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A multicenter retrospective study of endoscopic submucosal tunnel dissection for large lesser gastric curvature superficial neoplasms

Xing Zhang[1] · Dongtao Shi[1] · Zhuwen Yu[1] · Rui Li[1] · Weichang Chen[1] · Feihu Bai[2] · Xudong Wu[3] · Cuie Cheng[4] · Ruihua Shi[5] · Pengfei Liu[6]

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Abstract

Background and aim Endoscopic submucosal tunnel dissection (ESTD) has been used for dissection of esophageal and gastric lesions. However, outcomes of ESTD for large lesions in the lesser gastric curvature had not been acknowledged because previous reports had the limitations of being single-center studies. We aimed to clarify the outcomes of ESTD for large lesser gastric curvature superficial neoplasms and provide our experience to accelerate its application.

Methods Between July 2014 and July 2016, 87 patients with early cancer in the lesser gastric curvature treated at six Chinese institutions were enrolled. Our primary outcome was dissection speed. Moreover, both efficacy and safety clinical data were collected and analyzed retrospectively.

Results All of the 87 patients were found to successfully undergo ESTD or ESD. Of these, 32 underwent ESTD and 55 underwent endoscopic submucosal dissection (ESD). The ESTD group had a higher dissection speed (18.0 mm^2/min vs. 7.8 mm^2/min, $p<0.01$) and was associated with higher en bloc resection rate (100% vs. 87.3%, $p=0.035$) and curative resection rate (100% vs. 85.5%, $p=0.024$) compared with the ESD group. No perforation or muscular injury occurred in the ESTD group and its intraprocedural bleeding rate was lower (59.4% vs. 100%, $p<0.01$) than that of the ESD group.

Conclusions In this multicenter retrospective study, outcomes of ESTD were excellent with a higher dissection speed and radical curative rate compared with ESD.

Keywords Early cancer · Lesser gastric curvature · Endoscopic submucosal dissection · Endoscopic submucosal tunnel dissection

Endoscopic submucosal dissection (ESD) is a well-established treatment for early esophageal and gastric cancers. For large lesions, however, it is still time consuming and can be accompanied by significant adverse events. Recently, endoscopic submucosal tunnel dissection (ESTD) has achieved widespread use in the treatment of large superficial esophageal squamous cell neoplasms (SESCNs) and submucosal tumors with excellent results. Based on the same principle, we predict that this technology produce a higher operation efficacy and safety than ESD in other parts of the digestive tract. However, outcomes for large lesser gastric curvature superficial neoplasms are limited in that they are single-center studies. In this study, we describe the procedures, outcomes, adverse events, and advantages of ESTD in this retrospective review of patients treated with both modalities in six institutions.

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✉ Rui Li
lrhcsz@163.com

[1] Department of Gastroenterology, The First Affiliated Hospital of Soochow University, Suzhou 215006, China

[2] Department of Gastroenterology, Ningxia Hui Autonomous Region People's Hospital, Yinchuan 750021, China

[3] Department of Gastroenterology, Yancheng First Peoples' Hospital, Yancheng 224005, China

[4] Department of Gastroenterology, Changshu Second People's Hospital, Changshu 215500, China

[5] Department of Gastroenterology, Zhongda Hospital Affiliated to Southeast University, Nanjing 210009, China

[6] Department of Gastroenterology, Jiangsu Province People's Hospital, Jiangyin 214400, China

Methods

Study population

This is a retrospective review of previously collected data, the selection of patients for which procedure was not at random, but at the discretion of the endoscopist performing the procedure. Six Chinese institutions with accumulated experience in endoscopic resection were selected for this retrospective study (Table 1). From July 2014 to July 2017, the series of 87 consecutive patients with large lesser gastric curvature superficial neoplasms (≥ 3 cm) were enrolled for data analysis. Of these, 32 underwent ESTD and 55 underwent ESD. All patients provided written informed consent for the procedure and underwent enhanced computed tomography (CT) scan to confirm that they were free of metastatic lymph nodes.

Equipment

A single-channel endoscope (GIF-H260Z, GIF-Q260J, GIF-H290I; Olympus, Tokyo, Japan) with a transparent cap attached (D-201-11804; Olympus) was used during procedures. The dual knife (KD-650U, KD-650L, Olympus) was used for dissection. Other equipment included Coagrasper (FD-410LR, FD-411UR, Olympus), Endoclip (ROCC-D-26-195, Weichuang, Nanjing, China), injection needle (NM-200L-0423, Olympus), high-frequency generator (VIO 200D, ERBE, Tübingen, Germany), 0.2% indigo carmine dye (MICRO-TECH, Nanjing, China), and submucosal injection (a mixed solution of 250 mL glycerol or normal saline solution + 1 mL indigo carmine + 2 mL norepinephrine). CO_2 insufflation was achieved using a CO_2 insufflator (UCR, Olympus).

Procedure

The endoscopic submucosal dissection (ESD) procedure is as follows: marking – injection – circumferential incision – submucosal dissection [1–3].

The ESTD process can be divided into three stages (Fig. 1).

