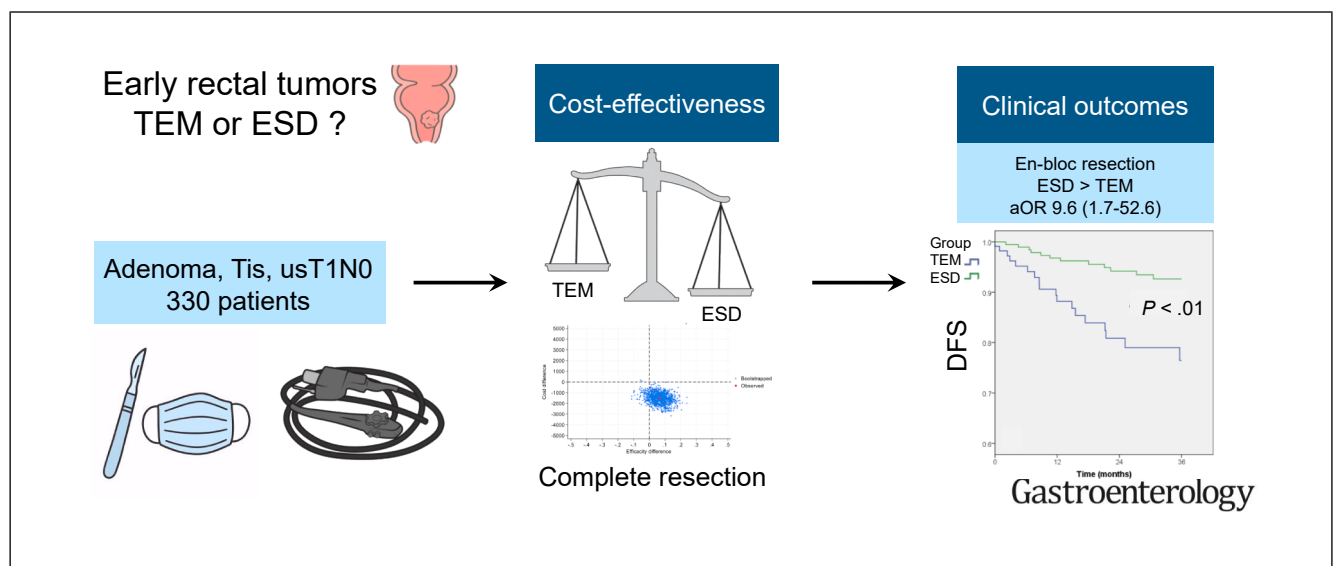




Transanal Endoscopic Microsurgery or Endoscopic Submucosal Dissection in Early Rectal Tumors: A Clinical and Cost-Effectiveness Analysis: The MUCEM Study

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BACKGROUND & AIMS: For the local excision of early rectal tumors (ERTs), the relative effectiveness of endoscopic submucosal dissection (ESD) vs transanal endoscopic microsurgery (TEM) is subject to debate. The comparisons are limited to retrospective, single-center studies lacking a health economic assessment. **METHODS:** A cost-effectiveness analysis was conducted alongside a nonrandomized, 2-arm, comparative, multicenter study. The main inclusion criterion was an ERT (adenomas, in situ and uT1N0 carcinomas) that could be resected with ESD or TEM, depending on the center. The primary effectiveness criterion was complete resection. A health care system perspective and a 1-year horizon were adopted for the cost evaluation. The results of the analysis were adjusted for baseline covariates: age, sex, body mass index, American Society of Anesthesiologists score, histology, and previous pelvic surgery. **RESULTS:** A total of 213 ESD and 117 TEM procedures were analyzed. At 1 year and with a willingness to pay of €2500 for complete resection, the incremental net monetary benefit of ESD was significant (€1797; 95% confidence interval, €861–€3,032; $P < .001$). ESD was more cost-effective for decision thresholds ranging from €0 to €6000. In terms of secondary outcomes, the en bloc excision rate favored ESD (99.0% vs 92.5%, $P < .01$). There were no significant between-group differences in overall and major morbidity. At 3 years, a cost-utility analysis did not reveal between-group differences in health-related quality of life, and the overall survival rates were similar. However, the disease-free survival rate was higher after ESD (94.3% vs 84.6% for TEM; adjusted hazard ratio, 3.55; 95% confidence interval, 1.64–7.75; $P < .001$). **CONCLUSIONS:** For ERT, ESD was more cost-effective and offered higher-quality excision and lower recurrence rates than TEM. ([ClinicalTrials.gov](https://doi.org/10.1053/j.gastro.2026.01.006), Number: NCT02885142)

Keywords: Local Excision; Health Economics; Surgery; Endoscopy; Rectal Cancer.

Local excision (LE) is the standard of care for early rectal tumors (ERTs), which are defined as rectal adenomas or carcinomas staged in situ (Tis) or staged as uT1N0.^{1–3} The benefits of LE for the treatment of benign lesions and Tis are undisputed, and the technique is less aggressive than total mesorectal excision (TME) for the treatment of early invasive carcinomas. TME is associated with a high morbidity rate (32%–38%, depending on the study),⁴ impairments in sexual functioning (10%–35% of cases) and urinary functions (5%), and poor digestive quality of life (QoL) (in 50% of cases).^{5,6} Indeed, LE has proven its oncological safety in cases of “low-risk” carcinoma (where the depth of invasion is less than 1000 μ m; pT1sm1), R0 excisions, cases with no lymphovascular or perineural invasion, cases with no budding >1 , and histologically well-to-moderately differentiated tumors.⁷

At present, LE can be performed via transanal endoscopic microsurgery (TEM) or endoscopic submucosal dissection (ESD). Both procedures are superior to earlier types of LE: TEM is superior to conventional transanal excision in terms of the en bloc resection rate, the complete

WHAT YOU NEED TO KNOW

BACKGROUND AND CONTEXT

Only retrospective, single-center studies have compared transanal endoscopic microsurgery and endoscopic submucosal dissection for the local excision of early rectal tumors, and no health economic assessments have been conducted.

NEW FINDINGS

Endoscopic submucosal dissection appeared to be superior to transanal endoscopic microsurgery for early rectal tumors in terms of cost-effectiveness, the en bloc excision rate (99.0% vs 92.5% for transanal endoscopic microsurgery, $P < .01$), and disease-free survival (94.3% vs 84.6% for transanal endoscopic microsurgery, adjusted hazard ratio, 3.55; 95% confidence interval, 1.64–7.75; $P < .001$).

