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Retrospective Study to Assess Feasibility and to Evaluate Shorterm Outcomes of Laparoscopic Surgery in Rectal Cancer

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Introduction

Cancer of the rectum, defined as a tumor within 15cm from the anal verge, accounts for approximately 30% of all colorectal malignancies. Colon and rectum cancer are the second leading cause of cancer death in the United States. Colorectal cancer is a relatively uncommon malignancy in India when compared with the western world but incidence of cases below 50yrs is increasing. [1,2]

Treatment of rectal cancer is predominantly surgical excision with addition of neoadjuvant therapy (radiotherapy or chemoradiotherapy) or adjuvant therapy in selected cases. Total mesorectal excision (TME) is now considered the gold standard, with fewer local recurrences and better overall survival [3,4].

Laparoscopic colectomy for malignant disease is widely used and has been readily accepted as being more advantageous than the open approach. Its benefits include less intraoperative blood loss, less postoperative pain, shorter hospital stay, faster return to work, and better quality of life [5-9].

Laparoscopic surgery for rectal cancer, however, has not been universally accepted. Laparoscopic approaches for rectal cancer first were reported in the early 1990s and are generally considered more technically challenging. Laparoscopic surgery is with advanced technology in instrumentation and imaging. To make this advance available to the entire Indian community irrespective of socio-economic status, it is imperative to spread this advance to every surgeon in India. Laparoscopic colectomy needs more learning experience because of more complex pelvic anatomy. laparoscopic procedures are still not the standard of care because of its steep learning curve, concerns with oncological outcomes, lack of randomized control trials (RCTs) and initial reports on high recurrences which occurred after curative resections.

The safety and short-term benefits of laparoscopic colectomy for cancer remain debatable. Many trials were done to assess the safety and benefit of laparoscopic resection compared with open resection.

Many of the controversies revolving around laparoscopic rectal cancer surgery include adequacy of resection margins, lymph node harvest, local recurrence rates, survival rates, safety and cost. In the past decade, there has been a rapid evolution of laparoscopic techniques, instrumentation and energy delivery to treat colorectal disease, as surgeons have sought to make laparoscopic colectomy more routine.

Although there are fewer large, multicenter RCTs evaluating minimally invasive rectal cancer surgery than for colon cancer, there still is a substantial body of literature examining these outcomes. Most of these studies are observational although several large studies comparing laparoscopic and open resections suggest that laparoscopic rectal cancer surgery is safe, with favorable short-term patient oriented and oncologic outcomes. Overall, the published RCT reports to date give supportive evidence to suggest that laparoscopic rectal cancer surgery provides earlier postoperative recovery and allows comparable oncologic resections compared with an open approach. Aim of the study is to determine the feasibility and evaluate short term outcomes of a laparoscopic rectal surgery in a single institution, “learning curve” experience. The objectives of this study were to determine short-term outcomes of laparoscopic surgery and compare the short-term outcomes of laparoscopic surgery of rectal cancer (surgical, postoperative and oncologic outcomes) in present study to international standards.

Research Question

What are the Shorterm Outcomes of Laparoscopic Surgery In Rectal Cancer and is it Feasibile?.

Aims and Objectives

The retrospective cohort study was conducted with following objectives

Primary objective

To evaluate the short-term surgical outcomes and oncological resection outcomes of laparoscopic surgery in rectal cancer in Indian population.

Secondary objective

To study the feasibility of laparoscopic surgery, compare to open surgery in the treatment of rectal cancer in Indian population.

Materials and Methods

The study included 50 consecutive patients of carcinoma of rectum operated between 1/5/2013 and 31/03/2015 at Department of Surgical Oncology of Basavatarakam Indo-American Cancer Hospital and Research Institute, Hyderabad by laparoscopic surgery. Preoperatively all patients were investigated in the same manner with hematological and biochemical investigations, chest radiograph, electrocardiogram and a colonoscopy with biopsy, Magnetic Resonance Imaging (MRI) scan of abdomen and pelvis. Patients symptomatic or suspicious of metastasis on chest x ray were underwent Computed Tomography (CT) scan of chest.

Inclusion criteria

1. Biopsy proven Adenocarcinoma Rectum
2. ECOG Performance status 0, 1

Exclusion criteria

1. Patients with metastatic disease.
2. Synchronous primary colon cancer.
3. Recurrent Rectal cancer.
4. History of laparotomy.
5. Patients with disease progression after NACRT.
6. Patients requiring exenteration surgery.

Surgery

All patients underwent per rectal examination under anesthesia before starting surgery for assessment of tumor location. Laparoscopic assessment was done. Metastasis excluded. Laparoscopy assisted Anterior resection (AR) with total or modified total mesorectal excision (mesorectal excision 5cm below tumor margin) was performed for lesions located in the proximal third (10-15cm from anal verge) of Rectum.

