Journal of Robotic Surgery (2025) 19:222
https://doi.org/10.1007/s11701-025-02375-5

RESEARCH

Short-term clinical outcomes of open, laparoscopic, and robotic-assisted rectal resections: a multicenter real-world evidence study from Indian collaborative group on rectal resections (ICGRR)

A. S. Ramakrishnan[1] · Jagdish Kothari[2] · Surender Kumar Dabas[3] · Venkatesh Munnikrishnan[4] · O. V. Sudheer[5] · Jeewan Ram Vishnoi[6] · Shivendra Singh[7] · Jagannath Dixit[8] · Sandeep Nayak[9] · Ashwani Sharma[10] · Devendra Parikh[2] · Venkat Paneer[11] · Priya Kapoor[11] · S. P. Somashekhar[12] · Krishna M. S. Bharadwaj[13] · Divya Gupta[14] · Akhil Dahiya[15]

Received: 26 October 2024 / Accepted: 25 April 2025

Abstract

This multi-centric real-world study was carried out to assess the perioperative and histopathological clinical outcomes of rectal resections employing open, laparoscopic, and robotic-assisted techniques. A retrospective chart review was undertaken for patients who underwent rectal resections for Stages I, II, and III rectal cancer (RC) between April 2012 and August 2023. All surgical procedures were performed with the principles of total mesorectal excision (TME) or partial mesorectal excision (for tumors located higher in the rectum). The study analyzed data from 829 patients of which 314 were in the robotic-assisted group (RAS), 206 in the laparoscopic surgery group (LG), and 309 in the open-surgery group (OG). The TNM staging and location of RC were evenly distributed across the three groups. The RAS group had a significantly lower length of hospital stay than LG and OG. Compared to LG and OG, the RAS group had less blood loss and postoperative complications, but significantly longer mean operating room time. The conversion rate of the RAS group was significantly lower than that of the LG group ($p = 0.03$). In comparison to the OG and LG groups, the RAS group had significantly lower ($p < 0.05$) rates of positive circumferential resection margin (CRM). Adjuvant treatment was administered in the RAS group significantly earlier (median, 24.5 days, IQR 18–37) compared to the LG (median, 31 days, IQR 23–41) and OG (median, 32.5 days, IQR 27–42). This largest multi-centric study by the ICRR group has validated the value of a relatively newer technology like RAS in real-world Indian settings for rectal resections.

Keywords Rectal resections · Robotic-assisted surgery · Laparoscopic group · Open group · Low anterior resection · Abdominoperineal resection

Abbreviations

RR	Rectal resections
RAS	Robotic-assisted surgery
LG	Laparoscopic group
OG	Open Group
LAR	Low anterior resection
APR	Abdominoperineal resection

Introduction

Rectal cancer (RC) is the cause of up to 35% of all incidences of colorectal carcinoma [1]. A previous study projected the number of cases of RC at 700,000 worldwide in 2020, along with the estimated 340,000 fatalities from the disease [2]. Estimates from India indicate that there are approximately 70,000 new cases of colon and RC every year in India. Population-based registries indicate that RC is more prevalent than colon cancer in India [2, 3].

From a treatment standpoint, clinical staging by a multidisciplinary team determines the selection of primary treatment and its intent, whether palliative or curative [4]. For patients eligible for resection, there are multiple surgical options based

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Published online: 16 May 2025

on the location and severity of the disease. These surgical options include transanal local excision, transabdominal resections with principles of TME (e.g. low anterior and abdominoperineal resection, etc.), as well as the novel transanal TME [4]. To the best of our knowledge, Indian surgeons have not adopted transanal TME in their practice. In addition, since transanal local excision is limited to very early-stage RC with strict criteria, a vast majority of Indian patients are ineligible for this approach. Thus, Transabdominal TME remains the cornerstone of rectal resections in India as well as a sizable majority of surgeons outside of India [5, 6].

Open and laparoscopic surgical approaches have long been employed for Transabdominal rectal resections using principles of TME [6]. Laparoscopy, a major technological breakthrough, brought in the age of minimally invasive procedures and provided a viable substitute for open procedures [7]. Nonetheless, studies have shown that during laparoscopic surgery, surgeons encounter difficulties like a narrower lesser pelvis, intricate anatomy, and constrained surgical field of view [8]. The challenges with laparoscopic rectal resection can potentially be addressed by robotic-assisted rectal resections. Pigazzi and colleagues originally published the concept of robotic TME for RC in 2006, after it first gained traction in 2001 [9]. robotic surgery outperformed open surgery in terms of blood loss, surgical site infection, duration of hospital stay, lack of conversion, negative resection margins, and quantity of lymph nodes retrieved, as determined by a meta-analysis [6, 7]**.** Additionally, a meta-analysis showed that in terms of conversion rates, blood loss, reoperation rates, and negative CRM, robotic surgery outperformed laparoscopic surgery [6, 7, 10, 11]. However, some studies have not found a meaningful difference in conversion rates and rates of margin positivity between robotic and laparoscopic resections, including the ROLARR trial [6, 12–14].

For several decades, laparoscopic and open transabdominal rectal procedures have been performed by RC surgeons in India utilizing TME concepts. robotic rectal resections have also seen significant adoption in the past 15 years. However, there are no Indian multicentric collaborative studies, or commercial databases, or National Cancer Registries, that have evaluated the clinical outcomes of these various surgical approaches. Therefore, the current study was conducted to assess the short-term clinical outcomes of colectomy for stage I to III RC utilizing open, laparoscopic, and robotic-assisted procedures in a real-world scenario.

