Outcomes of Endoscopic Mucosal Resection for Large Superficial Non-Ampullary Duodenal Adenomas

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Research Article

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Abstract

Background

Endoscopic mucosal resection (EMR) is the recommended treatment for superficial non-ampullary duodenal epithelial tumors larger than 6 mm. This endoscopic technique carries a high risk of adverse events. Our aim was to identify the risk factors for adverse events following EMR for non-ampullary duodenal adenomas.

Methods

We retrospectively analyzed a prospectively collected database of consecutive endoscopic resections for duodenal lesions at a tertiary referral center for therapeutic endoscopy. We analyzed patients with non-ampullary duodenal adenomas ≥ 10mm resected by EMR, and searched for factors associated with adverse events after EMR.

Results

167 duodenal adenomas, with a median (range) size of 25 (10–90) mm, were resected by EMR between January 2015 and December 2020. Adverse events occurred in 37/167 (22.2%) after endoscopic resection, with 26/167 (15.6%) delayed bleeding, 4/167 (2.4%) immediate perforation and 4/167 (2.4%) delayed perforation. In logistic regression, the size of the lesion was the only associated risk factor of adverse events (OR = 2.81, 95%CI [1.27; 6.47], p = 0.012). Adverse events increased mean hospitalization time (7.7 ± 9 vs. 1.9 ± 1 days, p < 0.01). None of the currently recommended preventive methods, particularly clips, affected the adverse event rate.

Conclusions

EMR of centimetric and supracentimetric duodenal adenomas carries a high risk of adverse events, increasing with the size of the lesion and with no benefit from any preventive method. These results suggest that these procedures should be performed in expert centers, and underline the need for novel endoscopic tools to limit the rate of adverse events.

Introduction

Superficial non-ampullary epithelial tumors (SNADETs) are encountered in 1-4.6% of upper gastrointestinal endoscopies[1–3]. They can be sporadic or occur in the setting of a hereditary predisposition syndrome, mainly familial adenomatous polyposis (FAP). Duodenal adenomas have the potential to progress towards invasive adenocarcinoma, warranting resection for any sporadic adenoma

and for all significant lesions (> 10 mm or sign of high-grade dysplasia) in patients with FAP[4]. The progresses of endoscopic techniques allowing for a better detection of duodenal adenomas, explain the apparent increasing incidence of these lesions[3]. The specific anatomical conditions of the duodenum, such as the thin muscle layer, the narrow lumen and the rich vascularization, make the endoscopic treatment more challenging than in other parts of the gastrointestinal tract. In 2021, the European Society of Gastrointestinal Endoscopy (ESGE) released guidelines advising to practice cold snare polypectomy for lesions < 6 mm, endoscopic mucosal resection (EMR) being the first-line endoscopic resection technique for non-malignant SNADETs over 6 mm in size[5]. Studies reporting on the outcomes of EMR for duodenal adenomas, including large lesions, and endoscopic follow-up data on a significant number of patients are scarce. The aim of this study is to determine the risk factors for adverse events (AE) following EMR of large duodenal adenomas.

Patients And Methods

Patients

Consecutive patients who underwent endoscopic resection at our tertiary digestive endoscopy center from January 2015 to December 2020 were included. We included all patients treated by EMR for SNADETs ≥ 10 mm. We excluded patients with ampullary adenoma, non-adenomatous histology (neuroendocrine tumor, Brunner's gland hyperplasia, gastric ectopic mucosa…), or treated by submucosal dissection (ESD) or by a hybrid resection technique.

This is a retrospective study of a prospectively collected database. Patients' clinical and endoscopic data were extracted from computerized medical records.