LIMITATIONS

Although this cost-effectiveness analysis was conducted alongside a 2-arm, multicenter, controlled study, randomization was deemed to be unfeasible because of the geographic distance between the expert centers for endoscopic submucosal dissection and the expert centers for transanal endoscopic microsurgery.

CLINICAL RESEARCH RELEVANCE

Despite its limitations, the present study is the largest yet to have compared transanal endoscopic microsurgery and endoscopic submucosal dissection, and is the first prospective, multicenter study of this topic. To reduce potential bias, the analyses were adjusted for a range of clinical and demographic variables. Although the current guidelines recommend both techniques for early rectal tumor, the results of the present study might influence clinical practice and prompt future guidelines to favoring endoscopic submucosal dissection over transanal endoscopic microsurgery for early rectal tumors.

BASIC RESEARCH RELEVANCE

This study highlights the need for further technological and translational research into advanced endoscopic platforms and devices to better understand how instrument design and tissue–device interactions may influence resection quality, safety, and long-term oncologic outcomes in early rectal tumors.

Abbreviations used in this paper: ASA, American Society of Anesthesiologists; BMI, body mass index; CI, confidence interval; CRR, complete resection rate; DFS, disease-free survival; ERT, early rectal tumor; ESD, endoscopic submucosal dissection; GIQLI, Gastrointestinal Quality of Life Index; GLM, generalized linear model; ICER, incremental cost-effectiveness ratio; ICUR, incremental cost-utility ratio; INMB, incremental net monetary benefit; LE, local excision; LOS, length of hospital stay; NMB, net monetary benefit; OR, odds ratio; OS, overall survival; QALY, Quality-adjusted life years; QoL, quality of life; SF-36, Short Form-36; TEM, transanal endoscopic microsurgery; Tis, in situ tumor; TME, total mesorectal excision.

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resection rate (CRR), and the local recurrence rate,⁸ whereas ESD is superior to endoscopic mucosal resection in terms of the en bloc and R0 resection rates.⁹

Hence, both TEM and ESD can be used to achieve the same oncological outcome. The few published studies to have compared ESD and TEM directly did not evidence any significant benefit of one procedure over the other; however, all of these studies had a retrospective, single-center design and a small sample size.^{10–13} Consequently, the current guidelines recommend both techniques for ERT.^{1–3} Furthermore, cost-effectiveness data for TEM vs ESD have not been published, and data on the actual cost of each procedure are also scarce. We reasoned that a large-scale, multicenter, health economic study would be needed to determine which of the 2 techniques is more clinically effective and cost-efficient.

Methods

The Early Rectal Cancer: Endoscopic Submucosal Dissection or Transanal Endoscopic Microsurgery? (MUCEM)–Groupe de Recherche en Chirurgie du Rectum (GRECCAR) 13– Fédération de Recherche en Chirurgie (FRENCH) 04 prospective, 2-arm, nonrandomized, multicenter study (NCT02885142) compared TEM and ESD for the management of ERT. In the study's quasi-experimental design, centers were allocated to the experimental group (ESD) or the control group (TEM) based on organizational considerations, rather than by randomization (Figure 1).¹⁴ A quasi-experimental design is considered to be appropriate when randomization is not feasible or ethical. The study's results were reported in compliance with the Consolidated Standards of Reporting Trials 2010 statement¹⁵ and the design was approved by an independent expert committee during the French National Cancer Institute's review of a grant application for the study. Participants were recruited from June 2017 to January 2021. The total duration of the study was 52 months. Participants were followed for periods ranging from 12 to 36 months, depending on the year of enrollment.

Study Population

Patients were aged 18 years or older and presented with an ERT (ie, a rectal adenoma or rectal carcinoma Tis or staged as uT1N0 on endorectal ultrasound) that could potentially be resected using TEM or ESD and that had been confirmed histologically after a preoperative biopsy. More specifically, the lesion had to be located within 12 cm of the anal verge for an anterior tumor or within 15 cm of the anal verge for a posterior tumor, so that it was suitable for resection by TEM. All patients underwent an endorectal ultrasound examination before inclusion. Other patient inclusion criteria included social security coverage and the prior provision of written, informed consent. Included centers had to demonstrate sufficient expertise and advancement on the learning curve, namely a minimum of 10 TEM procedures or 50 ESD procedures before study entry.^{16,17} The exclusion criteria included "palliative" excision for T2/3/4, N+, or M+ tumors; preoperative radiochemotherapy; pregnancy; breastfeeding; incarceration; and legal guardianship in accordance with the French legislation.

Outcome Measures

Demographic characteristics such as age, sex, American Society of Anesthesiologists (ASA) score, and body mass index (BMI) were collected, along with the history of surgery, anti-coagulant therapy, and/or treatment with immunomodulators/steroids. Preoperative tumor characteristics (including the distance from the anal verge, the size, and circumferential involvement) were also documented. Results of the histological assessment were delivered as soon as possible after LE, which enabled "rescue" TME to be considered if necessary.

Primary outcome measure. The primary outcome measure was the incremental net monetary benefit (INMB) of ESD, when compared with TEM. The net monetary benefit (NMB) is a composite outcome, defined as the difference between the monetized effectiveness and the cost. The INMB is the difference in NMB between groups and is closely related to the incremental cost-effectiveness ratio (ICER). The effectiveness criterion was the CRR. The time horizon was set to 1 year. Costs were assessed from the health care system perspective, and neither health outcomes nor costs were discounted. The economic evaluation was conducted in accordance with the methodological guidelines established by the French National Authority for Health (Haute Autorité de Santé, Paris, France). Calculation of the CRR was based on a histological analysis: resections were considered to be complete if both horizontal and vertical margins of the specimen were tumor free, regardless of other histological results (including freedom from carcinoma and low- or high-grade dysplasia). The size of the tumor-free margin was defined as 1 mm.

Secondary outcome measures. Histological outcomes included the en bloc resection rate, the "single R0" resection rate (defined as carcinoma with low-grade dysplasia at the resection margins), the histological category (invasive carcinoma, in situ carcinoma, villous adenoma, or nonvillous adenoma), and the invasiveness (invasive vs noninvasive).

