Laparoscopic versus Open Total Mesorectal Excision: A Comparative Study on Short-Term Outcomes

A Single-Institution Experience regarding Anterior Resections and Abdominoperineal Resections

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Key Words

Laparoscopy • Total mesorectal excision • Rectal cancer •
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Abstract

Background: Laparoscopic total mesorectal excision (TME) is being used in rectal cancer more frequently. The aim of this study was to analyze the differences in short-term outcomes between open and laparoscopic TME. **Methods:** In this nonrandomized consecutive study, the short-term outcomes of 100 patients undergoing TME for proven rectal cancer were analyzed. **Results:** Two groups of 50 patients underwent an open or laparoscopic TME for rectal cancer. Both groups were comparable. Laparoscopic surgery took longer to perform (250 vs. 197.5 min, $p < 0.01$), but was accompanied by less blood loss (350 vs. 800 ml, $p < 0.01$). Enteric function recovered sooner after laparoscopy. The numbers of major and minor complications were comparable between both groups, although fewer patients had major complications in the laparoscopic group (6 vs. 15 patients, $p = 0.03$). Hospital stay was shorter for patients who underwent a laparoscopic abdominoperineal resection (10 vs. 12 days, $p = 0.04$). Median follow-up was 17 months for the lap-

aroscopic group and 22 months for the open group. Survival analyses between the groups showed no statistical difference in disease-free and overall survival. **Conclusion:** This study shows that laparoscopic TME for rectal cancer is a safe and feasible technique with some short-term benefits over open TME.

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Introduction

Since its introduction in 1982, the total mesorectal excision (TME) concept by Heald et al. [1] has become the gold standard in surgical treatment of rectal cancer [2, 3]. It includes the standard excision of the total mesorectum, through the avascular ‘holy plane’, removing potential micrometastases enclosed in the mesorectum. At present, TME in combination with preoperative radiation therapy offers the lowest local recurrence rate (<5%) and the highest 5-year survival rate (80%) in patients with mid- and low-rectal cancer [4, 5].

There are however problems with open TME surgery, mainly pertaining to difficulties in pelvic dissection, often leading to functional urogenital problems – especial-

ly in male patients – and possibly a less radical resection. Moreover, the increased use of coloanal anastomosis has also increased the need for better visualization during pelvic dissection. The laparoscopic approach to rectal cancer may be an attractive alternative for open TME because it offers better visualization, more delicate instrumentation and better tissue handling. This in turn, may lead to an adequate dissection up to the pelvic floor in combination with a better preservation of the hypogastric plexus and erigent nerves, possibly resulting in an improved functional and oncological outcome.

Several recently published randomized studies have shown short-term benefits of the laparoscopic approach to colon cancer over the open approach, without compromising oncological outcome [6–9]. Hence, we performed a study to compare laparoscopic TME with open TME in terms of perioperative and oncological outcomes in patients with rectal cancer.

Materials and Methods

Patients

In April 2002, a laparoscopic TME trial was started at the Vrije Universiteit Medical Center (VUMc), with a planned evaluation after approximately 3 years. Subsequently, a series of 50 consecutive patients who underwent conventional open TME with curative intent for rectal cancer, operated just before the laparoscopic TME trial was initiated, was compared with a group of 50 consecutive patients who underwent laparoscopic TME for rectal cancer. The conventional group included patients who were operated on in the pre-laparoscopic period between February 1999 and April 2002, whereas the laparoscopic group included patients who were operated on between April 2002 and November 2005.

Patients with previous abdominal surgery via median laparotomy were excluded from this study, as were patients undergoing palliative surgery or surgery for benign tumors. No fast-track postoperative recovery programs were used in either group. Patients from both groups were operated on by the same surgical team from the VUMc with extensive previous laparoscopic experience in colectomies (participants in the COLOR I trial), palliative rectal resections and esophageal resections for cancer.

All patients received the same pretreatment workup, including a colonoscopy with biopsies, MRI or rectal endoscopic ultrasound for local staging, and an abdominal CT scan, chest X-ray and carcinoembryonic antigen level for dissemination status. Tumors had to be located within 17 cm of the anal verge, measured by rigid scope, and were defined according to Goligher [10]: 7 cm or less from the anal verge = low rectum; over 7 cm but less than or equal to 12 cm = mid-rectum; over 12 cm but less than or equal to 17 cm = high rectum.

