ORIGINAL ARTICLE

AG-2022-59
doi.org/10.1590/S0004-2803.20220300075

# Efficacy analysis of endoscopic submucosal dissection for the early gastric cancer and precancerous lesions

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Received: 20 April 2022
Accepted: 17 June 2022

**ABSTRACT – Background –** Endoscopic treatment of precancerous lesions and early gastric cancer has been widely accepted in recent years. Endoscopic submucosal dissection (ESD), following established indication criteria, can lead to cure of the disease in more than 90% of cases. **Objective –** This study aimed to analyze the use of ESD in patients with early gastric cancer and precancerous lesions, as well as the results of the procedure, its complications and effectiveness in controlling the disease. **Methods –** This is a retrospective cohort study composed of 41 patients aged from 53 to 87 years (mean age: 65 years; 58.53% male) who were analyzed from 2008 to 2019. The variables collected from the medical records were: comorbidities, classification of the lesion regarding resection criteria, type of resection, histology, degree of invasion, resection margin, complications, disease recurrence. Statistical analysis was performed using the Kruskal-Wallis test, the McNemar's test, and the Mann-Whitney test, with 5% statistical significance ($P<0.05$). **Results –** The most frequent site of the lesion was the gastric antrum and the predominant presentation by the Japanese or Paris classification was the one with depressed components in 56.09%. Adenocarcinoma occurred in 75.6% of the biopsies, and the remainder were adenomas without neoplasia. En-bloc resection occurred in 97.57% of cases, and compromise of the safety margin occurred in one patient. The main pre-existing comorbidity was liver cirrhosis in 29.26% of cases. There was a significant increase in post- ESD adenocarcinoma compared to pre-resection diagnosis. The mean follow-up time was 38.4 months, with one recurrence (2.43%) and two metachronous lesions (4.87%). Complications during and after the procedure occurred in three patients (7.31%), being due to bleeding (two cases) and perforation (one case). There was one death due to a cardiac event not directly related to the procedure. **Conclusion –** Endoscopic submucosal dissection proved to be a safe procedure, with a low complication and recurrence rate. Its recommendation must occur within the established criteria; however, it can be indicated for patients outside the criteria, if there is a high risk for surgical treatment.

**Keywords –** Endoscopy; gastric neoplasms; endoscopic mucosal resection.

## INTRODUCTION

In 1962, the Japanese Society for Gastric Cancer Research defined early gastric cancer (EGC) as cancer whose depth of invasion is limited to the mucosa or submucosa, regardless of the presence of lymph node metastases or lesion size. That is, they are those lesions classified up to T1b by the TNM staging system[1,2].

There are two main macroscopic classifications of early gastric cancer. The Japanese Classification of Digestive Endoscopy subdivides the lesions into protruding, superficial, and excavated; in the superficial, we have the elevated, flat, and depressed. The Paris endoscopic classification (FIGURE 1), also used by the Japanese consensus, subdivides early gastric cancer into type 0-I (polypoid); type 0-II (nonpolypoid and non-excavated); and type 0-III (nonpolypoid with frank ulcer). Type 0-II includes three variants: slightly elevated (0-IIa); completely flat (0-IIb); and slightly depressed without ulcer (0-IIc)[3-7].

For suspicious lesions or with dysplasia, the Vienna classification (TABLE 1) is used, ranging from 1 to 5, which is already diagnosed as neoplasia[8].

**TABLE 1.** Vienna classification of gastrointestinal epithelial neoplasia.

| |
|---|
| Category 1 Negative for neoplasia/dysplasia |
| Category 2 Indefinite for neoplasia/dysplasia |
| Category 3 Non-invasive low grade neoplasia (low grade adenoma/dysplasia) |
| Category 4 Non-invasive high grade neoplasia |
| 4.1 High grade adenoma/dysplasia |
| 4.2 Non-invasive carcinoma (carcinoma in situ) |
| 4.3 Suspicion of invasive carcinoma |
| Category 5 Invasive neoplasia |
| 5.1 Intramucosal carcinoma |
| 5.2 Submucosal carcinoma or beyond |

Declared conflict of interest of all authors: none
Disclosure of funding: no funding received
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The indications for the endoscopic treatment of gastric cancer proposed by the Japanese Gastric Cancer Association have been expanded. Patients with mucosal-restricted, non-ulcerated, well-differentiated lesions larger than 2 cm, as well as those still mucosal-restricted, ulcerated, well-differentiated, smaller than or equal to 3 cm and lesions that invade up to 500 micrometers of the mucosal muscle (SM1), well differentiated and smaller than or equal to 3 cm, would be subject to curative endoscopic treatment by endoscopic submucosal dissection (ESD)[9].