Materials and methods

This retrospective, multi-center, real-world evidence study was conducted at 11 Indian centers. A retrospective chart review was undertaken for consecutive patients who had undergone rectal resection for RC either by an open, laparoscopic, or robotic-assisted approach using the da Vinci Surgical System, between April 2012 and August 2023. As the treatments were administered as part of routine clinical practice, the choice of surgical approach was primarily influenced by factors such as technology availability, surgeon expertise, patient demographics, case complexity, and patient affordability. At each participating center, one or two designated surgeons typically performed the different surgical procedures. Only patients with complete data related to baseline characteristics and preoperative and postoperative outcomes were eligible for the data collection. Patients with incomplete histopathological outcomes and follow-up at 90 days post-surgery were allowed only if they had complete data for perioperative outcomes. All surgical procedures were performed with the principles of TME or partial mesorectal excision (for tumors located higher in the rectum). Lymph nodes at the origin of the inferior mesenteric artery were dissected and the right and left hypogastric nerves were preserved. Location of disease in the rectum was defined as low, middle, and upper rectum; where the distance of ≤ 5 cm from the anal verge was low rectum, >5–10 cms was middle, and beyond 10 cms was upper rectum. All participating surgeons were past their learning curve for open and laparoscopic approaches. No restriction related to the learning curve was placed for robotic-assisted surgery. All participating surgeons had surpassed their learning curve for the robotic procedure; however, the data also includes their initial cases performed during the learning phase.

Specific eligibility criteria for patients included that the patients had to be over the age of 18 and should have undergone rectal resection to treat non-metastatic RC (Stage I, II, and III as per AJCC TNM Stage 8th edition), regardless of gender. Preoperative chemotherapy and/or radiation was allowed, as per treatment protocol at the participating institute. Patients who had undergone rectal resection for metastatic RC or with the intention of palliative care were not eligible. Additionally, patients who had undergone radical rectal resection as an emergency procedure for primary treatment of RC were excluded. The study was conducted following the ethical principles specified in the most recent edition of the Helsinki Declaration and the applicable guidelines for good clinical practice. Each participating center obtained institutional ethics committee or institutional review board permission, and the study was registered at the Clinical Trials Registry of India portal under registration number CTRI/2023/03/050448.

Data collection and analysis

Deidentified data for the preoperative variables such as demographics, patient characteristics, and the patient's preoperative medical history was extracted from their

medical records. The intra-operative data including operative time, procedure type (e.g., low-anterior resection, abdominoperineal resection, intersphincteric resection), the technique of rectal resection (open, laparoscopic, or robotic-assisted), anastomosis technique, estimated blood loss, transfusion, conversion, and complications related to the procedure was also collected. The complications were categorized using the Clavien-Dindo classification. Additionally, information on the length of hospital stay, short-term follow-up, and postsurgical complications was collected. Data on the pathological stage, margin status, extent of resection, and lymph nodes, was collected from the histopathological records. All the data was recorded on a predesigned proforma.

Frequency and percentages were used to summarize categorical variables. The statistical association between the group variable and the categorical variables was ascertained using the chi-square test (i.e., three surgical techniques). The normality of the quantitative data was checked, and the mean (SD) was used to summarize variables that followed a normal distribution. To compare mean values between the three groups, a one-way Analysis of variance (ANOVA) was employed, followed by post hoc ANOVA for pairwise comparison, if necessary. Non-normal variables were summarized as median (range, interquartile range), and the median across the three groups was compared using the Kruskal–Wallis non-parametric test, which was followed, if necessary, by the Wilcoxon rank sum test for pairwise comparison. In cases where an overall statistically significant difference was found among the three groups, pairwise comparisons were conducted using Bonferroni correction for the p-values. Two-tailed tests were employed in all statistical analyses. For each outcome variable, bivariate logistic regression was initially performed to compute the unadjusted relative risk ratio (RRR) along with the 95% confidence interval (CI) and p-value. Subsequently, multivariable logistic regression analysis was conducted to calculate the adjusted RRR (95% CI) and p-value, adjusting for age, BMI, hypertension, diabetes, and neoadjuvant radiation therapy. In this study, a p-value of less than 0.05 was considered statistically significant. Data analysis was done using Stata statistical software, Stata IC 13.1 (StataCorp LLC, Texas USA).

Results

Data from 829 patients was analyzed. Out of the 829 patients, 314 (37.88%) underwent robotic-assisted rectal resections by the da Vinci surgical system, 206 (24.85%) were operated by laparoscopy, and 309 (37.27%) patients underwent open surgery. Although all the centers utilized open, laparoscopic, and robotic-assisted approaches, the distribution varied across centers depending on factors such as technology availability, surgeon expertise, patient demographics, and case complexity.

Baseline and preoperative variables

The average age and body mass index (BMI) of the study population were 54.57 years, and 24.21 kg/m^2 respectively. The RAS group had significantly older patients compared to the OG. Since the choice of surgical approach was part of routine clinical practice, it was not considered a concern for anesthesiology, despite the longer operative time typically associated with the robotic approach. Similarly, the RAS group had significantly higher BMI compared to both OG ($p=0.004$) as well as LG ($p=0.007$) (mean- 24.98 in RAS vs. 23.69 in LG vs. 23.80 in OG). A significantly higher number of patients received any type of neoadjuvant treatment in the OG group (83.82%) compared to both RAS (66.56%) and LG groups (73.30%); OG and RAS, $p<0.001$; OG and LG, $p=0.004$. Approximately 30% of patients in the OG received only neoadjuvant radiation, which was significantly higher than both RAS (3.18%) and LG groups (13.11%). A significantly higher number received a combination of neoadjuvant chemotherapy and radiation in the RAS group (62.42%) compared to LG (58.74%) and OG (52.10) groups. The descriptive characteristics of other preoperative variables are presented in Table 1.

Perioperative outcomes

Table 2 provides the perioperative results of the study population. Among all procedure types, low-anterior resection accounted for 41.25% of the overall population. Abdominoperineal resection was the second most common at 22.68%. The RAS group had a significantly lower mean length of hospital stay than LG (7.84 ± 4.62 vs 10.33 ± 6.91, $p<0.001$) and OG (7.84 ± 4.62 vs 14.05 ± 7.77, $p<0.001$). The study population's mean operating room time was 290.28 ± 115.76 min. The RAS group had significantly higher mean operating room time (326.14 ± 106.37 min) than the OG (255.83 ± 126.51 min, $p<0.001$) and LG (287.30 ± 95.06 min, $p<0.001$) groups. In addition, LG had a higher mean operative room time compared to OG ($p=0.005$). The RAS group had a significantly lower estimated blood loss than OG.

