Over-the-Scope Clip in the Management of Gastrointestinal Defect and Intractable Non-Variceal Bleeding

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Recently, as the numbers of diagnostic endoscopic procedures and therapeutic procedures such as endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD), and full-thickness resection of subepithelial tumors are increasing, the incidence of iatrogenic perforations is also increasing. The use of natural orifice transluminal endoscopic surgery (NOTES) techniques also essentially leads to intentional perforations. Postoperative anatomic and staple line leaks also occur and increase morbidity and mortality. Endoscopic treatments for such perforations include mechanical closure with through-the-scope (TTS) clips, and sometimes self-expandable metal stents (SEMSs) and band ligation. Recently, TTS clips have been most widely used for repairing deep defects in the gastrointestinal (GI) tract. TTS clips are relatively easy to use, clipping of large defects and access to the proper position for repairing the defect are difficult. In addition, TTS clips have limited opening widths and closing strengths, and are usually ineffective in the setting of fibrotic tissue. A high rate of leakage of 20% was found in animal studies.

The over-the-scope clip (OTSC; Ovesco Endoscopy AG, Tübingen, Germany) has a wider mouth and more strength, and thus able to close a larger GI defect. In animal studies, the OTSC could close large perforations and NOTES incision sites owing to its great compressive force and large mouth. It could also control arterial bleeding.

First, the defective tissue around the perforation is sucked into the cap, and then the clip is released. In cases of fibrosis of the defect, a large defect, or difficulty to approach the defect properly, the anchor or twin grasper can be used for proper approximation. Correct capture of the defective tissue is the key point for tight closure.

Some case reports and series have demonstrated the efficacy of the OTSC system for closure of full-thickness GI defects. The first multicenter US experience with OTSC that was published involved 45 patients who underwent OTSC treatment. The overall clinical success rate was 71% (32/45 patients). Immediate hemostasis without recurrence was achieved in 100% of the patients (7/7 patients); Clinical success rate in closure of iatrogenic perforation was 75%(3/4) and in anatomic leaks and fistulae was 65%(20/31).

Haito-Chavez et al. conducted a multicenter, international, retrospective review of 188 patients with GI fistulas, leaks, or perforations who underwent OTSC placement. Technical success was achieved in 151 (93.8%) of the 161 cases analyzed, with one OTSC placed in 142 patients. Immediate technical failures occurred in 10 cases, 9 (90%) of which were due to retracted, necrotic, or fibrotic borders. Of the 151 cases with technical success, 140 (92.7%) achieved immediate clinical success. None of the patients had adverse events related to OTSC placement. The overall long-term clinical success was...
60.2% during a median follow-up of 146 days. The long-term clinical success was significantly higher with primary therapy than with rescue therapy (69.1% vs. 46.9%). Technical success was achieved in 93.4% (85/91), 97.5% (39/40), and 90% (27/30) of the patients with fistulae, perforations, and leak, respectively. The overall long-term clinical success rate was 90% for perforations, 73.3% for leaks, and 42.9% for fistulae. The only significant factor identified in the multivariate analysis was the type of defect. In this study, Argon plasma coagulation (APC) ablation in the epithelial surface of the fistula was applied in only a third of patients. In the remainder of patients, OTSCplacement was applied without APC ablation, which may have led to failure of therapy. However, Baron et al.\textsuperscript{4} reported that the use of APC on the epithelium of the fistula or mechanical trauma caused by the cytology brush may not be helpful in the OTSC system. Thermal damage may cause tissue edema, which may lead to more difficulty in the approximation of the defect. The aids of APC ablation in the fistula tract before OTSC placement remains to be evaluated.

The main limitation of the study by Haito-Chavez et al.\textsuperscript{12} is its retrospective nature and selection bias. In addition, procedures were performed by multiple endoscopists with variable expertise with the OTSC device. In the present study, Goenka et al.\textsuperscript{13} performed a single-center prospective study of 12 patients with GI leaks or fistulae, and ongoing refractory nonvariceal GI bleeding. OTSCs were used only in those with GI bleeding cases in which conventional endoscopic therapy (thermal coagulation, APC, and/or injection of adrenaline) had failed. The fistula and perforations were marked by injecting India ink to accurately localize the site while deploying the OTSC. All endoscopic procedures were performed by a single experienced endoscopist. Of six cases of GI bleeding, two had bleeding from the duodenum; two, from the pyloric channel; one, from the stomach; and one, from the lower esophagus, close to the gastroesophageal junction. All cases were initially managed with adrenaline injections, and gold probe or APC application. Clinical and technical success were achieved in all six bleeding cases. The authors seemed to choose OTSC rather than TTS clips after failure of thermal and injection therapies because of TTS clips are difficult to apply.

Of the GI wall defect cases, three were iatrogenic perforations with less than a 1-week interval between the detection of the defects and clip application. Despite the rather long interval between, all the cases were managed successfully with an OTSC clip without any recurrence. The remaining three cases of GI wall defects were fistulae due to Boerhaave syndrome (one case) and necrotizing pancreatitis (two cases, one in the stomach and the other in the colon). The colonic fistula was closed only partially with an OTSC and was managed with an additional endoscopic procedure by deploying a fully covered colonic nitinol metal stent. In all cases of GI defect, the authors marked the site of the defect by tattooing with India ink, which seems to have helped them to accurately deploy the clip. The benefits of tattooing may need to be evaluated in a further study. They successfully used the anchoring device with non-sharp edges in two fistulae because of large defects of around 2 cm. In the study by Baron et al.,\textsuperscript{4} an anchor or a twin grasper was used in 25 of 48 procedures. The type of accessories depended on the location, type, and fibrosis of the defect. The overall success rate in combined GI bleeding and GI wall defect cases was 91.7% without adjunctive therapies to OTSC placement, such as brushing, glue injection, APC to the fistural edges and metal stents. The authors did not mention the size of the defects, except for one large defect in a case of gastric perforation caused by necrotizing acute pancreatitis. Gubler and Bauerfeind\textsuperscript{14} recommended application of OTSC devices in perforations smaller than 30 mm in diameter. No complications related to the use of the OTSC or to the clip application technique were observed. Although this device is relatively safe, endoscopists should be careful when deploying the OTSC device in difficult and angulated positions especially in the small intestine, where the accidental inclusion of opposing walls into the OTSC cap during suction could occur and cause complete intestinal obstruction.\textsuperscript{4}

Fibrosis or necrotic, inflamed tissue surrounding defective lesions may lead to clip failure. The hard fibrotic tissue is difficult to suck or grasp. Another cause of failure was related to improper alignment of the endoscope tip with the lesion.\textsuperscript{15,16}

As the authors mentioned, the main disadvantage of the OTSC is its high cost. A steep learning curve is required to perform successful OTSC application to full-thickness defects of the GI tract.\textsuperscript{4} The advantages of the OTSC device are its simple application, rare adverse events, and effective full-thickness closure of defective lesions. The OTSC may be used more frequently in the field of therapeutic endoscopy and reduce the frequency of surgical interventions, which will eventually lead to cost-effectiveness.

Conflicts of Interest
The author has no financial conflicts of interest.

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