



## COMPARATIVE EFFECTIVENESS, SAFETY AND CLINICAL OUTCOMES OF LAPAROSCOPIC VERSUS OPEN SURGERY FOR COLORECTAL CANCER.

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### Abstract

Background: Colorectal cancer represents one of the leading cause of death worldwide. Despite the theoretical advantages of laparoscopic surgery, it is still not considered the standard treatment for colorectal cancer patients because of criticism concerning oncologic stability. The aim of this study was to evaluate the short term follow-up, clinical outcomes, oncologic safety, potential advantages and effectiveness of laparoscopic surgery versus open surgery for colorectal cancer. This prospective study was carried out in patients who underwent surgery for stage I–III colorectal cancer from March 2023 to July 2025 at the Department of General Surgery, DR. KNS-MIMS, Barabanki, UP, India. A total of 200 patients, 100 in each group (Lap=A Vs Open=B surgery), who underwent the laparoscopic-assisted procedure showed a significantly faster recovery than those who underwent open surgery, namely, less time to first passing flatus, time of first bowel motion, time to resume normal diet, and time to walk independently. Laparoscopic colorectal surgery caused less pain for patients, leading to lower need of analgesic and less hospital recovery time and stay as compared with the patients who underwent open surgery. No differences were found in 3 months, 6 months, 12 months and 18 months overall and disease-free survival rates. The study was concluded as the laparoscopic approach was as safe as the open alternative. Laparoscopic-assisted surgery has been shown to be a favorable surgical option with better short-term outcomes and safe, effective oncological control as compared to open resection. Large sample size and long term follow up, up to 5 to 8 years are required to establish Laparoscopic-assisted surgery for colorectal cancer in rural population of India.

**Key words:** Colorectal cancer, Epidemiology, Laparoscopic surgery, Open surgery.

### Introduction:

Colorectal cancer (CRC) holds significant socio-sanitary importance worldwide. It is ranked as the third most common cancer in terms of both incidence and mortality, following breast and lung cancer among women and prostate and lung cancer among men [1,2]. Colorectal cancer (CRC) incidence in India is relatively low compared to global rates, but it is rising, with a steady annual increase of 2-3% [3-5]. India has traditionally been considered a low incidence country. However, there is a recent

perception among clinicians of a rising trend especially of young onset CRC in India [6]. Over 1.9 million CRC cases (males:1,045,413; females:826,706) occurred globally in 2022, with an age adjusted rate per 100,000 (AAR) of 17.8 . Additionally, 881,984 deaths occurred due to CRC (mortality AAR 7.8) . CRC contributes to more than 9% of the world's cancer incidence and mortality [6]. As per the international classification of diseases (ICD10), this anatomical grouping includes colon (C18), rectosigmoid junction (C19) and rectum (C20) [6-8].

Colorectal cancer incidence in India:

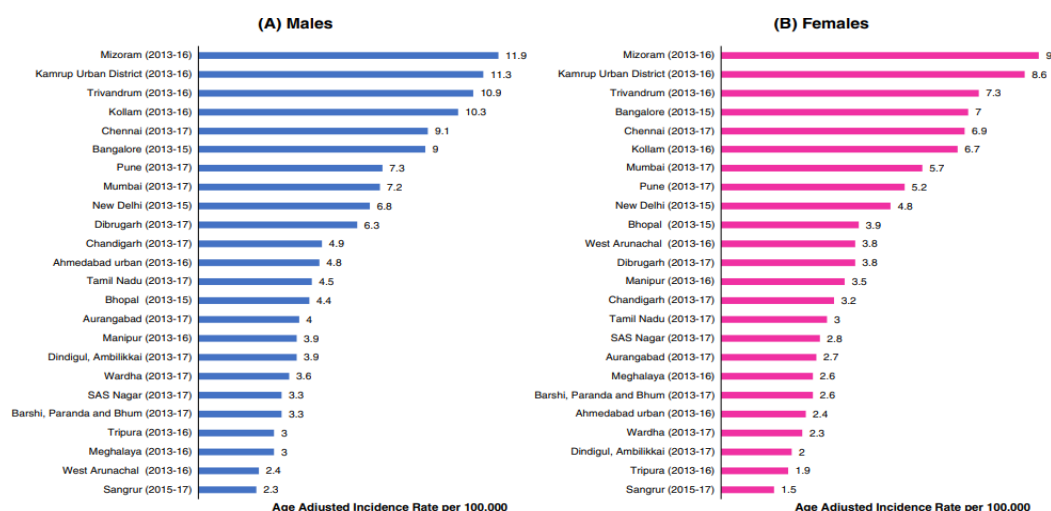
Colorectum ranks among the most common sites of cancer incidence in India, with 40,430 cases in males and 24,433 cases in females in 2022 [6]. Incidence is greater among males (AAR 5.7) than females (AAR 3.4), as shown in Table-1. CRC contributes to more than 4% of India's cancer incidence and mortality. A wide disparity in regional incidence is apparent within India [2], as visualized in Figure-1. The impact of urbanism on CRC incidence was marked among Indian cancer registries [2, 9]. Using data from the 12th volume of Cancer Incidence in Five Continents for 2013–17, we computed incidence rate ratios (RaR) between urban and rural areas of same regions. In the north and west regions, urban areas had twice the incidence of CRC than rural areas, in both sexes: Chandigarh vs. Sangrur (males:RaR 2.13, 95% CI 1.55–2.92; females:RaR 2.13, 95% CI 1.41–3.22) in Punjab and Mumbai vs. Barshi (males:RaR 2.18, 95% CI 1.78–2.68; females:RaR 2.19, 95% CI 1.75–2.74) in Maharashtra. Highest urban-rural difference was observed in north-eastern men (Kamrup urban district had almost five times greater incidence than Tripura state [RaR 4.71, 95% CI 3.50–6.34]) and southern women (Chennai had more than thrice the incidence of CRC than Dindigul [RaR 3.45, 95% CI 2.99–3.99]). By histology, about 93% of CRCs seen at Indian hospitals were adenocarcinomas [11]. Over 45% of colon cancers and 55% of rectal cancers were diagnosed at locoregional disease stage [11-16].

Table-1: Incidence and mortality of colorectal cancer in India, by site and sex as per GLOBOCAN 2022 [6].

		Male				Female				Total			
		Number	CR	AAR	Cum.Risk (0–74)	Number	CR	AAR	Cum.Risk (0–74)	Number	CR	AAR	Cum.Risk (0–74)
<b>Incidence</b>	Colon	21,602	3.0	3.0	0.36	12,444	1.8	1.7	0.20	34,046	2.4	2.4	0.128
	Rectum	18,828	2.6	2.6	0.31	11,989	1.8	1.7	0.19	30,817	2.2	2.2	0.25
	Colorectum	40,430	5.5	5.7	0.67	24,433	3.6	3.4	0.40	64,863	4.6	4.5	0.54
<b>Mortality</b>	Colon	13,116	1.8	1.9	0.22	7,513	1.1	1.1	0.12	20,629	1.5	1.5	0.17
	Rectum	10,843	1.5	1.5	0.18	6,895	1.0	0.96	0.11	17,738	1.3	1.2	0.14
	Colorectum	23,959	3.3	3.4	0.39	14,408	2.1	2.0	0.23	38,367	2.7	2.7	0.31

GLOBOCAN Global Cancer Observatory, CR colorectal, AAR age adjusted rate

Figure-1: Comparison of colorectal cancer incidence in India in 2013–17 using data from Cancer Incidence in Five Continents [6].



