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-AAO) non-variceal upper gastrointestinal bleeding (NVUGIB). The Rockall data and a historic cohort of the same institution (82 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 polyectomy and endoscopic ultrason-guided fine-needle aspiration of pancreatic 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-AAO NVUGIB. OTSC should be considered as first-line treatment for HR-AAO bleeding.


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

The 28th 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 the 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 ESGE 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. Bartneck, M. 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%), EFT (6.4%) and stent fixation (0.7%). Complete luminal obstruction was a secondary treatment in 3% of cases across all studies. 24/81 papers reported the need for surgery despite OTSC placement (30/873 patients, 13.4%).

Indications for OTSC placement in Group B were fistula closure (37.5%), bleeding (33.9%), stenoses (14.1%), EFT (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 (DUOB). Between 4/2014 and 03/2018, 100 patients with peptic ulcer bleeding (Forrest la-lb), 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 84.9%. 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, peptic ulcer bleeding. Potential risk factors for treatment failure are location in the duodenal bulb, longer ICU stay, peptic ulcer bleeding. Potential risk factors for treatment failure are location in the duodenal bulb, longer ICU stay, primary NSAID use or anticoagulation. 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.

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November 2018 | Conference Report DGVS / DGAV
The 37th annual conference of the German Society of Gastroenterology, and Digestive and Metabolic Diseases with Endoscopy Section (DGAV) was held 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, innovations and video footage at hands-on training sessions, Dr. med. Eva Ehlers (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 Waldhäuter presented retrospective data gathered in the University Hospital of Marburg while evaluating different endoscopic modes of therapy for non-variceal upper gastrointestinal bleeding (NVUGIV). Between 09/2016 and 12/2018, 203 patients (median age 68 years, 77 male) with NV-UGB were treated. In 68 patients, the bleeding was controlled immediately (primary failure) and in 135 patients bleeding control was achieved by other therapy (secondary failure). Blood loss ≥ 1.5 L was considered 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 were: lack of waiting time in the presence 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).


Augsburg: closure of ulcer bleedings with high risk of recurrence: one and done in 75%
S Gölder et al. presented a retrospective study comprising all patients with high-bleeding-risk ulcers (Forrest la-lb), treated with OTSC at the Augsburg Hospital. A total of 100 patients with peptic ulcer, primarily or secondarily treated with OTSC, were included. Significant differences were found in 57 patients suffering rebleeding from duodenal ulcer compared with 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 ot other therapy 8% vs 8%). The authors concluded that the OTSC was highly effective for the treatment of acute ulcer bleeding with the OTSC proves to be highly efficient as primary and secondary therapy. 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.
OTSC® Hemostasis Update 4 | Research & clinical trials

Küller et al. presented a retrospective evaluation of all patients, that had been treated since 2014 at the University Hospital Goettingen for iatrogenic esophageal perforation (IAP) 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 preparative radiochemotherapy (5 CROSS, 11CF, 1 FLOT+RTC, 2 FLT, 1 RT, 1 GASTRIPEC, 1 unknown). Overall 8 patients received a fully-covered esphagostent 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. In all cases the additional 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.

Multiple endoskopische Behandlung von Ösophagusperforationen und postoperativen Anastomoseninsuffizienzen nach onkologischen Reksectionen. Was ist die richtige Strategie? (Multimodal endoscopic treatment of esophageal perforation and post-surgical anastomotic insufficiency: patient-choosing surgical resection. Which is the correct strategy?)


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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 patient-choosing surgical resection. 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-Scop-e Clips (OTSC) in daily endoscopic routine


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, Ludwigburg, 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 of first-line OTSC treatment the rebleeding rate was 28.9% (1345) compared to 43.3% (1330) 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 antithromboplasts 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.

group and 6.0 % in the OTSC group (P=0.01). 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=0.01).

Gastroenterology. 2018 May 24. pii: S0016-5085(18)34670-0. 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. Schmitt A1, Gälser S1, Goetz M1, Meising A1, Lau J2, von Delius S1, Escher M1, Hoffmann A1, West P1, Messmann H1, Krat T1, Walter B1, Bettinger D1, Caca K1.

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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, Dr. A. Braun, SRO Langenthal, Switzerland, presented personal data on OTSC application for emergency treatment of acute hemorrhage.

Bettmann and colleagues reported on 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 24 cases (14 Forrest la, 15 Forrest lb, and 5 Forrest Ia) and in the lower GI tract in 14 cases (4 Forrest la, 7 Forrest lb and 3 Forrest Ia). 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 F1, 9 F2) 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 authors conclude 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 Douayy 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 gastrointestinal 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 the OTSC® with the preloaded polypropylene suture which 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.


OTSC® Hemostasis Update 2

February 2018 | OTSC® prevents rel bleeding in otsc® hemostasis Update

J Brandt 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 were lesions situated in the area of a major artery and larger than 2mm in diameter and for a deep penetrating, excavating fibrous 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, hemostatic, 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 analysed. 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 medical therapy (n=3).

