

Robotic versus Laparoscopic Proctectomy for Rectal Cancer: A Meta-analysis

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ABSTRACT

Background. Robot-assisted laparoscopic surgery is being performed more frequently for the minimally invasive management of rectal cancer. The objective of this meta-analysis was to compare the clinical and oncologic safety and efficacy of robot-assisted versus conventional laparoscopic surgery.

Methods. A search of the Medline and Embase databases was performed for studies that compared clinical or oncologic outcomes of conventional laparoscopic proctectomy with robot-assisted laparoscopic proctectomy for rectal cancer. The methodological quality of the selected studies was critically assessed to identify studies suitable for inclusion. Meta-analysis was performed by a random effects model and analyzed by Review Manager. Clinical outcomes evaluated were conversion rates, operation times, length of hospital stay, and complications. Oncologic outcomes evaluated were circumferential margin status, number of lymph nodes collected, and distal resection margin lengths.

Results. Eight comparative studies were assessed for quality, and seven studies were included in the meta-analysis. Two studies were matched case-control studies, and five were unmatched. A total of 353 robot-assisted laparoscopic surgery proctectomy cases and 401 conventional laparoscopic surgery proctectomy cases were analyzed. Robotic surgery was associated with a significantly lower conversion rate ($P = 0.03$; 95% confidence

interval 1–12). There was no difference in complications, circumferential margin involvement, distal resection margin, lymph node yield, or hospital stay ($P = \text{NS}$).

Conclusions. Robot-assisted surgery decreased the conversion rate compared to conventional laparoscopic surgery. Other clinical outcomes and oncologic outcomes were equivalent. The benefits of robotic rectal cancer surgery may differ between population groups.

Laparoscopic colorectal surgery has been proven to be as safe and effective as open surgery and to offer a number of benefits.^{1–3} However, the proportion of laparoscopic colorectal resections performed compared to open resections still remains low.⁴ Robot-assisted laparoscopic surgery (RALS) using the da Vinci surgical system (Intuitive Surgical, Sunnyvale, CA) has been used to perform minimally invasive colorectal procedures since 2002. However, until recently, most experience has been with colonic resections.⁵ A recent meta-analysis comparing RALS and conventional laparoscopic surgery (CLS) for colorectal surgery showed minimal benefits of the robotic approach.⁶ In this study colonic and rectal resections were analyzed as a single group and rectal RALS series comprised only two of the seven series analyzed. However, the potential of RALS to significantly facilitate pelvic dissection may be realized when performing minimally invasive rectal surgery.

Confirmation of the long-term oncologic safety of CLS for colonic resection has been established by multicentre randomized trials, but the efficacy of laparoscopic rectal cancer surgery is still being examined.^{7,8} Long-term data from the CLASICC study demonstrated oncologic equivalence of laparoscopic and open rectal cancer surgery

despite an increased circumferential resection margin (CRM) involvement in the laparoscopic group in the initial report.^{1,7} There are a number of reports examining RALS for rectal resection, and two multicentre randomized controlled trials: Robotic versus laparoscopic assisted resection for rectal cancer (ROLARR) and American college of surgeons oncology group (ACOSOG)-Z6051 are now recruiting. However, it will be a number of years until the results are available.^{9,10}

The aim of this study was to undertake a meta-analysis of studies comparing RALS with laparoscopic surgery for rectal cancer to compare the safety and efficacy of each approach.

MATERIALS AND METHODS

A systematic review of the studies in the literature examining RALS for colon and rectal surgery was performed. The Medline database was searched with PubMed using the following search strategy: robot* [tw] OR "Da Vinci" [tw] OR Davinci [tw] OR robotics [MeSH Major Topic] AND (colo* [tw] OR *rectal [tw]) and the Medline and Embase databases were searched with Embase using the following search strategy: robot*:ab OR 'Da vinci':ab OR Davinci:ab OR robotics:de AND (colo*:ab OR rectal:ab) since 2002. No other search restrictions were applied. A manual review of references from selected papers was also performed to identify additional relevant articles. The last search was performed in March 2011. Abstracts selected for the systematic review were required to document clinical outcomes of robot-assisted laparoscopic colorectal surgery in humans, be published in English, and be performed using robotic systems that are currently manufactured. Studies assessing robotic or voice-activated endoscopes and remote telerobotics were excluded. Studies selected for assessment for the meta-analysis were required to compare CLS and RALS proctectomy for rectal cancer. The definition of proctectomy included: low anterior resection, total mesorectal excision (TME), coloanal anastomosis and abdominoperineal resection. Comparative studies that included patients undergoing high anterior resection and rectopexy were excluded. The methodological quality of the selected studies was critically assessed with a checklist based on the questionnaire of Guyatt et al. to assess the quality of the selected studies and to identify studies suitable for inclusion in the meta-analysis.^{11,12} Relevant data from included studies were extracted by two independent observers and summarized. When additional information not supplied in the articles was required, the authors were contacted via personal correspondence.