### Age and time trends in incidence:

A general perception among Indian oncologists is that CRC presents in younger age groups in India, as compared to the west [17]. This notion is supported by data from Indian hospitals as most CRC patients visiting them are within 50-69 years [18], while a majority of CRC cases in the US and UK are of ages 65 and above [3, 19]. However, age specific incidence rates of CRC in the Indian population show no such spike among the younger ages [20], as visualized in Fig. 2. The higher number of young CRC subjects could be a reflection of the larger proportion of young population in India [21]. Currently, CRC incidence is low in India; 1 in 149 men and 1 in 250 women diagnosed in 2022 [6]. However, contrary to their developed counterparts, India and other LMICs such as Uganda and Thailand are experiencing an increasing trend of CRC [22]. Estimates from the Global Cancer Observatory suggest that CRC incidence and mortality in India shall double by 2050 [23]. This rise in incidence could be attributed to the improvement in healthcare facilities and cancer registration methodology. Changes in lifestyle and dietary practices, especially in urban regions, also contribute to this trend. India has observed a steady rise in CRC incidence with an Annual Percentage Change (APC) of 2% to 3% for the past two decades [22]. Higher APCs were observed for colon cancer incidence in females of regions such as Chennai (5.5%), Trivandrum (10.4%), Mumbai (2.7%), Bengaluru (4%) and Pune (5.3%) [24]. In males, colon cancer incidence is increasing by 2.5%, 3.6% and 6.8% in Mumbai, Bengaluru and Dibrugarh, respectively. Rectal cancer is increasing in both sexes by 3.8% to 4.1% in Chennai, 5.9% to 7.6% in Trivandrum and 2.8% to 6.4% in Mizoram and by 4.7% in females of Kollam and 5.2% in males of Pune [24].

### Outcomes of CRC in India:

India has the second highest number of deaths due to rectal cancer, following China [6]. Mortality, like incidence, was greater for males (AAR 3.4) than females (AAR 2.0), as mentioned in Table-1. SurvCan-3 reports the five-year net survival (2008-12) for CRC in India to be 34.2% for colon cancer and 37.9% for rectal cancer [22]. Five-year relative survival of CRC in high income countries such as the US (65% for 2014–2020) and England (58.4% for 2016–2020) are higher than the survival rates of India [18, 23-30]. Through a comprehensive literature review, statistically significant risk factors associated with CRC have been identified, for primary prevention and risk stratification.

### Dietary factors:

Considering the role of bowel mucosa in digestion, diet has been explored multiple times as an etiological factor for CRC. Consumption of red and processed meat has been heavily associated with CRC [30–33], especially in men [24, 34]. Colon cancer seemed more affected by this association than rectal cancer [35,36]. Associations observed were strongest in North America and weakest in Asian populations [37]. In southern India, consumption of beef quadrupled the risk of CRC (odds ratio [OR]

4.25, 95% CI 2.02–8.94) while not consuming beef showed a protective effect (OR 0.07, 95% CI 0.03–0.19), both at high statistical significance ( $p=0.000$ ) [38]. Substantial increases in CRC risk were observed for consumption of eggs more than twice a week (OR 3.67 95% CI 1.23–9.35,  $p=0.013$ ) [39] and mutton consumption more than twice a month (OR 5.4, 95% CI 1.55–19.05,  $p=0.008$ ) [40]. In western India, red meat consumption was associated with more than two times elevated risk of CRC in women (OR 2.4, 95% CI 1.2–4.7) [41]. Risk increased with frequency of consumption ( $p=0.012$ ) [39]. Consumption of processed meat doubled the risk of CRC (OR 2.10, 95% CI 1.17–3.78,  $p=0.013$ ) [32]. Alternatively, choosing lean and cold meats reduced the risk of CRC in Denmark (hazard ratio [HR] 0.81, 95% CI 0.71–0.92) [33]. Consumption of fish was found to be protective against CRC [26, 29–31, 33] in general, but the dose response relationship was not significant [29].  $n-3$  poly unsaturated fatty acids (PUFAs) such as eicosapentaenoic acid (EPA) (RR 0.89, 95% CI 0.80–0.99) and docosahexaenoic acid (DHA) (RR 0.88, 95% CI 0.81–0.96), which are antiinflammatory agents abundant in seafood, were associated with lower risks of CRC [34]. Consumption of fruits and vegetables is protective against CRC [29, 30, 32, 35]. The risk decreases with increasing number of servings consumed per day [25, 32, 36]. Increased consumption of solanaceous vegetables such as tomatoes (OR 0.59 95% CI 0.40–0.88), peppers (OR 0.48 95% CI 0.33–0.7) and brinjals (OR 0.42 95% CI 0.29–0.62) provided protection against CRC probably due to possible anti-cancer agents such as pectin, anthocyanins, glycosidic alkaloids and carotenoids [42]. In an Indian study, cabbage consumption reduced the risk of developing CRC by half (OR 0.5, 95% CI 0.3–0.8) [31]. Daily consumption of fruits and vegetables reduced CRC risk by about 90% in another Indian study [32]. This could be attributed to dietary fibre which is a well explored protective agent against CRC [36]. Contrarily, increased consumption of starchy vegetables such as potato (OR 1.76; 95% CI: 1.26–2.47) [43] and tapioca (OR 2.70, 95% CI 1.32, 3.31,  $p = 0.000$ ) [29], has been associated with an elevated risk of developing CRC. Thirteen studies on nuts consumption found it to be protective against CRC, especially in Asia (RR 0.44, 95% CI 0.29–0.68) [44]. Twenty-nine studies concluded that CRC risk and legume consumption are inversely associated (RR 0.90, 95% CI 0.83–0.98) [45]. Increment in servings of nuts and legumes brought about a risk reduction of 21% to 33%. Consumption of whole grains is also protective against CRC [46]. Meta-analysis of multiple cohort studies revealed that higher intake of dairy products was protective against CRC with a significant dose response relationship [38]. It also reduced CRC mortality [38]. The association was significant for milk [38] and for fermented dairy products, including cheese and yoghurt [39] and stronger in Europe [38, 39]. The protective effect of vitamins has been demonstrated to cause 12% to 25% reduction against CRC in multiple meta-analyses [36, 40–43]. Risk reduction was stronger in women and further reduced with increasing dosage [46–48]. Multivitamin supplements (RR 0.92, 95% CI 0.87–0.97) were also protective against CRC [42]. Among minerals, calcium is a well-established protective agent against CRC [49], that may be involved in the protective effect extended by dairy products. About 16% of disability-adjusted life-years (DALYs) caused by CRC in South Asia have been attributed to diets low in calcium [50]. Calcium supplements significantly decreased CRC risk (RR 0.86; 95% CI 0.79, 0.95) [51]. A pro-inflammatory diet which is calorie dense but deficient in dietary fibre caused a 40% increase in risk of CRC (RR 1.40, 95% CI 1.26–1.55), especially in men. Processed diet pattern (including confectioneries and fast food) in Malaysia increased the risk of CRC by over three times (OR 3.45, 95% CI 1.25–9.52,  $p=0.017$ ) [45]. Daily and incremental intake of sugary beverages is positively associated with CRC incidence and mortality, especially among the physically inactive and obese [46]. Intake of fried food more than twice a month doubled the risk of CRC in a south Indian case-control study (OR 2.03, 95% CI 0.95–4.43,  $p=0.06$ ) [44]. Having a plant based diet was protective against CRC in the US, especially if ultra-processed elements such as refined sugars or flour were avoided [47]. Similarly, the micronutrient-rich Mediterranean diet showed a significant reduction in CRC risk in Italy. However, no single dietary component was attributed individually for the risk reduction [48]. This emphasises the importance of a well-balanced diet to bring about risk reduction. Adherence to dietary guidelines that promote such well-balanced and healthy diets has been observed to reduce CRC risk by half [52].