Early rel bleeding (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 rel bleeding 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 therapy in patients with gastrointestinal bleeding: an Italian multicentric experience in a large cohort of patients.


November 2017 | Recommendation for OTSC® as first-line therapy in non-varical 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 (NUGIB) 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 Wied et al. with 100 patients with NVUGIB and first-line OTSC management and a reported 94% success rate for primary hemorrhage. Besides, the study of Richter-Schrag et al is cited, including 100 patients with both NVUGIB and lower gastrointestinal bleeding and showing similar results. However, the paper also names problems that can lower the success of OTSC hemorrhage, 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 conventional treatment. In summary, the editorial recommends the application of OTSC in patients with hemorrhagic 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: E833–E865

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 hemoglobin of 4.6g/dl. Endoscopy revealed bleeding from a 2-cm chronic ulcer below the pylorus, with a large gastric embolectomy to her right gastroduodenal artery (GDA). Three days later, she again experienced massive bleeding. A pulsatile vessel at the ulcer base was disclosed and treatment with an OTSC clip induced. The clip 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 hemoglobin of 7.5 g/dl. He reported on a history of recurrent bleeding from a chronic 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 anile 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 hemostasis. The patient was discharged 4 days later without any further bleeding.

March 2017 | High-risk GI bleeding: primary hemostasis in first-line OTSC® treatment in 95% of patients with scores < or ≥ 7. HU 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 OTSC 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 19.9 d (range 1-79). Primary success in 94.9% of cases (90/98). 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=0.0808). 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. Overall, 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, Glatt T, Walker C, Fischer A, Thimme R (2016) World J Gastroenterol 2016 Nov 7; 22(41): 0000-0000. ISSN 1007-9327 (print) ISSN 2191-2840 (online) 364

November 2016 | Large single-center experience with 101 OTSC® applications in patients with severe hemorrhage, perforations and fistulae: 89% overall primary clinical success Wied E and colleagues, Strasbourg University Hospitals, Strasbourg, France and St. Bernard Academic Teaching Hospital, Hildesheim, Germany, and Icahn School of Medicine at Mount Sinai, New York, United States, and Bergamo University, Bergamo, Italy, 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 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 (89.2%). In detail OTSC was primary successful to 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 47/47 (100%) patients with scores < or ≥ 7 (57.1%) 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 in 3/3 cases of fistula closure. Two application-related complications were seen (2%). In conclusion, this study proves 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 Wied 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. Famik, university hospital Frankfurt am Main, and colleagues in four German tertiary endoscopic centers (Frankfurt, Tübingen, Jena, Dortmund). Technical, primary 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
OTSC® Hemostasis Update 4 | Research & clinical trials

May 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 ulcer bleeding. A bleeding ulcer with a large ulcer crater and 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 patient to surgery.”

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

Chan SM, Chu PWY, Teh 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 carcina 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 complications. No local complications occurred. The clinical effectiveness was 77.8% (79%), while two patients with specific conditions developed rebleeding after OTSC application due to chronically fibrotic ulcers because of residual tumor infiltrating into adjacent tissues.

Chan and colleagues discuss that, in 810 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 when tackling bleeding from, for example, conventional clips, surgery or angiographic embolization. Use of Over-The-Scope Clip for treatment of refractory upper gastrointestinal bleeding: a case series


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

S Kothan, T Kothan 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 4-year 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, mesenteric ischemia, and acute variceal bleeding in hematologic 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 gastrointestinal endoscopy, and again angiography. 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 and for finally, a tortuous, varix-like, prominent blood vessel with a central small ulceration, bleeding actively, was identified in the proximal jejunal segment. Ethanolamine injection into the varix did not achieve hemostasis. Finally, a size 12/61 OTSC clip was applied over the actively bleeding jejunal varix using a wire placed inside a feeding tube was advanced into the organ lumen in

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

In an observational retrospective case series, Dr. Matthew Skinner, Dr. Juan P. Gutierrez, Dr. Helmut Neumann, Dr. K. Bruce Woon, Dr. Chad Bursk and Dr. Klaus Mönkemüller of the Basel I. Hirschweg, Endoscopic Center of Excellences, Department of Gastroenterology, University of Alabama, Bir- mingham, USA, evaluated the efficacy and safety of OTSC clip placement in patients with upper gastrointestinal bleed- ing 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: 28–86) with ongoing upper gastrointestinal bleeding despite 3 or previous sessions of angiographic embolization, percutaneous therapy, parenteral therapy, or either a 2015 American College of Surgeons 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 units, range 2–12). Bleeding was due to duodenal ulcer (6), gastric ulcer (2), Dieulafy lesion (2), andastogenic 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 gastroscopy was maneuvered towards it. Once the OTSC cap was positioned on top of the lesion, the device was applied and after the clipping tool was fully engufed 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...
OTSC® Hemostasis Update 4 | Research & clinical trials

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, Rochester; Dr. A. Bharaj et al., Departamento de Gastroenterología, 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 recurrent mild 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.