For most patients with tumors in the middle third (6-10cm from anal verge) of rectum laparoscopic assisted low anterior or ultra-low anterior resection with total mesorectal excision (TME) was done.

Diversion ileostomy was done in cases of anterior resections as required. Laparoscopic Abdominoperineal resection (APR) with TME was performed for patients with lesions located in the distal third of Rectum (0-5cm from anal verge) and extending into anal canal.

Outcome Evaluation

Intra operative, post-operative and pathological parameters were recorded and analyzed. Intra operative parameters recorded were 1) Type of surgery done (AR with or without diversion, APR, Laparoscopic OR Lap assisted), 2) Duration of surgery, 3) Conversion to open surgery and reasons, 4) Amount of intra operative blood loss

Post-operative parameters recorded were 1) Number of days of Intensive care unit (ICU) stay, 2) Post-operative day (POD) of first passage of flatus or stoma function, 3) anastomotic leak, 4) surgical site infection, fistula formation, stoma complications & others. 4) POD of discharge. Post-operative complications were graded as described by Dindo et al. [3] described below.

Classification of Surgical Complications

Grade I: Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside

Grade II: Requiring pharmacological treatment with drugs other than such allowed for grade I complications Blood transfusions and total parenteral nutrition are also included

Grade III: Requiring surgical, endoscopic or radiological intervention Grade, IIIa: Intervention not under general anesthesia, Grade IIIb: Intervention under general anesthesia

Grade IV: Life-threatening complication (including CNS complications) * requiring intermediate care/ intensive care unit management

Grade IVa -Single organ dysfunction (including dialysis) Grade IVb –Multiple organ dysfunctions

Grade V: Death of a patient

*Brain hemorrhage, ischemic stroke, sub arachnoidal bleeding, but excluding transient ischemic attacks: CNS, central nervous system.

Histopathological Examination of Specimen

The surgical specimen was examined according to a standardized protocol that included location of tumor site; T stage (depth of tumor infiltration); number of retrieved (examined) and involved lymph nodes, N stage; macroscopic mesorectum (TME) intactness, any perforation in specimen, status of proximal, distal & circumferential resection margins (CRM), tumor grade, lympho vascular space invasion & perineural invasion, any tumor deposits, Tumor Regression Grading (TRG). The system used to grade tumor response as modified from Ryan R et al. [4] is shown below **(Table 1).** Final Histopathological TNM staging was assigned according to the 8th edition of the American Joint Committee on Cancer Staging 2016.

Statistical Analysis

Statistical analysis was performed with SPSS software, version 15.0 for Windows (SPSS Inc., Chicago, IL, USA). Results were given

Table 1: Tumor Regression Grading [4].

0	Complete response: No remaining viable cancer cells.
1	Moderate response: Only small clusters or single cancer cells remaining
2	Minimal response: Residual cancer remaining, but with predominant fibros
3	Poor response: Minimal or no tumor kill; extensive residual cancer

as percentages, mean and standard deviations, or median and ranges. One-way ANOVA Test used to find significant difference among laparoscopic groups.

Feasibility of laparoscopic surgery analyzed by Quantitative and qualitative variables were compared with open surgery using one sample T-test. P-value of less than 0.05 was considered statistically significant.

Observations and Analysis

Mean age of all patients is 53.46 ± 13.946 years. As shown in table 2 out of 50 patients 29 (58%) were male and 21 (42%) were females.

Fifty cases of laparoscopically operated rectal carcinoma patients were included in this study. Out of 50 patients as shown in **Table 2**, 22 patients (44%) had tumor in lower third rectum, 19 patients (38%) had tumor in mid third & above, and 9 patients (18%) had tumor in upper third rectum & above.

Clinically stage I (T1 or T2, N0) patients were 8 (16%) and underwent upfront surgery. 42 (84%) patients were clinically T3 or T4 or N+ and received NACRT followed by surgery **(Table 3).** 20 out of 22 (90.9%) patients with lower third rectal tumors and 18 out of 19 (94.74%) with middle third tumors and 4 out of 9 (44.4%) patients with upper third rectal tumors received NACRT followed by surgery. APR was done in 24(48%) patients (21 in lower third and 3 in mid third tumors). AR was done in 26 (52%) patients out of which 18 (36%) patients also needed diversion ileostomy who all received NACRT **(Table 4).**

Intraoperative Surgical Outcomes

As seen in **Table 5** All APR cases (n=24, 100%) were done by total laparoscopic surgery and perineal dissection. All Anterior resections were laparoscopically assisted except in one case which was totally laparoscopic surgery done with stapled anastomosis. In one case of anterior resection conversion to open surgery was done because of tumor adherent to bladder anteriorly (conversion rate 2%).

As shown in **Table 6**, the mean blood loss was 159ml in all patients and it is higher in APR group around 206ml (P= 0.00004) which is statistically significant using one-way ANOVA.

