

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 <7 or ≥ 7 in rebleeding and rebleeding-associated mortality. The authors concluded that the reduction of primary failure in endoscopic treatment of severe acute gastrointestinal bleeding was best achieved when 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

Endoscopy, the official blog of "GIE: Gastrointestinal Endoscopy" recently published a video on OTSC use by Dr. James Y. W. Lau. The video, called "Over-the-scope clip treatment of refractory peptic ulcer bleeding", presented two cases in which OTSC was used to treat chronic peptic ulcerations with refractory bleeding after failed angiographic embolization and endoscopic treatment respectively. Dr. Lau concluded that, "Endoscopists should consider the use of OTSC when tackling challenging bleeding lesions especially when other standard treatments have failed and certainly before referring your patients to surgery."

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

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

The case series from included nine patients (4 men, 5 women) with a median age of 72.5 years (range 39 - 91 years), suffering from bleeding gastric ulcers (n=2), bleeding duodenal ulcers (n=5), bleeding gastrointestinal stromal tumor in the stomach (n=1), and bleeding from ulcerative carcinoma of the pancreas (n=1). Median diameter of the ulcers was 2.5 cm (1-4 cm). Six of the nine patients underwent previous endoscopic hemostasis attempts. A total of 10 OTSCs were applied in the nine patients. The technical success rate of OTSC was 100% (10/10). Endoscopic hemostasis was achieved in all patients. No local complications occurred. The clinical effectiveness was 77.8% (7/9), while two patients with specific conditions developed rebleeding after OTSC application due to chronically fibrotic ulcers because of residual tumor infiltration and previous radiotherapy.

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

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

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

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

S Kothari, T Kothari and V Kaul of the Center for Advanced Therapeutic Endoscopy, Division of Gastroenterology and Hepatology at the University of Rochester/Strong Memorial Hospital in Rochester, NY, USA presented a case of successful treatment of massive gastrointestinal bleeding from a jejunal varix with OTSC after several other treatment options had failed. The 67-year old male patient had a medical history of coronary artery disease, chronic renal insufficiency and Laennec's cirrhosis before he was admitted for a laparoscopic left radical nephrectomy for renal cell carcinoma. Afterwards, the patient suffered from several complications, including superior mesenteric vein thrombosis, melena with a significant drop in hematocrit and clinical signs of bleeding, which led to identification and unsuccessful treatment of several possible bleeding sites. The patient underwent anticoagulation, a tagged red blood cell scan, angiography, coil-embolization, repeat mesenteric angiography and repeat (push) enteroscopy. The patient also received a total of 38 units of packed red cells, 13 units of thawed plasma, 9 units of fresh frozen plasma, 3 units of platelets and 2 units of cryoprecipitate. Due to multiple comorbidities, he was deemed as a high-risk patient unfit for surgery.

Finally, a tortuous, varix-like, prominent blood vessel with a central small ulceration, bleeding actively, was identified in the proximal jejunum. Ethanolamine injection into the varix did not achieve hemostasis. Finally, a size 12/6t OTSC clip was applied over the actively bleeding jejunal varix using a pediatric colonoscope. Instant and complete hemostasis was achieved with this single clip. No additional transfusions

were required and his hematocrit stabilized over the next few days. Due to his overall poor prognosis and multiple comorbidities, the patient's family opted for "comfort measures only" and he passed away several days later. The authors emphasize the fact that they were able to quickly and effectively treat a massively bleeding jejunal varix, which had resisted multiple evaluations and courses of treatment. They deem the OTSC device a major advance in endoscopic management of high-risk patients in a variety of challenging clinical settings, especially in case of poor candidates for surgical intervention. They also note that endoscopic perforation management with the OTSC clip may avoid the cost and morbidity of surgery and other interventions. Statement by Ovesco Endoscopy: the treatment of jejunal varix hemorrhage is not a common indication for the use of OTSC and there is limited experience with such application.

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

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

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

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

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

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

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

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

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

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

The study was conducted at a large tertiary care hospital, comprising 12 patients (8 male, 4 female), mean age of 59 (range: 29–86) with ongoing upper gastrointestinal bleeding despite two or three previous sessions of endoscopic therapy. Patients had a mean ASA score of 3 (range: 2–4), mean hemoglobin of 7.2 g/dL (range: 5.2–9.1), and shock was present in 75% of patients. They had all received packed red blood cells (mean 5.1 units, range 2–12). Bleeding was due to duodenal ulcer (6), gastric ulcer (2), Dieulafoy lesion (2), anastomotic ulceration (1) and Mallory-Weiss tear (1). Hemostasis was achieved in all patients, but rebleeding occurred in two patients 1 day and 7 days* after OTSC placement. There were no complications associated with OTSC application.

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

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

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

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

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

Endoscopy International Open 2014; 02: E37–E40 171

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

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

The group around Prof. J. Hochberger presented their data on OTSC in the treatment of severe gastrointestinal hemorrhage. Dr. E. Wedi, Dept. Of Gastroenterology and Digestive Endoscopy, University Hospital, Strasbourg, France summarized cases admitted to emergency care due to severe GI bleeding. All patients had Hb <7g/dl upon admission. Median age 73 yrs (29–97). 80% were under concomitant anti-coagulation or antiplatelet therapy. In 87.2% (48/55) bleeding was from a gastroduodenal peptic ulcer, and the remaining from various other causes. OTSC clips were placed. The overall clinical success rate

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

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

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

Dr. Vijay Jayaraman and colleagues, Cedars Sinai Medical Center, Los Angeles, recently presented a retrospective study on their experience with the OTSC System in the treatment of GI bleeding, fistula and perforation. Their case series consisted of 24 consecutive patients treated between January 2011 and April 2012 (mean age 70 years) included the following indications for OTSC placement (28 clips): postsurgical enterocutaneous fistula (n=10), spontaneous perforation (n=1), anastomotic leak (n=4), perforation after mucosal resection (n=3), prophylactic closure of mucosal defect after EMR (n=1), postpolypectomy bleeding (n=2), postendoscopic perforation (n=2), tracheoesophageal fistula (n=1) and leakage from a percutaneous jejunostomy site (n=1). Instruments or modalities used to grasp the tissue were dedicated devices (OTSC Twin Grasper and OTSC Anchor) in 16 and nondedicated devices (rat tooth/alligator forceps or suction alone) in 15.