Statistical heterogeneity was evaluated by I^2 and it was considered high when greater than 50%. If statistical

heterogeneity was high, a sensitivity analysis was performed to by repeating the meta-analysis with any outlying studies excluded.¹³ In meta-analysis, the random-effects method was used. For dichotomous variables, meta-analysis of risk ratios was performed. In such analyses, if one of the studies reported no events in any treatment group, meta-analysis of risk difference was performed. For continuous variables, meta-analysis of the differences between means was performed by the inverse variance method.

Meta-analyses and graphical representation of the results were undertaken by Review Manager (RevMan) software version 5.0 (The Nordic Cochrane Centre, Copenhagen, Denmark). Risk ratio, risk difference and mean differences are presented with 95 per cent confidence intervals. A result was considered significance if $P \leq 0.050$.

RESULTS

The Medline and Embase database search and manual search identified 744 abstracts. After excluding duplicates, 568 abstracts were electronically reviewed to identify 111 articles that were retrieved for comprehensive review. 38 of these articles were excluded leaving 73 articles suitable for inclusion in the systematic review. Eight articles compared RALS and CLS proctectomy for rectal cancer and were assessed for quality. One comparative study was excluded as a result of significantly unequal proportions of patients in the RALS and CLS proctectomy groups undergoing restorative and nonrestorative surgery, leaving seven studies eligible for inclusion in the meta-analysis (Fig. 1).¹⁴ A total of 353 RALS patients and 401 CLS patients were analyzed. Table 1 outlines the characteristics and operative outcomes of patients in the seven studies included in the meta-analysis.¹⁵⁻²¹ All studies were case-control studies with prospective data collection on all patients. The studies by Kwak et al. and Park et al.^{19,22} were matched for preoperative patient characteristics. Overall, the quality of the studies was satisfactory (Table 2). Consecutive patients were reported and specific details of operative approach were provided. Preoperative patient and disease characteristics were consistently reported and well matched for most characteristics. A significantly higher percentage of patients in two studies had lower tumors and higher rates of preoperative chemoradiotherapy in RALS patients, and in one study, higher rates of preoperative chemoradiotherapy in the RALS patients.^{15,18,21} Specific details of operative management was provided in all studies apart from the study by Kim and Kang.¹⁸ Both patient groups were operated on at the same institutions over a similar time period in all studies, differing only in method of surgery. Intention to treat analysis was used in all studies and patient follow-up was adequate for the purposes of the meta-analysis. After data

