GE – Portuguese Journal of Gastroenterology

Research Article

GE Port J Gastroenterol 2024;31:33–40
DOI: 10.1159/000528102

Received: July 7, 2022
Accepted: October 23, 2022
Published online: January 19, 2023

Endoscopic Submucosal Dissection for Resections Larger than 10 cm: Outcomes from a Portuguese Center

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Keywords
Endoscopic submucosal dissection · Early gastrointestinal cancer · Therapeutic endoscopy

Abstract
Background: Endoscopic submucosal dissection (ESD) is a minimally invasive technique for en bloc resection of superficial neoplastic lesions, independent of their size. However, for giant gastrointestinal superficial neoplasia, the risk of invasive cancer is higher, and ESD is typically challenging. Despite the increasing literature on giant resections, data on their efficacy and safety are still lacking. ***Objective:*** The aim of this study was to describe ESD outcomes from a Portuguese center, compare them with other international studies, and analyze the possible risk factors influencing outcomes. ***Methods:*** We conducted a retrospective single-center review using a prospectively collected database, including patients with rectal ESD resections larger than 10 cm, between January 2016 and December 2021. Clinical, procedural, and pathological data were collected and analyzed. Revision of the literature for comparison with international results was done through PubMed. Data were analyzed and statistical analysis performed, using Microsoft Excel and SPSS, to identify significant risk factors. ***Results:*** The study included 15 rectal resections, with a mean diameter of 140.9 mm (range 105–270), corresponding to lesions of 125.9 mm (87–238). The overall en bloc resection rate was 100% (n = 15). According to ESGE criteria, procedure was considered curative in 53.3% (n = 8), non-curative with high risk in 13.3% (n = 2), and local-risk recurrence in 33.3% (n = 5). Adverse events occurred in 26.7% (n = 4): 1 minor perforation and 3 stenosis, most endoscopically managed. For non-curative resections with local-risk recurrence, surveillance without adjuvant therapy was performed in all cases. For high-risk non-curative resections, surgery was performed in 1 patient and adjuvant chemoradiation therapy in another. Follow-up (mean 16 months) demonstrated a recurrence rate of 0%. Statistical analysis revealed resection size ≥20 cm as a risk factor for perforation (p value 0.067), and involvement of ≥90% of the circumference and procedural time ≥4 h as risk factors for stenosis (p value 0.029 and 0.009, respectively). ***Conclusions:*** Although challenging, ESD for giant lesions seems effective and safe, with a still relevant rate of complications, which were mostly endoscopically treated. Rigorous characterization of lesions is crucial to predict and avoid complications or the need for therapy escalation.

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Disseção endoscópica da submucosa em resseções maiores que 10 cm: outcomes de um centro português

Palavras Chave
Disseção endoscópica da submucosa · Cancro gastrointestinal precoce · Endoscopia terapêutica

Resumo
Background: A disseção endoscópica da submucosa (DES) é uma técnica minimamente invasiva para resseção em bloco de tumores superficiais, independentemente do seu tamanho. No entanto, nas neoplasias superficiais gastrointestinais gigantes, o risco de cancro invasivo está aumentado e a DES é tipicamente desafiante. Apesar do incremento da literatura acerca de resseções gigantes, dados da sua eficácia e segurança são ainda escassos. ***Objetivo:*** Descrição de outcomes de DES de um centro português e comparação com estudos internacionais. Análise de eventuais fatores de risco influenciando os outcomes. ***Métodos:*** Revisão retrospetiva de um centro, usando a sua base de dados prospectivamente colhida, incluindo pacientes com resseções rectais por DES maiores que 10 cm, entre janeiro 2016 e dezembro 2021. Dados clínicos, endoscópicos e patológicos foram colhidos e analisados. A literatura foi revista através do PubMed, para comparação com resultados internacionais. A análise dos resultados e estatística foi realizada, utilizando o Microsoft Excel e SPSS, para a identificação de fatores de risco com impacto significativo nos outcomes. ***Resultados:*** O estudo incluiu um total de 15 resseções retais, com uma média de diâmetros de 140,9 mm (intervalo 105–270), correspondendo a lesões 125,9 mm (intervalo 87–238). A taxa de resseção em bloco foi de 100% ($n = 15$). Segundo os critérios da ESGE, o procedimento foi curativo em 53,3% ($n = 8$), não curativo com alto risco em 13,3% ($n = 2$) e com risco de recorrência local em 33,3% ($n = 5$). Eventos adversos ocorreram em 26,7% ($n = 4$): 1 microperfuração e 3 estenoses, a maioria geridas endoscopicamente. Os 5 casos não curativos com risco de recorrência local ficaram apenas sob vigilância. Nas ressecções não curativas de alto risco, um paciente foi submetido a cirurgia e outro a quimioradioterapia adjuvante. O follow-up (média de 16 meses) demonstrou uma taxa de recorrência de 0%. A análise estatística demonstrou o tamanho da ressecção ≥20 cm como fator de risco significativo para perfuração (p value 0.067); e envolvimento de ≥ 90% da circunferência do lúmen e tempo de procedimento ≥4h como fatores de risco significativos para estenose (p value 0.029 e 0.009, respetivamente). ***Conclusão:*** Apesar de desafiante, a DES para lesões gigantes parece eficaz e segura, com uma taxa de complicações importante, possíveis de tratamento endoscópico. A caracterização rigorosa destas lesões é crucial para predizer e evitar complicações ou a necessidade de escalada terapêutica.

