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ESD vs TAMIS for Early Rectal Neoplasms


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This summary reviews de Frutos Rosa D, Alonso Sebastián I, Barquero Declara D, et al. A randomized trial of endoscopic submucosal dissection vs transanal minimally invasive surgery in early rectal neoplasms: DSETAMIS-2018 Study. Gastroenterology. 2026;170(1):161-173.

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COLON

STRUCTURED ABSTRACT

Question: Is endoscopic submucosal dissection (ESD) noninferior to transanal minimally invasive surgery (TAMIS) for preventing local recurrence after local resection of early rectal neoplasms?

Design: Multicenter, open-label, parallel-group, noninferiority randomized controlled trial with 1:1 allocation. Patients were assigned through simple unrestricted randomization using a computer-generated sequence, with allocation concealment through the REDCap randomization module. Blinding of participants and procedural investigators was not feasible because of the inherent differences between the 2 treatment strategies and their associated care protocols.

Setting: Three tertiary academic hospitals in Spain enrolled participants from April 2019 through December 2023.

Patients: Adults with nonpedunculated sessile, laterally spreading rectal lesions

>20 mm in diameter, located between 3 and 14 cm from the external anal margin, with circumferential involvement ≤50%, and no clinical suspicion of deep submucosal invasion. Seventy-three patients were randomized (34 TAMIS, 39 ESD). The ITT analysis included 33 TAMIS and 37 ESD patients after 3 post-randomization dropouts. Exclusion criteria comprised refusal to provide informed consent, inflammatory bowel disease involving the rectum, pregnancy, and severe anorectal fibrosis resulting from prior surgery. Patients were also excluded if they had granular homogeneous-type laterally spreading tumors, for which piecemeal endoscopic mucosal resection is considered standard therapy, lesions >50 mm with endoscopic features suggestive of advanced histology (NBI International Colorectal Endoscopic 3/Japan NBI Expert Team 3 or Kudo's classification type VN), or synchronous neoplasms requiring radical rectal surgery irrespective of local resection.

Intervention: Both groups (Control TAMIS and Experimental ESD) underwent bowel preparation with polyethylene glycol or sodium picosulfate. In the TAMIS arm, procedures were performed under general anesthesia in the lithotomy position using a dedicated transanal access port with carbon dioxide insufflation. Circumferential marking around the lesion was performed using electrocautery, maintaining a margin of 5 to 10 mm and resected using traction-assisted mucosal or full-thickness excision at the surgeon's discretion, followed by hemostasis and defect suturing. In the ESD arm, procedures were performed under deep sedation or general anesthesia with carbon dioxide insufflation, submucosal injection, and dissection using an electrosurgical knife; visible vessels were prophylactically coagulated, and defect closure was discretionary.

Outcomes: Primary outcome was histologically confirmed local recurrence at the resection scar 12 months after treatment. Secondary outcomes included technical success, en-bloc and R0 resection, curative resection, early local recurrence rate, procedure time, adverse events, hospital stay, and cost.

Data Analysis: Both intention-to-treat (ITT) and per-protocol analyses were performed. ESD was considered noninferior if the upper boundary of the two-sided 90% confidence interval for the recurrence-risk difference did not exceed the noninferiority margin. The noninferiority margin was set at 10%.

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Results: During the follow-up, no local recurrences occurred after ESD, whereas 2 recurrences occurred after TAMIS (within 6 months of the procedure). The ITT recurrence-risk difference was −6.7% (90% CI, −14.2 to 0.8), meeting the prespecified criterion for noninferiority of ESD. Technical success was 100% with ESD versus

90.9% with TAMIS in ITT analysis. Median hospital stay was shorter after ESD than TAMIS (1 vs 2 days; $P < 0.001$), and the median direct total cost was lower with ESD (€6,167.14 vs €11,289.27; $P < 0.001$). Median procedure time was longer with ESD (140 vs 110 minutes; $P = 0.02$, per-protocol). Overall, early and delayed complication rates were not statistically different.

COMMENTARY

Why Is This Important?

Rectal lesions with a risk of superficial submucosal invasion require en-bloc local resection to enable accurate histopathologic staging, assess resection margins, and determine whether additional radical surgery is necessary. In addition, in early superficial submucosal invasive rectal adenocarcinoma with favorable histologic features (depth of submucosal invasion < 1000 microns, lack of perineural and lymphovascular invasion, well to moderate differentiation and low tumor budding), an R0 resection can be considered curative. While ESD and TAMIS can both achieve en-bloc resection, prior comparative studies were largely retrospective, and DSETAMIS-2018 is a randomized controlled trial directly comparing the 2 approaches. The trial supports ESD as a potentially organ-preserving alternative to TAMIS in carefully selected early rectal neoplasms. Beyond comparable short-term local control, ESD avoided conversion to another approach, reduced hospitalization, and substantially lowered direct costs.