Endoscopic procedure and follow up

All methods were carried out in accordance with relevant guidelines and regulations. Endoscopy was performed at a tertiary endoscopy center by five expert endoscopists under general anesthesia with orotracheal intubation, CO2 insufflation, and in the supine position. A gastroscope with or without a cap, a duodenoscope, a pediatric colonoscope, or a combination of different endoscopes were used for morphological characterization of the lesions and resection, according to location. Duodenal polyps were described according to the Paris classification[6], and their size was assessed by the operator in the report, or if necessary by consultation of the endoscopy images. In accordance with Klein et al, lesions were classified as large (10–29 mm) or giant (≥ 30 mm)[7]. When lesion margins were not well defined, virtual chromoendoscopy (NBI, Olympus, Japan; FICE or BLI, Fujifilm, Japan) or indigo carmine chromoendoscopy was used. Indigo carmine chromoendoscopy was also routinely used in the evaluation of patients with FAP. Submucosal lifting was performed with saline stained with indigo carmine, with or without epinephrine according to the operator's preference, a commercially available submusocal lifting solution (Orise, Boston Scientific, USA), or a 5% fructose and 10% glycerol submucosal lifting solution produced by the hospital pharmacy[8].

Resection was performed with braided or condensed strand multifilament or single stranded (monofilament) resection snares. Diameters of the snares were 10 mm (SD-990– 10, Olympus), 15 mm (SD-990-15, Olympus), 20 mm (POL1-B7-20-23-220-OL, Medwork, Germany), 22 mm (POL1-B8-22-23-220-OL, Medwork,), 25 mm (SD-990– 25, Olympus) or 30 mm (POL1-B3-30-23-220-OL, Medwork). The resection was performed with the Q endocut mode on a VIO300 D or VIO 3 electrosurgical generator (Erbe, Tubingen, Germany). If needed, through the scope clips (Resolution, Boston Scientific; Instinct, Cook medical; Novaclip, Vytil) were used to close the mucosal defect.

Following the ESGE recommendations, antiplatelets were stopped 5 days before the procedure; anti-vitamin K drugs were stopped 5 days before the procedure until a maximum INR of 1.5 was reached; direct oral anticoagulants (Dabigatran, Rivaroxaban, Apixaban) were stopped 48–72 hours before the procedure[5]. All patients were admitted to the hospital following the endoscopic procedure. Re-feeding was allowed the same evening unless otherwise instructed by the operator, and blood counts were monitored at day 1 and day 2 before discharge. An endoscopic control was systematically planned at 3 months and at 1 year.

Outcomes

The primary outcome was the rate of clinically significant AE: delayed bleeding, perforations during the procedure, and delayed perforations. The secondary outcomes were the rate of recurrence after endoscopic resection, the feasibility of the endoscopic treatment for recurrences, the number of endoscopic treatment sessions required, and the rate of surgical intervention.

Adverse events:

AE were recorded during the procedure, during the 48 hours of hospital admission following the procedure, and during a follow-up consultation one to three months after the endoscopy. The severity of the AE was assessed using the American Society of Gastrointestinal Endoscopy classification[9]. Delayed bleeding was defined as the presence of hematemesis and/or melena after the patient left the endoscopy room. Bleeding was classified as major when it resulted in a hemoglobin drop of more than 2g/L. Intraprocedural perforation was defined as a visible defect in the muscularis propria, associated or not with the visualization of periduodenal structures. Delayed perforation was diagnosed when post-procedural imaging justified by abdominal pain or general symptoms (fever, malaise, tachycardia) showed fluid in the periduodenal area or oral contrast extravasation.

Statistical analysis:

Data was collected in a database using the Excel software (Microsoft Corp., Seattle, Washington, U.S.A), and analyzed with the Graphpad software (Graphpad, San Diego, CA) and Pvalue.io software (Pvalueio, Medistica, Paris, France). Continuous variables are presented as mean ± standard deviation (SD) or median with ranges or interquartile range (IQR). Categorical or ordinal variables are expressed as percentages. Comparison of nominal or ordinal variables was performed using the Chi-2 test or Fisher's exact test. A p value < 0.05 is considered significant. For the comparison of categorical data, a Fisher’s

exact test was used. Univariate and multivariate analyses were used to determine independent risk factor of complications and recurrence.

