

Congress report Viszeralmedizin (Visceral medicine) 2021

Joint Annual Meeting of the German Society for Gastroenterology, Digestive and Metabolic Diseases with Endoscopy section (DGVS) together with the German Society of General Surgery and Visceral Surgery (DGAV)

13.–18. September 2021 in Leipzig, hybrid event

Congress presidents:

Prof. Dr. Christian Trautwein, Aachen

Prof. Dr. Natascha C. Nüssler, Munich

Dr. Ulrich Rosien, Hamburg

Ovesco Endoscopy AG congratulates Dr. Benjamin Meier, Klinikum Ludwigsburg, on winning the Endoscopy Research Award of the DGVS 2021, which is the most prestigious research award in the field of endoscopy in German-speaking countries. Dr Meier was honoured for his high-ranking published work on the effectiveness and safety of endoscopic full-thickness resection. Ovesco products were also present in lectures, posters, sessions, video forums, workshops and hands-on training courses.

- **Sting II – OTSC superior to standard treatment for acute non-varicose upper GI bleeding with high risk of rebleeding**
- **Initial data from Freiburg and Würzburg shows that stentfix OTSC can significantly reduce migration risk**
- **Initial multicentre data demonstrates intuitive and effective use of the OTSG Xcavator in clinical use**
- **New data on EFTR in early colorectal carcinomas shows the increasing importance of the technique in this indication**

OTSC® System

Sting II: OTSC first-line treatment is superior to standard treatment for acute non-varicose upper GI bleeding with high risk of rebleeding.

B. Meier, Ludwigsburg, presented the final data of the multicentre randomised controlled STING II study on the use of the OTSC system in severe, non-varicose upper GI bleeding. In the treatment of recurrent bleeding, OTSC has become established due to the significantly lower rebleeding rates compared to standard treatment (STING study). STING II was consequently initiated to investigate whether OTSC treatment is superior to standard treatment also in acute, non-varicose upper GI bleeding with a high risk of rebleeding ("complete Rockall score" ≥ 7 points). Standard treatment consisted of at least 2 conventional clips or thermal procedure plus adrenaline injection. OTSC treatment consisted of primary OTSC application (injection allowed). The study included $n = 100$ patients with endoscopically proven acute (non-varicose) OGI haemorrhage and a "complete Rockall Score" ≥ 7 points according to case number calculation (power 80 %). Exclusion criteria included prior endoscopic treatment within the last 4 weeks to rule out treatment of recurrent bleeding. The primary endpoint was successful haemostasis without recurrent bleeding within 7 days.

After randomisation, $n = 52$ patients were evaluated in the standard arm and $n = 48$ patients in the OTSC arm. Both groups show good correspondence to the baseline. 42.3% of patients in the standard arm and 39.6% in the OTSC arm were on anticoagulation or platelet aggregation inhibition. The median age of patients was 79 years (51–96) in the standard arm and 78 years (42–92) in the OTSC arm. The median Rockall score was 8 points in both groups, and the predominant localisation was in the duodenum (46.1% standard vs. 60.4% OTSC). Predominantly peptic ulcer bleeding was present with over 80% in both arms. In each case approx. 60% of the bleedings were active (Forrest Ia/Ib).

Analysis of the data shows that the OTSC System is significantly superior ($p = 0.019$) to standard treatment at 91.7% (44/48) to 73.1% (38/52) in successful haemostasis. There was no persistent bleeding with the OTSC compared with 6 (11.5%) persistent bleeding in the standard arm ($p = 0.027$). All persistent bleeding in the standard arm could be successfully stopped with OTSC. In the OTSC, 8.3% (4/48) of rebleeds occurred within 7 days compared with 15.4% (8/52) in the standard arm ($p = 0.362$). The treatment time was comparable at 27 min (OTSC) and 28 min. There were no significant differences with regard to the other endpoints (blood transfusion, stay in intensive care, length of hospitalisation, mortality and need for second-line treatment).

Meier concluded that OTSC is superior to standard treatment for acute non-varicose upper GI bleeding with a high risk of rebleeding and that primary haemostasis by OTSC is highly effective (no persistent bleeding in the OTSC arm). No additional time is required for OTSC treatment. Furthermore, the subgroups that benefit from OTSC treatment still need to be better defined.

