

# The value of endoscopic resection for non-ampullary duodenal lesions: A single-center experience

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## Abstract

**Background:** To observe and preliminarily evaluate the efficacy and safety of endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) in the treatment of non-ampullary duodenal lesions (NADLs).

**Methods:** This retrospective observational study included 84 patients who underwent endoscopic resection (ER) with non-ampullary duodenal lesions, between March 2010 and November 2020, at the Cancer Hospital of the Chinese Academy of Medical Sciences (Beijing, China). Data on patient demographics, therapeutic outcomes, and follow-up results were analyzed.

**Results:** There were 44 patients undergoing EMR, and 40 patients accepting ESD. The overall en bloc resection rate was 98.8% (83/84). For the neoplastic lesions, the overall en bloc resection rate and curative rate were 98.5% (67/68) and 89.7% (61/68), respectively. The procedure-related bleeding and perforation rates were 2.4% and 10.7%, respectively. Univariate analysis results indicated that the main correlation factor of non-curative pathologic resection was tumor size ( $p = 0.004$ ) and resection size ( $P < 0.01$ ). There showed a higher curative rate in patients with tumors less than 25 mm in diameter. Multivariate logistic regression analyses determined that the tumor size (OR 0.935; 95% CI 0.878-0.995;  $P = 0.035$ ) was associated with non-curative resection. No recurrences were observed in patients who had undergone a complete ER during a follow-up period of 42.8 months (range, 3-127 months).

**Conclusion:** Endoscopic resection is an effective, safe, and feasible treatment for non-ampullary duodenal lesions.

**Keywords:** Endoscopic resection, non-ampullary duodenal lesions

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## INTRODUCTION

The possibility of finding a duodenal lesion in a patient on upper endoscopy is low, with studies reporting rates from

less than 1%.<sup>[1,2]</sup> Recently, with the rapid development of endoscopic diagnosis and endoscopic resection (ER), many epithelial tumors in esophagus, stomach, and colon can be treated, of which the endoscopic mucosal resection (EMR)

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and the endoscopic submucosal dissection (ESD) are representative.<sup>[3-5]</sup> There are also guidelines for the endoscopic resection in esophagus, stomach and colon.<sup>[6-8]</sup> However, there is still no guideline for the endoscopic resection in duodenum, although many researches have reported such a technique.<sup>[1,9,10]</sup> Therefore, the aim of this study was to investigate the clinical outcomes in patients with duodenal lesions who accepted the ER operation and to determine possible predictive factors for non-curative resection.

The endoscopic resection of duodenal lesions is challenging. Factors include (1) the narrow lumen which restricts the movement of endoscope, especially in some flexible actions like flipping, (2) the “C-loop” shape that makes maintaining endoscope position difficult, (3) the short external endoscope, which makes stabilizing the endoscope hard, (4) the Brunner’s glands in the submucosal layer that stiffen the wall and make mucosal lifting difficult, (5) the poor extensibility of mucous membrane and the difficulty encountered for suture, (6) the thin deep muscle layer that results in a higher rate of perforation, (7) rich blood supply, and (8) the difficult access if emergency or salvage surgery becomes necessary.<sup>[1]</sup> Considering all the factors above, the ER of duodenal lesions is the most difficult among that of the whole digestive tract.

## PATIENTS AND METHODS

### Patients

We retrospectively analyzed our database of all patients who underwent a duodenal ER at the Cancer Hospital of the Chinese Academy of Medical Sciences (Beijing, China) between March 2010 and November 2020. A total of 84 patients who had non-ampullary duodenal lesions underwent ER. All the patients agreed to undergo ER after they were given detailed explanations of the risks and benefits associated with the procedure, which included the complications associated with ER and a possible need for an additional surgical treatment. Written informed consent was obtained from all the patients before they underwent ER, and the study protocol was reviewed and approved by the Clinical Trials Center of National Cancer Center.