The intraoperative outcomes included the operating time (in minutes), full-thickness excision, and intraoperative complications (overall, hemorrhage, and perforation). Endoscopic perforation was defined as deep, mural injury (stage IV or V in the Sidney classification).¹⁸ Stage IV corresponds to transmural injury without contamination (the equivalent of an unplanned full-thickness resection) and stage V corresponds to transmural injury with contamination. In contrast, TEM perforations were defined as direct communication with the abdominal cavity. Clinically significant intraoperative hemorrhage was defined as blood loss exceeding 300 mL.

The main short-term clinical outcomes were overall morbidity (including hemorrhage and surgical site infection), major morbidity (according to the Clavien-Dindo classification),¹⁹ and events occurring during the hospital stay or during the 30 days post surgery. Additional outcomes included the requirement for blood transfusion, the length of hospital stay (LOS), rescue TME, and readmission rates at 1 month.

The long-term outcomes were 3-year overall survival (OS) and disease-free survival (DFS), both of which were calculated from the date of resection. DFS was defined as being free from both cancer and adenoma. QoL was assessed preoperatively and at 1, 6, 12, 24, and 36 months postoperatively, using the Short Form-36 (SF-36) questionnaire,²⁰ the EuroQol-5 Dimensions-5 Levels (EQ-5D-5L) questionnaire,²¹ and the Gastrointestinal Quality of Life Index (GIQLI).²²

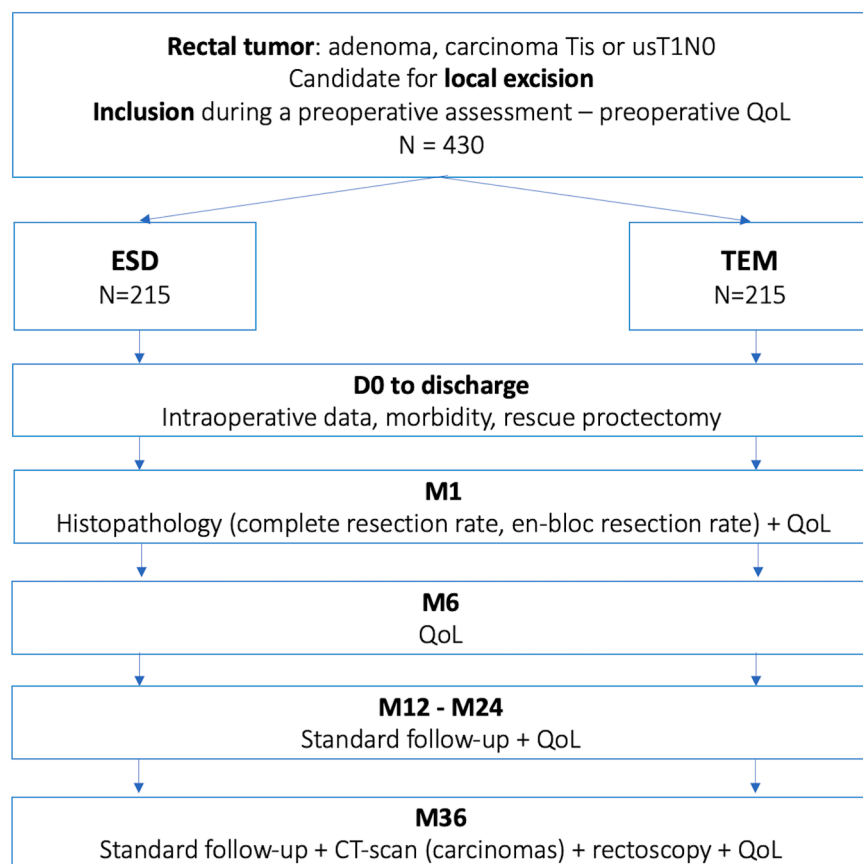


Figure 1. A schematic diagram of the study's inclusion and follow-up procedures. CT, computed tomography; D, day; M, month; us, ultrasound.

Implemented Techniques

Various devices can be used for each of the surgical techniques studied here, and each center was free to use its usual reusable or single-use equipment (Supplementary Material, Appendix 1). For the purposes of the present study, transanal minimally invasive surgery using a disposable device was considered to be TEM because the surgical technique is the same.

Sample Size

The sample size calculation was based on the INMB (Appendix 2).²³ The CRR was forecast to be 88% for TEM¹⁶ and 84% for ESD.¹⁷ Procedure costs were derived from a pilot study conducted at 2 centers (one specializing in TEM and the other specializing in ESD) on 10 consecutive patients. The mean (standard deviation) costs for TEM and ESD were €2300 (€720) and €1860 (€765), respectively. The decision threshold was set to €2500 for a complete resection, based on the assumptions regarding survival by tumor status after surgery, the proportion of cancers among ERTs, and a willingness-to-pay threshold of €30,000 per life year gained.²⁴ After the application of these assumptions, the mean (standard deviation) NMB was calculated to be –€99 (€1310) for TEM and €240 (€1050) for ESD. To test the INMB against the null with an alpha coefficient of 5% and a power of 80%, a total of 410 patients were required. Allowing for a 5% dropout rate, the recruitment of 430 patients (215 per group) was planned.

Quality-Adjusted Life Years

Quality-adjusted life years (QALYs) were calculated by combining QoL data and survival data. EQ-5D-5L utility scores were derived using the French value set.²⁵ The utility scores ranged from zero (death) to 1 (full health). Health states were assigned negative scores when perceived by patients to be worse than death. The area-under-the-curve method was applied, with linear interpolation between repeated measurements.

Costs

The costing methodology comprised the microcosting of ESD and TEM procedures, the method for valuing the initial stay during which the procedure took place, and the care received by patients during the follow-up period (Appendix 3).

The initial hospital stay. Detailed data on medical devices (including instruments, energy devices, and suturing devices) were collected from 5 TEM centers and 3 ESD centers. Two of the 5 TEM centers used a reusable rectoscope (Karl Storz, Tuttlingen, Germany) and the other 3 used single-use devices (GelPOINT Path, Applied Medical, Rancho Santa Margarita, CA). The mean cost of medical devices per procedure was estimated. Reusable medical devices were amortized over a 5-year period. The surgical team's composition was recorded and used to calculate personnel costs, based on the mean French national gross wage rates (including salaries and social benefits) for each category of personnel. In the microcosting procedure, operating room occupation time was

used to compute the procedure-related staff costs. Additional costs related to hospital stays after procedures (medical wards, supplies, logistics, general administration, and infrastructure) were obtained from French annual hospital cost studies (Études Nationales de Coûts à Méthodologie Commune)²⁶ using a diagnosis-related group classification and adjusted for the LOS. Overhead costs, medical device costs, and personnel costs were subsequently combined to estimate the mean cost per procedure and the total cost of the procedure-related hospital stays.

