# *Endoscopic submucosal dissection versus transanal endoscopic surgery for the treatment of early rectal tumor: a systematic review and meta-analysis*

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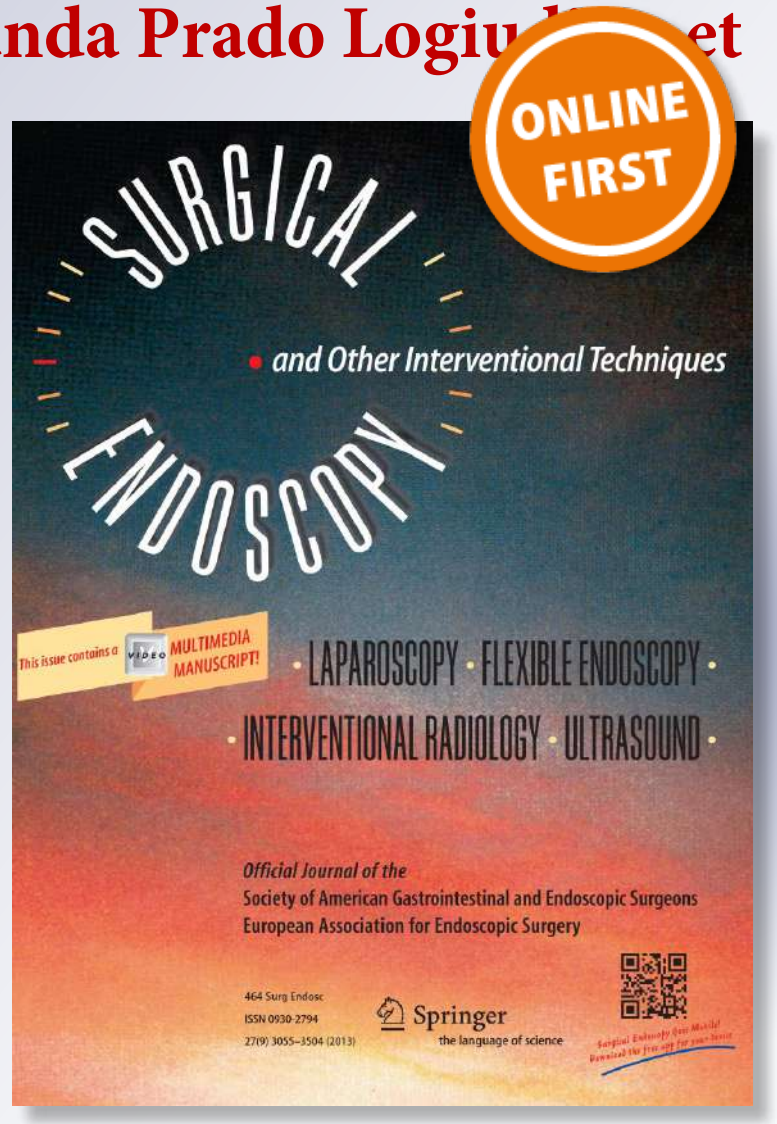


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REVIEW ARTICLE

# Endoscopic submucosal dissection versus transanal endoscopic surgery for the treatment of early rectal tumor: a systematic review and meta-analysis

**Vitor Massaro Takamatsu Sagae[1] · Igor Braga Ribeiro[1] · Diogo Turiani Hourneaux de Moura[1,2] · Vitor Ottoboni Brunaldi[1] · Fernanda Prado Logiudice[1] · Mateus Pereira Funari[1] · Elisa Ryoka Baba[1] · Wanderley Marques Bernardo[1] · Eduardo Guimarães Hourneaux de Moura[1]**

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## Abstract

**Background** Minimally invasive treatment of early-stage rectal lesion has presented good results, with lower morbidity than surgical resection. Transanal endoscopic microsurgery (TEM) and transanal minimally invasive surgery (TAMIS) are the main methods of transanal surgery. However, endoscopic submucosal dissection (ESD) has been gaining ground because it allows en bloc resections with low recurrence rates. The aim of this study was to analyze ESD in comparison with transanal endoscopic surgery.

**Methods** We searched MEDLINE, EMBASE, SciELO, Cochrane CENTRAL, and Lilacs/Bireme with no restrictions on the date or language of publication. The outcomes evaluated were recurrence rate, complete (R0) resection rate, en bloc resection rate, length of hospital stay, duration of the procedure, and complication rate.

**Results** Six retrospective cohort studies involving a collective total of 326 patients—191 in the ESD group and 135 in the transanal endoscopic surgery group were conducted. There were no statistically significant differences between the groups for any of the outcomes evaluated.

**Conclusions** For the minimally invasive treatment of early rectal tumor, ESD and surgical techniques do not differ in terms of local recurrence, *en bloc* resection rate, R0 resection rate, duration of the procedure, length of hospital stay, or complication rate, however, evidence is very low.

