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# A meta-analysis of randomized controlled trials that compared robot-assisted and conventional laparoscopic surgery for rectal cancer

**Hiroshi Ohtani[1], Shinya Nomura[1], Yoshihito Yamakoshi[1], Mizuki Nagamori[1], Hiroji Nakagawa[1], Yoshioki Ohno[1], Yoshiteru Ohno[2], Kiyoshi Maeda[3], Hisashi Nagahara[3], Masatsune Shibutani[3], Tatsunari Fukuoka[3], Yasuhito Iseki[3], Kosei Hirakawa[3], and Masaichi Ohira[3]**

[1] Department of Surgery, Ohno Memorial Hospital, Osaka, Japan
[2] Department of Internal Medicine, Ohno Memorial Hospital, Osaka, Japan
[3] Department of Gastroenterological Surgery, Osaka City University Graduate School of Medicine, Osaka, Japan

***Corresponding Author:** **Hiroshi Ohtani**, Department of Surgery, Ohno Memorial Hospital, 1-26-10, Minamihorie, Nishi-ku, Osaka 550-0015, Japan. Tel: +81-6-6531-1815, Fax: +81-6-6536-6390, Email: m5051923@msic.med.osaka-cu.ac.jp

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## Abstract

### Background

A meta-analysis was conducted to evaluate and compare the outcomes of robot-assisted and conventional laparoscopic surgery for rectal cancer.

### Methods

We searched MEDLINE, EMBASE, Science Citation Index, and the Cochrane Controlled Trial Register for relevant papers published between 2010 and June 2020 by using the search terms "robotic", "robot-assisted", "laparoscopic", "laparoscopy-assisted", "rectal cancer", and "randomized controlled trial". We performed an analysis comparing the outcomes of robot-assisted surgery and laparoscopic surgery. Data on the patient characteristics, perioperative period, clinical course, postoperative complications, and pathological findings were examined.

### Results:

We identified 6 papers reporting results that compared robot-assisted surgery with laparoscopic surgery for rectal cancer. Our meta-analysis included 879 patients with rectal cancer; 438 had undergone robot-assisted surgery and 441 had undergone laparoscopic surgery. No significant differences were found in patient characteristics between the two groups. Robot-assisted surgery is significantly associated with a greater operative time, a longer distal margin, and lower rate of erectile dysfunction, compared to laparoscopic surgery. The conversion rate to laparotomy was lower in robot-assisted surgery than in laparoscopic surgery with no significant difference.

### Conclusions:

It is suggested that robot-assisted surgery may be preferred over laparoscopic surgery for treatment of rectal cancer.

**Key words:** robot-assisted surgery, laparoscopic surgery, rectal cancer, randomized controlled trial, meta-analysis

## Introduction

The essential treatment for rectal cancer includes total mesorectal excision (TME), preoperative chemoradiotherapy, and postoperative adjuvant chemotherapy. In 1982, Head RJ introduced TME or sharp dissection for the rectal tumor and posterior sheath of the endopelvic fascia en bloc to the levator ani muscle along the visceral pelvis fasciation [1]. Adoption of TME as a surgical approach has reduced the local recurrence rate to 5.6% with preoperative radiotherapy and 10.9% without preoperative

radiotherapy [2].