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

The 44th DGE-BV Congress of the German Society for Gastroenterology and Endoscopy 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, Mais J, Kraus F). Ovesco presented their new products, the DC Clip Cutter and the FTR 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, Ludwigswiese, 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 takes 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 of care due to the high success rate and the low rate of complications 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

Häfler M, Vienna, Austria

M. Häfler 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


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

Chan SM, Chiu PW, Teoh YT, Lau JY, Hsu MF, Lam WY. Gastrointest Endosc. 2014 Nov;70(5):841-3; doi: 10.1016/j.gie.2014.06.038 Epub 2014 Sep 1

• 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, Obse A, Bauer B, Reps M, Altenburg, Germany

They 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.

Some data was 89% for hemorrhage. In both of these indications 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 in difficult 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), n=9, n=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 1a, 7 F 7 Ib, and 2 F IIa. All patients presented with an acute decrease of hemoglobin, with hematemia, 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 endoscopies were eventful 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 HU, Fischer A, Freiburg, Germany

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

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

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 severely variceal upper gastrointestinal bleeding in whom prior endo-scopic treatments 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 from more than 72 hours after therapy is usually regarded as a new incident.

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OTSC® Hemostasis Update | Research and clinical trials | Version 4 | 2018-12-31
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**


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

Apart from using the OTSC System in acute and chronic perforations (i.e., perforations, anastomotic leakage, fistulae) the authors of the renowned Institute of Digestive Disease, Department of Surgery, Chinese University of Hong Kong are reporting of patients in whom OTSC was used for endoscopic control of refractory or major upper gastrointestinal bleeding from lesions in the gastro-intestinal 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 78.3% (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 flexible 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 controlled randomized trials treated patients ranged between 7.1% and 8.5% though. Similarly, complications were very rare and 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 clips and constitutes a one-time 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 can be performed as a 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]

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 93.1 %, durable clinical success rate 82.6 %. The authors concluded that 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 (median age 77 years, range 25–90). 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 stilt, fibrotic lesion edges. The overall clinical success rate (complete cure plus using new OTSC System) was 78.3% (18/23). The OTSC System can overcome the limitations of conventional clips in the treatment of patients with acute GI bleeding. According to Leung & Lau a single clip suffices for most circumstances and therefore the procedure is endoscopic treatment for acute GI bleeding after failure of conventional techniques


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

Dr B. Mangiavillano and colleagues, Gastrointestinal Endoscopy, Azienda Ospedaliera San Paolo University, Hospital-University of Milan, Italy, present a case study of a 69-year-old woman with an episode of melena. EGD showed a Dieulafoy’s bleeding lesion in the proximal third of the posterior wall of the stomach associated with an epiphrenic 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


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

Uler 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 hypertension 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 solution and endoclips placement was performed. The patient bleeding was still ongoing and 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. According to Leung & Lau a single clip suffices.

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


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 situations for most circumstances and therefore the procedure is OTSC® Hemostasis Update 4 | Research & clinical trials | Version 4 | 2018-12-31
OTSC® Hemostasis Update 4 | Research & clinical trials

8

shorter when compared to multiple applications of hemoclots.

Comment by Ovesco: In a recently published series of 93 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 (Krafl T et al., Poster DGE-2013 meeting, Munich 3/2013)

New endoscopic hemostasis methods

Leung Ki EL, Lau JY


April 2013 | Conference report | OTSC® at German Endoscopy Conference (DGE-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: treatment of acute GI lesions, 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

Weid 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 laparoscopic endoscopic retrograde duodenoscopy. 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.

Two 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 have required surgical approach.

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

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

Large single center cohort on OTSC hemostasis in severe GI bleeding

Kraft T, Stüker D, Gräppler 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%), patient in hemorrhagic shock (31.1%), immediate blood transfusion (33.8%), INR elevation (21.6%) and the need for a surgical approach in 3.6% of patients. The rate of OTSC placement was 72% in 72 cases 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% of cases respectively. Late relapse bleeding (>72 hrs) was observed in 3.6% of cases. 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.Kraft et al., Tübingen

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

Thomens T, Berthold B, Khribanchian M, and Trabrandt 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 an Klinikum Neubrandenburg T. Thomen, B. Berthold, M. Khribanchian, and I. Trabrandt, Neubrandenburg

OTSC for stopping gastrointestinal artery bleeding in duodenal ulcer

Kraft T, Stüker D, Kirschnak 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 fibrosis glue injection 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”


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

Dr. Todd H. Baron and colleagues, Division of Gastroenterology & Hepatology, Mayo Clinic, Rochester MN, USA report about their experience with 45 patients and 48 OTSC clip placements from March 2011 to January 2012. Median follow-up time in this mixed cohort was 77 days (30–330 days). Indication break-down included hemostasis (n=7), closure of chronic fistula (n=28), closure of iatrogenic perforations (n=5), closure of post-esophagectomy anastomotic leak (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 85%. 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 CRD, 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.


(English)


(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 an immediate success of 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, Knökelmüller K

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

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