LOW ANTERIOR RESECTION POST-NEOADJUVANT CHEMORADIATION IN RECTAL CANCER

(LAPAROSCOPIC Vs. OPEN)

By

Alaa M. Soliman, Saied H. Bendary, Abd El-Fattah T. El-Shiekh and Wael H. El-Sheshtawy

Department of General Surgery, Al-Azhar Faculty of Medicine

Corresponding author: Alaa Mohammed Snosy Soliman, Mobile: 01128855930,

E-mail: <u>Alaasnosy99@gmail.com</u>

ABSTRACT

Background: Laparoscopic surgery for rectal cancer is widely performed all over the world and several randomized controlled trials have been reported. However, the safety and efficacy of laparoscopic surgery compared with open surgery has not been demonstrated sufficiently, especially after preoperative chemoradiotherapy for low rectal cancer.

Objective: The aim of this study was to investigate the hypothesis that laparoscopic low anterior resection is safe and effective when compared with the open approach for locally advanced mid or low rectal cancer after neoadjuvant chemoradiotherapy.

Patients and methods: A prospective study on 40 patients suffering from locally advanced rectal cancers (stage II-III), an age of at least 18 years and fit for elective surgery after receiving neoadjuvant therapy, during the period from 20/5/2016 to 15/11/2019. Twenty patients underwent low anterior resection by laparoscopic technique, and the other 20 patients were operated upon by conventional open technique. Clinical characteristics, perioperative outcomes, pathological results, oncologic outcomes, and two-year follow-up for recurrence free survival, overall survival rates were compared between both groups.

Results: Laparoscopic low anterior resection (LAR) with total mesorectal excision (TME) showed significantly less blood loss and shorter time to pass first flatus and to start a liquid diet in addition to shorter hospital stay compared to those on open surgery. However, the mean operation time was significantly longer in laparoscopic group. Other perioperative outcomes, including postoperative morbidity rates, number of harvested lymph nodes, and nerve preservation, were not significantly different between the two groups. Oncological results, local recurrence rate, overall and disease-free survival rates showed no significant differences between open and laparoscopic groups.

Conclusion: Laparoscopic surgery after preoperative chemoradiation for mid or low rectal cancer was safe and feasible. In addition, it has short-term advantages compared with open surgery. The oncological outcome was equivalent.

Key words: Rectal cancer, laparoscopy, neoadjuvant.

INTRODUCTION

Less than a half century ago, rectal cancer had a poor prognosis, with cancer recurrence rates in the pelvic or perineal area (loco-regional recurrence) of up to 40% and 5- year survival rates after surgical resection of less than 50% (*Torre et al., 2015*).

Colorectal cancer is the third most common cancer worldwide and accounts for nearly 1.4 million new cases and 694,000 deaths per year (*Bonjer et al.*, 2015).

Approximately one-third of all large bowel cancers are located in the rectum and considered as a major cause of death worldwide, and the number of patients has increased (*Dziwiatr et al., 2017*).

Neoadjuvant chemoradiotherapy (nCRT) followed by surgery with total mesorectal excision (TME) is currently the standard treatment for patients with locally advanced rectal cancer; a reduction in local recurrence rate and an improved survival rate have been achieved with the standard treatment (*Fleshman et al.*, 2019).

Although, nCRT causes tissue edema, fibrosis, and extensive mist and exudates which may impede dissection and further increase the difficulty of laparoscopic resection for mid-low rectal cancer. laparoscopic surgery for mid-low rectal cancer is technically demanding due to the limited pelvic space, in addition, total mesorectal excision (TME) and autonomic nerve preservation are prerequisites for functional oncological and safety (Ishihara et al., 2014). Several studies have shown that laparoscopic surgery has technical benefits, such as a magnified view, over open surgery; and some randomised trials involving patients with mid or low rectal cancer have shown that laparoscopic surgery does not compromise oncological outcomes compared with open types of surgery, however, they did not control for preoperative chemoradiotherapy (*Jeong et al., 2014*).

Moreover, only a few studies have reported the outcomes of laparoscopic TME for mid-low rectal cancer following nCRT (*Lu et al.*, 2018).

The aim of this study was to investigate the safety and feasibility of laparoscopic low anterior resection (LAR) with total mesorectal excision (TME) after neoadjuvant therapy in compare with conventional open technique with regard to the perioperative outcomes and short term survival rate.