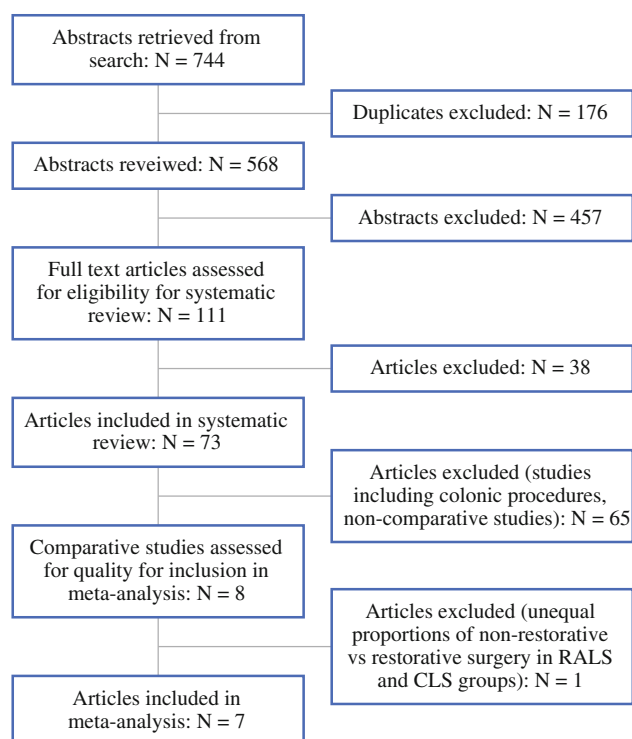


FIG. 1 Flow diagram of study selection for meta-analysis

extraction and evaluation, the results of Patrity et al.²¹ appeared noticeably different to the other studies. However, because it met the eligibility criteria, it was included in the analysis, which was then repeated, excluding the study, as a sensitivity analysis.

Four studies were from Korea.^{16,18,19,22} Two were from Italy.^{17,21} One was from the United States.¹⁵ Notable differences in technique are apparent. In the studies from Korea splenic flexure mobilization was performed less frequently, mean body mass index was lower, few patients had previous abdominal surgery, preoperative radiotherapy was infrequent, and anastomoses were defunctioned less often. The majority of studies used a hybrid technique (CLS for colonic mobilization and vessel ligation, and RALS for rectal dissection).

Clinical Outcomes

Conversion Rates The conversion rate was higher for laparoscopic surgery compared to robot surgery in all studies (Fig. 2). Meta-analysis found a significant risk difference of 7% [95% confidence interval (CI) 1–12] favoring RALS. Patrity et al.²¹ reported the most discrepant results, but even excluding this study the heterogeneity is still high ($I^2 = 61\%$), indicating wide variation in the risk differences for conversion between studies. As there is significant overlap between the confidence intervals, the observed heterogeneity may be a result of the small numbers of patients in the studies.

Operation Time Mean differences in operation time varied widely among the studies ($I^2 = 95\%$). The Forest plot shows two clusters: one with studies reporting a shorter operation time for CLS proctectomy and the other cluster showing no difference (Fig. 3).^{15–20} Patrity et al.²¹

TABLE 1 Characteristics of patients in studies included in the meta-analysis

Study	Country	RALS, CLS (n) and operation	Mean BMI	Sex, M:F	Mean tumor height	Previous surgery (%)	Preop CRT (%)	Robotic technique	Flexure mobilized	Ileostomy (%)	Leak rate (%)
Park ²²	Korea	RALS: 41 TME	23.4	24:17	5.7	9	34	Hybrid	Yes	5	9.7
		CLS: 82 TME	23.4	49:33	5.9	14	21			5	7.3
Kim ¹⁸	Korea	RALS: 100 TME	23.6	70:30			14			30	8.2
		CLS: 100 TME	23.5	57:30			7			27	11.1
Kwak ¹⁹	Korea	RALS: 59 TME	24.3	39:20	8.0		14	Total	37%	42	13.6
		CLS: 58 TME, 1 APR	23.8	42:17	8.0		9		31%	44	10.2
Baek ¹⁵	USA	RALS: 35 TME, 6 APR	25.7	25:16		24	83	Hybrid		94	8.6
		CLS: 35 TME, 6 APR	26.7	25:16		44	44			40	2.9
Bianchi ¹⁷	Italy	RALS: 18 TME, 7 APR	24.6	18:7			52	Total (75%), hybrid (25%)	Yes	55	5.5
		CLS: 19 TME, 6 APR	26.5	17:8			40			26	10.5
Baik ¹⁶	Korea	RALS: 56 TME	23.4	37:19	9.6	2	9	Hybrid	No	0	1.8
		CLS: 57 TME	23.2	34:23	9.5	9	12				7
Patrity ²¹	Italy	RALS: 26 TME, 5 APR	24	1:1.6	5.9	62	24	Hybrid	Yes	0	8.3%
		CLS: 34 TME, 3 APR	25.4	1:2	11.0	30	5.4				2.9%

