Laparoscopic versus open total mesorectal excision in rectal cancers: a randomized-controlled trial

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Background
Laparoscopic total mesorectal excision (lap TME) is a widely used approach for rectal cancers, but sometimes, it faces some challenges especially in obese patients with low rectal tumors and after chemoradiation. Some trials proved noninferiority of lap TME, whereas others failed, and much debate exists.
Purpose
This study was designed to compare the pathologic outcomes of laparoscopic and open TME regarding distal resection margin and circumferential resection margin. It also aimed to compare the operative and recovery data, in addition to the intraoperative and postoperative complication.
Patients and methods
We prospectively reviewed the medical records of 120 patients who underwent TME between February 2017 and February 2019. Cases were selected randomly using a closed envelope for the first admitted 120 patients. Patients were divided into two groups: laparoscopic and open groups.
Results
Each group had 60 patients with similar characteristics. Both groups revealed similar pathologic outcomes; circumferential resection margin was involved three (5.0%) in laparoscopic TME group versus five (8.33%) in open TME, with *P* value of 0.464. TME quality was complete or near complete in 57 (95.0%) in laparoscopic group versus 54 (90.0%) in open group, with *P* value of 0.298. Our trial revealed that laparoscopic TME had earlier recovery and shorter hospital stay compared with the open approach. Overall complications were similar: 19 (31.67%) in laparoscopic TME versus 25 (41.67%) in open TME (*P*=0.256); however, the blood loss and wound infection were higher in the open group.
Conclusion
Laparoscopic TME improves postoperative recovery, achieves similar morbidity rates, and seemingly does not jeopardize the short-term oncological parameters compared with open surgery. However, further trials are still required.

Keywords:
circumferential resection margin, minimally invasive surgery, rectal cancer, total mesorectal excision

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Introduction

Rectal cancer is one of the most common cancers worldwide. Its surgical strategy has developed over the past years from local excision to total mesorectal excision (TME), from open to minimally invasive surgery, from laparoscopic to robotic, and from abdominal to transanal approach [1].

The evolution of the concept of TME which was first revealed by Heald [2] in 1982 made a major shift in the treatment strategies. TME described clear definitions of distal resection margin (DRM), circumferential resection margin (CRM), and least number of harvested lymph nodes [3,4]. This led to improved oncological outcomes, and this influenced locoregional recurrence and survival rates [5].

Recent technologies have led to the development of less-invasive approaches. Laparoscopic total mesorectal excision (laparoscopic TME) revealed in many randomized trials (including COLOR II and COREAN) better clinical and oncological results and proved noninferiority compared with open TME. However, another two big trials, ACOSOG and ALACART, failed to prove it [6–9].

Laparoscopic TME may be associated with less blood loss, earlier recovery, and lower morbidity. The

magnified view of the pelvis may facilitate identification of the small nerves and vessels and thus prevents these injuries [10,11]. In addition, minimal surgical trauma will reduce the immunologic response and preserves postoperative immunologic defenses. This may lead to not only lower rate of infections but also lower local recurrences and distant metastases, as these defense mechanisms might be related to preventing tumor metastasis. Furthermore, tissue handling occurs with less manipulation, and this reduces the spread of cancer cells [12].

Laparoscopic TME is a widely used approach for rectal cancers; however, till this moment, it is not standardized. In addition, conversion rate varies from 1.2 to 17%, and it is even higher if BMI is more than or equal to 30 [13]. Recent NCCN guidelines reported that laparoscopic TME should be considered only if the surgeon has adequate experience, and it is not indicated for advanced tumors, where open TME is the preferred option [14].

Low anterior resection is technically challenging in obese males with low and anterior rectal tumors especially after neoadjuvant chemoradiotherapy owing to distortion of the anatomical planes [15,16]. In this subset of patients, it is difficult to obtain a proper view of the dissection plane, which threatens the integrity of TME and carries the risk of positive margins, which is related to higher rates of local recurrence [17].