In terms of conversion to an open procedure, fewer patients needed conversion in the RAS group (1.59%) compared to LG (4.85%) and this difference was of statistical significance ($p=0.030$). The RAS group experienced considerably fewer postoperative complications than OG (13.69 vs. 36.57%; $p<0.001$) and had numerical superiority over LG, narrowly missing statistical significance (13.69 vs. 19.90%; $p=0.06$). Even the LG had significantly lower

Table 1 Descriptive characteristics of pre-operative variables

Variable	All (N = 829)	Robotic (N = 314)	Laparoscopic (N = 206)	Open (N = 309)	*p*-value		
					RAS vs. OG	RAS vs. LG	LG vs. OG
Age, mean ± SD, year	54.57 ± 14.52	56.20 ± 14.99	56.31 ± 14.51	51.74 ± 13.61	< 0.001*	1.000	0.001*
Sex, n (%)							
Male	523 (63.09)	201 (64.01)	128 (62.14)	194 (62.78)	0.750	0.664	0.882
Female	306 (36.91)	113 (35.99)	78 (37.86)	115 (37.22)			
Weight, mean ± SD, kg	63.77 ± 13.06	66.29 ± 13.64	62.48 ± 11.94	62.15 ± 12.83	< 0.001*	0.005*	1.000
BMI, mean ± SD, kg/m^2	24.21 ± 4.37	24.98 ± 4.63	23.69 ± 4.06	23.80 ± 4.22	0.004*	0.007*	1.000
Co-morbidities, n (%)							
Hypertension	259 (31.24)	115 (36.62)	73 (35.44)	71 (22.98)	< 0.001*	0.783	0.002*
Diabetes	223 (26.90)	98 (31.21)	53 (25.73)	72 (23.30)	0.027*	0.178	0.529
Chronic kidney disease	10 (1.21)	5 (1.59)	0 (0.00)	5 (1.64)	0.980	0.162	0.163
Chronic liver disease	7 (0.84)	1 (0.32)	2 (0.97)	4 (1.29)	0.214	0.566	1.000
Anticoagulation medication, n (%)							
Yes	33 (3.98)	16 (5.10)	13 (6.31)	4 (1.29)	0.011*	0.555	0.004*
No	796 (96.02)	298 (94.90)	193 (93.69)	305 (98.71)			
Chronic steroid/immunosuppressant use, n (%)							
Yes	5 (0.60)	1 (0.32)	4 (1.94)	0 (0.00)	1.000	0.083	0.025*
No	824 (99.40)	313 (99.68)	202 (98.06)	309 (100.00)			
Previous abdominal surgery, n (%)							
Yes	53 (6.39)	17 (5.41)	9 (4.37)	27 (8.74)	0.105	0.593	0.057
No	776 (93.61)	297 (94.59)	197 (95.63)	282 (91.26)			
Neoadjuvant treatment, n (%)							
Yes	619 (74.67)	209 (66.56)	151 (73.30)	259 (83.82)	< 0.001*	0.103	0.004*
No	210 (25.33)	105 (33.44)	55 (26.70)	50 (16.18)			
Neoadjuvant radiation alone, n (%)	130 (15.68)	10 (3.18)	27 (13.11)	93 (30.10)	< 0.001*	< 0.001*	< 0.001*
Neoadjuvant chemotherapy alone, n (%)	11 (1.33)	3 (0.96)	3 (1.46)	5 (1.62)	0.502	0.685	1.000
Neoadjuvant chemotherapy + radiation, n (%)	478 (57.66)	196 (62.42)	121 (58.74)	161 (52.10)	0.009*	0.400	0.138

*Statistically significant

SD standard deviation, *BMI* body-mass index, *RAS* robotic-assisted group, *OG* open-surgery group, *LG* laparoscopic surgery group

complication rates than OG. In terms of Clavien-Dindo grading of complications, the RAS group had considerably fewer grade III or higher complications (4.78%) than the LG (11.65%; $p = 0.003$) and OG (27.51%; $p < 0.001$) groups.

Histopathological findings

Table 3 presents the histopathological results for the study cohort. RC Stages II and III were the most common in the study population, 65.02% of the overall population. The stages were evenly distributed across groups; 62.74% in RAS, 68.93% in LG, and 64.73% in OG. The lower one-third rectum was the most common location of RC among the three groups, 50.96% in RAS, 50.97% in LG, and 61.17% in OG. Regarding the positive CRM, the RAS group had the lowest positivity rate (2.87%), which was notably lower than that of the OG (26.54%, $p < 0.001$) and LG (6.80%, $p = 0.033$) groups. There was no difference in the distal resection margins across the groups, with almost 99% of the individuals in each group having negative margins. Information related to the quality of the mesorectum was available for only 677 out of the 829 analyzed patients. The mesorectum's resection was assessed as complete to nearly complete for 97.05% of the patients. The RAS group had a significantly higher percentage of patients who were graded "complete" compared to LG, 89.63 vs 80.14% ($p = 0.007$) whereas there was no difference between RAS and OG groups, 89.63 vs 90.80% ($p = 0.649$). When the rates of "complete" and "near complete" mesorectums were combined, there was no statistical difference among the three groups (RAS- 97.04%, LG- 97.95%, OG- 96.55%). The mean lymph node yield for the study population was 14.42 ± 8.66; the three groups did not differ statistically significantly from one another.