Follow-up costs. Health-related costs during the follow-up period were assessed using a self-reported Resource Utilization Questionnaire. Data were recorded at each scheduled protocol visit. Hospital admissions due to complications or recurrences were costed based on annual hospital cost studies (Etude Nationale des Coûts [ENC], using the diagnosis-related group classification), after adjustment for the LOS. Interactions with physicians or nurses in an outpatient setting were valued according to the French relative value scales for medical procedures (the Nomenclature Générale des Actes Professionnels²⁷ or the Classification Commune des Actes Médicaux²⁸). Laboratory procedures were valued based on the French nomenclature for laboratory procedures (Nomenclature des Actes de Biologie Médicale²⁹). Medication costs were estimated using the listed prices. Costs were expressed in 2020 Euros (€) and were adjusted using consumer price indices for health care goods and services published by the French national statistics office (Institut National de la Statistique et des Études Économiques³⁰).

Statistical Analysis

An intention-to-treat analysis was performed. Because the study was nonrandomized and baseline imbalance existed between groups, covariates included in the statistical analyses were age, sex, BMI, ASA score, tumor histology (invasive cancer vs other), and history of pelvic surgery. The statistical analysis was conducted using SPSS software (version 20.0; IBM Corp, Chicago, IL) and the health economic analysis was performed using Stata software (version 18.0; Stata Corp, College Station, TX). The threshold for statistical significance was set to $P < .05$. No interim analyses were performed.

Cost-effectiveness (the primary endpoint). A bivariate mixed generalized linear model (GLM) was used to estimate the ICER and account for the correlation between effectiveness and cost. A random center effect was included. A GLM model with a Poisson family distribution and a log link function was used for complete resection.³¹ A GLM model with a gamma family distribution and a log link function was used for cost. In both equations, differences in effectiveness and cost were estimated as the mean marginal effects of the treatment dummy variable. The 95% confidence interval (CI) for the ICER was calculated using the bias-corrected bootstrap approach and 1000 replications.³² A graph depicting the INMB and its 95% CI was plotted across a wide range of decision thresholds, from €0 to €6000 per complete resection.

Patients with unknown resection status were excluded from the cost-effectiveness analysis. Missing data were handled using multiple imputation by chained equations, with the application of predictive mean matching for continuous variables and logistic regression for binary variables. The imputation model incorporated baseline characteristics,

treatment group, and outcomes. Rubin's rules were used to combine treatment effect estimates across the multiple imputed datasets. A sensitivity analysis was conducted using Medicare financing rules (Appendix 4) for TEM and ESD.

Secondary endpoints. ESD and TEM were compared using a χ^2 test or Fisher's exact test for categorical variables and Student t test for continuous variables. Results were reported as unadjusted values and after adjustment for age, sex, BMI, ASA score, tumor histology, and history of pelvic surgery. For categorical variables, logistic regression models were used, with the results expressed as the odds ratio (OR) and the corresponding 95% CI. For continuous variables, linear regression models were applied, with the results expressed as standardized beta coefficients. Three-year OS and DFS were estimated using the Kaplan-Meier method. Between-group comparisons were based on the log-rank test or the Renyi test, as appropriate. Cox proportional hazards models (adjusted for the same covariates) were also fitted, and the results were expressed as the hazard ratio (HR) (95% CI). The groups' QoL levels were compared at each follow-up time point.

Cost-utility. QoL and cost data were censored as per the study design. Over a 36-month time horizon, differences in QALYs and costs were estimated using 2 separate linear mixed effects models.³³ A random center effect was incorporated. A graph depicting the INMB and its 95% CI was plotted for a wide range of decision thresholds (from €0 to €50,000 per QALY).

Patient and Public Involvement Statement

The study protocol was approved by an institutional review board (Comité de Protection des Personnes Sud Méditerranée I, Marseille, France; reference: 2016-A01363-48). All patients were given a study information sheet before enrollment and retained the right to withdraw at any time. Personal data were anonymized after collection. The study was endorsed by 3 learned societies: the Groupe de Recherche en Chirurgie du Rectum (GRECCAR, Paris, France), the Fédération de Recherche en Chirurgie (FRENCH, Paris, France), and the Société Française d'Endoscopie Digestive (SFED, Paris, France).

Results

Study Population

A total of 334 patients (215 for ESD and 119 for TEM) participated at 23 centers. The objective of 215 inclusions in the TEM group could not be reached during the study period, despite a 12-month extension for inclusions and follow-up. Data other than the inclusion date were unavailable for 4 patients; that is, no details of the procedure were given. Therefore, 330 patients (213 for ESD and 117 for TEM) were included in the analysis.

The ESD and TEM did not differ greatly in terms of preoperative tumor characteristics (Table 1). For example, the difference in the prevalence of circumferential involvement (3% for ESD vs 5.7% for TEM, $P = .50$) was not significant. However, in the ESD group, the lower margin was situated significantly farther from the anal verge ($P = .04$), and the lesion was larger (39.2 ± 19 mm vs 30.5 ± 17 mm for TEM, $P < .01$).

Table 1. Demographic and Preoperative Characteristics of 330 Patients Having Undergone Rectal Local Excisions Performed With ESD or TEM

	MD	ESD n = 213	TEM n = 117	P
Age, y	0	67.1 ± 11	67.5 ± 12	.71
Female/male, %	0	105 (49.3)/108 (50.7)	43 (36.8)/74 (63.2)	.03
BMI, kg/m ²	6	25.5 ± 5	26.5 ± 5	.06
ASA score 1–2/3–4, %	7	163 (79.1)/43 (20.9)	91 (77.8)/26 (22.2)	.89
Preoperative therapy, %				
Anticoagulant	11	29 (14.1)	16 (14.2)	1
Steroids/immunomodulator	14	11 (5.4)	3 (2.6)	.24
History of local excision, %	8	1 (0.5)	6 (5.4)	.01
Site/anal verge, cm	19			.04
0–5		57 (51.4)	32 (65.3)	
>5–10		30 (27)	14 (28.6)	
>10–15		24 (21.6)	3 (6.1)	
Tumor size, mm	178	39.2 ± 19	30.5 ± 17	< .01
Circumferential tumor, %	42	3 (3)	6 (5.7)	.50

NOTE. Data are reported as the mean ± standard deviation or the frequency (percentage). Bold values indicate statistically significant results ($P < .05$). MD, missing data.