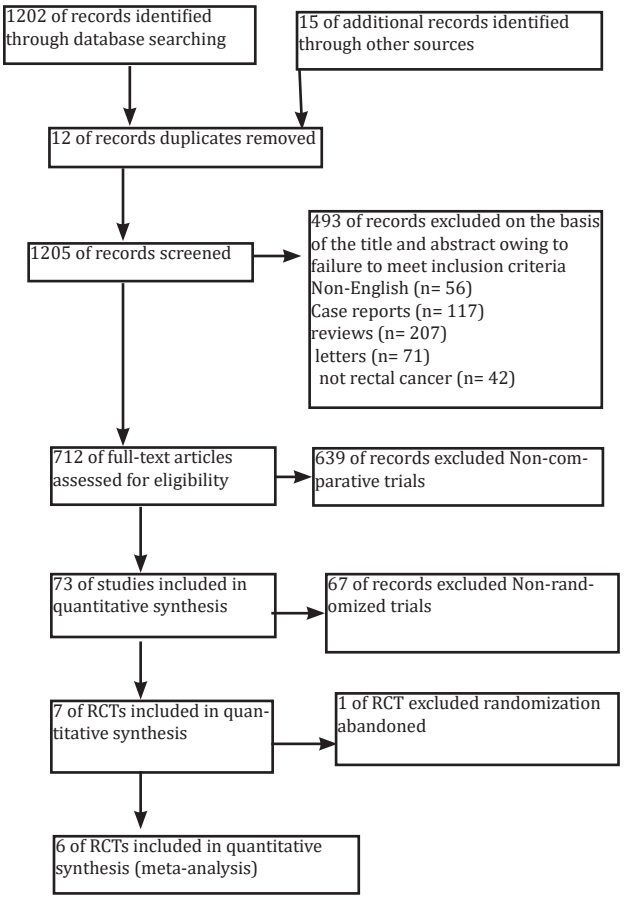
As a minimally invasive surgery, laparoscopic surgery (LAS) for colorectal cancer was first described in 1991 [3] and has since been widely applied by surgeons to treat patients with colorectal cancer. Several randomized trials and meta-analyses described that LAS for colon cancer results in smaller surgical incisions, reducing intraoperative blood loss, shorter recovery and hospital stays, and similarity of morbidity rate in the short-term, and is oncologically equivalent in the long-term, comparing to open surgery [4,5]. The application of LAS for rectal cancer was controversial in the previous Medical Research Council Conventional versus Laparoscopic-Assisted Surgery In Colorectal Cancer (MRC CLASICC) trial [6]. In 2013, the MRC CLASICC indicated that long-term results continue to support the use of LAS for both colonic and rectal cancer [7]. In several randomized trials and our meta-analysis, LAS for rectal cancer is described to have the benefits of reducing intraoperative blood loss, earlier resumption of oral intake, and shorter duration of hospital stay in the short-term, and equivalent long-term outcomes, with comparison to open surgery [8,9]. However, LAS for rectal cancer has technical disadvantages such as inadequate two-dimensional (2D) view with a movable video camera, a limited range for maneuver of the long, straight and rigid laparoscopic instruments in the narrow pelvic cavity, and a reduction in tactile sense. Robot-assisted surgery (RAS) for rectal cancer was introduced to compensate these disadvantages of LAS. Several studies describe safety and feasibility of RAS for rectal cancer [10] after RAS for CRC was first reported in 2002 [11]. The advantages of RAS are a stable 3-dimensional view, an increased dexterity for maneuvering instruments with excellent ergonomics, and physiologic tremor filtering. RAS for rectal cancer may be of use to manipulate instruments in the narrow pelvic cavity. The value of RAS for rectal cancer has remained controversial because the short- and long-term outcomes have not been clarified. To accurately evaluate the efficacy of RAS for rectal cancer, the short- and long-term outcomes of RAS for rectal cancer must be compared to those of LAS. We previously conducted a meta-analysis comparing RAS with LAS for rectal cancer by non-randomized controlled trials[12]. In recent years, there have been a few randomized controlled trials comparing RAS with LAS for rectal cancer [13-18]. This time, we have conducted a meta-analysis comparing RAS and LAS for rectal cancer using randomized controlled trials.

## Methods

### Literature search

To identify papers relevant to our study, we searched the major medical databases—MEDLINE, EMBASE, Science Citation Index, and the Cochrane Controlled Trial Register—for studies published between 2010 and June 2020. The following search terms were used: "robotic", "robot-assisted", "laparoscopic", "laparoscopy-assisted", "rectal cancer", and "randomized controlled trial". Appropriate data from the studies were used for this meta-analysis. This meta-analysis was prepared in accordance with the Preferred Reporting Items for Systemic reviews and Meta-Analysis (PRISMA) statement (Figure 1) [19].

**Figure 1. Flow diagram of this meta-analysis in accordance with PRISMA Statement.**

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### Inclusion criteria

To enter this meta-analysis, studies had to: (1) be written in English; (2) be a randomized trial; (3) compare RAS with LAS for rectal cancer; (4) have patients whose tumor location from anal verge is not significantly different between RAS and LAS; and (5) report on at least one of the outcome measures mentioned below.