Ethical aspects

All patients signed a written consent for therapeutic endoscopy after being informed about the procedure, its benefits and risks, especially in terms of complications. All patients provided informed consent for the use of their medical data for medical research. The study was approved by our local ethics committee (Comité Local d'Ethique des Publications de l'Hôpital Cochin), CLEP -n° AAA-2021-08014.

Results

Patients and lesions characteristics

Between 2015 and December 2020, 276 endoscopic resections were performed in 226 patients for duodenal lesions. Of these, 167 non ampullary duodenal adenomas of 10 mm and more were resected by EMR. We excluded infracentimetric lesions, submucosal dissection and other histological diagnosis. The study flowchart is presented in Fig. 1.

Patients and lesions' characteristics are summarized in Table 1. A total of 167 patients were treated for a non-ampullary duodenal adenoma with a median (IQR) follow-up time of 13.9 (3.7–26.9) months. The median (IQR) age was 63.7 (54.4–72.3) years and 90/167 (53.9%) were women. Some 17/167 (10.2%) patients were treated by antiplatelet and 11/167 (6.6%) by anticoagulant therapy. Sporadic lesions represented 118/167 (70.7%) of lesions, while 49/167 (29.3%) lesions were related to genetic predisposition syndromes, including 34/167 (20.4%) patients with FAP. The vast majority of duodenal adenomas were located in the second part of the duodenum (133/167, 79.6%). Paris 0-IIa subtype was recorded in 149/167 (89.2%) cases, and the median (IQR) size was 25 (25–40) mm. 94/167 (56.3%) lesions were considered as large (< 30mm) and 73/167 (43.7%) as giant (≥ 30mm). Low-grade dysplasia was recorded in 64/167 (38.3%), high-grade dysplasia in 97/167 (58.1%), and invasive carcinoma in 1/167 (0.06%) of the duodenal adenomas.

Table 1
Baseline patients and lesions characteristics

Patients - n	**n = 167**
Age (mean ± SD), years	62.2 ± 14.2
Sex, Male/Female - n	77/90
ASA score 1/2/3 - n	77/57/33
Antiplatelet agent - n (%)	17 (10.2)
Anticoagulation (VKA/DOA) - n (%)	11 (6.6)
Hereditary predisposition syndrome - n (%)	49 (29.3)
FAP	34 (20.4)
Lynch syndrome	2 (1.2)
MUTYH polyposis	6 (3.6)
Juvenile polyposis	1 (0.6)
Peutz-Jeghers syndrome	3 (1.8)
Sporadic - n (%)	118 (70.7)
Concurrent colonic adenoma/Colonoscopy- n (%)	83/106 (78.3%)
Hereditary predisposition syndrome	44/48 (91.7%)
Sporadic	39/58 (67.2%)
Lesion site- n (%)	17 (10.2)
D1	133 (79.6)
D2	17 (10.2)
D3/D4	
Size in mm, median (IQR)	25 (40 – 25)
Size repartition - n (%)	94 (56.3)
10–29 mm	73 (43.7)
≥ 30 mm	

VKA: Vitamin K antagonist; DOA: Direct oral anticoagulant, n: number

SD: standard deviation

Patients - n	**n = 167**
Paris Classification - n (%)	16 (9.6)
0-Is	149 (89.2)
0-IIa	2 (1.2)
0-Ip	
Histology- n (%)	64 (38.3)
Low-grade dysplasia	102 (61.1)
High-grade dysplasia	1 (0.6)
Invasive adenocarcinoma	
Time of follow up in month - median (IQR)	13.9 (26.9–3.7)
VKA: Vitamin K antagonist; DOA: Direct oral anticoagulant, n: number	
SD: standard deviation	