Costs

The mean medical device cost was €614 for ESD, €957 for TEM with a single-use device, and €1146 for TEM with a reusable device. To prevent any bias in favor of ESD, the cost of single-use TEM was used in the cost-effectiveness analysis. Operating time and room occupancy time were significantly shorter in the TEM group (Table 1). TEM required a larger surgical team (including both medical and nonmedical staff) than ESD. When accounting for these cost factors, the mean cost per procedure was higher for TEM (€1378 vs €840 for ESD, $P < .01$). Furthermore, the LOS was 1.3 days longer for TEM ($P < .01$) (Table 2). Overall, the total mean cost for the procedure-related hospital stay was significantly higher for TEM (€4369 vs €3193 for ESD, $P < .01$) (Table 2). TEM hospital costs were higher in nearly all follow-up sub-periods. In both groups, the follow-up costs declined over time. Nonhospital costs were relatively low (Table 2). Forty-nine patients (23.8%) in the ESD group and 31 (28.7%) in the TEM group were hospitalized at least once during the first year of follow-up.

Cost-effectiveness analysis. Sixteen cases (7 for ESD and 9 for TEM) with missing CRR data were excluded. The cost difference was estimated to be 0.07 (95% CI, –0.06 to 0.19), $P = .30$ in favor of ESD (Supplementary Table 1). At 1 year, the adjusted cost difference was –€1.635 (95% CI, –€3400 to €129, $P = .06$) in favor of ESD. On average, ESD was both slightly less costly and more effective than TEM. In the cost-effectiveness plane, the scatter plot from 1000 bootstrapping simulations was distributed uneven; most values (89.4%) fell in the lower right quadrant (indicating that ESD is more effective and less costly than

TEM) and a smaller proportion (10.4%) fell in the lower left quadrant (indicating that ESD is less effective but still less costly than TEM) (Figure 2). The INMB was positive and significantly different from zero across willingness-to-pay thresholds ranging from €0 to €6000 (Figure 3). For a willingness-to-pay threshold of €2500, the INMB was estimated to be €1797 (95% CI, €861–€3,032), $P < .001$.

Sensitivity analysis (cost-effectiveness). The cost-effectiveness results were essentially the same when subgroups of patients (eg, those with a history of excision, invasive carcinoma, or rescue TME) were excluded from the analysis. Using data from the United States, the costs of ESD and TEM were estimated to be \$4720.5 and \$4823.5, respectively. To convert French 12-month outpatient and inpatient costs into US dollars, the World Health Organization's "Choosing Interventions that Are Cost-Effective" relative price index was used (ie, 1.25 for outpatient care and 1.45 for inpatient care). Applying these assumptions, the costs for ESD and TEM at 12 months were \$14,450 and \$17,282, respectively; hence, the cost was \$2832 lower for ESD.

In conclusion, the results of the sensitivity analysis did not alter the conclusions of the main cost-effectiveness analysis: ESD was more cost-effective than TEM.

Cost-utility analysis. Over a 3-year follow-up period, the QALY difference was 0.003 (95% CI, –0.17 to 0.18; $P = .97$), whereas the cost difference was –€1225 (95% CI, –€3186 to €737; $P = .22$) (Supplementary Tables 2 and 3). The INMB did not significantly differ from zero across willingness-to-pay thresholds ranging from €0 to €50,000. At a willingness to pay of €30,000 per QALY, the

Table 2. Descriptive Statistics on Costs and Utility Scores

		Periods					
		Baseline/Intervention	From baseline to 1 mo	From 1 mo to 6 mo	From 6 mo to 12 mo	From 12 mo to 24 mo	From 24 mo to 36 mo
TEM	Hospital admission costs						
	Number of missing values	5	7	19	37	48	64
	Number of patients with zero values	0	93	85	74	62	50
ESD	Mean cost (SD), €	4369 (1891)	1056 (3084)	700 (2287)	728 (3073)	420 (1347)	297 (1266)
	Number of missing values	2	9	19	33	63	78
	Number of patients with zero values	0	193	166	164	139	126
	Mean cost (SD), €	3193 (885)	115 (569)	890 (3190)	397 (2199)	263 (1152)	317 (1649)
	Non-hospital admission costs						
TEM	Number of missing values		7	19	37	48	64
	Number of patients with zero values		34	50	48	36	29
	Mean cost (SD), €		53 (85)	9 (182)	92 (195)	227 (466)	120 (218)
ESD	Number of missing values		9	19	33	63	78
	Number of patients with zero values		39	80	85	70	53
	Mean cost (SD), €		73 (171)	108 (260)	87 (171)	171 (592)	235 (572)
Utility scores							
TEM	Number of missing values	25	57	53	78	74	83
	Mean utility score (SD)	0.92 (0.14)	0.91 (0.17)	0.90 (0.21)	0.88 (0.26)	0.82 (0.31)	0.76 (0.36)
ESD	Number of missing values	13	35	63	74	104	109
	Mean utility score (SD)	0.92 (0.14)	0.94 (0.13)	0.94 (0.14)	0.92 (0.22)	0.83 (0.3)	0.83 (0.31)

SD, standard deviation.