### Pre-resection evaluation

All the patients underwent a NBI, a magnifying endoscopy and a staining endoscopy. If necessary, endoscopic ultrasound and duodenoscopy were applied to show the lesion. In addition, all patients were examined by abdominal computed tomography (CT) to confirm that there is no invasion of lymph nodes or distant metastasis before the procedure. Additionally, if it was difficult to judge the

position relation of the lesion and bile papilla, magnetic resonance cholangiopancreatography (MRCP) was done.

### Endoscopic resection

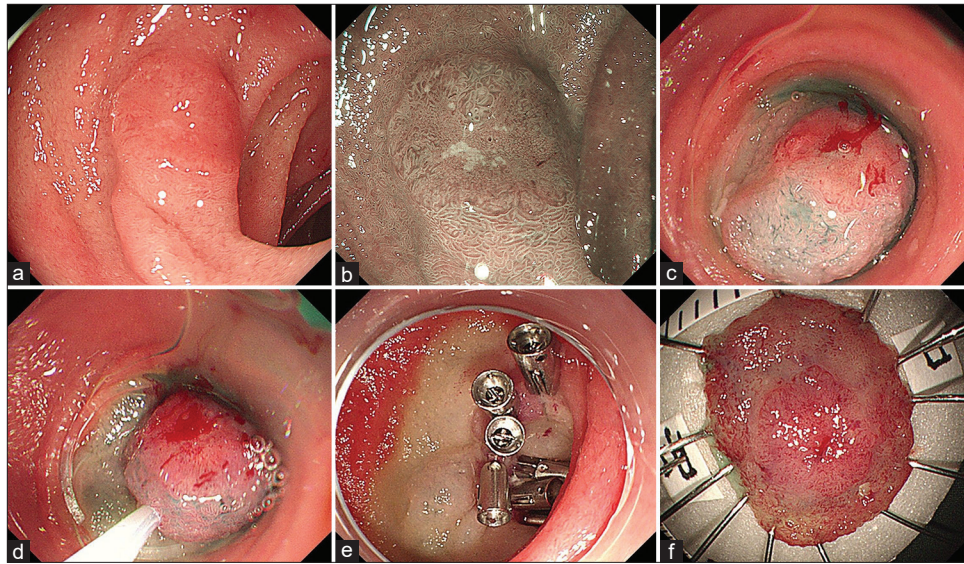
All the ERs (EMR or ESD) were performed by experienced endoscopists in Cancer Hospital of the Chinese Academy of Medical Sciences, while patients were under general anesthesia with cardiorespiratory monitoring. A conventional single-channel endoscope (GIFQ260, GIF-H260, Olympus) was used. For EMR, a normal saline solution mixed with a small amount of epinephrine (0.002 mg/mL), indigo carmine dye and sodium hyaluronate were injected into the submucosal layer to reduce the risks of perforation and hemorrhage. The tumor was then resected using a snare (Olympus Co., Tokyo, Japan) [Figure 1]. For ESD, a normal saline solution mixed with a small amount of epinephrine (0.002 mg/mL), indigo carmine dye and sodium hyaluronate were injected into the submucosal layer around the tumor and then a circumferential incision was made using a dual knife (Olympus Co., Tokyo, Japan) or an insulation-tipped (IT) nano knife (Olympus Co., Tokyo, Japan). Afterwards, the normal tissue just beneath the tumor was dissected directly using the dual knife or the IT nano knife after an additional injection of saline beneath the lesion to sufficiently separate the lesion from the proper muscle layer.

After removing the lesion, electro-surgical hemostatic forceps (FD-410LR, Olympus, Tokyo, Japan) were used on the mucosal defect to prevent and control bleeding. LOCKADO clips (Micro Tech, Nanjing, China) were used to close the mucosal defect to prevent postoperative bleeding and perforation. As part of standard practice in our center, all mucosal defects after endoscopic resection are closed.

### Aftercare

For the EMR patients, they were fasted for 1 day. On the second day, they were allowed to drink water and the routine blood test and blood biochemistry was done. On the third day, they were allowed to eat full flow food. On the fourth day, they were allowed to eat semiliquid diet and the gastric tube was removed. On the fifth day, they were allowed to eat soft diet and were allowed to be discharged on the seventh day. The patients received a continuous intravenous drip of a proton pump inhibitor (PPI) twice a day for two days. PPI medicine was taken for 2 weeks.