Surgical Technique

Laparoscopic TME. Using a 6-trocar approach the inferior mesenteric vessels were taken down with left ureter identification, followed by retromesenteric dissection from medial to lateral.

Going up, the splenic flexure was mobilized, followed by laparoscopic TME dissection with preservation of the hypogastric plexus and nerves. Following the principles of the TME, three different operations were performed:

For tumors in the high rectum (12–17 cm), a high TME or partial mesorectal excision was performed laparoscopically with transection of the mesorectum 5 cm distal of the tumor, followed by a double-stapled anastomosis.

For tumors located in the mid- (7–12 cm) and distal rectum (anal verge to 7 cm), a complete TME was performed laparoscopically, after splenic flexure mobilization. Hereafter, the rectum was transected with an endoscopic or conventional stapler through a Pfannenstiel incision at the level of the pelvic floor (with at least a 2-cm distal margin from the tumor). A transanal coloanal anastomosis was performed if at least 1 cm from the dentate line could be spared with an adequate oncological distal margin of 2 cm. Higher anastomoses were double stapled.

An abdominoperineal resection without mobilization of the splenic flexure was considered appropriate for tumors with sphincter involvement, a margin of less than 3 cm to the dentate line thus making a coloanal anastomosis impossible and in patients with sphincter dysfunction making a functional outcome after a coloanal anastomosis unlikely.

Protective loop ileostomy was left to the discretion of the surgeon. In our institution a liberal policy concerning protective loop ileostomies is maintained. In patients with a mid- or low anastomosis, or in the case of marginal donuts, a diversion of fecal load is created.

Open TME. Open TME was performed according to previously described techniques [11].

Collected Data

- Patient data: age, body mass index and preoperative morbidity.
- Perioperative data: operating time, blood loss and complications.
- Postoperative data: length of hospital stay (including preoperative night spent in hospital), time to first liquid intake, time to unrestricted food intake, time to first stool passage and postoperative complications.
- Pathology data: Astler-Coller classification, total number of lymph nodes harvested, length of the resected specimen, tumor diameter, tumor distance to distal resection margin and circumferential margin status.
- Follow-up: time to local recurrence, time to occurrence of distant metastases, overall survival (OS) and disease-free survival (DFS) were noted.

Patients with low- and mid-rectum tumors (T2 and T3) received neoadjuvant therapy as depicted in table 1.

Statistical Analysis

Statistical analysis was performed using the SPSS software package (SPSS 11.5 for Windows; SPSS, Chicago, Ill., USA). All data were analyzed according to the 'intention-to-treat' principle. Medians and interquartile ranges were calculated and subsequently depicted when appropriate. The Mann-Whitney U test, χ^2 test or Fisher's exact test were applied when appropriate for group comparisons. Survival curves were obtained using the Kaplan-Meier method. Survival of both groups was compared with the log-rank test. Significance was set at $p < 0.05$.

Results

Patient and Tumor Characteristics

Patient characteristics are depicted in table 1. The laparoscopic group (n = 50) included 28 men and 22 women with a median age of 67 years (interquartile range: 58–75). The open group (n = 50) included 32 men and 18 women with a median age of 64.5 years (interquartile range: 56–72; p = 0.21). The median body mass index for the laparoscopic group was 25 (interquartile range: 23–27) and for the open group 26 (interquartile range: 23–27; p = 0.43). The median distance between tumor and anal verge was 8.0 cm (range: 2–17) in the laparoscopic group and 10.0 cm (range: 2–15) in the open group (p = 0.81). In each group 26 patients (52%) underwent neoadjuvant radiation therapy. In the laparoscopic group 2 patients (4%) also received neoadjuvant chemotherapy. The median delay between the last dose of radiation therapy and surgery was 44.5 days (interquartile range: 9–52) for the laparoscopic group and 42 days (interquartile range: 14–49) for the open group (p = 0.74).

In the laparoscopic group, 34 (68%) of the patients underwent a TME with primary anastomosis, including 10 patients with a coloanal anastomosis because of very distal cancer in the rectum. The other 16 (32%) patients underwent an abdominoperineal resection. In the open group, 33 patients (66%) underwent a TME with primary anastomosis, and 17 (34%) an abdominoperineal resection.