Endoscopic characteristics

The endoscopic characteristics of the duodenal adenomas are summarized in Table 2. EMR was performed with a gastroscope in 103/167 (61.7%) cases and with a pediatric colonoscope and pediatric colonoscope respectively in 21/167 (12.6%) and 43/167 (25.7%) cases. A distal attachment cap was added in 43/124 (34.7%) endoscopies. EMR were typically performed with a 15 mm monofilament endoscopic resection snare (98/167, 58.7%), after submucosal lifting with a mixture of saline and indigo carmine (125/167, 74.9%). En bloc resection was achieved in 63/167 (37.7%) cases and the resection bed was closed with clips in (65/167, 38.9%) of cases.

Table 2
Endoscopic procedural characteristics

Type of endoscope - n (%)	**103 (61.7)**
Gastroscope- n (%)	**21 (12.6)**
Duodenoscope - n (%)	**43 (25.7)**
Pediatric Colonoscope - n (%)	**43 (25.7)**
Cap - n (%)	
Submucosal injection - n (%)	127 (76.0)
Saline and indigo carmine	37 (22.2)
Glycerol-Fructose	3 (1.8)
Commercial submucosal lifting gel	
Endoscopic resection snare type -, n (%)	79 (47.3)
Braided or condensed multifilament snare	88 (52.7)
Monofilament snare	
Snare diameter - n (%)	30 (18.0)
10 mm	98 (58.7)
15 mm	21 (12.6)
20 mm	12 (7.2)
25 mm	6 (3.6)
30 mm	
Resection modality - n (%)	63 (37.7)
En bloc	104 (62.3)
Piecemeal	
Closing by clips - n (%)	65 (38.9)
Length of hospital stay, median (IQR), days	2 (2–2)

Adverse events

AE occurred in 37/167 (22.2%) resections with 26/167 (15.6%) delayed bleedings, 4/167 (2.4%) immediate perforations and 4/167 (2.4%) delayed perforations. Univariate analysis showed a positive association with AE and giant vs. large duodenal adenomas (34.2% vs 12.8%, $p < 0.001$), monofilament vs. braided or condensed strands (28.4% vs 12.2%, $p = 0.04$), and not using clips (29.3% vs 15.3%, $p = 0.003$) (Table 3). In multivariate analysis, only giant lesions were associated with AE (OR = 2.81, 95%CI

[1.27; 6.47], p = 0.012) (Table 4). There was no association between the occurrence of clinically relevant AE and patients' or lesions' characteristics: age, sex, medical history, sporadic or genetic syndrome, the use of antiplatelet agent or anticoagulant, localization of the lesion in the duodenum, Paris classification; nor with resection techniques: type or size of the resection snare, size of the snare, closure with clips, type of endoscope, presence of a cap, type submucosal lifting solution, adjunction of epinephrine.

Table 3
Adverse events after endoscopic mucosal resection for duodenal adenomas in univariate analysis.

		AE (n = 37)	No AE (n = 130)	n	p
Numbers of clips	0	24 (29.3%)	58 (70.7%)	82	0.003
	≥ 1	13 (15.3%)	72 (85.7%)	85	
Size, in mm	< 30 mm	12 (12.7%)	82 (87.2%)	94	< 0.001
	> 30 mm	25 (34.2%)	48 (65.8%)	73	
Resection snare	Braided or condensed multifilament snare	12 (15.2%)	67 (84.8%)	79	0.04
	Monofilament snare	25 (28.4%)	63 (71.6%)	88	
AE: adverse events, n: number					

Table 4
Adverse events after endoscopic mucosal resection for duodenal adenomas in multivariate analysis.