For ESD patients, they were fasted for 2 days. On the second day, the routine blood test and blood biochemistry was done. On the third day, they were allowed to drink water. Full flow diet was allowed on the fourth day. On the fifth



**Figure 1:** Endoscopic mucosal resection of a high grade intraepithelial neoplasia. (a) An epithelial tumor was present in the descendant duodenum. (b) The narrow band imaging was used to show the lesion. (c) A saline solution containing a small amount of epinephrine, indigo carmine dye and sodium hyaluronate was injected beneath the lesion to elevate the lesion. (d) The lesion was aspirated into the ligation device, followed by deployment of the elastic band. Then, a snare resection was performed using a blended electrosurgical current. (e) Metal clips were used to close the wound. (f) The resected specimen

day, they were allowed to eat semiliquid diet and the gastric tube was removed. On the sixth day, they were allowed to eat soft diet and were discharged on the seventh day. The patients received a continuous intravenous drip of a PPI twice a day for 3 days, followed by oral PPI for 2 weeks. In addition, intravenous octreotide was given at a dose of 1.2 mg a day for 3 days.

It should be noted that the above is a routine schedule. If complications occurred, extra treatment was adopted.

### Histopathologic evaluation

The formalin-fixed resected specimens were serially sectioned at 2-mm intervals, and tumor involvement of the horizontal and vertical margins was assessed. In addition, if the lesion was diagnosed as a carcinoma, the histopathologic type, tumor size, depth of invasion, and lymphovascular invasion were evaluated microscopically.

### Outcome parameters

The primary outcome parameter was the success of the ERs, including the en bloc resection rates and the curative resection rate. En bloc resection was defined as the resection of the lesion as a single piece. Curative resection was defined based on the following criteria: (1) performance of an en bloc resection; (2) no involvement of the lateral or vertical margins, and, in cases of carcinoma, tumor invasion was limited to the submucosal layer, and lymphovascular invasion was not additionally detected.<sup>1,6,7</sup>

The secondary outcome parameters were the procedure time, procedure-related complications, and the local recurrence rate. The procedure time was defined as the time from the start of the injection of the saline solution to the complete removal of the lesion. Procedure-related bleeding was defined as bleeding shown via endoscopic evaluation within 2 weeks, clinical evidence of melena or hematemesis, or massive bleeding requiring transfusion. Perforation was diagnosed on the presence of free air on post-procedural chest or abdomen radiographs.

### Follow-up

Patients with abdominal pain underwent post-procedural chest and abdominal radiography. Post-procedural discharges were carried out within 5-7 days. When the pathologic results showed benign lesions, follow-up endoscopy was conducted at the third month after the ER and annually thereafter. Follow-up endoscopy, and abdominal CT were performed at the 12th month after the ER and annually thereafter.

### Statistical analysis

Variables were expressed as medians and ranges or as simple proportions. Univariate analyses were performed where continuous variables were analyzed using the Mann-Whitney U test and categorical variables were analyzed using the Chi-squared test or Fisher's exact test as appropriate. Multivariate logistic regression analysis was used to identify possible covariates that were significant predictors of non-curative resection. All statistical analyses were performed with SPSS version 25.0 for Windows

**Table 1: Demographic characteristics of the patients and neoplasms**

Characteristic	Number
Median age, years (range)	57.2 (35-78)
Gender, n (%)	
Male	53 (63.1)
Female	31 (36.9)
Tumor location, n (%)	
Bulb	32 (38.1)
The junction of bulb and descendant duodenum	17 (20.2)
Descendant duodenum	35 (41.7)
Macroscopic type <sup>a</sup> , n (%)	
Is	37 (44.0)
Ip	22 (26.2)
Ii	25 (29.8)
IIa	21 (25)
IIb	1 (1.2)
IIc	3 (3.6)
Median tumor size, mm (range)	17.5 (2-56)
Tumor size, n (%)	
≤20 mm	55 (65.5)
>20 mm	29 (34.5)
Pathologic diagnosis, n (%)	
Brunner's gland hyperplasia	8 (9.5)
Well-differentiated neuroendocrine tumor	16 (19.0)
Lipoma	2 (2.4)
Ectopic gastric mucosa	4 (4.8)
Inflammatory fibroid polyp	1 (1.2)
Gastrointestinal stromal tumor	1 (1.2)
Tubular adenoma	3 (3.6)
Leiomyoma	1 (1.2)
Low grade intraepithelial neoplasia	18 (21.4)
High grade intraepithelial neoplasia	19 (22.6)
Adenocarcinoma	11 (13.1)
En bloc rate%	98.8
Procedure-related bleeding rate%	2.4
Procedure-related perforation rate%	10.7
Follow-up period, months (range)	42.8 (3-127)

