The effect of laparoscopically assisted versus open resection of rectal cancer on short-term and pathological outcomes: a randomized controlled trial

Radwan A. Torky, Ashraf A. Helmy, Ahmed Ali, Abdallah B. Abdallah, Ahmed T. Zayan

Department of Surgery, Faculty of Medicine, Assiut University, Assiut, Egypt

Correspondence to Radwan A. Torky, MBBCh, MSc, Department of Surgery, Faculty of Medicine, Assiut University, Assiut, Egypt. Tel: +20 882 154 254; fax: 088/2350177; e-mail: radwantorky20@gmail.com

Received 10 October 2018
Accepted 6 December 2018

The Egyptian Journal of Surgery 2019, 38:214–220

Background
Laparoscopic surgery in colon cancer is well established, but its use in rectal cancer is still controversial as it needs a long duration of learning curve; moreover, its oncological adequacy is questionable. This study was conducted to compare laparoscopic and open approaches regarding the short term as well as the oncological outcomes.
Materials and methods
A prospective randomized study was conducted to compare between open and laparoscopic surgeries regarding short-term and oncological outcomes. Two groups (31 patients in LAP group and 32 patients in the OPEN group) were classified in the study.
Results
A total of 63 patients with rectal cancer included in the study in the period between January 2015 and March 2016 were classified into two groups: LAP group (31 patients) and OPEN group (32 patients). They underwent rectal cancer resection according to the allocated surgery. There was a longer operative time in LAP group with a significant improved short-term outcomes (blood loss, postoperative pain, postoperative hospital stay, and rapid gastrointestinal tract recovery). There was no difference in morbidities and local and distant recurrence between the two groups. The conversion rate was 12.9% in the LAP group, whereas the median number of removed lymph nodes was 12 in the LAP group and 10 in the OPEN group, with no significant difference.
Conclusion
Laparoscopy can be used safely in rectal cancer resection with an acceptable short-term outcomes, but it is a difficult technique and needs a learning curve. Its oncological outcomes are still a matter of debate.

Keywords:
comparison, laparoscopy, rectal cancer

Egyptian J Surgery 38:214–220

1110-1121

Introduction

Worldwide, colorectal cancer is the third most common cancer, and ~one-third of cases are localized in the rectum [1]. In USA, ~40 000 new cases of rectal cancer are diagnosed annually [2]. Despite the improvement in chemoradiotherapy, the surgical excision of the primary tumor remains the mainstay for treatment. Based on this principle, Professor Heald developed a new technique for resection called total mesorectal excision (TME) in which he sharply dissects the tumor and its enveloping fascia (mesorectum) down to the levator ani muscle [3].

In the early 1990s, the use of laparoscopic approach in resection of colon cancer was advocated, and the initial results raised concerns for the adequacy of oncological resection by the laparoscopy as well as port site metastases in up to 21% of cases [4].

In recent years, laparoscopic colon surgery has replaced traditional open one owing to several advantages and favorable short-term outcomes, such as less postoperative pain, shorter postoperative ileus, better cosmesis, reduced blood loss, and shorter hospital stay [1]. Since then, many randomized controlled trials and meta-analyses showed that laparoscopic surgery for colon cancer is considered safe and to some extent equivalent to open surgery on long-term outcomes [5].

On the contrary, the first clinical trial for laparoscopic rectal cancer resection that compared between the Conventional versus Laparoscopic-Assisted Surgery

 DOI: 10.4103/ejs.ejs_167_18

in Colorectal Cancer (CLASSIC) showed unfavorable results regarding the high rate of positive circumferential resection margin (CRM) in laparoscopic cases in comparison with the open ones (12 vs. 6%, respectively). Although the long-term results of this trial and the results of others showed similarity or better survival data, laparoscopic approach in rectal cancer resection remains controversial and widely debated [6].

Consequently, laparoscopic technique is still not generally accepted by many surgeons owing to the narrow pelvis, especially in male patients; it is technically demanding; and it is in need for a learning curve. Moreover, the morbid obesity, local infiltration of the tumor, and technical difficulties increase the rate of conversion in comparison with laparoscopic colon cancer surgery [7].

The aim of this study was to compare between laparoscopic and open approaches for rectal cancer resection regarding the oncological and short-term outcomes.

