OXFORD

BJS Open, 2022, zrab135
https://doi.org/10.1093/bjsopen/zrab135
Original Article

Comparing outcomes of robotic *versus* open mesorectal excision for rectal cancer

Rosa M. Jimenez-Rodriguez [1], Jessica Flynn[2], Sujata Patil[2], Maria Widmar[1], Felipe Quezada-Diaz[1], Patricio Lynn[1], Paul Strombom[1], Larissa Temple[1], J. Joshua Smith[1], Iris H. Wei[1], Emmanouil P. Pappou[1], Jose G. Guillem[1], Philip B. Paty[1], Garrett M. Nash[1], Martin R. Weiser [1] and Julio Garcia-Aguilar[1,*]

[1]Department of Surgery, Memorial Sloan Kettering Cancer Center, New York, New York, USA
[2]Department of Epidemiology & Biostatistics, Memorial Sloan Kettering Cancer Center, New York, New York, USA

Correspondence to: Colorectal Service, Department of Surgery, Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10065, USA (e-mail: garciaaj@mskcc.org)

Abstract

Background: The outcomes of robot-assisted mesorectal excision for rectal cancer, compared with open resection, have not been fully characterized.

Methods: A retrospective analysis of pathologic, short-term, and long-term outcomes in patients with rectal adenocarcinoma who underwent total or tumour-specific mesorectal excision at a high-volume cancer centre between 2008 and 2017 was conducted. Outcomes after robotic and open surgery were compared on an intention-to-treat basis.

Results: Out of 1048 resections performed, 1018 patients were reviewed, with 638 who underwent robotic surgery and 380 open surgery. Robotic surgery was converted to the open approach in 17 (2.7 per cent) patients. Patients who underwent robotic surgery were younger (median 54 (range 22–91) years *versus* median 58 (range 18–97) years; $P < 0.001$), had higher tumours (median 80 (range 0–150) mm from the anal verge *versus* median 70 (0–150) mm; $P = 0.001$), and were less likely to have received neoadjuvant therapy (64 per cent *versus* 73 per cent; $P = 0.003$). For patients who underwent a robotic total mesorectal excision, the operating time was longer (median 283.5 (range 117–712) min *versus* median 249 (range 70–661) min; $P < 0.001$). However, the rate of complications was lower (29 per cent *versus* 45 per cent; $P < 0.001$) and length of hospital stay was shorter (median 5 (range 1–32) days *versus* median 7 (range 0–137) days; $P < 0.001$). Median follow-up of survivors was 2.9 years. The proportion of patients with a positive circumferential resection margin did not differ between the groups, nor did the rate of local recurrence (robotic *versus* open: 3.7 per cent, 95 per cent c.i. 1.9 to 5.6 *versus* 2.8 per cent, 95 per cent c.i. 1.0 to 4.6; $P = 0.400$), systemic recurrence (robotic *versus* open: 11.7 per cent, 95 per cent c.i. 8.5 to 14.8 *versus* 13.0 per cent, 95 per cent c.i. 9.2 to 16.5; $P = 0.300$), or overall survival (robotic *versus* open: 97.8 per cent, 95 per cent c.i. 96.3 to 99.3 *versus* 93.5 per cent, 95 per cent c.i. 90.8 to 96.2; $P = 0.050$). The same results were documented in a subanalysis of 370 matched patients, including 185 who underwent robotic surgery and 185 open surgery, for the overall incidence of any postoperative complications, overall survival, disease-free survival, local recurrence, and systemic recurrence.

Conclusion: In patients with rectal cancer who are candidates for curative resection, robotic mesorectal excision is associated with lower complication rates, shorter length of stay, and equivalent oncologic outcomes, compared with open mesorectal excision.