**Keywords** Rectal neoplasms · Transanal endoscopic microsurgery · Endoscopic mucosal resection · Endoscopic submucosal dissection · Learning curve

Colorectal cancer is the third most common type of cancer and the second leading cause of cancer-related death worldwide [1, 2]. Colorectal carcinomas that invade only the submucosal layer (without invading the deeper layers) are classified as T1 tumors. Early diagnosis and treatment of T1 tumors confer an excellent prognosis, unless there are lymph node metastases [3]. The treatment is challenging, given that the lymph node involvement can be verified only after surgical lymphadenectomy. Therefore, although the standard treatment is surgical resection, modalities of local resection are possible treatments in cases where there is little lymph node involvement. The available techniques for local excision are classical transanal resection, endoscopic mucosal resection (EMR), and endoscopic submucosal dissection (ESD), as well as two types of transanal endoscopic surgery (TES)—transanal endoscopic microsurgery (TEM) and transanal minimally invasive surgery (TAMIS).

**Electronic supplementary material** The online version of this article (https://doi.org/10.1007/s00464-019-07271-2) contains supplementary material, which is available to authorized users.

✉ Igor Braga Ribeiro
igorbraga1@gmail.com

[1] Gastrointestinal Endoscopy Unit, Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo – HC/FMUSP, Av. Dr. Enéas de Carvalho Aguiar, 255 – Instituto Central - Prédio dos Ambulatórios – Cerqueira César, São Paulo, SP CEP: 05403-000, Brazil

[2] Division of Gastroenterology, Hepatology and Endoscopy, Harvard Medical School, Brigham and Women's Hospital, Boston, MA, USA

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For the treatment of rectal tumors, TEM is a well-established procedure. Through the use of TEM, with a rectoscope, rectal tumors located 4–18 cm from the anal verge can be totally resected from the rectal wall [4]. Developed in 2009, TAMIS is a hybrid technique, combining TEM and laparoscopy, in which a single portal is used as a transanal access platform for the excision of rectal lesions [5]. For early-stage rectal tumors, EMR and ESD are the two main endoscopic treatments. There are certain limitations to the use of EMR [6]: it can be employed only for lesions smaller than 20 mm; it involves piecemeal resection; it has a resection rate of only approximately 50%; and it does not allow adequate evaluation of the margins or depth of invasion. In contrast, ESD is used for larger lesions, involves en bloc resection, and has a higher resection rate. In addition, the rate of recurrence is lower among patients treated with ESD than among those treated with EMR. Therefore, for early-stage rectal lesions greater than 2 cm, TEM, TAMIS, and ESD are all considered minimally invasive and can be performed, producing good results, in selected cases.

To date there is no consensus regarding which technique is most appropriate for the treatment of early rectal tumors. The TEM technique is well established and has been shown to produce better results than classical transanal excision [7]. There have been few studies comparing ESD with TES (TEM and TAMIS). Therefore, we performed this systematic review and meta-analysis to compare these techniques in terms of their efficacy and safety in the treatment of early rectal tumors.

## Materials and methods

### Protocol and registration

This study was registered in the International Prospective Register of Systematic Reviews database (PROSPERO): CRD42018106040.

### Eligibility criteria

We selected comparative studies, with no restrictions on date of publication or language. The eligibility criteria were as follows: patients who had early-stage lesions of the rectum that could be resected endoscopically or through TES; ESD being the experimental intervention; the control intervention being TES—either TEM, TAMIS, or variants of those techniques; and evaluating early or late outcomes—recurrence rate, en bloc resection, complete (R0) resection, length of hospital stay, duration of the procedure, and complication rate. Because of its limitations for en bloc resections of lesions greater than 20 mm, EMR was not included in this meta-analysis, and it was not considered equivalent (and therefore not comparable) to TEM and TAMIS.

### Search strategies

Searches were performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [8]. We searched the following databases: MEDLINE (PubMed); Excerpta Medica (EMBASE); Scientific Electronic Library Online (SciELO); Literatura Latinoamericana y del Caribe en Ciencias de la Salud (LILACS, Latin-American and Caribbean Health Sciences Literature); and Cochrane Central Register of Controlled Trials (CENTRAL), to November 2018 and without restrictions on the publication language. The search syntax is shown in Online Appendix 1.

### Data collection process

The primary outcome measures were recurrence rate, en bloc resection, and R0 resection. Secondary outcomes were length of hospital stay, duration of the procedure, and rate of complications (perforation and bleeding). Not all outcomes were assessed in all of the studies. We analyzed only those outcome measures for which there were sufficient data.

### Selection of articles

The database searches were conducted by two researchers, working independently, who also evaluated and selected the articles. Any disagreements were resolved by consensus. The studies were selected on the basis of the eligibility and exclusion criteria. The outcomes evaluated were recurrence rate, R0 resection rate, en bloc resection rate, length of hospital stay, duration of the procedure, and complication rate.

