.5 years, range 39–91) with bleeding gastric ulcers (n=2), bleeding duodenal ulcers (n=5), bleeding gastrointestinal stromal tumor in the stomach (n=1), and bleeding from ulcerative carcinoma of the pancreas (n=1). The median size of the ulcers was 2.5 cm (range 1–4). Six of the nine patients had undergone previous endoscopic hemostasis. Technical success (defined as hemostasis achieved at index endoscopy) was achieved in all patients and the clinical effectiveness was 77.8 % (defined as technical success with no rebleeding). All procedures were carried out by two experienced endoscopists. Those two patients that experienced rebleeding suffered from complex duodenal ulcer. One of them had been treated with radiotherapy for residual disease after resection of common bile duct cholangiocarcinoma. After several additional EGDs, transarterial embolization, and one surgical intervention which all failed to stop the bleeding, the patient died eventually. The second patient bled from the inferior pancreaticoduodenal artery and needed arterial embolization as well.
The authors discuss a meta-analysis of 1156 patients in 15 randomized trials where endoclips were shown to be superior to injection alone, and as effective as heater probe treatment. The overall rate of rebleeding in those conventionally treated patients ranged between 7.1 % and 9.5 % though. Since rebleeding correlates with the adverse outcome of this indication they speculate that control of bleeding would have a positive impact on patient outcome. Even though the study was carried out in patients with complex duodenal ulcer and underlying malignancies the technical success rate of OTSC was 100 %. They also point out that usually in cases like these the application of conventional clips is difficult; the repeated application of heater probe being associated with a higher risk of perforation. Whereas the application of OTSC allows for larger amounts of tissue and constitutes a quite durable treatment (OTSC in situ after a median of 28 days in this study). The authors conclude that the use of OTSC is a safe and effective method of endoscopic hemostasis for major bleeding from miscellaneous upper gastrointestinal causes and should be considered in refractory bleeding after conventional endoscopic hemostasis, before surgery or angiographic embolization.
Comment by Ovesco: a prospective controlled randomized multicenter trial with 64 patients with recurrent upper GI bleeding is recruiting in Germany (Endoscopic Treatment of Recurrent Upper GI Bleeding: OTSC [Over the Scope Clip] Versus Standard Therapy (STING). ClinicalTrials.gov Iden- tifier: NCT01836900)

Use of Over-The-Scope Clip for treatment of refractory upper gastrointestinal bleeding: a case series
Chan SM, Chiu PW, Teoh AY, Lau JY
Endoscopy. 2014 Feb 6.
[Epub ahead of print] **162**

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

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

Efficacy and safety of over-the-scope clip: including complications after endoscopic submucosal dissection
Nishiyama N, Mori H, Kobara H, Rafiq K, Fujihara S, Kobayashi M, Oryu M, Masaki T
World J Gastroenterol. 2013 May 14;19(18):2752-60
126

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

The OTSC System can overcome the limitations of conventional clips in the treatment of patients with acute GI bleeding by providing compression of large amounts of tissue, leading to a more efficient hemostasis. Dr. R. Manta and colleagues, Gastroenterology and Endoscopy Unit, New S. Agostino Hospital, Modena, Italy draw this conclusion on the basis of a retrospective analysis of a consecutive case series of 30 patients with severe acute GI bleeding treated with the OTSC System after failure of conventional techniques.
Data were collected from six high-volume endoscopy units in a period between December 2011 and September 2012. All 30 patients suffered from bleeding lesions unresponsive to saline/adrenaline injection and through-the-scope clipping located in the upper and lower GI tract in 23 and 7 cases, respectively. Bleeding lesions included duodenal ulcer (n=12), gastric ulcer (n=6), Mallory-Weiss (n=2), Dieulafoy (n=2) and surgical anastomosis (n=1) in the upper GI tract and endoscopic mucosal resection (n=5), endoscopic submucosal dissection (n=1) and colonic diverticulum (n=1) in the lower GI tract.
Primary hemostasis with OTSC was achieved in 29 of 30 cases (97 %). Rebleeding in two cases was successfully treated with injection of saline and adrenaline. Endoscopic follow-up after 2–4 days and after 1 month revealed correct placement of the OTSC clip and no procedure-related complications. Thus, the OTSC is an effective and safe device for treatment of acute GI bleeding and represents a useful adjunct to the therapeutic armamentarium in endoscopic emergencies.

Over-the-scope clip (OTSC) represents an effective endoscopic treatment for acute GI bleeding after failure of conventional techniques
Manta R, Galloro G, Mangiavillano B, Conigliaro R, Pasquale L, Arezzo A, Masci E, Bassotti G, Frazzoni M
Surg Endosc. 2013 Sep;27(9):3162-4 **114**

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

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

Successful treatment with an over-the-scope clip of Dieulafoy´s gastric lesion resistant to conventional endoscopic treatment
Mangiavillano B, Arena M, Morandi E, Viaggi P, Masci E
Endoscopy. 2012;44 Suppl 2 UCTN:E387 **105**

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

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

Utility of the „bear claw", or over-the-scope clip (OTSC) system, to provide endoscopic hemostasis for bleeding posterior duodenal ulcers
Mönkemüller K, Toshniwal J, Zabielski M, Vormbrock K, Neumann H
Endoscopy. 2012;44 Suppl 2 UCTN:E412-3.
[Epub 2012 Nov 20] **108**

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

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

shorter when compared to multiple applications of hemoclips.