The mean operating time was 3.21hrs, AR group is less operating time taking 2.83 ± 0.41 hrs., P=0.0164 which is statistically significant difference among groups. Identification and preservation of Hypogastric nerves in 74% which is clinically significant.

Postoperative Surgical Outcomes

The median duration of ICU stay was 2 days, mean 2.44 ± 0.95 (*P*-value = 0.19519) there is significant difference among 3 groups & median postoperative day (POD) of first stoma function or flatus passage was 2 days (interquartile range 2-3 days and mean 2.14 ± 1.1 (P=0.0003) which is significantly different among laparoscopic groups. In AR group without diversion median POD of first flatus passage is 3 days, which is slightly higher than other groups. The median POD of discharge from hospital were 7 days (interquartile range 6-8 days and mean 6.76 ± 1.46 (P=0.43618) respectively which is significant difference among groups **(Table 7).**

Grade 1 and 2 surgical site infection was developed in 6 (12%) patients (4 in APR surgery and 2 in AR with diversion surgery). Grade 2 postoperative ileus was seen in 4 (8%) patients (3 in APR and 1 in AR group) and all patients were managed conservatively. Anastomotic leak occurred in 2(4%) patients of AR without diversion for one (2%) patient in APR group, revision of colostomy stoma was done.

Reintroduction of Foleys catheter after removal was done in 8 (16%) patients (5 in APR group and 3 in AR with diversion). One patient died (mortality rate 2%) postoperatively because of sepsis due to anastomotic leak. Surgical complications were seen in 11 patients. The overall morbidity rate was 22% **(Figure 1 & 2) (Table 8).**

Oncological Resection Outcomes

CRM: On final histopathological assessment involved or close CRM (</= 1mm) was present in 3 patients (6%). 47 patients (94%) have free CRM (>/= 2mm) as shown in (**Table 9).**

Macroscopic TME intactness: Complete macroscopic TME intactness was present in 37(74%) and nearly complete in 10 (20%) patient's specimens on gross pathological examination. Only 3 patients (6%) had incomplete mesorectum. Overall macroscopic combined complete and nearly complete TME percentage was 94% **(Table 10).**

Lymph nodal yield: The average number of lymph nodes examined **(Table 11)** in the specimens was 12.60 (SD +/- 5.2) in all patients. In NACRT group it was 12.0 (SD +/- 4.8) and in upfront surgery arm it was 15.75 (SD +/- 6.36).

Pathologically negative lymph nodes were seen in 35 (70%) patients. 10 patients (20%) had pN1 stage (with N1a in 6 patients and N1b in 4 patients). 5 patients (10%) had pN2 stage (4 or more positive lymph nodes).

Out of 36 (72%) patients who were clinically stage III and received NACRT, only 11 (22%) patients were stage III on final pathology. Down staging after NACRT was seen in 69.4% of clinically stage III patients. Complete pathological response (pCR) pT0N0 was seen in 5 out of 42(11.9%) patients who received NACRT followed by surgery.

On final histopathology 16 (32%) patients had pathological stage 1 disease (T1, T2, N0) out of which 9 patients were in post NACRT

Table 2: Showing age and duration of habit in Grade 2 OSF.

Tumor site in Rectum	Surgery		
	APR	AR	AR with Diversion
Lower third (n=22	21 (95.4%)	1 (4.5%)	0 (0%)
Middle third (n=19	3 (15.7%)	1 (5.2%)	15 (78.9%)
Upper third (n=9)	0 (0%)	6 (66.6%)	3 (33.3%)
Total (n=50)	24(48%)	8(16%)	18(36%)

Table 4: Age and duration of habit in Grade 3 OSF.

	Upfront Surgery	NACT+RT
Total Patients (n=5	8 (16%)	42 (84%)
Males (n=29)	4(13.7%)	25(86.3%)
Females (n=21)	4(19.1%)	17(80.9%)
Lower third (n=22)	2 (9.1%)	20(90.9%)
Middle third (n=19)	1 (5.26%)	18(94.74)
Upper third (n=9)	5 (55.6%)	4(44.4%)
APR (n=24)	2 (8.3%)	22 (91.7%)
AR (n=8)	6 (75%))	2 (25%)
AR with Diversion(n=18	0	18(100%)

Table 5: The comparison of epithelial thickness, capillary density, Luminal diameter and circumference in different grades of oral sub mucous fibrosis.

	Surgery			Total
	APR	AR	AR with Diversion	
Totally lap	24(96%)	1 (4%)	0 (0%)	25
Lap Assisted	0 (0%)	7 (28%)	18 (72%)	25
Total	24 (48%)	8 (16%)	18 (36%)	50

Table 6: Comparison of mast cell count in different grades of OSF.