		Odds-Ratio	p
Size, in mm	≥ 30 vs 10–29 mm	2.81 [1.27; 6.47]	**0.012**
Resection snare	Mono vs. multifilament	2.03 [0.922; 4.66]	0.084
Numbers of clips used	0 vs. 1	0.534 [0.234; 1.19]	0.11

A lesion size > 30 mm (62% vs. 38%, p = 0.046) and a type 0-Is of the Paris classification (77% for 0-IIa lesions; 23% for 0-Is lesions; 0% for 0-Ip lesions, p = 0.044) were significantly associated with a greater occurrence of delayed bleeding.

Management of adverse events after endoscopic resection

Delayed bleeding was managed during a second endoscopy by clipping the bleeding site (14/26 patients, 53.8%) patients, by applying hemostatic compounds, such as Purastat (3D Matrix, Japan) or Hemospray

(Cook Medical, USA) in 5/26 (19.2%) patients, or by conservative medical treatment in 7/26 (26.9%) patients. Thirteen (50%) patients had red blood cell transfusions with median (IQR) of 2 (5 − 2) red blood cell.

In case of immediate perforation, through the scope clips were used in 2/4 (50%) patients to close the defect, an over the scope clip was used in 1/4 (25%) patient and surgery was necessary in 1/4 (25%) patient.

Delayed perforation was managed surgically in 2/4 (50%) patients, or by placing through the scope clips (1/4, 25%) or an over the scope clip (1/4, 25%).

The median (IQR) hospital stay was significantly longer in patients experiencing AE vs no AE (4 (2–8) vs 2 (2–2), $p < 0.001$), delayed bleeding (4 (2–7), $p < 0.01$), immediate perforation (9.5 (6–16), $p < 0.01$) and delayed perforation (18 (15–21), $p < 001$). No patient died following duodenal EMR.

Recurrence

For the analysis of recurrence, we included all patients with at least one follow-up endoscopy. A total of 117 patients were included. Local recurrence occurred after 65/117 (55.6%) endoscopic resections of centimetric or supracentimetric duodenal adenomas. Univariate analysis showed that a FAP syndrome (92.3% vs. 45.1%, $p < 0.001$), a piecemeal resection (62.3% vs. 42.5%, $p = 0.041$), and positive resection margins (62.8 vs. 35.5%, $p = 0 < 0.01$) were potential risk factors for local recurrence (Table 5). The first endoscopic follow-up was normal in 52/117 (44.4%) patients, and the second in 24/65 (36.9%) patients. Among patients with recurrence, there were a median (IQR) of 2 (3 − 1) endoscopic resections. 2/167 (1.2%) patients underwent surgery after endoscopic treatment failure.

Table 5
Factors influencing local recurrence after endoscopic mucosal resection for duodenal adenoma, univariate analysis

		Recurrence (n = 65)	No Recurrence (n = 52)	n	p
FAP	Yes	24 (92.3%)	2 (7.7%)	26	0.042
	No	41 (45.1%)	50 (54.9%)	91	
Positive resection margins	Yes	54 (62.8%)	32 (37.3%)	86	< 0.01
	No	20 (65.5%)	11 (35.5%)	31	
Resection	En-bloc	17 (42.5%)	23 (57.5%)	40	0.031
	Piecemeal	48 (62.3%)	29 (37.7%)	77	

FAP: Familial adenomatous polyposis

Discussion

Among 167 SNADETs over a period of 5 years, we recorded a 22.2% rate of clinically significant AE, and found a lesion size ≥ 30 mm to be the only statistically significant risk factor for AE. Noticeably, the risk of AE was not increased associated with patients' or lesions' characteristics, and currently recommended technique prophylactic measures, such as the closure of the resection bed with clips, had no influence on the risk of AE.