### Risk of bias

To assess the risk of bias in cohort studies, we used both the Newcastle–Ottawa Quality Assessment Scale for Cohort Studies [9], detailed in Online Appendix 3, and the Risk of Bias in Non-randomized Studies-of Interventions (ROBINS-I) [10], detailed in Online Appendix 3.

### Statistical measures and analysis

Data were collected from each group for each outcome (expressed as absolute values) to calculate the risk difference between them. The analysis was performed using Review Manager (RevMan) software, version 5.3. The risk differences for dichotomous variables were calculated using a fixed effect model, resulting in forest and funnel plots. The Mantel–Haenszel test was applied in order to calculate a

95% CI for each outcome. Values of $p < 0.05$ were considered statistically significant. Consistency among the studies was calculated and reported as Chi-square and inconsistency index ($I^2$) values.

Studies with an $I^2 < 25\%$ are considered indicative of little heterogeneity, 25–50%, low heterogeneity; 50–75%, moderate heterogeneity; and over 75% indicative of high statistical heterogeneity. Because we pool TEM and TAMIS in the same analysis group, we attributed random effect model for the outcomes in this meta-analysis.

## Results

### Articles selected

A total of 26,279 articles were identified through our searches of the PubMed database. An additional 2639 articles were identified in the EMBASE, LILACS, SciELO, and CENTRAL databases. Duplicate articles were removed. After the eligibility criteria had been applied, six retrospective cohort studies (two in abstract form and four full text articles) remained and were included in the meta-analysis [11–16]. The selection process is shown in Fig. 1 and Table 1 shows individual characteristics of the studies selected.

### Characteristics of the studies

Of the six retrospective cohort studies selected, two presented comparisons between ESD and TAMIS, whereas the other four compared ESD and TEM. Collectively, the six studies evaluated 191 patients in the intervention (ESD) groups and 135 patients in the control (TES) groups. All patients who underwent the procedures were included, regardless of the post-resection histological findings in the sample.

### Risk of bias among the studies

All of the selected studies had a score ≥ 7 on the Newcastle–Ottawa Quality Assessment Scale for Cohort Studies [9], however when evaluated with ROBINS-I [10], they all presented at least a moderate risk of bias. When the methodology employed in each study was evaluated individually, other biases were identified.