Introduction

Endoscopic submucosal dissection (ESD) is a recently differentiated minimally invasive endoscopic technique used for the resection of superficial gastrointestinal lesions that cannot be completely addressed by conventional endoscopic mucosal resection (EMR) nor are invasive enough to undergo surgery. According to the updated European Society of Gastrointestinal Endoscopy (ESGE) guidelines, ESD is the treatment of choice for several gastrointestinal lesions, including large pre-carcinomatous adenomas and early (T1) cancers. Indications depend on precise characterization of the lesion and its aggressiveness, which is preferably achieved by high-definition white-light and virtual chromoendoscopy, allied to internationally validated classifications such as the Paris, NICE, and JNET ones. In general, no other imaging study is required before dissection [1].

Comparing to EMR or surgery, ESD entails numerous advantages and limitations. Compared with EMR, ESD has higher en bloc and complete resection rates and lower recurrence rates. However, it implies a higher perforation risk, technical difficulty, and procedural time. Compared with surgery, ESD is associated with lower procedural time, length of hospital stays and costs, adverse events, and procedure-related morbidity and mortality. However, a higher recurrence risk and lower disease-free survival are generally associated [1, 2]. Therefore, an accurate decision based on the lesion's resectability, the patient's performance status, and the instrumentalist's expertise is crucial [3].

This study focuses on giant ESD resections (>10 cm) located in the rectum. Currently, rectal ESD should be considered for lesions endoscopically suspected of only limited submucosal invasion (demarcated depressed area with irregular surface pattern or large protruded or bulky component) or that cannot be completely removed by EMR [1].

Giant ESD resections are usually challenging and have been associated with longer procedural time and higher

adverse event rates (bleeding and perforation). The en bloc resection and curative rate have been comparable to smaller lesions, with no posterior salvage surgeries, strictures, local recurrences, or metastasis [2]. Numerous studies have discriminated tumor size, submucosal fibrosis, invasive depth, and procedure time as risk factors for complications and incomplete resections [4].

Despite increasing literature on giant resections, data on their efficacy and safety are still lacking. Overall, we propose to analyze our outcomes for rectal resections larger than 10 cm, comparing them to other international experiences. Additionally, we propose to identify any possible risk factors significantly associated with different outcomes or complications.

Materials and Methods

This is a single-center uncontrolled study conducted by the Gastroenterology Department at *Centro Hospitalar de Lisboa Ocidental* (CHLO) in Lisbon, Portugal. Consecutive patients with rectal resections larger than 10 cm submitted to ESD from January 2016 to December 2021 were included. A total of 15 rectal ESDs were performed. All patients were informed about the risks and benefits of ESD, and provided written informed consent. Patient information, follow-up exams, and consultations were obtained from their electronic medical record or telephonic contact. Outcomes included en bloc and curative resection rates, complications, the need for future endoscopic management, chemoradiation therapy or surgery, disease recurrence, and disease-related mortality. Statistical analysis for patient and lesions' characteristics, outcomes, and identification of possible risk factors significantly related to them was done through Microsoft Excel (version 2018) and SPSS (version 29). Comparison with other international studies was obtained through search and evaluation of already published scientific articles in PubMed.