Stage 1: preparation (Fig. 2)

Marking lesion margin

Chromoendoscopy banded with magnifying narrow-band imaging to delineate the boundary of the lesion. Cautery markings are placed 5 mm outside the edge by the electrosurgical knife or argon plasma coagulation.

Submucosal injection

In our study, the injection fluid is a mixture of 250 mL normal saline solution or glycerol–fructose, 2 ml norepinephrine, and 1 mL indigo carmine. If necessary, hyaluronic acid can replace the normal saline solution to maintain an acceptable submucosal fluid cushion for a longer period of time.

Stage 2: dissection (Fig. 3)

Curved incisions

The mucosa is cut open, curved in the anal–oral sequence. Moreover, curved incisions can reduce gas accumulation, thus preventing a sharply rising pressure and avoiding the risk of air-related perforation [2].

Table 1 Participating institutions and numbers of patients

Institution	Number of patients	ESTD	ESD
The First Affiliated Hospital of Soochow University	28	9	19
Ningxia Hui Autonomous Region People's Hospital	17	6	11
Yancheng First Peoples' Hospital	15	5	10
Changshu Second People's Hospital	12	5	7
Zhongda Hospital Affiliated to Southeast University	8	3	5
Jiangyin City, Jiangsu Province People's Hospital	7	4	3
Total	87	32	55

ESTD endoscopic submucosal tunnel dissection, *ESD* endoscopic submucosal dissection

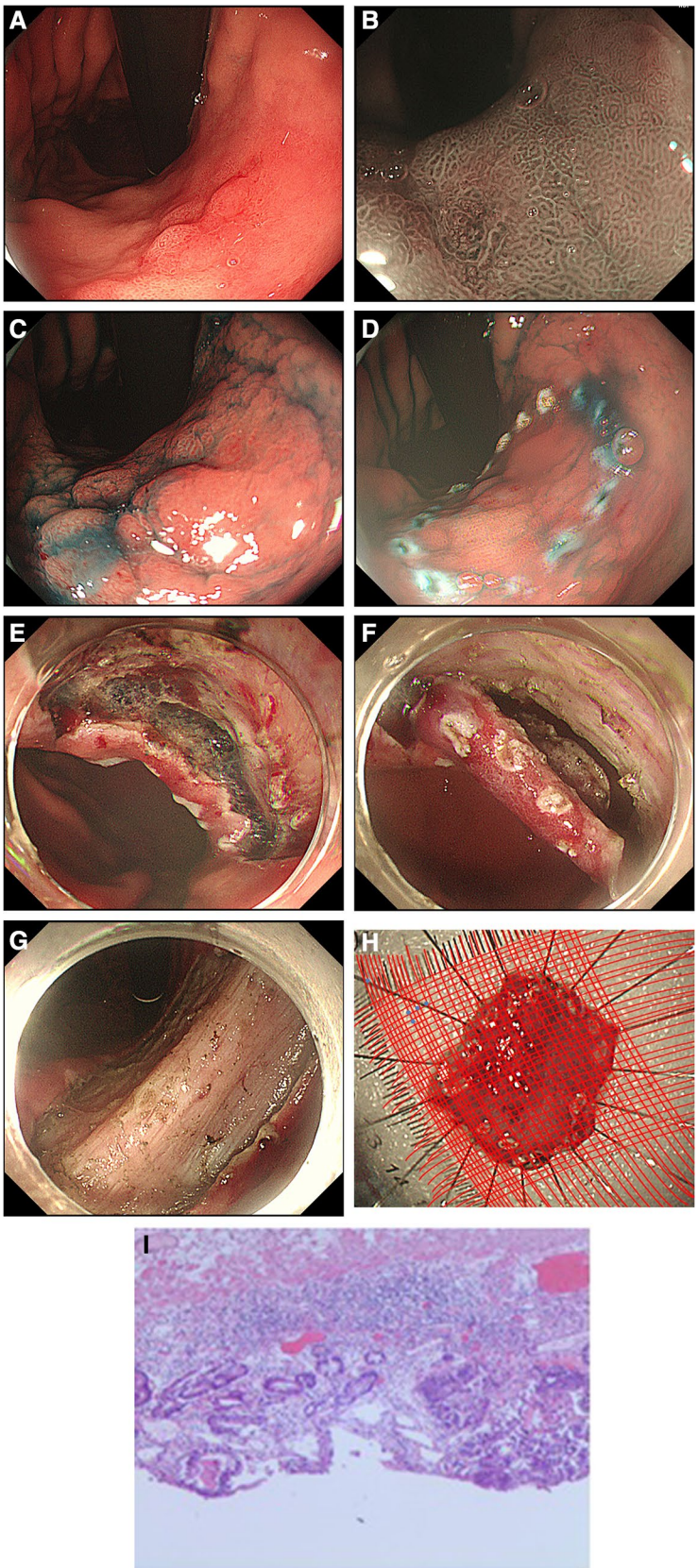

Fig. 1 Endoscopic submucosal tunnel dissection (ESTD) procedure. **A**–**C** Chromoendoscopy and magnifying narrow-band imaging were used to delineate the lesion. **D** The margin was marked by the electrosurgical knife. **E** Anal and oral incisions were performed successively with a dual knife. **F** A submucosal tunnel was created from the anal to the oral side. **G** Lateral resection is carried out until the lesion was removed completely. **H** The specimen was retrieved to measure its area. **I** Histopathological examination revealed a high-grade intraepithelial neoplasia, free on the lateral and vertical margins