Materials and methods

This is a prospective randomized cohort study conducted in two academic centers between January 2015 and March 2016. Colorectal Surgery Unit (Alexandria University) and Department of Surgery (Assiut University). All patients with rectal adenocarcinoma within 15 cm from the anal verge at the period of study in the two institutes were included. Metastatic and complicated tumors are excluded. Informed consent was obtained from each patient included in the study. All surgeries were done by well-trained and experienced consultant surgeons. Patients were randomly assigned to 1 : 1 ratio to be operated on either laparoscopically or by open surgery according to randomization numbers.

Preoperative evaluation

All patients had computed tomography of the abdomen and pelvis, MRI of the pelvis, colonoscopy, and punch biopsy. The tumor size and the number and size of lymph nodes were determined by the MRI pelvis. The distance of the lower end of the tumor from the anal verge was judged by both MRI and colonoscopy. The tumor was categorized as upper-third rectal cancer (the lower end of the tumor, 10–15 cm from the anal verge), middle-third rectal cancer (5–10 cm), and lower-third rectal cancer (<5 cm).

According to the NCCN guidelines, patients with any tumor >cT2N0 or any T with positive lymph nodes as evidenced by preoperative imaging studies were candidates for preoperative chemoradiotherapy.

Data collection

Preoperative, operative, and postoperative data including the follow-up period for all patients were recorded.

Group assignment

Patients were classified into two groups, the LAP group and the OPEN group, and assigned preoperatively according to randomization mentioned before. Laparoscopic cases that were converted to open procedure remained in the laparoscopic group for all outcomes by intention-to-treat analysis.

The outcome

Postoperative complications were those occurring within 30 days after surgery. The CRM is considered positive when the distance from the tumor to the mesorectal fascia is less than 1 mm. Postoperative recurrences may be either local or distant metastasis and diagnosed by computed tomography, MRI, bone scan, and/or PET scan as well as surgical exploration or biopsy. Local recurrence was defined as the presence of pelvic tumor detected on routine follow-up at the previous site of surgery either isolated or associated with remote metastases. Distant metastasis was defined as any metastases outside the pelvis [7].

The following items were evaluated: operative time, intraoperative blood loss, postoperative complications, postoperative pain, postoperative gastrointestinal tract (GIT) recovery, length of hospital stay, and follow-up period (rate of recurrence).

Surgical technique

All patients scheduled for resection underwent preoperative bowel preparation, both chemical and mechanical, for 3 days with prophylactic antibiotics.

For upper-third rectal tumors, anterior resection with tumor-specific mesorectal excision was done to ensure a distal margin of 5 cm below the tumor. On the contrary, for middle- and lower-third rectal tumors, the standard TME was done. For tumors that extended down to the anal canal or infiltrated the anal sphincters, abdominoperineal resection was done.

In laparoscopic technique, medial to lateral approach is the standard for mobilization of the sigmoid and left colon as well as rectal dissection through the holy plane of TME using sharp dissection by either monopolar coagulation or ultrasonic dissector.

In both approaches, high ligation for the inferior mesenteric artery and vein was done to ensure radicality, and also mobilization of the splenic flexure was mandatory for all cases with low-lying rectal tumors.

In low-lying rectal cancer, laparoscopic resection was performed using laparoscopic-assisted approach through a small suprapubic incision through which the resection was completed using a mechanical stapler. A double-stapling technique was used for anastomosis in most cases. A hand-sewn coloanal anastomosis with or without intersphincteric resection was performed in three patients with distal cancer. In both groups, patients who underwent TME with sphincter preservation had diversion ileostomy.

Conversion was defined as the need for abdominal incision in the presence of any difficulty during laparoscopic surgery such as difficult access and massive bleeding.

Postoperative evaluation

Postoperative morbidities and mortalities were recorded. Analgesics were used according to the visual analogue scale for pain. Oral feeding was used immediately after passage of stool. Nasogastric, urinary catheter, and intra-abdominal drain were removed after 2–3 days postoperatively.

Histopathological examination

It included the assessment of T-stage, N-stage, distal resection margin, proximal resection margin, CRM, number of lymph nodes harvest, and mesorectal grade (complete, near complete, or incomplete).