ESD Procedure

All ESD procedures were performed by the same therapeutic endoscopist (PB) in a onetime session. Patients were under general sedation and endotracheal intubation by an anesthesiologist. In longer procedures, patients were covered with blankets and warmed up to avoid hypothermia. A transparent cap on the endoscope tip and CO_2 insufflation were used. Lesions were previously analyzed by white light and narrow-band imaging to detect signs of invasiveness. Submucosal injection was done with a mixture of 4% gelatin solution (Gelafundin 4%, B. Braun Melsungen AG, Germany), indigo carmine dye, and adrenaline (1:250,000). Electrocautery marking, mucosal incision, and submucosal dissection were performed using the Flush knife (Fujinon-Toshiba ES System Co., Omiya, Japan) alone or in combination with IT knife nano (KD-612L, Olympus). The electrosurgical ERBE ICC 200 generator unit (ERBE Elektromedizin, Tubingen, Germany) was set at "Endocut" (effect 3, 60 W) for mucosal incision, "Forced Coag" (45–55 W) for submucosal dissection, and "Soft Coagulation" for hemostasis (45–55 W). The scar's visible vessels were routinely electrocoagulated to prevent delayed bleeding. By routine, multiple tunneling and patient mobilization methods were used. No traction or pocket-creation methods were used. For piece recovery, a large snare was routinely used with anal lubrification and digitation help. After the procedure, all patients stayed hospitalized for clinical surveillance according to protocol. Follow-up bloodwork or exams were requested only if complications were suspected. For endoscopic resections with more than 75% circumferential resection, prophylactic topical corticotherapy (budesonide) was used. Endoscopic reports included macroscopic description of lesions (location, size, and Paris and JNET classifications) and procedural description (time, methods, en bloc resection, early adverse events).

Histopathology Assessment

All ESD resected specimens were pinned down with needles, measured, fixed in 4% neutral buffered formalin, and sent to the pathology department. Pathology reports included dimension, histology (Vienna classification), differentiation, involvement of resection margins (RX resection), budding, and lymphovascular invasion.

Definitions

En bloc resection was considered when removal of the entire lesion in a single piece was achieved. Complete R0 resection referred to ≥1 mm tumor-free horizontal margin and negative vertical margins on histology. Resections were classified as curative, non-curative with high-risk, or non-curative with local-risk recurrence, according to the updated ESGE criteria. Adverse events assessed included intraoperative or delayed perforation, bleeding, and stenosis. Intraoperative perforation was defined as an injured muscle layer with peritoneal cavity or fat tissue visualization identified during the procedure. Delayed perforation was defined as perforation manifested clinically (such as fever, abdominal pain, clinical instability) with imaging studies showing fluid collections and/or free intraperitoneal air. Bleeding was considered major if it was not controlled by endoscopy (need for surgery or radiological intervention) or if there was a need for transfusion or clinical instability. Minor bleeding included the need for change in the procedural plan (for instance, application of hemoclips) or >5 min for endoscopic control. Delayed bleeding referred to hematochezia or hemoglobin fall of >2 g/L in the first 30 days after ESD. Stenosis was defined as a luminal narrow and inability to pass a pediatric colonoscope or clinical symptoms of sub-occlusion/occlusion.

Results

Description of Resections and Outcomes

A total of 15 patients underwent giant rectal ESD resections between January 1st, 2016, and December 31st, 2021, at our center. The clinicopathological characteristics and results are summarized in Table 1.