Surgery	Blood loss (ml) Mean	OP time (hrs.) Median IQR		MEAN	Identification & preserva of Hypogastric nerves (%
APR (n=24)	206.25 ±77.05	3.3	0.3	3.18 ± 0.53	17 (70.8%)
AR (n=8)	96.87 ±28.14	3	0.8	2.83 ± 0.41	5 (62.5%)
AR with Diversion(n=18)	126.11 ±48.88	3.3	0.7	3.43 ± 0.48	15 (83.3%)
Total	159.90 ±76.48	3.3	0.3	3.21 ± 0.53	37(74%)

Table 7: Multiple comparison within the group by Tukey HSD.

Surgery	ICU Stay (median days)	Mean	Stoma function first flatus pass (median POD) I		Mean	Discharge (median POD		Mean	
APR (n=24)	2 1	2.67 ±1.	2	0	2.21	6.5 3		6.7 9 ±1.6	
AR (n=8)	3 1	2.50 ±0.7	3	1	3.38	6.5 1.75		6.63	±1.06
AR with Diversion (n=18)	2 0	2.11 ±0.3	2	1	1.50	7 1.5		6.78	±1.35
Total	2 1	2.44 ±0.9	2	1	2.14	7	2	6.76	±1.46
P- Value	0.19519		0.0003			0.43618			

group. 14 (28%) patients had pathological stage 2 (T3, T4, N0) disease & 15 patients (30%) had pathological stage 3 (node positive) disease **(Table 12).**

Out of 50 patients no residual tumor seen in 5 patients after NACRT. 11 had well differentiated, 27 had moderately differentiated and 7 had poorly differentiated adenocarcinomas **(Table 13)**.

Mean operating time was 192.6 min (3.21hrs ± 0.53) in the present study for laparoscopic rectal surgeries and it was much lesser than in COREAN trial (244.9 min) [10-15]. P=0.0346 significant difference among the groups.

The rate of conversion laparoscopic to open surgery in the present study was 2%. Conversion rates to open surgery in COREAN trial is 38% although the definition of conversion is not standardized, which makes comparison is difficult [12]. The most common reason for conversion is tumor extension. The conversion rate is decreased from 38% in year one to 16% by year 6, suggesting a learning curve. In the present study surgeries were performed by experienced laparoscopic surgeons, so conversion rate was low and comparable.

The mean blood loss in present study was 159.6 ml and was less compared to laparoscopic arms in COREAN TRIAL 217.5 ml

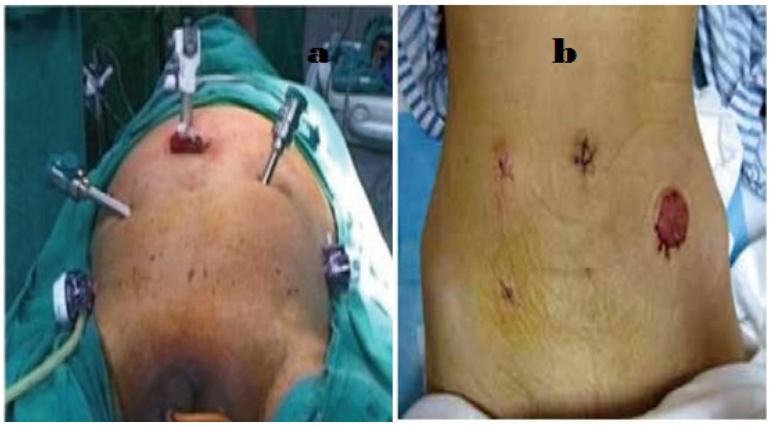

Figure 1 (a) Laparoscopy assisted Anterior resection (AR) (b) recovery wounds after laparoscopic surgery. COURTESY: Basavatarakam Indo-American Cancer Hospital and Research Institute.

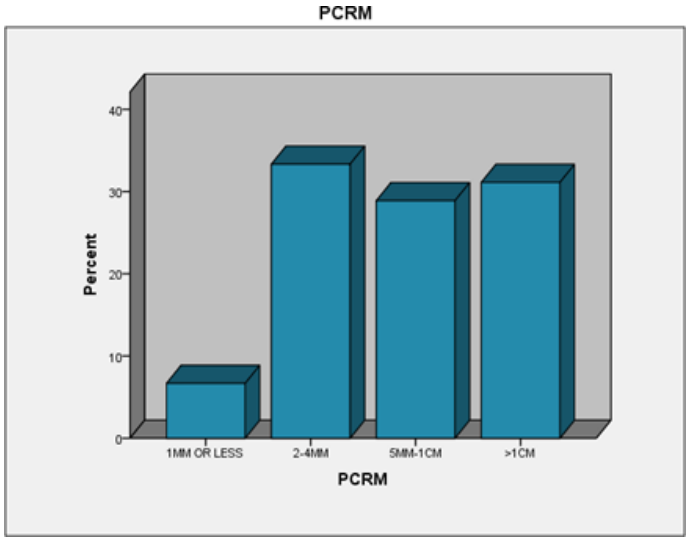

Figure 2 Circumferential resection margins.