In addition, limitations of instrumentation and difficulties of distal cross-stapling in narrow pelvis, which often requires multiple firings, are associated with higher risk of anastomotic leakage. All these challenges have created much debate about the standard approach for rectal cancers, and this led to the development of new technologies such as surgical robotics and new techniques such as transanal TME [18,19]

Patients and methods

Patients and data collection

The medical records of patients who underwent laparoscopic or open TME owing to pathologically confirmed rectal cancer were reviewed prospectively. Data were collected in the period from February 2017 till February 2019. Cases were selected randomly after meeting the inclusion criteria using a closed envelope for the first 120 patients presented to Menoufia University hospitals with rectal adenocarcinoma and treated with a curative intent by TME resection. We included only operable cases by MRI and computed tomographic scan criteria, which did not include extensive local spread and encasement of either major vascular structures or distant metastases. We excluded patients with stage IV, recurrent rectal cancers, combined malignancy, and patients presented with perforation or obstruction. We also excluded cases that were converted from laparoscopy to laparotomy for the sake of oncological safety or fear of DRM involvement. All the procedures were done on an elective basis.

Permission for the study was provided by Faculty of Medicine, Menoufia University Ethical Committee according to the Declaration of Helsinki. Informed written consent was obtained from all patients.

Patients were divided into two groups: laparoscopic group, which included 60 patients who underwent laparoscopic TME, and open group, which included 60 patients who underwent open TME. For the analysis, patients who required conversion to laparotomy were included in the laparoscopic group according to the principle of intent to treat. The data were retrieved from prospectively maintained patient records. The patient-, tumor-, and treatment-related variables were compared between both groups.

Outcomes

The primary outcome was the involvement of the resection margin (R1), which is CRM involvement or DRM involvement. The secondary outcomes were the other pathological results such as TME quality and the number of harvested lymph nodes, operative and recovery data, in addition to intraoperative and postoperative complications.

Perioperative management

All patients underwent through preoperative evaluation, including full history taking, physical examination, colonoscopy, and biopsy to confirm rectal cancer. Local tumor staging was achieved using MRI of pelvis. We also did chest and abdominopelvic computed tomography and carcinoembryonic antigen level assessments as a metastatic workup. After that, a multidisciplinary team decided if the patient would benefit from neoadjuvant therapy. If it is decided, MRI scan was repeated to evaluate the tumor response.

Preoperatively, patients underwent mechanical bowel preparation 2 days before surgery, and antibiotic prophylaxis was administered intravenously on the

day of surgery. We also performed prophylaxis against deep venous thrombosis in the form of elastic stockings and postoperative low-molecular-weight heparin in high-risk patients. Postoperatively, an enhanced recovery program in the form of early mobilization, early feeding, and proper pain control was applied whenever feasible.

Operative techniques and follow-up

Laparoscopic TME was achieved using a multiport setup with achievement of curative TME resection, whereas open approach was achieved as usual through lower midline abdominal incision. After TME resection, coloanal anastomosis was constructed using circular stapler or hand sewn. Diversion ileostomy was fashioned on an individual basis. One of our major concerns was the sphincter preservation, and abdominoperineal resection (APR) was indicated whenever there was invasion of the sphincter complex or fear of DRM involvement in terms of oncological safety. If APR was decided, TME was achieved in either open or laparoscopic approach, and then the patient was positioned in modified lithotomy position followed by elliptical perianal incision and perineal dissection till levator ani muscle. Terminal colostomy was then achieved. Conversion is defined as the inability to achieve the procedure laparoscopically as intended, and it is completed through laparotomy.

Patients were ambulated early. Intravenous fluid replacement was given to maintain a urine output of greater than 30 ml/h. Nasogastric decompression was not required unless the patient became nauseated, and the diet was advanced as tolerated. Patients were given prophylactic antibiotics for 24 h. If a diverting ileostomy is constructed, the patient received adequate stoma care. The incision has to be checked daily. Statistical analysis was used to evaluate the outcome differences between both groups at 3-month follow-up period. Patients continued to be followed up systematically to detect 3-year disease-free survival and overall survival, which was published later on after completion of the follow-up period.