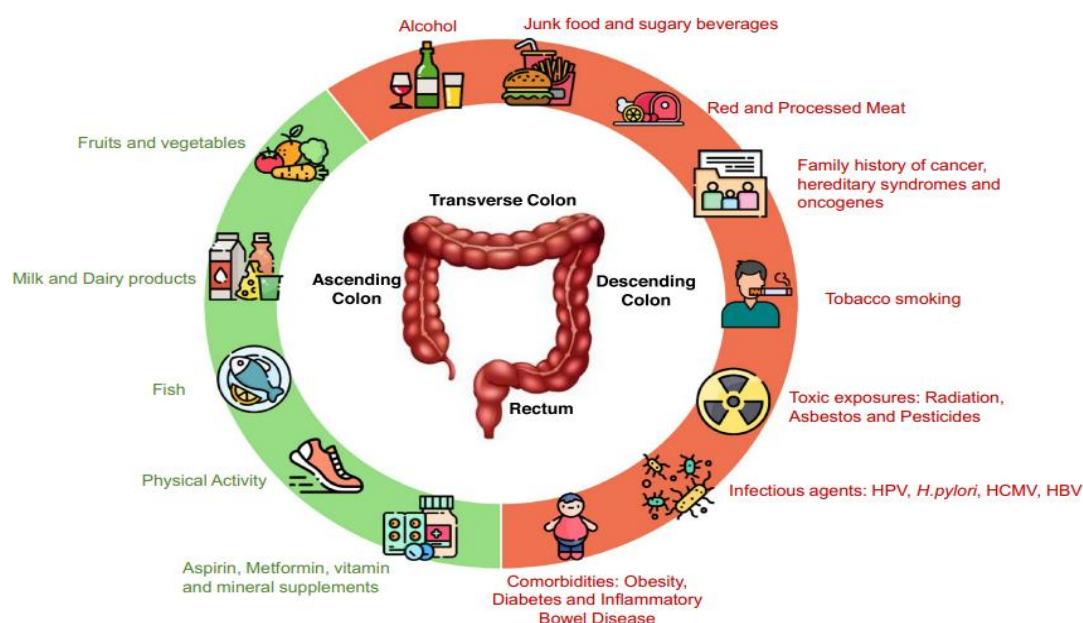
**Behavioral factors:**

Physical activity is a protective factor supported by multiple cohort studies [5, 25, 53]. A meta-analysis of 18 studies found a 38% lower risk of CRC among physically active subjects (RR 0.63, 95% CI 0.47–0.84) [49]. Risk was lower among participants with low BMI and no family history of CRC. Strong evidence from multiple studies supports that regular and greater intake of alcohol is associated with elevated risk of CRC [5, 27, 32, 54], with stronger association in men [50]. Longer duration in years and higher intake further increased risk in men [50]. Smoking was positively associated with CRC [5, 25, 55]. In Indian case-control studies, ORs for tobacco smoking were 2.77 in the west and 8.79 in the south [29, 32]. The risk increased significantly with amount and duration of cigarettes smoked [25, 32, 56]. Even passive smoking had an evident association with CRC (RR 1.14; 95% CI 1.05–1.24) [57], especially in males.

**Genetic factors:**

An analysis of 19 studies found a 14% increase in risk with every 10-cm increase in height (HR 1.14, 95% CI 1.11–1.17,  $p < 0.001$ ), with greater risk for colon cancer [52]. Postulated attributions for this association are increased body organ size due to greater stature and related hormonal and genetic factors affecting carcinogenesis [52]. Family history of CRC was significantly associated with an increased risk of CRC [5, 13, 14, 25], especially early onset CRC [33]. This risk increased further with genetic closeness of the relative such that having first degree relatives with CRC doubled the risk [23]. Even the presence of colorectal polyps or adenomas in first degree relatives was found to increase CRC risk by about 40% (OR 1.40, 95% CI 1.35–1.45) [44]. A 16 fold increase in risk for early onset CRC was observed among those having two or more first degree relatives with both polyps and CRC (OR 16.57, 95% CI 4.81–57.13) [44]. Thus, the hereditary component in early onset CRC is significantly stronger. A meta-analysis of 14 studies found the presence of BRCA1 mutation to be a risk factor for CRC (OR 1.58, 95% CI 1.23–1.98).

Figure-2: Risk factors of colorectal cancer [6].



In 2020, Italy witnessed an estimated 45,000 new cases of CRC (24,000 in men and 21,000 in women) [58]. Aging has also emerged as a pivotal factor in the development of CRC, with its prevalence steadily increasing over the past decade, particularly among individuals aged 65 and older [33,34, 59]. Approximately 90% of newly diagnosed cases occur in individuals aged 50 and above, with 60% of them being older than 65 [6]. The prognosis for CRC has improved significantly due to early detection and advancements in clinical management. Over the last two decades, there has been a notable

increase in 5-year survival rates, particularly among patients with advanced tumors [37]. The first laparoscopic colectomy was introduced by Jacobs in 1991 [58]. Minimally invasive colorectal surgery offers numerous advantages, including smaller incisions, improved aesthetic outcomes, reduced postoperative pain, quicker recovery of intestinal function, shorter hospital stays, and lower postoperative mortality and morbidity rates, while also maintaining comparable oncological outcomes compared to open surgery [19,10]. The safety and feasibility of minimally invasive techniques have been substantiated by various randomized trials [31–33,60]. Nevertheless, in clinical practice, laparoscopic surgery has not been universally adopted for very elderly patients due to the prolonged operative times and the potential adverse effects of pneumoperitoneum on heart and lung function, especially in patients with a higher Charlson Comorbidity Index (CCI), such as the very elderly population (those over 80 years old).

