Published in final edited form as:

Gastrointest Endosc Clin N Am. 2020 January ; 30(1): 163–171. doi:10.1016/j.giec.2019.08.006.

The Use of the Overstitch to Close Endoscopic Resection Defects

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Keywords

Endoscopic mucosal resection; Endoscopic submucosal dissection; Resection defect; Endoscopic clip; Endoscopic suturing

INTRODUCTION

Endoscopic resection of luminal gastrointestinal neoplasia offers a minimally invasive, lower risk alternative to surgery that can be highly successful in the appropriate setting. The concept and techniques were pioneered by our colleagues in Asia in the 1990s and have since gained momentum in the United States as an organ-sparing, first-line approach for many clinical scenarios, including Barrett's esophagus-related neoplasia, superficial squamous cell carcinoma of the esophagus, early gastric adenocarcinoma, duodenal adenomas, and colorectal neoplasia.

Advanced endoscopic resection draws on a long history of standard polypectomy performed during routine colonoscopy. Recognition of flat or sessile polyps prompted development of a new technique called endoscopic mucosal resection (EMR), which uses special tools to lift up the lesion and limit damage to the underlying gastrointestinal wall. EMR techniques include injection-assisted EMR, cap-assisted EMR, ligation-assisted EMR, and underwater EMR.¹ Endoscopic resection techniques also include endoscopic submucosal dissection (ESD). ESD has the added advantage over EMR that larger, histologically more advanced lesions can be resected en bloc, preserving the lateral resection margins for histologic assessment. This procedure provides more confidence in the diagnosis of a T1 lesion and ensures complete removal with subsequent significantly lower rates of neoplasia recurrence. ESD can potentially achieve a complete (R0) oncologic resection with curative intent.

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SUPPLEMENTARY DATA

Supplementary data related to this article can be found online at <https://doi.org/10.1016/j.giec.2019.08.006>.

Video content accompanies this article at <http://www.giendoc.theclinics.com>.

ADVERSE EVENTS OF ENDOSCOPIC MUCOSAL RESECTION AND ENDOSCOPIC SUBMUCOSAL DISSECTION

The most common adverse events that occur with EMR and ESD include bleeding, perforation, and stricture formation. Intraprocedural bleeding or perforation can generally be treated endoscopically, whereas delayed presentations might require additional therapies.

Bleeding

Bleeding is the most common adverse event associated with endoscopic resection. EMR related bleeding occurs most commonly in the duodenum (11.5%–19.3% for lesions <3 cm) followed by the colon and stomach (approximately 11%), and rarely in the esophagus (1.2%).² The rates of intraprocedural and delayed bleeding with EMR of large colorectal lesions ranges from 1% to 11%, but there is a wide variation with some studies suggesting higher risk.^{3,4} Predictors for immediate bleeding include polyp morphology (Paris classification 0-IIa + Is; odds ratio [OR], 2.12; $P = .004$), villous histology (OR, 1.84; $P = .007$), large lesions (OR, 1.24/10 mm; $P < .001$), proximal location, and lower volume centers.^{5,6} Intraprocedural bleeding and proximal colon location (OR, 3.72; $P < .001$) are risk factors for postprocedural bleeding.⁵ A similar trend was seen in a large study of 477 patients who underwent gastric EMR where delayed bleeding occurred in 5.3% of patients and the strongest predictor was the presence of immediate bleeding.⁷ EMR for nonampullary duodenal polyps is particularly high risk for bleeding, especially in lesions measuring greater than 3 cm.⁸

Intraprocedural bleeding during ESD is generally expected and can be managed with coagulation through the ESD knife or coagulation forceps. Delayed bleeding after ESD occurs most commonly with gastric lesions (4.5%–15.6%)⁹ compared with colorectal (2%) or esophageal sites (0%–5.3%).^{10,11} Antacid therapy can be used to decrease the risk of post-ESD gastric ulcer formation.¹² In a large study of ESD for 377 colorectal lesions, delayed bleeding occurred at a rate of 6.6% and was associated with rectal location and submucosal fibrosis.¹³

Perforation

Perforation rates with colon EMR are low, but early identification is critical. Careful examination of the postresection site in the colon (or on the resected specimen) can identify a classic target sign suggesting resection through the muscular propria¹⁴ (Fig. 1). Prompt recognition and placement of conventional endoscopic clips is generally adequate to seal a small defect in the muscle layer. A meta-analysis examining outcomes in colorectal ESD showed pooled perforation rates of 4%.¹⁰