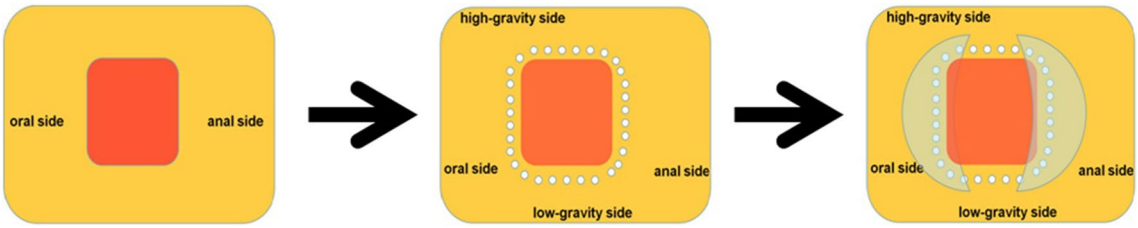

Fig. 2 Stage 1: delineating the lesion, marking, and submucosal injection

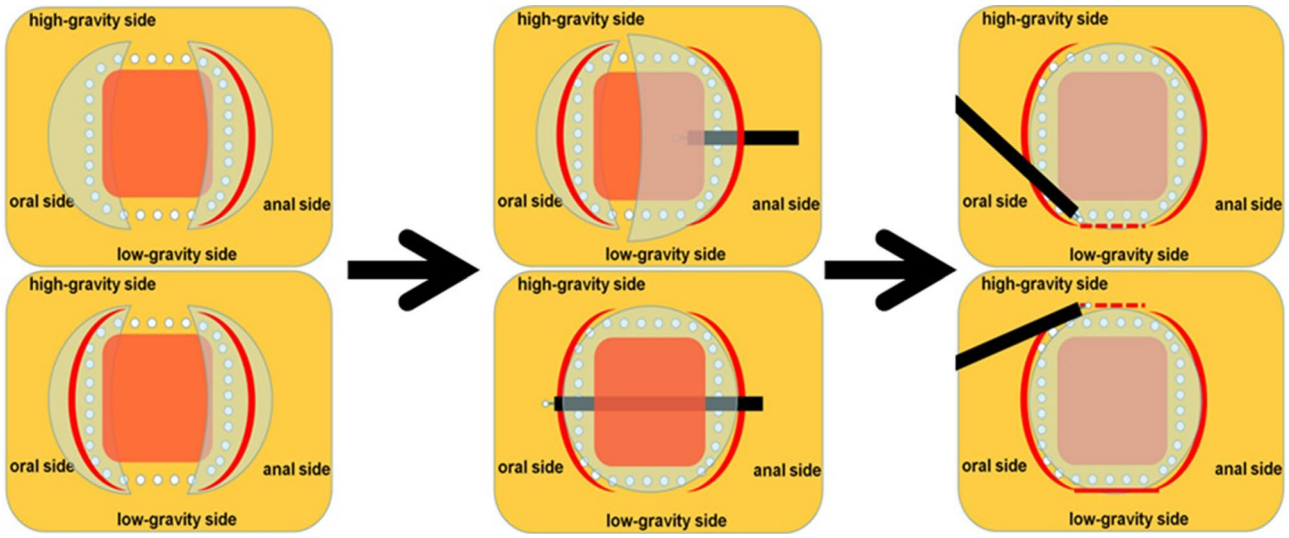

Fig. 3 Stage 2: mucosal incision performed in the anal–oral sequence. A submucosal tunnel is created from the anal to the oral side. Finally, lateral resection is performed for complete removal of the lesion

Establishment of submucosal tunnel

Various electrosurgical knives are available to create the tunnel from the anal side to the oral side, including the dual knife, insulated tip (IT) knife, and hook knife. The hybrid knife can simplify the operation because of its multifunctionality, such as injection and electrocoagulation. During this procedure, repeated submucosal injection is the critical point to maintain an operating space and the submucosal fibers should be caught in the center of the tunnel for electric cutting to avoid muscularis propria (MP) injury. For lateral dissection of the tunnel, mucosal dots are a marking of the tunnel boundary. Repeated observation from the outside of the tunnel can ensure suitable tunnel size and avoid excessive dissection.

Lateral resection

After the tunnel is completed, the dual knife is used for lateral mucosal resection. The dissection is carried out simultaneously on both the sides. However, the linkages are cut off in order of the low-gravity side to the high-gravity side. In this way, traction of the contralateral mucosa and gravity make the operation easier.

Stage 3: management of artificial ulcer (Fig. 4)

Coagulation of the visible vessels on the artificial ulcer with hemostatic forceps can prevent delayed bleeding. For obvious MP injury, preventive clips should be placed to avoid postoperative perforation.