<sup>a</sup>According to the Paris classification

software (SPSS Inc., Chicago, IL, USA) and  $P < 0.05$  was considered statistically significant.

## RESULTS

### Demographics and clinicopathologic characteristics

The baseline clinicopathologic characteristics of the patients and the neoplasms were summarized in Table 1. This study included 84 patients with 53 men and 31 women with a median age of 57.2 years (range, 35–78 years). The median size of the lesions was 17.5 mm (range, 2–56 mm). There were 32 lesions (38.1%) located in the bulb, 17 lesions (20.2%) located in the junction of bulb and descendant duodenum and 35 lesions (41.7%) located in the descendant duodenum.

### Outcomes from the endoscopic resection

The overall en bloc resection rate of all lesions was 98.8% (83/84). Table 2 shows the treatment outcomes from the ERs of duodenal neoplasms. The median resection size of EMR was 12.3 mm in diameter, which was smaller than that of ESD (26.6 mm) ( $P < 0.01$ ). EMR

was performed on 44 lesions (52.4%), while ESD on 40 lesions (47.6%). The median procedure time of ESD was 86.5 min, which was longer than the procedure time of EMR (21.6 min) ( $P < 0.01$ ). It showed a higher rate of complications in ESD than that in EMR ( $P < 0.01$ ). Delayed bleeding was noted in 2 cases (2.4%), which had undergone EMR, both with tumors located in the descendant duodenum. Bleeding was controlled successfully with endoscopic electrocoagulation and hemoclipping. Perforation occurred during ER in 9 cases (10.7%), and all were closed immediately by hemoclips. As a result, all of these patients recovered non-operatively. One patient underwent delayed perforation and recovered non-operatively with total parenteral nutrition, gastrointestinal decompression, and intravenous antibiotics for 5 weeks.

### Clinical results of the ER of neoplastic lesions

Table 3 shows the treatment outcomes of the ERs of duodenal neoplasms. Considering all the neoplastic lesions (well-differentiated neuroendocrine tumor, gastrointestinal stromal tumor, tubular adenoma, low-grade intraepithelial neoplasia, high grade intraepithelial neoplasia, adenocarcinoma), the overall en bloc resection rate and the curative rate were 98.5% (67/68) and 89.7% (61/68), respectively. There were 32 patients (47.1%) with duodenal tumors receiving EMR operations, while 36 (52.9%) underwent ESD.

### Factors associated with non-curative resection

In the univariate analyses, the tumor size and resection size appeared to be significantly associated with non-curative pathologic resection ( $P = 0.004$  and  $< 0.01$ , respectively) [Table 4]. With tumor sizes less than 25 mm in diameter, a higher curative rate was observed. On the other hand, multivariate logistic regression analysis showed that only tumor size (OR 0.935; 95%CI 0.878-0.995;  $P = 0.035$ ) was associated with non-curative resection [Table 5].

### Follow-up

Of the 84 patients, the median follow-up period was 42.8 months (range, 3-127 months). No tumor recurrences were observed in any of the patients in whom complete ERs were achieved, irrespective of whether a curative resection was performed. One patient with neuroendocrine tumor non-curative resection underwent an additional surgical resection 3 months after ER and lived without recurrence for the next 37 months.