Table 2 Peri-operative outcomes of the study population

Peri-operative outcomes	All (N = 829)	Robotic (N = 314)	Laparoscopic (N = 206)	Open (N = 309)	*p*-value		
					RAS vs. OG	RAS vs. LG	LG vs. OG
Operating room time, mean ± SD, min	290.28 ± 115.76	326.14 ± 106.37	287.30 ± 95.06	255.83 ± 126.51	< 0.001*	< 0.001*	0.005*
Estimated blood loss, mean ± SD, ml	213.24 ± 225.84	162.80 ± 150.77	185.39 ± 215.97	283.06 ± 273.26	< 0.001*	0.285	< 0.001*
Length of hospital stay, mean ± SD, days	10.77 ± 7.05	7.84 ± 4.62	10.33 ± 6.91	14.05 ± 7.77	< 0.001*	< 0.001*	< 0.001*
Intra-Operative blood transfusion, n (%)							
Yes	45 (5.43)	18 (5.73)	9 (4.37)	18 (5.83)	0.960	0.493	0.468
No	784 (94.57)	296 (94.27)	197 (95.63)	291 (94.17)			
Type of operation, n (%)							
Abdominoperineal resection	188 (22.68)	67 (21.34)	54 (26.21)	67 (21.68)	0.916	0.198	0.235
Extra levator abdominoperineal resection	64 (7.72)	12 (3.82)	15 (7.28)	37 (11.97)	< 0.001*	0.082	0.083
Intersphinteric resection	40 (4.83)	16 (5.10)	12 (5.83)	12 (3.88)	0.465	0.718	0.306
Low-anterior resection	342 (41.25)	144 (45.86)	85 (41.26)	113 (36.57)	0.019*	0.302	0.284
Ultra Low anterior resection	114 (13.75)	44 (14.01)	21 (10.19)	49 (15.86)	0.518	0.198	0.066
Transanal local excision	1 (0.12)	0 (0.00)	0 (0.00)	1 (0.32)	0.313	–	0.414
Others	80 (9.65)	31 (9.87)	19 (9.22)	30 (9.71)	0.945	0.806	0.854
Anastomosis created, n (%)							
Yes	523 (63.09)	206 (65.61)	130 (63.11)	187 (60.53)	0.188	0.560	0.554
No	306 (36.91)	108 (34.39)	76 (36.89)	122 (39.48)			
Technique of anastomosis, n (%)							
Intracorporeal	320 (61.19)	144 (69.90)	97 (74.62)	79 (42.25)	< 0.001*	0.350	< 0.001*
Extracorporeal	51 (9.75)	15 (7.28)	25 (19.23)	11 (5.88)	0.577	0.001*	< 0.001*
Information not available on technique of anastomosis	152 (29.06)	47 (22.82)	8 (6.15)	97 (51.87)	< 0.001*	< 0.001*	< 0.001*
Staple line leak test done, n (%)							
Yes	412 (78.78)	124 (60.19)	112 (86.15)	176 (94.12)	< 0.001*	< 0.001*	0.016*
No	111 (21.22)	82 (39.81)	18 (13.85)	11 (5.88)			
Was leak detected, n (%)							
Yes	3 (0.73)	1 (0.81)	2 (1.79)	0 (0.00)	0.233	0.503	0.075
No	409 (99.27)	123 (99.19)	110 (98.21)	176 (100.0)			
Fluorescence imaging used to assess perfusion, n (%))							
Yes	45 (5.43)	33 (10.51)	7 (3.40)	5 (1.62)	< 0.001*	0.003*	0.190
No	784 (94.57)	281 (89.49)	199 (96.60)	304 (98.38)			
Intra-Operative complications, n (%)							
Yes	17 (2.05)	3 (0.96)	5 (2.43)	9 (2.91)	0.087	0.275	0.740
No	812 (97.95)	311 (99.04)	201 (97.57)	300 (97.09)			
Conversions to open, n (%)	15 (1.81)	5 (1.59)	10 (4.85)	Not Applicable	Not Applicable	0.030*	Not Applicable

Table 2 (continued)

Peri-operative outcomes	All (N = 829)	Robotic (N = 314)	Laparoscopic (N = 206)	Open (N = 309)	*p*-value		
					RAS vs. OG	RAS vs. LG	LG vs. OG
Post-Operative complications, n (%)							
Yes	197 (23.76)	43 (13.69)	41 (19.90)	113 (36.57)	< 0.001*	0.060	< 0.001*
No	632 (76.24)	271 (86.31)	165 (80.10)	196 (63.43)			
Clinically significant complications/ (Clavien-Dindo Grade III or more, n (%)	124 (14.96)	15 (4.78)	24 (11.65)	85 (27.51)	< 0.001*	0.0036*	< 0.001*

*Statistically significant

SD standard deviation, *RAS* robotic-assisted group, *OG* open-surgery group, *LG* laparoscopic surgery group

Table 3 Histopathological findings of the study population

Histopathological findings	All (N = 829)	Robotic (N = 314)	Laparoscopic (N = 206)	Open (N = 309)	*p*-value		
					RAS vs. OG	RAS vs. LG	LG vs. OG
Pathological stage							
0	37 (4.46)	21 (6.69)	8 (3.88)	8 (2.59)	0.015*	0.173	0.407
I	253 (30.52)	96 (30.57)	56 (27.18)	101 (32.69)	0.571	0.406	0.184
II	251 (30.28)	90 (28.66)	74 (35.92)	87 (28.16)	0.888	0.081	0.062
III	288 (34.74)	107 (34.08)	68 (33.01)	113 (36.57)	0.515	0.801	0.407
Location of tumor							
Lower rectum	454 (54.76)	160 (50.96)	105 (50.97)	189 (61.17)	0.010*	0.997	0.022*
Middle rectum	180 (21.71)	57 (18.15)	46 (22.33)	77 (24.92)	0.040*	0.242	0.500
Upper rectum	156 (18.82)	81 (25.80)	40 (19.42)	35 (11.33)	0.000*	0.092	0.011*
Not available	39 (4.70)	16 (5.10)	15 (7.28)	8 (2.59)	0.104	0.303	0.012*
Status of circumferential (Radial) margin, n (%)							
Positive	105 (12.67)	9 (2.87)	14 (6.80)	82 (26.54)	< 0.001*	0.033*	< 0.001*
Negative	724 (87.33)	305 (97.13)	192 (93.20)	227 (73.46)			
Status of distal margin, n (%)							
Positive	5 (0.60)	2 (0.64)	1 (0.49)	2 (0.65)	0.987	0.823	0.813
Negative	824 (99.40)	312 (99.36)	205 (99.51)	307 (99.35)			
Quality of mesorectum, n (%)							
Complete	596 (88.04)	242 (89.63)	117 (80.14)	237 (90.80)	0.649	0.007*	0.002*
Near complete	61 (9.01)	20 (7.41)	26 (17.81)	15 (5.75)	0.441	< 0.001*	< 0.001*
Incomplete	20 (2.95)	8 (2.96)	3 (2.05)	9 (3.45)	0.751	0.582	0.425
Lymph nodes harvested, n (%)							
Yes	819 (98.79)	310 (98.73)	203 (98.54)	306 (99.03)	0.720	0.860	0.687
No	10 (1.21)	4 (1.27)	3 (1.46)	3 (0.97)			
Total number of lymph nodes harvested, mean ± SD	14.42 ± 8.66	14.20 ± 7.87	13.72 ± 8.46	15.11 ± 9.47	0.611	0.263	0.119