Histologic examination

The resected tissue is stretched flat on Styrofoam mats with pins. Subsequently, the specimen is cut into 2-mm wide strips serially and embedded in paraffin after being fixed in formalin solution for 2 days. Finally, serial sections are stained with hematoxylin–eosin staining (H&E), and the histologic diagnosis is determined by pathologists.

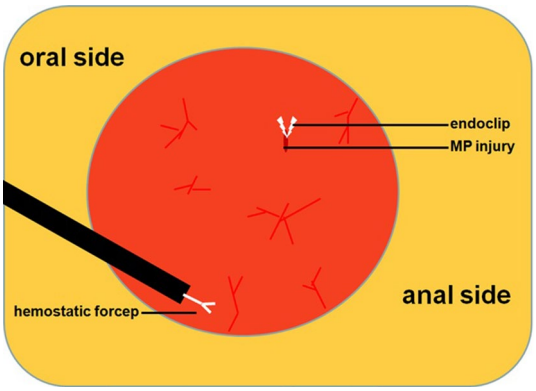

Fig. 4 Stage 3: preventive coagulation and preventive clips for the artificial ulcer

Postoperative management and follow-up

Vital signs including heart rate, oxygen saturation, and blood pressure should be monitored and other postoperative symptoms such as fever, abdominal pain, and delayed bleeding should be considered. Proton pump inhibitors and hemostatic agents were administered for 3 days. Endoscopic examinations were scheduled at 1, 3, 6, and 12 months, and annually thereafter. To avoid loss to follow-up, we attempted to identify details by telephone conversations with the patients who delayed their follow-up periods. On follow-up gastroscopy, the prior ESTD/ESD site, which was identified due to the presence of scar tissue, was observed carefully by narrow-band imaging. Biopsy was performed for suspicious lesions. Local recurrence was defined as neoplastic tissue at or near the prior site.

Main outcome measures

Our primary outcome of interest was dissection speed, and secondary outcomes were operative time, en bloc resection rate, and curative resection rate. Moreover, other information collected and analyzed included gender, age, macroscopic type, tumor size, adverse events (hemorrhage, perforation, MP injury), and prognosis.

Specimen size was defined as the surface area when the lesion was pinned onto a grid pattern board (each dot was spaced a millimeter apart; Fig. 5). It was determined using Peake's theorem: $S\ (mm^2) = n + s/2 - 1$ (S: tumor area; n: the number of dots inside the boundary; s: the number of dots on the boundary).

The duration of the procedure was defined as the time from commencement of marking around the lesion to the end of prophylactic hemostasis of the resected area. The speed of dissection (mm^2/min) was defined as the specimen area (mm^2) divided by duration (min). Procedure-related bleeding included immediate bleeding and delayed bleeding.

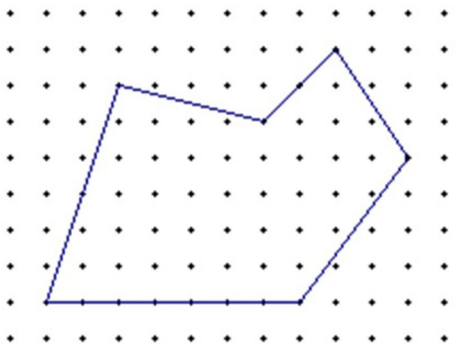

Fig. 5 According to Peake's theorem, s = 14, n = 39, and S = 45 mm^2

Delayed bleeding was defined as bleeding occurring after the operation that required transfusion or surgical intervention, or bleeding that caused the hemoglobin level to fall by 2 g/dL [4]. Immediate bleeding was defined as active bleeding which failed to coagulate itself and required management with endoscopic hemostasis during the procedure. MP injury was defined as the finding of a defect caused by careless electrocoagulation in part of the muscle layer. Perforation was defined as the entire muscle layer being sectioned (Fig. 6).

We defined an en bloc resection as a one-piece resection of the entire lesion as observed endoscopically. A curative resection was achieved when both the lateral and vertical margins of the specimen were free of cancer and there was no invasion deeper than 1000 μm from the muscularis mucosae, lymphatic invasion, vascular involvement, or poorly differentiated component.

Statistical analysis

All data were expressed as the mean ± standard deviation. Results were analyzed using the Student's *t* test. All statistical analyses were performed with SPSS Version 24.0 for Windows software (SPSS Inc., Chicago, IL, USA). A *p* value less than 0.05 was considered statistically significant.