## DISCUSSION

The prevalence of non-ampullary duodenal lesions

**Table 2: Treatment outcomes after endoscopic resection of duodenal lesions according to the treatment methods**

	EMR (n=44)	ESD (n=40)	P
Median age, years (range)	55.5 (35-78)	59.0 (37-77)	0.116
Gender, n (%)			0.425
Male	26 (59.1)	27 (67.5)	
Female	18 (40.9)	13 (32.5)	
Tumor location, n (%)			0.228
Bulb	16 (36.4)	16 (40.0)	
The junction of bulb and descendant duodenum	12 (27.2)	5 (12.5)	
Descendant duodenum	16 (36.4)	19 (47.5)	
Median tumor size (mm, range)	16.7 (2-56)	19.8 (5-50)	0.285
Median resection size (mm, range)	12.3 (5-50)	26.6 (8-80)	<0.01
Median resection time (min, range)	21.6 (3-107)	86.5 (21-220)	<0.01
En bloc rate	97.7	100	
Complications, n (%)			<0.01
Perforation	1 (2.3)	8 (20.0)	
Delayed perforation	0	1 (2.5)	
Delayed bleeding	2 (4.5)	0	
Macroscopic type <sup>a</sup> , n (%)			0.041
Is	20 (45.5)	17 (42.5)	
Ip	15 (34.1)	6 (15.0)	
Ii	9 (20.4)	17 (42.5)	

<sup>a</sup>According to the Paris classification

is extremely low, mainly including Brunner's gland hyperplasia, neuroendocrine tumor, lipoma, ectopic gastric mucosa, inflammatory fibroid polyp, gastrointestinal stromal tumor, tubular adenoma, leiomyoma, low grade intraepithelial neoplasia, high grade intraepithelial neoplasia, and adenocarcinoma.<sup>[1,2]</sup> In the past, non-ampullary duodenal lesions were treated mainly with surgical operations, with a high perioperative mortality rate and many postoperative complications.<sup>[1,2,11]</sup> With the development of endoscopic instruments and the maturity of endoscopic technique, endoscopic resection (mainly including EMR and ESD) has been widely used in the treatment of early gastrointestinal tumors.<sup>[12]</sup> However, despite recent advances, ER is not easy in the duodenum. First, the anatomical position of duodenum is relatively special as it connects the stomach and jejunum and stays close to the posterior abdominal wall, and is relatively fixed. Moreover, because of its rich blood supply, relatively thin wall, and narrow lumen for the endoscopic action, complications such as perforation and bleeding are easy to occur after ER operation, which increases the difficulty and risks of endoscopic treatment.<sup>[13,14]</sup>

The important goal of ER is to obtain curative resection.<sup>[15,16]</sup> In our study, compared with ESD, EMR

operation is less difficult with shorter operation time but smaller resection size. There were no local recurrences during the median follow-up period of 42.8 months (range 3-127 months). Curative resection was influenced significantly by the tumor size. Previous studies have shown that tumor diameter  $\geq 20$  mm is a predictive risk factor for metastasis.<sup>[13,14]</sup> Our results illustrated that the tumor diameter  $\leq 25$  mm indicated a higher curative rate. In the multivariate analyses tumor size was a significant predictor of non-curative resection. These findings could assist practitioners to assess an ER operation for a non-ampullary duodenal lesion in advance in order to avoid unnecessary potential risks.

In spite of a higher en bloc resection rate in ESD, when compared with EMR, the procedure time of ESD is prolonged therefore, the risk of perforation and hemorrhage is increased.<sup>[2,17,18]</sup> Our research showed that in comparison with EMR, the median resection size in ESD was much larger with a higher perforation rate. In our study, 9 patients with perforation received clamping with metal clips or the "bag suture".<sup>[19]</sup> Only one of our patients suffered from a delayed perforation, who was cured non-operatively by fasting, gastrointestinal decompression, and intravenous antibiotics for 5 weeks.