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

New endoscopic hemostasis methods

Leung Ki EL, Lau JY

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

87

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

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

Clinical presentations confirm efficacy of OTSC clipping in a range of indications

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

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

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

Wedi E, Menke D, and Hochberger J, Strasbourg (France) reported about a cohort of 84 patients with OTSC clipping for GI bleeding, fistula and GI wall insufficiency. 101 OTSC clips have been used in this cohort, or 1.2 clips per patient. Indications included mainly severe upper GI peptic ulcer hemorrhage (n=38) and preventive clipping to avoid rebleeding (n=12) or secondary perforation (n=18) after large area ESD. The clinical success rate in peptic ulcer bleeding was 79 %, most patients had already been treated unsuccessfully with other hemostatic techniques before OTSC clipping or had been candidates for surgical hemostasis.

2 complications were encountered: 1 inadvertent clipping of an instrument with OTSC and fixation of the instrument to the tissue and one perforation of the sigmoid with the OTSC cap. The authors state that OTSC application is an effective procedure to deal with endoscopic situations that otherwise would require a surgical approach.

Der Einsatz des OTSC-Makroclips bei 84 Patienten mit schwerer GI-Blutung, Fisteln und Insuffizienzen – ein Résumé

E. Wedi, D. Menke, and J. Hochberger, Strasbourg

Large single center cohort on OTSC hemostasis in severe GI bleeding

Kratt T, Stüker D, Gräpler F, Küper M, Wichmann D, Königsrainer A, Tübingen, showed data from their cohort on OTSC in endoscopic hemostasis (n=85). The bleeding location was in the upper GI tract in 63 % (21 % peptic gastric ulcers and 40 % peptic duodenal ulcers) and in the lower GI tract in 37 % (mostly bleeding after polypectomy in the rectum).

The characteristics of the cohort underline the severity of bleeding: life-threatening bleeding (28.4 %), patient in hemorrhagic shock (31.1 %), immediate blood transfusion (33.8 %), patient under anti-coagulation (21.6 %), Forrest I bleeding (72.3 %). OTSC placement was achieved with cap suction in 72 cases and with an OTSC Anchor in 2 cases. Technically successful hemostasis for 72 hrs was achieved in 92.8 % of cases, a persistent bleeding and an early relapse bleeding (<72 hrs) were seen in 3.6 %, respectively. Late relapse bleeding (>72 hrs) was observed in 3.6 %. No severe complications were observed; in 3 cases mucosal esophageal lesions from device introduction were seen. In 14.5 % OTSC clipping was done for recurrence of an initially successful other endoscopic therapy and in 13.3 % for failure of other methods in the same treatment session. In 35.1 % OTSC clipping was seen as an ultima ratio and as an alternative to surgical therapy otherwise becoming necessary. The summary of the authors is that the simple and easy to handle OTSC System is an effective treatment in severe GI bleeding and can avoid surgery in several cases.

Das OTSC-Clip-System: Klinische Erfahrungen zur Therapie der schweren GI-Blutung bei 85 Patienten

T. Kratt et al., Tübingen

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

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

Endoskopische Interventionen mit dem OTSC-System am Klinikum Neubrandenburg

T. Thomsen, B. Berthold, M. Khiabanchain, and I. Trabandt, Neubrandenburg

OTSC for stopping gastroduodnal artery bleeding in duodenal ulcer

Kratt T, Stüker D, Kirschniak A, Heininger A, Wietek B, Königsrainer A, Tübingen, showed a case series (n=7) in which OTSC was applied in upper GI emergency hemostasis to stop bleeding from the gastroduodenal artery. Gastroduodenal artery bleeding is besides aortoduodenal fistula considered the most severe bleeding complication in the digestive tract, associated with high morbidity and mortality. In many cases surgical emergency hemostasis is inevitable.

In all cases reported here the gastroduodenal artery was verified as the bleeding source by angiography after successful endoscopic treatment. In all 7 patients the acute bleeding from an ulcer at the posterior duodenal wall was successfully controlled with OTSC, in 4 cases fibrin glue was additionally applied. After the initial 72 hrs, 3 patients suffered from rebleeding, which was then controlled surgically. No mortality was encountered in this case series. The authors draw the conclusion that OTSC is effective in emergency management of gastroduodenal artery bleeding. In more than half of the cases endoscopic management was the only therapy. In the other patients OTSC was a successful "bridge to surgery" and allowed stabilizing the patient before the operation.

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

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

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

Dr. Todd H. Baron and colleagues, Division of Gastroenterology & Hepatology, Mayo Clinic, Rochester MN, USA report about their experience with 45 patients and 48 OTSC clip placements from March 2011 to January 2012. Median follow-up time in this mixed cohort was 77 days (30–330 days). Indication break-down included hemostasis (n=7), closure of chronic fistula (n=28), closure of iatrogenic perfo- rations (n=5), closure of post-esophagectomy anastomotic leakage (n=3) and miscellaneous (n=2).

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

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

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

Baron TH, Song LM, Ross A, Tokar JL, Irani S, Kozarek RA

Gastrointest Endosc. 2012 Jul;76(1):202-8

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

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

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

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

http://www.ovesco.com/fileadmin/Downloads/OTSC_System_clinical_data_eng_Rev01_2012-10-22.pdf (English)

http://www.ovesco.com/fileadmin/Downloads/OTSC_System_KlinischeDaten_deu_Rev01_2012-10-22.pdf (German)

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

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

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

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

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

Vormbrock K, Zabielski M, Mönkemüller K

Gastrointest Endosc. 2012 Oct;76(4):917-8