In 2020, the Japanese Guideline for endoscopic treatment of early gastric cancer was updated[2]. The main updates were that lesions previously treated as an expanded indication for endoscopic treatment have been integrated into absolute indications. Lesions of the undifferentiated subtype, non-ulcerated, smaller than or equal to 2 cm restricted to the mucosa were included as an indication for performing ESD. Furthermore, those lesions described above characterized as early gastric cancer have become indications concerning it.

This study aimed to analyze the use of ESD in patients with early gastric cancer and precancerous lesions, as well as the results of the procedure, its complications and effectiveness in controlling the disease.

## METHODS

This is a retrospective cohort study carried out by reviewing medical records from 2008 to 2019, followeds up at the *Hospital das Clínicas* from Unicamp and at the Diagnostic Center for Digestive System Diseases (Gastrocentro). The study was approved by the Research Ethics Committee of FCM/UNICAMP, with CAAE no. 28848120.0.0000.5404.

Data from 41 patients were included with their age ranging from 53 to 87 years old (mean 65 years), with prevalence of males (58.53%).

Inclusion criteria were patients with early gastric cancer or suspicious lesions confirmed after histological study. No patient submitted to ESD in the period was excluded from the study.

The variables collected for the study were: age, sex, comorbidities, classification of the lesion (Paris Classification – FIGURE 1) in terms of resection criteria, type of resection, histology for early gastric cancer and Vienna classification (TABLE 1) for suspicions lesions, degree of invasion, resection margin, complications, disease recurrence (TABLE 2).

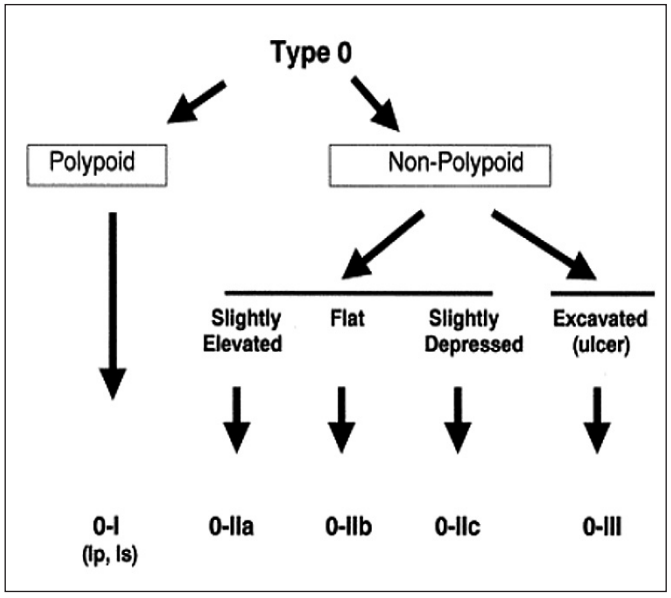


**FIGURE 1.** Paris endoscopic classification.

1. Technical aspects of ESD.

The accessories used for the resection were: Needle Knife (Olympus Inc., Japan), IT Knife2 (Olympus Inc., Japan), and a Flush Knife (Fuji Inc., Japan), as well as a transparent tip hood attached to the endoscopes and a high frequency electric scalpel (Olympus Inc., Japan).

The following steps were standardized and followed in all procedures: lesion identification (FIGURE 2); chromoscopy with 0.4% indigo carmine (FIGURE 3); demarcation of the periphery of the lesion with a needle knife (FIGURE 4); submucosal injection of a solution containing 250 mL of 10% mannitol, 1 mL epinephrine, and 2 mL 0.4% indigo carmine or hyaluronic acid; making small incisions circumferentially to the lesion made with the Needle Knife; and dissection of the submucosa with the IT knife and/or Flush Knife (FIGURE 5). Hemostasis was performed, when necessary, with coagulation forceps or endoscopic clips[10] and the specimen was sent for histopathological study (FIGURE 6).