Follow-up

All patients were referred to the medical oncologist for adjuvant chemotherapy. The postoperative follow-up included clinical follow-up at 1 and 3 months after surgery and then every three months in the first year and every 4 months in the second year. The follow-up included a detailed history and clinical examination for all patients with routine blood tests, including carcinoembryonic antigen. Radiological investigations were used when there was a suspicion of local or distant recurrence. Three months later, and after completion of adjuvant treatment, distal loopogram was done for patients with ileostomy, and for whom anastomotic leakage was absent, closure for ileostomy was done; on the contrary, if there was an anastomotic leak, closure was done after healing. Colonoscopy was also done before closure of ileostomy in patients who underwent TME with low anterior resection or coloanal anastomosis to exclude anastomotic recurrence not detected by imaging studies.

The primary end points were the in-hospital morbidity and mortality in the first 30 days after surgery, whereas the secondary end points were the adequacy of surgery (resection margins, number of retrieved lymph nodes, mesorectal grade, and the rate of recurrence).

Statistical analysis

Quantitative data were expressed as medians, means, minimum, and maximum and were compared by Mann–Whitney *U*-test. Qualitative data were expressed as numbers and percentages and were compared by χ^2-test or Fischer's exact test when appropriate. Log-rank test was used to compare the time to recurrence between the two groups. A significance level of *P* value less than 0.05 was used in all statistical tests. Data analyses were performed using SPSS v20.0 (Statistical Product and Service Solutions Inc., Chicago, Illinois, USA).

Results

Patients' characteristics

Between January 2015 and March 2016, 63 patients were eligible for the study, with 31 (49.2%) patients who underwent laparoscopic surgery and 32 (50.7%) patients who underwent open surgery. Patients who underwent open surgery had significantly advanced primary tumor (T-stage) (*P*=0.006) compared with patients who underwent laparoscopic surgery, with no significant differences in the regional lymph node involvement (N-stage) (*P*=0.254). There were no significant differences between the two groups

Table 1 Patients' characteristics

	LAP group (*n*=31) [*n* (%)]	OPEN group (*n*=32) [*n* (%)]	*P* value
Sex			0.527
Male	17 (54.8)	15 (46.9)	
Female	14 (45.2)	17 (53.1)	
Age (years)	47 (24–65)	52.5 (21–70)	0.189
Primary tumor (T-stage)			0.006
T1	0 (0)	0 (0)	
T2	13 (41.9)	3 (9.4)	
T3	13 (41.9)	16 (50)	
T4	5 (16.1)	13 (40.6)	
Regional lymph node (N-stage)			0.254
N0	7 (22.6)	6 (18.8)	
N1	14 (45.2)	13 (40.6)	
N2	8 (25.8)	13 (40.6)	
N3	2 (6.5)	0 (0)	
Neoadjuvant chemoradiotherapy			0.059
Yes	18 (58.1)	11 (34.4)	
No	13 (41.9)	21 (65.6)	

*Percentages are rounded, so the total may not equal 100%.

Table 2 Operative findings

	LAP group (*n*=31) [*n* (%)]	OPEN group (*n*=32) [*n* (%)]	*P* value
Distance of the tumor from the anal verge (cm)[a]			0.73
Lower (<5 cm)	10 (32.3)	10 (31.3)	
Middle (5–10)	13 (41.9)	11 (34.4)	
Upper (10–15)	8 (25.8)	11 (34.4)	
Operative time [median (range)] (min)	240 (180–360)	210 (150–240)	0.001
Intraoperative blood loss [median (range)] (ml)	0 (0–2000)	1000 (0–3000)	0.001
Diverting ileostomy			0.378
Yes	13 (41.9)	10 (31.3)	
No	18 (58.1)	22 (68.7)	
Length of specimen [median (range)] (range)	9 (5–13)	8 (5–12)	0.114
Types of operation[a]			0.107
Abdominoperineal resection	10 (32.3)	11 (34.4)	
Anterior resection	8 (25.8)	11 (34.4)	
Low anterior resection	9 (29)	10 (31.3)	
Ultra-low anterior resection	4 (12.9)	0	

[a]Percentages are rounded, so the total may not equal 100%.

