Cost effectiveness analysis

Treatment with OTSC® shows higher success rates than former standard therapy. As first-line procedure for UGI bleeding, OTSC® prevents GI hemostasis.

A study proves cost-effectiveness of OTSC® for hemostasis in comparison to former standard therapy.

The data of Kuellmer et al. demonstrate that the clinically superior OTSC® treatment is also cost-effective and even cost-reducing.

Average Cost-Effectiveness Ratio (ACER): average costs (in Euro) per successful hemostasis (without re-bleeding)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>ACER overall treatment</th>
<th>ICER overall treatment</th>
<th>ICER hemostasis</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTSC® therapy</td>
<td>2,312 €</td>
<td>-600 €</td>
<td>-500 €</td>
</tr>
<tr>
<td>Former standard therapy</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Further reading:


Further details on clinical data of the OTSC® System can be found on pages 4–6 of this bulletin.
### application techniques

**Suction technique**

- Position the OTSC® Anchor and fix the tissue;
- Align the OTSC® cap to the lesion by pulling the anchor and advancing the endoscope.
- Mobilize the tip of the anchor and advance the endoscope.

**Anchor technique**

- In cases of lesion at a fixed site (e.g., angle of cards II) the OTSC® Anchor can be placed in a pre-routed fashion: advancing the lesion until the OTSC® Anchor can be pulled out the endoscope. The anchor is then held and the sheath is advanced into the colon.

**Suction technique**

- The OTSC® Anchor is available in two sizes, 6 t and 12 t. Insertion for the OTSC® Anchor 12 t and OTSC® 12 t has shown superior puncture resistance with anchoring forces.
- Once the target tissue is captured inside the cap, hemostasis is achieved by turning the handwheel to release the OTSC® clip around the cap – suction technique.

**Mobilization**

- Once an OTSC® clip is successfully deployed it will stay in situ for several weeks to several months. The exact duration depends on the amount and texture of the tissue secured. The OTSC® clip will leave the GI tract naturally in the majority of cases. Occasionally, it may be overgrown with tissue.

**Follow-up**

- Long-term follow-up is recommended every 3 months. Two patients (0.4%) required re-endoscopy after OTSC® deployment due to a possible post-deployment bleeding signal (grade 1). In both patients, recurrent bleeding was stopped by OCTAS® devices.

### case examples

**OTSC® placement in case of hemorrhage**

- **Bleeding**
  - Due to an actively bleeding arterial injury, the OTSC® Anchor was deployed immediately to treat a severe hemodynamic situation. The post-deployment analysis showed a strongly improved hemodynamic parameter (e.g., systolic blood pressure).
- **Train-of-results**
  - The high technical success rate (95.3%) and low re-bleeding rate (1.7%) make the OTSC® System an excellent first-line therapy for hemorrhage.

**Spurring arterial bleeding from peptic duodenal ulcer**

- The images show HD® clips on a spurring arterial bleeding from peptic duodenal ulcer. The HD® clip was deployed using the OTSC® clip. The OTSC® clip was then re-disengaged to allow for full dissection of the ulcer edge.

**Dressing bleeding from Ulcer Desubluxation**

- A 70-year-old male patient was hospitalized for hematemesis with ulcers. He was treated for his bleeding ulcer by an endoscopic therapeutic approach. The images show the OTSC® clip in situ with the ulcer desubluxated. The clip is visible as a white line above the ulcer edge. Once the ulcer is desubluxated, the OTSC® clip can be engaged again to achieve hemostasis.

**Perforation bleeding from peptic duodenal ulcer**

- The images show an OTSC® clip in two different settings. The clip is visible as a white line above the ulcer edge. Once the ulcer is perforated, the OTSC® clip can be engaged again to achieve hemostasis.

**Postoperative colonic anastomotic bleeding**

- Endoscopy was done one day later. A 70-year-old female patient was hospitalized for bronchopulmonary infection and a medical history of stroke. The images show the OTSC® clip in situ with the ulcer desubluxated. The clip is visible as a white line above the ulcer edge. Once the ulcer is desubluxated, the OTSC® clip can be engaged again to achieve hemostasis.

### clinical evidence

**OTSC® in rather to other techniques in SIH hemorrhage**

- Never again since the use of the OTSC® System has hemorrhage been seen.

**Meta-analysis**

- The clinical evidence of OTSC® has been demonstrated in several publications. The results of several studies confirm the efficacy of OTSC® clip in the treatment of hemorrhage. The study included publications that used the OTSC® System in the treatment of hemorrhage.

**Surgery**

- The evidence review and meta-analysis has now confirmed these findings. This current meta-analysis includes in total 20 clinical studies involving hemorrhage by OTSC® clip therapy. The results of this pooled analysis and meta-analysis have now confirmed this again.

**Table 2: Multicenter evaluation of first-line endoscopic treatment with the OTSC in acute non-varical upper GI bleeding**

<table>
<thead>
<tr>
<th>Risk-group</th>
<th>Observed mortality</th>
<th>Observed re-bleeding (Rockall)</th>
<th>Predicted probability</th>
<th>Pooled Proportion (95 % CI)</th>
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<td>Risk-group ≤3</td>
<td>7.0 33 (0–71.0) 1/3 n.a.</td>
<td>1.0</td>
<td>10.9</td>
<td>0.95 (0.92–0.98)</td>
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<td>Risk-group ≥ 4</td>
<td>92.6 67 (35.8–100%) 2/3 n.a.</td>
<td>20.0</td>
<td>10.9</td>
<td>0.95 (0.92–0.98)</td>
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**Clinical success**

- Clinical success was defined as a lack of any further bleeding after discharge or re-intervention. The clinical success rate was significantly higher with OTSC® compared to standard therapy (84.8 % vs 42.4 %; p = 0.001).

**Follow-up**

- Clinical success for OTSC® was 89.2 % (90.2 %–95.4 %) and 87.5 % (85.0 %–90.0 %) for standard therapy. The median follow-up time was 7 days after successful hemostasis. In case of further bleeding, patients were treated with additional endoscopic interventions.

**Conclusion**

- The prospective multicenter STING trial determined that treatment with OTSC® leads to significantly higher technical success (successful hemostasis according to protocol) than standard therapy (93.9 % vs 57.6 %; p = 0.001).

**Table 1: Analysis of 286 consecutive patient cases showed that OTSC® placement is an effective first-line treatment for endoscopic hemostasis**

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<th>AE</th>
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<td>28 (9.9)</td>
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