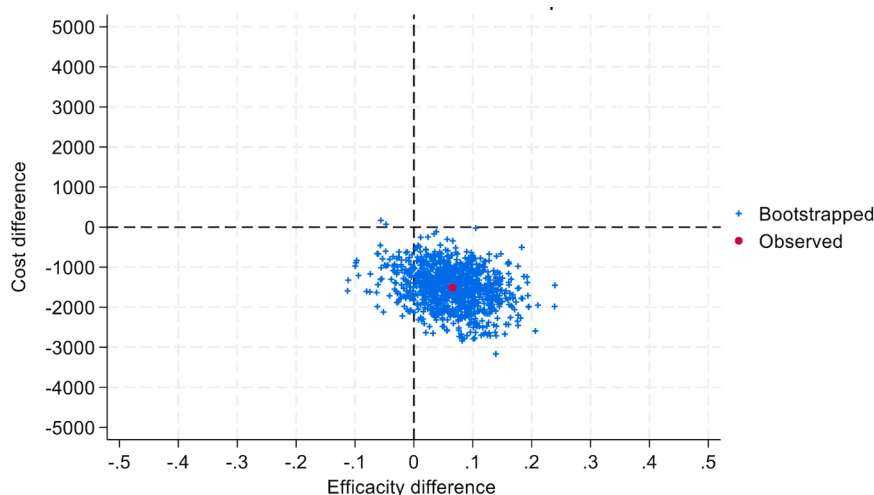


Figure 2. Cost-effectiveness scatter plot.

INMB was €1312 (95% CI, -€4247 to €8064; $P = .67$) (Supplementary Figure 1). At 36 months and with the integration of health-related QoL, ESD could not be considered to be more cost-effective than TEM.

Secondary Outcomes

Full-thickness excision was performed in 72.2% of the patients in the TEM group and 2.3% of those in the ESD group (Table 3). The most commonly resected histological type was a villous tumor in the TEM group (26.8%) and a nonvillous adenoma in the ESD group (41.5%). In the unadjusted analysis, the groups were significantly different ($P < .009$) in terms of the distribution of histological types, with more invasive carcinomas in the TEM group. However, this difference was no longer significant in the adjusted analysis (adjusted OR, 0.53; 95% CI, 0.28–1.01; $P = .053$).

The en bloc resection rate was higher for ESD than for TEM (99% vs 92.5%, respectively; adjusted OR, 9.60; 95% CI, 1.73–52.63; $P = .010$). The 2 groups did not differ significantly with regard to the overall morbidity rate and the major morbidity rate. There were 22 (10.3%) intra-operative complications in the ESD group and 6 (5.2%) in the TEM group; these included 10 and 2 perforations, respectively. Two ESD patients (0.9%) and 3 TEM patients (2.6%) required a blood transfusion. At 3 years, there was no significant difference (Figure 4) in the OS rate (95.8% for ESD vs 96.6% for TEM; adjusted hazard ratio [HR], 1.10; 95% CI, 0.33–3.70; $P = .88$), whereas the DFS rate was significantly higher in the ESD group (94.3% vs 84.6% in the TEM group; adjusted HR, 3.55; 95% CI, 1.64–7.75; $P < .001$).

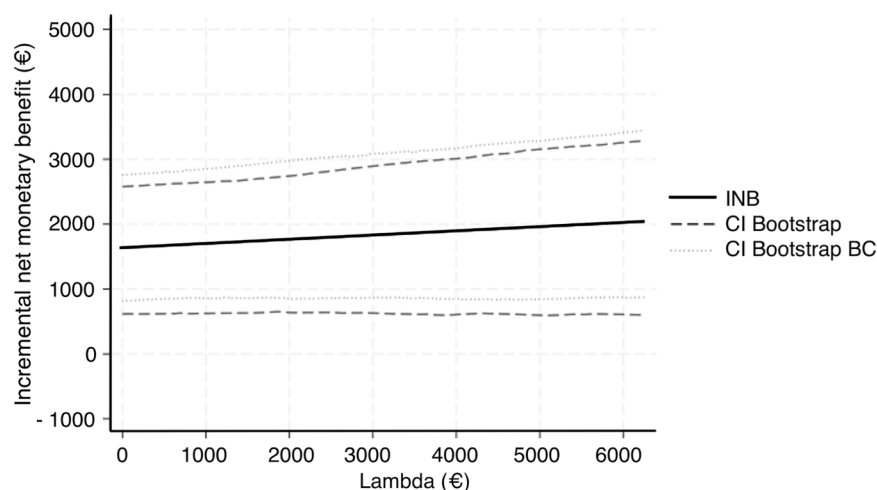
At baseline, the ESD and TEM groups were similar with regard to the SF-36 and GIQLI results (Supplementary Figures 2 and 3). The SF-36 mental composite score was better in the ESD group than in the TEM group at 1 month ($P = .03$), 1 year ($P = .03$), and 3 years ($P = .04$). The SF-36 physical composite score was significantly better in the ESD group than in the TEM group at 2 years only ($P = .03$). The GIQLI was also significantly better in the ESD group than in the TEM group at 1 month ($P < .01$), 1 year ($P = .01$), 2 years ($P = .02$), and 3 years ($P < .01$).

Twenty-one patients underwent rescue TME (Supplementary Table 4), including 11 after ESD and 10 after TEM. The most frequent procedure was TME with hand-sewn colo-anal anastomosis (41.2%), whereas 29.4% of patients underwent stapled colorectal anastomosis and 29.4% underwent abdominoperineal resection. The surgical approach was conventional laparoscopy in 53.3% of cases, robotics in 26.7%, open surgery in 13.3%, and laparoscopic TaTME in 6.7%. Only 2 patients were node-positive: 1 patient was T1N1a and 1 patient was T0N1b (ie, no residual tumor after LE). Three-year OS and DFS rates in this subgroup were 100% and 95.2%, respectively. A sensitivity analysis excluding these 21 patients showed consistent results for 3-year OS ($P = .82$) and 3-year DFS ($P < .001$, in favor of ESD). Likewise, a sensitivity analysis excluding patients with prior LE also gave consistent results for 3-year DFS ($P < .01$, in favor of ESD).

Discussion

The results of the present cost-effectiveness analysis favored ESD over TEM. Given the absence of cost analyses of ESD vs TEM in the literature, the study design was chosen to provide a simultaneous assessment of both the clinical effectiveness and the economic relevance of each procedure. Furthermore, the likelihood of demonstrating between-technique differences in the CRR was low. This approach proved to be relevant because no significant differences in CRR were observed in the present study—probably because of a lack of power (84.5% for ESD vs 76.9% for TEM, $P = .12$). The demonstration of a between-group difference in the CRR would have required a much larger TEM group. Given that the CRR was considered to be the most relevant criterion for patients with in situ or invasive carcinoma, cost-effectiveness (with CRR as the effectiveness criterion) was preferred over cost-utility as the primary endpoint. The absence of cost-per-procedure data justified our calculation of the sample size based on exploratory data from a pilot study conducted at 2 academic tertiary care centers: the first was an expert center in TEM, and the second was an expert center in ESD.