Lesions were subdivided according to the Paris Classification (FIGURE 1) and grouped according to the lowest probability of submucosal invasion in group 1 (I, IIA, and IIA+IIB) and greater probability of submucosal invasion in group 2 (IIA+IIC, IIC, IIC+IIA, IIA+III).

The patients were followed up on an outpatient basis to see biopsy analysis of the piece resecting in the ESD and had a repeated endoscopic examination 60 days after submucosectomy to evaluate healing and repeat the biopsy in the resection area. After that, outpatient return was performed every 6 months and then annually with new upper digestive endoscopy and biopsies.

Statistical analysis was performed using the Kruskal-Wallis test to compare the time of the procedure between the lesion sites, the McNemar's test to evaluate the agreement between the pathological study before and after resection, the Mann-Whitney test to compare the resection time between groups 1 and 2 and Fisher's exact test was used to compare the degree of differentiation of adenocarcinomas between groups 1 and 2.

The significance level adopted for the statistical tests was 5% ($P<0.05$).

## RESULTS

Of the sample studied it can be observed that it was evidenced that most of the evaluated patients had a cardiovascular risk represented as ASA II and 29.26% of them had associated liver cirrhosis, in addition to other conditions in a lower percentage (TABLE 2).

Outpatient ESD was performed in 28 patients (68.29%), and 13 (31.71%) procedures were performed in the operating room under general anesthesia, in cases of higher risk of complications due to existing comorbidities (TABLE 2).

Most lesions were located in the gastric antrum, but with no statistically significant difference regarding the resection time for the other locations, *P*-value =0.2802 (Kruskal-Wallis test). The number of metachronous lesions was two (4.87%).

The mean resection time was 108.3 minutes and 136.8 minutes in group 1 and group 2, respectively, with a statistically significant difference ($P=0.0488$, $P<0.05$) (Mann-Whitney test) (TABLE 2).

**TABLE 2.** Data: epidemiological, histological, endoscopic submucosal dissection, time, complications, death.

| Number | Male | | Female | | *P* value |
|---|---|---|---|---|---|
| 41 | 24 | 58.53% | 17 | 41.47% | |
| Age | 53y–87y | X=65y | | | |
| Comorbidities | cirrhosis | 29.26% | | | |
| Procedure | Outpatient | | Hospital | | |
| | 28 | 68.29% | 13 | 31.71% | |
| Hystopatology | pré-ressection | | pós-ressection | | |
| adenoma | 18 | 43.9% | 10 | 24.39% | |
| adenocarcinoma | 23 | 56.1% | 31 | 75.61% | 0.0067 |
| In bloc ressection | 40 | 97.57% | | | |
| Committed margin | 1 | 2.43% | | | |
| Procedure time | Group 1 | | Group 2 | | |
| | 108.3 minutes | | 36.8 minutes | | 0.048 |
| Complications | 3 | 7.31% | 2 bleeding | 1 perforation | |
| Death | 1 | 2.43% | | unrelated to the procedure | |

