

Congress report UEG Week Virtual 2021

October 3-5, 2021, Vienna, Austria & online

Two major RCTs regarding OTSC first line therapy were presented at this year's UEG Week and have the same outcome. OTSC is the superior therapy for the first-line treatment in non-variceal upper GI bleeding.

Highlights:

- **OTSC treatment can be considered as the first-line treatment for larger peptic ulcers. The cost to avert further bleeds was cheaper with use of OTSC.** - James Lau (Hong Kong)
- **OTSC first-line therapy is superior to standard treatment in patients with acute NVUGIB and high-risk of rebleeding.** - Benjamin Meier (Ludwigsburg, Germany)

OTSC® System

OTSC is superior and can be considered as the first-line treatment for larger peptic ulcers

J. Lau, Hong Kong, presented a poster on his multicentre RCT to compare OTSC to standard endoscopic treatment in patients with non-variceal upper gastrointestinal bleeding. Primary outcome was 30-day bleeding free probability. They finally recruited 190 patients and they were randomized into an OTSC arm (n = 93) and a standard arm (n= 97). The baseline characteristics of the patients were comparable with a mean age of 62.4 y vs 64.1 and most male patients (~80 %). The mean Glasgow Blatchford score was 10.9 and 11.0. 29.0% of patients in the OTSC arm and 35.0% in the standard arm were on anticoagulation or platelet aggregation inhibition. In both groups most bleedings occurred from a peptic ulcer (92.5% and 89.7%)

Analysis was by intention-to-treat. The 30-day bleeding free probability in OTSC group and standard treatment group was 96.8% (90/93) vs 85.4% (83/97) respectively (HR, 0.21; 95% CI 0.06 to 0.73; P=0.006). Failure to control bleeding at first endoscopy (1 vs. 6; OR, 0.16, 95% CI 0.02 to 1.4) and 30-day recurrent bleeding (2 vs. 8; OR, 0.23, 95%CI 0.05 to 1.12) were lower in the OTSC group. In ulcers ≥10mm in size, OTSC significantly reduced the rate of further bleeding (1 of 48 vs. 8 of 46; OR, 0.10, 95% CI 0.01 to 0.84). The 30-day re-intervention (2 vs. 8; p=0.138) and death did not differ significantly between the two groups (2 vs. 4; p=0.438). The cost to avert further bleeds was cheaper with use of OTSC. The ICER was – 647 USD.

Lau concluded that OTSC treatment can be considered as the first-line treatment for larger peptic ulcers.

OVER-THE-SCOPE CLIPS (OTSC) VERSUS STANDARD ENDOSCOPIC TREATMENT IN PATIENTS WITH ACUTE NON-VARICEAL UPPER GASTROINTESTINAL BLEEDING

Lau J, Tan C.H., Sun X, Song H, Li L, Li R, Li P, Feng J, Wang B, Leung W.K., Hartley I, Moss A.C., Suen B.Y., Yu Y, Chan F.K.L

Poster presentation (P0895) UEG Week 2021

Conflict of interests: No

STING II: OTSC first-line therapy is superior to standard therapy in acute nonvariceal OGI bleeding with high risk of rebleeding

B. Meier, Ludwigsburg, Germany presented the final data on the multicentre RCT STING II 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 therapy (STING study). STING II was subsequently 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). According to the calculation of the number of cases (power 80%), n = 100 patients with endoscopically confirmed acute (non-varicose) upper GI bleeding and a "complete Rockall score" ≥ 7 points were included. Exclusion criteria included prior endoscopic

treatment within the last 4 weeks to rule out treatment of recurrent bleeding. Primary endpoint was successful haemostasis without recurrent bleeding within 7 days.

After randomisation, n = 52 patients could be 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). Peptic ulcer bleeding was predominant in both arms, with more than 80% in each. Approximately 60% of each bleed was active (Forrest Ia/Ib).

Analysis of the data showed that the OTSC system was significantly superior to standard therapy at 91.7% (44/48) with 73.1% (38/52) in successful hemostasis ($p = 0.019$). 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 arm, 8.3% (4/48) of rebleeds occurred within 7 days compared with 15.4% (8/52) in the standard arm ($p = 0.362$). Treatment time was comparable at 27 min (OTSC) and 28 min, respectively. There were no significant differences in other endpoints (blood transfusion, ICU stay, length of hospitalisation, mortality and need for second-line treatment).

Meier concluded that OTSC is superior to standard therapy for acute nonvariceal upper GI bleeding with a high risk of rebleeding. No additional time was required for OTSC therapy. Furthermore, the study once again highlighted the efficacy of OTSC salvage therapy after unsuccessful hemostasis.