Key Study Findings

This randomized, noninferiority, open-label, multicenter clinical trial comparing ESD vs TAMIS in early rectal neoplasms reported no recurrence in the ESD group, compared with 2 cases of recurrence in the TAMIS group; the trial met its prespecified noninferiority criterion for ESD. Technical success in ESD was 100%, while the TAMIS group had 90.9% (P = 0.10); 6 patients assigned to TAMIS underwent ESD 3 due to patient preference and 3 because the lead surgeon considered them unsuitable candidates for the procedure. En-bloc resection was high and similar with both techniques, at 97.3% with ESD and 97.0% with TAMIS in ITT analysis. Median hospital stay was shorter after ESD than TAMIS (1 vs 2 days; $P < 0.001$), and the median direct total cost was lower with ESD (€6,167.14 vs €11,289.27; $P < 0.001$). Both interventions had generally favorable safety profiles. Although differences were not statistically significant.

Caution

The noninferiority conclusion should be interpreted cautiously. The sample size of the trial was small, with 73 randomized patients and only 2 local-recurrence events, both in the TAMIS

group. The absence of recurrence events after ESD limits the precision of recurrence and recurrence-free survival estimates. Secondly, the study used a 10% noninferiority margin despite an anticipated recurrence rate of approximately 2.5% after either technique. Although the observed 90% confidence interval met the prespecified noninferiority criterion, this margin could permit an absolute recurrence difference that some patients and clinicians would consider clinically important. Third, blinding was not feasible because the endoscopic and surgical interventions required distinct procedural and perioperative pathways. To reduce potential ascertainment bias for the primary outcome, follow-up was performed by routine endoscopy-unit staff, and endoscopists and pathologists were often unaware of the preceding resection. Fourth, the population was highly selected: lesions were > 20 mm, located 3–14 cm from the anal verge, involved no more than 50% of the rectal circumference, and had no clinical suspicion of deep submucosal invasion. Therefore, the findings should not be generalized to extensive circumferential lesions, very distal lesions, or lesions with a high likelihood of deep invasion or unfavorable histology. Finally, procedures were performed by experienced operators at tertiary centers; outcomes may not translate directly to settings without substantial rectal ESD expertise, coordinated surgical backup, and expert gastrointestinal pathology.

Our Practice

Patient selection and local expertise are key factors when choosing between ESD and TAMIS. Large rectal neoplasms need special consideration because of the risk of submucosal invasion. In addition, rectal surgeries are associated with higher morbidity as compared to colon surgeries[1,2]. Therefore, in our practice, careful optical assessment is carried out for all rectal neoplasms regardless of size to evaluate for overt (Kudo Vi) or covert features of submucosal invasive cancer (dominant nodule) before deciding on the best resection approach[3]. For any lesions with concern for submucosal invasion or advanced dysplasia, our preference is to perform en-bloc resection with a goal for R0 resection. En-bloc resection allows for optimal histological assessment for staging, and R0 resection (defined as a negative lateral or deep margin for dysplasia) can be curative if no high-risk pathological features are present. Favorable histological features include depth of submucosal invasion < 1000 microns, lack of perineural and lymphovascular invasion, well to moderate differentiation and low tumor budding. If an R0 resection is achieved with these favorable histological features, it is considered to be a “curative resection”. If a patient has a diagnosis of early-stage superficial rectal adenocarcinoma prior to resection, then we discuss these cases in a multidisciplinary conference to determine TAMIS vs ESD. It is

important to note that despite the growing popularity of ESD, TAMIS remains a useful alternative when ESD is not technically feasible, when local ESD expertise is unavailable, or when a surgical full-thickness excision is judged necessary. Decisions should be made in a multidisciplinary setting with advanced endoscopists, colorectal surgeons, radiologists, and gastrointestinal pathologists, particularly for lesions with a meaningful risk of covert invasive cancer[2,3,5]

For Future Research

Larger randomized controlled trials with longer oncologic follow-up are needed to compare ESD and TAMIS for recurrence, salvage surgery, functional outcomes, quality of life, and cost-effectiveness. Future studies should include a broader spectrum of rectal lesions and should evaluate whether advanced approaches such as endoscopic intermuscular dissection can safely expand the endoscopic treatment boundary for selected superficial T1 cancers.

Conflict of Interest

Dr. Bilal is a consultant for Boston Scientific, Steris Endoscopy, Microtech, OVESCO, and Cook Medical. Dr Saeed reports no relevant conflicts of interest.

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