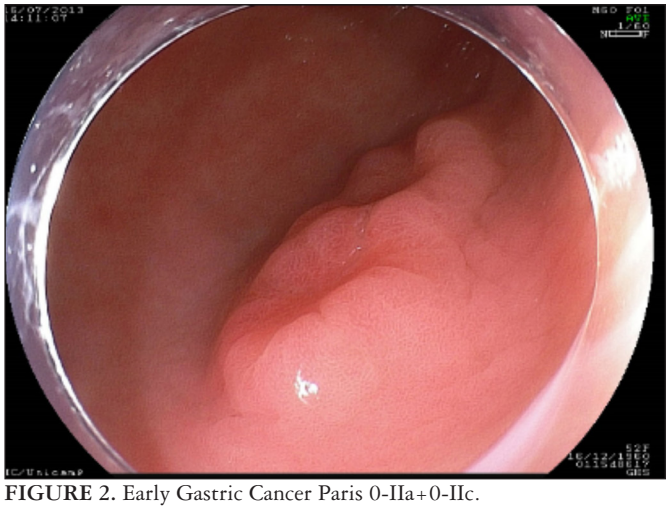

**FIGURE 2.** Early Gastric Cancer Paris 0-IIa+0-IIc.

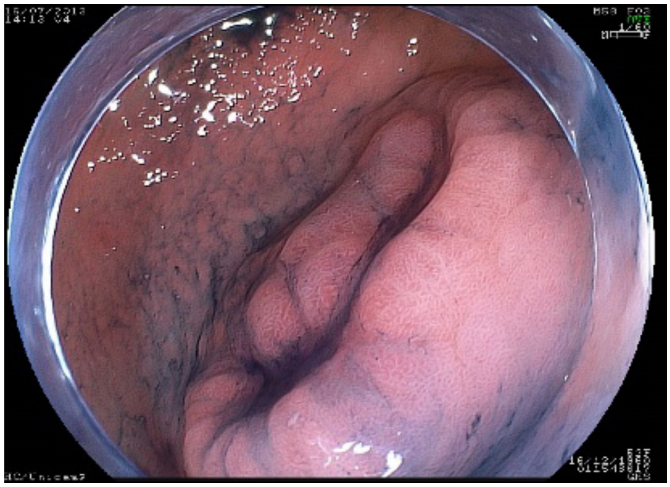

**FIGURE 3.** Chromoscopy with Indigo-Carmin.

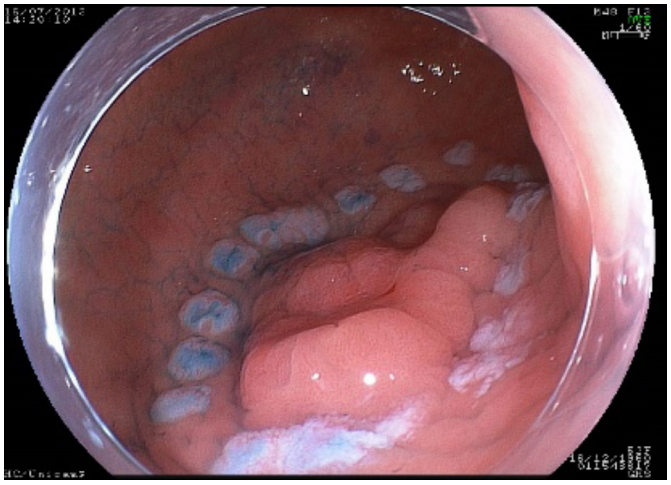

**FIGURE 4.** Demarcation of the lesion.

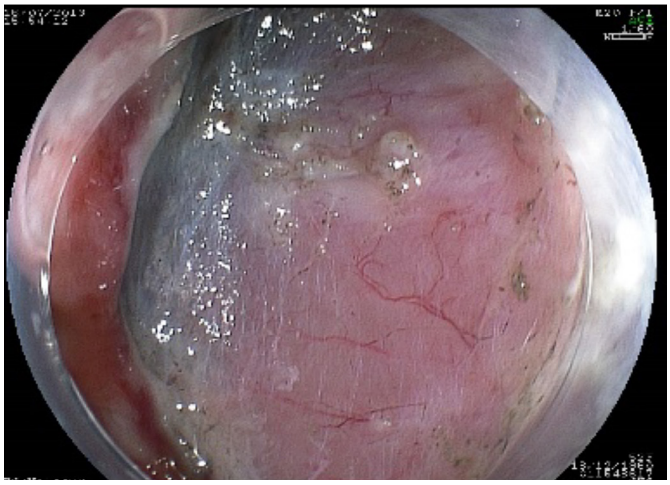

**FIGURE 5.** Final aspect after endoscopic submucosal dissection.

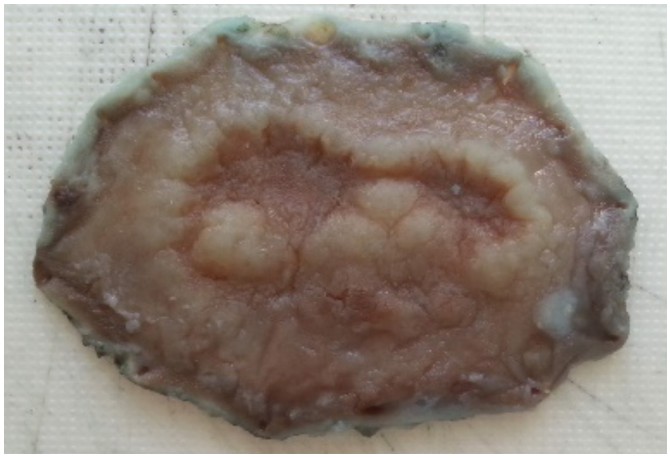

**FIGURE 6.** Piece - Anatomopathological: tubular adenoma in stomach with focus of NIEAG/DI (Vienna 4), Tis. Free margins.