Operative Data

Operative data are listed in table 2. The median operating time for laparoscopic operations was longer than for open procedures (250 vs. 197.5 min, p < 0.01). Median blood loss was less in the laparoscopic group (350 vs. 800 ml, p < 0.01). Operative complications occurred in 1 patient (2%) of the laparoscopic group and in 9 patients (18%) of the open group (p = 0.01).

A diverting loop ileostomy was performed in 18 of 34 patients (53%) with a primary anastomosis in the laparoscopic group, and in 15 of 33 patients (46%) with a primary anastomosis in the open group (p = 0.54).

The laparoscopic procedure was converted to an open procedure in 4 patients (8%). In all of these patients, colonic dissection, and in 1 patient rectal dissection, was performed by means of laparoscopy. Two conversions were necessary due to the combination of a narrow male pelvis and a large tumor, 1 conversion due to adhesions around the splenic flexure (thus preventing proper mobilization), and 1 conversion due to extreme obesity. The

Table 1. Patient and tumor characteristics

Variable	Laparoscopic TME (n = 50)	Open TME (n = 50)	p value
Gender			0.41
Male	28 (56)	32 (64)	
Female	22 (44)	18 (36)	
Age, years			0.21
Median	67	64.5	
Interquartile range	58–75	56–72	
Body mass index			0.43
Median	25	26	
Interquartile range	23–27	23–27	
Previous abdominal surgery	12 (24)	21 (42)	0.06
Cardiovascular disease	19 (38)	16 (32)	0.53
Other systemic disease	5 (10)	3 (6)	0.72
<i>Preoperative tumor staging</i>			0.43
T1	1 (2)	1 (2)	
T2	7 (14)	6 (12)	
T3	26 (52)	19 (38)	
Tumor inaccessible to rectal ultrasound evaluation	16 (32)	24 (48)	
Median distance from anal verge to tumor, cm	8.0	10.0	0.81
Range	2–17	2–15	
<i>Tumor localization</i>			0.26
High rectum	13 (26)	8 (16)	
Mid-rectum	14 (28)	21 (42)	
Low rectum	23 (46)	21 (42)	
<i>Neoadjuvant therapy</i>			0.53
5 fractions of 5 Gy	22 (44)	23 (46)	
28 fractions of 1.8 Gy	2 (4)	3 (6)	
Chemoradiation	2 (4)	0 (0)	

Values are shown as numbers with percentages in parentheses, unless otherwise indicated.

data regarding converted patients was analyzed with the laparoscopic group in an intention-to-treat analysis.

One of the 4 converted patients required secondary surgery after 9 days following the initial surgery due to an infected hematoma. Although the surgery was technically without complications, the patient died perioperatively due to cardiac ischemia. The other 3 patients recovered quickly without any major complications.

Postoperative Data

Postoperative data are shown in table 3. Return of bowel function (liquid intake, unrestricted food intake and passage of stool) occurred sooner in the laparoscopic group. Median hospital stay in the present study included

Table 2. Operative data and complications

Variable	Laparoscopic TME (n = 50)	Open TME (n = 50)	p value
Operating time, min	250 [210–285]	197.5 [165–220]	<0.01
Anterior resections	242.5 [200–267]	175 [160–215]	<0.01
Abdominoperineal resections	287.5 [253–322.5]	205 [180–230]	<0.01
Blood loss, ml	350 [150–700]	800 [510–1,000]	<0.01
Anterior resections	300 [130–500]	700 [500–950]	<0.01
Abdominoperineal resections	700 [225–1,050]	950 [800–1,500]	0.03
Operative complications	1 (2)	9 (18)	0.01
Anterior resections	1 (2)	7 (21)	0.03
Abdominoperineal resections	0 (0)	2 (12)	0.48
Intra-abdominal bleeding	0 (0)	4 (8)	
Ureter damage	1 (2)	2 (4)	
Rectum perforation	0 (0)	2 (4)	
Small bowel perforation	0 (0)	1 (2)	
Total protective loop ileostomies	18 (53)	15 (46)	0.54
High rectums (12–17 cm)	0	1 (13)	
Mid-rectums (7–12 cm)	10 (66)	11 (52)	
Low rectums (0–7 cm)	8 (100)	3 (75)	

Values are shown as numbers with percentages in parentheses, or medians with interquartile ranges in square brackets.

the preoperative night spent in hospital and did not differ significantly between groups. Only patients undergoing laparoscopic abdominoperineal resections had a significantly shorter hospital stay (10 vs. 12 days, $p = 0.04$).