PATIENTS AND METHODS

This study was a prospective study on 40 patients, comparing open versus laparoscopic low anterior resection (LAR) with total mesorectal excision (TME) after preoperative chemoradiotherapy in patients with mid or low operable rectal cancers (stageII-III). Ages of at least 18 years and fit for elective surgery were admitted in Al-Azhar University Hospitals during the period from May 2016 to November 2019. Written informed consents were obtained from all subjects of the study, and the study was approved by the Ethics Committee of Faculty of Medicine, Al-Azhar University. Eligibility criteria were age between 18 and 70 years with clinical stage II/III mid or low rectal cancer (tumor below 10 cm from anal neoadjuvant verge) and received radiotherapy or chemoradiotherapy. The patients received either short or long course therapy; for the short course, a total of 25gray (Gy), 5 fractions of five Gy per fraction (one week treatment); and for the long course, a total of 45–50.4Gy, 25–28 fractions of 1.8 Gy each, five times per week for 5 weeks. The most common chemotherapy regimens were two cycles of an intravenous bolus of fluorouracil (400 mg/m² per day) and racemic D,Lleucovorin (20 mg/m² per day) for 3 days in the first and fifth weeks of radiotherapy, or continuous oral administration of capecitabine (1650 mg/m² daily) during radiotherapy.

The interval between surgery and the end of the neoadjuvant chemoradiotherapy (nCRT) was 6-8 weeks for both groups.

The exclusion criteria included multiple primary cancers, history of treatment for other pelvic malignancy, and emergent presentations such as intestinal obstruction or perforation.

Surgery was done 6-8 weeks after completion preoperative of chemoradiotherapy, by single team of surgeons who had experience of laparoscopic colorectal resection before the study. All patients underwent same surgical principles for low anterior resection through achieving high ligation of inferior mesenteric artery (IMA), performing total mesorectal excision and autonomic nerve preservation, and the extent of resection was the same for the open and laparoscopic methods. Access in laparoscopic surgery was obtained using five trocars. The inferior mesenteric artery was ligated close to its origin with clips, using the medial approach. For tensionfree anastomosis, full splenic flexure mobilisation was done in case of a lack of redundancy of the sigmoid colon as an intraoperative finding. Fine dissection was performed with monopolar cautery or harmonic scalpel into the presacral space, while keeping the proper plane of dissection between the fascia propria of the rectum and the presacral fascia. Mobilisation of the mesorectum was done very cautiously, to avoid any damage to the underlying hypogastric nerve plexus. the rectum was Once completely mobilised, and after an adequate distal resection margin was guaranteed by digital rectal examination, the distal lumen of the tumour was clamped and rectal washout was done with a 5% povidone iodine solution. One or two endoscopic linear stapling devices were introduced through the right lower port and the rectum was transected. Surgical specimens were subsequently removed via a 4-6-cm grid iron incision in the left lower quadrant, under a wound protector sleeve or via transanal retrieval. Bowel anastomoses were performed intracorporally by double staple technique or by transanal suture. Conversion to an open procedure was defined as an abdominal incision larger than necessary for specimen retrieval. A protective loop ileostomy was recommended for patients with very low set tumors. For those who underwent covering ileostomy, the intestinal continuity was re-established after completion of postoperative adjuvant therapy.

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Diet was resumed as soon as the first flatus had been passed. Patient-controlled analgesia was given on demand and calculated of as the amount morphine/morphine analogue used. Patients were discharged if they considered themselves sufficiently

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recovered, with tolerable diet for 24h, analgesic-free. safe ambulation, and afebrile status without major complications. Pathological assessment of the specimens with focuses on the extent of distal and circumferential resection margin (CRM), quality of the TME specimen, and number of harvested lymph nodes. The CRM was considered positive when the distance from the tumour to the mesorectal fascia was 1 mm or less. tumour stage was assessed according to classification the TNM system. Postoperative pain was measured using the visual analogue scale (VAS).

The mean follow-up period was 27 months (range, 12–42). Follow up was obtained at 3, 6,12 month, then every year via physical examination including DRE, and investigation with CEA, CT/MRI scans.

The primary end points of this study were operative time, blood loss, tumor pathology, length of hospital stay, postoperative pain, ileus and anastomotic leakage.

Secondary end points were short-term oncological outcomes: local recurrence, port-site / incision recurrence and distant metastases, recurrence free survival (RFS) and overall survival (OS).