Complications during and after the procedure occurred in three patients (7.31%), being two cases of bleeding and one case of perforation. There was one (2.43%) death due to a cardiac event not directly related to the procedure (TABLE 2).

The distribution of lesions by the Paris classification and the possibility of invasion was divided into Group 1 (I, IIA, and IIA+IIB) with 18 patients (43.90%) and in Group 2 (IIA+IIC, IIC, IIC+IIA, IIA+III) with 23 patients (56.10%) (FIGURE 7).

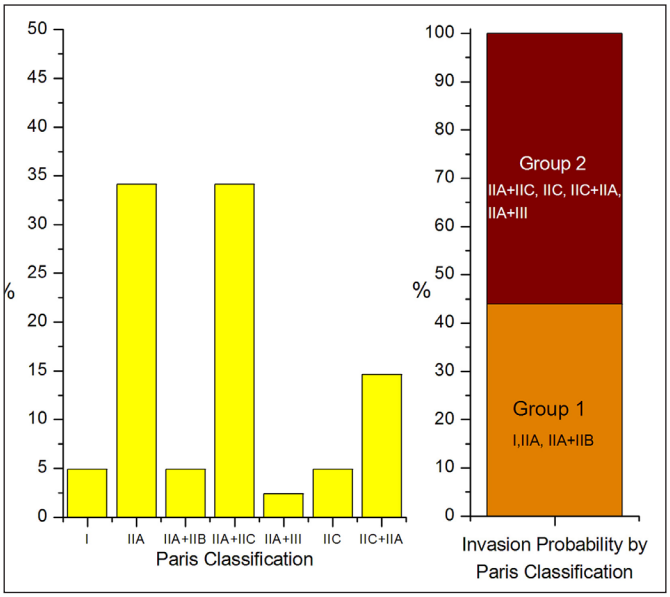


**FIGURE 7.** Percentage distribution of the Paris Classification and the probability of invasion.

The percentage distribution of pre-resection pathological findings showed that 23 casos (56.1%) of the lesions were adenocarcinoma, 91.03% of which were well differentiated, and that, of the 18 (44.9%) of adenomas, 55.55% were high-grade dysplasias. The same data after resection showed 31 (75.61%) of adenocarcinoma with a predominance of well-differentiated and 10 (24.39%) of adenomas, 50% of which were high-grade and 50% low-grade dysplasias. The mean size of the lesions was 31.4 mm (±10.4 mm) (TABLE 2).

The percentage distribution of endoscopic resection criteria, histopathological signs of lesion invasion, post-resection margins, and histopathological cure criteria are shown in FIGURE 8, with 40 (97.56%) of the lesions being resected en bloc. Only one patient (2.43%) had a resection with a compromised margin and was followed up because he presented an increased surgical risk due to existing comorbidities (TABLE 2).

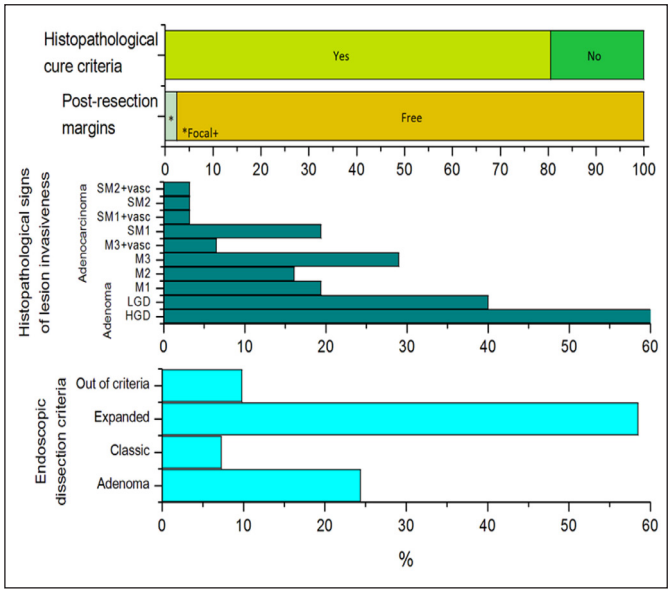


**FIGURE 8.** Percentage distribution of endoscopic resection criteria, histopathological signs of lesion invasion, post-resection margins, and histopathological cure criteria.