The total number of major complications did not differ significantly between groups or subgroups. However, these major complications occurred in fewer patients in the laparoscopic group (6 vs. 15 patients, $p = 0.03$), significantly expressed by the abdominoperineal subgroup. The total number of minor complications did not significantly differ between groups or subgroups and occurred in a similar number of patients (13 vs. 17, $p = 0.38$).

Anastomotic leakage was found in 5 patients (15%) in the laparoscopic group and in 3 patients (9%) in the open group. A pelvic abscess was found in none of the patients in the laparoscopic group and in 2 patients (4%) in the open group. Mortality was 2% (1 patient) in each group.

Secondary surgery within 30 postoperative days was necessary in 7 patients (14%) in both groups.

Pathology Specimen

Tumor classification is shown in table 4. No significant difference in the median number of harvested lymph nodes was observed between the laparoscopic and the open group (7 vs. 6, $p = 0.65$).

On average, a significantly longer bowel segment was resected in the open group (28 vs. 22 cm, $p < 0.01$), but

not in the abdominoperineal resection subgroup (27.5 vs. 36 cm, $p = 0.09$). Tumors were larger in the open group (40 vs. 25 mm, $p = 0.01$), but not in the anterior resection subgroup (30 vs. 40 mm, $p = 0.15$). The median distances between tumor and distal resection margin were similar for the laparoscopic and the open group (30 vs. 32.5 mm, $p = 0.61$). A circumferential margin of 2 mm or more was achieved in 92% of cases in both groups.

Follow-Up Data

The median follow-up was 17 months (interquartile range: 6–26) for patients treated with laparoscopic resection and 22 months (interquartile range: 10–38) for patients treated with open resection. Kaplan-Meier analyses for OS and DFS are depicted in figures 1 and 2, respectively. OS at 36 months was 98% (95% CI: 56–100) for the laparoscopic group and 72% (95% CI: 56–88) for the open group ($p = 0.08$). DFS at 36 months was 79% (95% CI: 63–96) for the laparoscopic group and 57% (95% CI: 40–74) for the open group ($p = 0.08$). Separate analysis of the anterior and abdominoperineal resection subgroups yielded no statistical differences in OS or DFS.

Two patients (4%) in the laparoscopic group and 6 (12%) in the open group presented with a local recurrence ($p = 0.14$). Five patients in the laparoscopic group and 10 in the open group presented with distant metastases ($p = 0.16$). No portsite recurrences were found in this study.

Table 3. Postoperative data including complications within 30 days

Variable	Laparoscopic TME (n = 50)	Open TME (n = 50)	p value
Hospital stay, days	10.5 [8–14]	12 [9–15]	0.22
Anterior resections	11.5 [7–15]	11 [9–14]	0.84
Abdominoperineal resections	10 [8.5–11.5]	12 [10–18.5]	0.04
First liquid intake, days	1 [1–2]	2 [1–3]	<0.01
Anterior resections	1 [1–2]	2 [1–2.5]	0.02
Abdominoperineal resections	1 [1–1.5]	2 [2–3]	<0.01
Unrestricted food intake, days	4 [4–5.5]	6 [5–7]	<0.01
Anterior resections	4 [4–5]	6 [4–8]	<0.01
Abdominoperineal resections	4.5 [4–6]	6 [5–7]	0.09
First stool, days	4 [3–5]	5 [4–6]	<0.01
Anterior resections	4 [3–5]	6 [4–6]	<0.01
Abdominoperineal resections	4 [3–5]	5 [4.5–6]	0.02
Mortality	1 (2)	1 (2)	1.0
Major complications	10 (20)	16 (32)	0.17
Anterior resections	10 (29)	14 (42)	0.27
Abdominoperineal resections	0 (0)	2 (12)	0.49
Intra-abdominal bleeding	0 (0)	1 (2)	
Anastomosis leak	5 (15)	3 (9)	
Pelvic abscess	0 (0)	2 (4)	
Lung embolism	1 (2)	1 (2)	
Cardiac complaints	2 (4)	5 (10)	
Pneumonia	1 (2)	3 (6)	
Ischemic stoma	1 (2)	1 (2)	
Major complications per patient ¹	6 (12)	15 (30)	0.03
Anterior resections	6 (18)	11 (33)	0.14
Abdominoperineal resections	0 (0)	4 (24)	0.04
Minor complications	16 (32)	21 (42)	0.30
Anterior resections	7 (21)	12 (36)	0.37
Abdominoperineal resections	9 (56)	9 (53)	0.94
Wound infection	4 (8)	6 (12)	
Perineum infections	3 (6)	2 (4)	
Paralytic ileus	0 (0)	3 (6)	
Urinary tract	9 (18)	10 (20)	
Minor complications per patient ¹	13 (26)	17 (34)	0.38
Anterior resections	7 (21)	11 (33)	0.24
Abdominoperineal resections	6 (38)	6 (35)	0.90
Secondary surgery	7 (14)	7 (14)	1.0
Pelvic abscess drainage	2 (4)	2 (4)	
Anastomosis leak	3 (6)	2 (4)	
Intra-abdominal bleeding	0 (0)	1 (2)	
Ischemic stoma	1 (2)	0 (0)	
Other	1 (2)	2 (4)	