Retrospective studies suggested that delayed bleeding occurred in 4.4–17.4% of cases after EMR of duodenal adenomas [10–17], and that the risk increased with the size of the lesion and the presence of a protruding (Paris type 0-Is) lesion. In a prospective study including 110 lesions and 118 patients, delayed bleeding occurred in 18.6% of cases[18]. Aschmoneit-Messer et al., in a prospective study including 50 patients and 61 lesions, showed that prophylactic argon plasma coagulation (APC) of the resection bed lowered the risk of delayed bleeding after EMR of duodenal adenomas > 20 mm and/or in case of visible vessels ≥ 1 mm[19]. Lepilliez et al., in a retrospective study including 36 patients and 37 lesions, found that no delayed bleeding occurred in patients treated by prophylactic clipping or prophylactic argon plasma coagulation, or in patients treated for intraprocedural bleeding. In the meantime, delayed bleeding occurred in 21.7% of the rest of the patients[16]. Nonaka et al., in a retrospective study including 113 patients and 121 lesions, showed that delayed bleeding rate dropped from 32–7% in cases of prophylactic clipping ($p < 0.004$)[17]. Therefore, ESGE guidelines recommend prophylactic treatment of delayed bleeding by placing clips to close the mucosal defect or by non-contact hemostatic measures[5]. While the 15.6% delayed bleeding rate was in keeping with the literature data, we did not observe any statistically significant benefit of clipping the resection bed. This is likely to be explained by the large size of the resected lesions, with over 45% of lesions > 30 mm, precluding a complete closure of the resection bed with clips.

Immediate perforation, defined by a breach in the muscularis propria during endoscopic resection, occurs in 2.2-6% of the resections[10–17]. The management of immediate perforations consists in the closure of the perforation with clips, preferably after completing the resection. Perforation typically occur in pretreated or multibiopsied lesions with submucosal fibrosis, or insufficient submucosal injection. In our cohort, immediate perforation occurred in 2.4% of the resections.

Delayed perforations of the duodenal wall, caused by the thermal damage to the muscularis propria, possibly in conjunction with chemical aggression by bile acids, is the most feared AE after endoscopic resection. After EMR for duodenal adenomas, the reported rates range from 1.7 to 7.4%, and account for the 1% mortality associated with this procedure[10–17]. Our findings were in line with these numbers, with no mortality, and also illustrate the feasibility of endoscopic management of delayed perforations.

Based on retrospective studies, local recurrence rate ranges from 9 to 37%[10,13–15]. It appears to be maximal for piecemeal resections of lesions > 20 mm in size. We found an overall 55.6% recurrence rate and identified FAP syndrome, piecemeal resection, positive resection margins as risk factors. These high

numbers can be explained by the high proportion of patients with FAP, and the large size of the lesions resected in our cohort.

The strengths of our study were the large number of resections, performed in consecutive and prospectively recorded patients at a single center, including large and giant lesions, with available follow-up data, allowing to assess the recurrence rates. Main limitations are the heterogeneity of the resection tools, reflecting the number of operators involved, and the retrospective analysis of the outcomes.

In conclusion, EMR for supracentimetric duodenal adenomas is associated with AE such as delayed bleeding or delayed perforation in 22.2% of the cases, particularly in lesions ≥ 30 mm. Preventive measures, such as the complete closure of the mucosal defect with clips is often technically impossible in large lesions, while prophylactic coagulation of the resection bed might increase the risk of delayed perforation. Novel preventive techniques, such as wound covering agents, or suturing of the duodenal mucosa, could help in limiting the high rate of adverse events following duodenal endoscopic mucosal resection.

Declarations

Author contributions:

MA analyzed information sources and drafted the manuscript

MB supervised and corrected the manuscript

MD provided a significant critical revision of the manuscript

AB analyzed and interpreted the data and provided a revision of the manuscript

RC and SC provided a significant critical revision of the manuscript

FP, EAB, AP, RH, AD, BT provided a revision of the manuscript

Conflict of interest:

MB discloses receiving honoraria from Medtronic and participation to boards for Norgine. The other authors did not disclose any conflict of interest.