It was observed that 33 (80.48%) of the patients had histopathological criteria for cure and most had free margins after dissection, with only one case presenting a compromised margin. The rate of local recurrence, complications, and death was below 10%.

FIGURE 9A shows a significant change in the result between the pre- and post-resection assessments. The histopathological examination showed a significant increase in adenocarcinomas ($P$=0.0067, $P$<0.05) (McNemar's test). Figure 9B shows no significant change in grade for adenomas between pre- and post-resection assessments ($P$=0.1573, $P$>0.05) (McNemar's test). Figure 9C also shows no significant change in differentiation for adenocarcinomas between pre- and post-resection assessments, ($P$=0.2839, $P$>0.05) (Symmetry test).

Of the 41 patients, regarding the endoscopic resection criteria, 10 were classified as adenoma without a focus of adenocarcinoma, three as classic criteria, and 24 as expanded. Of the four patients who did not meet the criteria for cure after endoscopic resection, two was involved of the deep submucosa and two was involved of the superficial submucosa, but with a lesion larger than 30 mm.

The total number of adenocarcinomas in group 1 was 5 patients (27.8%), while in group 2 it was 17 patients (73.9%). Group 1 had 13 adenomas (72.2%) and group 2 had 6 (26.1%).

Regarding the degree of differentiation of adenocarcinomas, in group 1, three patients were classified as well differentiated (60%) and two as moderately differentiated (40%). Group 2 had 17 well-differentiated patients (100%) ($P$=0.0433, $P$<0.05).

The number of relapses was one (2.43%) among the 41 patients evaluated over the mean follow-up time of 38.4 months.

