

# Transanal Total Mesorectal Excision in Rectal Cancer

## Short-term Outcomes in Comparison With Laparoscopic Surgery

*María Fernández-Hevia, MD,\* Salvadora Delgado, MD, PhD,\* Antoni Castells, MD, PhD,† Marta Tasende, MD,\* Dulce Momblan, MD,\* Gabriel Díaz del Gobbo, MD,\* Borja DeLacy, MD,\* Jaume Balust, MD, PhD,\* and Antonio M. Lacy, MD, PhD\**

**Objective:** The aim of this study was to compare short-term results obtained with transanal total mesorectal excision (TME) and laparoscopic surgery.

**Background:** Transanal TME appears as an alternative in the treatment of rectal cancer and other rectal disease. Natural orifices transluminal endoscopic surgery using the rectum as access in colorectal surgery is intuitively better suited than other access routes.

**Methods:** All consecutive patients with middle or low rectal cancer submitted to surgery were included into a prospective cohort and treated by transanal TME assisted by laparoscopy. They were compared with a retrospective cohort of consecutive patients of identical characteristics treated by laparoscopic TME in the immediate chronological period.

**Results:** Thirty-seven patients were included in both study groups. No differences were observed between them with respect to baseline characteristics, thus emphasizing the comparability of both cohorts. Surgical time was higher in the laparoscopy group ( $252 \pm 50$  minutes) than in the transanal group ( $215 \pm 60$  minutes) ( $P < 0.01$ ). Moreover, coloanal anastomosis was performed less frequently (16% vs 43%, respectively;  $P = 0.01$ ) and distal margin was lower ( $1.8 \pm 1.2$  mm vs  $2.7 \pm 1.7$  mm, respectively;  $P = 0.05$ ) in the laparoscopy group than in the transanal one. Although there was no significant difference in 30-day postoperative complication rate (laparoscopy, 51% vs transanal, 32%;  $P = 0.16$ ), early readmissions were more frequent in the laparoscopy group than in the transanal one (22% vs 6%, respectively;  $P = 0.03$ ).

**Conclusions:** Evaluation of short-term outcomes demonstrated that transanal TME is a feasible and safe technique associated with a shorter surgical time and a lower early readmission rate.

**Keywords:** anterior resection, laparoscopy TME, Natural orifices transluminal endoscopic surgery, rectal cancer, transanal TME

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In the last 30 years, the treatment of rectal cancer has changed extensively. At present, it is accepted that it represents the paradigm of a multidisciplinary approach, being total mesorectal excision (TME) the gold standard from a surgical point of view.<sup>1</sup>

The use of minimal invasive techniques in the surgical treatment of rectal cancer is still controversial. Several prospective randomized studies have shown that laparoscopic surgery does not com-

promise oncological outcomes compared with open surgery in low rectal cancer.<sup>2,3</sup> In addition, a recent large randomized controlled trial (the COREAN trial) has demonstrated that laparoscopic surgery was feasible and safe, with some short-term benefits over open surgery for patients with middle or low rectal cancer treated with neoadjuvant chemoradiation.<sup>2</sup> Besides, the COLOR II trial has shown that there were no statistically significant differences between laparoscopic and open surgical procedures with respect to TME in high and middle rectal tumors, but the first approach was superior in low rectal tumors probably due to the fact that laparoscopy gets a better view in this subset of patients.<sup>3</sup> It is important to mention, however, some limitations of this technique in rectal surgery, including the approach to patients with narrow pelvis or obesity and sphincter preservation, which are still points of concern.

Natural orifices transluminal endoscopic surgery using the rectum as access in colorectal surgery is intuitively better suited than other access routes because it does not require incisions in viscera not directly implicated in the process. It is also a universal way, which is not limited by patients' sex and it seems to have several advantages with respect to other approaches, especially in obese patients and in those with narrow pelvis. Furthermore, it has a significant gain in avoiding abdominal incisions for organ extraction and, therefore, it may represent the natural evolution of minimally invasive colorectal surgery.<sup>4–8</sup>

The first transanal TME resection assisted by laparoscopy was published in 2010.<sup>8</sup> Since then, there have been publications showing a few reports with short series of cases demonstrating how this technique can be performed safely and preserving oncological TME principles.<sup>9–18</sup> The largest series published so far has included 30 patients and suggested the potential benefit of using this technique in patients with unfavorable characteristics, such as male, obesity, and narrow pelvis.<sup>15</sup> Similarly, we have reported our initial experience in 20 patients demonstrating the safety and feasibility of transanal minilaparoscopy-assisted natural orifice surgery for rectal tumors.<sup>16</sup> Finally, only 1 case of pure natural orifices transluminal endoscopic surgery transanal rectal resection has been published so far.<sup>18</sup>

In this article, we report short-term results of the first study in which transanal TME assisted by laparoscopy has been compared with laparoscopic surgery for the resection of middle and low rectal cancer.