Figure 3. The INMB for ESD vs TEM and its bootstrapped 95% CI for willingness-to-pay per complete resection, varying from €0 to €6000. Time horizon: 1 year. BC, bias-corrected; CI, confidence interval; INB, incremental net benefit.



The CRR for ESD in our study (84.5%) is in line with the literature data, where the values range from 84% to 88%.^{17,34,35} In the most recently published series, however, the CRR for ESD exceeded 86%.⁹ Given that our inclusion of participants ended in 2021, this difference might be due to the use of new surgical strategies (such as the use of traction and underwater techniques) and the recent implementation of training programs.³⁶ Furthermore, the short operating time observed for ESD is in line with recent publications, with a mean procedure time of 47 minutes for 40-mm lesions in a randomized trial and 80 minutes for 60-mm lesions in a study of the impact of center volume.^{9,37} These favorable outcomes might be due to the implementation of ESD-specific training programs in Western countries. In contrast, the CRR for TEM in our series (76.9%) was lower than conventional estimates (88.5%).^{8,38–40} This discrepancy might be because of the high rate of invasive carcinoma in our TEM group (25%) and the 5.4% prevalence of prior LE. Nevertheless, our cost-effectiveness analysis of ESD and TEM remains robust, given the consistent CRR and en bloc resection outcomes in adjusted analyses and in analyses excluding patient subgroups (such as those with invasive carcinoma or prior LE). Moreover, the results of a sensitivity analysis based on Medicare reimbursement rates did not alter the findings of the cost-effectiveness study. Even when considering the very similar procedural costs for ESD and TEM (\$3649 and \$3347, respectively), ESD remained less expensive than TEM at the 12-month follow-up time point (\$14,450 and \$17,282, respectively).

There are few comparisons of TEM and ESD in the literature. Of the 4 studies to have compared TEM and ESD in ERT, none found relevant differences. However, all 4 studies had a retrospective, single-center design and a small sample size.^{10–12} Park et al¹⁰ included 63 patients and did not find a significant difference in the CRR; the only significant difference was a shorter LOS in the ESD group. In the study of 24 cases by Kawaguti et al,¹¹ there were no significant differences in the CRR or the en bloc resection rate. A recent study of 98 patients found a lower recurrence rate with ESD (1.4% vs 18.5% for TEM, $P = .001$), although

the follow-up duration was shorter in the ESD group (37.6 months vs 53.9 months for TEM).¹³ As a result, the current guidelines recommend both techniques equally for ERT.^{1–3} Although the primary endpoint of the present study was economic rather than clinical, new guidelines on ERT should favor ESD over TEM; ESD was associated with higher en bloc excision and DFS rates in both unadjusted and adjusted analyses.

The present study is the largest-yet comparison of TEM and ESD and the first comparison to have adopted a prospective, multicenter design. We applied a controlled quasi-experimental approach, which was chosen because (1) most of the French expert centers for TEM or ESD participated and (2) all but 2 of these centers were technique specific (ie, performing TEM only or ESD only).¹⁴ A randomized study was deemed unfeasible because of the geographic distance between the expert centers for each technique; this would have hindered the acceptance of randomized group attribution for both patients and practitioners. The goal of our prospective, quasi-experimental approach was to compare the ESD vs TEM groups' respective outcomes after adjusting for the lack of randomization and by accounting for center-to-center variability. However, it should be noted that the results of studies with a quasi-experimental design may nevertheless be influenced by between-center differences in expertise, resources, and patient populations. Only expert centers participated in the present study, which helped to limit these potential biases. Another concern in our study was the significant proportion of missing data. To address this concern, we adjusted our analysis and used linear mixed models that have been recently validated for trial-based cost-effectiveness analyses.³³

The inclusion criterion for centers was performance of at least 10 TEM procedures or 50 ESD procedures before study entry. These thresholds were not arbitrarily defined but were derived from the literature data on the learning curves for these procedures.^{16,17} The difference between 10 procedures and 50 procedures is explained by (1) the fact that ESD requires more advanced technical skills

Table 3. Secondary Outcomes (Histological, Intraoperative Results, and Short-Term Postoperative Results) of 330 Rectal Local Excisions Performed Using ESD or TEM

		ESD n = 213	TEM n = 117				
		n (%) M ± SD	n (%) M ± SD	P ^a	aOR (95% CI) ^b β ^b	P ^c	MD
Histological results							
En bloc resection	Yes ^d	202 (99.0)	99 (92.5)	.004	9.60 (1.73–52.63)	.010	19
Single R0 rates	Yes ^d	174 (84.5)	83 (76.9)	.096	1.57 (0.83–2.97)	.159	16
Histological type	Invasive ^d	29 (14.0)	28 (25.9)	.009	0.53 (0.28–1.01)	.053	15
	Noninvasive ^e	178 (86.0)	58 (74.1)				
Histological type	Invasive carcinoma	29 (14.0)	28 (25.0)	—	—	—	11
	In situ carcinoma	72 (34.8)	13 (11.6)				
	Villous adenoma	18 (8.7)	30 (26.8)				
	Nonvillous adenoma	88 (42.5)	37 (33.0)				
	Other	0	4 (3.6)				
Intraoperative complications							
Operating time, min		92.5 ± 69.2	48.2 ± 37.5	<.001	0.309	<.001	9
Intraoperative complications	All	22 (10.3)	6 (5.2)	.114	1.51 (0.53–4.31)	.437	2
	Hemorrhage	7 (3.3)	1 (0.9)	.227	—		
	Perforation	10 (4.7)	2 (1.7)	.269	—		
Short-term outcomes							
Overall morbidity	All	35 (17.4)	22 (20.2)	.548	0.93 (0.49–1.76)	.819	20
	Hemorrhage	10 (4.8)	3 (2.7)	.554	—		7
	SSI	0	1		—		
Major morbidity		6 (2.9)	7 (6.2)	.233	0.54 (0.16–1.82)	.322	7
Time to bowel movements, d		1.1 ± 2.7	1.7 ± 1.8	.101	—		111
LOS, d		2.2 ± 1.4	3.5 ± 3.0	<.001	— 0.245	<.001	7
One-month readmission		17 (8.8)	15 (14.2)	.148	0.69 (0.30–1.57)	.376	30
Rescue TME		11 (5.5)	10 (9.7)	.172	0.95 (0.31–2.78)	.918	27

NOTE. Data are reported as n (%) or M ± SD. aOR (95% CI), adjusted OR (95% CI) for ESD (vs TEM); β, standardized beta coefficients for ESD (vs TEM); M, mean; MD, missing data; SD, standard deviation; SSI, surgical site infection.