*Statistically significant

SD standard deviation, *RAS* robotic-assisted group, *OG* open-surgery group, *LG* laparoscopic surgery group

Short-term follow-up (at 90 days post-surgery)

The 90-day outcomes for the study participants are shown in Table 4. This data was available for 727 out of the 829 analyzed patients. At day 90 following surgery, most individuals (> 91%) reported no complications; the RAS group had a higher percentage of patients in this category (93.02%) than the OG (88.97%) and LG (92.74%). While

mortality was reported in 2 (1.12%) and 5 (1.72%) patients in the LG and OG, respectively, there was none in the RAS group. There was no discernible difference in the three groups' rates of re-admission or re-operation. Adjuvant treatment was administered in the RAS group significantly earlier (median, 24.5 days, IQR 18–37) compared to the LG (median, 31 days, IQR 23–41) and OG (median, 32.5 days, IQR 27–42), RAS and OG, $p < 0.001$; RAS and LG, $p = 0.005$.

Logistic regression to account for confounders

The logistic regression analysis to account for potential confounders is shown in Tables 5 and 6. For each of the outcome variables, first, bivariate logistic regression was used to compute unadjusted relative risk ratio (95% CI) and p-value; followed by adjusted relative risk ratio (95% CI) and p-value, adjusting for age, BMI, hypertension, diabetes, and neo-adjuvant radiation therapy using multivariable logistic regression analysis. The adjusted relative risk ratio revealed a significant difference in postoperative complications before discharge between the OG and LG groups ($p = 0.000$), as well as between the OG and RAS groups ($p = 0.000$). Similarly, for circumferential margin status, significant differences were observed among the three groups: OG vs. LG ($p = 0.000$), OG vs. RAS ($p = 0.000$), and LG vs. RAS ($p = 0.023$).

Discussion

This study aimed to shed light on the histological, perioperative, and postoperative results of open, laparoscopic, and robotically-assisted rectal resections for RC in the Indian population. This is India's first multicentric, collaborative, three-way comparator study for RC involving a sizable patient population. In India, clinical evidence for surgical outcomes of rectal resections has thus far been restricted to a few single-centric, single-arm, or two-arm studies. A single-centric prospective randomized study by Somashekhar SP et al. reported few superior outcomes in robotic-assisted arms compared to open. The improved outcomes included reduced hospital stay, lower estimated blood loss, shorter distal margin, and 100% complete TME [15]. A propensity case-matched analysis for robotic and laparoscopic TME at Tata Memorial Hospital in Mumbai revealed comparable conversion rates, blood losses, and durations of hospital stays. However, the study found that the robotic TME arm had noticeably fewer adverse events and anastomotic leak rates [16].

When we compare the baseline characteristics of our patients to other studies, we note that the higher BMI and higher weight reported in our RAS group, compared to LG and OG, is in line with several studies from India and other countries [6, 7, 15]. For the location of RC, the lower rectum was the most common location in our study population; 54.76% of the overall population with a significantly higher proportion in the OG group compared to the RAS and LG

Table 4 Short-term follow-up data of the study population (at 90 days post-surgery)

Follow-up variables	All (N = 727)	Robotic (N = 258)	Laparoscopic (N = 179)	Open (N = 290)	*p*-value		
					RAS vs. OG	RAS vs. LG	LG vs. OG
Complications at day 90 post-surgery, n (%)							
Yes	63 (8.67)	18 (6.98)	13 (7.26)	32 (11.03)	0.100	0.909	0.178
No	664 (91.33)	240 (93.02)	166 (92.74)	258 (88.97)			
Re-admission, n (%)	44 (6.05)	18 (6.98)	10 (5.59)	16 (5.52)	0.480	0.560	0.975
Re-operation, n (%)	14 (1.93)	6 (2.33)	5 (2.79)	3 (1.03)	0.318	0.759	0.269
Mortality at 90 days, n (%)	7 (0.96)	0 (0.00)	2 (1.12)	5 (1.72)	0.034*	0.167	0.713
Post-Operative adjuvant therapy, n (%)							
Yes	477 (65.61)	149 (57.75)	121 (67.60)	207 (71.38)	–	–	–
No	250 (34.39)	109 (42.25)	58 (32.40)	83 (28.62)			
Type of adjuvant therapy, n (%)							
Radiation	1 (0.21)	0 (0.00)	0 (0.00)	1 (0.48)	–	–	–
Chemotherapy	458 (96.02)	142 (95.30)	114 (94.21)	202 (97.58)			
Chemotherapy + radiation	17 (3.56)	6 (4.03)	7 (5.79)	4 (1.93)			
Not available	1 (0.21)	1 (0.67)	0 (0.00)	0 (0.00)			
Time to start of adjuvant therapy, median (IQR), days	31 (22 – 41)	24.5 (18 – 37)	31 (23 – 41)	32.5 (27 – 42)	< 0.001*	0.005*	0.098

*Statistically significant

SD standard deviation, *RAS* robotic-assisted group, *OG* open-surgery group, *LG* laparoscopic surgery group