## METHODS

All consecutive patients with middle or low rectal cancer submitted to surgery in the Hospital Clínic of Barcelona from November 2011 to March 2013 were included in this prospective study and treated by transanal TME assisted by laparoscopy (transanal group). To minimize any potential bias, they were compared with a retrospective cohort of consecutive patients of identical characteristics treated by laparoscopic TME (laparoscopy group) in our center in the immediate chronological period (from August 2010 to October 2011) in a 1:1 ratio.

From the Departments of \*Gastrointestinal Surgery; and †Gastroenterology, Institute of Digestive and Metabolic Diseases, Hospital Clínic, IDIBAPS\*, Centro de Investigación Biomédica en Red en Enfermedades Hepáticas y Digestivas (CIBERehd), University of Barcelona, Centro Esther Koplowitz, and Cellex Biomédical Research Centre, Barcelona, Catalonia, Spain.

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Reprints: Antonio M. Lacy, MD, PhD, Department of Gastrointestinal Surgery, Hospital Clínic, Villarroel 170, 08036, Barcelona, Spain. E-mail: alacy@clinic.ub.es; steres@clinic.ub.es.

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The trial was approved by the Institutional Review Board of the Hospital Clínic of Barcelona and conducted according to the principles of good clinical practice. Informed consent to participate in the study was obtained from all patients.

### Patient Selection

Eligibility criteria included patients with middle and low rectal histologically confirmed adenocarcinoma located up to 10 cm from the anal verge. Therefore, patients with high rectal cancer and those requiring an abdominoperineal resection were not included. Preoperative staging included blood analyses with carcinoembryonic antigen serum concentration, total colonoscopy, transanal ultrasonography, rigid rectoscopy, rectal magnetic resonance imaging, and thorax and abdominal computed tomography (CT).

Neoadjuvant chemoradiation was done in all patients with T3–T4 N0 or T1–T4 N1–N2 tumors according to the preoperative staging. Patients with T3a tumors with favorable magnetic resonance imaging or pathological factors were evaluated by a multidisciplinary committee and, in some occasions, they did not receive neoadjuvant or adjuvant treatment. The protocol included a total dose of 45 Gy, with a daily dose of 1.8 Gy administered 5 days each week, and chemotherapy with continuous 5-fluorouracil infusion, 225 mg/m<sup>2</sup>/d, during 5 days, concomitantly with radiation therapy.

### Surgical Techniques

Patients received mechanical bowel cleansing the day before. All of them also received antibiotic prophylaxis with 2 g of cefoxitin, or 400 mg of ciprofloxacin and 500 mg of metronidazole in patients with allergy to penicillin, intravenously. Patients were fixed and placed in lithotomy position with legs in padded, adjustable stirrups. The rectum was irrigated with diluted iodine solution and prepared in the usual way. In the transanal group, 2 fields were prepared for both abdominal and perineal accesses. A urinary catheter was inserted in sterile conditions.

### Laparoscopy Group

It was usually used 0-degree or 30-degree scope at the umbilicus with a 12-mm port, 12-mm and 5-mm ports at low right quadrant, 5-mm port at low left quadrant, and, in some cases, a fifth port suprapubic (useful during pelvic dissection) and/or 5-mm port subxiphoid (if splenic flexure mobilization was needed). After division of the inferior mesenteric artery and vein, the left colon was completely mobilized and, only if it was necessary, the splenic flexure was mobilized as well. TME was carried out up to down, according to the key principles of a correct oncologic surgical procedure. Rectum was sectioned using lineal stapler below the tumor (through 12-mm port at low right quadrant). A Pfannenstiel was often used as an assisted incision, unless we could take advantage of previous incisions, its length depending on tumor size. In 3 cases, the specimen was extracted transanally and in 1 case, transvaginally. Anastomoses were performed with a circular stapler in all cases. A diverting stoma was generally done and a suction drain was placed in the deep pelvis. Further details are published elsewhere.<sup>19</sup>

We defined conversion in laparoscopy group when the procedure was completed by open surgery, not including hand port. In our series, no patient needed hand port–assisted surgery.

### Transanal Group

Two surgical teams worked at the same time, the first performing the abdominal phase as it was described for the laparoscopy group, and the second performing the perineal phase.