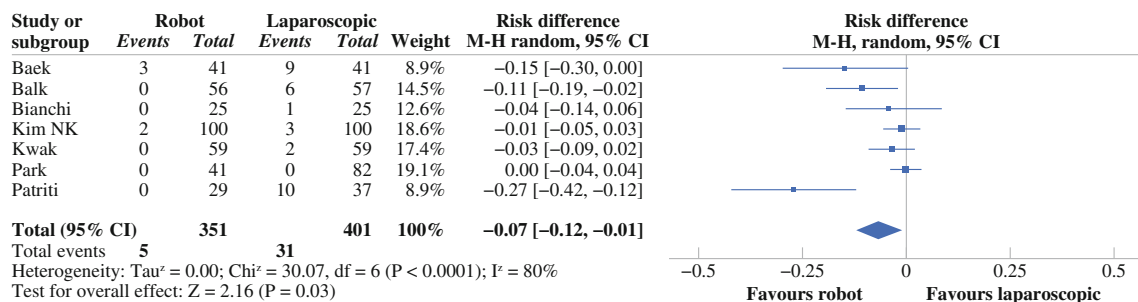
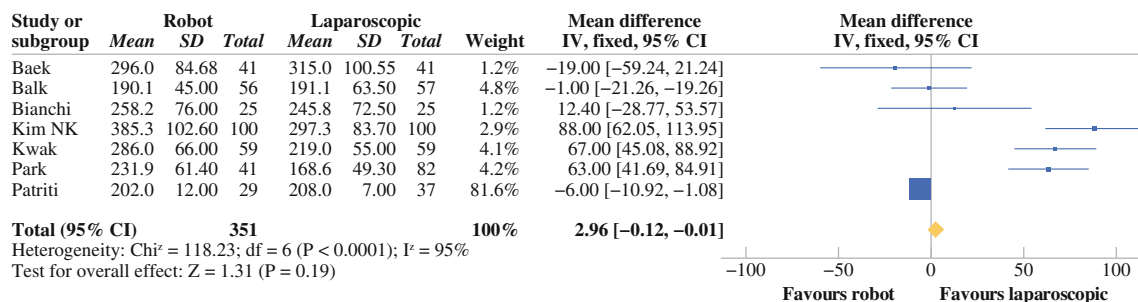
BMI body mass index, Preop CRT preoperative chemoradiotherapy, APR abdominoperineal resection, TME restorative low anterior resection or ultralow anterior resection

TABLE 2 Quality of studies included in the meta-analysis

Study	Study type	Objective	Randomized	Follow-up	Blinding	Equal baseline characteristics	Intervention
Park ²²	Prospectively collected data, case-matched study	Yes	No	Yes	No	Yes	Yes
Kim ¹⁸	Prospectively collected data, comparative study	Yes	No	Yes	No	Yes ^a	Yes
Kwak ¹⁹	Prospectively collected data, case-matched study	Yes	No	Yes	No	Yes	Yes
Baek ¹⁵	Prospectively collected data, comparative study	Yes	No	Yes	No	Yes ^b	Yes
Bianchi ¹⁷	Prospectively collected data, comparative study	Yes	No	Yes	No	Yes	Yes
Baik ¹⁶	Prospectively collected data, comparative study	Yes	No	Yes	No	Yes	Yes
Patriti ²¹	Prospectively collected data, comparative study	Yes	No	Yes	No	Yes ^a	Yes

^a More patients received chemoradiotherapy and there were more low cancers in the RALS group

^b More patients received chemoradiotherapy in the RALS group

**FIG. 2** Forest plot showing a meta-analysis of conversion rates for rectal RALS versus CLS. Risk differences are shown with 95% CIs**FIG. 3** Forest plot showing a meta-analysis of operation times for rectal RALS versus CLS. Mean differences are shown with 95% CIs

were the only ones to show a mean operating time favoring the robot. The standard deviation of mean operation times for Patriti et al. was notably smaller compared to the other studies, which resulted in over 80% of the weight of the meta-analysis given to this study. A reason for their narrow range of operating times could not be established. Meta-analysis of all studies revealed no significant difference in the operating times between the techniques. Analysis after excluding the data from Patriti et al. demonstrated a statistically significant difference in operating time of 43 min (95% CI 32–53) favoring CLS. However, the heterogeneity still remained high ($I^2 = 90\%$).

