

# Safety and efficacy of endoscopic resection for the treatment of duodenal subepithelial lesions

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**Background:** Endoscopic management of duodenal subepithelial lesions is challenging, and there are only a few studies on this topic. This study aimed to evaluate the safety and efficacy of endoscopic resection for the treatment of duodenal subepithelial lesions.

**Methods:** We retrospectively analyzed the clinical data, including epidemiologic characteristics, therapeutic outcomes, complications, and follow-up results, of 49 patients with duodenal subepithelial lesions who underwent endoscopic resection at our hospital between August 2010 and September 2019.

**Results:** We performed 35 endoscopic submucosal dissection, 9 endoscopic mucosal resection, 3 endoscopic submucosal excavation, and 2 endoscopic full-thickness resection. The *en bloc* resection rate and R0 resection rate were 95.9% and 89.8%, respectively. Delayed perforations developed in 2 (4.1%) patients; surgical intervention was required for both. Coagulation syndrome developed in 1 (2.0%) patient; however, it was treated conservatively. Delayed bleeding or other serious complications did not occur. One patient underwent complementary surgery after endoscopic resection. One (2.3%) recurrence occurred in patients who underwent endoscopic resection at a median follow-up duration of 24 months (range, 1–88 months).

**Conclusions:** Endoscopic resection is an effective, safe, and minimally invasive method for the histopathologic assessment and curative treatment of duodenal subepithelial lesions originating from the submucosal or muscularis propria.

Keywords: Endoscopic resection; duodenal subepithelial lesions (D-SELs); therapeutic outcomes; efficacy; safety

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# Introduction

Duodenal subepithelial lesions (D-SELs) are mostly asymptomatic lesions that are incidentally detected during endoscopic examinations. Most D-SELs are benign, including Brunner's gland hyperplasia, lipomas, and ectopic pancreases; however, some are malignant or have malignant tendencies, such as neuroendocrine neoplasms (NENs) and gastrointestinal stromal tumors (GISTs) (1). The initial management of SELs depends on the accurate diagnosis and evaluation of the malignant potential of the lesions. Biopsy samples are obtained with difficulty due to the subepithelial location of the lesions. Endoscopic ultrasonography (EUS) is the most helpful imaging technique for evaluating SELs. EUS-guided fine-needle aspiration can be beneficial in some cases (2,3). However, the final diagnosis can only be obtained by performing tumor resection (4).

There is controversy regarding the optimal treatment



Figure 1 Flow diagram based on the results of endoscopic resection for duodenal SELs. SELs, subepithelial lesions; ESD, endoscopic submucosal dissection; EMR, endoscopic mucosal resection; ESE, endoscopic submucosal excavation; EFTR, endoscopic full-thickness resection.

strategy for D-SELs. Surgery, including limited resection and pancreaticoduodenectomy, is invasive, expensive, and involves a high risk of severe complications, such as hemorrhage, pancreatic fistula, and intra-abdominal infection (5). With the recent rapid development of endoscopic techniques and devices, endoscopic resection (ER) has become an alternative method of diagnosing and treating D-SELs. The main ER types are endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD), endoscopic submucosal excavation (ESE), and endoscopic full-thickness resection (EFTR) (6-8). However, ER for D-SELs remains challenging and is associated with a high incidence of complications because of the narrow cavity, thin wall, and large vascular network of the duodenum. Only a few studies on the efficacy and safety of ER for the treatment of duodenal lesions are available, and these studies rarely focused on D-SELs. Therefore, we aimed to perform a retrospective study of 49 patients with SELs in the duodenum to evaluate the efficacy and safety of ER for the treatment of D-SELs (6,7,9).

We present the following article in accordance with the STROBE reporting checklist. Available at http://dx.doi. org/10.21037/jgo-20-301.