After positioning the Lone star retractor (CooperSurgical Inc., Stafford, TX) and exploring the rectum, 2 options existed. In very

low tumors (ie, those located up to 3 cm from the anal verge), it was needed to perform an intersphincteric dissection after sectioning the dentate line with electrocautery. Once the full thickness of the rectal wall was completely sectioned, a purse-string suture was placed through the rectum to tightly occlude it. Thereafter, it was necessary for the transanal dissection of the first 4 to 4.5 cm of the anal canal to insert a Gelpoint path Transanal Access Platform (Applied Medical, Inc., Rancho Santa Margarita, CA) as shown in Figure 1. CO<sub>2</sub> was insufflated to a pressure of 10 to 12 mm Hg, and it was adapted during the progression of the dissection. A 3-dimensional (3D) flexible-tip endoscope (Olympus KeyMed, Hamburg, Germany) was used. Once introduced into the presacral plane, the mesorectum was mobilized; the posterior dissection proceeded cephalic in the avascular presacral plane in accordance with TME principles. This plane of dissection was extended medially, laterally, and anteriorly to achieve circumferential rectal mobilization. The dissection was performed circumferentially and progressively to avoid retraction of the rectum that could make the division of one side difficult. Finally, the peritoneal reflection was visualized and divided to achieve the sigmoid colon mobilization, with both teams collaborating to complete it. We considered that the transanal team should open the peritoneal reflection to avoid problems with the pneumorectum, because opening too early could have hindered the transanal dissection because of an inadequate distension. The device was removed and the specimen was carefully extracted transanally. The section of sigmoid colon was performed proximal to the vascular pedicle with scalpel. The division of the remaining mesentery and the marginal artery were completed with the specimen exteriorized. A handsewn coloanal anastomosis was performed between the proximal sigmoid colon and the distal anorectal cuff.

In middle and low rectal tumors, after positioning the Lone star retractor, the Gelpoint path Transanal Access Platform (Applied Medical, Rancho Santa Margarita, CA, USA), with the same ports described previously, was positioned in the anal canal. Most cases were performed using a 3D system, which was not available previously and, accordingly, it could not be used in any patient from the laparoscopy group. A purse-string suture was placed through the rectal mucosa to tightly occlude it distally to the lesion. Endoscopic transection of the full-thickness rectal wall was performed and, thereafter, another purse-string suture was placed in the distal rectal mucosa. The mesorectum mobilization was made as previously described. The specimen was exteriorized transanally, the colon was

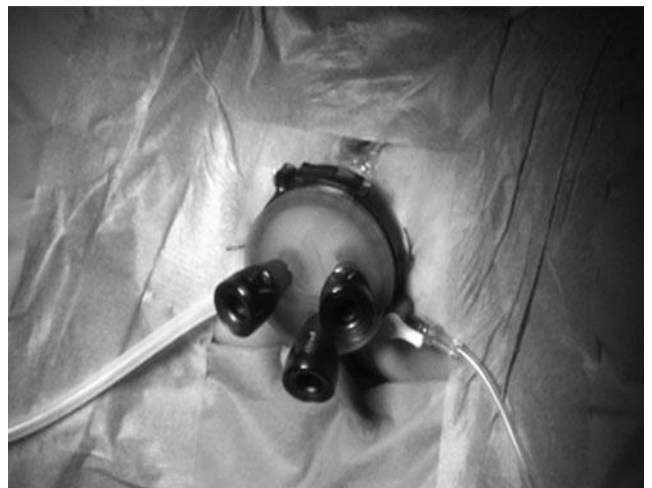


FIGURE 1. Transanal device (Gelpoint path Transanal Access Platform; Applied Medical, Inc. Rancho Santa Margarita, CA).

sectioned, and a purse-string suture was placed and the anvil inserted. The rectal anastomosis was performed with a circular stapler EEA 33-mm single-use stapler with 4.8-mm staples (Autosuture, Covidien, Mansfield, MA). Depending on tumor location, the anastomosis could be purse-string handsewn coloanal or purse-string lateral/end-to-end stapling. Generally, a diverting stoma was performed and a suction drain was placed in the deep pelvis and exteriorized through the left lower quadrant 5-mm port site. Finally, when there was a large tumor, a bulky mesentery, or a size mismatch between the rectum and the specimen, an assisted incision was performed to specimen extraction (Pfannenstiel or previous incision).

We defined conversion in the transanal group when TME was not completed down to up transanally. Assisted incision was not considered as a conversion criteria because it was not possible to extract the specimen transanally by the causes explained before.

Ileostomy was generally indicated in irradiated patients with low or ultralow anastomosis, although the final decision was always made during the surgical procedure.

### Postoperative Control

Postoperatively, patients mobilization started the day after surgery, whereas diet was initiated when bowel movement were present. No fast track was established in our center when the study was performed. We evaluated perioperative complications, including intraoperative complications, and those occurring within the 30-day postoperative period and the readmission rate.

### Statistical Methods

Continuous variables are described as mean  $\pm$  standard deviation (range) and compared by the Student *t* test or the Mann-Whitney *U* test, depending on their distribution. Categorical variables are reported as percentages and compared by the  $\chi^2$  test, applying the Yates correction when needed. A *P* value of less than 0.05 was defined as statistically significant.

