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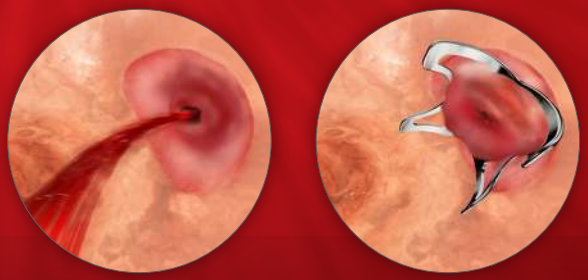
OTSC® – superior outcome in hemostasis

Three randomized controlled trials (USA, Europe, Asia) on first-line OTSC® therapy demonstrate a significant clinical benefit compared to former standard treatment. Clinical success rates:

96.0% vs. 71.4% (p=0.017) in ulcer & Dieulafoy; Jensen DM et al., Clin Gastroenterol Hepatol 2021[1]
91.7% vs. 73.1% (p=0.019) in high-risk lesions; Meier B et al., Gut 2022[2]
96.8% vs. 86.5% (p=0.007) in all cases of NVUGIB; Lau J et al., UEGW 2021[3]

1st line



1 Jensen DM, Kovacs T, Ghassemi KA, Kaneshiro M, Gornbein J. Clin Gastroenterol Hepatol. 2021 Nov;19(11):2315-2323
2 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. Gut. 2022 Jul;71(7):1251-1258.
3 Lau J, Tan CH, Sun X, Song H, Li L, Li R, Li P, Feng J, Wang B, Leung WK, Hartley I, Moss AC, Suen BY, Yu Y, Chan FK. Over-the-scope clips versus standard endoscopic treatment. UEG Week Virtual (October 3-5) 2021

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Three randomized controlled trials (USA, Europe, Asia) on first-line OTSC® therapy demonstrate a significant clinical benefit compared to former standard treatment

- OTSC significantly reduced rates of rebleeding, severe complications, and post-randomization red cell transfusions. – Dennis M. Jensen (Los Angeles)
- OTSC first-line therapy appears to be superior to standard treatment with clips in patients with acute NVUGIB and high-risk of rebleeding. – Benjamin Meier (Ludwigsburg)
- 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)

Abstracts:

Randomized Controlled Trial of Over-the-Scope Clip as Initial Treatment of Severe Nonvariceal Upper Gastrointestinal Bleeding.

Background and aims: No prior randomized controlled trial (RCT) has reported patient outcomes of large over-the scope clip (OTSC) compared to standard hemostasis as initial endoscopic treatment of severe NVUGIB. This was our study aim.
Methods: Patients with bleeding ulcers or Dieulafoy's lesions and major stigmata of hemorrhage – SRH (active spurting bleeding, visible vessel, or clot) - or lesser SRH (oozing bleeding or flat spots – with arterial blood flow by Doppler probe) were randomized to OTSC or standard endoscopic hemostasis (with hemoclips or multipolar electrocoagulation – MPEC). Patients and their healthcare providers were blinded to treatments and made all post-randomization management decisions. Ulcer patients received high dose intravenous infusions of proton pump inhibitors (PPI) for 3 days, then 27 days of oral PPI. 30-day outcomes were prospectively recorded; data management was with SAS; and data analysis was by a statistician.
Results: 53 patients (25 OTSC, 28 Standard) were randomized, with similar baseline risk factors. However, there were significant differences in OTSC vs. Standard groups in rates of rebleeding (4% vs. 28.6%; p [0.017; relative risk 0.10, 95% confidence intervals 0.01, 0.91; number needed to treat 4); severe complications (0 % vs. 14.3%); and post-randomization units of red cell transfusions (0.04 vs. 0.68). All rebleeds occurred in patients with major SRH and none with lesser SRH.
Conclusion: 1. OTSC significantly reduced rates of rebleeding, severe complications, and post-randomization red cell transfusions. 2. Patients with major stigmata benefited significantly from hemostasis with OTSC, but those with lesser stigmata did not.

Jensen DM, Kovacs T, Ghassemi KA, Kaneshiro M, Gornbein J. Randomized Controlled Trial of Over-the-Scope Clip as Initial Treatment of Severe Nonvariceal Upper Gastrointestinal Bleeding. Clin Gastroenterol Hepatol. 2021 Nov;19(11):2315-2323.e2

Over-the-scope-clips versus standard treatment in high-risk patients with acute non-variceal upper gastrointestinal bleeding: a randomised controlled trial (STING-2).

Objective: Acute non-variceal upper gastrointestinal bleeding (NVUGIB) is managed by standard endoscopic combination therapy, but a few cases remain difficult and carry a high risk of persistent or recurrent bleeding. The aim of our study was to compare first-line over-the-scope-clips (OTSC) therapy with standard endoscopic treatment in these selected patients.
Design: We conducted a prospective, randomised, controlled, multicentre study (NCT03331224). Patients with endoscopic evidence of acute NVUGIB and high risk of rebleeding (defined as complete Rockall Score ≥7) were included. Primary endpoint was clinical success defined as successful endoscopic haemostasis without evidence of recurrent bleeding.
Results: 100 patients were finally randomised (70% male, mean age 78 years; OTSC group n=48, standard group n=52). All but one case in the standard group were treated with conventional clips. Clinical success was 91.7% (n=44) in the OTSC group compared with 73.1% (n=38) in the ST group (p=0.019), with persistent bleeding occurring in 0 vs 6 in the OTSC versus standard group (p=0.027), all of the latter being successfully managed by rescue therapy with OTSC. Recurrent bleeding was observed in four patients (8.3%) in the OTSC group and in eight patients (15.4%) in the standard group (p=0.362).
Conclusion: OTSC therapy appears to be superior to standard treatment with clips when used by trained physicians for selected cases of primary therapy of NVUGIB with high risk of rebleeding. Further studies are necessary with regards to patient selection to identify subgroups benefiting most from OTSC haemostasis.

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. Over-the-scope-clips versus standard treatment in high-risk patients with acute non-variceal upper gastrointestinal bleeding: a randomised controlled trial (STING-2). Gut. 2022 Jul;71(7):1251-1258.22

Over-the-scope clips (OTSC) versus standard endoscopic treatment in patients with acute non-variceal upper gastrointestinal bleeding

Introduction: Current methods in endoscopic hemostasis has a small but significant failure rate in the control of acute non-variceal bleeding. The role of OTSC as the first treatment has not been defined.
Aims & Methods: We did a multicenter RCT that compared OTSC to standard endoscopic treatment in patients with non-variceal upper gastrointestinal bleeding. Primary outcome was 30-day bleeding free probability.
Results: 190 patients were randomized (OTSC 93, standard treatment 97). Analysis was by intention-to-treat. The 30-day bleeding free probability in OTSC group and standard treatment group was (90 of 93, 96.8%) and (83 of 97, 85.4%) 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 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. ICER was - USD$647 dollar.
Conclusion: OTSC treatment can be considered as the first-line treatment for larger peptic ulcers.

Lau J, Tan CH, Sun X, Song H, Li L, Li R, Li P, Feng J, Wang B, Leung W.K, Hartley I, Moss AC, Suen BY, Yu Y, Chan FK. Over-the-scope clips (OTSC) versus standard endoscopic treatment in patients with acute non-variceal upper gastrointestinal bleeding. UEG Week Virtual (October 3-5) 2021