Table 5 Logistic regression for pre-operative variables

Variables	OG	LG	RAS	F value/ Chi-square	*p*-value
Age, mean ± SD	56.31 ± 14.51	51.73 ± 13.61	56.20 ± 14.99	9.54	0.0001*
Weight, mean ± SD	62.48 ± 11.93	62.15 ± 12.83	66.29 ± 13.64	8.71	0.0002*
BMI, mean ± SD	23.68 ± 4.06	23.80 ± 4.21	24.98 ± 4.62	6.84	0.0011*
Hypertension, n (%)					
No	133 (64.56)	238 (77.02)	199 (68.76)	15.7470	0.000*
Yes	73 (35.44)	71 (22.98)	259 (31.24)		
Diabetes, n (%)					
No	153 (74.27)	237 (76.70)	216 (68.79)	5.1459	0.076
Yes	53 (25.73)	72 (23.30)	98 (31.21)		
Radiation, n (%)					
No	179 (86.89)	216 (69.90)	304 (96.82)	86.2829	0.000*
Yes	27 (13.11)	93 (30.10)	10 (3.18)		
Chemotherapy, n (%)					
No	203 (98.54)	304 (98.38)	311 (99.04)	0.5575	0.757
Yes	3 (1.46)	5 (1.62)	3 (0.96)		
CTRT, n (%)					
No	85 (41.26)	148 (47.90)	118 (37.58)	6.9204	0.031*
Yes	121 (58.74)	161 (52.10)	196 (62.42)		

*Statistically Significant

groups. Upper and middle RC were reported in 18.82 and 21.71% of patients in the overall population. A large colorectal cancer demographic study from AIIMS-Delhi, India reported cancers in the lower rectum in approximately 58% of patients, whereas middle rectal disease was present in approximately 31% of patients presenting with RC [17]. When compared to relevant international studies which did not limit themselves to the location of disease in the rectum, we find that The ALaCaRT randomized trial comparing open to laparoscopic rectal resections reported RC in the lower rectum in 35% in each arm and approximately 44% in the middle rectum in either arm [18]. The ACOSOG Z6051R trial comparing laparoscopic to open resections noted that the lower rectum was the most common location (48–51% cases) followed by the middle rectum (35–40%) [19]. In terms of the reported TNM stage of our study population, Stages II and III accounted for 65.02% of cases. The AIIMS-Delhi study also observed that Stages II and III are the most common stages of presentation in Indian RC patients [17]. Most of our study population had undergone neoadjuvant chemoradiation (57.66%). Many other international studies like ROLARR, REAL, etc. have allowed neoadjuvant therapy. In the ROLARR trial, approximately 47% study population had taken prior chemoradiation whereas in the REAL trial, 43–44% of patients had this treatment [20].

We found that the RAS group had substantially longer operating room times than that of the LG (326.14 ± 106.37 vs. 287.30 ± 95.06; $p < 0.001$) and OG (326.14 ± 106.37 vs. 255.83 ± 126.51; $p < 0.001$) groups, respectively. The results were corroborated by a previous study carried out in India, which revealed that the RAS group's mean operating time was much greater than the OG (310 vs. 246 min; $p < 0.05$) [15]. Likewise, a meta-analysis revealed that the RAS group had a longer operating room time (sum of the docking time and operation time) than the LG group (mean difference = − 36.29; 95% CI − 47.34 to − 25.25; $p < 0.001$) and OS group ((mean difference = − 66.90, 95% CI − 93.35 to − 40.46; $p < 0.001$) [6]. According to a study, the longer operating times associated with robotic procedures may be related to the time required to set up, dock, and undock the robotic system before beginning surgery [21–24]. Additionally, it has been shown that robot docking times were longer during the initial learning period and significantly decreased as the operating experience increased [15]. The findings of this study, which indicated that the RAS group had a much lower mean estimated blood loss than the OG (165.14–189.14 vs. 406.04–527.04 ml, $p < 0.001$), are supported by a previous study [7, 15]. A meta-analysis showed that the RAS group had considerably less blood loss than the OG (mean difference = 156.63, 95% CI 62.36 to 250.91; $p = 0.001$) and LG (mean difference = 20.47; 95% CI 7.57 to 33.36; $p = 0.002$) groups, but there was no statistically significant difference between the RAS and LG groups (120 vs. 150 ml; $p = 0.285$) of our study [6]. According to a study, the robot's improved vascular management over the open approach may be due to its enhanced 3D imaging, instrumental agility, and precise resection, which all contribute to decreased blood loss [6, 25–29]. The RAS group in this study had a much shorter hospital stay (from admission to discharge) than the LG (6.5 vs. 9 days; $p = 0.000$) and OG

Table 6 Logistic regression for intra-operative complications, post-operative complications, and circumferential margin

	OG vs LG	OG vs RAS	LG vs RAS
Intra-operative complications			
Unadjusted RRR	1.206	0.387	0.321
95% CI	0.398, 3.651	0.091, 1.640	0.086, 1.199
p-Value	0.740	0.198	0.091
Adjusted RRR[†]	0.625	0.289	0.463
95% CI	0.192, 2.031	0.052, 1.605	0.085, 2.498
p-Value	0.435	0.156	0.371
Post-operative complications before discharge			
Unadjusted RRR	0.431	0.275	0.638
95% CI	0.285, 0.651	0.185, 0.409	0.399, 1.021
p-Value	0.000*	0.000*	0.061
Adjusted RRR	0.361	0.259	0.716
95% CI	0.225, 0.580	0.165, 0.407	0.420, 1.222
p-Value	0.000*	0.000*	0.222
Circumferential margin			
Unadjusted RRR	0.201	0.081	0.404
95% CI	0.110, 0.367	0.040, 0.166	0.171, 0.953
p-Value	0.000*	0.000*	0.038*
Adjusted RRR	0.266	0.077	0.290
95% CI	0.139, 0.508	0.030, 0.199	0.100, 0.844
p-Value	0.000*	0.000*	0.023*
Post-operative complications after discharge up to 90 days			
Unadjusted RRR	0.631	0.604	0.957
95% CI	0.321, 1.238	0.330, 1.105	0.456, 2.007
p-Value	0.181	0.102	0.909
Adjusted RRR	0.540	0.752	1.392
95% CI	0.242, 1.203	0.370, 1.529	0.585, 3.309
p-Value	0.132	0.432	0.454

[†]Adjusted for age

*Statistically significant

BMI hypertension, diabetes, and radiation

RRR relative risk ratio

(6.5 vs. 12 days; $p=0.000$). The present study's findings are consistent with a previous study that revealed considerably shorter hospital stays (7.52–8.52 days vs. 11.24–13.24 days) for the RAS group compared to the OG [7, 15]. Furthermore, a meta-analysis revealed that the RAS group's hospital stay was shorter than that of the OG ($p=0.03$) and LG ($p=0.99$) groups [6].