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Figures

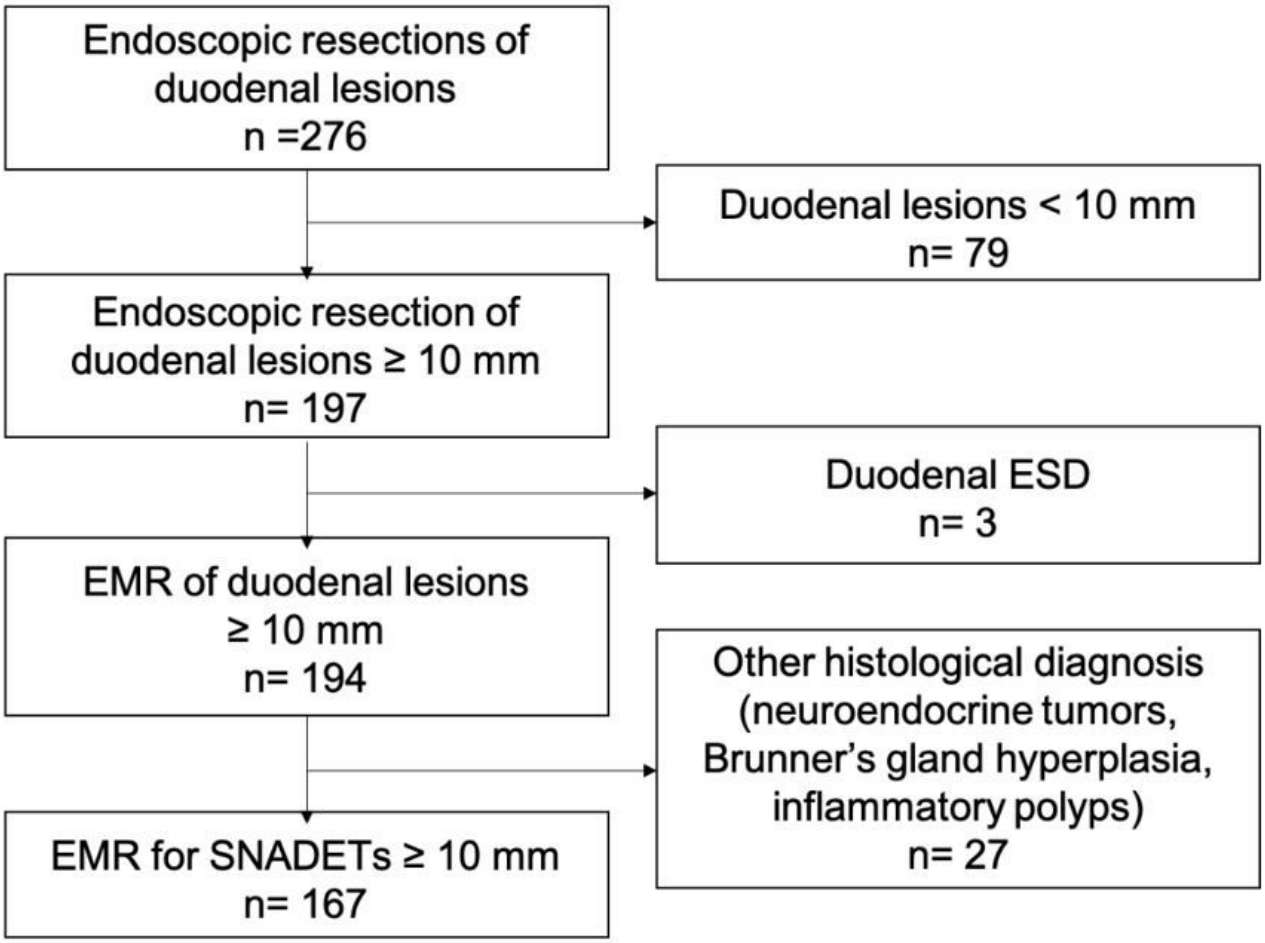

Figure 1

Study Flowchart