A 319 Die primäre OTSC-Therapie ist der endoskopischen Standardtherapie bei Hochrisikopatienten mit akuter oberer (nicht variköser) Gastrointestinalblutung überlegen (STING-2 Studie)

Meier B¹, Wannhoff A¹, Denzer U², Schumacher B³, Albers D³, Feisthammel J⁴, Walter B⁵, Meining A⁶, Wedi E⁷, Zachäus M⁸, Pickartz T⁹, Küllmer A¹⁰, Schmidt A¹⁰, Caca K¹

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Retrospective comparative study on OTSC type-a vs. type-t clips in duodenal ulcer bleeding

M. Hollenbach, Leipzig, reported on a retrospective analysis comparing OTSC type-a versus type-t clips in the treatment of duodenal ulcer bleeding. For this purpose, data from 2009 – 2020 from 6 endoscopy centres was analysed and all patients treated with the OTSC System for duodenal ulcer bleeding during an emergency endoscopy were included in the analysis.

Data from 173 patients has been evaluated so far. Data from a further 80 – 100 patients is to be included in the analysis after acquiring a centre at short notice. Of the patients evaluated so far, 93 were treated with type-a and 80 with type-t. The analysis showed that the baseline characteristics age (71.2 y vs. 71.6 y, $p = 0.255$), gender (men: 69.9% vs. 67.5%, $p = 0.735$), use of anticoagulants (32.9% vs. 43.0%, $p = 0.176$) and Rockall score (7.2 vs. 7.4, $p = 0.917$) were comparable between the groups. However, there were significant differences in the bleeding characteristics. The type-a group had significantly fewer ulcers with active bleeding (Forrest Ia/b) than the type-t group (51.1% vs. 62.5%, $p = 0.020$). In addition, type-t was used more often as first-line treatment (95% vs. 77.8%, $p = 0.004$). Analysis of the data to date showed that initial haemostasis (type-a: 93.5%, type-t: 90%, $p = 0.421$) was comparable and bleeding-associated lethality was not significantly different (type-a: 3.2%, type-t: 7.8%, $p = 0.125$). However, the OTSC-t group showed a significantly increased rate of rebleeding (37.2% vs. 6.5%, $p < 0.001$).

Hollenbach concluded that the OTSC is highly effective in the haemostasis of bleeding duodenal ulcers in both first- and second-line treatment. Type-a should be considered the standard of care for endoscopic treatment of duodenal ulcer bleeding, if an OTSC is used, because of the significantly lower rate of rebleeding. However, it is important to wait for the other included cases before making a final assessment and to note the differences in the bleeding characteristics.

Analyse des traumatischen vs. atraumatischen over-the-scope-clip (OTSC) bei der Behandlung von duodenalen Ulkusblutungen

Hollenbach M¹, Schmidt A², Decker A², Möschler O³, Jung C⁴, Mechie N.-C⁵, Barhoom T⁵, Hegelein A⁵, Knoop R⁶, Blasberg T⁵, Wedi E⁵

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stentfix OTSC® System

First evaluations of the University Medical Centre Freiburg and the University Medical Centre Würzburg show that the migration risk can be significantly reduced with stentfix OTSC

Lecture University Medical Centre Würzburg

K. Groneberg, Würzburg, presented initial data on the effectiveness of the stentfix OTSC system. The stentfix OTSC system has been examined to prevent stent migration in fully covered self-expanding metal stents (FC-SEMS). These are used in the endoscopic management of stenosis or leakage in the upper gastrointestinal tract and their main limitation is migration, which occurs in one third to one half of all patients, depending on the indication.

The data of 25 patients was retrospectively considered for the evaluation. In these patients, an FC-SEMS was fixed using stentfix OTSC within a period of 24 months following the introduction of the system in April 2019. The general feasibility and effectiveness of this new method were evaluated.

In 13 patients, stent implantation was due to stenosis (malignant = 4, benign = 9). In the other 12 cases, the stent was implanted to treat a fistula or leakage. The average duration of the stent implantation including clip application was 6.5 minutes and in regards to the clinical problem, a satisfactory result was achieved in all patients. In the follow-up examination, stent dislocation was detected in only 2 patients (8%). In 5 other patients (20%), the stentfix OTSC had detached from the mucosa without migration of the FC-SEMS. Fixation-associated side effects were not observed.

Groneberg concluded that based on this initial data, fixation of FC-SEMS in the oesophagus using stentfix OTSC is safe and easy to perform. In the short term, stent migration can be prevented in the vast majority of cases.

