ESD and Pit Pattern Diagnosis: Lessons from a Japanese Endoscopist Working in the United States

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Clin Colon Rectal Surg 2020;33:329–334.

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Abstract

Endoscopic submucosal dissection (ESD) was developed in 2000s to overcome the limitations of endoscopic mucosal resection (EMR), especially to accomplish en-bloc resection, and it has been accepted worldwide in the past decades. Many ESD devices and diagnosis modalities are currently available, which include pit pattern and narrow band imaging (NBI) diagnoses to evaluate the depth of the tumor preoperatively with sensitivities of 70 to 90%. Depending on the Japanese colorectal guideline, the intramucosal cancer and shallow invasion of the submucosal layer are the main good indications of ESD; however, the ESD practices between Japan and Western countries still vary, including pathologic definition of cancer, tumor/node/metastasis classification, and handling of ESD specimen. In the United States, despite the large demand for treatment of colorectal neoplasm, pit pattern and magnified NBI diagnoses are not widely accepted yet, and piecemeal EMR is still the major method in most of the institutions. Moreover, the specific guideline of ESD is also not available yet. More new technologies are being developed other than conventional ESD methods in Eastern and Western countries, and ESD is now expected to change in the next generation. It is recommended that not only gastroenterologists but also colorectal surgeons have appropriate knowledge of colorectal lesions and their management to ensure current treatments is applied to patients.

Keywords

- ESD
- Kudo's pit pattern
- JNET classification
- traction device

For treating colorectal neoplasms, many studies have shown that, compared with endoscopic mucosal resection (EMR) or piecemeal EMR, endoscopic submucosal dissection (ESD) has higher en-bloc resection rate, negative margin resection rate, and significantly lower recurrence rate.^{1,2} However, ESD is still known as a technically difficult and time-consuming procedure. Yet, progress of multiple devices for the past few years enabled ESD to be more commonly performed in Western countries, and ESD rapidly has been recognized as a relatively acceptable procedure than before, with many institutions performing ESD as a daily procedure. Table 1 shows current available equipment used for ESD in Japan and the United States, demonstrating that both countries now have many common or similar solution, equipment, or devices; it can be said that there is almost no huge gap

between Japan and United States from this point of view.³ In this article, we described the remaining difference in ESD procedures between Japan and the United States.

Indication and Contraindications

Current indications of ESD for colorectal lesions in Japan are as follows: lesions for which en-bloc resection is difficult to perform (> 20 mm), nongranular lateral spreading tumor (LST), Kudo Vi pit pattern, nonlifting neoplasia, large depressed type tumors, and carcinoma with shallow T1 (SM) invasion 4 (► **Table 1**). In 2017, the European Society of Gastrointestinal Endoscopy (ESGE) stated in their guideline that ESD can be considered for lesions with high suspicion of superficial submucosal invasion that cannot be

Table 1 Current available ESD equipment in Japan and the U.S.

	Japan	U.S.
Solution	Mucoup (Boston Scientific, Japan)	Eleview (Olympus America)
	Glycerol (Taiyo Pharma)	Glycerol (TER Chemichals)
	5% glucose solution	ORISE (Boston Scientific)
		5% glucose solution
Knives	DualKnife, DualKnife J (Olympus)	DualKnife, DualKnife J (Olympus America)
	Flush knife (Olympus)	Flush knife (Olympus America)
	ITknife 2, ITknife nano (Olympus)	ITknife 2, ITknife nano (Olympus America)
	Triangle Tip Electrosurgical Knife (Olympus)	Triangle Tip Electrosurgical Knife (Olympus America)
	HookKnife, Hookknife J (Olympus)	HookKnife (Olympus)
	FlexKnife (Olympus)	FlexKnife (Olympus America)
	Clutch Cutter (Fujifilm)	Clutch Cutter (Fujifilm)
	FlushKnife BT-S, FlushKnife N-S (Fujifilm)	FlushKnife BTS, FlushKnife NS (Fujifilm)
	SB Knives (Sumitomo Bakelite)	SB Knives (Sumitomo Bakelite, Olympus America)

optimally removed by standard polypectomy or EMR. In the United States, magnified colonoscopes are not commonly used yet; therefore, similar indication has been used as ESGE guideline in actual clinical practice. Recently, many gastroenterologists have been using similar classifications of colorectal lesions⁵; therefore, the indication of colorectal ESD in the United States is gradually adjusted compared with that in Japan. Many patients in the United States are undergoing transanal endoscopic microsurgery (TEM) or combined endoscopic–laparoscopic surgery, as an alternative of ESD, for colorectal lesions.⁶ A systemic review and meta-analysis comparing ESD with TEM showed higher en-bloc resection for TEM and lower postoperative complication rate for ESD, which might require surgeons to reconsider performing slightly different strategies of ESD for rectal lesions in the United States.⁷ These situations must be changed in the next decades.