Introduction

Laparoscopic colectomy for treatment of colon cancer is widely accepted[1–3] because it expedites recovery, reduces complications, and improves cosmetic results without reducing survival, as compared with open surgery. However, broad adoption of laparoscopy for rectal cancer surgery remains low, due to the technical challenge of working in the confined pelvic space with rigid instruments and unfavourable ergonomics.

Prospective trials comparing laparoscopic and open total mesorectal excision (TME) in patients with rectal cancer have yielded conflicting results. Some studies found that laparoscopic TME is equivalent to open TME in short- and long-term oncological outcomes[4,5]. Other trials that used a non-inferiority design, with composite pathologic score (completeness of mesorectal excision, clear circumferential resection margin (CRM), and clear distal margin) as primary endpoint, failed to show that laparoscopic TME is not inferior to open TME and raised questions about the oncological outcomes of the laparoscopic approach[6–10]. A planned analysis of secondary outcomes of these studies found no difference in recurrence and survival between the laparoscopic and open groups. However, the number of events was low and the confidence intervals wide, and the authors concluded that their findings could not exclude a detriment from laparoscopic surgery[7,10]. The authors concluded that their data may not support laparoscopic resection of rectal cancer as a routine standard for surgical treatment of patients with locally advanced rectal cancer[7,10].

The da Vinci robot (Intuitive Surgical Inc., Sunnyvale, CA, USA), which provides enhanced visualization, dexterity, and

Received: May 27, 2021. **Accepted:** November 23, 2021

ergonomics, is particularly well suited for pelvic surgery. Evidence supporting the use of the da Vinci robot for rectal cancer surgery was obtained in retrospective case series and a prospective trial that compared robotic surgery with laparoscopy[11–13]. The ROLARR trial[13] has recently shown that robotic TME is at least equivalent to laparoscopic TME in short-term outcomes. With laparoscopy recently challenged as the preferred approach to TME in patients with rectal cancer, the use of laparoscopic TME as a benchmark has been questioned.

In this study, the short- and long-term outcomes of robotic mesorectal excision for rectal cancer were evaluated, as compared with open mesorectal excision, at a high-volume cancer centre.

Methods

Patients

A retrospective review of the cancer centre's database was conducted, searching for patients who underwent robotic or open mesorectal excision between 1 January 2008 and 31 May 2017 for primary metastatic rectal adenocarcinoma located within 15 cm from the anal verge. Preoperative diagnostics included colonoscopy and biopsy, serum tumour markers, and MRI and/or endorectal ultrasound. Neoadjuvant therapy was administered based on consensus guidelines (https://www.nccn.org) and recommendations of the institution's colorectal cancer disease management team. Clinical, demographic, operative, and pathologic data were collected and analysed. Data on postoperative complications were collected from a prospectively maintained institutional database. Patients were excluded from analysis if they had clinical complete response after neoadjuvant therapy and were under a watch-and-wait policy, tumour regrowth after watch-and-wait, or advanced tumours requiring multivisceral resection or perineal flap reconstruction (*Fig. 1*).

Surgical procedures

Mesorectal excision, total or tumour-specific depending on the location of the tumour, was performed according to standard techniques. The procedure was considered open when rectal dissection was performed under direct vision using standard surgical instruments, independent of the technique used to mobilize the colon. The procedure was considered robotic when rectal dissection was performed using the da Vinci robotic platform, independent of whether the colon was mobilized using laparoscopic instruments or the da Vinci platform. Conversion to an open approach was defined as the need to perform a laparotomy larger than initially planned for any part of the procedure or the need to perform any part of the mesorectal excision by any procedure other than robotic. In all cases, the anastomosis was stapled or handsewn according to tumour location and the surgeon's preference.

Pathologic analysis

Surgical specimens were processed according to the guidelines of the College of American Pathologists[14]. The circumferential resection margin was considered positive when the tumour extended to less than or equal to 1 mm from the inked margin.