Table 8: Complications in Patients.

COMPLICATION	LAP APR (n=24)	LAP ASSISTED (n=8)	LAP ASSISTED AR +DIVERSION (n=18)	TOTAL
Surgical site infection (grade 1&	4 (16.6%)	0	2 (11.1%)	6(12%)
Postoperative Ileus (grade 2)	3 (12.5%)	1 (12.5%)	0	4(8%)
Stoma complications	1 (4.1%)	0	0	1(2%)
Anastomotic leak	0	2 (25%)	0	2(4%)
Recatherisation	5 (20.8%)	0	3 (16.6%)	8(16%)
Mortality	0	1 (12.5%)	0	1(2%)

Table 9: Frequency of pCRM.

pCRM	Frequency	Percent
1MM OR LESS	3	6.0
2-4MM	15	30.0
5MM-1CM	13	26.0
>1CM	14	28.0
Total	45	90.0
COMPLETE RESPONSE	5	10.0

Table 10: Macroscopic TME intactness.

Mesorectum Intactness	Frequency	Percent
Complete	37	74.0
Nearly complete	10	20.0
Incomplete	3	6.0
Total	50	100.0

Table 11: Lymph nodal yield.

LNS positive	Frequency	Percent
0(pN0)	35	70
1(pN1a)	6	12
2(pN1b)	1	2
3(pN1b)	3	6
4(pN2a)	1	2
7(pN2b)	2	4
8(pN2b)	1	2
11(pN2b)	1	2
Total	50	100
NACRT	**Mean number of examined**	**Std. Devia**
Yes (n=42)	12	4.829
No (n=8)	15.75	6.364
Total	12.6	5.218

Table 12: Histopathology in post NACRT group.

Stage	cTNM (%)	pTNM (%)
Stage 0	0	5 (10)
Stage I (T1,2,N0)	8 (16)	16 (32)
Stage II (T3,4,N0)	6(12)	14 (28)
Stage III (anyT,N1,2)	**36(72)**	**15 (30)**

Table 13: Significant difference of histology among the groups.

Final histology (n=50)	Frequency (%
Well differentiated	11 (22%)
Moderately differentiated	27 (54%)
Poorly differentiated	7 (14%)
No residual tumor	5 (10%)

Table: 14: Oncological Resection Outcomes [12].

Author/Trial	Year	Macroscopic TME (% complete)	Number of Lymph Node	Positive CRM (%)
Kang et al. COREAN	2010	Open - 74.7 Lap - 72.4	Open - 18 Lap - 17	Open - 4.1 Lap - 2.9
PRESENT STUD		Lap – 74	Lap- 12.6	Lap – 6

Table: 15: Short term surgical outcomes [12].

Author/ Year/ Trial	Operative time (min)	Conversion (%)	Blood loss (mL)	Leak rate (%)	Morbidity (%)	Mortality (%)	Length of stay (days)
Kang et al. 201 COREAN	Open– 197 Lap– 244.9	38	Open- 21 Lap - 200	Open - 4 Lap - 1.2	Open-23.5 Lap - 21.2	Open - 2 Lap - 0	Open - 9 Lap - 8
Present Study	Lap–192.60	2	Lap– 159	Lap– 4	Lap– 22	Lap– 2	Lap– 6.76
Guillou et al. 2005 CLASICC	Open– 135 Lap– 180	34	NR	Open - 7 Lap - 8	Open - 37 Lap - 32	Open - 5 Lap - 4	Open - 13 Lap - 10
Kang et al. 2010 COREAN	Open– 197 Lap– 244.9	1.2	Open- 217.5 Lap - 200	Open - 0 Lap - 1.2	Open- 23.5 Lap - 21.2	Open - 0 Lap - 0	Open - 9 Lap - 8
Van der Pas et al. 2013 COLOR II	Open– 188 Lap– 240	16	Open - 400 Lap - 200	Open - 10 Lap - 13	Open - 37 Lap - 40	Open - 2 Lap - 1	Open - 9 Lap - 8
Present study	Lap–192.60	2	Lap– 159.4	Lap– 4	Lap– 22	Lap– 2	Lap– 6.76

Table: 16: Master Chart.