Contraindications of ESD are defined in the abovementioned guideline, including especially the lesion strongly suggestive of T1b cancer (submucosal invasion > 1,000 μm).⁴ The nonlifting sign is a well-known endoscopic finding,⁸ which differentiates SM invasive cancer from intramucosal lesion, with relatively low sensitivity (61.5%) compared with conventional endoscopic examination findings. Therefore, the evaluation of the nonlifting sign is becoming a complementary method.⁹

Decision-Making Algorithm for ESD, Focusing on Pit Pattern Diagnosis and Magnified NBI Diagnosis

Kudo’s classification by magnified chromo endoscopy is a well-established method and has been widely used to identify lesions as a neoplasm or not.^{10,11} Based on Kudo’s classification, types IIIS, IIIL, and IV strongly suggest adenomatous lesion, type VI as highly correlated with early colorectal cancer, and type VN strongly suspicious for deep submucosal invasion.

In addition, invasive or noninvasive pattern is also a widely accepted method, which can provide additional information about depth of invasion with high accuracy, using the same magnified chromoendoscopy.¹² By this method, type VI lesions are differentiated into lesions with noninvasive pattern and those with invasive pattern. Endoscopic treatment is applied for lesions with noninvasive pattern, whereas those with invasive pattern are treated with surgery.

After development of narrow band imaging (NBI), many studies have been conducted for colorectal lesions, and multiple classifications have been reported. Recently, a multicenter agreement has been published to include this information, which was referred to as the Japan NBI Expert Team (JNET) classification.^{13,14} With the JNET classification, the colorectal lesions were classified as type 1, type 2A, type 2B, or type 3, and treatment is made depending on each classification. Considering the relatively low sensitivity and sensitivity of type 2A/2B and many borderline lesions with type 2A-2B, additional magnified chromoendoscopy using the Kudo’s pit pattern classification is required to be performed in Japan.^{15,16}

In the United States, the magnified colonoscope has limited use as described above, and no specific guideline for colorectal ESD is still available. However, despite that these magnified classifications are still not widely used, the concept of magnified endoscopy for pre-treatment evaluation is gradually gaining attention.¹⁷

Tips and Tricks of ESD (in Japan and Upcoming New Technologies in the United States)

The basic concept of ESD is to achieve adequate lift of the submucosal layer and perform particular submucosal dissection with a clear visualization to avoid unexpected bleeding and perforation. For good visualization, different caps have been developed and used.¹⁸ Small caliber transparent (ST) cap is one of the indispensable caps used for colorectal ESD, which enables the creation of a flap during the early stages of ESD and

accomplishment of specific submucosal dissection.¹⁹ Nowadays, almost a similar cap for ESD is also available in the United States.

Other different types of devices have also been developed for ESD and are available worldwide. IT knife, specifically the IT knife nano that has a small ceramic ball at the tip of the knife, allows quick ESD because of its relatively long blade.²⁰ Hook knife, specifically the triangle knife, has a similar function that hooks tissues by the tip of the knives. Needle-type knives represented by the Flush knife (DN2618N; Fujifilm, Tokyo, Japan)/Dual knife (KD-650Q; Olympus, Tokyo, Japan)/B-knife (Zeon Medical, Tokyo, Japan) have an advantage of free incision, and some new generation knives provide waterjet function through the knife.²¹ Cesar-type knives, represented by clutch cutter/SB knife, are also very useful for trainees.

Solutions are indispensable for ESD. Solutions are injected into the submucosal layer to provide a nice cushion for preventing perforation and allowing good visualization during the ESD procedure. Initially, the solutions for ESD only included saline, glucose water, glycerol, and sodium hyaluronate (Mucoup, Boston Scientific, Tokyo, Japan) in Japan.^{22,23} In the United States, hydroxyethyl starch and Eleview (Cosmo Pharmaceuticals NV, Dublin, Ireland),^{24,25} which includes water, medium chain triglycerides, sodium chloride, polyoxyl-15-hydroxystearate, methylene blue, and poloxamer-188, have been mainly used for ESD. Recently, ORISE gel is approved by US Food and Drug Administration (FDA) and is now available for EMR and ESD.²⁶

Many handmade traction devices and commercially available devices have been developed to address the technical difficulty of ESD. Initially, handmade traction device included clip and line/dental floss in many institutions.^{27,28} Magnetic countertraction device is also a traction device, which uses magnet from outside of the body.²⁹ However, magnet traction devices may have limited use, because it depends on the thickness of patient's abdominal wall and concerns of the possible effect of the magnet to the patient's tissue are also an issue.³⁰ S-O clip (Zeon Medical, Tokyo, Japan) is among the commercially available devices in Japan, which allows counter traction by hooking the part of the lesion to the opposite site of the gastrointestinal tract, which helps in determining the direction of traction (► Fig. 1).^{31,32} Apart from these methods, double-scope ESD,³³ internal traction method, or other novel techniques have been reported from many institutions.^{34–36}