Statistical analysis

The data collected from both groups were analyzed using χ^2, Fisher's exact, and Wilcoxon rank-sum tests whenever appropriate. *P* value less than or equal to 0.05 was considered of statistical significance. Data were collected, tabulated, and statistically analyzed using an IBM personal computer with statistical package for the social sciences (IBM; version 22; SPSS Inc., Chicago, Illinois, USA).

Results

Demographic characteristics of the study population

A total of 120 patients were included in this study in the period from February 2017 till February 2019 after applying the inclusion criteria, and each group enrolled 60 patients. Patient and tumor characteristics among studied groups are listed in Table 1.

Patients of both approaches revealed similar data regarding patient-, tumor-, and treatment-related characteristics. It is to be noticed that most of patients had low rectal cancers, with 27 (45.0%) in laparoscopic TME versus 24 (40.0%) in open group, and cT3 tumors, with 36 (60.0%) in laparoscopic TME versus 30 (50.0%) in open group, and approximately half of the patients in both approaches received neoadjuvant therapy. In addition, threatened mesorectal fascia was detected in 12 (20.0%) patients in laparoscopic group versus 15 (25.0%) in open group.

Short-term oncological outcomes

Patients of both approaches revealed similar R1 resection rate (Table 2), and DRM involvement was not found in our study. Moreover, patients in laparoscopic group retrieved longer DRM length, but it was not significant (29.4±2.30 versus 26.6 ±5.76 mm, respectively; *P* value of 0.051). Adequate CRM was achieved in 95.0% of cases in laparoscopic group versus 91.67% in open group, with *P* value of 0.464. Regarding TME quality, most patients of both approaches had a complete or near complete quality, and the number of incomplete TME was three (5.0%) in laparoscopic TME versus six (10.0%) in open group, with *P* value of 0.298.

There were no significant differences between laparoscopic and open approaches regarding the total number of harvested lymph nodes (mean, 24.9 vs. 22.5, respectively). Complete pathological response after the neoadjuvant therapy was noted in three (5.0%) in each group.

Operative data and intraoperative adverse events

The operative data are listed in Table 3. The operative duration for the laparoscopic procedures was longer, but it is not significant (211.5±31.8 versus 200.0 ±30.2 min; *P* value of 0.249). Blood loss was significantly lesser in laparoscopic group (400.5 ±269.9 versus 840.0±347 ml; *P* value of 0.001). There was another significant advantage for the laparoscopic group, which was the incision length. It was significantly smaller (7.17 versus 20.3 cm; *P* value of 0.001).

Table 1 Patient and tumor characteristics among the studied groups (*N*=120)

Patients characteristics	Studied groups [*n* (%)]		Test of significance	*P* value
	Group A (Laparoscopic) (*N*=60)	Group B (Open) (*N*=60)		
Age (years)				
Mean±SD	57.9±10.1	59.6±10.9	*t* test	0.613
Range	35–73	38–80	0.510	
Sex				
Male	39 (65.0)	36 (60.0)	χ^2	
Female	21 (35.0)	24 (40.0)	0.320	0.572
BMI				
Mean±SD	27.0±5.08	27.7±5.41	*t* test	0.676
Range	19–40	19–40	0.421	
Comorbidities				
Yes	12 (20.0)	15 (25.0)	χ^2	0.512
No	48 (80.0)	45 (75.0)	0.430	
Previous abdominal surgery				
Yes	6 (10.0)	8 (13.33)	χ^2	0.569
No	54 (90.0)	52 (86.67)	0.320	
Tumor location				
Low	27 (45.0)	24 (40.0)	χ^2	0.828
Middle	21 (35.0)	24 (40.0)	0.380	
High	12 (20.0)	12 (20.0)		
MRF+ by MRI				
Yes	12 (20.0)	15 (25.0)	χ^2	0.512
No	48 (80.0)	45 (75.0)	0.430	
Preoperative T stage				
T1	3 (5.00)	3 (5.00)	χ^2	
T2	12 (20.0)	15 (25.0)	1.31	0.727
T3	36 (60.0)	30 (50.0)		
T4	9 (15.0)	12 (20.0)		
Preoperative N stage				
N–	24 (40.0)	21 (35.0)	χ^2	
N+	36 (60.0)	39 (65.0)	0.320	0.572
Preoperative neoadjuvant				
Yes	30 (50.0)	27 (45.0)	χ^2	
No	30 (50.0)	33 (55.0)	0.300	0.583

FE, Fisher exact test; MRF, mesorectal fascia.