Standard oncologic surgery consists of en-bloc bowel resection with appropriate proximal and distal resection margins and more than 12 harvested lymph nodes [40-43]. The use of laparoscopic colectomy for colon cancer is now an acceptable treatment not only for early colon cancer, but also for advanced cases because of its oncological safety and feasibility [61]. The laparoscopic colectomy showed comparable oncologic results to the open colectomy group and even better survival rates in the patients with stage III disease. These results were later confirmed on long term follow-up [62-65]. The laparoscopic approach for colon resection is widely accepted, but its definitive role in rectal tumors is still controversially debated due to technical difficulties and missing long-term results. Tumor size and volume and pelvic dimensions may influence intraoperative and/or immediate outcome. The good exposure of the pelvic cavity by laparoscopy and the magnification of anatomical structures seem to facilitate pelvic dissection [66].

In view of above facts and to the best of knowledge no study was done on comparative effectiveness, safety, clinical outcomes against short-term follow up, of laparoscopic versus open surgery of colorectal cancer in rural population of Barabanki, UP, India. Hence, The present study was carried out to establish and evaluate the short term follow-up, clinical outcomes, oncologic safety, potential advantages and effectiveness of laparoscopic surgery versus open surgery for colorectal cancer.

## **Materials and Methods:**

### **Materials:**

**Study site:** Department of General Surgery, DR KNSMIMS, GADIA, BARABANKI, UP, INDIA.

**Study Design:** Comparative Prospective study

**Study groups:** Two Groups . Gr.B= Open Surgery; Gr.A= Laparoscopic.

**Study Period:** March 2023 to July 2025, after obtaining Institutional Ethical Committee approval and written informed consent from patients.

**Sample size:** A total of 200 Patients of colorectal cancer, 100 in each group. Aged 18 to 70 years.

**Study Subjects:** A total of 200 patients of colorectal cancer who underwent surgery either open or laparoscopic method were enrolled.

**Inclusion Criteria:** All patients were included in this study after obtaining prior consent letter.

**Exclusion Criteria:** Patients with AIDS, Pregnant women and not willing for surgery were excluded from this study.

### **Methods:**

Preoperative characteristics were obtained regarding age, gender, body mass index, American Society of Anesthesiologists score, and co-morbidities. Pathological and perioperative data were analyzed included tumor location, operative time, blood loss, sample length, proximal and distal margin length, number of retrieved lymph nodes, tumor size, pathological differentiation, and clinical stage. Postoperative data were also analyzed included analgesic usage, peristalsis recovery time, time until flatus, off-bed, first liquid, and semi-liquid intake, and duration of hospital stay. Early and late postoperative complications were also collected and analysed.

Randomization:

Randomization was performed at the patient level. Laparoscopic and open surgery were performed at all participating centers. Eligible patients were randomly assigned in a 2:1 ratio to undergo either laparoscopy or open surgery according to a list of randomization numbers with treatment assignments. This list was computer-generated, with stratification according to hospital, tumor location, and the presence or absence of preoperative radiotherapy. An Internet application allowed central randomization.

All patients were followed up after being discharged from the hospital. Survival was calculated in months from the date of diagnosis to the date of death or to the date of the last visit to the outpatient clinic. For patients who did not visit our hospital, telephone interviews were used. The last date for follow-up was July 2025. Data for patients who died or who remained alive at the date of last follow-up were censored.

#### **Surgical technique**

All operations were performed and supervised by a stable group of colorectal surgeons within a single surgical team for both laparoscopic-assisted and open surgery procedures. All patients had cefuroxime (1.5 g) and metronidazole (500 mg) administered intravenously at the time of induction of general anesthesia for systemic antibiotic prophylaxis. Other preoperative procedures were standardized, as followed for traditional abdominal surgeries. For conventional open surgery, the patients were placed in the supine position, and a midline or right paramedian skin incision was performed. Open procedures were performed according to the standard techniques followed by the operating surgeon. For laparoscopic surgery, the operations were performed with the patient in the modified lithotomy and Trendelenburg position. Pneumoperitoneum was created by the open method. In general, three to five 12-mm ports were used: an umbilical port for the laparoscopic camera and two (or one) ports each in the right and left sides. For extended right colectomy and transverse colectomy, the surgeon and camera operator stood to the left side of the patients, and for extended left colectomy, the surgeon and camera operator stood to the right side of the patients. The first assistant stood on the side opposite the surgeon, and the scrub nurse stood between the patient's legs. The retroperitoneum and right colon mesocolon were divided, exposing the ventral aspect of the superior mesenteric vein. The ileocolic vessels, right colic vessels, and midcolic vessels were identified in that order. In transverse colectomy, both the transverse colon and the mesocolon were stretched for identification of the midcolic vessels. The terminal ileum, cecum, and ascending colon were mobilized up to the hepatic flexure, while the duodenum and right ureter were being protected. In extended left colectomy, using the medial approach, we identified the left colic artery. In the laparoscopic group, anastomosis was performed by a small laparotomy.

#### **Postoperative period:**

All patients enrolled in this study were managed postoperatively. Patients in both groups were supported by infusions in the very first several hours after surgery. After confirmation of the peristalsis recovery, liquid diet was supplied. Semiliquid diet was considered suitable for patients after report of flatus. For pain control, patients were given patient-controlled anesthesia or short-acting drugs according to their own choice. Prophylactic antibiotics were used during the 72-hour period after surgery; however, if there was any indication of infection, this interval was prolonged. The catheter was removed as early as possible except for patients with tumors located in the lower region of the rectum. One month after surgery and every 3 months thereafter up to 18 months, a physical examination was performed, and laboratory markers such as serum carcinoembryonic antigen and carbohydrate antigen 19.9 levels were assessed. At each patient visit, symptoms were recorded, and wound scars were examined. Either ultrasonography or computed tomography scan of the abdomen, in addition to chest X-ray, was performed every 6 months, and total colonoscopy was performed at 12 and 18 months.

### Statistical Analysis:

Data were presented as frequencies and percentage and compared by the chi-squared test. Parametric and non-parametric continuous data were presented as mean and standard deviation and evaluated by Student's t test and Mann–Whitney U test, respectively. Comparisons between the two groups were made on an intention-to-treat basis. The Kaplan–Meier method was used to calculate the survival data, and their differences were compared by the logrank test. A P value of 0.05 was considered as significant. All calculations were performed by using the SPSS software package version 26.1 (SPSS Inc., Chicago, IL).

### Results:

A total of 200 patients, aged 18 to 70 years, both sexes were enrolled and analyzed in this study. A total of 100 patients were under laparoscopic-assisted colorectal resections (Group A), and 100 were under conventional open surgeries (Group B). No statistically significant difference was found in the majority of the demographic parameters between the two patient populations (Table-2, fig- 3 and 4).