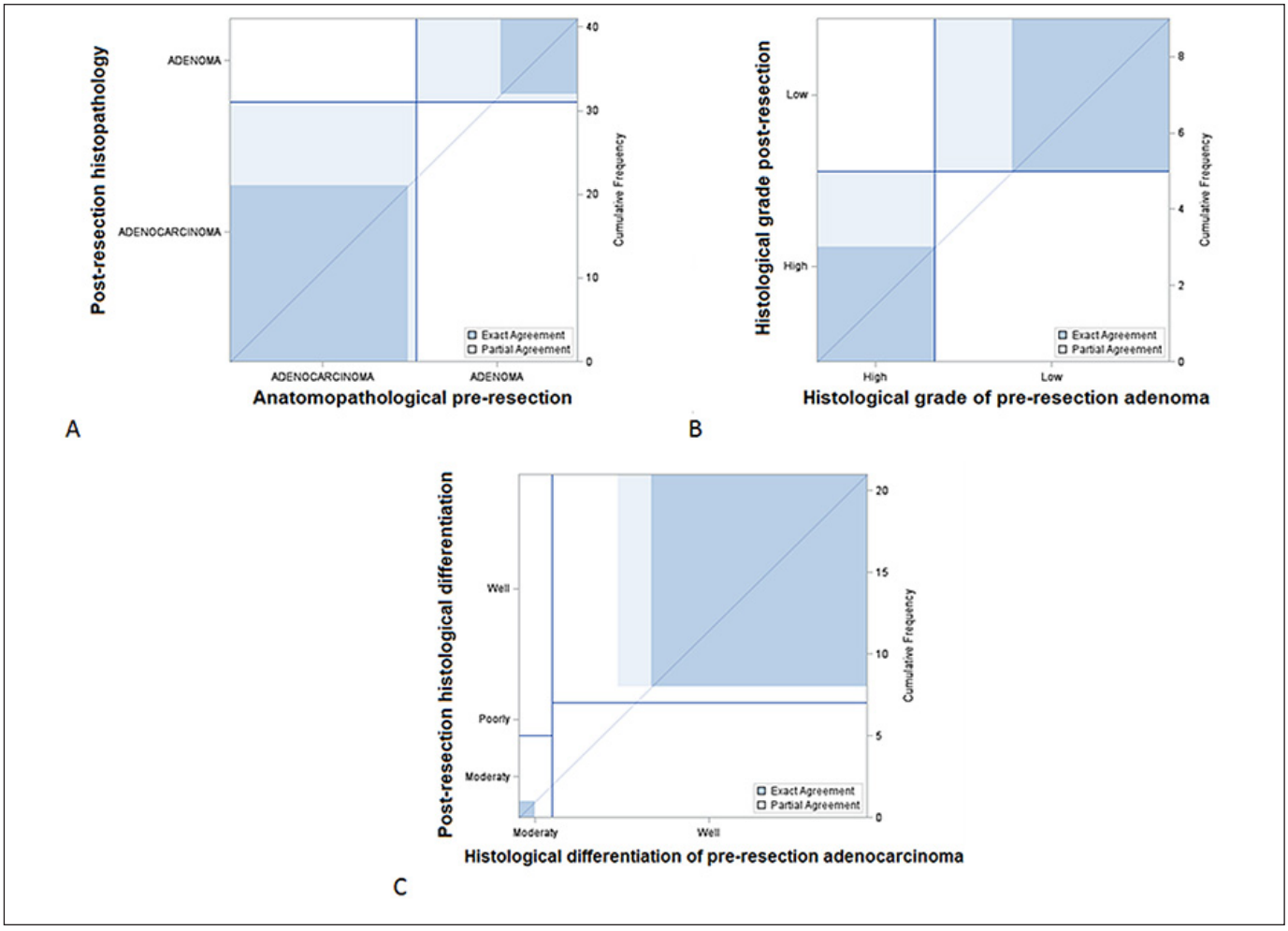


**FIGURE 9.** Frequency distribution to assess agreement between the pre- and post-resection anatomopathological study.

## DISCUSSION

The main comorbidity in this series was liver cirrhosis in 30% of the patients, and there was no increase in complications in the endoscopic resection procedure. The review by Barakat et al. (2017) also showed a risk of complications such as bleeding and perforation in cirrhotic patients similar to the control group[11].

Analyzing the characteristics of the lesions according to the Paris Classification regarding the higher probability of submucosal invasion, a predominance of 55% of depressed lesions was observed, with a higher prevalence of type IIa+IIc (35%). Scheerer et al. (2018) found the same prevalence of lesions, with a similar number of patients as in this study[12]. The study by Suzuki et al. (2019), analyzing 10.821 patients, showed 57% of depressed lesions[13], very similar to our data.

Comparing the time of the endoscopic procedure in the two types of injury, a longer time was found for the group of patients with suspected early lesion.

In addition, the higher prevalence of well-differentiated adenocarcinoma showed, with statistical significance, the importance of the Paris Classification to predict early gastric cancer and the greater technical difficulty in the resection of depressed lesions[13].

The mean lesion size was 31.4 mm, the en bloc resection rate was 97.5%, with one resection with compromised margin, one case of recurrence, two cases of metachronous lesion in a follow-up time of 38.4 months. The prevalence of complications (two bleedings, one perforation, and one death related to a cardiovascular event) was similar compared to the study by Scheerer et al. (2018), and we found a higher rate of en bloc resection and fewer cases with compromised margins[12].

Considering the resection criteria according to the Paris Classification, this study showed that, of the 41 cases analyzed, 10 were adenomas, 31 adenocarcinomas, of which three were included the classic criterion, 24 included the expanded criterion, and four were out of criteria (two with involvement of deep submucosa (sm2); two with involvement of the superficial submucosa (sm1) but with lesions larger than 30 mm). In the study by Scheerer et al. (2018), the classic criterion predominated[12].

However, in the study by Tate et al. (2019) with 135 patients, 37 lesions were classified as classic criteria, 30 as expanded criteria, and 26 as out of criteria[14].

Therefore, when patients are at high surgical risk, it is possible to use expanded or even non-criteria to indicate endoscopic resection.

During the follow-up period, an 80.4% rate of disease control

and no recurrence was observed, with 97.5% of en bloc resection and eight non-curative resections. When compared with eastern and western studies such as those by Suzuki et al. and Tate et al., both from 2019, similar rates of disease control were observed, using en bloc resection and r0 resection, within the recommendations proposed by the societies[9,13,14].

Analyzing only the pre-resection biopsy of the adenomas, a statistically significant increase in cases of adenocarcinoma was recorded. These findings reinforce the concept that all adenomatous lesions with dysplasia, regardless of their grade, should be submitted to endoscopic resection, in addition to cases included in the classic and expanded criteria already established for adenocarcinoma.

Finally, it is important to remember that both adenoma with high-grade dysplasia, carcinoma in situ or suspected of carcinoma, all fall under category 4 of the Vienna Classification, standardizing protocols and procedures[8,15].