Table 3 Postoperative findings

	LAP group (*n*=31) [*n* (%)]	OPEN group (*n*=32) [*n* (%)]	*P* value
Postoperative peristalsis (days)	1 (0–4)	2 (1–5)	< 0.001
Postoperative flatus (days)	2 (0–6)	2 (1–6)	0.026
Postoperative stool (days)	2 (0–7)	3(1–6)	0.013
Postoperative hospital stay (days)	4 (2–15)	7 (5–15)	< 0.001
Re-admission			0.81
Yes	6 (19.4)	6 (18.75)	
No	25 (80.6)	26 (81.25)	
Incisional hernia			0.023
Yes	2 (6.5)	9 (28.1)	
No	29 (93.5)	23 (71.9)	
Stoma complications			0.47
Yes	5 (16.1)	3 (9.4)	
No	26 (83.9)	29 (90.6)	
Morbidities			0.527
Yes	14 (45.2)	17 (53.1)	
No	17 (54.8)	15 (46.9)	
Erectile dysfunction			0.757
Yes	4 (14.8)	5 (15.6)	
No	27 (87.1)	27 (84.4)	

*Percentages are rounded, so the total may not equal 100%.

regarding sex, age, pathology, type of operation, and neoadjuvant chemoradiotherapy. Characteristics of patients in each group are shown in Table 1.

Operative findings

Although operative time was significantly longer in the laparoscopic group compared with the open group, intraoperative blood loss was significantly more in the open group (*P*=0.001). No significant differences were found in the distance of the lower edge of the tumor from the anal verge, the length of specimen (9 cm in laparoscopic group vs. 8 cm in the open group; *P*=0.114), and the use of diverting ileostomy between the two groups. Details are shown in Table 2.

Of the 31 patients in the laparoscopic group, four (12.9%) cases were converted to open surgery owing to massive bleeding in two cases and technical difficulties owing to narrow pelvis in the other two.

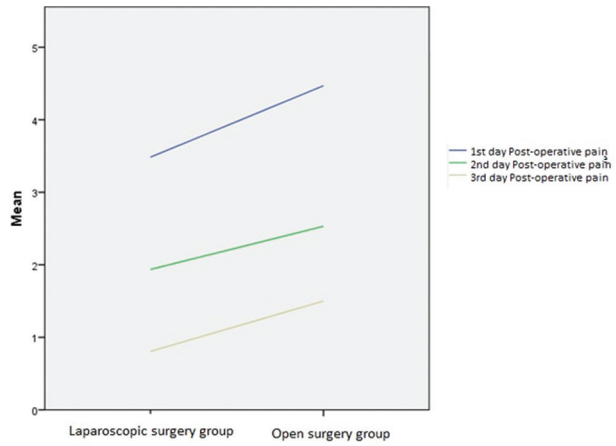
Postoperative events

Table 3 shows the postoperative recovery which was significantly smoother in the laparoscopic group with early recovery of intestinal peristalsis and early passage of stool and flatus postoperatively. Postoperative pain was less in the laparoscopic group compared with the open one, with details shown in Fig. 1.

The length of hospital stay was significantly short in the laparoscopic group compared with the open group

(4 vs. 7 days, respectively; *P<0.001*). Although incisional hernia postoperative was significantly higher in the open group compared with the laparoscopic group (*P*=0.023), there were no significant differences in stoma complications, postoperative morbidities, erectile dysfunction in male patients, and hospital re-admission between the two groups. Twelve (19.04%) patients (six patients in each group) were re-admitted to the hospital. Causes for re-admission were anastomotic stricture in 25% (3/12) of the patients (one patient in laparoscopic group vs. two patients in the open group), wound dehiscence in 16.6% (2/12) of the patients (perineal wound dehiscence in one patient in laparoscopic group and abdominal wound dehiscence in one patient in the open group), abdominal collection (urine) in further two patients (one patient in each group) owing to missed ureteric injury, subhepatic abscess in one patient, and stoma bleeding in another in the laparoscopic group. Of the 12 re-admitted patients, three (25%) were owing to adhesive intestinal obstruction and occurred only in the open group.

Figure 1



Line graph showing the post-operative pain in 1st, 2nd and 3rd day after laparoscopic and open surgery.

Postoperative pathology

There were no significant differences between the two groups regarding the number of retrieved LNs, number of positive LNs, proximal margin, distal margin, CRM, and mesorectal grade, as shown in Table 4.

Recurrence

Patients were followed for 24 months after surgery. Four patients recurred in the laparoscopic group, with three patients recurred in the anastomotic site and one patient developed liver metastasis. Ten patients recurred in the open group with three patients developed metastasis in the perineum after abdominoperineal resection, five patients developed liver metastasis, one patient developed peritoneal metastasis, and one patient developed para-aortic lymph nodes metastasis.