Results

Clinicopathologic characteristics and overall outcomes (Table 2)

All patients underwent surgery successfully. According to the Paris endoscopic classification, macroscopic types were classified as 0-IIa + IIc in 18 cases, 0-IIb in 47 cases, 0-IIc in 4 cases, and 0-IIa in 18 cases. The Vienna classification was used for this study; 24 showed mucosal carcinoma, 42 showed high-grade intraepithelial neoplasia, and 21 showed low-grade intraepithelial neoplasia. One patient in the ESD

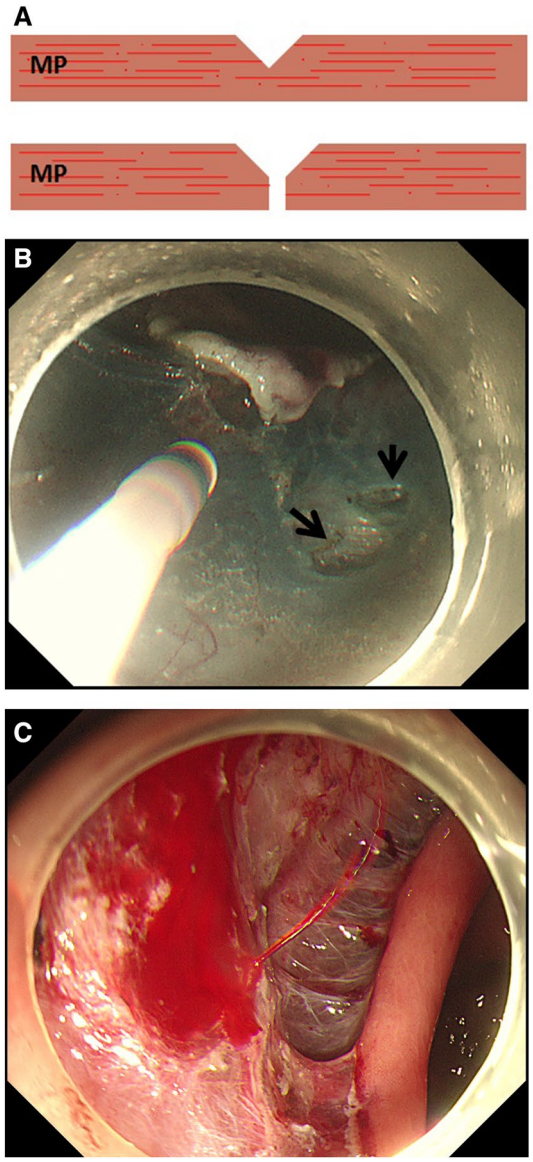

Fig. 6 **A** Difference between MP injury and perforation; **B, C** MP injury and active bleeding occurring in the procedure

group with a positive margin underwent appended surgical management.

Comparative results (Table 3)

The dissection speed of ESTD was significantly higher than in ESD (18.0 ± 7.1 mm^2/min vs. 7.8 ± 4.8 mm^2/min, $p < 0.01$). No perforation and delayed bleeding occurred in this study. The rate of intraprocedural bleeding (59.4% vs. 100%, $p < 0.01$) and muscular injury (0 vs. 13.5%, $p < 0.01$) were significantly higher in the ESD group. All immediate bleeding was managed with hemostatic forceps and muscular injury was managed with preventive clips. The ESTD group had no significant difference in recurrence rate

Table 2 Clinicopathologic features and outcomes of 87 patients

Male/female	48/39
Age (years)	64.0 ± 11.3
Macroscopic type (IIa/IIb/IIc/IIa + IIc)	18/47/4/18
Pathology (l/h/m)	21/42/24
Endoscopic resection (ESTD/ESD)	32/55
Operation time (min)	105.7 ± 52.3
En bloc resection rate	92.0% (80/87)
Curative resection rate	90.8% (79/87)
Negative margin rate	98.9% (86/87)
Complications (bleeding/MP injury)	74/8
Additional surgery	1
Follow-up (months)	12.4 ± 6.8
Loss to follow-up	3
Recurrence	1.2% (1/83)

l low-grade intraepithelial neoplasia, *h* high-grade intraepithelial neoplasia, *m* mucosal carcinoma, *ESTD* endoscopic submucosal tunnel dissection, *ESD* endoscopic submucosal dissection

($p = 0.437$) and *negative margin rate* ($p = 0.443$) compared with ESD. However, the en bloc resection and radical curative rate of the ESTD group was significantly greater than that of the ESD group (100% vs. 87.3%, $p = 0.035$, 100% vs. 85.5%, $p = 0.024$).

Follow-up

Of the 87 patients, three were lost to follow-up (two in ESD group, one in ESTD group), and one (in ESD group) underwent additional surgery due to a positive margin. Finally, 83 patients underwent gastroscopy and were included in the follow-up (Fig. 7). The mean follow-up period was 12.4 months. Recurrence was found in one patient (high-grade intraepithelial neoplasia confirmed by pathology) in the ESD group and was treated with radiofrequency ablation (Fig. 8). No recurrence occurred in the ESTD group.

Discussion

ESD is a recognized technique for the resection of early gastrointestinal cancer [5–7]. Similar to traditional surgery, a sufficient operative view is a vital prerequisite for successful treatment. Nevertheless, with respect to large lesions, especially tumors with a diameter exceeding 3 cm, it is considered to be a time-consuming and high-risk method. In conventional ESD, a circumferential incision is made to delineate the extent of the lesion. However, it also tends to facilitate diffusion of injection, thus reducing the duration of the submucosal fluid cushion. On the other hand, the submucosal endoscopic view becomes less clear because of shrinking of the resected mucosa [2, 8].