Statistical analysis of data were done using SPSS (statistical package for social description science) with the of quantitative variables as mean ± SD. Clinical and pathological variables were analyzed with the χ^2 test (Fisher's exact test) and Student's t-test or the Wilcoxon rank-sum test. depending on the distribution of the variables. P value <0.05 was significant. Kaplan-Meier estimator was used to estimate the survival functions and to compare survival curves between both groups.

RESULTS

The open and laparoscopic groups were balanced in terms of their baseline characteristics (age, sex, physical status, previous abdominal surgery, clinical staging before preoperative radiotherapy and chemoradiotherapy regimens). The protective ileostomy was opened in 10 patients in open group and 11 patients in laparoscopic group (**Table1**).

Groups	Open LAR Laparoscopic LAR		*P	
Parameters	(n 20)	(n 20)	1	
Age (y), mean \pm SD	48.30 ± 15.594	48.85 ± 12.001	>0.05	
Sex, n (male/female)	13/7	12/8	>0.05	
ASA level				
Ι	4	5		
II	14	12		
III	2	3		
BMI , mean \pm SD	26.99 ± 4.670	28.20 ± 4.502	>0.05	
Previous abdominal	2(10%)	1(5%)	>0.05	
surgery	=(1070)			
Neoadjuvant radiotherapy	2(10%)	3(15%)	>0.05	
Neoadjuvant	18(90%)	17(85%)	>0.05	
chemoradiotherapy	10(9070)	17(0570)		
Tumor distance from AV, cm				
4–6	8(40%)	7(35%)		
7–10	12(60%)	13(65%)		
Protective ileostomy	10(50%)	11(55%)	>0.05	
Data are expressed as number of patients (% of total group), unless otherwise specified. AV, anal verge; ASA, American Society of Anesthesiologists. * χ^2 test.				

Table(1): Base line characteristics

The mean length of stay in the intensive care unit (ICU) as well as the whole hospital stay was longer in the open group than in the Laparoscopic group (P 0.014 and < 0.001 respectively). Anastomotic leakage was observed in three patients (two patients in laparoscopic group, and one patient in open group), only one patient (among the laparoscopic group) need to be reoperated because of anastomotic leak, with no significant differences between the two group.

There was statistically significant difference between both groups with regard the postoperative ileus (2.30 ± 0.78) days in laparoscopic, 3.45 ± 0.75 days in open LAR) and highly significant difference regarding the need for parenteral analgesia as the patients in laparoscopic group consumed much less. And for Surgical site infections, no significant difference was reported (**Table 2**).

Groups	Open LAR	Laparoscopic LAR	Р		
parameters	- r -		_		
Operation time (min)	142.55 ± 8.268	189.7 ± 11.765	<0.001*		
Operative blood loss(mL)	310 ± 66.540	151.83 ± 67.083	0.017#		
Operative death	0	0	1.00^		
Time to flatus (h)	35.35 ± 7.962	28.45 ± 3.561	< 0.002*		
Time to liquid diet (h)	44.45 ± 8.537	32.2 ± 5.606	< 0.001*		
Time to normal diet (h)	86.3 ± 22.245	51.1 ± 12.034	<0.001#		
Stay in ICU (d)	1.82 ± 1.147	$.88\pm0.673$	0.014#		
Total hospital stay (d)	6.37 ± 1.422	4.27 ± 0.715	< 0.001*		
Parenteral analgesia (d)	4.60 ± 0.92	2.55 ± 0.81	<0.001#		
Postoperative ileus(d)	3.45 ± 0.75	2.30 ± 0.78	< 0.001*		
Surgical site infection	2(10%)	1(5%)	0.623^		
Anastomotic leakage	1(5%)	2(10%)	0.477^		
Re-operation	1(5%)	1(5%)	1.00^		
Data are expressed either as the mean ±SD or number of patients (% of total group).					
ICU, intensive care unit.					
* Student's t test, # Wilcoxon rank-sum test, ^Fisher's exact test.					

 Table (2): Operative and Postoperative Results

In histopathological examinations of the specimens, there was distal margin involvement in one patient in open LAR group, while one patient in laparoscopic LAR group had circumferential margin involvement of less than 1 mm, without significant differences between both groups. The number of dissected lymph nodes was greater in the Laparoscopic LAR group than in the open LAR group (18 ± 5 and 16 ± 6 , respectively), however, this difference was not significant (P.077). Moreover, no significant difference was observed between the groups for the histopathological typing of the tumors (**Table 3**).