^aUnadjusted P value.

^bAdjustment for age, sex, body mass index, ASA score, histology, previous pelvic surgery.

^cAdjusted P value.

^dReference modality for OR.

^eNoninvasive cases including in situ carcinoma, villous adenoma, and nonvillous adenoma.

(single-handed maneuvers and identification of a fine submucosal plane rather than a 2-handed full-thickness excision) and (2) the relatively recent introduction of ESD, a long learning curve, and thus the existence of a “pioneering” phase (as has also been observed in laparoscopic hepatic surgery, for example).⁴¹ Nevertheless, only expert centers were included in this study, with surgeons at each center having performed more than 50 TEM procedures.

The INMB was preferred to the ICER or the incremental cost-utility ratio (ICUR) in both the main economic analysis (the cost-effectiveness analysis with a 1-year time horizon) and the complementary analysis (the cost-utility analysis with a 3-year time horizon), due to the small differences in cost and effectiveness between TEM and ESD (Appendix 5). In this case, the statistical inferences and the interpretation of the results were easier with the INMB than with the ICER or the ICUR. The decision rule was not changed, and the

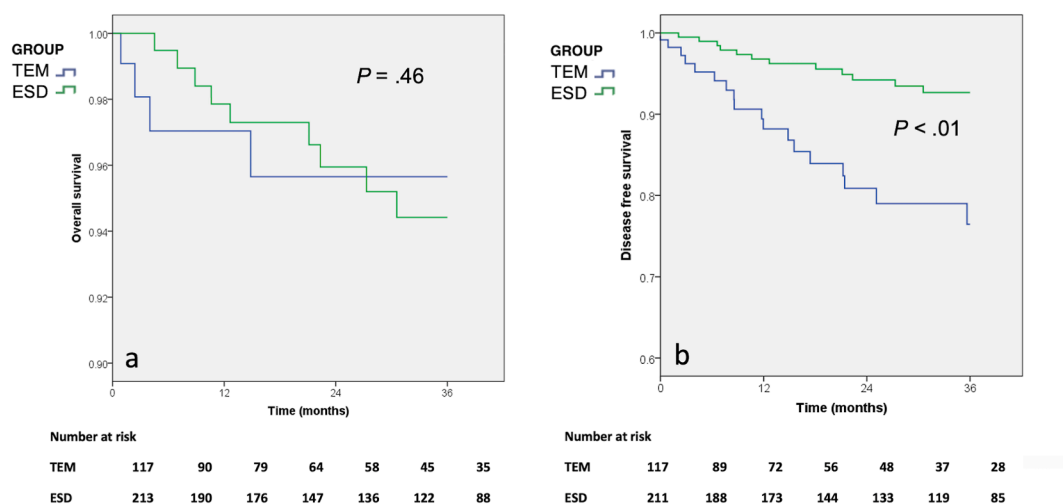


Figure 4. Three-year OS (A) and DFS (B) in 213 patients having undergone ESD and 117 patients having undergone TEM; between-group differences were assessed with the Renyi test and the log-rank test, respectively.

boundaries of the 95% CIs for the INMB, ICER, and ICUR could be compared. In settings in which there is no official cost-effectiveness threshold (such as France), the ability to plot the INMB curve and its 95% CI over a wide range of lambda values is valuable for decision making.

In the TEM group, the recruitment target was not met; this was probably because of changes in clinical practice. In France, ERTs are primarily managed by gastroenterologists, who subsequently refer cases to expert endoscopy centers. Furthermore, the anatomical limitations of TEM (which must be performed below the peritoneal reflection) might have prompted nonexpert gastroenterologists to refer ERT patients to expert ESD centers rather than to surgical teams. It became increasingly challenging to enroll patients in the TEM group over the course of the study because most patients underwent ESD. These issues also might explain the differences in tumor types between the groups; in particular, invasive carcinomas and villous adenomas were more frequent in the TEM group. Despite the robustness of our adjustments and sensitivity analyses, these differences constitute a study limitation.

The cost-utility analysis revealed no difference in QALYs at 3 years. There were no differences in the OS rate or QoL (as assessed by EQ-5D) between the ESD and TEM groups. However, the SF-36 and GIQLI results indicated that certain dimensions of QoL were better in the ESD group than in the TEM group. Although the EQ-5D is the internationally recommended instrument for economic evaluations, other instruments may be more sensitive for detecting differences in health-related QoL associated with treatments for ERTs.⁴²

Importantly, the present study assessed ERTs only and not organ-preservation strategies; the latter are becoming paramount in the field of advanced rectal cancer. In this paradigm shift, the clinician seeks to prioritize QoL while maintaining optimal oncological outcomes via LE of the remaining scar or a “watch and wait” strategy. In trials having evaluated LE, the rate of effective organ preservation ranges from 50% to 83%, and 5-year recurrence-free

survival rates range from 70% to 88%.⁴³ However, only surgical LE with TEM has been evaluated in this context,⁴⁴ and no endoscopic procedures have been assessed to date.

Conclusions

In the management of ERT, ESD appears to offer advantages over TEM in terms of cost-effectiveness, the en bloc resection rate, the DFS rate, and QoL. Importantly, these conclusions apply exclusively to benign tumors and in situ or *uT1N0* carcinomas and not to organ-preservation strategies in which TEM remains the standard in the event of resection. However, health care sustainability and the CO₂ equivalent are now fundamental factors in the choice between techniques, and we intend to perform a post hoc analysis of this aspect.

Supplementary Material

Note: To access the supplementary material accompanying this article, visit the online version of *Gastroenterology* at www.gastrojournal.org, and at <https://doi.org/10.1053/j.gastro.2026.01.006>.

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Conflicts of interest

The authors disclose no conflicts.

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Data Availability

The data that support the findings of this study are available from the corresponding author on reasonable request. Because of ethical and regulatory restrictions related to patient confidentiality, the data are not publicly available.