Patients in the RAS group in this study had numerically fewer intra-operative complications than those in the LG and OG, and there was no significant difference. Furthermore, a meta-analysis revealed no noticeable differences in intraoperative complications between robotic and open-surgery arms (OR = 1.21; 95% CI 0.42 to 3.48; $p=0.73$) or between robotic and laparoscopic arms (OR = 1.48; 95% CI 0.95 to 2.32; $p=0.26$) [6]. Additionally, the RAS group's patients experienced fewer postoperative problems than those in the OG (13.69 vs. 36.57%; $p<0.001$) and LG (13.69 vs. 19.90%; $p=0.060$) groups. A subgroup analysis of two trials found a significant difference in postoperative adverse events between the RAS and OG (OR = 3.21; 95% CI 1.77 to 5.82; $p<0.001$) [15, 30]. Moreover, a meta-analysis found no significant differences in postoperative adverse events between the RAS and LG (OR = 1.11; 95% CI 0.86 to 1.43; $p=0.44$) [6]. Numerous other studies have also not found any substantial difference in the frequency of postoperative complications between the robotic and laparoscopic surgery groups [21, 31, 32]. The low prevalence of postoperative complications might be attributed to the robotic method's minimally invasive approach [23, 33]. Higher conversion rates have been linked to higher mortality and less favorable oncological outcomes [7]. In this study, we found that the RAS group had a statistically lower conversion rate than the LG. We hypothesize that with experience and expertise in robotic surgery, the rate of conversion sees a decline. This hypothesis may be supported by the analysis of RoLARR and REAL trials [20, 34]. While the RoLARR trial did not find any difference between conversion rates in RAS vs LG, the REAL trial did show higher conversion rates in LG. This could be attributed to the fact that in the ROLARR trial, surgeons with varying experience in robotic procedures performed RAS while in the latter, only very experienced robotic surgeons performed the procedure. Hence, experience in RAS likely contributes to lesser conversion rates. The authors of the REAL trial also observe that apart from expertise; improved visibility, operative access to the pelvic region, and surgical dexterity are most likely associated with low conversion rates in robotic procedures [34] A meta-analysis revealed that 7.38% of laparoscopic procedures resulted in open surgery, which was more than the 3.01% of robotic procedures (OR = 3.13; 95% CI 1.87 to 5.21; $p<0.001$) [6].

Additionally, this study revealed, robotic surgery had a higher rate of negative CRM than open and laparoscopic techniques. The lower rate of CRM positivity observed in the RAS group is a noteworthy finding. However, the absence of key preoperative data—such as T-stage, tumor distance from the anal verge, and whether the mesorectal fascia was involved before treatment—makes it difficult to draw firm conclusions. Without this information, it is challenging to determine whether the improved CRM outcomes in the RAS group truly reflect the oncological superiority of the technique, or are simply due to differences in case selection or tumor characteristics. Our circumferential margin results need to be read with caution. This is a noteworthy limitation of our study owing to its retrospective design. In this study, the total number of lymph nodes harvested from each of the three surgical techniques was comparable. An Indian study supports these findings by demonstrating that although the

robotic approach recovered somewhat more lymph nodes (16.88 vs. 15.20) than the open approach, the difference was not statistically noteworthy [15]. A meta-analysis, however, revealed that although the RAS and LG did not vary significantly (mean difference = 0.38; 95% CI − 0.39 to 1.16; $p = < 0.33$), the RAS did retrieve significantly more lymph nodes than the OG (mean difference = 0.86; 95% CI 0.14 to 1.59; $p = 0.02$) [6]. In this study, more patients in the RAS group had a grading of complete mesorectal excision than in the LG, similarly OG arm was better than the LG arm. There was no difference in the rates of "complete" and "near complete" mesorectums when these were added (RAS- 97.04%, LG- 97.95%, OG- 96.55%). Literature has looked at both these rates separately like the REAL trial and trial by Somashekhar SP whereas others have looked at the combined rates [6, 15, 20, 34]. The REAL trial reported a complete grade in 95.4% of patients in the RAS arm compared to 91.8% in the LG arm. A previous study found that all patients in the RAS had complete mesorectal excision, whereas two patients in the OG had partial mesorectal excision [15]. Research indicates that the mesorectal grade, which is linked to oncological outcomes, is a crucial determinant of whether rectal excision is appropriate [35], more recent data suggests that macroscopic completeness of total mesorectal excision may not be as valuable a prognostic indicator as in the past especially with increasing use of neoadjuvant therapy [36].

At 90-day post-surgery follow-up, the RAS group in this study had fewer complications and no deaths compared to the LG and OG. Also, in comparison to the LG and OG, the RAS group required a significantly shorter time to begin adjuvant treatment. In a previous study, an early (within about 3 weeks) initiation of adjuvant chemotherapy was linked to improved oncological outcomes, particularly disease-free survival [37]. However, owing to the controversial role of adjuvant therapy in rectal cancer and the increasing use of total neoadjuvant therapy, the clinical impact of this finding is uncertain. This group also intends to report long-term oncological outcomes from this study in a separate publication.

Conclusion

In conclusion, this is the largest multi-centric research on surgical and histopathological outcomes for rectal resection in Indian settings, using a three-way comparative analysis. The study demonstrates that Robotic-assisted rectal resection appears to be a good substitute for conventional surgical methods because of its possible advantages in terms of perioperative, histological, and postoperative outcomes. The study results have the potential to inform the real-world clinical practice of RC surgeons in India.