Perforation is uncommon with gastric EMR (<1%), but pooled risk in meta-analyses point to 4.5 times higher rates with gastric ESD.^{9,15} Gastric perforations of less than 1 cm can be successfully managed with endoscopic clips the majority of the time and an omental patch can be helpful for larger perforations.¹⁶ Perforation with esophageal EMR is rare but nearly 2-fold higher with esophageal ESD (pooled perforation rate of 2.3%).^{11,17}

TECHNIQUES TO DECREASE ADVERSE EVENTS

Prophylactic Clipping

The relatively high rates of bleeding associated with EMR of large colorectal lesions prompted multiple observational studies evaluating the use of prophylactic clipping. In 2015, Zhang and colleagues¹⁸ performed the first prospective, randomized controlled study comparing clip closure of resection defects (EMR and ESD) compared with no closure in 348 patients with large (1–4 cm) colorectal tumors. The rate of delayed bleeding was significantly lower in the clip compared with no clip group (1.1% vs 6.9%; $P = .01$). Subjects in the clip group also had shorter hospital stay (3.1 vs 4.7 days; $P = .03$), less abdominal pain (2.8% vs 16.7%; $P < .01$), and higher patient satisfaction. Results from a recent multicenter randomized clinical trial of clip closure versus no closure for large (20 mm) nonpedunculated colorectal polyps demonstrated lower rates of postprocedure bleeding with clip closure (3.5% vs 7.1%; absolute risk difference, 3.6%; 95% confidence interval, 0.7%–6.5%) independent of antithrombotic medications or polyp size.¹⁹ The impact of clipping seems to be driven largely by benefit for proximal polyps (3.3% vs 9.6%; absolute risk difference, 6.3%; 95% confidence interval, 2.5%–10.1%).

Modified Techniques for Larger Defects

Conventional endoclips can typically achieve successful closure of defects up to 2 cm; however, adaptations to the design allow for closure of even larger mucosal defects. In 2004, Matsuda and colleagues²⁰ demonstrated a new technique using the endoloop and clips using a double channel endoscope to close a large 5 cm mucosal defect after colonic EMR.

Adaptations to the endoloop system enabled closure through a single channel colonoscope. The predetached endoloop strategy was used to close right sided colonic ESD defects in 18 patients without any immediate or delayed complications.²¹ A similar method has also been used to successfully close gastric perforations with no delayed complications even in patients on anticoagulation.^{22,23} Data for use of other successful technologies²⁴ including over the scope clips for closing ESD defects^{25,26} is presented in an earlier chapter.

Endoscopic Suturing to Close Resection Defects

The Overstitch (Apollo Endosurgery, Austin, TX) endoscopic suturing device is the only currently available device approved by the US Food and Drug Administration to close perforations, fistulas, and for bariatric endoscopy. An overview of its development and applications is described in previous chapters. Herein we focus on its potential to close endoscopic resection defects.

As compared with endoscopic clips or endoloops that were designed for hemostasis, endoscopic suturing is intended for tissue apposition and thus can effectively close a large defect. Although currently not standard of care for closure of ESD defects, this technique has potential—in the hands of expert endoscopists—to decrease adverse events and reduce or eliminate hospitalization, thereby reducing costs.^{27,28}

Limited data are available on the efficacy of endoscopic suturing after ESD and no standard technique currently exists for this indication. In a retrospective single-center study by Kantsevov and colleagues,²⁹ 12 patients underwent ESD of 3–8 cm lesions in the stomach (n = 4), colon (n = 4), and rectum (n = 4). Endoscopic suturing of the post-ESD defect was performed with use of a double channel endoscope and the Overstitch system with either a continuous suture line or separated stitches. The technical success rate was 100% and accomplished efficiently with a mean closure time of 10.0 ± 5.8 minutes per patient. The average cost of closure using 1 suture and cinch approximated \$875 per patient (equivalent cost to 5–6 endoclips), but afforded greater cost savings by allowing all patients to be discharged on the same day. None of the patients experienced any immediate or delayed adverse events, including bleeding or perforation. In a retrospective analysis comparing clipping versus suturing to close iatrogenic colonic perforations in 21 patients (11 related to ESD and 5 related to EMR), primary closure was performed with endoscopic clips in 5 patients and endoscopic suturing in 16 patients. All patients who underwent clip closure had worsening abdominal pain after the procedure, 4 patients required laparoscopy and 1 patient required rescue colonoscopy with endoscopic suturing. In the suturing group, 2 patients had abdominal pain after the procedure and underwent diagnostic laparoscopy, which confirmed adequate complete endoscopic closure. The other 14 patients did not require any further intervention.³⁰

The steps for using the Overstitch device have been previously described.³¹ In our institution, upon completion of the ESD procedure in either the stomach or rectum, we use the double-channel therapeutic gastroscope (Olympus, Tokyo, Japan) loaded with the OverStitch endoscopic suturing system (Apollo Endosurgery). Suturing is typically performed in the antegrade position. Starting with the edge most distal to the scope insertion site, endoscopic suturing of the ESD defect is initiated. The suture is typically placed through the mucosal and submucosal flap at the edge of the resection, as opposed to the muscle layer (Videos 1 and 2). This technique of suturing is used to maintain visualization throughout the entire suturing process, facilitate handling of the endoscope with the suturing system and avoid significant narrowing of the lumen at the end of the suturing. As shown in the video, we typically use a single stitch in a continuous running suture line moving side to side down the resection defect and eventually secure the suture with 1 cinch.