## RESULTS

Thirty-seven patients with middle and low rectal cancer treated by transanal TME assisted by laparoscopy were included in the study. According to the study design, 37 consecutive patients with middle and low rectal cancer treated by laparoscopy surgery in the immediate chronological period were included as control group. Characteristics of these patients are shown in Table 1.

As it is shown, there are no statistically significant differences between both groups with respect to age, sex, body mass index, previous abdominal surgery, American Society of Anesthesiologists grade, tumor stage, and tumor location. On the contrary, patients in the transanal group received neoadjuvant chemoradiation more frequently than those in the laparoscopy group, probably because of a higher proportion of stage T3 tumors in the former group. Finally, there are no statistically significant differences with respect to tumor size, number of lymph nodes evaluated, circumferential margin involvement (considering as a positive circumferential margin  $<1$  mm), and pTN staging, thus confirming the comparability of both groups. It is important to mention that TME completeness, the most important measure of the quality of rectal surgery, was assessed as complete or almost complete in most patients of both groups (Table 1); indeed, only 1 patient from the transanal group, in whom a total colectomy was performed previously, had an incomplete resection.

Table 2 describes characteristics of surgery in both groups of patients. Surgical time was higher in the laparoscopy group ( $252 \pm 50$  minutes) than in transanal group ( $215 \pm 60$  minutes) ( $P < 0.01$ ); this difference probably reflects the fact that 2 teams were working simultaneously in the transanal group. A 3D technology was used in most patients from the transanal group, whereas a 30-degree 10-mm scope

was employed in the remaining 2 cases. On the contrary, coloanal anastomosis was performed less frequently in the laparoscopy group than in the transanal one (16% vs 43%, respectively;  $P = 0.01$ ), mainly due to the fact that all patients treated by transanal TME at the beginning of the study required this type of anastomosis because they were diagnosed with low rectal tumors, and we did not have the stapler until the seventh case. Indeed, after excluding from the analysis those patients treated before the first stapler was used, this difference was attenuated (16% vs 32%, respectively;  $P = 0.10$ ). In the laparoscopic group, no patient was performed using hand-assisted procedure. Splenic flexure mobilization was significant more frequently in the transanal group than in the laparoscopy group (37.8% vs 13.5%, respectively;  $P = 0.02$ ), in association with a higher incidence of coloanal anastomoses. Assisted incision was performed only in 1 patient from the transanal group because the tumor was larger than 6 cm and he had a bulky mesentery. There were 4 patients in the laparoscopy group without assisted incision in whom the specimen was extracted transanally in 3 of them and transvaginally in the remaining 1. Finally, the distal margin was lower in the laparoscopy group than in the transanal one ( $1.8 \pm 1.2$  mm vs  $2.7 \pm 1.7$  mm, respectively;  $P < 0.01$ ). When we separated the series according to tumor location, we found that distal margin remained statistically significantly lower in the laparoscopy group than in the transanal group for patients with medium rectal tumors ( $2.2 \pm 1.2$  mm vs  $3.2 \pm 1.7$  mm, respectively;  $P = 0.02$ ), but this difference was not statistically significant for those with low rectal tumors (Table 2).

Table 3 describes short-term outcomes after surgery in both groups of the study. As it is shown, although starting diet period and length of stay were shorter in the transanal group, these differences do not reach statistical significance. Similarly, the proportion of patients with 30-day postoperative complications was higher in the laparoscopy group than in the transanal one [19 (51%) vs 12 (32%)], although this difference is not statistically significant ( $P = 0.16$ ). In that sense, it is important to mention that the anastomotic leak rate is lower in patients treated by transanal TME than in those from the laparoscopy group [2 (5.4%) vs 4 (11%), respectively;  $P = 0.39$ ]. The number of collections is higher in laparoscopic group than in the laparoscopy group, although this difference is not statistically significant. Two patients from the laparoscopy group and 1 from transanal group were readmitted because of this cause, all of them presented with fever, with an abdominal computed tomographic scan demonstrating the presence of a collection without gas, and with an adequate evolution after antibiotic therapy. The remaining 3 patients were diagnosed at the initial admission: 2 of them presented with fever, had an enema—computed tomographic scan demonstrating absence of anastomotic leak, and with an adequate evolution after antibiotic therapy; finally, a collection was identified in an abdominal computed tomographic scan obtained because of a long postoperative ileus in 1 patient with a local problem with ileostomy, which required subsequent surgery. Moreover, whereas acute urinary retention was observed more frequently in the laparoscopy group, the incidence of postoperative ileus was higher in the transanal TME, although none of these differences achieved statistical significance. Finally, there was no difference between groups with respect to intraoperative complications and need of a second look surgery.

Readmissions were more frequent in patients from the laparoscopy group than in those treated by transanal TME [8 (22%) vs 2 (6%), respectively;  $P = 0.03$ ], with no difference in the need of surgery during readmission.