Diversion ileostomy was fashioned in 18/52 (34.61%) patients with a primary anastomosis in laparoscopic TME, which was similarly compared with 15/50 (30.0%) in the other group. The laparoscopic procedure was converted in 5/60 (8.33%) cases to laparotomy. These conversions were necessary owing to a combination of factors, such as narrow pelvis, morbid obesity, and intraperitoneal adhesions. The intraoperative adverse events that occurred in patients of both approaches revealed similar results (Table 4).

Early postoperative recovery data

Restoration of normal bowel functions (liquid intake, unrestricted food intake, and first bowel motion) occurred earlier in patients of the laparoscopic approach ($P<0.05$) (Table 5). Additionally, activation of enhanced recovery after surgery protocol was more obvious and applicable in patients who underwent laparoscopic TME.

Another advantage of laparoscopic TME, earlier independent ambulation, was obvious in this group. Most of the patients of the open group required the use of narcotics postoperatively (33 (55.0%) versus 15 (25.0%); *P* value of 0.008). The hospital stay was significantly longer in patients of the open group (11.1±2.46 versus 7.15±2.43 days; *P* value of 0.001).

Postoperative morbidity

Postoperative complications were classified by Clavien–Dindo classification and are listed in Table 6. The overall number of incidences of Dindo more than or equal to III complications did not differ significantly between both approaches; however, it seemed to be expressed more during open TME. It is to be noted that more than one complication had occurred in the same patient. Intra-abdominal bleeding occurred in three (5.0%) of laparoscopic TME versus four (6.67%) in open group. Anastomotic leakage was

Table 2 Short-term oncological outcomes

Studied variables	Studied groups [*n* (%)]		Test of significance	*P* value
	Group A (Laparoscopic) (*N*=60)	Group B (Open) (*N*=60)		
LN harvest				
Mean±SD	24.9±3.59	22.5±5.91	*t* test	0.110
Range	20–35	15–32	1.63	
Specimen length				
Mean±SD	23.1±4.98	24.5±5.91	*t* test	0.440
Range	15–35	15–35	0.780	
DRM+				
R0	60 (100)	60 (100.0)	FE	1.00
R1	0 (0.00)	0 (0.00)	0.00	
DRM length (mm)				
Mean±SD	29.4±2.30	26.6±5.76	*t* test	0.051
Range	25–34	8–32	2.01	
CRM+				
Yes	3 (5.00)	5 (8.33)	FE	0.464
No	57 (95.0)	55 (91.67)	0.540	
CRM length (mm)				
Mean±SD	7.62±3.15	7.10±3.25	*t* test	0.608
Range	4–13	3–12	0.517	
Tumor diameter (mm)				
Mean±SD	25.4±6.12	26.4±7.68	*t* test	0.636
Range	15–39	16–44	0.478	
TME quality			FE	0.298
Complete or near complete	57 (95.0)	54 (90.0)	1.08	
Incomplete	3 (5.0)	6 (10.0)		
Astler-Coller classification				
A	3 (5.00)	3 (5.00)		
B1	9 (15.0)	9 (15.0)	χ^2	0.875
B2	15 (25.0)	12 (20.0)	1.81	
C1	12 (20.0)	18 (30.0)		
C2	18 (30.0)	15 (25.0)		
X	3 (5.00)	3 (5.00)		
Pathological T				
T1	3 (5.00)	3 (5.00)	χ^2	0.976
T2	9 (15.0)	9 (15.0)	0.480	
T3	33 (55.0)	30 (50.0)		
T4	12 (20.0)	15 (25.0)		
X	3 (5.00)	3 (5.00)		
Pathological N				
N0	30 (50.0)	27 (45.0)	χ^2	0.823
N1	18 (30.0)	21 (35.0)	0.390	
N2	12 (20.0)	12 (20.0)		

CRM, circumferential resection margin; DRM, distal resection margin; FE, Fisher exact test.

experienced in six (10.0%) in laparoscopic approach versus five (8.33%) in open group. Moreover, secondary surgical intervention was required in a similar rate by patients of both groups (Table 7).