Hospital Stay There is high heterogeneity among the studies regarding hospital stay ($I^2 = 68\%$). Kwak et al.¹⁹

did not report the duration of the hospital stay. The studies by Baik et al. and by Kim and Kang were the only to find a significant difference, both favoring shorter stay in the RALS group.^{16,18} The result of the meta-analysis shows no difference between the two methods: mean difference –0.57 days (95% CI –1.83 to 0.69) favoring RALS proctectomy, $P = 0.38$.

Complications There was a similar incidence of complications among all studies, with low heterogeneity ($I^2 = 29\%$). All studies showed no difference in the overall complication rate except for that by Baik et al.¹⁶ which showed a difference favoring the robotic technique. Meta-analysis indicates no evidence of a difference in the number of complications between the two methods: risk ratio = 0.93 (95% CI 0.67–1.29), $P = 0.67$.

Oncologic Outcomes

CRM Status The risk difference in CRM status was similar for all studies ($I^2 = 0\%$). None of the studies showed a difference between the RALS and CLS approaches (Fig. 4). The result of the meta-analysis shows no risk difference for CRM involvement between the two methods ($P = 0.77$).

Lymph Nodes Collected The studies showed high heterogeneity in the differences between the number of lymph nodes collected, between the two techniques ($I^2 = 57\%$). Two studies found a significant difference in the number of nodes collected both favoring RALS proctectomy.^{17,22} The result of the meta-analysis shows no difference between the two methods in the mean number of lymph nodes collected: mean difference = -0.90 nodes (95% CI -1.94 to 1.80) favoring RALS proctectomy, ($P = 0.94$).

Distal Resection Margin (DRM) Mean DRM distances comparing the two methods were similar among the studies, except for the findings of Patriiti et al. who reported a high standard deviation for CLS proctectomy (7.2 cm) and who also were the only group to find a significant difference between the two techniques, favoring CLS proctectomy.²¹ The six other studies found no difference between DRMs and all reported small standard deviations (<2.2 cm). Despite the discrepant findings of Patriiti et al., because of its low weighting it has minimal impact on the meta-analysis result. Meta-analysis showed no difference in mean DRM distances between the two methods: mean difference -0.03 cm, 95% CI -0.30 to 0.24 , $P = 0.84$.

DISCUSSION

As with many other procedures, the application of minimally invasive surgery to the management of rectal cancer is attractive to both surgeons and patients because of the possible benefits of reduced morbidity, improved

cosmesis and faster convalescence over the open approach. However, CLS has been slow to gain popularity in the management of rectal cancer, largely as a result of the technical difficulties associated with extensive dissection in the pelvis.⁴ The da Vinci surgical system has been popularized in urology for performing robot-assisted laparoscopic radical prostatectomy because it offers technical features which help overcome such difficulties. As robotic surgical systems have become increasingly commonplace, there has been growing interest among colorectal surgeons in the use of this device to perform RALS proctectomy.

The results of this meta-analysis suggest some benefits for RALS over CLS proctectomy. The findings support the safety and oncologic quality of RALS proctectomy as equivalent to CLS but do need to be interpreted with some caution. Although the overall quality of the studies was good, selection bias may have affected outcomes as none of the studies were randomized or blinded and preoperative patient characteristics were not equal in all studies, tending to favor the CLS patients. High heterogeneity for some of the outcomes analyzed may preclude useful meta-analysis of these outcomes. However, it indicates the significant impact of factors other than the surgical method that affect these outcomes which needs to be acknowledged when interpreting multicentre trials.

RALS was associated with a significantly lower conversion rate with an absolute risk reduction of 7%. A number of aspects of RALS may influence this. RALS increases the technical ease and dexterity with which the surgeon can perform dissection: articulated instruments with seven degrees-of-freedom; motion scaling and tremor filtration; a magnifiable, steady, high definition 3-dimensional operator controlled image; stable retraction, and reduced postural strain and fatigue all may contribute to a more achievable minimally invasive proctectomy.