Follow-up

All patients underwent standard follow-up during the immediate postoperative period and then every 3 months for the first 2 years and every 6 months for an additional 3 years (https://www.nccn.org). Tumour marker assessment, MRI and/or CT were routinely performed as part of the follow-up.

Outcomes of interest

Postoperative complications were categorized using the Clavien–Dindo classification system[15]. Local recurrence was defined as radiologic or histologic evidence of tumour at the primary site after primary resection. Systemic recurrence was defined as any distant metastasis confirmed by radiologic study and/or biopsy. Disease-free survival was defined as the length of time after surgery during which the patient survives without any signs of cancer, and overall survival was defined as the length of time after surgery during which the patient is still alive.

Statistical analysis

Qualitative variables were summarized using absolute frequencies and percentages, and quantitative variables were summarized using median and ranges. Differences in qualitative variables by operative approach were tested, using the chi-square test and Fisher's exact test for qualitative variables and Wilcoxon's rank sum test for quantitative variables. The Kaplan–Meier methodology was used to estimate the 3-year rates of disease-free survival, overall survival, and local and systemic recurrences. The cumulative incidence of local and systemic recurrences was plotted from the inverse of the Kaplan–Meier estimates using a cause-specific approach. The

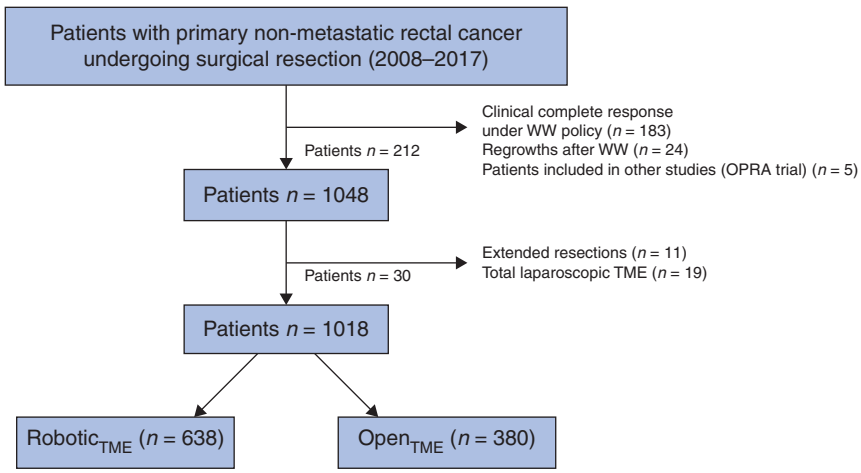

Fig. 1 Inclusion and exclusion of patients in the analysis

WW, watch-and-wait; TME, total mesorectal excision.

log rank test was used to compare survival distributions across operative approaches. A multivariable Cox proportional hazard model was used to analyse the effect of operative approach on disease-free survival after adjusting for demographic and clinical covariates (age, tumour distance from the anal verge, TNM stage, neoadjuvant therapy). The robotic cohort was adopted at a later time period and had a shorter follow-up. As a result, all survival plots were truncated at 6 years. However, all hazard ratio estimates and log rank *P* included all follow-up times. As a sensitivity analysis to ensure balance between the two groups, a matched analysis for postoperative complications, overall survival, disease-free survival, local recurrence, and systemic recurrence endpoints was conducted. In this matched analysis, the two groups were matched based on age, neoadjuvant therapy, tumour location, and clinical stage. Patients who were not matched were not included in the matched analysis. Statistical significance was set at $P < 0.050$. All analyses were conducted in R v3.6.2.