The overall minor complications also did not reveal significant differences between both approaches, except for surgical site infections. It occurred more frequently in patients of open group (15 (25.0%) versus three (5.0%); *P* value of 0.002). In conclusion, the overall postoperative morbidity rate was similar in both groups (19 (31.67%) for laparoscopic TME versus 25 (41.67%) for open; *P* value of 0.256). In addition, mortality occurred in one (1.67%) in open group, and it was owing to pulmonary embolism.

Discussion

At first, the higher successful resection rate by both approaches and only 8.33% conversion rate for laparoscopic approach reveal the high quality of the performed surgery. Most cases in both approaches were males, and we included patients with high BMI, with range from 19 to 40.

Table 3 Operative data in both groups

Studied variables	Studied groups [*n* (%)]		Test of significance	*P* value
	Group A (Laparoscopic) (*N*=60)	Group B (Open) (*N*=60)		
Operative time (min)				
Mean±SD	211.5±31.8	200.0±30.2	*t* test	0.249
Range	180–300	150–250	1.17	
Type of operation				
LAR	52 (86.67)	50 (83.33)	χ^2	0.609
APR	8 (13.33)	10 (16.67)	0.260	
Blood loss (ml)				
Mean±SD	400.5±269.9	840.0±347.0	*U*	0.001
Range	150–1000	500–1600	3.84	
Incision length (cm)				
Mean±SD	7.17±2.36	20.3±6.05	*U*	0.001
Range	3–10	13–30	5.43	
Diversion				
Yes	18/52 (34.61)	15/50 (30.0)	χ^2=0.250	0.618
Conversion				
Yes	5 (8.33)			

APR, abdominoperineal resection; *U*, Mann–Whitney test.

Table 4 Intraoperative adverse events in both groups

Studied variables	Studied groups [*n* (%)]		Test of significance	*P* value
	Group A (Laparoscopic) (*N*=60)	Group B (Open) (*N*=60)		
Bladder injury				
Yes	0 (0.00)	1 (1.67)	FE	0.315
No	60 (100)	59 (98.33)	1.01	
Bowel injury				
Yes	2 (3.33)	3 (5.00)	FE	0.648
No	58 (96.67)	57 (95.0)	0.21	
Ureter injury				
Yes	2 (3.33)	1 (1.67)	FE	0.558
No	58 (96.67)	59 (98.33)	0.340	
Seminal vesicle injury				
Yes	1 (1.67)	3 (5.00)	FE	0.309
No	59 (98.33)	57 (95.0)	1.03	
Rectal perforation				
Yes	6 (10.0)	7 (11.67)	χ^2	0.769
No	54 (90.0)	53 (88.33)	0.090	
Intraoperative bleeding				
Yes	6 (10.0)	10 (16.67)	FE	0.282
No	54 (90.0)	50 (83.33)	1.15	

FE, Fisher exact test.

Moreover, most of the patients had low or middle rectal cancers, but only 13.33% in laparoscopic group and 16.67% in open group performed APR with permanent stoma. This correlates with a higher rate of coloanal anastomosis and successful sphincter-saving procedures.

One of the most essential prognostic indicators is CRM involvement (CRM+), as it is related to higher local recurrence and lower survival rates [20]. In our trial, most patients of both approaches had clear CRM (95.0% in the laparoscopic approach versus 91.67% in the open group). Similarly, COLOR II trial reported CRM+ in 7.0% for laparoscopic TME versus 9.0% in the other [6]. However, Guillou [20] revealed a higher CRM involvement rate in laparoscopic TME (12.0%) versus open TME (6%). In addition, ACOSOG trial also retrieved higher CRM+ rates in laparoscopic TME (12.1 versus 7.7%) [8]. So, our results for laparoscopic TME were favorable compared with open TME and as good as other recent trials. This might be related to improved visualization of the lower pelvis with easier dissection and stapling.