The postoperative bleeding rate after EMR or ESD for the rectal carcinoid tumors has been reported to be approximately 3–6%.<sup>[18,20]</sup> To avoid such events, it is important to confirm the bleeding vessel during the procedure, and to clamp the vessel by thermal biopsy forceps or burn it with argon after the operation. It is

**Table 3: Treatment outcomes after endoscopic resection of duodenal neoplastic lesions according to the treatment methods**

	EMR (n=32)	ESD (n=36)	P
Median tumor size (mm, range)	16.8 (2-56)	19.0 (5-50)	0.479
Median resection size (mm, range)	12.3 (5-50)	25.8 (8-80)	<0.01
Median resection time (min, range)	24.7 (5-107)	90.9 (29-220)	<0.01
En bloc rate (%)	96.9	100	
Curative rate (%)	90.6	91.7	0.88

**Table 4: Univariate analyses of the predictive factors for curative pathological resection after endoscopic resection of duodenal neoplastic lesions**

	Curative resection (n=61)	Non-curative resection (n=7)	P
Median age, years (range)	57.5 (35-78)	56.9 (37-75)	0.893
Gender, n (%)			0.277
Male	39 (63.9)	3 (42.9)	
Female	22 (36.1)	4 (57.1)	
Tumor location, n (%)			0.250
Bulb	19 (31.1)	4 (57.1)	
The junction of bulb and descendant duodenum	13 (21.3)	0	
Descendant duodenum	29 (47.5)	3 (42.9)	
Median tumor size (mm, range)	16.6 (2-56)	31.3 (12-50)	0.004
Median resection size (mm, range)	17.3 (5-45)	36.4 (15-80)	<0.01
Median resection time (min, range)	56.6 (5-220)	87.1 (11-185)	0.219
Tumor size, n (%)			0.007
≤25 mm	52 (85.2)	3 (42.9)	
>25 mm	9 (14.8)	4 (57.1)	
Macroscopic type <sup>a</sup> , n (%)			0.456
Is	27 (44.3)	4 (57.1)	
Ip	11 (18.0)	2 (28.6)	
Ii	23 (37.7)	1 (14.3)	
Treatment method, n (%)			0.814
EMR	29 (47.5)	3 (42.9)	
ESD	32 (52.5)	4 (57.1)	

EMR - endoscopic mucosal resection, ESD - endoscopic submucosal dissection. <sup>a</sup>According to the Paris classification

important to place a stomach tube and a nutrition tube so as to observe the drainage's color to identify delayed bleeding as soon as possible. In our study, the 2 delayed bleeding patients were treated immediately with endoscopic hemostasis.

Routine gastrointestinal decompression is needed after endoscopic treatment of duodenal lesions, because a lot of gases are accumulated in the patient's digestive tract and the duodenal wall is edematous due to some physical irritants during the procedure.<sup>[2]</sup> Gastrointestinal decompression can help patients drain gas and greatly reduce the incidence of postoperative abdominal pain and delayed perforation.<sup>[21]</sup> In addition, gastrointestinal decompression is also helpful for practitioners to observe the possibility of delayed bleeding after operation. According to our past experience, we advise practitioners to place both a gastric tube and a duodenal nutrition tube.

This study has several limitations. First, it is a retrospective study conducted in a single center. Second, the sample size is relatively small and the follow-up period of this study is somewhat insufficient to accurately assess the outcomes of endoscopic resection. Multi-institutional studies and larger population-based datasets are needed in future to obtain relatively accurate results.

To sum up, the ER of duodenal lesions is safe and effective. EMR and ESD can achieve en block resection of duodenal lesions and obtain curative resection, with small operation trauma, mild postoperative pain, and fast recovery.

However, the incidence of complications is relatively high. Owing to the difficulties of ER in duodenum mentioned above, it is recommended that the operation should be performed by experienced doctors.

With the early detection of duodenal lesions by endoscope, the improvement of endoscopic treatment techniques and the accumulation of experience, the success rate of EMR and ESD in the treatment of duodenal lesions will continue enhancing, such procedures could become the best treatment for early duodenal space-occupying lesions.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

**Table 5: Multivariate logistic regression analyses of the predictive factors for curative resection after endoscopic resection of duodenal neoplastic lesions**

Risk factor	OR	95%CI	P
Operation method	1.378	0.126-15.119	0.793
Tumor size	0.935	0.878-0.995	0.035
Operation time	0.994	0.974-1.014	0.527

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