A 293 Effektivität der Fixierung von SEMS im Ösophagus mittels Stentfix OTSC

Groneberg K, Reimer S, Meining A, Universitätsklinikum Würzburg DOI 10.1055/s-0041-1733767

Lecture University Medical Centre Freiburg

A first evaluation of the effectiveness of the stentfix OTSC was also presented by the University Medical Centre Freiburg. M. Schirmer investigated whether the use of the stentfix OTSC system significantly reduces the migration rate of oesophageal SEMS and performed a retrospective comparative monocentric analysis. The primary endpoint was stent migration. Univariable and multivariable logistic regression models were used to evaluate predictive factors for stent migration.

The intervention group consisted of 26 patients who underwent oesophageal SEMS insertion using the stentfix OTSC system between 02/2019 to 12/2020. As a control group, 51 cases of oesophageal SEMS inserts without fixation were analysed between 04/2017 and 01/2019. The main indications in the stentfix OTSC group were malignant stenosis (57.7%) and perforation/insufficiency (32%) which were treated with 50% partial and 50% full coverage stents. The application of the stentfix OTSC was technically successful in all cases and was accomplished without complications. In the control group without fixation, 71% had partially covered stents. The indication was malignant in 74.5% and benign in 25.5%. There was no difference in the other characteristics.

In both groups, data on the presence of stent migration could be collected in 92% of cases. This occurred significantly less frequently in the stentfix OTSC group (7.7%) than in the control group (33.3%, relative risk reduction (RRR): 76.9%, $p < 0.001$). Univariable analyses showed that overstenting of the cardia tended to be associated with a higher risk of stent migration. The use of the stentfix OTSC led to a significant reduction in the risk of migration in this subgroup (8.3 vs. 50%, RRR: 83.4% $p = 0.024$). Stent removal after stentfix OTSC was performed in 11 patients (42%) without complications. The presence of malignant disease or the type of stent coating had no influence on stent migration.

Schirmer concluded that the use of the stentfix OTSC system can significantly reduce the risk of stent migration. This is especially true in patients with overstenting of the cardia.

A 294 Effektive Reduktion der Migrationsrate von Ösophagus-Stents durch ein neues Clipsystem (stentfix OTSC®)

Schiemer M, Schmidt A, Bettinger D, Mueller J, Schultheiß M, Thimme R, Kuellmer A; Universitätsklinikum Freiburg DOI 10.1055/s-0041-1733768

OTSG Xcavator™

A new and effective instrument for pancreatic necrosectomy, blood coagel and foreign body removal

M. Brand presented the first standardised evaluation of procedures with the new OTSG Xcavator. Between November 2020 and April 2021, 34 procedures with the OTSG Xcavator were recorded from 7 centres. Of the 34 procedures, n=24 were pancreatic necrosectomies (19 transgastric, 3 transduodenal).

In 67% (n=16) of the necrosectomies, access to the necrotic cavity was via a lumen apposing metal stent (LAMS). In one case the OTSG Xcavator could not be inserted into the cavity (transduodenal approach), in two other cases there was a dislocation of the LAMS. The technical and clinical success of necrosectomy was 97%, with a mean of 7 (2-19) pieces of necrosis removed. The mean procedure time was 47 min (15-120 min). Suction/irrigation was used to remove the necrotic material, and in some cases removal of the endoscope was necessary to clean the instrument.

Furthermore, n=4 cleanings of insufficiency cavities prior to Endovac treatment, n=4 removals of foreign bodies in oesophagus or stomach and n=2 removals of blood clots in case of ulcer bleeding in the duodenum were performed. Here, the technical and clinical success rate was 100%. Clinically relevant complications were not reported in any of the 34 cases.

Brand concluded that the OTSG Xcavator is a simple and safe tool for pancreatic necrosectomy. It is also useful and effective for foreign body removal and blood coagulation management in Forrest IIb situations.

OTSG Xcavator - Erste multizentrische Daten zum klinischen Einsatz

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FTRD® System

Report on STER and FTRD: procedure, areas of application and study data

In his lecture, J. Hochberger discussed STER (Submucosal Tunneling Endoscopic Resection) as a so-called *exposure technique* and presented an overview of the available study data. Two patient cases were displayed, a leiomyoma which could not be removed by atraumatic cranial salvage due to its tumour size. A second case showed a patient with a tumour originating from the propria muscle in the fundus. In both cases, the STER technique was successfully applied and incision closure was performed using the OTSC system. J. Hochberger concluded that the STER technique is still a limited technique due to the scarce and retrospective data, but could be a real alternative to surgery in the oesophagus.