Results

Out of 1048 patients undergoing rectal resection during the study period, 11 were excluded as they did not meet study criteria. Also, during the study period, only 19 patients had a fully laparoscopic TME and they were not included in the analysis. Apart from these, 212 patients underwent a watch-and-wait policy during this period and were also excluded from the analysis, regardless of the need for surgery during follow-up. On this basis, a total of 1018 patients (638 robotic and 380 open mesorectal excision) were analysed. Patient and treatment characteristics are listed in *Table 1*. Distribution of patients by surgical approach and year is shown in *Fig. S1*. Patients who underwent robotic surgery were younger (median 54 (range 22–91) years *versus* median 58 (range 18–97) years; $P < 0.001$), had tumours located farther from the anal verge (median 8 (range 0–15) cm *versus* median 7 (range 0–15) cm; $P = 0.001$), and were less likely to have received neoadjuvant therapy (64 per cent *versus* 73 per cent; $P = 0.003$) (*Table 1*).

Table 1 Demographic and preoperative data

	Robotic$_{TME}$ ($n = 638$)	Open$_{TME}$ ($n = 380$)	*P*
Age, median (years)	54 (22–91)	58 (18–97)	< 0.001
Sex			0.20
Men (%)	368 (57.7)	235 (61.2)	
BMI, median	27.4 (16.3–55.8)	27.1 (16.6–52.2)	0.21
Missing	5 (0.49%)		
ASA			0.727
I	8 (1.3)	5 (1.3)	
II	247 (41.0)	159 (41.8)	
III	342 (57.0)	210 (55.3)	
IV	5 (0.8)	6 (1.6)	
Missing	36 (3.5)	0	
Tumour location			< 0.001
Upper (11–15)	175 (27)	62 (16)	
Middle (6–10)	282 (44)	179 (47)	
Lower (0–5)	181 (28)	139 (37)	
Clinical stage			< 0.001
0 (Tis)	66 (11)	26 (7)	
I	183 (30)	77 (21)	
II	109 (18)	91 (25)	
III	262 (42)	175 (47)	
Not determined	18 (2.8)	11 (2.9)	
Neoadjuvant therapy	410 (64)	279 (73)	0.003

Number in parentheses are percentages.

Perioperative and pathologic outcomes

Intraoperative variables and postoperative outcomes are listed in *Table 2*. Robotic surgery took longer (median 283.5 (range 117–712) min), compared with open surgery (median 249 (range 70–661) min; $P < 0.001$). A low anterior resection with a diverting ileostomy was performed in 370 patients (58 per cent) in the robotic surgery group and in 199 patients (52 per cent) in the open surgery group ($P = 0.110$). A stapled anastomosis was performed in 473 patients (86 per cent) in the robotic surgery group and in 257 patients (83 per cent) in the open surgery group. A handsewn anastomosis was performed in 87 patients (14 per cent) in the robotic surgery group and in 61 patients (17 per cent) in the open surgery group ($P = 0.189$). The operation was converted from a robotic approach to an open approach in 17 (2.7 per cent) patients. Of the 638 robotic surgery patients, 185 (29 per cent) had surgical complications, compared with 171 (45 per cent) of the 380 open surgery patients ($P < 0.001$). The rate of surgical site infections (including superficial, deep, and organ space infections) was significantly lower in the robotic group (6.9 per cent *versus* 21.3 per cent; $P < 0.001$), as was the median length of stay (median 5 (range 1–32) days *versus* median 7 (range 0–137) days; $P < 0.001$).

Table 3 lists the pathology findings from the resected specimens. The proportion of patients with a positive circumferential resection margin was not significantly different in the robotic and open surgery groups (5.3 per cent *versus* 7.2 per cent, respectively; $P = 0.299$). The number of lymph nodes harvested was significantly higher in the robotic surgery group (18 (0–105) *versus* 15.5 (3–64); $P < 0.001$).