### Exclusion criteria

Studies were excluded from this analysis if the outcomes of interest were not reported for the two surgical techniques.

### Data extraction

Three researchers (H.O., S.N., and H.N.) extracted data from each article by using a structured sheet and entered the data into a database. We collected data on the patient characteristics, perioperative period, clinical course, postoperative complications, and pathological findings. The patient characteristics includes ages, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) classification, the number of patients whose tumor location is in the lower or middle rectum, clinical TNM stage II or III, pathological T3 or T4, and previous history of abdominal surgery. For the perioperative period, we collected data on conversion rate to open surgery, operation time, estimated blood loss, the number of the patients undergoing the neoadjvant radiochemotherapy (CRT), sphincter-preserving surgery, and temporary diverting stoma, and operative mortality. Time to bowel movement and duration of hospital stay were examined as the data of clinical course. For the postoperative complications, overall complications, intraabdominal bleeding, anastomotic leakage, wound infection, intraabdominal abscess, ileus, deep vein thrombosis, pneumonia, urinary tract infection, and erectile dysfunction were analyzed. Number of retrieved lymph nodes, circumferential resection margin, length of distal margin, length of proximal margin, number of cases with complete TME, nearly complete TME and incomplete TME, were examined for the pathological data.

### Assessment of study quality

The quality of the randomized controlled trials was assessed using Jadad's scoring system. Two reviewers (H.O., H.N.) assessed all studies that met the inclusion criteria [20].

### Statistical analysis

Weighted mean differences (WMDs) and odds ratios were used for the analysis of continuous and dichotomous variables, respectively. Random effects models were used to identify heterogeneity between the studies, and the degree of heterogeneity was assessed using the $\chi 2$ test. For the analysis of the conversion rate, the $\chi 2$ test was used. The confidence interval (CI) was established at 95%, and p values of less than 0.05 were considered to indicate statistical significance. For the computation of the CI, estimates of the mean and standard deviation were obtained using formulas proposed by Hozo et al. [22]. Statistical analyses were performed using the Review Manager (RevMan) software, version 5.3, provided by the Cochrane Collaboration, Copenhagen, Denmark.

## Results

### Search results

The present meta-analysis met the PRISMA statement. Overall, 1202 citations were retrieved from the search strategy. Fifteen additional articles were identified by contacting clinical experts and searching bibliographies. Twelve studies were excluded because of duplicate reports. Four hundred and ninety-three studies were removed from the 1205 because they were not written in English, reported carcinomas of the other organs except the rectum, and were described in the form of case reports, letters, and review. Six hundred and thirty-nine studies were excluded on account of non-comparative trials. Sixty-seven studies were excluded in terms of non-randomized trials. Finally, one study was removed because randomization was abandoned. We identified 6 trials that compared RAS with LAS for rectal cancer for this meta-analysis. The characteristics of each trial are presented in Table I.

**Table I Characteristics of all the trials**

| | | Year | reference number | number of patients | | preoperative treatment | | conversion to laparotomy | | reasons for conversion | | Operation method | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | RAS | LAS | RAS | LAS | RAS | LAS | RAS | LAS | RAS | LAS |
| 1 | Jayne D et al. | 2017 | 13 | 237 | 234 | CRT (46.8%) | CRT (46.2%) | 19 (8.1%) | 28 (12.2%) | U | U | HAR (11.9%) LAR (67.1%) APR (18.1%) other (1.7%) | HAR (8.3%) LAR (67.5%) APR (17.9%) other (0.4%) |
| 2 | Kim MJ et al. | 2018 | 14 | 66 | 73 | CRT (77.3%) | CRT (79.5%) | 1 (1.5%) | 0 (0%) | intraoperative bleeding | - | LAR (98.5%) APR (1.5%) Hartmann (0%) | LAR (95.9%) APR (2.7%) Hartmann (1.4%) |
| 3 | Debakey Y et al. | 2018 | 15 | 21 | 24 | CRT (57.1%) | CRT (45.8%) | 1 (4.8%) | 2 (8.3%) | bulky tumor very narrrow pelvis | U | AR (42.9%) LAR (33.3%) ultra LAR (19%) APR (4.8%) | AR (54.2%) LAR (29.1%) ultra-LAR (4.2%) APR (12.5%) |
| 4 | Tolstrup R et al. | 2018 | 16 | 25 | 26 | U | U | 1 (4%) | 10 (38.5%) | U | U | AR (52%) ISR (12%) APR (36%) | AR (57.7%) ISR (19.2%) APR (23.1%) |
| 5 | Wang G et al. | 2017 | 17 | 71 | 66 | CRT (18.3%) | CRT (16.7%) | U | U | U | U | LAR (97.2%) Hartmann (4.5%) | LAR (95.5%) Hartmann (2.8%) |
| 6 | Baik SH et al. | 2008 | 18 | 18 | 18 | U | U | 0 (0%) | 2 (11.1%) | - | severely narrow pelvis bleeding at the pelvic wall | AR (100%) | AR (100%) |