**Table-2: Demographic and Preoperative Characteristics of two groups**

Variables\ Groups			Laparoscopic Surgery (n = 100), Group A	Open Surgery (n = 100), Group B	P value
Gender	Male		58 (58%)	54(54%)	0.84
	Female		42 (42%)	46 (46%)	
Age-Years	18-30	Male	6	5	0.063
		Female	4	6	
	31-50	Male	14	17	
		Female	11	12	
	51-70	Male	38	32	
		Female	27	28	
BMI Kg/ m <sup>2</sup>		Male	24.33±2.54	24.86±2.91	0.342
		Female	25.57± 2.98	26.31± 2.76	
ASA Score	1		12	13	
	2		53	55	
	3		31	29	
	4		4	3	
Preoperative					
co-morbid diseases			38	40	
Cardiovascular (CV)			11	10	
Respiratory (RESP)			4	5	
Hepatic cirrhosis(HEP-CIRR)			1	2	
Renal failure (RF)			2	1	
Cerebral infarction(CI)			3	1	
Diabetes(DIAB)			13	15	
Autoimmune (AUIMM)			1	2	
Others			3	4	

ASA, American Society of Anesthesiologists



Figure-3: Age related Demographic Characteristics of two groups

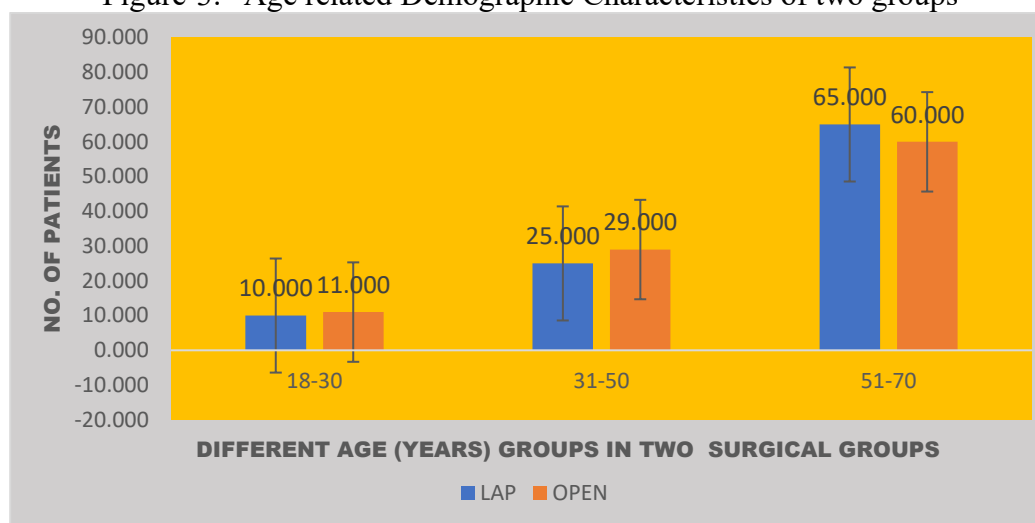
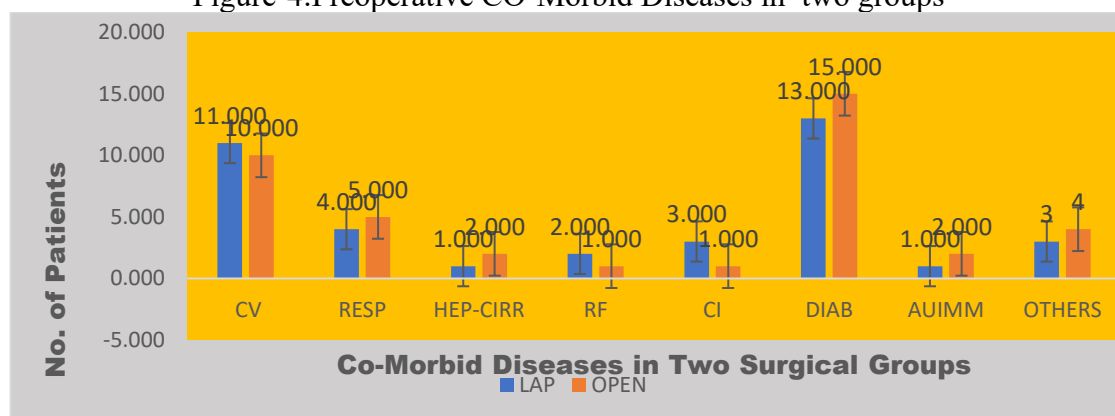


Figure-4: Preoperative CO-Morbid Diseases in two groups



### Operative and pathological parameters:

Most of the cancers/ tumors (38% in Gr. A and 34% in Gr. B) were located in the rectum (Table-3, fig-5). Resection margins were similar in both groups, and none of them was found to be positive. There were no significant differences in number of lymph nodes retrieved and in pT, pN, and overall TNM staging (Table-3 ). A significant difference in the operative time between the two groups was observed ( $166.73 \pm 36.22$  minutes for laparoscopic-assisted versus  $152.31 \pm 38.43$  minutes for open surgery,  $P = 0.024$ ) (Table-4 ). Moreover, significantly lower blood loss during laparoscopic surgery compared with open surgery was found ( $118.44 \pm 37.21$  in Gr.A;  $139.08 \pm 121.32$  in Gr.B,  $P=0.047$ )

Table-3: Pathological parameters

Variables\ Groups			Laparoscopic Surgery (n = 100), Group A	Open Surgery (n = 100), Group B	P value
Tumor location	Right hemicolon	Male	13	13	0.384
		Female	11	15	
	Transverse colon	Male	2	1	0.411
		Female	0	1	
	Left hemicolon	Male	4	5	0.397
		Female	2	3	

	Sigmoid colon	Male	18	15	0.382
		Female	12	13	
	Rectum	Male	21	20	0.369
		Female	17	14	
Tumor size (cm)		Male	4.63± 1.39	4.99± 1.87	0.261
		Female	4.49± 2.11	5.23± 1.94	
Proximal margin (cm)			11.63±2.31	11.98±2.76	0.672
Distal margin (cm)			8.96±3.32	9.23±3.69	0.543
Total sample length (cm)			26.88±5.42	27.57±5.83	0.712
Lymph nodes retrieved			13.62± 4.74	14.16±3.89	0.644
Grade		I	25	24	0.742
		II	63	67	
		III	8	6	
		IV	4	3	
pT		pT1	12	14	0.854
		pT2	27	25	
		pT3	32	34	
		pT4	29	27	
pN		pN0	49	51	0.746
			34	31	
		pN1			
		pN2	2	3	
		pN3	16	15	
TNM Stage		I	18	20	0.673
		II	32	29	
		III	50	51	
				Chemothera py	53