Table 3 Comparison of the resection efficiency, safety, and recurrence between groups

	ESTD	ESD	*p*
Cases	32	55	–
Macroscopic type (IIa/IIb/IIc/IIa + IIc)	7/17/1/7	11/29/4/11	–
Pathology (l/h/m)	4/18/3/7	17/24/6/8	–
Operation time (min)	87.3 ± 32.6	136.7 ± 64.5	< 0.01
Specimen area (mm^2)	1573.0 ± 634.7	930.1 ± 472.0	< 0.01
Dissection speed (mm^2/min)	18.0 ± 7.1	7.8 ± 4.8	< 0.01
En bloc resection rate	100% (32/32)	87.3% (48/55)	0.035
Curative resection rate	100% (32/32)	85.5% (47/55)	0.024
Negative margin rate	100% (32/32)	98.2% (54/55)	0.443
Complication			
Bleeding	59.4% (19/32)	100% (55/55)	< 0.01
Muscular injury	0 (0/32)	14.5% (8/55)	0.024
Loss to follow-up	1	2	–
Recurrence	0 (0/31)	1.9% (1/52)	0.437

l low-grade intraepithelial neoplasia, *h* high-grade intraepithelial neoplasia, *m* mucosal carcinoma, *ESTD* endoscopic submucosal tunnel dissection, *ESD* endoscopic submucosal dissection

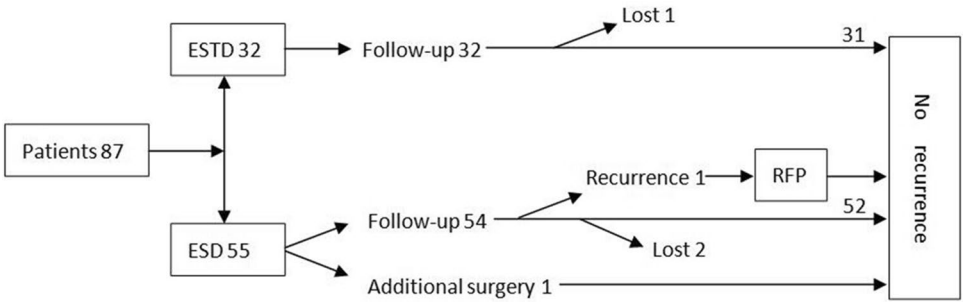

Fig. 7 Clinical outcomes in the ESD and ESTD groups

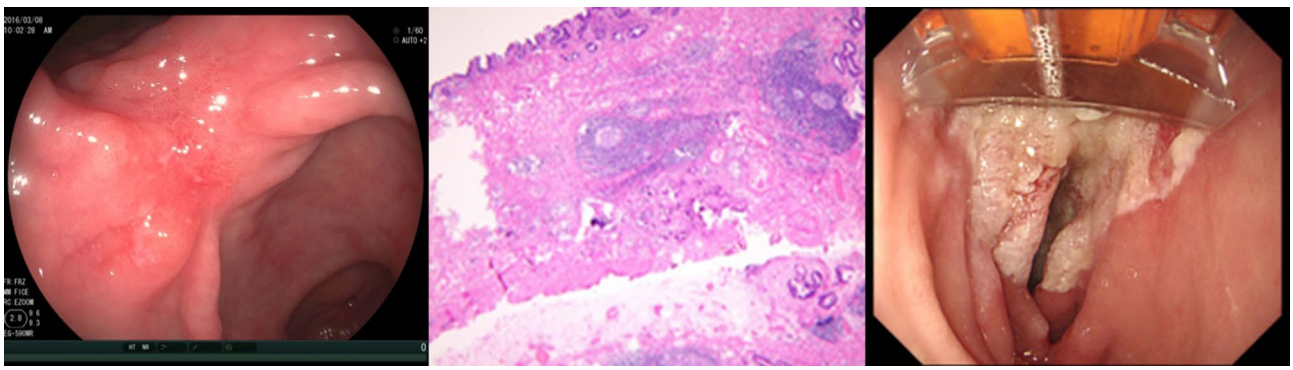

Fig. 8 The lesion at the prior site was confirmed as high-grade intraepithelial neoplasia by pathology. Then it was treated with radiofrequency ablation

Due to its particular position, operation in the lesser gastric curvature, especially at the gastric angle, becomes more complicated,[9, 10] for the following reasons: (1) the natural curves and thinner muscular layer may increase risk of perforation; (2) it is hard to control the cutting obliquity and direction by the method of reverse gastroscope. Consequently, ESD procedure for large lesser gastric curvature lesions is more time-consuming and requires highly skilled endoscopists. To overcome these problems, some endoscopic assist devices were introduced,[11–13] but produced very little effect or were unsuitable for extensive standardized application.

Early in 2009, Linghu et al. [14] successfully achieved removal of circumferential SESCNs by ESTD. This derived procedure becomes a new treatment strategy for early tumors with a higher operative efficiency and clearer view. At present, ESTD is used in the clinic for SESCNs and SMTs [15–17]. We report this study to clarify the outcomes of ESTD for large lesser gastric curvature superficial neoplasms and to provide our experience to accelerate its application.