Strengths and limitations

This is the largest and first collaborative study ever conducted in India on the surgical and clinical outcomes of RC. The study had several strengths, including a large sample size in each surgical group, high-quality data, and equitable participation from public and private institutions. Subsequent papers on long-term oncological outcomes will be published from the present database. Nevertheless, our study had several limitations as well. This is a retrospective, unmatched study and therefore, is subject to selection bias. The involvement of different surgeons and institutions might have influenced the results due to heterogeneity in the surgical techniques, and inconsistencies in the dosage or regimen of neoadjuvant and adjuvant therapy. While RAS and laparoscopic surgeries were likely to have been performed by senior experienced surgeons, it is possible that a good proportion of open surgeries were performed by less experienced surgeons especially in teaching institutions. Data related to significant parameters like T stage, distance of disease from anal verge and pre-operative involvement of mesorectal fascia were not available for wider population. All these had a negative bearing on interpretation of histopathological outcomes like positivity of circumferential margins and completeness of resection.

Acknowledgements The authors express their gratitude to Catalyst Clinical Services Pvt. Ltd. for helping with paper writing, and publication submission.

Author contributions Every author took part in the collection and analysis of data as well as the review of the draft versions of the manuscript. All author's comments were taken into consideration while drafting the final version of the manuscript. The corresponding author assumes full responsibility for the accuracy and reliability of the data analysis and guarantees this work.

Funding This work was supported by the grants from Intuitive Surgical India Pvt. Ltd, a subsidiary of Intuitive Surgical, California, US.

Data availability No datasets were generated or analysed during the current study.

Declarations

Conflict of interest AD and KB are employees of Intuitive Surgical, California, US. The other authors declare that they have no conflicts of interest concerning the publication of this work. The study was conducted independently, and the authors have no connections to, affiliations with, or financial relationships to any organizations that could unduly prejudice the content of this work.

Ethics approval The institutional ethics committee (IEC) or institutional review board (IRB) of each participating center granted permission for the study. The study was registered at the Clinical Trials Registry of India website with registration number CTRI/2023/03/050448.

Consent to participate Since this was a retrospective study that involved the collection of de-identified data without any direct participant interaction, the IRB/IEC waived the requirement for informed consent. Every study procedure conforms to the ethical norms of the participating institutions as well as the Declaration of Helsinki.

Consent to publish The corresponding author gives consent for this work to be published on behalf of all the authors.

Financial interests There are no financial interests of the authors that ought to be disclosed.

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Authors and Affiliations

A. S. Ramakrishnan[1] · Jagdish Kothari[2] · Surender Kumar Dabas[3] · Venkatesh Munnikrishnan[4] · O. V. Sudheer[5] · Jeewan Ram Vishnoi[6] · Shivendra Singh[7] · Jagannath Dixit[8] · Sandeep Nayak[9] · Ashwani Sharma[10] · Devendra Parikh[2] · Venkat Paneer[11] · Priya Kapoor[11] · S. P. Somashekhar[12] · Krishna M. S. Bharadwaj[13] · Divya Gupta[14] · Akhil Dahiya[15]

✉ Akhil Dahiya
akidoc31@gmail.com

A. S. Ramakrishnan
ram_a_s@yahoo.com

Jagdish Kothari
jagdishmkothari@hotmail.com

Surender Kumar Dabas
surenderdabas318@yahoo.co.in

Venkatesh Munnikrishnan
venky247@gmail.com

O. V. Sudheer
ovsudheer@yahoo.com

Jeewan Ram Vishnoi
drjvishnoi@gmail.com

Shivendra Singh
drshivendraonco@gmail.com

Jagannath Dixit
drjdixit@gmail.com

Sandeep Nayak
nayak.dr@gmail.com

Ashwani Sharma
drash12@gmail.com

Devendra Parikh
drdevendragp@gmail.com

Venkat Paneer
venkatsurgeon@hotmail.com

Priya Kapoor
dr.priyaskapoor@gmail.com

S. P. Somashekhar
somusp@yahoo.com

Krishna M. S. Bharadwaj
krishna.BharadwajMS@intusurg.com

Divya Gupta
guptadivya23@gmail.com

[1] Department of Surgical Oncology, Cancer Institute (WIA), Adyar, Chennai, Tamil Nadu, India

[2] GI and Hepatobiliary Services, HCG Cancer Centre, Ahmedabad, Gujarat, India

[3] Surgical Oncology and Robotic Surgery, Dr. B. L. Kapur Memorial Hospital, Rajendra Place, New Delhi, India

[4] Consultant Colorectal and Robotic Surgeon, Apollo Hospitals, Chennai, Tamil Nadu, India

[5] Department of Gastrointestinal Surgery, Amrita Institute of Medical Sciences and Research Centre, Kochi, Kerala, India

[6] Department of Surgical Oncology, All India Institute of Medical Sciences (AIIMS), Jodhpur, Rajasthan, India

[7] GI Oncosurgery, Rajiv Gandhi Cancer Institute and Research Centre, Rohini, Delhi, India

[8] Gastrointestinal Oncology, HCG Cancer Centre, Bengaluru, Karnataka, India

[9] Department of Surgical Oncology, Fortis Hospital, Bannerghatta Road, Bengaluru, Karnataka, India

[10] Department of Surgical Oncology, Dr. B. L. Kapur Memorial Hospital, Rajendra Place, New Delhi, India

[11] Surgical Oncology, Apollo Cancer Centre, Chennai, Tamil Nadu, India

[12] Surgical & Gynaecological Oncology & Robotic Surgeon, Aster CMI Hospital, Bengaluru, Karnataka, India

[13] Department of Clinical Affairs, Intuitive Surgical, Sunnyvale, California, USA

[14] Clinical Operations, Catalyst Clinical Services Pvt. Ltd, Pitampura, Delhi, India

[15] Department of Clinical and Medical Affairs, Intuitive Surgical, Sunnyvale, California, USA