SLN0	Age y / Sex	MRNO	cT/N	Tumor Site	NACRT	Surgery	LAP	B. L(ml)	Surg time (hrs)	ICU stay	P.D flat	P.D F.R	P.D dis	Hist	pT	CRM	TME	LNE	LNP
1	68/M	116653	2/0	3	2	2	2	50	2.3	2	5	5	8	W	T2	2	1	10	0
2	46/F	107197	3/1	1	1	1	1	250	3.3	2	2	4	5	P	T4	1	2	10	0
3	45/F	117872	3/1	1	1	1	1	300	3	2	2	5	6	M	T2	4	1	24	0
4	60/F	121264	2/0	1	2	1	1	100	3	2	3	6	7	M	T2	2	1	12	0
5	56/F	120077	3/1	1	1	1	1	100	3.3	2	2	5	5	M	T2	4	1	8	0
6	25/M	119570	3/1	2	1	3	2	50	3	2	1	6	8	P	T3	1	1	13	0
7	75/F	122823	3/1	1	1	1	1	200	2	2	1	5	6	M	T3	2	3	20	0
8	55/M	122472	3/1	3	1	2	1	150	2.3	1	2	7	8	M	T2	2	1	13	0
9	53/F	122888	3/1	3	1	3	2	120	4	2	1	6	7	M	T2	4	1	24	3
10	55/M	125514	3/1	3	1	3	2	200	4	2	1	6	7	W	T3	4	1	6	0
11	50/F	136262	2/0	2	2	2	2	100	3.3	3	3	5	6	M	T3	3	1	5	0
12	46/M	131422	3/0	1	1	1	1	200	3.3	2	2	6	7	W	T2	4	2	6	0
13	45/M	131458	3/1	2	1	1	1	200	3.3	2	2	7	8	M	T3	1	3	20	7
14	70/F	130708	2/0	3	2	2	2	75	2.45	3	3	4	5	M	T2	2	2	21	3
15	49/F	136115	3/1	1	1	2	2	100	3.3	3	3	5	6	P	T3	3	2	14	0
16	30/M	137394	3/1	1	1	1	1	200	4	2	2	10	7	N	T0			5	0
17	39/M	136933	4/0	1	1	1	1	400	4	4	2	8	9	M	T4	3	1	20	0
18	21/M	139324	3/0	2	1	1	1	200	3.3	2	1	7	10	N	T0			7	0
19	50/F	140018	3/1	2	1	3	2	100	3.3	2	2	5	6	N	T0			11	0
20	60/F	143703	2/0	3	2	2	2	100	3	2	4	5	6	M	T2	3	2	11	0
21	37/F	145143	3/2	1	1	1	1	150	3.3	2	2	5	5	M	T3	3	2	9	0
22	60/F	145069	3/1	2	1	3	2	100	3.3	2	2	5	5	M	T3	3	1	9	0
23	72/M	146185	3/1	2	1	3	2	100	3.45	2	1	5	6	M	T2	3	1	8	0
24	50/M	144139	3/1	2	1	3	2	200	3.15	2	2	6	7	M	T3	2	1	8	0
25	62/F	145943	3/1	1	1	1	1	150	3.3	2	1	5	5	M	T3	4	1	15	0
26	59/M	145103	3/1	2	1	3	2	200	4	3	2	10	7	M	T2	4	1	19	11
27	65/M	140095	3/1	2	1	3	2	150	4	2	1	7	8	M	T3	2	2	18	8
28	58/M	116847	2/0	1	2	1	1	200	3	2	2	10	6	M	T2	2	1	23	1
29	55/M	112883	3/0	1	1	1	1	250	3	3	2	6	10	W	T1	2	2	6	1
30	57/F	114184	3/1	2	1	3	2	200	3.3	2	2	7	7	M	T3	3	1	9	0
31	63/M	119250	3/1	2	1	3	2	50	2.3	2	1	5	6	N	T0			13	0
32	50/F	116677	3/1	1	1	1	1	150	3	2	1	5	6	M	T3	2	1	16	0
33	64/M	121254	3/1	2	1	3	2	100	4	2	1	5	6	M	T2	4	2	15	1
34	45/F	124143	3/1	3	1	3	2	100	3.3	2	2	3	4	W	T2	4	1	6	0
35	55/M	126132	3/1	2	1	1	1	150	3.3	3	2	5	6	M	T1	2	1	15	0
36	26/M	126687	3/1	2	1	3	2	150	4	2	1	5	6	P	T3	4	1	10	3
37	68/M	125032	3/1	1	1	1	1	250	3.3	2	2	4	5	W	T3	2	1	13	0
38	69/M	128127	3/1	1	1	1	1	200	2	4	3	6	7	W	T3	3	1	17	0
39	65/F	126035	3/1	2	1	3	2	100	3	3	2	6	8	W	T2	3	1	9	1
40	65/F	126035	3/1	2	1	3	2	100	3	2	2	6	8	W	T2	3	1	9	0
41	55/M	127759	3/1	1	1	1	1	150	2.3	2	2	5	5	N	T0			12	4
42	78/M	135540	3/1	1	1	1	1	250	4.3	5	4	10	10	W	T3	2	3	14	1
43	38/M	132926	3/1	1	1	1	1	300	3.45	7	7	8	8	P	T2	3	1	8	0
44	75/F	136853	3/0	1	1	1	1	350	3.3	3	2	6	7	M	T3	2	1	16	0
45	43/M	143651	2/0	3	2	2	2	100	3	3	4	6	7	W	T3	4	1	9	7
46	40/M	143586	2/1	2	1	3	2	150	3.3	2	2	7	10	M	T3	4	1	7	2
47	20/F	145862	2/1	1	1	1	1	100	3.3	2	2	4	5	P	T3	3	1	12	1
48	60/M	144779	3/1	1	1	1	1	150	3	3	2	7	8	M	T1	2	1	13	0
49	61/M	145588	3/0	2	1	3	2	100	3.5	2	1	6	6	P	T3	4	2	20	0
50	60/M	150164	2/0	3	2	2	2	100	3	3	3	6	7	M	T3	4	1	12	0