The mean age was 67 years (range 38–85), with a male to female ratio of 9:6. The mean larger diameter of the resection piece was 140.9 mm (range 105–270) and lesion was 125.9 mm (87–238), with 53.3% (n = 8) involving ≥75% of the lumen circumference, and 13.3% (n = 2)

≥90%. Lesions were located in >1 rectal segment (*n* = 12, 80.0%) and distal rectum (*n* = 3, 20.0%), with 60% (*n* = 9) involving the pectinate line. Macroscopic morphology demonstrated 11 LST-G (73.3%, 1 homogenous, and 10 nodular mixed) and 4 LST-NG (26.7%). In virtual chromoendoscopy, lesions were JNET 2B in 73.3% and JNET 2A in 26.7%. All lesions were naive to previous therapeutics. Figure 1 illustrates the procedure related to one of the nodular-mixed LST-G resections.

The mean procedural time was 220 min (range 80–540 min) and mean post-procedural hospital stay was 2 days (range 1–5 days). En bloc resection was achieved in 100% (*n* = 15). Procedural complications occurred in 4 patients (26.7%), being discriminated as intraprocedural microperforation in 6.7% (*n* = 1) and delayed local stenosis in 20.0% (*n* = 3). The perforation was successfully closed by endoscopic clipping. No bleeding complications were observed, early or delayed. Regarding stenosis, all lesions involved the pectinate line and ≥75% of the lumen's circumference (2 of them involved ≥90% of the circumference). Of these patients, one was submitted to surgery because of concomitant high-risk non-curative resection, and the other two were submitted to endoscopic dilation, with favorable clinical response. Fibrosis and muscle retracting sign were observed in 33.3% of cases (*n* = 5). None of the procedures was interrupted because of complications nor was converted into surgery.

Pathologically, there were 3 submucosal carcinomas (20.0%), with a mean of 1,617 micromillimeters of deep invasion. The remainder of the lesions were adenomas: 7 tubulovillous (46.7%), 3 sessile serrated (20.0%), 1 tubular (6.7%), and 1 villous (6.7%), divided into 9 with high-grade (75.0%) and 3 with low-grade (25.0%) dysplasia.

On histology, R0 resection was achieved in 8 patients (53.3%). Patients who did not achieve R0 included 5 (33.3%) with only positive horizontal margins (RX), 1 (6.7%) with only positive vertical margin (R1), and 1 (6.7%) with both margins positive (R1). Budding and/or lymphovascular invasion were noted in 2 (13.3%) patients. According to the ESGE criteria, resections were considered curative in 8 patients (53.3%), non-curative with high risk in 2 (13.3%), and local risk in 5 (33.3%). In the latter, 60% (*n* = 3) involved the pectinate line. Characterization of non-curative resections is summarized in Table 2.

Additional treatments (chemoradiation or surgery) were indicated in 2 patients (13.3%): 1 had been submitted to surgery and 1 had undergone chemoradiation, with no recurrence detected. For the other patients, endoscopic follow-up was recommended (3–6 months for RX and 1 year for R0). The mean follow-up interval was 16.0 months, where 76.9% (*n* = 10) respected the recommended surveillance, with no recurrence identified (rate, 0%).

Table 1. Clinicopathologic characteristics and treatment results

Characteristic/result	Value
Age, mean (range), years	67 (38–85)
Gender, male:female	9:6
Resection size, mean (range), mm	140.9 (105–270)
Lesion size, mean (range), mm	125.9 (87–238)
Lesion location, *n* (%)	
>1 rectal segment	12 (80.0)
Distal rectum	3 (20.0)
Pectinate line involvement	9 (60.0)
Macroscopic type, *n* (%)	
LST-G	11 (73.3)
LST-NG	4 (26.7)
Circumferential involvement, *n* (%)	
<75%	7 (46.7)
75–89%	6 (40.0)
90–99%	1 (6.7)
100%	1 (6.7)
Fibrosis/MRsign, *n* (%)	5 (33.3)
Histology, *n* (%)	
Low-grade adenoma	3 (20.0)
High-grade adenoma	9 (60.0)
Submucosal invasion	
SM1 (<1,000 μm)	2 (13.3)
SM2 (>1,000 μm)	1 (6.7)
En bloc resection, *n* (%)	15 (100.0)
Curative resection (R0), *n* (%)	8 (53.3)
Non-curative, *n* (%)	
High-risk (R1)	2 (13.3)
Local-risk (RX)	5 (33.3)
Perforation, *n* (%)	1 (6.7)
Stenosis, *n* (%)	3 (20.0)
Procedure time, min (range)	220.4 (80–540)
Hospital stay time, days (range)	2 (1–5)

MRsign, muscle retracting sign.