Table 5 Postoperative recovery data in both groups

Studied variables	Studied groups [*n* (%)]		Test of significance	*P* value
	Group A (Laparoscopic) (*N*=60)	Group B (Open) (*N*=60)		
First liquid intake (day)				
Mean±SD	1.15±0.36	1.85±0.74	*U*	0.001
Range	1–2	1–3	3.29	
Unrestricted food intake (days)				
Mean±SD	4.95±0.82	6.10±1.25	*U*	0.002
Range	4–6	4–8	3.12	
First bowel motion (days)				
Mean±SD	3.95±0.82	5.15±0.81	*U*	0.001
Range	3–5	4–6	3.69	
Independent ambulation (days)				
Mean±SD	1.35±0.58	1.90±0.71	*U*	0.011
Range	1–3	1–3	2.53	
Use of medication				
Narcotics	15 (25.0)	33(55.0)	χ^2	0.008
NSAIDS	35 (75.0)	27(45.0)	6.93	
Hospital stay (days)				
Mean±SD	7.15±2.43	11.1±2.46	*U*	0.001
Range	5–12	7–16	3.93	

U, Mann–Whitney test.

DRMs were the most widely debated pathological indicator of oncological safety. In our study, all DRMs were clear. The mean length of DRM was comparable in both approaches (29.4 mm for laparoscopic TME versus 26.6 mm for open). The COREAN trial also revealed similar results for DRM, with a median length of 2 cm in both groups (*P* value of 0.543). Moreover, they stated that laparoscopic procedure might threaten the oncological safety in obese patients with large tumors, so patients with cT4 lesions should not be indicated for laparoscopy [7]. Additionally, Yang et al [22] reported that DRM involvement was 14/1177 (1.2%) in open TME versus 6/463 (1.3%). In another trial comparing laparoscopic, open, and robotic TME, the mean DRM did not differ between laparoscopic and open TME groups ($P > 0.05$), but it was a little longer in robotic group [23].

There is another essential oncological parameter used to assess the quality of surgery for rectal cancer resection, which is the quality of TME. Complete TME quality can be judged when the mesorectum is intact and smooth with defects less than 5 mm, there is no coning, and CRM is smooth and regular. If the muscularis propria is visible through defects, there is moderate to marked coning and an irregular CRM; this can be called incomplete quality. Our article reported that most cases performed by either approach had a complete or nearly complete TME, and the rate of incomplete TME was three (5%) for laparoscopic TME versus six (10%) for the other. Many trials recorded in their reports that the rate of incomplete TME ranged from 3 to 16% [24,25]. Similarly, COREAN trial revealed that the rate of incomplete TME was eight (4.7%) for laparoscopic TME versus 11 (6.5%) for open (*P* value of 0.414) [7]. In COLOR II study, the rate of incomplete TME was also similar in both approaches (19/666 (3%) for laparoscopic group versus 9/333 (3%) in open, with *P* value of 0.250 [6]. However, their results are better than our study; this may be owing to the differences in sample size, patient's characterization, and study design.

There is growing evidence supporting the clinical and oncological importance of the lymph node harvest. We found higher harvest in both approaches (mean 24.9 for laparoscopic TME versus 22.5 in open; *P* value of 0.110). Lujan [25] also reported that the higher lymph node harvest was in favor of laparoscopic TME (mean, 13.63 vs. 11.57). On the contrary, Strohlein [26] reported that the open approach yielded higher number of lymph nodes (mean 16.9 versus 13.5). We suggest that laparoscopic approach might have this advantage, as it provides better visualization, more precise dissection, and less tissue manipulation.

The results in our trial and the similarity in the short-term oncological parameters between both approaches are remarkable, and it is worthwhile mentioning that the surgeons are still developing their learning curve for laparoscopic TME, whereas open TME is a well-established approach through a very long experience.