#### **Methods**

# Patients

We retrospectively analyzed the clinical data of patients with D-SELs who underwent ER at the Second Xiangya Hospital between August 2010 and September 2019 (Figure 1). All D-SELs included in this study originated from the submucosal or muscularis propria (MP) layer, as ascertained by EUS (U-ME1 or A75; Olympus, Tokyo, Japan) before the procedure. The indications for ER were as follows: (I) D-SELs suspected or confirmed to be potentially malignant tumors with no risk of metastases by preoperative EUS, abdominal computed tomography (CT), and/or histopathology; (II) symptomatic SELs; (III) SELs increasing rapidly in size during the followup period; or (IV) a strong desire to undergo ER. The exclusion criteria were as follows: (I) signs of metastases or invasion outside the duodenum; (II) imaging features indicating high risk, such as poorly defined margins and heterogeneity; (III) periampullary lesions; (IV) inability to tolerate the procedure; and (V) severe coagulation disorders. Written informed consent was obtained from the patients before endoscopic treatment. The study was



**Figure 2** Endoscopic submucosal dissection of a Brunner's gland hyperplasia. (A) Endoscopic view of the subepithelial lesion located in the duodenal bulb; (B) the tumor originated from the submucosal layer on EUS; (C) submucosal dissection; (D) wound surface after tumor removal; (E) wound closure with clips; (F) the resected specimen. EUS, endoscopic ultrasonography.

conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study protocol was approved by the Ethics Review Board of the Second Xiangya Hospital (No. LYF2020129).

# ER procedures

Thirty-six (73.5%) ER procedures were performed with patients under general anesthesia, while 13 (26.5%) were performed with patients under conscious sedation. ER was performed with a single-channel endoscope (GIF-Q260J; Olympus) with an attached transparent cap (D-201-11802; Olympus). Other equipment included an argon plasma coagulation unit (APC300; ERBE; Tübingen, Germany), a high-frequency generator (ICC 200, ICC 300, or VIO 200D; ERBE), a carbon dioxide insufflator (UCR; Olympus), an injection needle (NM-4L-1; Olympus), hot biopsy forceps (FD-1U-1; Olympus), a dual knife (KD-650Q; Olympus), an insulation-tip knife (KD-611L; Olympus), and hemostatic clips (HX-600-90; Olympus). During EMR, a solution (100 mL normal saline, 1 mL

indigo carmine, and 1 mL epinephrine) was injected into the submucosal layer. Subsequently, the lesion was resected using a snare. For ESD (*Figure 2*) and ESE, dots were marked around the lesion using a dual knife (KD-650Q; Olympus), followed by administration of a submucosal injection. After precutting the mucosa and submucosa, the tumor was dissected (ESD) or excavated as deep as the MP layer around the lesion (ESE) using a dual knife or insulation-tip knife. Thereafter, the mucosal defect was closed using metal clips or an endoloop combined with metal clips, as necessary. The EFTR procedure was performed as reported previously (10) (*Figure 3*). All resected specimens were embedded in paraffin and then sectioned for pathological assessment.

#### Postoperative management

For all patients, proton pump inhibitors, antibiotics, and hemostatics were administered intravenously for 3 days; then, oral proton pump inhibitors were prescribed for 1 month. Patients who underwent ESD, EMR, or ESE



**Figure 3** Endoscopic full-thickness resection of an ectopic pancreas. (A) Endoscopic view of the subepithelial lesion located in the duodenal bulb; (B) the tumor originated from the muscularis propria layer on EUS; (C) tumor resection; (D) duodenal wall defect after tumor removal; (E) wound closure with clips; (F) the resected specimen. EUS, endoscopic ultrasonography.

were kept nil per os for the first 24 to 48 h. Thereafter, they were allowed to consume a liquid diet for 3–5 days and were gradually allowed to return to a normal diet. Patients who underwent EFTR were kept nil per os for the first 72 h. Thereafter, they were allowed to consume a liquid diet for 5 days. On postoperative day 4, contrast roentgenography was performed to check for any leakage.

#### **Outcome parameters**

The main outcome parameters in this study were *en bloc* resection rate, R0 resection rate, delayed perforation rate, delayed bleeding rate, and recurrence rate. The procedure time, hospital stay duration, and cost were assessed as secondary outcomes.