-: not stated, U: unknown, CRT: chemoradiation
AR: anterior resection, HAR: high anterior resection, LAR: low anterior resection, ISR: intersphincteric resection, APR: abdominoperitoneal resection

Our meta-analysis included 879 patients with rectal cancer; of these, 438 had undergone RAS, and 441 had undergone LAS. The outcomes analyzed by meta-analysis are shown in Figure II and Figure III, respectively. The study quality by using Jadad's scoring system are shown in Table II.

**Table II Jadad's score**

| authors | number of reference | Randomization | Double Blinding | Withdrawals and dropouts | Jadad's score |
|---|---|---|---|---|---|
| Jayne D et al. | 13 | 2 | 0 | 1 | 3 |
| Kim MJ et al. | 14 | 2 | 0 | 1 | 3 |
| Debakey Y et al. | 15 | 2 | 0 | 1 | 3 |
| Tolstrup R et al. | 16 | 2 | 0 | 1 | 3 |
| Wang G et al. | 17 | 2 | 1 | 1 | 4 |
| Baik SH et al. | 18 | 2 | 2 | 1 | 4 |

Jadad's score (0-5), high quality: more than 2, low quality: 2 or less

## Patient characteristics

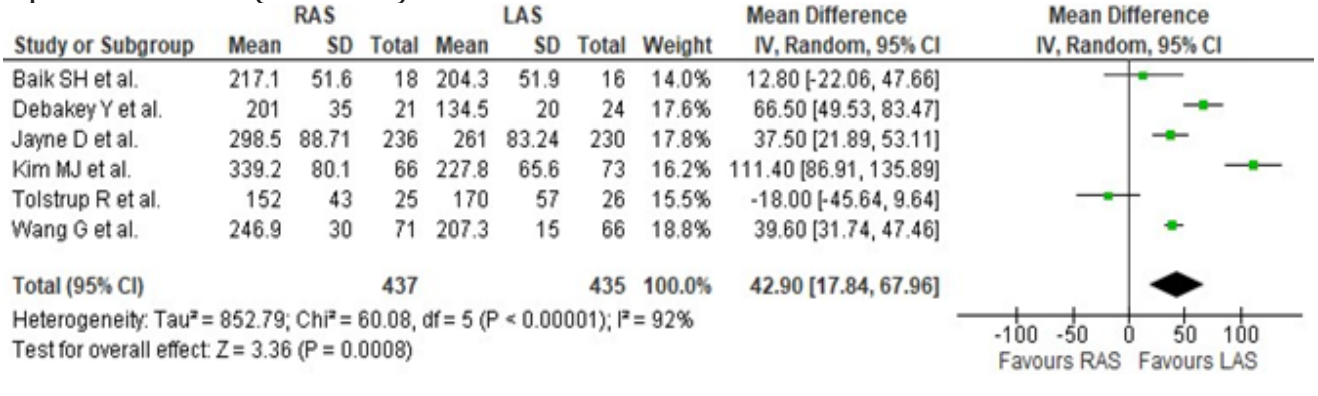
There were no significant differences in age, gender, BMI, ASA classification I/II, the number of patients with lower or middle rectal cancer, and the number of patients having a history of abdominal surgery between the RAS group and the LAS group. No differences were found in clinical TNM stage 0/I, II, III, and T3/4 between the 2 groups.

## Perioperative period

The operative time for RAS was significantly greater, by 42.90 min, than that for LAS (weighted mean difference = 42.90; 95% CI = 17.84–67.96; p = 0.0008) (Figure II).