as shown below. Blood loss less for the laparoscopic approach compare to open surgery where P= 0.052 which is statistically not significant.

The leak rate in present study is 4% which is like COREAN trial.

The morbidity rate in present study was 22% which is similar to COREAN trial [13,14] Morbidity 22% in the minimally (laparoscopic) invasive group and were similar to open group 23.5% as shown in COREAN trail [12]. The mortality rate in present study was 2% which is similar to open surgery.

As a result of earlier return of bowel function, ambulation, tolerability of diet, and better pain control, shorter length of stay for the minimally invasive (7 days) in present study compared to the open (9 days) group in COREAN Trail [12]. It is statistically significant P=0.0300 **(Table 14 & 15).**

The oncological resection outcomes in the present study were much comparable and equivalent to the reported results from COREAN study. Macroscopic Completeness of TME was 72.4 in the minimally invasive groups in the two reported COREAN study. In the present study it was 74%.

P-value=0.5000 No statistically significant difference between the numbers of lymph nodes removed between open and laparoscopic approach. The average lymph nodal yield in the present study was 12.6 (15.75 in upfront surgery and 12 in NACRT patients) and was comparable with COREAN study.

The rate of CRM positivity in the present study was 6% (4% in mid third and 2% in lower third rectal cases) which was comparable with the results of COREAN trial.

Discussion

At present, the American Society of Colon and Rectal Surgeons (ASCRS) have not endorsed laparoscopic proctectomy for cancer because of concerns over the ability to achieve adequate mesolectal excision and clear surgical margins using this technique. The ASCRS has encouraged initiation of properly designed trials to study the safety, efficacy, and benefits of laparoscopic surgery for rectal cancer

The present study is a retrospective study to asses' feasibility and to evaluate short term (surgical and oncological resection) outcomes of laparoscopic surgery in rectal cancer. Majority of rectal cancer patients presenting to our institute were in stage 2 or 3. Due to limited period only 50 patients were included in the study.

Mean operating time was 192.6 min (3.21hrs ± 0.53) in the present study for laparoscopic rectal surgeries and it was much lesser than in COREAN AND COLOR II trials [12,13,15]. Laparoscopy ranging from 180 - 245 minutes was statistically significantly longer compared to open group (ranging 135 - 197 minutes) in most studies as reviewed by Main WPL & Kelly [12].

The rate of conversion to open surgery in the present study was 2%. Conversion rates to open surgery ranged from 2% to 34%, although the definition of conversion is not standardized, which makes comparisons amongst trials difficult [12]. Unlike the CLASICC trial, the COLOR II and COREAN trials utilized preoperative imaging to evaluate depth of invasion. The conversion rate in the CLASICC trial decreased from 38% in year one to 16% by year 6, suggesting a learning curve. In the present study surgeries were performed by experienced laparoscopic surgeons, so conversion rate was low and comparable.

The mean blood loss in present study was 159.6ml and was less compared to laparoscopic arms in COREAN, COLOR II TRIALS and other studies shown above. Blood loss ranged from 20-321 mL with the laparoscopic approach, compared to 92-555.6 mL with open surgery in those studies and was statistically significantly less for the laparoscopic approach. Anastomotic leak rates in various studies ranged from 1.2-13% in the laparoscopic group. The leak rate in present study was 4% and is much comparable.

The morbidity rate in present study was 22% which is similar to COREAN trial [13,14] and less than the rate reported in many other trials. Morbidity ranged from 6.1-69% in the minimally (laparoscopic) invasive group and were similar to open group. The mortality rate in present study was 2% which is similar to mortality ranged from 0 - 4% for minimally invasive approaches in other studies.

As a result of earlier return of bowel function, ambulation, tolerability of diet, and better pain control, most studies revealed a statistically significant shorter length of stay for the minimally invasive (8-10.8 days) compared to the open (9-13.6 days) groups [12]. The average length of hospital stay in present study was 6.76 days which is less than all of the reported above studies.

The oncological resection outcomes in the present study were much comparable and equivalent to the reported results from various studies mentioned in Main WPL & Kelly [12].