*En bloc* resection was defined as resection of the lesion in one piece. R0 resection was defined as *en bloc* resection with tumor-free horizontal and vertical margins. Intraprocedural bleeding was defined as persistent bleeding that could not be managed by endoscopic methods and transfusion or other interventions were required during the procedure. Bleeding that occurred during the procedure and was controlled endoscopically was not considered intra-procedural bleeding. Delayed bleeding was defined as hematemesis, melena, or a decrease of more than 2 g/dL in the hemoglobin level after the procedure. Intraprocedural perforation was considered if an endoscopic view of an extra-duodenal structure was observed during the procedure. Delayed perforation was defined as a sudden onset of abdominal pain with retroperitoneal pneumatosis or free gas detected on CT scans or abdominal radiographs after resection of the lesion. Intentional perforation was not considered a complication of EFTR. Coagulation syndrome was considered when abdominal pain developed with or without fever and no sign of free gas was observed using abdominal imaging after the procedure (11,12). The costs included all the expenses incurred during hospitalization, which included the cost of preoperative assessment, procedure-related, and post-operative management.

 Table 1 Characteristics of 49 patients who underwent endoscopic

 resection for duodenal subepithelial lesions

Characteristics	Value
Median tumor size, cm (range)	1.5 (0.4–7.0)
Tumor size, n (%)	
<2 cm	31 (63.3)
≥2 cm	18 (36.7)
Tumor location, n (%)	
Bulb	37 (75.5)
Descending portion	6 (12.2)
Junction of the first and second portions	6 (12.2)
Layer of tumor origin, n (%)	
Submucosa	42 (85.7)
Muscularis propria	7 (14.3)
Macroscopic type, n (%)	
Sessile	39 (79.6)
Pedunculated	10 (20.4)

# Follow-up

Surveillance endoscopy or EUS with or without CT was performed at 1, 6, and 12 months postoperatively and annually thereafter to observe wound healing and check for residual tumors and metastases. Patients lost to follow-up were excluded when calculating the follow-up parameters such as recurrence rate, follow-up duration, etc.

# Statistical analysis

SPSS 23.0 software (SPSS Inc., Chicago, IL, USA) was used for statistical analyses. The categorical variables were represented as frequencies and analyzed using the chisquare test or Fisher's exact test. The continuous variables were expressed as mean  $\pm$  standard deviation or median and range and calculated using the Student's *t*-test or Mann-Whitney U test; P<0.05 was considered statistically significant.

# Results

### Characteristics of patients and SELs

All patients (24 men and 25 women; average age, 52.0±11.8 years; range, 26–72 years) underwent successful

Table 2 Postoperative histology for duodenal subepithelial lesions

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Histology	N (%)
Brunner's gland hyperplasia	20 (40.8)
Neuroendocrine neoplasms	8 (16.3)
Lipoma	8 (16.3)
Ectopic pancreas	6 (12.2)
GIST	2 (4.1)
Solitary Peutz-Jeghers polyp	1 (2.0)
Inflammatory fibroid polyp	1 (2.0)
Brunner gland cystadenoma	1 (2.0)
Fibroma	1 (2.0)
Gangliocytoma	1 (2.0)
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GIST, gastrointestinal stromal tumor.

ER. A total of 49 lesions were resected successfully. Their characteristics are summarized in *Table 1*. The median diameter of the lesions was 1.5 cm (range, 0.4-7.0 cm). The average diameter of NENs was  $1.1\pm0.5$  cm (range, 0.5-2.0 cm). Thirty-seven (75.5%) lesions were located in the bulb, 6 (12.2%) in the descending portion, and 6 (12.2%) at the junction of the first and second portions of the duodenum.

# Histology

Table 2 shows the postoperative histology. Forty-two (85.7%) lesions, including Brunner's gland hyperplasia (n=18), NENs [n=8, including 2 cases of G1 neuroendocrine tumors (NETs), 5 cases of G2 NETs, and 1 case of neuroendocrine carcinoma which was 0.5 cm in diameter and confined to the submucosa], ectopic pancreas (n=2), lipomas (n=8), GIST (n=1, very low risk category based on the modified National Institutes of Health criteria (13)], solitary Peutz-Jeghers polyp (n=1), inflammatory fibroid polyp (n=1), Brunner gland cystadenoma (n=1), fibroma (n=1), and gangliocytoma (n=1), were from the submucosal layer. Seven (14.3%) lesions including ectopic pancreas (n=4); Brunner's gland hyperplasia (n=2); and GIST (n=1, very low risk category), were from the MP. No cancerous changes were seen in the 20 Brunner's gland hyperplasia lesions.