Figure-5: Location of Tumor in two Surgical Groups

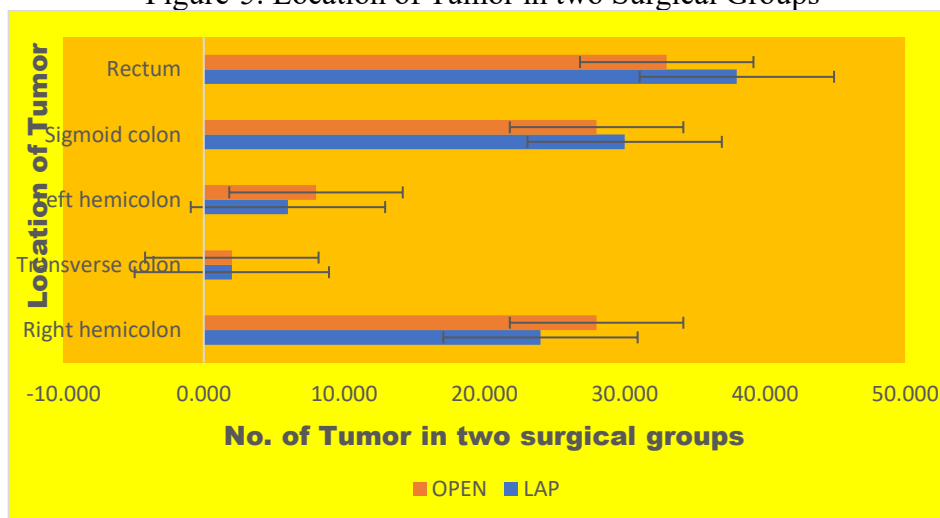


Table-4: Intraoperative Data and Postoperative Outcomes

Variables\ Groups		Laparoscopic Surgery (n = 100), Group A	Open Surgery (n = 100), Group B	P value
Operative time (minutes)		163.73± 36.22	158.31± 38.43	0.624
Blood loss (mL)		118.44 ±73.21	139.08 ±121.32	0.047
Postoperative analgesic requirement (number of injections)		5.86 ± 3.29	7.81 ± 3.69	0 .003
Time (days) to	First passing flatus	2.95 ±2.39	3.46± 2.44	0 .05
	First bowel motion	4.64 ± 2.95	5.11 ± 2.89	0 .031
	Resume normal diet	4.13 ±1.63	5.39 ± 1.89	0.046
	Walk independently	3.88 ±3.31	4.75 ±3.86	0.021
	Hospital stay (days)	8.62 ±2.24	9.79 ± 4.15	0.026

#### Perioperative recovery:

The patients who underwent the laparoscopic-assisted procedure showed a significantly faster recovery then those who underwent open surgery, namely, less time to first passing flatus ( 2.95± 2.39 days in Gr.A, 3.46± 2.44 days in Gr.B; P = 0.05), time of first bowel motion (4.64± 2.95 days in Gr.A; 5.11 ± 2.89 days in Gr. B; P = 0.031), time to resume normal diet (4.13± 1.63 days in Gr.A; 5.39± 1.89 days in Gr.B; P = 0.046), and time to walk independently (P = 0.021) (Table-4). Compared with patients who underwent open surgery, laparoscopic colorectal surgery obviously caused less pain for patients leading to lower need of analgesic (P = .002) and less hospital recovery time (8.62 ± 2.24 days for laparoscopic-assisted patients versus 9.79 ± 4.15 days for open surgery, P = 0.026).

#### Complications and recurrence:

No significant difference was found in the number of adverse events during the operation procedures between the laparoscopic-assisted and open surgery groups (Table-5 and fig.-6). Most of the late complications were minor in both groups, and almost all were due to wound infection and 521leus. No significant difference in the rate of recurrence between the two groups was found (Table-6 ).

Table-5: Early and Late Complications for Colorectal Cancer

Variables\ Groups		Laparoscopic Surgery (n = 100), Group A	Open Surgery (n = 100), Group B	P value
Intraoperative complications				
Massive hemorrhage (> 1000 mL)		1	2	0.972
Organ injury		2	1	0.786
Others		1	0	0 .183

Postoperative complications	Ileus	2	3	0.056
	Anastomotic hemorrhage	1	0	0.382
	Abdominal hemorrhage	1	2	0.918
	Peritonitis/septic shock	1	2	0.918
	Pelvic abscess	2	3	0.512
	Wound infection	2	3	0.347
	Incisional/port herniation	1	2	0.744
Systemic complications	Cardiovascular	1	3	0.388
	Renal	1	1	0.918
	Respiratory	0	1	0.544

Figure-6: Post operative Complications in two surgical groups

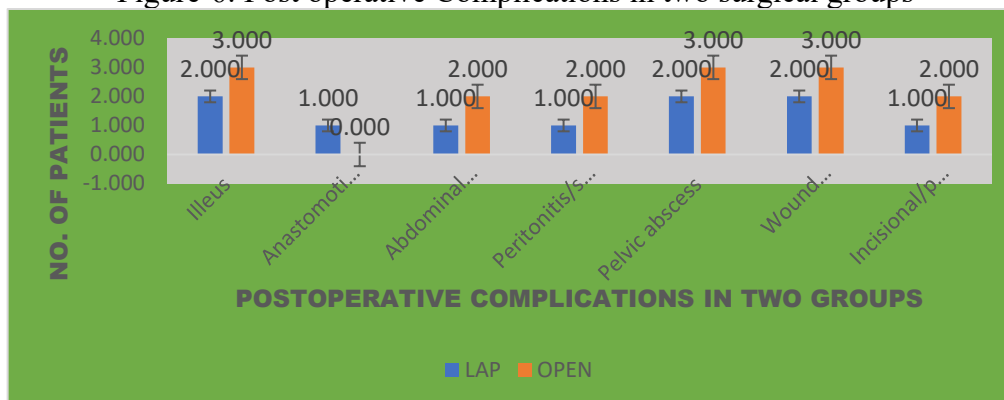


Table-6: Local and Distant Recurrences According to Cancer Location

Variables\ Groups		Laparoscopic Surgery (n = 100), Group A	Open Surgery (n = 100), Group B	P value
Recurrence				
Total		23	22	0.974
Colon		13	12	0.732
Rectum		10	10	0.783
Type of recurrence	Colon			
	Locoregional	7	5	0.523
	Distant	6	7	0.721
	Rectum			
	Locoregional	8	9	0.714
	Distant	7	7	0.534
Incision		0	1	0.187

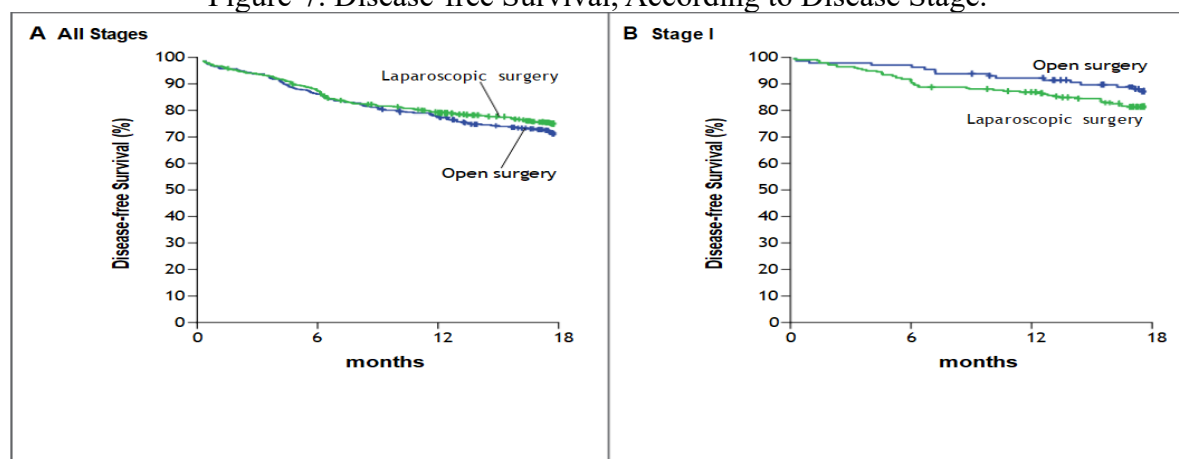
## Survival

The follow-up times were 1, 3, 6, 12, and 18 months in the laparoscopic and open surgically treated groups. The 12 and 18 months survival rate and disease-free survival rate were examined in 200 patients who could be followed up for longer than 36 months. Both colon and rectal cancer patients had almost similar recurrence rates at 12-months and 18 months follow-up, and found non significant, although a slightly lower survival was observed for patients with cancer of the rectum (Table-7 ). Among colon cancer cases, 12 and 18 months survival was 62 (100%) versus 66 (100%), respectively, whereas among rectal cancer cases it was 28 (100%) versus 24 (100%). According to the results of Kaplan–Meier analysis, laparoscopic and open surgery groups did not have significant differences in overall survival trend (Fig.-8) and disease-free survival (fig.-7) .