## DISCUSSION

This cohort study investigates short-term outcomes after transanal TME in rectal low-middle tumors. In comparison with the results obtained with laparoscopic surgery, this novel approach is

TABLE 1. Demographic Characteristics of Patients Included in the Study

	Laparoscopy Group (n = 37)	Transanal Group (n = 37)	P
Age, yr*	69.5 ± 10.5	64.5 ± 11.8	0.06
Sex			0.63
Male	22 (60%)	24 (65%)	
Female	15 (41%)	13 (35%)	
BMI (kg/m <sup>2</sup> )*	25.1 ± 4.0	23.7 ± 3.6	0.11
	(range, 15.0–31.6)	(range, 18.0–31.0)	
Overweight (BMI >25 kg/m <sup>2</sup> )	21 (56%)	16 (43%)	0.24
Obesity (BMI >30 kg/m <sup>2</sup> )	3 (9%)	4 (12%)	0.69
Previous laparotomy			0.26
Yes	10 (27%)	6 (16%)	
No	27 (73%)	31 (84%)	
ASA grade			0.37
I	1 (3%)	2 (6%)	
II	24 (65%)	28 (76%)	
III	12 (32%)	7 (19%)	
Tumor location			0.61
Medium rectum	24 (65%)	26 (70%)	
Low rectum	13 (35%)	11 (30%)	
Height of distal edge of the tumor (cm)*			
Medium rectum	8.2 ± 1.5	8.1 ± 1.7	0.41
Low rectum	3.9 ± 1.2	3.5 ± 1.2	0.82
Neoadjuvant chemoradiation			<0.05
Yes	21 (57%)	27 (73%)	
No	14 (38%)	9 (24%)	
Only radiotherapy	2 (5%)	1 (3%)	
T stage†			0.58
T2	10 (29%)	8 (22%)	
T3	21 (62%)	26 (72%)	
T4	3 (9%)	2 (6%)	
N stage†			0.78
N0	20 (58%)	22 (61%)	
N1	10 (29%)	10 (28%)	
N2	3 (9%)	4 (11%)	
M stage			0.16
M0	33 (89%)	36 (97%)	
M1	4 (11%)	1 (3%)	
Tumor size (cm)*	2.7 ± 1.5	2.6 ± 1.4	0.73
Circumferential margin involvement	0 (—)	0 (—)	—
Circumferential margin (mm)*, ‡	11 ± 0.6	12 ± 0.9	0.48
Mesorectal resection quality			0.60
Complete	35	34	
Almost complete	2	2	
Incomplete	0	1§	
Evaluated lymph nodes*			
Total series	14.7 ± 6.0	14.3 ± 6.0	0.94
Only nonirradiated patients	17.6 ± 7.1	16.4 ± 3.4	0.61
Complete remission			0.20
Yes	8 (22%)	4 (10.8%)	
No	29 (78%)	33 (89.2%)	
pT stage			0.22
T1	1 (3%)	3 (8%)	
T2	7 (24%)	7 (21%)	
T3	16 (55%)	22 (67%)	
T4	5 (17%)	1 (3%)	
pN stage			0.34
N0	31 (84%)	26 (70%)	
N1	5 (14%)	8 (22%)	
N2	1 (3%)	3 (8%)	

ASA indicates American Society of Anesthesiologists; BMI, body mass index.

\*Expressed as mean ± standard deviation.

†Assessed by magnetic resonance imaging. In 4 cases (3 from the laparoscopic group and 1 from transanal group), pretreatment T and N stages could not be assessed.

‡Circumferential margin has been evaluated only in those patients without complete response after neoadjuvant treatment.

§Patient with a previous total colectomy.

TABLE 2. Characteristics of Surgery in Both Groups of the Study

	Laparoscopy Group (n = 37)	Transanal Group (n = 37)	P
Surgery time (minutes)*	252 ± 50 (range, 135–290)	215 ± 60 (range, 120–360)	<0.01
Use of 3D technology	0 (—)	29 (78%)	<0.01
Type of anastomosis			0.01
Mechanical	31 (84%)	21 (57%)	
Coloanal	6 (16%)	16 (43%)	
Type of anastomosis†			0.10
Mechanical	31 (84%)	21 (68%)	
Coloanal	6 (16%)	10 (32%)	
Conversion	0 (—)	0 (—)	—
Splenic flexure mobilization	5 (13%)	14 (38%)	0.02
Assisted incision	33 (89%)	1 (3%)	<0.01
Diverting ileostomy	30 (81%)	32 (86%)	0.53
Distal resection margin (cm)*,‡			
Overall	1.7 ± 1.3	2.8 ± 1.8	<0.01
Medium rectal cancer	2.2 ± 1.2	3.2 ± 1.7	0.02
Low rectal cancer	1.1 ± 0.9	1.6 ± 1.3	0.33

\*Expressed as mean ± standard deviation.