 Table (3): Tumor Characteristics and Pathologic Parameters

Groups	Open LAR	Laparoscopic LAR	Р	
Distal margin involvement	1(5%)	0	0.543*	
Circumferential margin involvement	0	1(5%)	0.557*	
Number of lymph nodes, mean \pm SD	16 ± 6	18 ± 5	0.077#	
Histology				
Well-differentiated adenocarcinoma	1(5%)	0		
Moderately differentiated	12(60%)	14(70%)		
Poorly differentiated	7(35%)	6(30%)		
Data are expressed as number of patients (% of total group), unless otherwise				
specified.				
# Fisher's exact test. *Wilcoxon rank-sum test.				

The median follow up was 26, 28 months for the laparoscopic and open group respectively. Overall survival (OS)

did not differ between the laparoscopic and open surgery groups (Fig.1).

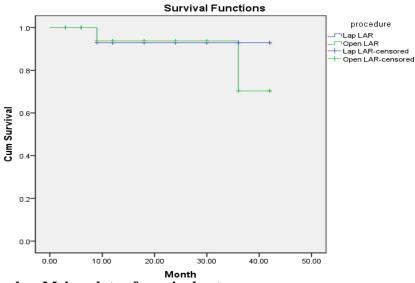


Figure (1): Kaplan-Meier plots of survival rate

The 2-year estimated OS for patients in the laparoscopic and open surgery groups was 94.12% and 94.45%, respectively, and the 2-year estimated recurrence free survival (RFS) was 84.34% and 86.24% (P 0.855), respectively. In terms of recurrence site, there was no significant difference between the laparoscopic and open surgery groups (**Table 4**).

Parameter	Recurrence			Death	
Groups	Local	Liver	LNs	Rectal cancer	Others
Open LAR	2(10%)	0	1(5%)	1(5%)	0
Lap LAR	1(5%)	0	1(5%)	0	1(5%)
Р	0.913			0.855	
Data are expressed as number of patients (% of total group), unless otherwise specified.					

Table(4): Recurrence and survival

DISCUSSION

Our results showed that patients who underwent laparoscopic resection had significantly less blood loss and shorter time to pass first flatus and to start liquid diet compared to those underwent open surgery. Moreover, there was a statistically highly significant reduction of postoperative pain judged by the time patients needed to control their pain by parenteral analgesics between the open and laparoscopic groups. Those finding correlate with the results reported in a recent meta-analysis by *Yongqu and his Colleagues (2019)*.

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We used the ability to resume oral diet indicator resolution as an of of postoperative ileus. The longer operative time is a well-known disadvantage of laparoscopic surgery according to several reports (Toda, et al., 2014). However, the result reported by Weiping et al., showed that the overall operative time was not different between the groups, but their result was affected by the difference in the proportion of patients who had lateral lymph node dissection. Lateral lymph node dissection takes about 1 hour per side, directly prolonging operative time if performed. In the open surgery group, the proportion of cases that had lateral lymph node dissection was significantly higher than that in the laparoscopic surgery group, and subgroup analysis using lateral lymph node dissection as a factor showed that the operative time of laparoscopic surgery was longer than in open surgery.

Differences might decrease with increasing experience and are likely to reach equivalence.

Other perioperative outcomes were comparable among the two groups. In this study, laparoscopic surgery did not increase anastomotic leakage compared with open surgery. We believe that aldiverting ileostomy can reduce anastomotic leakage, as noted in a metaanalysis of the role of defunctioning stoma in surgery for low rectal cancer (*Hüser et al.*, 2008).

There was a highly statistically significant decrease in hospital stay in cases having laparoscopic LAR when compared to those undergoing open resections. This result was in harmony with similar several studies in literatures (*Jiang et al.*, 2015). We contributed this to the longer period of postoperative ileus and control of postoperative pain with parenteral analgesics in the open group. On the other hand, the COREAN trial has shown no significant difference in hospital stay between laparoscopic and open group (Jeong et al., 2014), and this could be explained by the insurance system that covers the post-operative days with the surgery package. Vanderpas and his Colleagues (2013) stressed that length of hospital stay may depend more on preoperative counseling, discharge criteria, social arrangements, patient's health literacy, or type of health system than the means of surgical access.

Detailed pathological studies of the specimens revealed resected no statistically significant difference in the number of lymph nodes harvested and the adequacy of the margins during laparoscopic resections. А recent systematic review by Acuna et al. has reported similar results (Acuna et al., 2019).