Macroscopic Completeness of TME was 72.4 & 88% in the minimally invasive groups in the two reported COREAN [13] and COLOR [15] studies respectively. In the present study it was 74% which is between these two studies. Most of the above-mentioned studies revealed no statistically significant difference between the numbers of lymph nodes removed between open and laparoscopic approach. The average lymph nodal yield in the present study was 12.6 (15.75 in upfront surgery and 12 in NACRT patients) and was comparable with most of above-mentioned studies.

Majority of above trials defined positivity of CRM as a margin of 1mm or less, while the COLOR II trial used a definition of 2mm or less. The CLASSIC [9] trial noted a high rate of CRM positivity for laparoscopic versus open resections (12 *vs* 6%), though not statistically significant (p=0.19), and no difference was appreciated regarding local recurrence or survival with the 5 year follow up. The COLOR II [15] trial noted that in the subset of patients with rectal cancer located within 5 cm of the anal verge the rate of CRM positivity was lower in the laparoscopic group (9 *vs* 22%, p=0.014), which they postulated was the result of improved visualization with the laparoscope. They revealed the inverse with mid rectal cancers with 10% of laparoscopic procedures having a positive margin compared to 3% of open cases, though not statistically significant (p=0.068). No statistically significant differences were found between open and minimally invasive approaches regarding CRM positivity.

The rate of CRM positivity in the present study was 6% (4% in mid third and 2% in lower third rectal cases) which was comparable with the results of COREAN and COLOR II trials.

Our research has several limitations. Small sample size, Single site study, No generalizability, Study conducted quickly and inexpensively compared with RCTs. Comparison is done with international Large-sample and high-quality trials to strengthen our results.

Master Chart (Table 16).

MRNO: Medical Record Number

cT/N: Clinical T Stage/N Stage

Tumor Site: 1- Lower Third Rectum,

2- Middle Third Rectum,

3- Upper Third Rectum

NACRT: 1- Received,

2-Not Received

Surgery: 1- Abdomino Perineal Resection,

2- Anterior resection,

3-Anterior resection with diversion ileostomy

LAP: 1- Totally Laproscopic,

2- Laparoscopy Assisted

B.L (ml): Blood Loss during Surgery in Milliliters

Surg time (hrs): Duration of Surgery in Hours

ICU stay: Stay in Surgical Intensive Care Unit in days

P.D flat: Postoperative Day of First Passage of Flatus or Stoma Function

P.D F.R: Postoperative Day of Foleys Catheter Removal

P.D dis: Postoperative Day of Discharge from Hospital

Hist: Final Histopathological type of Tumor

W- Well differentiated Adenocarcinoma,

M- Moderately Differentiated Adenocarcinoma, P- Poorly Differentiated Adenocarcinoma,

N- No Residual Tumor

pT: Final Pathological Tumor-T stage

CRM: Circumferential Resection Margin

less than or Equal to 1 mm,

2 to 5 mm,

6 mm to 1 cm,

More than 1 cm Margin

TME: Macroscopic Intactness of Mesorectum

1. Completely Intact
2. Nearly Complete
3. Incomplete

LNE: lymph Nodes Examined (harvested)

LNP: lymph Nodes Positive

Final pTNM: Pathological Tumor and Nodal Stage grouping

SSI: Surgical Site Infection 1- No, 2- Yes

Conclusion

An important consideration for any new surgical approach is the learning curve faced by those who will be performing them. Like other laparoscopic procedures there is a learning curve associated with laparoscopic rectal cancer surgeries. Important aspect of any laparoscopic oncological procedure is the safety of procedure, adequacy of procedure and long-term outcomes. In the present study we have tried to investigate feasibility and short-term outcomes. Results of our study show that Laparoscopic surgery is a safe and oncologically adequate procedure for rectal cancer in the upfront or in post neoadjuvant settings in terms of feasibility, short term surgical and oncological resection outcomes.

Larger multi-institutional ongoing randomized studies such as COLOR II, ASCOG Z6051 and Japanese JCOG 0404 will confirm & help us to provide further clarity about the short and long-term patient oriented and, especially oncologic outcomes associated with this technique in comparison to open technique. Until then it is recommended that minimally invasive surgery for rectal cancer can be conducted within a setting with high experienced surgeons.

Recommendations

Multinational adequately powered randomized control studies needs to be conducted to readily accept and widely use laparoscopy technique in rectal cancer than open surgery.

Laparoscopic surgery for rectal cancer more is technically challenging than laparoscopic colectomies and needs more learning experience because of more complex pelvic anatomy.

The visual magnification and ability to enter tight spaces that are unique to the laparoscopic approach may be an advantage apart from benefits like less intra operative blood loss, less postoperative pain, shorter hospital stay, faster return to work, and better quality of life compared to open surgery.

Laparoscopy can be used safely even after post neoadjuvant chemo radiation for rectal cancer in the multimodality treatment approach.

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