Values are shown as numbers with percentages in parentheses, or medians with interquartile ranges in square brackets.

¹ More than one complication could have occurred per patient.

Discussion

Since the introduction of laparoscopic colonic surgery in 1991 [12], many questions have arisen concerning the oncological safety of this approach, following reports on

portsite metastases [13–15]. Randomized studies, comparing the laparoscopic approach to the open approach in colon cancer, have shown that the laparoscopic approach has short-term advantages with at least the same oncological long-term survival [6–9]. Portsite occurrence

Table 4. Pathology data

Variable	Laparoscopic TME (n = 50)	Open TME (n = 50)	p value
<i>Astler-Coller classifications</i> ¹			
A	3 (6)	2 (4)	0.58
B1	16 (32)	9 (18)	
B2	16 (32)	20 (40)	
C1	3 (6)	6 (12)	
C2	10 (20)	10 (20)	
X ²	2 (4)	3 (6)	
<i>Pathology outcomes</i> ³			
Lymph nodes	7 (3–12)	6 (3–10)	0.65
Anterior resections	6 (2–11)	7 (3.5–12.5)	0.51
Abdominoperineal resections	10 (4–14.5)	5 (3–7)	<0.05
Resected bowel, cm	22 (18–28)	28 (23–34)	<0.01
Anterior resections	21 (17–25)	26 (21–30)	<0.01
Abdominoperineal resections	27.5 (20.5–35)	36 (30.5–39)	0.09
Tumor diameter, mm	25 (20–37.5)	40 (25–50)	0.01
Anterior resections	30 (20–40)	40 (23–50)	0.15
Abdominoperineal resections	20 (15–30)	40 (32.5–45)	0.01
Distal margin, mm	30 (20–50)	32.5 (20–47.5)	0.61
Anterior resections	30 (15–40)	30 (20–45)	0.43
Abdominoperineal resections	45 (20–55)	40 (30–47.5)	0.762
Circumferential margin, mm	6.5 (4–11)	8 (5–16)	0.16
Anterior resections	7 (6–15)	12.5 (6.5–15)	0.18
Abdominoperineal resections	4.5 (3–10.5)	5 (3–8)	0.61
<i>Radical resection</i> ¹	46 (92)	46 (92)	1.0

¹ Values are shown as numbers with percentages in parentheses.

² Astler-Coller X: no malignant tumor found after radiation therapy.

³ Values are shown as medians with interquartile ranges in parentheses.

es were as infrequent as incisional metastases in these studies, making it very likely that portsite metastases in earlier reports were due to technical failure rather than to inherent problems with laparoscopy.

Three factors have stimulated the development of laparoscopic surgery for rectal cancer. Firstly, the technical difficulty of rectal dissections in a narrow pelvis, especially in male patients. Secondly, the inherent benefit of improved fine instruments and the improved visualization provided by the laparoscopic camera during pelvic dissection. Thirdly, the possibility to better dissect the rectum up to the pelvic floor in order to perform a colo-anal anastomosis, avoiding an abdominoperineal resection, in selected patients with very-low-rectal cancer.