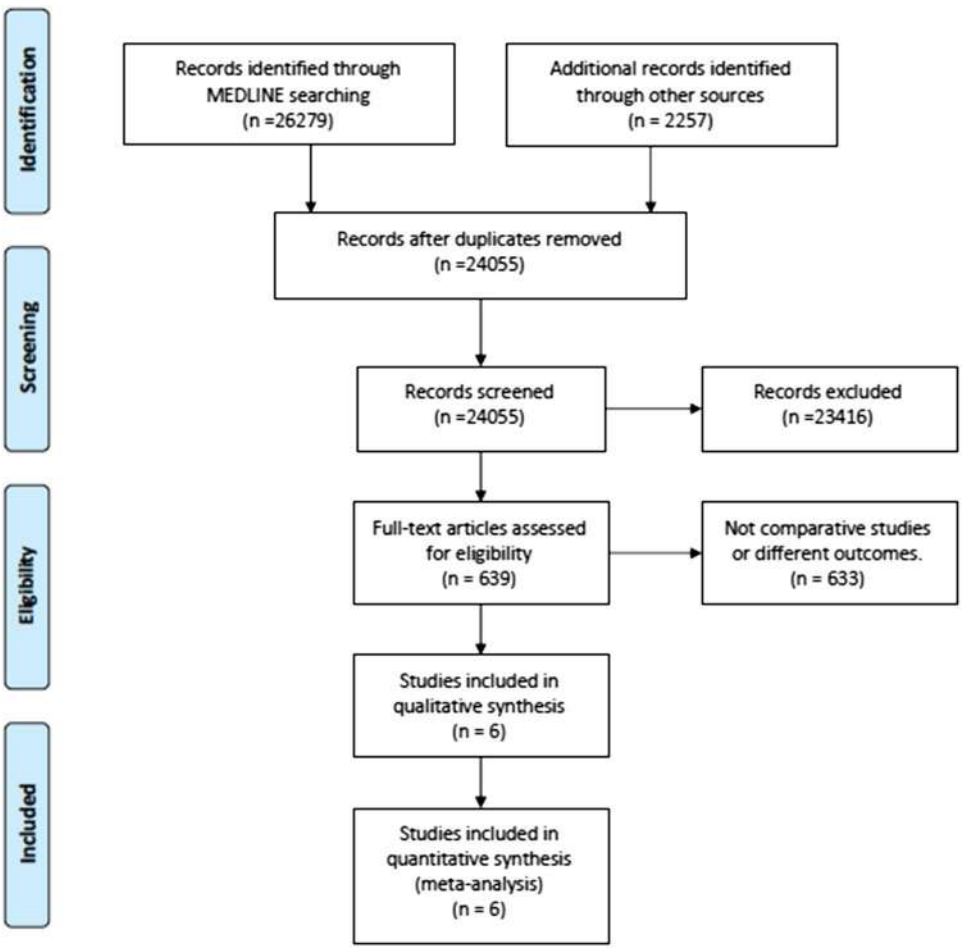


**Fig. 1** Flow diagram showing the article selection process

**Table 1** Characteristics of the retrospective cohort studies selected

| Study | Year | Patients | Intervention | Control | Outcomes |
|---|---|---|---|---|---|
| Park et al. [15] | 2012 | 63 patients with nonpolypoid high-grade dysplasia or cancer invading the submucosa | ESD (30 patients) | TEM (33 patients) | Recurrence, en bloc resection, R0 resection, duration of the procedure, length of hospital stay, bleeding, perforation |
| Kawaguti et al. [16] | 2014 | 24 patients with early-stage rectal cancer | ESD (11 patients) | TEM (13 patients) | Recurrence, en bloc resection, duration of the procedure, length of hospital stay, perforation |
| Tajika et al. (abstract) [12] | 2016 | 76 patients with lower rectal tumor | ESD (48 patients) | TEM (28 patients) | Recurrence, en bloc resection, duration of the procedure, length of hospital stay, complications |
| Mao et al. [13] | 2017 | 57 patients with early-stage rectal tumor | ESD (31 patients) | TAMIS (26 patients) | Recurrence, R0 resection, duration of the procedure, bleeding, perforation |
| Mittal et al. (abstract) [11] | 2018 | 50 patients with rectal polyps | ESD (31 patients) | TAMIS (19 patients) | Recurrence, en bloc resection, R0 resection, duration of the procedure, bleeding, perforation |
| Jung et al. [14] | 2018 | 56 patients with epithelial rectal tumor | ESD (40 patients) | TEM (16 patients) | Recurrence, en bloc resection, R0 resection, duration of the procedure, length of hospital stay, bleeding, perforation |

*ESD* endoscopic submucosal dissection, *TEM* transanal endoscopic microsurgery, *R0* complete (margin-negative), *TAMIS* transanal minimally invasive surgery

Because they were available in abstract form only, the studies conducted by Mittal et al. [11] and Tajika et al. [12] did not specify the inclusion criteria or duration of follow-up of the lesions evaluated. Mao et al. [13] evaluated ESD in comparison with a technique known as colonoscopy-assisted transanal minimally invasive surgery via glove port (CA-TAMIS-GP), which uses an anoscope attached to a glove as the portal; a colonoscope for optics, lighting, insufflation, and aspiration; and a laparoscopy forceps for resection. In the study conducted by Jung et al. [14], the lesions evaluated were divided into two groups—epithelial and subepithelial—and we analyzed only the data from the first group, since the indication for ESD in subepithelial tumors remains controversial [17] and the histopathology of the resected tumors was different from the other groups.

It is important to emphasize that the TES techniques (TEM and TAMIS), in their definition, are performed with full thickness resection of the rectum wall which may or may not be followed by suture of the defect or in cases of extraperitoneal lesions, while the ESD technique only performs partial thickness resection and no suture is required. Only three studies in which full thickness resections were performed accounted the rectum wall suturing to the total procedure time, Mao et al. [13], Jung et al. [14] and Kawaguti et al. [16], which may cause bias in the procedure time evaluation.

The duration of follow-up (time from the procedure to the first post-resection colonoscopy) differed among the studies: 1 month in the study conducted by Park et al. [15]; 3 months in the studies conducted by Kawaguti et al. [16] and Mao et al. [13]; and 6 months in the study conducted by Jung et al. [14]. Although the studies differed regarding the method used to evaluate the depth of the lesion before the procedure, the indication for the procedure was the same in all six studies: involvement to the superficial layer of the submucosa.

The methodology employed in each study was also evaluated for other possible biases. The quality of the evidence was assessed according to the Grading of Recommendations Assessment, Development and Evaluation Working Group [18] criteria (Online Appendix 4).

## Synthesis of the results

Table 2 shows the detailed results of the six studies analyzed. The outcomes are stratified by group (intervention vs. control).

## Recurrence

All six of the studies [11–16] selected compared recurrence rates between the two methods. In the collective sample,

which comprised 326 lesions (191 in the ESD group and 135 in the TES group), we found no significant difference between the intervention and control groups (RD = −0.02; 95% CI −0.09 to 0.04; $p = 0.46$; $I^2 = 38\%$) (Fig. 2).

## En bloc resection

Five studies [11, 12, 14–16] compared the en bloc resection rate, evaluating a collective total of 269 lesions—160 in the ESD group and 109 in the TES group—and we found no significant difference between the two groups (RD = −0.11; 95% CI −0.30 to 0.09; $p = 0.29$; $I^2 = 87\%$) (Fig. 3).

## R0 resection

Five studies [11, 13–16] compared the R0 resection rate, evaluating a collective total of 242 lesions—143 in the ESD group and 99 in the TES group—and the difference between the two groups was not statistically significant (RD = −0.01; 95% CI −0.06 to 0.04; $p = 0.72$; $I^2 = 6\%$) (Fig. 4).

