Use of an over-the-scope clipping device: multicenter retrospective results of the first U.S. experience (with videos)

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Through-the-scope (TTS) clipping devices have been available for nearly 20 years, and applications include the treatment of GI bleeding, closure of perforations and fistulae, and anchoring of feeding tubes.[1-4] Although these devices are relatively inexpensive and easy to use, they have limited opening widths and closing strengths and are usually ineffective in the setting of fibrotic tissue.

Recently, publications emerged demonstrating the feasibility and use of a novel over-the-scope clip (OTSC) device.[5] Experimental studies have demonstrated the ability of the OTSC to close perforations[6-8] and control arterial bleeding.[9] Comparative animal trials have shown the superiority of OTSCs relative to TTS clips for closure of perforations[10,11] and natural orifice transluminal endoscopic surgery (NOTES) access points.[12-14] Subsequent case reports and small case series in humans have shown great promise of the device for the treatment of arterial bleeding and for the closure of endoscopic perforations and fistulae.[15,16] The largest series published to date comprises 50 patients.[17] All of these studies have emanated from outside the United States because the OTSC device was approved by the U.S. Food and Drug Administration at the end of 2010[18] and made commercially available only recently. Herein, we describe the first multicenter U.S. experience and outcomes related to the use of the OTSC.

Abbreviations: OTSC, over-the-scope clip; NOTES, natural orifice transluminal endoscopic surgery; TTS, through-the-scope.

DISCLOSURE: *T. Baron received travel and research support from Boston Scientific and is a consultant and speaker for Cook Endoscopy, L.M. Wong Kee Song is a consultant for Boston Scientific, A. Ross received research support from Boston Scientific, S. Irani received research support from Boston Scientific, R.A. Kozarek received research support from Boston Scientific and honoraria from Cook Endoscopy. No other financial relationships relevant to this publication were disclosed.*

0016-5107/$36.00
http://dx.doi.org/10.1016/j.gie.2012.03.250

Received January 17, 2012. Accepted March 15, 2012.

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This video can be viewed directly from the GIE website or by using the QR code and your mobile device. Download a free QR code scanner by searching "QR Scanner" in your mobile device's app store.

PATIENTS AND METHODS

A retrospective review of all patients who underwent OTSC placement (OTSC system; Ovesco Endoscopy AG, Tubingen, Germany) at the 3 participating North American tertiary-care referral medical centers was undertaken. All OTSCs were placed by 1 of 6 experienced endoscopists. No endoscopist received formal training on the use of the device. Clips placed for any indication were included in the analysis. Data were abstracted for patient demographics, indication for OTSC application, previous therapy, type of endoscope and OTSC used, grasping or anchoring devices used (if any), and adjunctive therapies (stent placement, glue application, etc). The number of clips attempted and successfully deployed was used to define technical success. Clinical success was defined as immediate or delayed. Immediate success was determined in most cases by hemostasis (for bleeding) and lack of contrast extravasation or passage (for perforation and fistula closure, respectively) as well as immediate cessation of drain output when the OTSC was placed for fistulae. Delayed success was defined as resolution of the underlying problem, with or without need for adjunctive therapy, with at least 1 month follow-up after OTSC placement. Adverse events were graded as previously defined.[19] Institutional Review Board approval was obtained from all 3 participating centers.

RESULTS

A total of 45 patients (mean age 60 years [range 27-90 years]) underwent OTSC placement from March 2011 through January 2012. A total of 48 endoscopic procedures were performed in this patient cohort, with median follow-up of 77 days (range 30-330 days). Indications for OTSC placement included hemostasis (n = 7), closure of chronic fistulae (n = 28) (Fig. 1), closure of iatrogenic perforations (n = 5), closure of post-esophagectomy anastomotic leaks (n = 3), and miscellaneous (n = 2) (Table 1). Before OTSC placement, 22 patients (49%) had under-