In the United States, ESD is rapidly developing and it is also performed slightly in the original manner. One reason for this is that, based on the United States medical insurance system, ESD has not been coded yet; therefore the ESD procedures should be performed fast without complications. Tracking methods or devices, similar to those used in Japanese studies, are not common in the United States; however, recently, many different endoscopy platforms have been developed. The Lumen R retraction system (LumenR LLC, Oxford, CT) is one of endoscopic platforms that enable endoscopic tissue manipulation (► Fig. 2).³⁷ The double-balloon endoluminal intervention platform (EIP) (DiLumen, Lumendi, Westport, CT) was recently cleared by the FDA, and consists of an oversheath with two

Fig. 1 S-O clip (Zeon Medical Inc.).

independently inflatable balloons. This double-balloon device facilitates ESD through colon and endoscope stabilization, and tissue traction and manipulation.³⁸

Advantage and Disadvantage of ESD

The advantage of ESD is its higher curative resection rate by en-bloc resection, which enables pathologic assessment and results in decreased risk of residual or recurrence. In EMR, en-bloc resection could not be performed in lesions with ~20-mm size.³⁹ Especially for LST, piecemeal resection is known to increase the residual and recurrence rate.¹

For noncancerous polyps, lesions >6 mm in size are known to be accompanied by cancer; thus, endoscopic removal is recommended in these cases.⁴⁰ For lesions suspicious for cancer, treatment depends on the shape and endoscopic findings, that

Fig. 2 DiLumen (Lumendi Ltd.).

Fig. 3 (A) A 25-mm polypoid lesion with tattooing in the patient with ulcerative colitis. (B) Submucosal dissection. (C) En-bloc resection with safety margin. The final pathological result reveals a tubular adenoma.

is, white light endoscopy or magnified NBI. Tis or suspected shallow invasion into the submucosal layer lesion is an indication for attempting endoscopic treatment. For these lesions, piecemeal EMR has been performed for several years, and many studies have shown the long-term result after piecemeal EMR for colorectal neoplasm as 10 to 23%; thus, the local recurrence rate after en-bloc ESD is 0 to 3%.⁴¹ Furthermore, for even noncancerous lesions, endoscopic re-treatment of residual or recurrence lesion is highly difficult because of severe scarring. In spite of the time-consuming and slightly increasing complication risk of ESD compared with EMR (perforation rate is 0.58–0.8% in EMR vs. 2–14% in ESD), ESD is widely accepted worldwide for lesions that are difficult for snaring.

What Are the Difficult Cases?

Some previous studies reported the factors for the success of the ESD procedure, including location, experience, and fibrosis, and they have estimated the difficulty level of ESD.⁴² As described in these studies, the lesion location is an important factor for ESD. Lesion locations in the cecum, near appendix orifice, hepatic/splenic flexure, and near the anal verge are mainly known as difficult locations for colorectal ESD.^{43,44} In terms of lesion characteristics, LST-nongranular, scarred lesion with prior biopsy or partial EMR, and extremely large lesions are technically difficult. Another factor is the muscle-retracting sign, in which the muscularis propria appears to be involved by the tumor. In cases with the muscle-retracting sign, given the lower en-bloc resection and curative resection rates, discontinuing ESD should be considered and patients are then referred for surgery.⁴⁵

For inflammatory bowel disease (IBD) patients, their lesions are highly fibrous in the submucosal layer, and they have higher incomplete resection and perforation rates.⁴⁶ ▶**Fig. 3A–C** shows ESD of a patient with a long history of ulcerated colitis, with highly fibrous adenoma at the submucosal layer and tattooing, which causes poor visualization of the operative field; fibrosis is a challenge for endoscopists.⁴⁷

In the case of unclear or invisible margin for IBD patient, prior biopsies for clarifying the margin before ESD are recommended.⁴⁸ In such difficult cases, ESD has been performed and has achieved curative resection, but is still technically difficult to perform.⁴⁹ Hybrid ESD45 might also be a good option for

achieving curative resection,⁵⁰ and for filling the gap between EMR and ESD. In the United States, the number of IBD patients is increasing, and there is a large demand for endoscopic removal of nonpolypoid colorectal dysplasia; recently, ESD has been applied for these lesions.⁵¹ Given that there are only a few reports of the long-term result of ESD for IBD patients, further research and development are required.

For fibrotic lesions or scarred-down tissues, a recent novel pocket-creation method (PCM) has been developed and applied.⁵² The strategy of PCM is to create a large submucosal pocket with a small-caliber tip transparent hood (ST hood) without circumferential incision, which facilitates tissue traction without using other special devices.⁵³

In the United States, endoscopists still manage recurrent or residual lesions, and sometimes face to tattooed lesion after partial resection. Therefore, combining many kinds of techniques and devices are necessary, as well as educating general gastroenterologists.

Summary

Given the technological innovation, ESD is now performed worldwide, in both Eastern and Western countries. Moreover, it is expected that the demand for ESD will increase because of the increasing number of patients undergoing colonoscopy. It is recommended that not only gastroenterologists but also colorectal surgeons have appropriate knowledge of colorectal lesions and their management to ensure current treatments is applied to patients.

Conflict of Interest

Dr. Nishimura reports support from Lumendi, and Boston Scientific, outside the submitted work. The author is a consultant of Olympus America.

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