

Optimized hybrid endoscopic submucosal dissection for colorectal tumors: a randomized controlled trial CME

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Background and Aims: Colorectal endoscopic submucosal dissection (ESD) is difficult and time consuming. Optimization of ESD with snaring (optimized hybrid ESD) may shorten the procedure time. The purpose of this study was to prospectively compare ESD and optimized hybrid ESD in the colorectum.

Methods: We prospectively enrolled 70 patients with colorectal neoplasia ≥ 20 mm. The patients were randomized to receive either ESD (36 patients) or optimized hybrid ESD (34 patients). In the optimized hybrid ESD group, snare resection was performed after an adequate amount of submucosal dissection. The primary outcome was procedure time. Secondary outcomes were en bloc and complete resection rates and adverse event rates.

Results: ESD could not be completed in 5 patients (13.9%) in the ESD group because of technical difficulties. We tried hybrid ESD to finish the resection, and en bloc resection was achieved in 4 patients (80%). The mean procedure time was shorter in the optimized hybrid ESD group compared with the ESD group (27.4 vs 40.6 minutes; $P = .005$). The en bloc resection rates were similar (94.1% vs 100%; $P = .493$), as were the complete resection rates (91.2% vs 93.5%; $P > .999$) and perforation rates (3 patients [8.8%] vs 2 patients [6.5%]; $P > .999$).

Conclusions: Optimized hybrid ESD achieves shorter procedure times than ESD, with similar en bloc resection rates and adverse event rates. Optimized hybrid ESD in the colorectum may offer an easy alternative to colorectal ESD and a rescue method for failed ESD cases. (Clinical trial registration number: NCT01944540.) (Gastrointest Endosc 2016;83:584-92.)

Endoscopic submucosal dissection (ESD) originally was developed to achieve en bloc resection of large gastric neoplasms.¹ Gastric ESD is now accepted as one of the standard treatments for large gastric tumors. However, ESD is not yet widely used for colorectal tumors because of technical difficulty. The difficulty resides mainly in the process of submucosal dissection with endoknives. First, colorectal ESD, unlike laparoscopic operations, is a one-arm procedure without traction. Therefore, the dissected part of the lesion is sometimes not easily detached from the colon wall, which makes it difficult to clearly visualize the submucosa being dissected. Second, it is difficult to control an endoknife parallel to the submucosal layer

under lesions at specific locations in the colorectum, such as the cecum and hepatic flexure. Third, paradoxical movement because of redundancy of the colon and motion of the lesion in response to the heartbeat or breathing can interfere with endoscope maneuverability.^{2,3} These technical difficulties can lead to long procedure times and a high risk of adverse events, such as perforation. The average procedure time of colorectal ESD has been reported to be 54 to 116 minutes and the perforation rate 5% to 10%.⁴⁻⁸

To reduce the technical difficulty of colorectal ESD, several techniques have been introduced, such as the use of various clips or an additional thin endoscope for

Abbreviation: ESD, endoscopic submucosal dissection.

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traction of the dissected part of the lesion.^{9,10} These methods make submucosal dissection safer and easier. However, they require additional devices, which is cumbersome and results in little decrease in the procedure time. Therefore, these methods have not been used widely. Another simplification of ESD is ESD with snaring, that is hybrid ESD.^{4,11-13} In the hybrid ESD procedure, a certain amount of circumferential incision and submucosal dissection is performed initially, and the remainder of the lesion is removed by snare resection. The strength of this method is its easy applicability because snare resection techniques are familiar to most endoscopists. Moreover, because the amount of submucosal dissection, which is the most difficult part of colorectal ESD, can be reduced, this technique might decrease the procedure time and the risk of perforation. This theoretical advantage of hybrid ESD in the colorectum was supported by our previous retrospective investigation, in which the procedure time for hybrid ESD was significantly shorter than for ESD.⁴ However, the en bloc resection rate of hybrid ESD for colorectal lesions >20 mm was lower than that of ESD. A shorter procedure time but lower en bloc resection rate was also reported in another retrospective study.¹² Because these retrospective, nonrandomized studies cannot compare the performance of 2 procedures fairly, we planned a prospective, randomized, comparative study of ESD and hybrid ESD. We also devised a more objective, standardized hybrid ESD procedure to improve its performance, which we call optimized hybrid ESD. Thus, the purpose of this study was to compare the therapeutic outcomes of optimized hybrid ESD and ESD for colorectal tumors ≥ 20 mm.