Survival

Median follow-up of survivors was 2.9 years overall, 2.3 (range 0–6.78) years for the robotic surgery group, and 5.11 (range 0.03–9.45) years for the open surgery group. There were no significant differences in the 3-year local recurrence rates (3.7 per cent, 95 per cent c.i. 1.9 to 5.6 *versus* 2.8 per cent, 95 per cent c.i. 1.0 to 4.6; $P = 0.400$) or systemic recurrence rates (11.7 per cent, 95 per cent c.i. 8.5 to 14.8 *versus* 13.0 per cent, 95 per cent c.i. 9.2 to 16.5; $P = 0.300$) between the robotic and open groups (*Fig. 2*). No difference was documented in the 3-year disease-free survival rates between the robotic and open surgery groups (84.7 per cent, 95 per cent c.i. 81.3 to 88.3 *versus* 83.9 per cent, 95 per cent c.i. 80.1 to 88.0; $P = 0.300$). In a multivariable analysis, only age (hazard ratio (HR): 1.02 (95 per cent c.i. 1.01 to 1.03); $P = 0.003$) and pathologic stage (HR: stage I, 1.97 (95 per cent c.i. 0.94 to 4.11); stage II, 3.98 (95 per cent c.i. 1.95 to 8.14); stage III, 5.55 (95 per cent c.i. 2.78 to 11.1); $P < 0.001$) were significantly associated with disease-free survival, with older age and increased stage predicting worse disease-free survival (*Table 4*). Tumour height, use of neoadjuvant treatment, and surgical approach (robotic *versus* open) were not associated with disease-free survival. No difference was documented in the 3-year overall survival rates between the robotic and open groups (97.8 per cent (95 per cent c.i. 96.3 to 99.3) *versus* 93.5 per cent (95 per cent c.i. 90.8 to 96.2); $P = 0.050$) (*Fig. 3*). Inclusion of the surgeon performing the surgical procedure in the multivariable analysis did not change the results.

Matched analysis

In the subset of 370 matched controls, with 185 of patients undergoing robotic surgery and 185 open surgery, results of outcomes were similar to the those of the overall cohort ($P = 0.006$,

Table 2 Operative and postoperative data

	$Robotic_{TME}$ ($n = 638$)	$Open_{TME}$ ($n = 380$)	P
Operating time, median (min)	283.5 (117–712)	249 (70–661)	< 0.001
Procedure			0.042
LAR	560 (88)	318 (84)	
APR	78 (12)	62 (16)	
EBL, median (ml)	50 (10–3000)	200 (10–1900)	< 0.001
Missing		40 (3.9)	
Any complication	185 (29)	171 (45.3)	< 0.001
Complication (highest grade)			
I	36 (5.6)	38 (10)	
II	109 (17)	91 (23.9)	
III	39 (6.1)	39 (10.2)	
IV	1 (0.1)	4 (1)	0.145
Anastomotic leak	12 (2.1)	8 (2.5)	> 0.900
SSI	44 (6.9)	81 (21.3)	< 0.001
LOS, median (days)	5 (1–32)	7 (1–137)	< 0.001
Readmission at 30 days	68 (11)	53 (14.0)	0.140

LAR, low anterior resection; APR, abdominoperineal resection; EBL, estimated blood loss; SSI, surgical site infection; LOS, length of stay. Numbers in parentheses are percentages.

Table 3 Pathologic outcomes

	$Robotic_{TME}$ ($n = 638$)	$Open_{TME}$ ($n = 380$)	P
ypT classification			0.032
T0	105 (16.5)	68 (17.9)	
T1	129 (20.2)	48 (12.6)	
T2	164 (25.7)	117 (30.8)	
T3	231 (36.2)	141 (37.1)	
T4	9 (1.4)	6 (1.6)	
ypN classification			0.746
N0	454 (71.2)	275 (72.4)	
N1	128 (20.1)	77 (20.3)	
N2	56 (8.8)	28 (7.4)	
TNM stage			0.095
0	97 (15.2)	66 (17)	
I	235 (36.8)	114 (30)	
II	122 (19.1)	90 (23.7)	
III	184 (28.8)	110 (28.9)	
Lymphovascular invasion†	157 (24.6)	80 (21.1)	0.193
Venous invasion†	54 (8.5)	26 (6.8)	0.400
Perineural invasion†	120 (18.8)	70 (18.4)	0.934
Distal margin, median (mm)	27 (0–130)	25 (0–125)	0.012
N/A	35 (5.5%)	8 (2.1%)	
Positive circumferential margin resection	29 (5.3)	23 (7.2)	0.299
N/A	93 (14.5%)	62 (16.3%)	
Circumferential margin, median (mm)	12 (0–65)	10 (0–45)	0.011
N/A	91 (14.3%)	62 (16.3%)	
Lymph nodes harvested	18 (0–105)	15.5 (3–64)	< 0.001
Affected lymph nodes	0 (0–21)	0 (0–22)	0.813