Advantages

As suggested in this study, ESTD is associated with a higher rate of en bloc resection (100% vs. 87.3%) and lower rate of intraprocedural bleeding (59.4% vs. 100%). Several studies from different centers achieved similar favorable results. Linghu et al. [18] treated four gastric neoplasms, ranging from 40 to 50 mm in size, with ESTD. The average operative time was 65 min and en bloc resection was achieved in all lesions. In another report by Hyuk et al. [19] complete en bloc resection of EGC using ESTD was possible with a free resection margin and no other adverse events were noted during the procedure. In our study, ESTD had a more rapid dissection speed, almost twice that of ESD (18.0 mm^2/min vs. 7.8 mm^2/min). Curative resection was also more likely to be achieved with ESTD (100% vs. 85.5%).

These advantages of ESTD may be attributed to the following factors: (1) the transparent cap and CO_2 insufflation take on a blunt dissecting role to accelerate the procedure [20]. (2) Countertraction of the bilateral mucosa can prevent the lesion from elastic retraction and can help in dissection. Meanwhile, the submucosal tunnel provides clearer vision for dissection and coagulation, which can help to reduce bleeding. (3) The blade can be kept parallel to the MP to avoid injury while cutting submucosal fibers in the tunnel. (4) Tunnel injection can retain longer to make the lifting-effect satisfactory. In our study, the ESTD group showed a lower rate of MP injury (4.8% vs. 45.5%).

Adverse events

Bleeding and perforation are still major adverse events of ESTD. The following points are crucial to avoid adverse events.

Hemorrhage

Immediate bleeding The tunnel is established in the deeper submucosa, where rich vascular networks are absent, to reduce the risk of bleeding. The visible vessel trunks should be prophylactically coagulated (Fig. 9). For minute vessels or oozing bleeding, the dual knife in the coagulation mode is sufficient. For vessel trunks, hemostatic forceps are necessary. For massive active bleeding, compressing the hemorrhagic area with a transparent cap or applying a water jet is

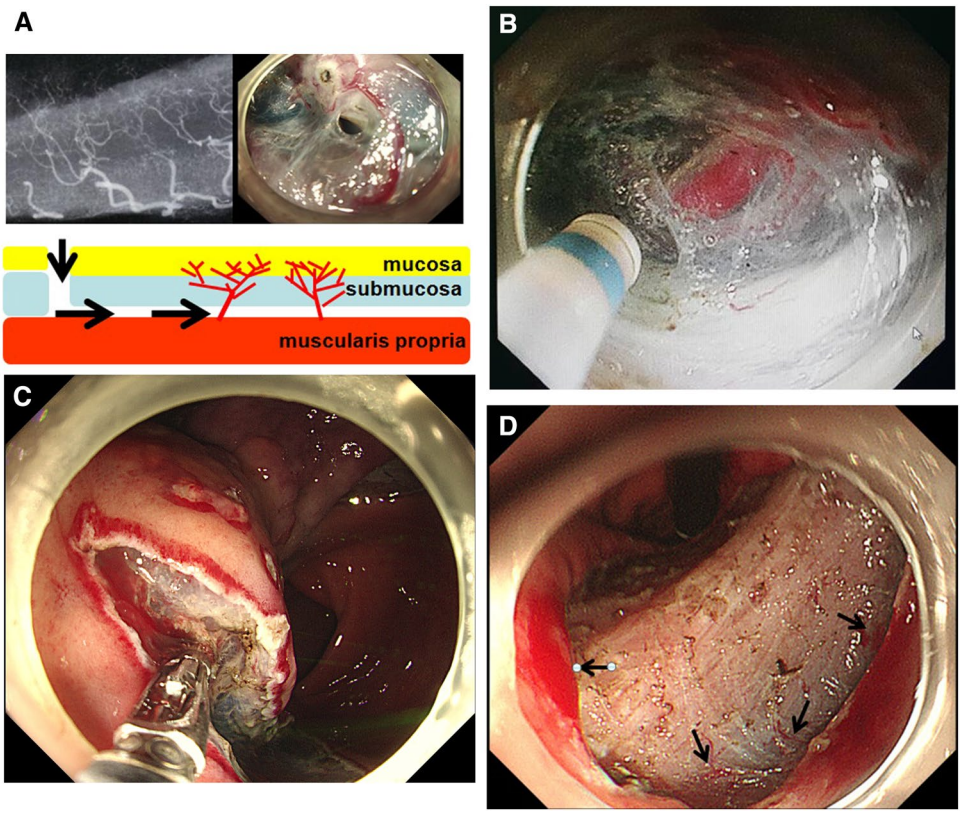

Fig. 9 **A** Creating a tunnel in the submucosa where rich vascular networks are absent. **B, C** Visible vessel trunks should be prophylactically coagulated. **D** Visible vessels and the edge of the ulcer should be constantly paid attention

more effective than blind coagulation to identify bleeding spots.

Delayed bleeding Delayed bleeding is a common adverse event which can cause hemorrhagic shock or even death. Coagulation of visible vessels (Fig. 9), especially the vessels on the edge of the ulcer, is critical to prevent delayed bleeding.