Statistical Analysis

Regarding curative rates and complications (perforation and stenosis), univariate analysis through Fisher's exact test in SPSS was applied in order to identify significant risk factors for these outcomes. Analysis revealed resection size ≥20 cm as significantly associated with perforation (*p* value 0.067) and involvement of ≥90% of the lumen's circumference and procedural time ≥4 h as significantly associated with stenosis (*p* value 0.029 and 0.009, respectively). No other factors were found to be significantly associated with the rate of complications or

Table 2. Description of non-curative high-risk and local-risk resections

Size, mm	Macroscopy	Location	Indicators	Follow-up
105	LST-G H	>1 R segment	HM+	No recurrence
150	LST-G N	>1 R segment	HM+	No recurrence
87	LST-G N	Distal rectum	SM2, HM+, VM+, LV+, B+	Surgery
130	LST-NG F	>1 R segment	HM+	Missed
111	LST-G N	Distal rectum	HM+	No recurrence
100	LST-NG F	>1 R segment	HM+	No recurrence
170	LST-G N	>1 R segment	SM1, VM+, B+	Chemoradiation

LST-G, granular laterally spreading tumor; LST-NG, nongranular laterally spreading tumor; N, nodular; F, flat; H, homogeneous; R, rectal; SM, submucosal; HM, horizontal margin; VM, vertical margin; LV, lymphovascular invasion; B, budding.