Table 6 Three-month postoperative morbidity and mortality

Major complications Clavien–Dindo ≥III	Studied groups [*n* (%)]		Fisher exact test	*P* value
	Group A (Laparoscopic) (*N*=60)	Group B (Open) (*N*=60)		
Intra-abdominal bleeding				
Yes	3 (5.0)	4 (6.67)	0.150	0.697
No	57 (95.0)	56 (93.33)		
Anastomotic leakage				
Yes	6 (10.0)	5 (8.33)	0.100	0.752
No	54 (90.0)	55 (91.67)		
Ischemic stoma				
Yes	2 (2.33)	3 (5.00)	0.210	0.648
No	58 (97.67)	57 (95.0)		
Pelvic abscess				
Yes	4 (6.67)	3 (5.00)	0.150	0.697
No	56 (93.33)	57 (95.0)		
Fascial dehiscence				
Yes	1 (1.67)	3 (5.00)	1.03	0.309
No	59 (98.33)	57 (95.0)		
Pulmonary embolism				
Yes	0 (0.00)	1 (1.67)	1.01	0.315
No	60 (100)	59 (98.33)		
Cardiac events				
Yes	3 (5.00)	5 (8.33)	0.540	0.464
No	57 (95.0)	55 (91.67)		
Renal insufficiency				
Yes	1 (1.67)	1 (1.67)	0.00	1.00
No	59 (98.33)	59 (98.33)		
Minor complications of Dindo I and II				
Wound infection				
Yes	3 (5.0)	15 (25.0)	χ^2	0.002
No	57 (95.0)	45 (75.0)	9.41	
Perineal wound dehiscence				
Yes	2/8 (25.0)	3/10 (30.0)	FE	0.813
No	6/8 (75.0)	7/10 (70.0)	0.060	
Paralytic ileus				
Yes	5 (8.33)	9 (15.0)	χ^2	0.255
No	55 (91.67)	51 (85.0)	1.29	
UTI				
Yes	6 (10.0)	6 (10.0)	χ^2	1.00
No	54 (90.0)	54 (90.0)	0.00	
Chest infection				
Yes	4 (6.67)	8 (13.33)	χ^2	0.223
No	56 (93.33)	52 (86.67)	1.48	
Overall complications			χ^2	
Yes	19 (31.67)	25 (41.67)	1.29	0.256
Mortality			FE	
Died	0 (0.00)	1 (1.67)	1.01	0.315

FE, Fisher exact test.

Our study retrieved longer operative duration during laparoscopic TME (mean 211.5 versus 200 min; *P* value of 0.249). Moreover, it is even shorter than that reported by many trials, with range of 250–420 min [27–29]. Other trials revealed significantly longer duration for laparoscopic procedure such as the trial by Boutros [29] (mean 245.4 versus 212.9 min; *P* value of 0.002) and Veenhof [30] (250 versus 197.5 min; *P* value less than 0.01).

Our study revealed two major operative advantages for the laparoscopic approach, which include the blood loss (mean 400 versus 840 ml; *P* value of 0.001) and also the length of incision was smaller (mean 7.1 versus 20.3 cm, with *P* value of 0.001). Similarly, COLOR II trial reported that laparoscopic TME was associated with minimal blood loss (mean, 200 vs. 400 ml and *P*=0.0001) [6]. This represents a major advantage for the laparoscopic approach. Many studies reported the

Table 7 Secondary surgical intervention in both approaches

Studied variables	Studied groups [*n* (%)]		Fisher exact test	*P* value
	Group A (Laparoscopic) (*N*=60)	Group B (Open) (*N*=60)		
Pelvic abscess drainage				
Yes	4 (6.67)	3 (5.00)	0.150	0.697
No	56 (93.33)	57 (95.0)		
Anastomotic leakage				
Yes	4 (6.67)	4 (6.67)	0.00	1.00
No	56 (93.33)	55 (93.33)		
Intra-abdominal bleeding				
Yes	2 (3.33)	2 (3.33)	0.00	1.00
No	58 (96.67)	58 (96.67)		
Ischemic stoma				
Yes	2 (3.33)	3 (5.00)	0.210	0.648
No	58 (96.67)	57 (95.0)		
Others				
Yes	3 (5.00)	3 (5.00)	0.00	1.00
No	57 (95.0)	57 (95.0)		

relation between perioperative blood transfusion and the increased risk of cancer recurrence and the higher postoperative morbidity. Additionally, the smaller incision length minimizes the wound-related morbidities [6].