Endoscopic Treatment of Non-variceal Upper GI-bleeding With High Risk of Recurrency - OTSC (Over-the-scope-clip) Versus Standard Therapy (STING2)

Meier B, Wannhoff A, Denzer U, Stathopoulos P, Schumacher B, Albers D, Hoffmeister A, Feisthammel J, Walter B, Meining A, Wedi E, Zachäus M, Pickartz T, Küllmer A, Schmidt A, Caca K
Lecture & poster presentation (MP061) UEG Week 2021

References: 1: Schmidt A, Gölder S, Goetz M, et al. Over-the-scope clips are more effective than standard endoscopic therapy for patients with recurrent bleeding of peptic ulcers. *Gastroenterology* 2018; 155:674–686

Conflict of interests: Meier B – fees for research activities and lecture fees from Ovesco Endoscopy; Meining A – consultant for Ovesco Endoscopy AG and lecture fees; Schmidt A – lecture fees and study grant from Ovesco Endoscopy AG; Wedi E and Caca K – lecture fees from Ovesco Endoscopy AG; Other authors have nothing to disclose.

Retrospective study compares efficacy and complications of OTSC type-a vs. type-t clips in duodenal ulcer bleeding

M. Hollenbach, Leipzig, Germany presented a poster 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.

Finally, the data of 173 patients could be evaluated. Of these, 93 patients were treated with type-a and 80 patients 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 some significant differences in the bleeding characteristics. Thus, 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 showed that initial haemostasis (type-a: 93.5%, type-t: 90%, $p=0.421$) and bleeding-associated lethality were not significantly different (type-a: 3.2%, type-t: 7.8%, $p=0.125$). However, the OTSC-t group showed a significantly increase rate of rebleeding (37.2% vs. 6.5%, $p<0.001$).

Hollenbach concluded that therefore the type-a should be considered the standard of care for endoscopic treatment of duodenal ulcer bleeding, when an OTSC is used, because of the lower rate of rebleeding.

Treatment of duodenal ulcer bleeding – Efficacy of traumatic and atraumatic over-the-scope-clips (OTSC) – a multicenter retrospective analysis

M. Hollenbach, A. Schmidt, A. Decker, O. Möscher, C. Jung, N.-C. Mechie, T. Barhoom, A. Hegelein, R. Knoop, T. Blasberg, E. Wedi

Poster presentation (P0903) UEG Week 2021

Presentation of recently updated non-variceal upper GI bleeding (ESGE update 2021)

I. Gralnek, Haifa, Israel gave a talk on the recently updated ESGE Guideline – Endoscopic diagnosis and management of nonvariceal upper gastrointestinal hemorrhage.

Besides several other changes regarding e.g., the pre-management with PPI, management of antiplatelet agents and the ideal timing of endoscopy Gralnek also spoke about the updated recommendations for the endoscopic therapy. In addition to the previous standard therapy with Endoclips now also the OTSC is recommended for the mechanical treatment of ulcer bleeding. Furthermore, the significance of the OTSC for the rescue therapy was highlighted.

During the following Q&A session a variety of questions regarding OTSC were discussed.

Upper GI Bleeding: Whats' New in 2021? "Non-Variceal Bleeding"

Gralnek I

Lecture presentation, UEG Week 2021

A. Meining, Würzburg, Germany, presented a case report of a 74-year-old patient with a history of gastrectomy with Roux-en-Y reconstruction for gastric carcinoma, right hemicolectomy for a tumor in the ascending colon that occurred several years later, and HIPEC therapy. Before being referred to the university hospital, the patient presented to a smaller center with acute pleural empyema on the left side with E. faecium and was treated with drainage. With drainage, the empyema disappeared. However, small air bubbles remained near the drainage, and there was persistent fluid formation with E. faecium. Gastroscopy with fluoroscopy failed to find leakage at the esophago-jejunal anastomosis. A colonoscopy was then performed, and a fairly large opening was found in addition to several diverticula. X-ray fluoroscopy revealed that a pleural-colonic fistula was present.

This unusual case was then closed with an optimized OTSC fistula closure technique developed by Meining. In this technique, he uses a needle knife to make an incision of the mucosal layer around the fistula opening. The size of the incision is approximately the same as the size of the OTSC cap, and the clip is placed in the incision. After placement of the clip, closure of the leak was demonstrated by injection of a contrast agent.

No leakage occurred later in the course, and the drainage could be extracted. The clip detached after 6 months and the last follow-up after 1 year showed no further complaints after the procedure.

Fistula from the colon to the pleura after surgery

Meining A

Lecture presentation, UEG Week 2021

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