# Outcomes of ER

ESD, EMR, ESE, and EFTR were performed for 35

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Table 3 Therapeutic outcomes of endoscopic resection for duodenal subepithelial lesions

Therapeutic outcomes	Value
En bloc resection, n (%)	47 (95.9)
R0 resection, n (%)	44 (89.8)
Procedure time, minutes [range]	45 [15–155]
Complication, n (%)	3 (6.1)
Delayed perforation	2 (4.1)
Coagulated syndrome	1 (2.0)
Recurrence, n (%)	1 (2.3)
Hospital stay, days [range]	7 [3–45]

(71.4%), 9 (18.4%), 3 (6.1%), and 2 (4.1%) lesions, respectively. The therapeutic outcomes of ER are summarized in Table 3. The overall en bloc resection rate was 95.9% [47/49]. Two patients underwent EMR using the piecemeal technique (one with Brunner's gland hyperplasia and the other with lipoma). The R0 resection rate was 89.8% [44/49]. Positive vertical margins were detected in 2 patients (one with G1 NET and the other with G2 NET) with ESD, and they refused additional treatment. No recurrence was noticed during the follow-up period of 8 and 23 months, respectively. In another case of G1 NET, the normal tissue covering the tumor was damaged during ER, and this resection was classified as non-R0 resection. The en bloc resection rate for ESD (100%, 35/35) was higher than that of EMR (77.8%, 7/9, P<0.05); however, the R0 resection rates for ESD and EMR were 91.4% [32/35] and 77.8% [7/9], respectively, with no significant difference (P>0.05). Patients who underwent EMR incurred lower costs (P<0.05) than those who underwent ESD (Table 4). The median procedure time was 45 min (range, 15-155 min). The median hospital stay duration was 7 days (range, 3-45 days).

#### **Complications**

Two (4.1%) patients, one with a 1.5-cm lipoma resected by EMR and the other with a 2.0-cm NET (G2) resected by ESD, developed delayed perforation; both tumors arising from the submucosa. Both patients recovered after open surgical closure of duodenal perforation. Coagulation syndrome occurred in 1 (2.0%) patient who underwent ESD; however, the patient recovered conservatively. Delayed bleeding, gas-related complications, or duodenal

Table 4 Comparison of therapeutic outcomes between ESD and

Tumor size, cm (range)	1.6 (0.4–7.0)	1.5 (0.5–4.0)	0.482
En bloc resection, n (%)	35 (100.0)	7 (77.8)	0.038
R0 resection, n (%)	32 (91.4)	7 (77.8)	0.267
Complication, n (%)	2 (5.7)	1 (11.1)	0.506
Delayed perforation	1 (2.9)	1 (11.1)	0.371
Coagulation syndrome	1 (2.9)	0 (0)	1.000
Procedure time, min [range]	40 [15–155]	30 [15–60]	0.066
Hospital stay, day [range]	6 [3–14]	7 [3–45]	0.790
Cost, USD (range)	3,096.4 (1,769.6– 9,889.2)	2,057.2 (1,165.7– 11,795.6)	0.011
Local recurrence, n (%)	1 (3.1)	0 (0)	1.000

ESD, endoscopic submucosal dissection; EMR endoscopic ucosal resection.

stricture was not observed in our study.

# Follow-up

EMR

Of 49 patients, four were lost to follow-up and one with a G2 NET underwent additional surgery because of tumor infiltration to the MP layer. Follow-up data were available for 44 (89.8%) patients. The median follow-up period was 24 months (range, 1–88 months). One (2.3%) case of tumor recurrence was noted in a patient with Brunner's gland hyperplasia at 42 months after ESD. The recurring tumor was resected using laparoscopic local resection. The two cases of GISTs were followed-up for 10 and 47 months, respectively, without recurrence. The patient who underwent R0 resection of a neuroendocrine carcinoma refused to undergo additional treatment; no recurrence occurred after 8 months of follow-up.