A protective stoma was similarly fashioned for patients in both groups. It was fashioned on an individual basis, and it was associated with the integrity of anastomosis. Similar to our study, COLOR II trial revealed that the rate of fashioning of a diversion stoma was low, and it was similar in both groups (35% during laparoscopic TME versus 38%, with *P* value of 0.34) [6]. Another trial reported that protective stoma was constructed much more during open TME (62.2 versus 56.2%, with *P* value of 0.012), but they explained that it is owing to routine use of diversion stoma in their early cases [22].

Unplanned intraoperative conversions from laparoscopy to laparotomy might reveal the efficacy and feasibility of the procedure. Our conversion rate was 8.33%, and these conversions were necessary to keep the parameters of the oncological safety and to avoid morbidities. The conversion rates varied greatly through several trials; it varied from 1.2% in COREAN trial to 16% in COLOR II trial, and it reached approximately 35% in UK MRC CLASICC trial [6,7,21]. These conversions are related to a combination of patient-related factors, technical difficulties, and learning curve.

Our trial revealed similar results in both groups regarding the intraoperative complications. Similarly, COLOR II trial revealed comparable data (12% during laparoscopic TME versus 14% with open; *P* value of 0.281) [6]. Contrariwise, Veenhof [31] reported significantly higher operative complications in open TME (21 versus 2%, with *P* value of 0.03).Compared with open surgery, laparoscopy has the advantages of earlier postoperative recovery and shorter hospital stay. We suggest that laparoscopy provides clearer visualization and can efficiently avoid injuring of small blood vessels and nerves, in addition to the smaller incision which is also reflective on the postoperative recovery. Similarly, Zhao [31] revealed that laparoscopic group had earlier first exhaust time by 0.32 day and earlier liquid intake by 1.04 days, with *P* value of 0.05. Hospital stay in our trial was similar to that in COLOR II [6] and COREAN [7] trials (mean 8 versus 9 days in open group), and it was even shorter by several days than CLASICC trial [21].

The safety profile of any procedure is of an utmost importance. Our analysis revealed comparable data regarding morbidity rates between laparoscopic and open surgery [19 (31.67%) versus 25 (41.67%), with *P* value of 0.256]. Anastomotic leakage occurred at a similar rate [six (10%) versus five (8.33%) in open TME]. Moreover, wound infection occurred more frequently in open group [three (5%) versus 15 (25%), with *P* value of 0.002]. Similarly, COLOR II trial showed similar morbidity rates [40.0% for laparoscopic TME versus 37.0% in open]. They also reported that the anastomotic leakage rates were 13% after laparoscopic TME versus 10% after open TME [6]. Our morbidity rate was lower than that in ACOSOG trial [8], which was 57.1% in laparoscopic TME versus 58.1% in open, with *P* value of 0.93. On the contrary, Boutros [30]

reported higher morbidity rated after open TME [43.1 versus 25.4%, with *P* value of 0.04], and this was owing to the higher incidence of wound infections. Additionally, Ng [32] reported higher short-term morbidity rate for open resections [55.0 versus 32.5%, with *P* value of 0.043], and these events were mainly wound infection and prolonged ileus.

We acknowledge that this study has some limitations. First, the sample size is small. Second, our trial did not address the long-term oncological outcomes owing to short-term follow-up periods; however, our study might add important survival data to other future meta-analyses. Finally, the quality of life (psychological, physical, and social functioning) and cost effectiveness were also not included.

Conclusion

In conclusion, this randomized prospective trial demonstrates that laparoscopic TME improves postoperative recovery, reduces hospital stay, retrieves similar postoperative morbidity rates, and does not jeopardize the short-term oncological parameters compared with open surgery for rectal cancers. However, further trials are required to precisely define the role of laparoscopy and to verify its exact indications in rectal cancer surgery.

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Conflicts of interest

There are no conflicts of interest.

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