†After excluding from the analysis those patients (n = 6) treated before the first stapler was used.

‡Patients with complete remission have been excluded from this analysis.

TABLE 3. Short-term Outcomes After Surgery

	Laparoscopy Group (n = 37)	Transanal Group (n = 37)	P
Starting diet period, d*	2.9 ± 3.3 (median, 2; range, 1–16)	2.4 ± 2.2 (median, 2; range, 1–11)	0.37
Time to discharge, d*	9.0 ± 7.6 (median, 6; range, 4–39)	6.8 ± 3.0 (median, 6; range, 3–17)	0.10
Intraoperative complications	0 (—)	0 (—)	—
30-d postoperative complications	19 (51%)	12 (32%)	0.16
Type of postoperative complication†			
Anastomotic leak	4 (11%)	2 (5%)	0.39
Collection	5 (13%)	1 (3%)	0.08
Hemorrhage	0 (—)	1 (3%)	0.31
Acute urinary retention	4 (11%)	1 (3%)	0.16
Ileus	2 (5%)	4 (11%)	0.39
Others‡	6 (16%)	3 (8%)	0.49
Surgery (2nd look)	3 (8%)	3 (8%)	0.97
Clavien-Dindo classification			0.17
None	18 (49%)	25 (68%)	
Grade I	10 (27%)	8 (22%)	
Grade II	4 (11%)	1 (3%)	
Grade III	4 (11%)	3 (8%)	
Grade IV	1 (3%)	0 (—)	
Readmission	8 (22%)	2 (6%)	0.03
Cause of readmission			
Anastomotic leak	2	0	—
Collection	2	1	—
Ileostomy complication	1	0	—
Subocclusion	2	0	—
Hemorrhage	1	0	—
Boerhaave syndrome	0	1	—
Surgery during readmission	3 (8%)	1 (3%)	0.44

\*Expressed as mean ± standard deviation.

†The number of individual complications exceeds the total number of complications, because 1 patient may have more than 2 complications.

‡Other complications include ascites, fever, and high ileostomy output.

associated with a shorter surgical time, similar achievement of oncological resection principles, and a lower early readmission rate.

As it was mentioned previously, duration of the surgical intervention was shorter in the transanal group. Although this circumstance is obviously due to the fact that 2 teams were

working simultaneously, it is especially noteworthy because this study includes all cases undergoing transanal surgery because this technique was introduced in our center and, therefore, it reflects the learning curve. This result emphasizes the feasibility of this novel technique by teams with experience in laparoscopic surgery.

Moreover, the collaboration between the abdominal and transanal teams provides us with a better control during surgery and respects the principle of laparoscopic surgery of traction/countertraction.

Achievement of the oncological resection principles is demonstrated by the identical number of lymph node resected in both groups of the study and by the preservation of the circumferential margin in all cases. It is well known that this latter parameter correlates with the risk of tumor recurrence after surgery. Indeed, complete or nearly complete mesorectal fascia is a recognized and universally accepted positive prognostic factor, whereas an incomplete one is associated with unfavorable oncological outcomes.<sup>20</sup> In that sense, the CLASSIC group published a higher proportion of affected circumferential margin in laparoscopic TME in comparison with open surgery,<sup>21</sup> being the relevance of this circumstance related to the fact that recurrence risk was 3 to 4 times increased when this margin was invaded by tumor cells.<sup>22</sup> One point of concern is the extension of the circumferential margin involvement, with some groups using a limit of 2 mm and others 1 mm. Nagtegaal et al<sup>23</sup> concluded that tumor growth between 1 and 2 mm from the circumferential resection margin was as relevant as within 1 mm, with a risk of local recurrence at 2 years after surgery of 16.0% in patients with margins smaller than 2 mm in comparison with a 5.8% risk in those with greater margins. In our study, none of the patients in both groups had the circumferential margin affected using a 1-mm limit for evaluating this criterion.

In contrast to the CLASSIC trial, others studies comparing laparoscopic and open surgery have not found differences on the circumferential margin involvement, with similar percentages in both groups. Interestingly, the COREAN trial did demonstrate a lower proportion of patients with affected circumferential margin in laparoscopic surgery than in open surgery (5.3% vs 8.3%, respectively), although this difference was not statistically significant.<sup>2</sup> More recently, short-term outcomes of the COLOR II trial have demonstrated that circumferential margin involvement was comparable in both approaches in upper and middle rectum tumors, but in patients with lower rectal lesions, there was a higher proportion of affected margins in the open group with respect to the laparoscopic one (22% vs 9%, respectively;  $P < 0.01$ ).<sup>3</sup> This circumstance was justified by the fact that laparoscopy allows a better view in the deep pelvis.<sup>3</sup> This rationale could also be applied to the transanal surgery, in which this approach provides an additional advantage during the dissection of complicate pelvis (ie, men, individuals with narrow pelvis, and obese patients). 3D technology may help this end, because this equipment allows a significant improvement in depth perception, spatial location, and precision of surgical performance compared with the conventional 2D laparoscopic cameras.