Table-7: Oncologic Outcome According to Cancer Location

Variables\ Groups\ Duration-Months	Laparoscopic Surgery (n = 100), Group A	Open Surgery (n = 100), Group B	Laparoscopic Surgery (n = 100), Group A	Open Surgery (n = 100), Group B	P value
Overall survival\ Months	12 months		18 months		
Total	100	100	100	100	0.999
Colon	62	66	62	66	0.416
Rectum	38	34	38	34	0.416
Disease-free survival					
Total	77	78	77	78	0.966
Colon	49	54	49	54	0.673
Rectum	28	24	28	24	0.541

Figure-7. Disease-free Survival, According to Disease Stage.





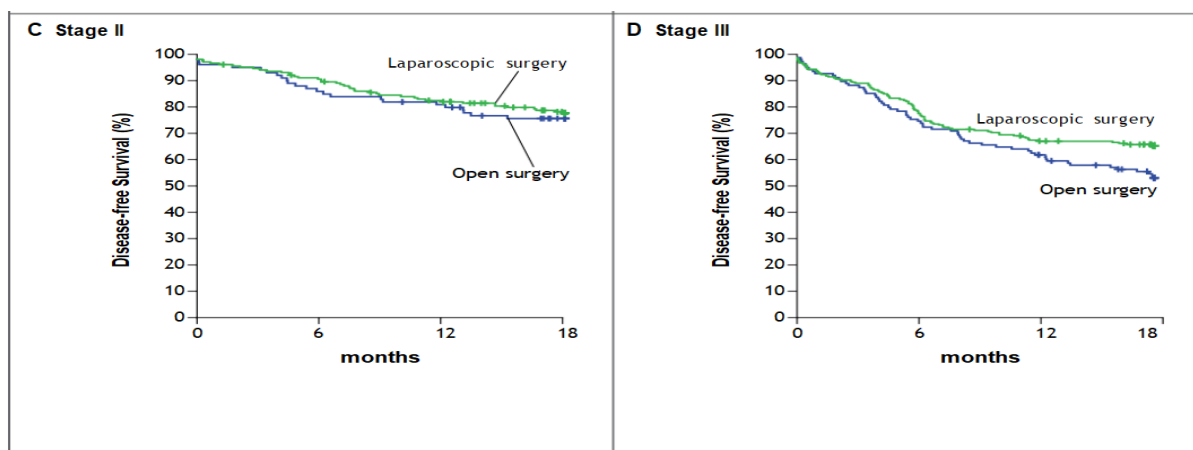
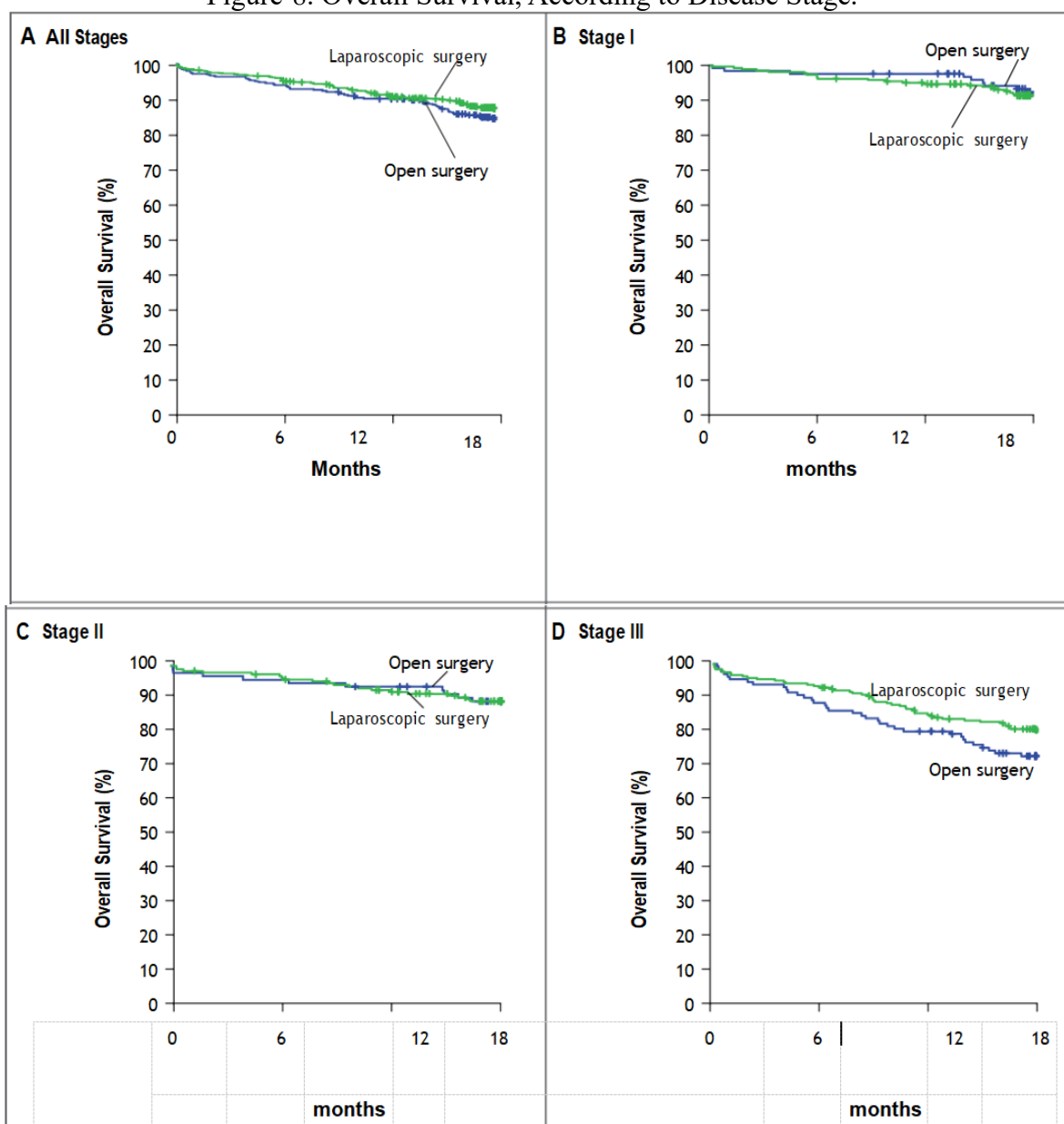
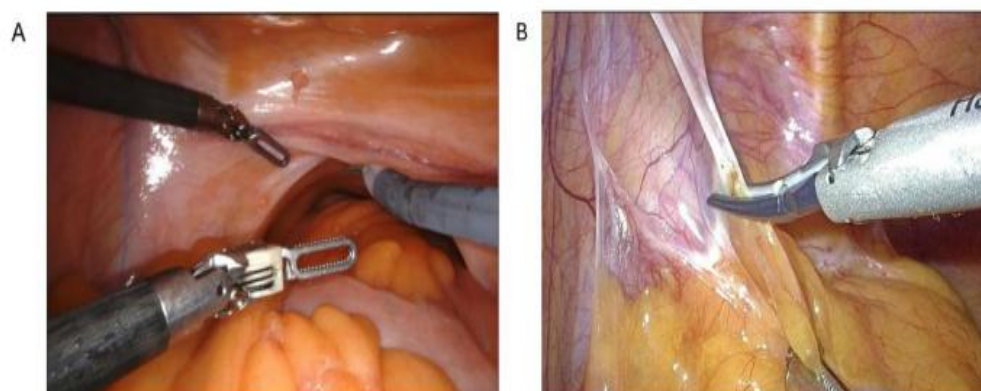