In the series presented here, there were some differences in short-term outcomes between the laparoscopic and the open group. Although the length of hospital stay was equal for both groups, patients undergoing laparoscopic abdominoperineal resections were discharged

sooner. In the laparoscopic group, enteric function returned sooner than in the open group. Although it took longer to perform a laparoscopic TME, it was accompanied by less blood loss and fewer operative complications. The major and minor complication rates were similar in both groups. However, major complications occurred in fewer patients in the laparoscopic group. Moreover, oncological resection (circumferential margin of 2 mm or more) does not appear to be compromised by the laparoscopic technique. The median number of lymph nodes harvested was below the 12 nodes suggested for adequate staging for both groups. This may well be explained by the high number of patients (26 for each group) receiving neoadjuvant radiation treatment followed by a long delay (average 6 weeks) to operation, which will reduce significantly the number of lymph nodes in the specimen. Although follow-up was short, the Kaplan-Meier survival curves showed no statistical difference on DFS and OS. The trend of better DFS and OS for the laparoscopic

Months	Patients at risk	
	Laparoscopic TME	Open TME
0	49	49
20	19	25
40	6	9
60	1	1

Fig. 1. Overall survival ($p = 0.08$).

Months	Patients at risk	
	Laparoscopic TME	Open TME
0	49	49
20	19	20
40	6	8
60	1	2

Fig. 2. Disease-free survival ($p = 0.08$).

group may be explained by the smaller tumors found after pathology staging. On the other hand, local tumor infiltration showed no statistical difference, according to Astler-Coller classification, between the groups.

In contrast to the study by Quah et al. [16], which reported worse male sexual outcome in laparoscopically operated patients, recent feasibility and comparative studies, as well as a randomized series between open and laparoscopic TME by Leung et al. [17], have shown short-term benefits to rectal cancer of the laparoscopic approach over the open approach, without compromising oncological outcome [17–22]. These studies reported mean operative times between 178 and 250 min with conversion rates between 10 and 23%. Morbidity rates varied from 18 to 37% with mortality rates of up to 3%. Mean hospital stay was reported to be between 7 and 12 days. These data are in line with the results of the present study. Reports on anastomotic leak rates have been widely divergent, ranging from 0.5% in the series of Leung et al.

[17] up to 17% in the series reported by Morino et al. [22]. Long-term results on oncological outcome have shown survival rates between 76 and 85%, which is in line with the data from the present study.

Interesting are the attempts to combine laparoscopic TME with a low or even ultralow anastomosis, and the different modalities in which this anastomosis can be fashioned. Important advances in this concept have been reported with acceptable morbidity rates and a good oncological outcome. Reliable data on functional outcome of patients with ultralow anastomosis are still few and far between. In the present series, 10 patients (20%) received a coloanal anastomosis. In 2 female patients the anastomosis was converted to an end colostomy because of severe fecal incontinence. A coloanal anastomosis can be fashioned by double-stapled anastomosis through a Pfannenstiel incision, or by transanal anastomosis, which is manually performed end to end or by constructing a small J pouch. Techniques according to Parks or Basso or

the intersphincteric approach are the most commonly used [23, 24]. In this series the transanal anastomosis according to Basso was performed.

As the 'fast-track' multimodal recovery program is now being used more frequently in patients requiring surgery for colonic cancer, this may well soon be implemented in rectal surgery, subsequently reducing hospital stay even further. Surprisingly, no shorter hospital stay was found for the laparoscopic anterior resection group in the present study, although enteric function recovered sooner in the laparoscopic group. Possibly this was due to difficulties in learning adequate ileostomy care.

One final consideration has to be made about the patient diversity and consequently technical diversity. In most of the papers, the only technical distinction made is about the level of the tumor, but not about the difference between the male and female pelvis or other important

factors such as neoadjuvant radiation therapy and body mass index. It is important to take these issues into consideration in further studies in order to stratify the results and permit comparison between series.

The operative and short-term advantages of laparoscopic TME have once more been shown by the present study. During surgery it seems that operating time is longer in the laparoscopic group with less blood loss. Important short-term advantages will be the quicker recovery of the bowel function with similar morbidity and mortality. Although follow-up is short, the laparoscopic approach to rectal cancer seems to allow an adequate oncological resection. Currently a multi-center randomized study, the COLOR II study, comparing laparoscopic TME to open TME, is well under way and will answer various questions regarding short-term outcomes and long-term survival.

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