One of the major concerns in rectal surgery is postoperative complications. In this study, although the overall 30-day postoperative complication rate is lower in the transanal group than in the laparoscopy arm (32% vs 51%, respectively), this difference does not reach statistical significance probably because of the limited sample size. Interestingly, when causes of postoperative complications were analyzed individually, the proportion of patients with anastomotic leak or collections was lower in transanal TME, whereas this approach was hampered by a higher incidence of postoperative ileus. The observed trend to a lower incidence of postoperative complications in the transanal group may explain the lower early readmission rate achieved in these patients in comparison with those of the laparoscopy group (6% vs 22%, respectively;  $P = 0.03$ ).

Another point of concern in laparoscopic surgery is rectal transection. This aspect is especially relevant in patients with low and middle rectal cancer and adverse circumstances (ie, men, obese, patients with narrow pelvis, and/or large tumors),<sup>15</sup> in whom a clear distal margin may be difficult to achieve and, consequently, it may

increase the likelihood of local recurrence. In that sense, it is important to point out that the first step in transanal TME is closing the rectal lumen distally to the tumor, so there is a direct control of the distal edge. Moreover, in our series, distal resection margin was significantly higher in patients of the transanal group than in those undergoing laparoscopic surgery.<sup>24,25</sup>

We are aware of some limitations of the study. First, it is not a randomized controlled trial and, therefore, we cannot definitely rule out potential biases. Indeed, there were some differences between the groups, including the use of neoadjuvant therapy, more frequent in the transanal group. The net effect of such a circumstance is not evident because although it is certain that chemoradiation might provide an advantage because of a potential downstaging of tumors, neoadjuvant treatment could also increase the risk of anastomotic failure. In that sense, it is important to mention that the prospective cohort design employed, in which all consecutive patients with middle or low rectal cancer submitted to transanal TME in our center during the study period were compared with a cohort of also all consecutive patients treated by laparoscopic TME and recruited in the immediate chronological period, limited this possibility. Second, data on anal functional evaluation are not provided, because preoperative and postoperative continence scores were not routinely registered in laparoscopic rectal surgery. This is an important aspect, currently being evaluated by our group, because transanal TME has been criticized because of the potential risk of sphincter damage during tumor extraction and employment of transanal devices. In that sense, limitations in the use of the transanal approach are mostly owing to the morbidity associated with a colotomy, size of the mass and potential rectal injury. According to literature, anal stenosis, small caliber of the rectum, large tumors, and bulky mesentery seem to be factors limiting transanal specimen extraction.<sup>5,26,27</sup> However, there is no objective criterion for predicting extraction failure, being major divergence between rectum and specimen sizes the most important factor. This circumstance occurred in 1 patient of our series, a man with body mass index of greater than 30 kg/m<sup>2</sup> and bulky mesentery, in whom we decided to perform an assisted incision.

## CONCLUSIONS

In summary, evaluation of short-term outcomes demonstrates that transanal TME is a feasible and safe technique associated with a shorter surgical time and a lower early readmission rate. If long-term functional and oncological outcomes confirm similar results than those obtained in laparoscopic surgery, transanal TME could become a valid alternative for patients with middle and low rectal cancer.

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## REFERENCES

1. Heald RJ, Husband EM, Ryall RD. The mesorectum in rectal cancer surgery: the clue to pelvic recurrence? *Br J Surg.* 1982;69:613–616.
2. Kang SB, Park JW, Jeong SY, et al. Open versus laparoscopic surgery for mid or low rectal cancer after neoadjuvant chemoradiotherapy (COREAN trial): short-term outcomes of an open-label randomized controlled trial. *Lancet Oncol.* 2010;11:637–645.
3. van der Pas MH, Haglind E, Cuesta MA, et al. Laparoscopic versus open surgery for rectal cancer (COLOR II): short-term outcomes of a randomised, phase 3 trial. *Lancet Oncol.* 2013;14:210–218.
4. Whiteford MH, Denk PM, Swamstrom LL. Feasibility of radical sigmoid colectomy performed as natural orifice transluminal endoscopic surgery (NOTES) using transanal endoscopic microsurgery. *Surg Endosc.* 2007;21:1870–1874.