Figure-8. Overall Survival, According to Disease Stage.





**Figure-9: Laparoscopic colorectal surgery.**

### **Discussion:**

This was a comparative prospective study, analyzed data on patients with colon and rectal carcinoma operated on with laparoscopic-assisted or conventional open surgery. To the best of knowledge, only a few studies conducted in abroad and in specialized urban cancer centers in India, have explored differences between laparoscopic-assisted and conventional open surgery. The present study results showed that laparoscopic-assisted surgery was associated with better early postoperative outcomes and comparable rates of complications and survival compared with the conventional open procedure. In this study it was also found significant improvements in postoperative recovery among laparoscopic-treated patients, with an earlier resumption of normal diet, shorter hospital stay, and earlier time to ambulation.

The postoperative hospital stay for patients who underwent the laparoscopic procedure ranged between about 5 to 8 days in some randomized controlled trials, [33,55,59], which was a shorter time than the  $8.62 \pm 2.24$  days reported in this study. Several confounding factors could affect the comparison of hospital stay between the two groups as well as between different studies. For example, disparities according to socioeconomic status are well documented in the United States, thus introducing bias in the results if they are not adjusted for this variable. In Italy, the healthcare system provides ensuring equity in the availability of care by as preoperative co-morbidities may affect postoperative patient recovery and patients could not be discharged until the end of the first regimen of postoperative chemotherapy, this study examined such covariates to find any substantial differences between the two groups. It was also assessed any significant advantages in the laparoscopic approach over the open surgical method for pain score and analgesic consumption. As the laparoscopic procedure causes less pain, patients who underwent laparoscopic-assisted surgery definitely required smaller doses of analgesic than their counterparts who received open surgery treatment. In the results of most studies reported previously, short-term outcomes after laparoscopic surgery for colorectal cancer were shown to be better than those of open abdominal surgery[ 66-72].

Results about mean operating time of the laparoscopic-assisted procedure versus open surgery vary among studies, with some reported no differences between the two groups[44,70-72] and others reported a significantly longer time for the laparoscopic-assisted procedure probably because of the higher complexity of technical expertise involved in such technique.[11, 34, 55, 60] In this study it was also determined a slightly longer operating time for the laparoscopic-assisted procedure than for open surgery, although this difference was not significant ( $p=0.642$ ). It is possible that as time passed the surgeon's experience with the procedure increased. Therefore, with the stabilization of the learning curve of the surgeon, the operating time was significantly reduced over the time. The conversion rate of this study was 15.9%, which was far lower than that reported in other studies, which ranged between 15% to 30%.[13,25,51–63] This variation among studies may be translated into an evolution of operating skills over time, thus reducing conversion rates in the most recent studies.

In this study, oncological safety was assessed by examining postoperative results, such as the resection margin and the number of resected lymph nodes. The present study results showed that laparoscopic-assisted procedure outcomes were comparable to those achieved by open surgery. In this study, none

of the resection margins was found to be positive, as reported in most previous articles with data on resection margins.[25,49,44–47]. The average number of resected lymph nodes was  $13.36 \pm 4.74$  in patients who underwent the laparoscopic-assisted procedure and  $14.16 \pm 3.89$ ;  $p=0.644$  in those who underwent open surgery, thus confirming that there were no differences in lymph nodes harvested between the two groups of patients. This findings demonstrated that the oncologic safety of our laparoscopic surgery was comparable to previous results of other laparoscopic surgery groups.[28,44–47]. In this study, the only short term oncological outcomes were assessed over a period of 18 months for both groups, including early and late complications, local and distant recurrence rate, overall survival, and disease-free survival. Most complications were minor and comparable between the two groups, regarding wound or urinary tract infections (although wound infections were slightly more frequent in patients who underwent the open procedure), as reported in previous studies [18,21, 33. 61. 66]. With regard to recurrence rate, patients who underwent laparoscopic surgery were shown to have rates comparable to those who underwent open abdominal surgery. The Present study revealed that the recurrence rate for colorectal cancer patients were similar compared with prospective trials, with about 5–7% and 7–9% local and distant recurrence rates, respectively.[6,27,29,60]. It is noteworthy that recurrence rates vary, stratifying patients by cancer location, namely, colon and rectal cancer. Indeed, both local and distant recurrence rates have been shown to be lower in colon (about 4% and 8%, respectively) than in rectal cancer (about 7% and 9%, respectively) patients. This is thought to be related to the different blood flow in the rectum than in the colon. Another possible reason is that the surgery for rectal lesions is difficult because of the location itself. However, even stratifying according to the tumor location, the number of patients who developed a recurrence was similar in laparoscopic-assisted and open surgery patients, and these results were comparable to ours. Similar overall and disease-free survival in the two groups confirmed the long-term oncologic safety of the laparoscopic approach compared with open surgery. Reviewing the results of short-term follow-up conducted in prospective studies, the 12 months survival rates neared about 99% in almost all studies,[26,59–63] whereas in other studies they were significantly lower ( $< 70\%$ ).[71,72]. Also, regarding the 18 months survival, a certain degree of controversy has been found among different studies (ranging between 65.3% and 79%)[6,8]. Based on the present findings, our results were in line with those finding slightly higher survival rates, being for patients who underwent laparoscopic-assisted surgery about 100% at 12 months and 100% at 18 months follow-up, seemingly equivalent to the open surgical method. The present study was limited in that the patients were partially randomized into the two treatment arms. However, because there were no differences in demographic data as well as the sample size was very small, it was believed that this bias had negligible impact on the results. Furthermore, this study should be strengthened by the large sample size and a long follow-up period, more than 5 years to compared with other studies.

In conclusion, this study results, suggested that the laparoscopic approach was as safe as the open alternative. Laparoscopic assisted surgery has been shown to be a favorable surgical option with better short-term clinical outcomes for oncological control compared with open resection for rural population of Barabanki, UP, India .

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