†Data including patients with no residual tumour in the specimen. Numbers in parentheses are percentages. N/A, not available.

$P = 0.300$, $P = 0.990$, $P = 0.900$, and $P = 0.400$ for the overal incidence of any postoperative complications, overall survival, disease-free survival, local recurrence, and systemic recurrence, respectively) (*Figs S2* and *S3*).

Discussion

In this study, comparable oncologic outcomes in rectal cancer patients treated with robotic or open mesorectal excision at a high-volume centre were documented. The robotic approach was associated with a longer operating time, but also with shorter length of stay, fewer postoperative complications, including surgical site infections, and greater lymph node harvest. These findings suggest that robotic mesorectal excision is a safe and effective minimally invasive approach for patients with rectal cancer.

Open TME is associated with excellent pathologic and oncologic outcomes but denies patients the well known benefits of minimally invasive surgery, including shorter length of stay, decreased analgesic requirements, and earlier return of bowel function[1,5,8]. Despite several decades of experience using laparoscopy for treatment of colon cancer, it has never been widely accepted for surgical treatment of rectal cancer owing to technical challenges of using inline, non-articulating instruments in a narrow pelvis[11–13]. These concerns have been borne out in two clinical trials comparing laparoscopic to open TME – the ALaCaRT and ACOSOG Z6051 trials, in which laparoscopic TME failed to reach the non-inferiority threshold with respect to pathologic

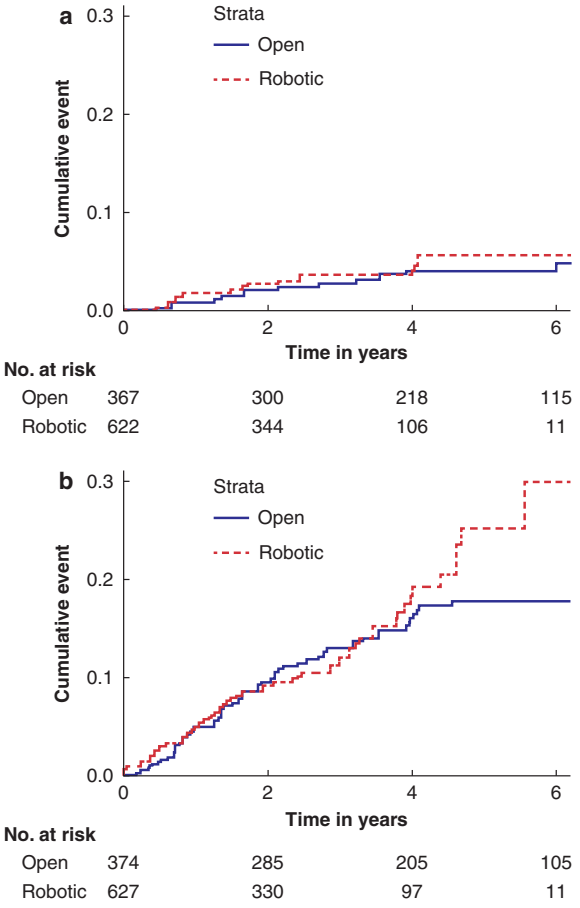

Fig. 2 Local (a) and systemic (b) recurrences in the robotic and open groups ($P = 0.400$ and $P = 0.300$, respectively)