The differences in mean hospital stay between operative approaches varied between studies and in most studies confidence intervals were wide also indicating significant variation in outcomes within studies. Factors that account for variability between study groups may include

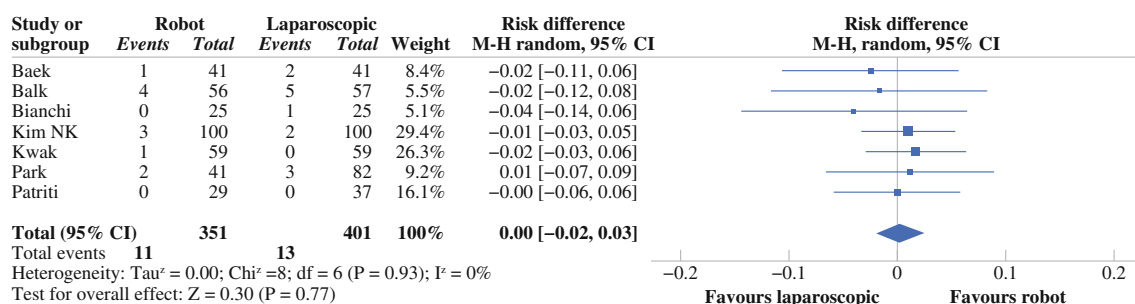


FIG. 4 Forest plot showing a meta-analysis of CRM status for rectal RALS vs. CLS. Risk differences are shown with 95% CIs

differences in discharge criteria or differences in operative complications as a result of differences in surgical techniques used such as defunctioning ileostomy. Factors which account for the wide confidence intervals observed for some studies may include confounding factors such as complications or social factors delaying discharge in a proportion of patients.

The heterogeneity in mean differences in operation times between studies was very high ($I^2 = 95\%$). However, the Forest plot suggests two distinct groups, each within which the heterogeneity appears to be significantly less, which may indicate two separate effects of RALS on operating times between these patient groups. Three Korean studies report mean operating times favoring CLS.^{18,19,22} In these studies, the times reported for RALS proctectomy are similar to the RALS times reported in the four other series. The reason for this difference is not clear. One explanation could be uncontrolled variations in the RALS or CLS operative approaches between the two clusters of studies. Variations in RALS approach can include aspects such as a hybrid versus a total laparoscopic technique, which can significantly affect operating times.²³ This observation as well as differences in patient anatomical characteristics and treatment approaches, such as use of chemoradiation, and defunctioning ileostomy, support future comparisons of RALS and CLS to be stratified within populations. The studies in this meta-analysis report the results of RALS procedures performed relatively early in the learning curve compared to CLS procedures. This is also likely to contribute significantly to the high heterogeneity found between studies for outcomes such as conversion rates and operating times. As has been seen with CLS experience, outcomes can improve significantly with experience and evolution of technique.²⁴ Thus, future improvements in RALS outcomes may yet be to be seen.

The oncologic outcome of rectal cancer surgery is related to two key variables: appropriate neoadjuvant treatment and the quality of mesorectal excision.^{25,26} Outcomes can be further improved by specialist training.²⁷ However, the completeness of TME even among specialists can be variable, as demonstrated by pathologic reporting of the TME specimens of patients in the CRO7 trial.²⁶ Performing precise surgery in the pelvis is inherently difficult and RALS may provide an advantage, especially in the management of low T3 or anterior tumors where complete mesorectal excision is critical. This meta-analysis, however, found no difference in CRM status of RALS compared to CLS proctectomy.

A major drawback to RALS is its cost. Initial purchasing costs, maintenance costs and equipment costs are currently too high to justify its routine use for proctectomy, given its current minimal clinical benefits. However, diversification of the market, dissemination of technology and

demonstration of further benefits may make RALS a more economically viable alternative in the future.

There is limited functional outcome data available for assessment, and data regarding the long-term oncologic outcome of RALS proctectomy is not yet mature. These potentially valuable benefits of RALS proctectomy will require assessment in future studies.

On the basis of the limited number of patients in the studies eligible for inclusion in this meta-analysis and the absence of randomized data, the current evidence suggests that robotic surgery decreases the conversion rate compared to CLS. Other clinical and oncologic outcomes appear equivalent. The benefits of robotic rectal cancer surgery may differ between population groups. Future larger randomized controlled studies assessing clinical, functional and oncologic outcomes are required to establish the true role of RALS in the minimally invasive management of rectal cancer.

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