In the second part of the lecture, endoscopic full-thickness resection with the FTRD System was presented as a so-called *non-exposure technique*, since the wall closure takes place before the resection. A review of data on the use of the FTRD System in the colon was shown, such as the WALL RESECT study with n=181 patients and the FTRD register with n=1178 patients. Both studies showed an R0 resection rate of about 80%. The presented Dutch FTRD register (n=367 patients) also achieved a similar R0 resection rate. When using the technique for early colon carcinomas, J. Hochberger concluded that eFTR is technically feasible and safe and the FTRD System allows an accurate histological classification of the tumour.

When the FTRD System is used for full-thickness resection of a tumour at the opening of the appendix, various past studies have shown an R0 resection rate between 64 and 85%. The appendicitis rate was between 11 and 17%. Another combination technique is hybrid FTRD, in which the lifting part is ablated using piecemeal EMR and the non-lifting part is resected using the FTRD System. An American abstract published in 2020 (Yuen et al.) with n=62 patients was able to achieve an R0 resection rate of 96% in this way.

J. Hochberger concluded that full-thickness resection with the FTRD System is an integral part of the colon and rectum repertoire, supported by clinical data. It also allows resections in difficult locations and in scar tissue. For use in early carcinomas, prospective studies would be desirable due to the limited amount of data available so far. The application possibilities in the stomach and small intestine already display very promising data.

STER und FTRD (Tumoresektion durch Tunnel oder Vollwand)

Hochberger J, Klinikum Berlin Friedrichshain

Successful treatment of complex early colorectal carcinomas with endoscopic full-thickness resection

A. Hoffmann presented a small case series (n=4) of patients with complex early colorectal carcinomas in whom the procedure of endoscopic transmural full-thickness resection was used.

The first case was a 75-year-old patient with an adenoma of approx. 3 cm in size on the right flexure, which could only be partially removed using the piecemeal technique (histology: severe dysplasia with focal pT1sm LOVOG1Rx early carcinoma). Despite scarring and difficult localisation, the recurrence was then successfully removed (histology: pT1sm1 LOVOG1R0).

In another case, a 69-year-old patient with a bioptic early carcinoma and a second suspicious polyp in the immediate vicinity was presented, in whom two endoscopic transmural full-thickness resections were successfully performed in parallel (histology: pTis LOVOG1/G2R0).

The remaining two cases were reports of successful endoscopic full-thickness resection for long-standing ulcerative colitis. During a routine outpatient colonoscopy, a 55-year-old female patient was found to have a conspicuous area that was difficult to define but clearly visible under virtual chromoendoscopy. The histology of the full-thickness resection showed colitis associated dysplasia with an early carcinoma pTis LOVOG2R0. In another case, a 56-year-old patient was found to have a biopsy-confirmed mucosal carcinoma in the rectum. In this case, full-thickness resection revealed a high-grade dysplasia that could be completely removed.

The authors conclude that endoscopic full-thickness resection with the FTRD can bypass surgery and that the resected tissue has good histological significance, especially in the case of early carcinomas.

A 338 Endoskopische Vollwandresektion als erfolgreiche Therapieoption bei komplexen kolorektalen Frühkarzinomen

Dorlöchter C, Hirsch A, Schmidt V, Conrad A, Hoffman A; Lehrkrankenhaus Klinikum Aschaffenburg Alzenau, DOI 10.1055/s-0041-1734068

eFTR is becoming increasingly important in the resection of early colorectal carcinomas with “low risk” histology

P. Stathopoulos presented a unicentric, retrospective analysis of the effectiveness, safety and oncological follow-up of patients with early colorectal carcinomas treated with eFTR. From November 2016 to April 2021, 89 underwent eFTR, of which 31 patients (12 women, median age 76) had early CRC. All lesions (22 colon (71.0%), 9 rectum (29%)) were reached. The median histological lesion size was 14 mm (3-25 mm), median procedure time was 47.5 min (25-70 min). The technical success rate was 83.9% and R0 resection was achieved in 67.7% (n = 21). In 9/31 patients, eFTR was performed after questionably incomplete polypectomy of early adenocarcinoma, but no carcinoma remnants were seen in full-thickness resections. 4/31 patients had a “low-risk” situation, of which one patient underwent lateral oncological resection due to R1 status. In the remaining 18/31 patients, histology revealed a “high-risk” situation. Of these, 8 patients underwent oncological resection and 10 patients underwent clinical endoscopic follow-up. During follow-up (median 15.5 months, 0-47), one patient died from another cause, and no tumour recurrence was documented in the remaining patients. There were 3 minor rebleeds (9.4%); one ileus (3.1%), which was treated conservatively, and one perforation (3.1%), which was closed endoscopically with OTSC. Stathopoulos concluded that eFTR is a safe endoscopic procedure that allows accurate risk stratification and can spare patients with early CRC and “low-risk” histology from oncological surgery. However, prospective studies with appropriate oncological follow-up are needed to evaluate the long-term effectiveness.