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

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

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

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

Jayaraman V, Hammerle C, Lo SK, Jamil L, Gupta K

Diagn Ther Endosc. 2013;2013:381873 137

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

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

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

Gómez V, Kyanam Kabir Baig KR, Lukens FJ, Woodward T

Endoscopy. 2013;45 Suppl 2 UCTN:E71. 129

April 2014 | Conference report | 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 Verschluss-techniken**

Caca K, Ludwigsburg, Germany

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

- **Update Endoskopie – meine Toppapers**

Häfner M, Vienna, Austria

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

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

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

Surg Endosc. 2013 Sep;27(9):3162-4 **114**

doi: 10.1007/s00464-013-2871-1 [Epub 2013 Feb 23]

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

Chan SM, Chiu PW, Teoh AY, Lau JY

Endoscopy. 2014 May;46(5):428-31

doi: 10.1055/s-0034-1364932 [Epub 2014 Feb 6] **162**

- **Clip-Karussell**

Groth S, Hamburg, Germany

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

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

Altogether five posters were dealing with OTSC:

- **Over-the-Scope Clip System (OTSC) – 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 endoscopic and surgical techniques are increasingly more complex and frequent Singhal et al. have searched and analysed the literature using the key words „endoscopy“ and „over-the-scope clip“ in order to identify human studies evaluating the application of OTSC from January 2001 to August 2012.

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

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

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

Singhal S, Changela K, Papafragkakis H, Anand S, Krishnaiah M, Duddempudi S

J Clin Gastroenterol. 2013 Oct;47(9):749-56 **128**

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

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

transarterial embolization, and one surgical intervention which all failed to stop the bleeding, the patient died eventually. The second patient bled from the inferior pancreaticoduodenal artery and needed arterial embolization as well.

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

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

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

Chan SM, Chiu PW, Teoh AY, Lau JY

Endoscopy. 2014 Feb 6.

[Epub ahead of print]

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

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

Efficacy and safety of over-the-scope clip: including complications after endoscopic submucosal dissection
Nishiyama N, Mori H, Kobara H, Rafiq K, Fujihara S, Kobayashi M, Oryu M, Masaki T

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

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

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

Data were collected from six high-volume endoscopy units in a period between December 2011 and September 2012. All 30 patients suffered from bleeding lesions unresponsive to saline/adrenaline injection and through-the-scope clipping located in the upper and lower GI tract in 23 and 7 cases, respectively. Bleeding lesions included duodenal ulcer (n=12), gastric ulcer (n=6), Mallory-Weiss (n=2), Dieulafoy (n=2) and surgical anastomosis (n=1) in the upper GI tract and endoscopic mucosal resection (n=5), endoscopic submucosal dissection (n=1) and colonic diverticulum (n=1) in the lower GI tract.

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

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

Manta R, Galloro G, Mangiavillano B, Conigliaro R, Pasquale L, Arezzo A, Masci E, Bassotti G, Frazzoni M
Surg Endosc. 2013 Sep;27(9):3162-4

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

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

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

Mangiavillano B, Arena M, Morandi E, Viaggi P, Masci E
Endoscopy. 2012;44 Suppl 2 UCTN:E387

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

Ulcer bleeding is one of the key indications for the OTSC System. In a recently published case series (n=4), Prof. Klaus Mönkemüller and colleagues, Dept. of Internal Medicine, Gastroenterology and Infectious Diseases,

Marienhospital Bottrop, Germany add to the growing clinical experience in using the OTSC System to control massive gastrointestinal bleedings and achieve life-saving hemostasis. All four patients (mean age 84.5) presented with hypotension and mean hemoglobin of 9 g/dL. After initial fluid resuscitation an emergent EGD displayed actively oozing ulcers in the posterior duodenum. As an initial therapy with injection of epinephrine-saline solution and standard clip placement failed and all patients suffered from re-bleeding, 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]

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July 2013 | Recommendation of OTSC System in complex GI bleeding

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

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

New endoscopic hemostasis methods

Leung Ki EL, Lau JY

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

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

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

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

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

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

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

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

hemostasis.

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

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

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

Large single center cohort on OTSC hemostasis in severe GI bleeding

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

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

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

T. Kratt et al., Tübingen

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

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

Endoskopische Interventionen mit dem OTSC-System am Klinikum Neubrandenburg

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

OTSC for stopping gastroduodenal artery bleeding in duodenal ulcer

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

In all cases reported here the gastroduodenal artery was verified as the bleeding source by angiography after successful endoscopic treatment. In all 7 patients the acute bleeding from an ulcer at the posterior duodenal wall was

successfully controlled with OTSC, in 4 cases fibrin glue was additionally applied. After the initial 72 hrs, 3 patients suffered from rebleeding, which was then controlled surgically. No mortality was encountered in this case series. The authors draw the conclusion that OTSC is effective in emergency management of gastroduodenal artery bleeding. In more than half of the cases endoscopic management was the only therapy. In the other patients OTSC was a successful "bridge to surgery" and allowed stabilizing the patient before the operation.

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

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

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

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

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

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

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

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

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

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

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

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