As a limitation of the study, we had a small number of patients in the period studied and could further improve the results with the greater experience gained with the use of the method.

## CONCLUSION

The study showed the clinical and epidemiological profile of patients diagnosed with early gastric cancer and preneoplastic lesions, highlighting the importance of using the Paris Classification and histopathological diagnosis (Vienna Classification) to determine the therapeutic approach. Within this context, the rate of complete resectability was considered very high and the control of the neoplastic disease during the follow-up period of the patients was effective and satisfactory.

Endoscopic submucosal dissection proved to be a safe procedure, with a low complication and recurrence rate. Its recommendation must occur within the established criteria; however, it can be indicated for patients outside the criteria, if there is a high risk for surgical treatment.

## ACKNOWLEDGEMENTS

We would like to thank *Espaço da Escrita – Pró-Reitoria de Pesquisa* – UNICAMP – for the language services provided.

### Authors' contribution

Costa LCS: conceived the project, collected participants' data, wrote and critically reviewed the manuscript. Santos JOM: validated the results. Miyagima MT: validated the results. Montes CG: accounted for supervision, performance and validation using reproducibility criteria. Andreollo NA, Lopes LR: evaluated medical records of the study participants and validated the results using reproducibility criteria. Costa LCS, Santos JOM, Lopes LR: analyzed and interpreted the data. All authors have read and approved the final version of the manuscript prior to submission.

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Costa LCS, Santos JOM, Miyajima NT, Montes CG, Andreollo NA, Lopes LR. Análise de eficácia da dissecção endoscópica da submucosa para o câncer gástrico precoce e lesões pré-cancerosas. Arq Gastroenterol. 2022;59(3):421-7.

**RESUMO – Contexto –** O tratamento endoscópico das lesões pré-cancerosas e do câncer gástrico precoce tem sido amplamente aceito nos últimos anos. A dissecção endoscópica da submucosa (submucosectomia), obedecendo a critérios estabelecidos de indicação, pode levar a cura da doença em mais de 90% dos casos. **Objetivo –** Este estudo teve como objetivo analisar o uso da dissecção submucosa endoscópica em pacientes com câncer gástrico precoce e lesões pré-cancerosas, bem como os resultados do procedimento, suas complicações e eficácia no controle da doença. **Métodos –** Foram analisados 41 pacientes, com idade variando de 53 a 87 anos (média de 65 anos), sendo 58,53% do sexo masculino, no período de 2008 a 2019, sendo este estudo do tipo coorte retrospectivo. As variáveis coletadas dos prontuários foram: comorbidades, classificação da lesão quanto aos critérios de ressecção, tipo de ressecção, histologia, grau de invasão, margem de resseção, complicações, recidiva de doença. A análise estatística foi feita com o uso do teste de Kruskal-Wallis, teste de McNemar e teste de Mann-Whitney, com significância estatística de 5% ($P$<0,05). **Resultados –** O local mais frequente da lesão foi o antro gástrico e a apresentação predominante pela classificação japonesa ou de Paris foram os com componentes deprimidos em 56,09%. O adenocarcinoma ocorreu em 75,6% das biópsias e o restante foram adenomas sem neoplasia. A ressecção em bloco ocorreu em 97,57% dos casos, e o comprometimento da margem de segurança ocorreu em um paciente. A principal comorbidade pré-existente foi a cirrose hepática em 29,26% dos casos. Houve um aumento significativo de adenocarcinoma após dissecção endoscópica da submucosa em comparação ao diagnóstico pré ressecção. O tempo médio de seguimento foi de 38,4 meses, sendo registrado uma recidiva (2,43%) e duas lesões metacrônicas (4,87%). As complicações durante e após o procedimento ocorreram em 3 (7,31%) pacientes, sendo por sangramento (dois casos) e perfuração (um caso). Houve um óbito por evento cardiológico, não relacionado diretamente com o procedimento. **Conclusão –** A ressecção endoscópica da submucosa mostrou ser procedimento seguro, com baixa taxa de complicação e de recidiva. A sua indicação deve ser dentro dos critérios estabelecidos, entretanto, pode ser indicada em pacientes fora de critérios, se há alto risco para o tratamento cirúrgico.

**Palavras-chave –** Endoscopia; neoplasias gástricas; ressecção endoscópica da submucosa.

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