**Table 2** Data extracted

| Studies | Recurrence (%) | | En bloc resection (%) | | R0 resection (%) | | Procedure time (min) | | Hospital stay (days) | | Perforation (%) | | Bleeding (%) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | *I* | *C* | *I* | *C* | *I* | *C* | *I* | *C* | *I* | *C* | *I* | *C* | *I* | *C* |
| Jung et al. | 2.5 | 6.2 | 95 | 93.7 | 92.5 | 87.5 | 71.5 ± 51.3 | 105.6 ± 28.2 | 4.3 ± 1.3 | 4.1 ± 4.1 | 7.5 | 12.5 | 7.5 | 12.5 |
| Kawaguti et al. | 9.0 | 15.3 | 90.9 | 84.6 | 81.8 | 84.6 | 133 ± 94.8 | 150 ± 66.3 | 3.8 ± 3.3 | 4.0 ± 1.7 | 18.1 | 15.3 | – | – |
| Mao et al. | 9.6 | 0 | – | – | 100 | 100 | 68.7 ± 41.8 | 49.5 ± 26 | – | – | – | – | 22.5 | 11.5 |
| Mittal et al. | 0 | 10.5 | 90.3 | 84.2 | 87 | 68.4 | – | – | – | – | 3.2 | 0 | 6.4 | 5.2 |
| Park et al. | 0 | 0 | 96.6 | 100 | 96.6 | 96.9 | 84 ± 51.2 | 116.4 ± 58.5 | 3.6 ± 1.2 | 6.6 ± 3.5 | 3.3 | 6 | 0 | 0 |
| Tajika et al. | 0 | 10.7 | 89.5 | 42.8 | – | – | – | – | – | – | 0 | 0 | 0 | 0 |

*I* intervention (ESD), *C* control (TEM or TAMIS)

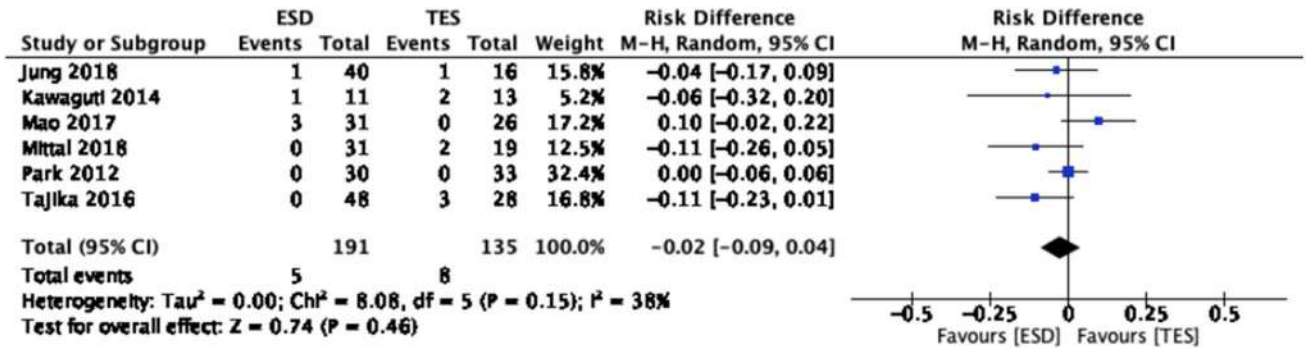


**Fig. 2** Recurrence rate

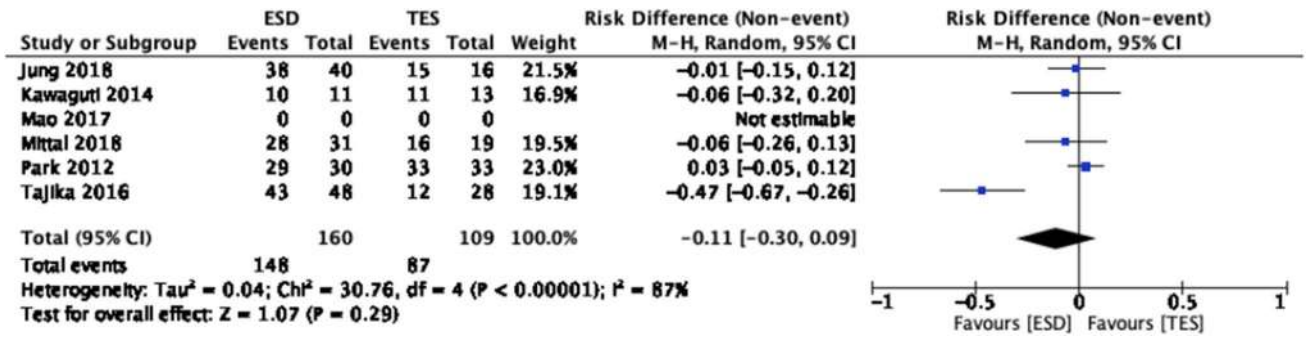


**Fig. 3** En bloc resection rate

## Duration of the procedure

Four studies [13–16] compared the duration of the procedure, evaluating 200 procedures (112 involving ESD and 88 involving TES), and there was no significant difference between the two techniques (MD = − 15.23; 95% CI −48.11 to 17.64; $p = 0.36$; $I^2 = 83\%$) (Fig. 5).