Discussion

Although laparoscopic treatment of colon cancer is equivalent to open surgery, the use of laparoscopy in the treatment of rectal cancer is still not well established. Furthermore, its use is more difficult than in colon surgery owing to narrow pelvis and the debate in its oncological safety. So it is still not recommended as a main line of treatment by many international guidelines [8]. Despite these obstacles, it has improved short-term outcomes (reduced severity of

Table 4 Postoperative pathology

	LAP group (*n*=31) [*n* (%)]	OPEN group (*n*=32) [*n* (%)]	*P* value
Pathology			0.634
Mucinous adenocarcinoma	8 (25.8)	5 (15.6)	
Well-differentiated adenocarcinoma	4 (12.9)	7 (21.9)	
Moderately differentiated adenocarcinoma	17 (54.8)	17 (53.1)	
Poorly differentiated adenocarcinoma	2 (6.5)	3 (9.4)	
Number of retrieved lymph nodes [median (range)]	12 (4–20)	10 (0–41)	0.244
Number of positive lymph nodes [median (range)]	2 (0–20)	2 (0–18)	0.190
Proximal margin [median (range)] (cm)	15 (10–22)	14 (10–20)	0.126
Distal margin [median (range)] (cm)	3 (1–5)	3.5 (2–6)	0.581
CRM			0.239
Negative	29 (93.5)	27 (84.4)	
Positive	2 (6.5)	5 (15.6)	
Mesorectal grade[a]			0.483
Complete	14 (45.2)	14 (43.8)	
Nearly complete	15 (48.4)	13 (40.6)	
Incomplete	2 (6.5)	5 (15.6)	

CRM, circumferential resection margin. [a]Percentages are rounded, so the total may not equal 100%.

pain, rapid GIT recovery, less blood loss, and short hospital stay), which is consistent with the results of the present study [4,9].

The laparoscopic procedure can take a longer duration of time than the open surgery with a documented time in the literature between 163 and 253 min [10]. This finding is consistent with our results. Although the incidence of incisional hernia was significantly higher in the open group, there were no significant differences for overall morbidity including sexual dysfunction between the two surgery groups, which were similar with other studies [11–15].

A lower rate of conversion is an important factor for laparoscopic benefits. A rate from 0 to 34% is reported in literature [9]. The current study resulted in a conversion rate of 12.9% which is more than that reported by Jiang *et al.* [13] and less than that reported by others [12,16]. Intraoperative bleeding and technical difficulties owing to narrow pelvis were the main causes of conversion.

Regarding the oncological outcomes, distal resection margin was an important predictor for oncological adequacy of rectal cancer surgery [7], but recently CRM positivity and completeness of TME are considered as prognostic factors for recurrence and survival [7,12]. Many studies [17,18] demonstrated that there were no significant difference in CRM between laparoscopic and open approaches; our results support those previous studies. Moreover, we found that there was no significant difference in the length of specimen in the two groups, and this was similar to those reported by Fleshman *et al.* [19] who in spite of those findings concluded that laparoscopic proctectomy for cancer is safe, but its oncological outcomes are still controversial.

The American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC) stated that 10–14 lymph nodes should be removed for staging [20]. In our study, the median number of lymph nodes harvested was 12 in the laparoscopic arm and 10 in the open arm, which was consistent with the recent study conducted by Allaix *et al.* [16]. Multiple studies [13,18,21] showed lower rates of local and distant recurrence, in favor of laparoscopic procedure; however, it was not statistically significant. The results of current study were similar to the results of the previous studies.

Our study was a prospective randomized study conducted in two large centers in Egypt, with one of them is a specialized colorectal center. The results of our study were similar to multiple recently published series [16,21,22]. On the contrary, the limitations of our study was the small sample size, the short period of follow-up, absence of fast track surgery protocol with our patients as well as the two separate surgical teams in both institutes. As oncological adequacy in laparoscopic rectal cancer surgery is still under investigation, large number of cases and long duration of follow-up are needed to assess survival and long-term outcomes.

Conclusion

Using laparoscopy in rectal cancer resection is not inferior to traditional open surgery. It gives acceptable short-term outcomes such as less pain postoperatively, short hospital stay, better cosmetic results, and rapid GIT recovery. In spite of these benefits, its oncological adequacy is still questionable, so long-term outcomes are needed to answer this question.

Acknowledgements

This study was conducted in Colorectal Surgery Unit (Alexandria University) and Department of Surgery (Assiut University).

All authors would like to acknowledge Dr Ahmed Ali, lecturer of General and Laparoscopic Surgery, Assiut University, Assiut, Egypt, for his technical help in some of laparoscopic cases.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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