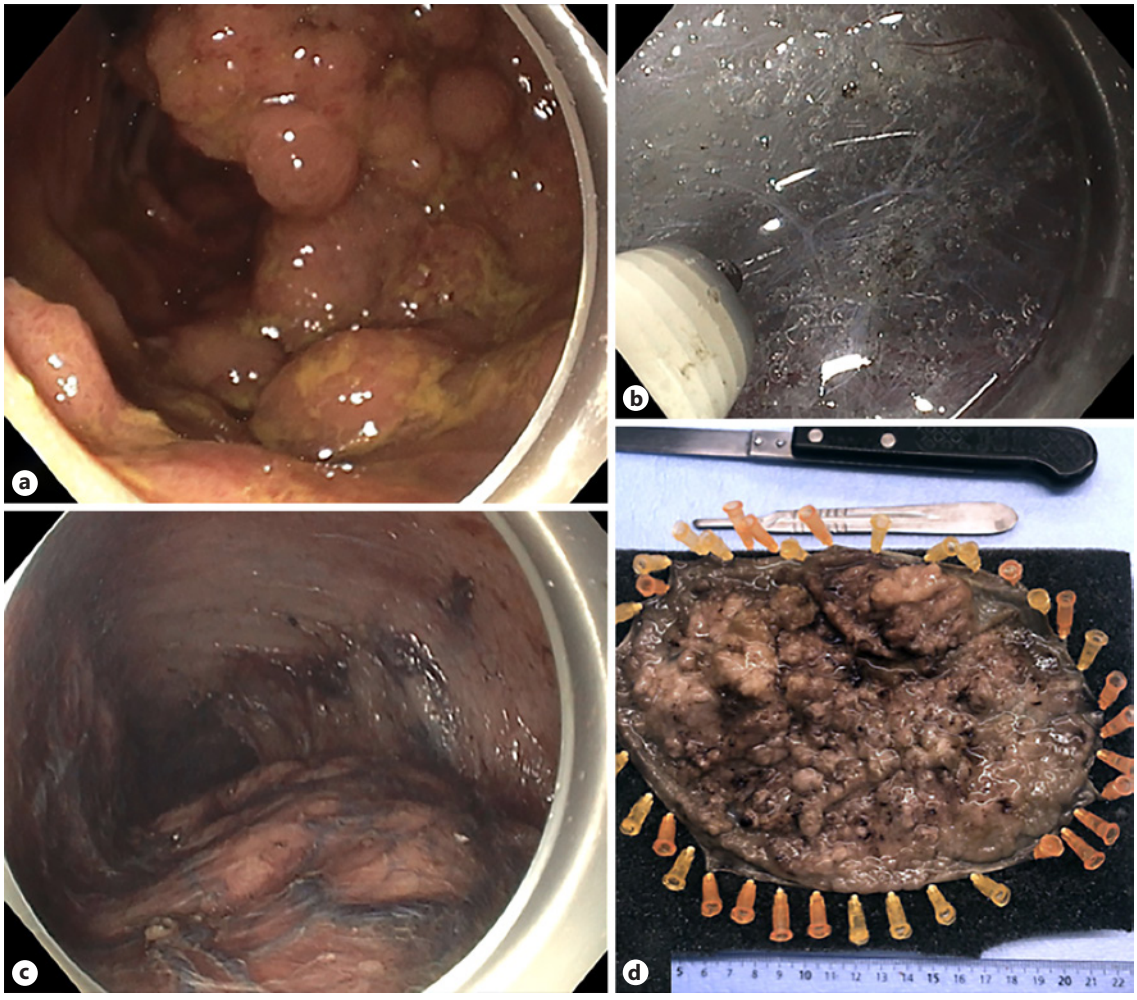

Fig. 1. Resection of a rectal nodular mixed LST-G. **a** Endoscopic appearance of a giant rectal lesion. **b** Submucosal dissection using a non-insulated tip knife. **c** Advanced phase of the procedure where the lesion lies below and the mucosal defect above. **d** Resection piece after formalin fixation.

Table 3. Univariate analysis for factors affecting non-curative resection

	Curative (*n* = 8)	Non-curative (*n* = 7)	*p* value
Curative versus non-curative resection			
Procedure time ≥4 h, *n* (%)	1 (13)	3 (43)	0.282
Resection size ≥20 cm, *n* (%)	1 (13)	0 (0)	1.000
Fibrosis/MRsign, *n* (%)	3 (38)	2 (29)	0.608
≥75% circumference, *n* (%)	5 (63)	3 (43)	0.315
JNET 2B classification, *n* (%)	6 (75)	5 (63)	0.569
Pectinate line, *n* (%)	5 (63)	4 (57)	0.608

MRsign, muscle retracting sign.

Table 4. Univariate analysis for factors affecting risk of perforation

	Perforation (*n* = 1)	No perforation (*n* = 14)	*p* value
Perforation versus no perforation			
Procedure time ≥4 h, *n* (%)	0 (0)	4 (29)	1.000
Resection size ≥20 cm, *n* (%)	1 (100)	0 (0)	0.067
Fibrosis/MRsign, *n* (%)	1 (100)	4 (29)	0.333
≥75% circumference, *n* (%)	0 (0)	8 (57)	0.467
JNET 2B classification, *n* (%)	1 (100)	10 (71)	1.000
Pectinate line, *n* (%)	1 (100)	8 (57)	1.000

MRsign, muscle retracting sign.

curative status, such as procedure time, the presence of fibrosis, JNET classification, and the involvement of the pectinate line (shown in Tables 3–5).

Table 5. Univariate analysis for factors affecting risk of stenosis

	Stenosis (*n* = 3)	No stenosis (*n* = 12)	*p* value
Stenosis versus no stenosis			
Procedure time ≥4 h, *n* (%)	3 (100)	1 (8)	0.009
Resection size ≥20 cm, *n* (%)	0 (0)	1 (8)	1.000
Fibrosis/MRsign, *n* (%)	1 (33)	4 (33)	1.000
≥90% circumference, *n* (%)	2 (67)	0 (0)	0.029
JNET 2B classification, *n* (%)	2 (67)	9 (75)	1.000
Pectinate line, *n* (%)	3 (100)	6 (50)	0.229

MRsign, muscle retracting sign.