# Discussion

The endoscopic management of D-SELs is challenging, and there are only a few studies on the efficacy and safety of endoscopic management. Our study reported that ER is an effective treatment for D-SELs associated with low complication rates and low recurrence risk.

The overall en bloc resection rate and R0 resection rate were 95.9% and 89.8%, respectively. The en bloc resection

rate for ESD was higher than that for EMR, which is in accordance with the results of previous studies on duodenal epithelial tumors (14,15). The R0 resection rates for ESD was higher than EMR. However, the difference was not statistically significant (91.4% versus 77.8%, P>0.05). However, these results should be interpreted with caution due to the small sample size.

Bleeding and perforation are the most common complications of ER. Delayed perforation developed in 2 patients in this study, resulting in a perforation rate of 4.1%, which was consistent with previous studies (6,7,16,17). The reported incidence of bleeding for duodenal ER ranges from 0% to 14.9% (6,7,14,17), and no delayed bleeding was observed in this study.

The indications for different ER methods for the treatment of D-SELs have not been standardized to date. The selection of ER methods is associated with the lesion features, such as macroscopic type, size, origin, growth pattern, and so on, which are ascertained by preoperative evaluation, including white light endoscopy, EUS, and/or CT. At our center, EMR is suitable for small (<2 cm), intraluminally growing SELs arising from the muscularis mucosa or superficial submucosa that can be removed in one piece using a snare. When lesions with intraluminal growth are confined to the deep submucosa or superficial MP layer, or cannot be resected in one piece by a snare (>2 cm), ESD is preferred. If SELs arise from the deep MP layer, then ESE is recommended. EFTR is optimal for SELs growing extraluminally or those that are tightly connected to the serosa.

All duodenal NENs have a potential for malignancy (18). ER is recommended for duodenal NENs that are  $\leq 1$  cm in size, non-ampullary, confined to the submucosal layer, and do not present with lymph node or distant metastasis (19). Eight NENs with an average diameter of 1.1±0.5 cm (range, 0.5-2.0 cm) were included in this study. All lesions were located in the bulb, originated from the submucosa, and were resected by ESD. The R0 resection rate for ESD of NENs in the present study was low (62.5%, 5/8), which may be related to the insufficiency of EUS for defining the lesion type. The differential diagnoses for hypoechoic and heterogeneous lesions from the submucosal and MP layers may be broad, such as GISTs, leiomyomas, and NENs, and EUS-guided fine-needle aspiration may be useful for determining the malignant potential of these lesions to guide further management (2). Therefore, for D-SELs >1 cm in size that are suspected to be or confirmed as NENs preoperatively, therapeutic management should be selected with caution.

Although our study showed that ER was effective and safe and that the long-term prognosis associated with ER was good, there are several limitations of this study. First, bias may potentially be present mainly because of the singlecenter retrospective design and relatively small sample size. Second, all procedures were performed by experienced endoscopists at a tertiary hospital; therefore, the results cannot be directly generalized. Third, a small number of EFTR and ESE procedures were performed owing to the endoscopist's concerns regarding perforation or bleeding during the selection of the management strategy. Due to these limitations, the results of our study should be interpreted carefully.

In summary, ER is an effective, safe, and minimally invasive method for the histopathologic assessment and curative treatment of D-SELs originating from the submucosal or MP layer and can serve as a promising alternative treatment for D-SELs. Its *en bloc* resection rate and R0 resection rate are high, and its recurrence rate and complication rate are low. Therefore, largescale, randomized, controlled, and multicenter studies are warranted to confirm the efficacy and safety of ER for D-SELs.

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## Footnote

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consent was obtained from the patients before endoscopic treatment. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study protocol was approved by the Ethics Review Board of the Second Xiangya Hospital (No. LYF2020129).

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