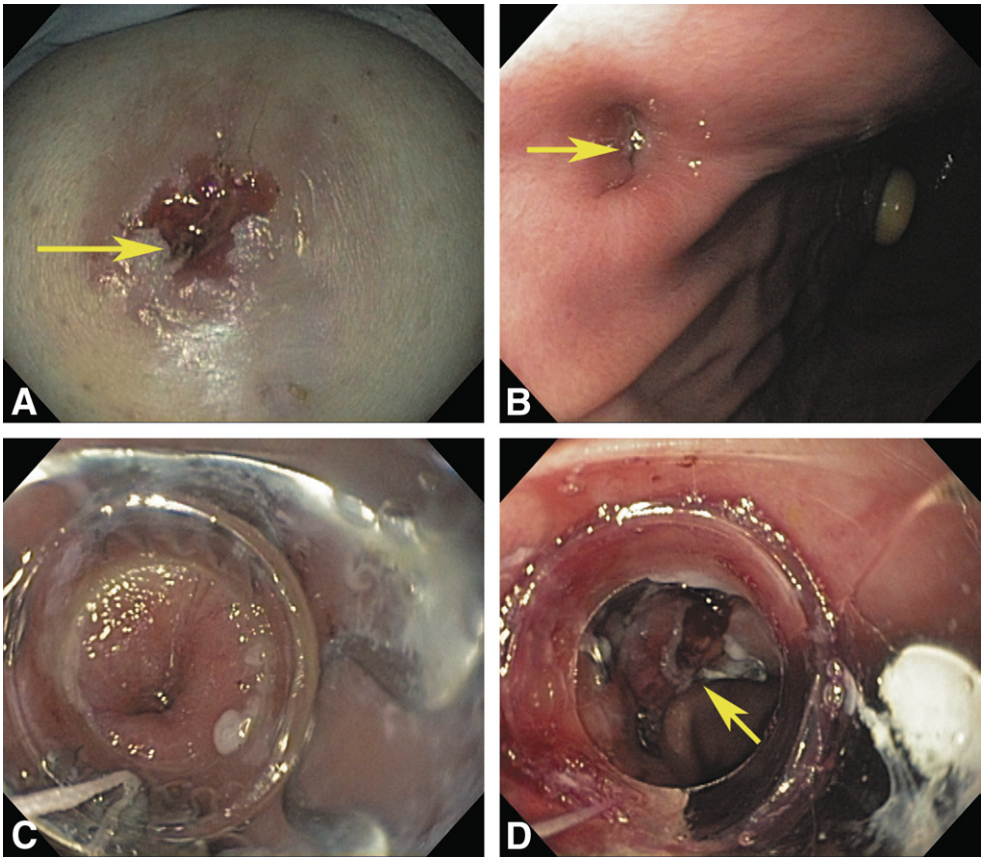

Figure 1. A, Chronic percutaneous endoscopic gastrostomy-induced fistula, skin side. **B,** Chronic percutaneous endoscopic gastrostomy-induced fistula, gastric side. **C,** Placement of over-the-scope-clip cap over a fistula. **D,** Closure of a fistula with an over-the-scope-clip.

gone therapies, such as standard TTS clips, stent placement, and cyanoacrylate (glue) injection, which failed.

A therapeutic channel upper endoscope was used in 90% of procedures, and fluoroscopic contrast studies were performed after OTSC placement in nonbleeding indications to assess success of closure. A pediatric colonoscope was used in 3 procedures, and a standard upper endoscope was used in 2 procedures. The number of procedures and type of OTSC used per location are shown in Table 2. Dedicated OTSC accessories were used in 25 of 48 procedures (52%), and the type of accessory used (anchor vs twin grasper) varied by location and type of lesion (Table 2).

Adjunctive therapies to OTSC placement were performed in 11 of 48 procedures (23%) and included the use of transgastric T-bars (n = 2) (Cook Medical Inc, Winston-Salem, NC), brushing followed by glue injection of the fistula tract (n = 1), fibrin sealant or cyanoacrylate injection alone of the fistula tract (n = 2), argon plasma coagulation to the fistula edges before OTSC deployment (n = 2), transpapillary stent placement (n = 1), epinephrine injection for temporary hemostasis (n = 1), and fully covered self-expandable metal stent placement over the OTSC (n = 1) and after a failed attempt at traversing an esophageal stricture with the OTSC cap (n = 1). Of the procedures in which adjunctive measures were used, only 2 were clinically successful and both were in patients with fistulae in whom glue injection was used. In 1 of these 2 cases, a negative endoscopic fistulogram was obtained after OTSC deployment but before glue injection.

Technical success was achieved in all but 2 patients. Failure of clip placement in 1 case was related to operator error and occurred early in the clinical experience (the initial device deployment failed); a second OTSC was subsequently successfully deployed. In the second patient, a radiation-induced esophageal stricture prevented passage of the OTSC cap through the esophagus in an attempt to close an associated large tracheoesophageal fistula despite dilation of the stricture before attempted insertion of the OTSC device. The mean number of clips placed at the initial session was 1.3 (range 1-3) (Table 2).

The overall clinical success was 71% (32/45 patients) and varied by indication. In all patients treated for GI bleeding, immediate hemostasis without bleeding recurrence was achieved in 100% (2 gastric postpolypectomy bleeds, 2 post EMR bleeds, 1 chronic rectal ulcer bleed, and 2 refractory duodenal ulcer bleeds). Anastomotic leaks and fistulae were closed in 20 of 31 patients (65%);