With regard to OS, RFS, and local RFS, there are no large studies showing a difference significant between laparoscopic and open surgery for rectal cancer. In the COLORII (Colon cancer laparoscopic or open resection) study, similar loco-regional recurrence after laparoscopic surgery to that after open surgery was demonstrated. Similarly, the COREAN study showed the noninferiority of disease-free survival after laparoscopic surgery compared with that after open surgery. Other 2 studies, the ALaCaRT trial (Stevenson et al., 2015), and the ACOSOG Z6051 (Fleshman et al., 2015) trial, the non-inferiority of a positive CRM rate could not be shown after laparoscopic surgery compared with open surgery, and long-term results are awaited. Our data were comparable with those reported by the COREAN trial (around 50% from the graph) and COLOR-II trial (laparoscopic group, 64.9%; open surgery group, 52.0%). In this study, there was no significant difference in OS and RFS between the 2 groups.

Laparoscopic surgery for rectal cancer did not differ significantly from open surgery in effects on 2-year recurrence or DFS and OS (*Solomon et al., 2019*).

This study provided strong evidence that it is feasible and safe to perform laparoscopic LAR with TME for locally advanced mid-low rectal cancer after nCRT.

CONCLUSION

Laparoscopic and open LAR with TMEs, which were performed in patients with mid- lower rectal cancer after neoadjuvant chemoradiation, have shown decreased blood loss, less post-operative pain, and shorter hospital stay in favor of laparoscopic approach. However, it has longer operation time, and although the early oncologic outcomes were statistically comparable between the two methods, long-term oncologic follow-up studies are needed before addressing the laparoscopic approach as a standard treatment for low rectal cancer post nCRT.

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LOW ANTERIOR RESECTION POST-NEOADJUVANT CHEMORA... ⁸⁹¹

خلفية البحث: أصبح إستخدام المنظار الجراحي في حالات أمراض المستقيم شائعا علي مستوي العالم، وقد سجلت در اسات عديدة في هذا الشأن. ومع هذا، فإن معدل أمان وفاعلية إجراء الجراحة عن طريق المنظار مقارنة بإجرائها عن طريق الفتح التقليدي لم توضح بالشكل الكافي خاصة في الحالات التي استخدمت العلاج الكيماوي والإشعاعي المساعد قبل إجراء الجراحة في حالات سرطان المستقيم المنخفض.

الهدف من البحث: بحث فرضية أن إستخدام المنظار الجراحي لإجراء عمليات الإستئصال الأمامي المنغض في حالات سرطان المستقيم المتوسط والمنخض بعد إستخدام العلاج الكيماوي والإشعاعي المساعد هو إستخدام آمن وفعال عند مقارنته باستخدام الجراحة عن طريق الفتح التقليدي.

المرضى وطرق البحث: أجريت هذه الدراسة على 40مريضا من الذين يعانون من سرطان المستقيم المتقدم موضعيا من الدرجة الثانية والثالثة، وقد خضعوا للعلاج الكيماوي والإشعاعي المساعد قبل إجراء الجراحه.

تـم تقسيم المرضي إلى مجموعتين متساويتين: الأولى يستم معالجتهم باستخدام منظار البطن، والثانية يستم معالجتهم باستخدام الجراحة عن طريق الفتح التقليدي. وتستم المقارنة بالنظر إلى الخصائص الإكلينيكية للمرضي والمضاعفات الناتجة اثناء وبعد الجراحة، وكذلك النتائج علي المدي القصير.

النتائج: إستخدام المنظار الجراحي بعد إستخدام العلاج الكيماوي والإشعاعي المساعد لعلاج حالات سرطان المستقيم المتقدم موضعيا له بعض الإيجابيات عند

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مقارنت باستخدام الجراحة عن طريق الفتح التقليدي من حيث تقليل مدة الإقامة بالمستشفى، وسرعة عودة حركة الأمعاء إلى طبيعتها، وكذلك قلة الدم المفقود أثناء الجراحة. ومع هذا، فقد كان وقت الجراحة أطول نسبيا في حالات إجراء الجراحة عن طريق المنظار. أما من حيث التأثير في جودة استصال الورم بمعامل أمان أو عدد الغدد الليمفاوية المستأصلة وكذلك معدل ارتجاع المرض فقد كانت النتائج متقاربه بين استخدام المنظار والفتح الجراحي.

الإستنتاج: إستخدام المنظار الجراحي بعد العلاج الكيماوي والإشعاعي المساعد في حالات سرطان المستقيم هو أسلوب آمن وفعال، إضافة إلى بعض الميزات علي الأمد القصير عند مقارنته بإجراء العملية عن طريق الفتح الجراحي.