MP injury and perforation

During the procedure, the blade should be parallel to the MP and the dissected layer should be conducted close to the mucosa side to avoid injury (Fig. 10). The transparent cap can be pushed gently for blunt dissection and expanding vision. However, excessive and forcible pushing may lead to laceration of the MP.

CO_2 insufflation is strongly recommended because of its highly safe performance. The emphysema is absorbed spontaneously after CO_2 insufflation and is strongly recommended in digestive endoscopic tunnel technique [2, 21–23]. The gas must be kept at an appropriate volume to protect the gastric wall from perforation caused by heavy pressure. Once perforation occurs, an endoclip is an efficient method for this adverse event, and for a large perforation, an endoscopic purse-string suture or over-the-scope clip (OTSC) is adequate. Then, the emphysema can be absorbed spontaneously after the operation [24].

Others

It technically was easier to perform ESTD when using glycerol or sodium hyaluronate as the submucosal injection solution [25–27]. Meanwhile, a low dose of norepinephrine can reduce intraprocedural bleeding and provide a sweeping view. During the procedure, minimizing the time of continuous electrocoagulation can avoid electrocoagulation syndrome.

Conclusion

In conclusion, ESTD appears to be safer and more effective than ESD in the management of lesser gastric curvature superficial neoplasms. ESTD can thoroughly overcome the obstacle of ESD and avoid adverse events. The promising results enable us to speculate that ESTD will replace ESD as standard treatment for lesser gastric curvature superficial neoplasms in the future.

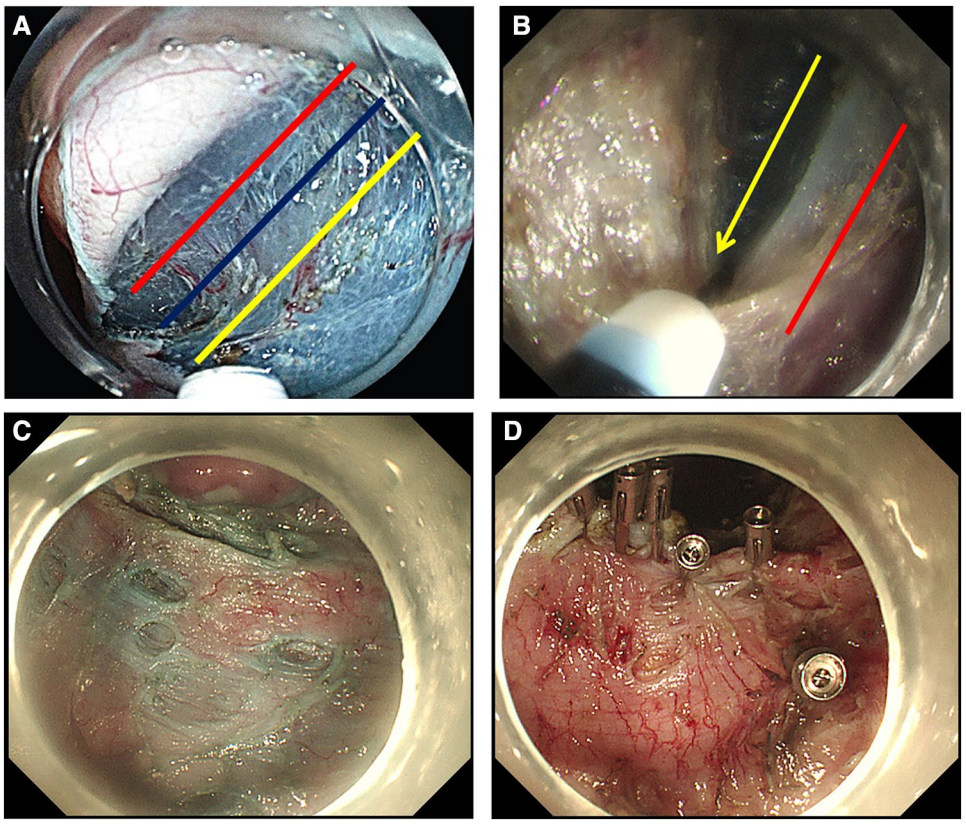

Fig. 10 **A** The blue string is the best dissected layer. **B** The blade should kept parallel as much as possible to the MP. **C, D** Preventive clips are placed for MP injury

Limitation

The main limitation of this study was that it was designed as a retrospective study and the sample size was not large enough. In addition, this study relied on reports from several institutions; there might exist heterogeneity in ESD experience among the six centers. Learning curve effect may also have influenced the results. However, in this article, we provide our experience to accelerate its application. For global standardization and development, further international collaboration is necessary. Each facility shares their own experience and an internet-based data registry may be a step toward a unified standard.

Compliance with ethical standards

Disclosures Drs. Xing Zhang, Dongtao Shi, Zhuwen Yu, Rui Li, Weichang Chen, Feihu Bai, Xudong Wu, Cuie Cheng, Ruihua Shi, and Pengfei Liu have no conflicts of interest or financial ties to disclose.

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