## Hospital stay

Three studies [14–16] compared the length of the hospital stay, evaluating 143 hospital stays (81 after ESD and 62 after TES), and there was no significant difference between the two techniques (MD = − 1.16; 95% CI −3.37 to 1.05; $p = 0.30$; $I^2 = 78\%$) (Fig. 6).

## Perforation

Five studies [11, 12, 14–16] compared the perforation rate after resection, evaluating a collective total of 269 lesions (160 in the ESD group and 109 in the TES group), and there was no significant difference between the two groups (RD = − 0.00; 95% CI −0.04 to 0.04; $p = 0.96$; $I^2 = 0\%$) (Fig. 7).

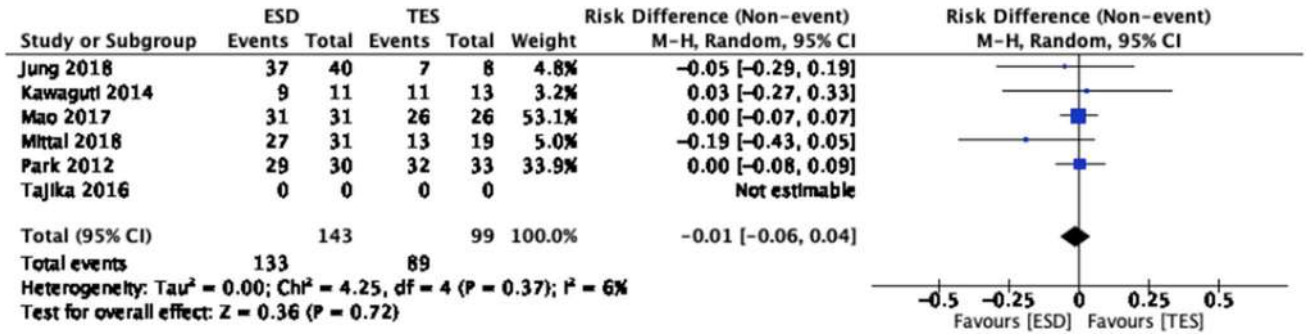


**Fig. 4** R0 resection rate

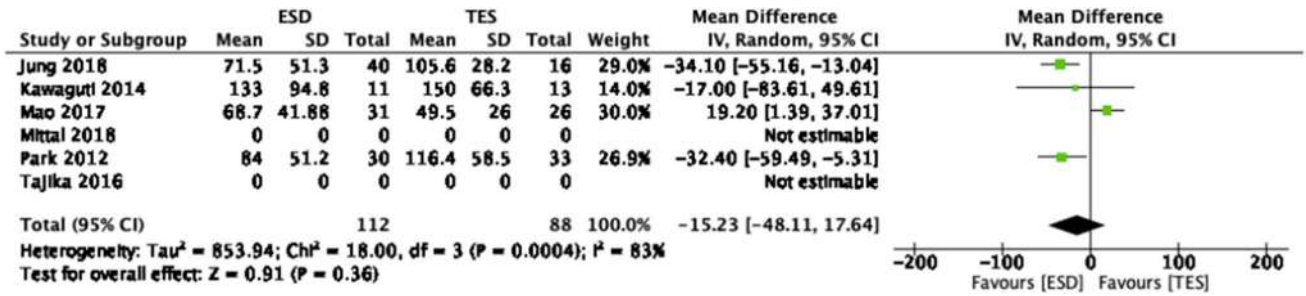


**Fig. 5** Duration of the procedure

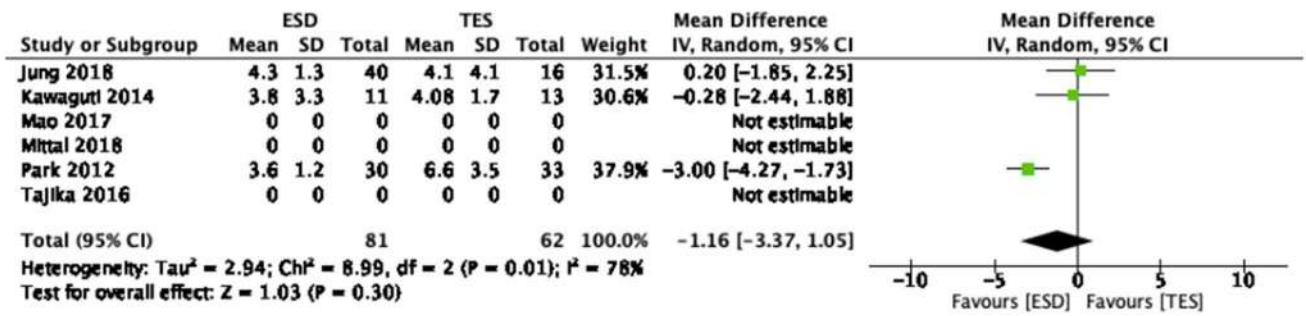


**Fig. 6** Length of hospital stay

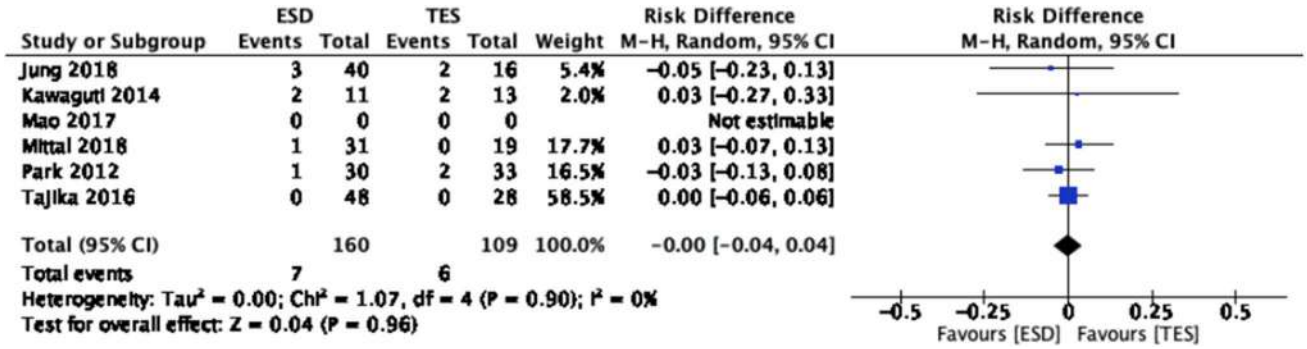


**Fig. 7** Perforation rate

## Bleeding

Five studies [11–15] evaluated bleeding after resection, evaluating a collective total of 302 lesions (180 in the ESD group and 122 in the TES group), and there was no significant difference between the two groups (RD = 0.00; 95% CI − 0.03 to 30.04; $p = 0.87$; $I^2 = 0\%$) (Fig. 8).

## Discussion

Our study compared ESD and TES (TEM and TAMIS) techniques for resection of early rectal tumors, suggesting that both techniques are equivalent effective and safe. Although there was no statistical difference in all the outcomes evaluated between the groups, this is the first systematic review with a meta-analysis that included only comparative studies that also involved a large collective sample of patients (191 in the ESD group and 135 in the TES group). However, since