METHODS

Study population and design

A single-center, prospective, randomized trial was conducted from January 2014 to October 2014. Patients with nonpedunculated colorectal neoplasms ≥ 20 mm in lateral diameter by endoscopic estimation were eligible for this study. Exclusion criteria were as follows: (1) suspected deep submucosal invasive cancers with endoscopic features of expansion appearance, deeply depressed surfaces with irregular bottoms, folds converging toward the tumor, and/or type Vn pit pattern, which was assessed by chromoscopy with or without narrow-band imaging;^{14,15} (2) tumors showing non-lifting signs suggestive of deep submucosal invasive cancer or severe submucosal fibrosis; (3) patients in poor medical condition unsuitable for colonoscopy procedures; (4) patients aged <18 years; and (5) patients who refused informed consent. The enrolled patients were randomly assigned to one of two groups (ESD or optimized hybrid ESD) by a computer-generated randomization program (Excel 2010; Microsoft, Redmond, Wash) (Fig. 1). The randomization process that used the

Excel program was performed by the assistant nurse once a decision was made to enroll a case in the study. All procedures were performed on inpatients. The therapeutic outcomes of the 2 groups were prospectively recorded. All patients were followed-up at 2 weeks after discharge in the outpatient clinic. The study was approved by the institutional review board of the Asan Medical Center (2013-0594), and informed consent was obtained from all patients. The study was reported according to the CONSORT guidelines and is registered at www.clinicaltrials.gov (NCT01944540).

ESD and optimized hybrid ESD procedures

All procedures were performed by a single experienced endoscopist (J.S.B.) who had experience of over 300 colorectal ESD cases before this study began. All procedures were performed with patients under conscious sedation with midazolam and pethidine. A single-channel endoscope (GIF-H260, GIFQ260J, and/or CF-H260AL; Olympus Co, Tokyo, Japan) was used. Either a fixed flexible snare knife (Kachu Technology Co, Seoul, Korea) or a dual knife (Olympus) was used as the main device for mucosal incision and submucosal dissection. A 33-mm oval Captivator II Snare (Boston Scientific, Natick, Mass) was used for optimized hybrid ESD. The electrosurgical unit was VIO300D (ERBE, Tübingen, Germany), and a sodium hyaluronate solution (Endo-Ease; Unimed Co, Seoul, Korea) was used to provide a submucosal cushion. A transparent hood was attached to the tip of the endoscope. The conventional ESD procedure was performed as described previously.⁴

In the optimized hybrid ESD procedure, snare resection was performed after an adequate amount of submucosal dissection. To standardize objectively the adequacy of the amount of submucosal dissection, we used the length of the slit on the tightened snare handle, which reflects the thickness of the attached, undissected submucosal tissue (Fig. 2). Based on our previous experience in which we achieved an en bloc resection rate $\geq 95\%$ in snare polypectomy after submucosal injection for colorectal tumors <15 mm in diameter, we assumed that an adequate diameter of undissected lesions would be <15 mm. Before beginning this study, we checked the length of slit on the snare handle when we tightened the snare for polypectomy of colorectal polyps <15 mm and found that it was <5 mm. We therefore used this maximum length of slit in the optimized hybrid ESD. The detailed steps of the optimized hybrid ESD were as follows: (1) Semicircular mucosal incision and submucosal dissection from the anal side of the lesion were performed as in conventional ESD; (2) submucosal dissection was ended when approximately 15 mm of the lesion remained undissected; (3) mucosal incision and trimming on the oral side of the lesion were made deep enough to create a groove to prevent snare slippage; (4) the snare was inserted into the oral mucosal incision site, pulled gently toward the anal side to fit into the dissection plane, and tightened with caution. (5) If

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