Discussion

ESD is a technically difficult procedure, available worldwide, used for the treatment of early gastrointestinal cancers or precancerous lesions. In this study, our ESD outcomes for giant gastrointestinal lesions have been reported. The en bloc and the curative resection rates were 100.0% and 53.3%, respectively, and the adverse event rate was 26.7%, mostly managed endoscopically. Resections with risk of local recurrence (RX) accounted for 33.3%, with 0% of recurrence rate during a mean of 16 months of follow-up. Previous studies revealed better rates; however, most are not comparable as they are not related to giant lesions. In one study (*n* = 9), the en bloc and curative resection rates of ESD for giant colorectal LST were 88.9% and 100%, respectively, with a higher rate of adverse events (44.4%) [2]. In another study (*n* = 10) of ESD for giant colorectal LST, the en bloc and curative resection rates were 100% and 90%, respectively, with 40% of adverse events [5]. As shown in Table 2, ESD was considered non-curative with high-risk or local-risk recurrence because of positive horizontal and/or vertical resection margins, submucosal invasion, lymphovascular involvement, or budding. During follow-up of these high-risk non-curative resections, 1 was submitted to surgery and 1 underwent chemoradiation, without any complications or recurrence. Of the patients with significant local recurrence risk, most respected follow-up, and none suffered disease recurrence until the time of the study. However, most follow-up times were less than 2 years.

As for factors affecting the curative resection rate, our analysis was not able to show any significant difference regarding factors such as procedure time, tumor size, the presence of fibrosis, or JNET evaluation (Table 3). This is not concordant with previous studies that correlated tumor size, submucosal fibrosis, invasive depth, and procedure time with incomplete resection [4]. Differences might be related to the small number of cases in our study and to our sample's universe being filtered to >10 cm lesions, which is rare and innovative and, therefore, not comparable with results from series of all kinds of ESD.

Regarding complications, our sample analysis revealed significant association between resection size and higher risk of perforation (Table 4). This is concordant with previous studies. A user-friendly risk score model for the prediction of risk of perforation has already been delineated, named SELF, which includes factors such as tumor size, endoscopist's experience, tumor location, and submucosal fibrosis [6]. In our study, location was not a variable, as all lesions were located in the rectum, the safest

site for ESD because of its thick wall and fixed position. There was 1 microperforation, treated endoscopically without the need for additional surgery.

Regarding stenosis, our analysis showed a significant association between involvement of ≥90% of the circumference and a higher risk of stenosis (Table 5). This result is concordant with previous literature, where in different gastrointestinal locations, lesions spreading to ≥75% and ≥90% of circumference were associated with higher stenosis rates [7]. Other studies have also associated the involvement of the dentate line with higher rates of postoperative pain and strictures, which was not significant in our sample [8]. Our patients had received some kind of stenosis prophylaxis (corticosteroids), which is still controversial and currently not recommended. From the 3 stenoses, 1 was operated on since the patient had concomitant high-risk non-curative resection, and the other 2 were submitted to endoscopic dilation with favorable responses. None had incapacitating symptoms. Regarding the association between procedural time and stenosis, it might be explained by the dependency of this variable on others (such as size, circumference involvement). Previous studies have only related procedure time to post-ESD coagulation syndrome [9].

As for bleeding complications, none were reported in our cohort, which might be explained by the routine prophylactic coagulation of visible vessels. There were several limitations to this study. First, we highlight the small sample size, one endoscopist, single-centered, and retrospective nature of the study. Second, no comparison was made with surgical outcomes of giant lesions or between groups of LSTs ≥10 cm versus <10 cm. A multicentered study with several endoscopists, higher sample and follow-up time is recommended to achieve more significant and generalizable results and outcomes. Variants of ESD with tunneling and pocket-creation methods might also be studied [10].

Moreover, according to our previous studies, a minimum of 30 procedures must be carried out to significantly increase en bloc resection, and 90 procedures are needed to achieve a R0 resection rate >75%, with concomitant speed improvement. Indeed, we suggest that, ideally, only experienced endoscopists (preferably with >90 previous procedures) should carry out giant resections [11, 12].

In conclusion, ESD is an important novel organ-sparing therapeutic endoscopy for the treatment of early gastrointestinal neoplasia. Once the learning curve for ESD is overcome, previous studies have demonstrated that this technique is safe, effective, and worth pursuing.

Statement of Ethics

Ethical approval was not required for this study due to the retrospective design of the study, in accordance with local/national guidelines. Written informed consent to participate in the study was not required in accordance with local/national guidelines.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Funding Sources

There are no funding sources to declare.

Author Contributions

All authors contributed to the conception of the study, acquisition of data, its analysis and interpretation, revision, and final approval of the work.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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