A 339 Endoskopische Vollwandresektion („endoscopic full-thickness resection“, eFTR) für das frühe kolorektale Karzinom (CRC) – eine retrospektive Analyse von 31 konsekutiven Fällen

Stathopoulos P, Zumblick M, Hoque S, Gress TM, Denkert C, Denzer UW; Universitätsklinik Marburg DOI 10.1055/s-0041-1734069

Further lectures involving Ovesco products

Endoscopic clips including OTSC are highly effective standard treatment for defect closure

In his study, K. Kouladouros, Mannheim, presented the clip closure of bowel wall lesions in endoscopic mucosal resections (EMR). For this purpose, all EMR cases in the lower gastrointestinal tract, for the period 2007 – 2020 were retrospectively analysed and all patients with intrainterventional bowel wall injuries requiring treatment were identified. Periinterventional factors, including type and number of clips applied, and outcomes of treatment were assessed.

157 intrainterventional bowel wall injuries were identified from 3782 endoscopic mucosal resections. Endoscopic clip closure was possible in 148 cases (94%). 11 of these initially endoscopically treated patients required surgical resection, making the clinical success rate of endoscopic clip closure 92.6%. The size of the resected tumour and the defect, as well as the number and type of clips applied (through-the-scope clips or OTSC) had no influence on the success of endoscopic clip closure.

Kouladouros concluded that endoscopic clip closure of bowel wall lesions during endoscopic resection is a reliable treatment option and eliminates the need for surgery in more than 90% of cases. That's why this is, and should always be, the initial treatment of choice.

A 297 Resektionsbedingte Darmwandverletzungen: ist ein Loch gleich ein Loch? Eine retrospektive Analyse von 3782 endoskopischen Mukosaresektionen

Kouladouros K, Belle S, Kähler G; Universitätsklinikum Mannheim, DOI 10.1055/s-0041-1733771

Evaluation of GKV routine data underlines the position of endoscopic treatment for ulcer bleeding

D. Horenkamp-Sonntag from Techniker Krankenkasse, Hamburg, presented an evaluation of acute ulcer bleeding on the basis of GKV routine data from the period 2016-2020. These are available for 10.8 million TK insurants. The aim of the study was to evaluate the role of anticoagulant drugs (anticoagulation [AK] and acetylsalicylic acid [ASA]) and endoscopic haemostasis measures with clip insertion in acute ulcer bleeding in routine clinical practice. The data was tailored by using specific disease information (ICD K25-28, Z92) and endoscopic services (OPS codes) to focus on insured patients with ulcer disease of the stomach and/or duodenum.

The study was based on hospital cases with acute peptic ulcer without bleeding (n = 19,167) or with acute bleeding (n = 17,635), while 41,241 outpatient cases with ulcers in the upper GI tract were not included. The main findings of the interim analysis were:

1. Patients with ulcer bleeding were older than those without bleeding
2. Treatment with ASA showed only minor differences between the groups, while AK or the combination of ASA and AK was significantly more frequent in the bleeding population.
3. Clips were used in about 1/3 of the bleedings, with OTSC clips (in 7-12%) mainly in duodenal ulcers
4. Clips were used significantly (p< 0.001) more often in patients with AK ± ASA than in those without coagulation, regardless of ulcer location.

Based on hospital patient billing data, anticoagulation is a risk factor for acute ulcer bleeding in every 3rd patient. ASA use may be relevant for ulcer pathogenesis, but less so for bleeding. Clips are an important tool in haemostasis, especially under anticoagulants. The OTSC clip is currently preferred for duodenal ulcers.

A 317 Akute Ulkusblutung: Rolle der Gerinnungshemmung und Einsatz von Clips in der endoskopischen Blutstillung

Horenkamp-Sonntag D¹, Koop H², Skupnik C¹

¹Techniker Krankenkasse, Hamburg; ²Helios Klinikum Berlin-Buch, DOI 10.1055/s-0041-1734047

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