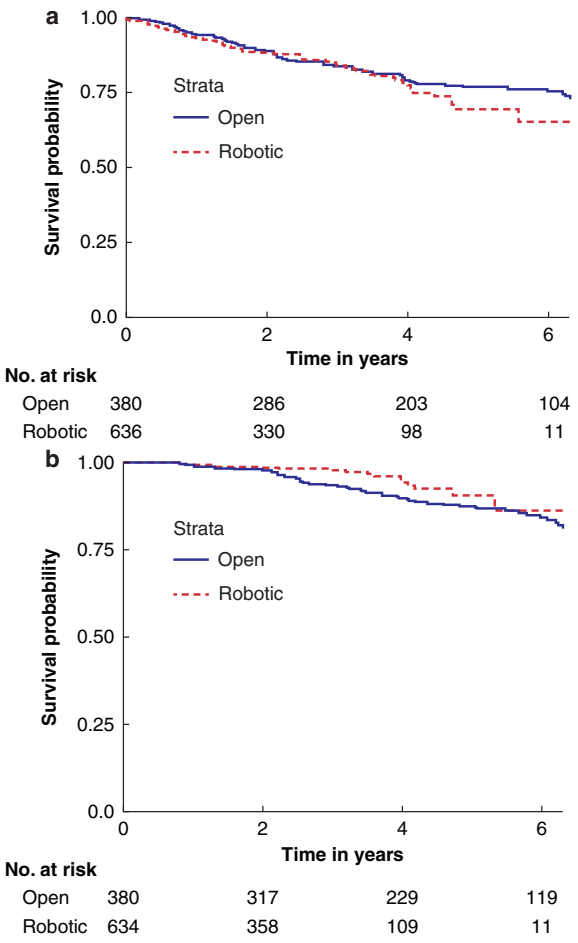

Fig. 3 Disease-free survival (a) and overall survival (b) in the robotic and open groups ($P = 0.300$ and $P = 0.050$, respectively)

Table 4 Multivariable analysis

Variable	Hazard ratio	95% c.i.	*P*
Age	1.02	1.01, 1.03	0.003
Tumour height			0.200
0–5.9 cm			
11–15 cm	0.65	0.39, 1.09	
6–10.9 cm	0.80	0.57, 1.13	
pTNM stage			< 0.001
0			
I	1.97	0.94, 4.11	
II	3.98	1.95, 8.14	
III	5.55	2.78, 11.1	
Neoadjuvant therapy	1.23	0.81, 1.88	0.300
Surgical approach	1.36	0.98, 1.89	0.064

outcomes[6,7,9,10]. Both transanal TME and robotic TME offer alternative approaches to overcome the challenges of minimally invasive proctectomy while optimizing postoperative outcomes. The da Vinci robot, with its three-dimensional visualization, articulating instruments with up to seven d.f., tremor filtering, multiple mechanical arms, and improved ergonomics, is particularly well suited for pelvic surgery. To date, there have been no prospective clinical trials comparing robotic to open mesorectal excision. Multiple institutional case series suggest that robotic surgery in rectal cancer patients is safe and associated with acceptable oncologic outcomes[11,12,16]. Previous research examined 276 patients with low and mid-rectal cancers who underwent robotic TME, with low rates of incomplete TME (less than 1 per cent), CRM positivity (≤1 mm; 2.5 per cent), and 3-year local recurrence (2.4 per cent)[16]. These results compare favourably with the 'superior' open arms of the ALaCaRT and ACOSOG Z6051 trials. A group in Korea compared robotic, open, and laparoscopic TME and found comparable, excellent oncologic results, including 3-year local recurrence rates of 2.5–3.4 per cent and low CRM positivity (less than 2.5 per cent)[17]. As expected, minimally invasive proctectomy (both robotic and laparoscopic) was also associated with shorter length of stay, less pain, and less surgical site infections. In this study, the robotic approach was also significantly associated with sphincter preservation and a lower conversion rate, compared with laparoscopic TME in published studies (34 per cent, 17 per cent, and 11 per cent)[4,6,8].