the number of studies is limited, with only cohort studies included, the strength of our conclusions is also limited, and therefore, with a certainty of evidence very low across outcomes. But this study is of paramount importance to guide the clinical decision-making process in cases of early-stage rectal tumors.

Because there have been technical advances, together with improvements in the equipment employed and wider dissemination of screening protocols, rectal lesions are now being diagnosed at earlier stages and can therefore be treated less aggressively, typically with minimally invasive techniques [19–22]. ESD has been shown to be a promising technique that can overcome some of the limitations of TEM and TAMIS, because ESD can be performed under conscious sedation, as well as effective for the resection of lesions located above the rectum or near the anal verge. However, its advantages and disadvantages in relation to TEM and TAMIS are yet to be well established.

In Asia, ESD is the standard technique for the treatment of early-stage gastrointestinal neoplasms. In the guidelines issued by the European Society of Gastrointestinal Endoscopy (ESGE) [23], ESD is also recommended as the first-line treatment for colorectal lesions in which there is evidence that the invasion is restricted to the submucosal layer because it allows en bloc resection with appropriate pathological evaluation. Nevertheless, its use in Western countries is still quite limited.

It is well known that TEM and ESD both have advantages over classic transanal excision [7, 24–28]. Literature is limited so far and there have been no randomized studies comparing ESD with TEM or TAMIS. In RCT study,