5. Knol J, D'Hondt M, Dozois EJ, et al. Laparoscopic-assisted sigmoidectomy with transanal specimen extraction: a bridge to NOTES? *Tech Coloproctol.* 2009;13:65–68.
6. Diana M, Wall J, Costantino F, et al. Transanal extraction of the specimen during laparoscopic colectomy. *Colorectal Dis.* 2011;13(suppl 7):23–27.
7. Franklin ME, Liang S, Russek K. Natural orifice specimen extraction in laparoscopic colorectal surgery: transanal and transvaginal approaches. *Tech Coloproctol.* 2013;17:S63–S67.
8. Sylla P, Rattner DW, Delgado S, et al. NOTES transanal rectal cancer resection using transanal endoscopic microsurgery and laparoscopic assistance. *Surg Endosc.* 2010;24:1205–1210.
9. Chen Y, Hu M, Lei J, et al. NOTES transanal endoscopic total mesorectal excision for rectal cancer. *China J Endosc.* 2010;16:1261–1265.
10. Zorron R, Phillips HN, Coelho D, et al. Perirectal NOTES access: 'down-to-up' total mesorectal excision for rectal cancer. *Surg Innov.* 2012;19:11–19.
11. Tuech JJ, Bridoux V, Kianifard B, et al. Natural orifice total mesorectal excision using transanal port and laparoscopic assistance. *Eur J Surg Oncol.* 2011;37:334–335.
12. Velthuis S, van den Boezem PB, van der Peet DL, et al. Feasibility study of transanal total mesorectal excision. *Br J Surg.* 2013;100:828–831.
13. Lacy AM, Adelsdorfer C, Delgado S, et al. Minilaparoscopy-assisted transrectal low anterior resection: a preliminary study. *Surg Endosc.* 2013;27:339–346.
14. Dumont F, Goere D, Honore C, et al. Transanal endoscopic total mesorectal excision combined with single-port laparoscopy. *Dis Colon Rectum.* 2012;55:996–1001.
15. Rouanet P, Mourregot A, Azar C, et al. Transanal endoscopic proctectomy: an innovative procedure for difficult resection of rectal tumors in men with narrow pelvis. *Dis Colon Rectum.* 2013;56:408–415.
16. Lacy AM, Rattner DW, Adelsdorfer C, et al. Transanal natural orifice transluminal endoscopic surgery (NOTES) rectal resection: "down-to-up" total mesorectal excision (TME)—short-term outcomes in the first 20 cases. *Surg Endosc.* 2013;27:3165–3172.
17. Sylla P, Bordeianou LG, Berger D, et al. A pilot study of natural orifice transanal endoscopic total mesorectal excision with laparoscopic assistance for rectal cancer. *Surg Endosc.* 2013;27:3396–3405.
18. Leroy J, Barry BD, Melani A, et al. No-scar transanal total mesorectal excision: the last step to pure NOTES for colorectal surgery. *JAMA Surg.* 2013;148:226–230.
19. Delgado S, Momblan D, Salvador L, et al. Laparoscopic-assisted approach in rectal cancer patients. Lessons learned from >200 patients. *Surg Endosc.* 2004;18:1457–1462.
20. Nagtegaal ID, van de Velde CJH, van der Worp E, et al. Macroscopic evaluation of rectal cancer resection specimen: clinical significance of the pathologist in quality control. *J Clin Oncol.* 2002;20:1729–1734.
21. Guillou PJ, Quirke P, Thorpe H, et al. Short-term endpoints of conventional versus laparoscopic-assisted surgery in patients with colorectal cancer (MRC CLASICC trial): multicentre, randomized controlled trial. *Lancet.* 2005;365:1718–1726.
22. Birbeck KF, Macklin CP, Tiffin NJ, et al. Rates of circumferential resection margin involvement vary between surgeons and predict outcomes in rectal cancer surgery. *Ann Surg.* 2002;235:449–457.
23. Nagtegaal ID, Marijnen CA, Kranenbarg EK, et al. Circumferential margin involvement is still an important predictor of local recurrence in rectal carcinoma: not one millimeter but two millimeters is the limit. *Am J Surg Pathol.* 2002;26:350–357.
24. Targarona EM, Balagué C, Pernas JC, et al. Can we predict immediate outcome after laparoscopic rectal surgery? Multivariate analysis of clinical, anatomic, and pathologic features after 3-dimensional reconstruction of the pelvic anatomy. *Ann Surg.* 2008;247:642–649.
25. Atallah S, Nassif G, Albert M, et al. Transanal minimally invasive surgery for total mesorectal excision (TAMIS–TME): a stepwise description of the surgical technique with video demonstration. *Tech Coloproctol.* 2013;17:321–325.
26. Franklin ME, Jr, Diaz JA. Laparoscopic left hemicolectomy with transanal extraction of the specimen. In: Ballantyne GH, ed. *Atlas of Laparoscopic Surgery.* Philadelphia, PA: WB Saunders Co.; 2000:386–404.
27. Nishimura A, Kawahara M, Suda K, et al. Totally laparoscopic sigmoid colectomy with transanal specimen extraction. *Surg Endosc.* 2011;25:3459–3463.