Multi-institutional studies have similarly demonstrated the safety and perioperative benefits of minimally invasive proctectomy. A National Cancer Database study revealed comparable pathologic and overall survival outcomes between laparoscopic and robotic proctectomy[18]. A single meta-analysis published in 2016 compared robotic and open TME, including seven studies with a mean of 70 robotic cases per study[19]. Robotic TME was associated with less blood loss, shorter length of stay, quicker return of bowel function, and comparable pathologic outcomes, including proximal, distal, and CRM margin status, as well as lymph node yield. Disease-free survival data (2-year and 5-year) were only available for two studies, and 5-year overall survival data for one study. A more recent review[20] did not compare

survival outcomes between robotic and open approaches. The present study shows no difference in recurrence or survival.

Complication and readmission rates in the robotic arm of the present study were either comparable or less than those of the ROLARR trial, the only prospective trial with a robotic proctectomy arm[13]. The lower conversion rate in the present study (2.7 per cent), compared with the ROLARR trial (8 per cent), can be attributed to greater surgeon experience in the robotic platform in the present study (133 procedures per surgeon; range 24–225), compared with the ROLARR trial. Comparing more broadly across robotic TME studies, short- and long-term results in the present study are similar to those previously reported, with estimated conversion and complication rates of 6 per cent and 35 per cent, respectively, and local and systemic recurrence rates of 3 per cent and 18 per cent, respectively[16,17,19].

This cohort had similar operating times and lengths of stay, compared with the open cohort in the ALaCaRT trial[9]. However, the postoperative complication rate was overall higher, although, interestingly, the rate of high-grade complications—those requiring procedural intervention for treatment—was comparable to those in published trials[6,9]. It is important to note that enhanced recovery and surgical site infection protocols were only routinely adopted at the Memorial Sloan Kettering Cancer Center in 2016. Similarly, the pathologic and oncological findings were also similar to those reported in the open surgery arms of the ALaCaRT and ACOSOG Z6051 trials[6,7,9,10].

The main limitations of this study are related to its retrospective design, which spans a 9-year study period, and the introduction of a new surgical platform. First, this investigation included robotic procedures performed during several surgeons' learning curves, whereas all had extensive experience in open surgery. However, the operating time and number of procedures required to reach proficiency in robotic colorectal surgery decrease significantly when there is institutional support, unlimited access to equipment, and a formal mentoring programme, as in this study[21]. Second, the significantly different follow-up times between robotic and open proctectomies limit the ability to draw strong conclusions about long-term oncologic outcomes. Finally, and perhaps most importantly, major aspects of rectal cancer diagnosis and treatment changed during the study period[22], including the imaging method for locoregional staging, the neoadjuvant therapy strategy, the time interval between completion of neoadjuvant therapy and surgery, and the adoption of a watch-and-wait strategy for patients with a clinical complete response to neoadjuvant therapy.

The strengths of the study include the large sample size and the extensive experience of the surgeons in a high-volume centre. The single-centre setting for this study, while potentially limiting the generalizability of the findings, also provided assurance that patients were managed pre- and postoperatively in a uniform, multidisciplinary fashion.

Funding

Research at Memorial Sloan Kettering Cancer Center is supported by NCI grant P30 CA008748.

Disclosure. J.J.S. has served as a clinical advisor for Guardant Health. J.G.-A. has received honoraria from Medtronic, Johnson & Johnson, and Intuitive Surgical, Inc. The authors declare no other conflict of interest.

Supplementary material

Supplementary material is available at *BJS Open* online.

Data availability

The data underlying this article are available from the corresponding author by request.

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