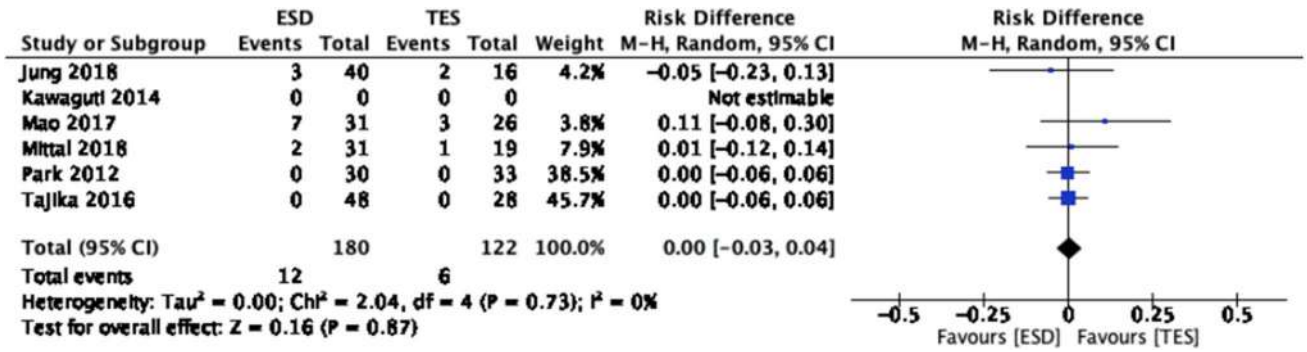


**Fig. 8** Bleeding rate

Barendse et al. [29] compared TEM and EMR for the resection of adenomas larger than 3 cm and found only a tendency toward a lower rate of complications and lower costs in the EMR group.

In our study, we evaluated all comparative studies of ESD versus TES (TEM or TAMIS) or other similar techniques such as the CA-TAMIS-GP procedure employed by Mao et al. [13] in terms of their effectiveness in the treatment of rectal lesions. The latter study [13] was included because the indications for the CA-TAMIS-GP procedure were the same as those for the other modalities, despite the technical differences. The CA-TAMIS-GP procedure was devised because it presented a lower cost, an aspect that was not evaluated in the present study. We excluded studies that drew comparisons with EMR because there are fewer indications for EMR, as well as ESD is associated with a lower rate of recurrence as a consequence of its higher en bloc resection rate [30]. Although we did not have statistically significant results, our analysis showed tendencies favoring the ESD technique in terms of recurrence rate, en bloc resection, R0 resection, duration of the procedure, and length of hospital stay, although none of the differences were statistically significant. The rate of complications was quite similar between the groups. These findings differ somewhat from those reported in other studies in the literature. In a systematic review published in 2014, Arezzo et al. [31] evaluated case series, comparing those involving the use of ESD ($n = 11$) and those involving the use of TEM ($n = 10$) for the non-invasive resection of rectal lesions greater than 2 cm. The authors found that TEM had higher rates of en bloc resection and R0 resection, as well as shorter procedure times, although the rate of complications was comparable between ESD and TEM. These differences are probably due to the fact that colorectal ESD is a technique that was developed more recently. Saito et al. [32] showed that greater experience on the part of endoscopists and better standardization of the procedure corresponded to a tendency toward lower rates of complications.

Our results suggest an equivalence between ESD and TES. Therefore, the clinical management of early rectal tumors should be defined on the basis of local expertise, the availability of equipment, and costs, given that the surgical and endoscopic techniques of transanal resections both promote high cure rates and low complication rates [33].

This study has some limitations. One limitation is the fact that the studies evaluated were of a retrospective observational character. In addition, the procedures analyzed in those studies were performed by professionals with different levels of experience and different learning curves. Furthermore, although the groups were similar to each other in each study, they did not show homogeneity across the studies. There were also significant differences in terms of the characteristics of the resected lesions, the duration of follow-up, and the specific techniques employed, which varied from center to center. Therefore, we found that the certainty of the evidence was very low for each of the outcomes analyzed. Finally, these limitations could be circumvented with large randomized controlled trials, which have a low risk of bias.

## Conclusion

There is no difference between endoscopic surgical techniques (TEM or TAMIS) and a purely endoscopic technique (ESD) in terms of local recurrence, the *en bloc* resection rate, the R0 resection rate, duration of the procedure, length of hospital stays, or the rate of complications (hemorrhage or perforation) for the minimally invasive treatment of early rectal tumors, however, evidence is very low.

**Author contributions** VS: acquisition of data, analysis, interpretation of data, drafting the article, revising the article, final approval; IBR: acquisition of data, analysis, interpretation of data, drafting the article, revising the article, final approval; IBR: analysis and interpretation of data, revising the article; DTHDM: analysis and interpretation of data, revising the article; VOB: acquisition of data, drafting the article, revising the article, final approval; FPL: analysis and interpretation of data, drafting the article, final approval; MPF: analysis and interpretation of data, drafting the article, final approval; FPL: analysis and interpretation of data, drafting the article, final approval; ERB: analysis and interpretation of data, drafting the article, final approval; WMB: analysis and interpretation of data, drafting the article, final approval; EGHDM: analysis and interpretation of data, drafting the article, revising the article, final approval.

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## Compliance with ethical standards

**Disclosure** Drs. Vitor Massaro Takamatsu Sagae, Igor Braga Ribeiro, Diogo Turiani Hourneaux de Moura, Vitor Ottoboni Brunaldi, Fernanda Prado Logiudice, Mateus Pereira Funari, Elisa Ryoka Baba and Wanderley Marques Bernardo, Dr. Eduardo Guimarães Hourneaux de Moura is consultant for Boston scientific and Olympus.

**Ethical approval** The study was approved by the Research Ethics Committee of the University of São Paulo School of Medicine Hospital das Clínicas.

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