Similar suturing technique can be applied after gastric (Fig. 2), duodenal (Fig. 3), and colon resection procedures (EMR and ESD). Healing of mucosal defects after endoscopic suturing does not seem to affect endoscopic surveillance, visualization, or sampling of the resection scar (Fig. 4).

Advantages to Endoscopic Suturing

Endoscopic closure of large resection defects can be useful for multiple reasons:

1. Most patients can be discharged the same day.
2. Suturing could potentially decrease the risk of adverse events. This is particularly helpful in elderly patients with comorbidities where severe adverse events such as major bleeding or perforation could be life threatening.

Our initial experience and observation with this technique (14 patients) allowed a large number of patients to be discharged the same day without the need for inpatient observation.

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Limitations of Endoscopic Suturing

As mentioned, the currently available Overstitch device is only used with a gastroscope; therefore, suturing in the proximal colon could be limited if the gastroscope cannot be inserted to that area. The use of an overtube system such as DiLumen (Lumendi, Westport, CT) could make insertion of the overstitch device to the right colon easier.

The use of Overstitch to close endoscopic resection defects prolongs the duration (need to switch scopes and the duration of suturing) and increases the cost of the procedure. Suturing after endoscopic resection typically takes around 10 minutes. The cost effectiveness of suturing all endoscopic resection defects (vs high-risk patients) needs to be further evaluated.

Although we have not seen any adverse events from endoscopic suturing of resection defects, adverse events could potentially include pain, bleeding, perforation, infection/sepsis, and injury to nearby intra-abdominal organs.

The Overstitch device requires special training and should be performed by an experienced endoscopist who is proficient in endoscopic suturing. Endoscopic suturing is technically challenging but can be learned through observation of experienced endoscopists and hands-on experience on ex vivo models.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Disclosure Statement:

J.M. Kolb is supported in part by the NIH Gastrointestinal Diseases Training Grant (T32-DK007038). H. Hammad is a consultant for Olympus, Wilson Cook and Medtronic.

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KEY POINTS

- Endoscopic mucosal resection and endoscopic submucosal dissection are safe and effective techniques for removal of gastrointestinal neoplasia.
- The most common adverse events include bleeding and perforation, which can be immediate or delayed. Use of conventional endoclips or modified approaches using endoloop and clips can decrease this risk.
- The Overstitch (Apollo Endosurgery, Austin, TX) endoscopic suturing device offers a novel approach for closure of the resection defect. Although limited data are available, initial experience with this technique demonstrates safety and high efficacy.
- Our approach is to start with the edge most distal to the scope insertion site (antegrade position). Sutures are placed through the mucosal and submucosal flat at the edge of the resection, as opposed to the muscle layer.
- We mostly use a single stitch in a continuous running fashion avoiding significant narrowing of the lumen.

Fig. 1.

A classic "target sign" seen on the resected colon specimen, indicating resection through and defect in the muscularis propria (perforation).

Fig. 2.

(A) Marking of a Paris IIa nodule at the incisura/proximal gastric antrum. Biopsies showed carcinoma. (B) Post-ESD defect. (C) ESD defect after suturing, forward view. (D) ESD defect after suturing, retroflex view. (E) Follow-up endoscopy 6 months later demonstrates a well-healed scar at the resection site.

Fig. 3. Suturing after duodenal EMR. (A) A 3-cm sessile polypoid lesion in the second portion of the duodenum. (B) Resection defect after EMR. (C) Suturing of EMR defect. (D) Resection site after defect closure with suturing. ([C] Courtesy of Apollo Endosurgery, Inc., Austin, TX.)

Fig. 4.

(A) A 5-cm sessile lesion at the hepatic flexure in a 41-year-old patient with Crohn's colitis. Biopsies showed low-grade dysplasia. (B) Wide-field mucosal resection site. (C) Mucosal resection site after endoscopic suturing using Overstitch. (D) Surveillance at 6 months showed a well-healed EMR scar with sutures in place. The sutures were removed and evaluation of the scar (endoscopic and histopathologic) showed no residual dysplasia. ([C, D] Courtesy of Apollo Endosurgery, Inc., Austin, TX.)