**Figure 2. Meta-analysis of the outcomes for clinical course and conversion rate to laparotomy**

Operation time (minutes)

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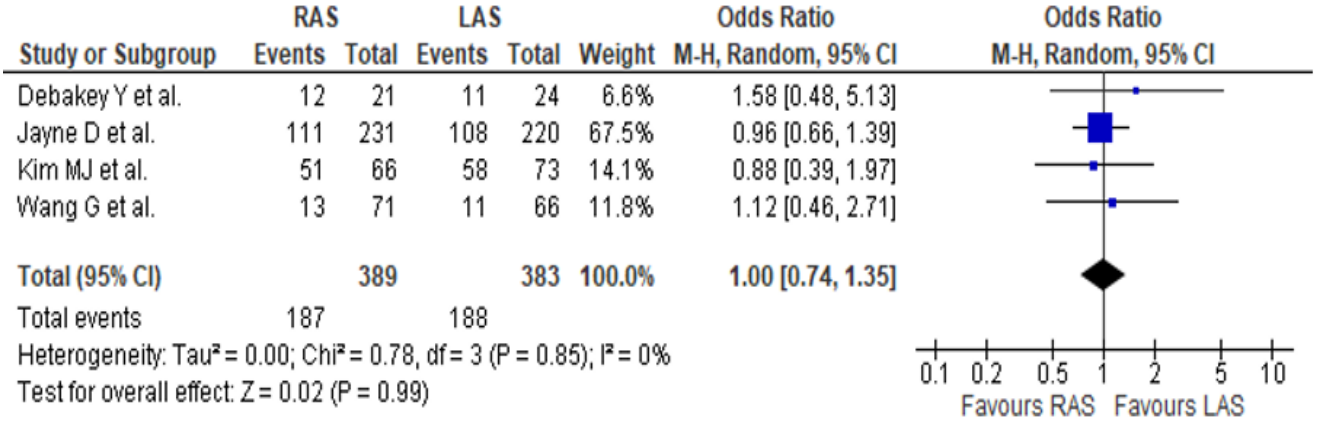
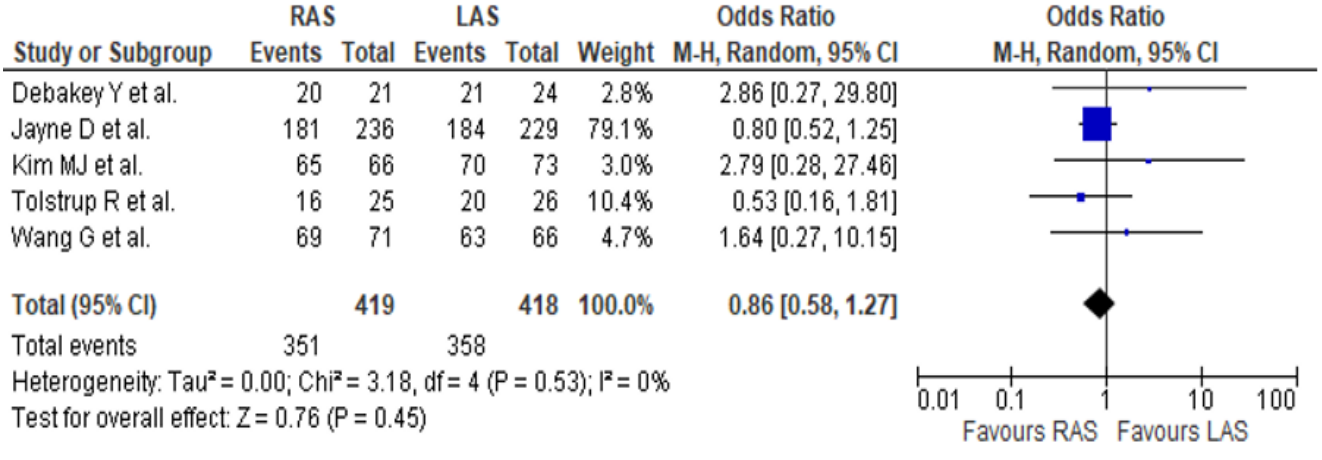
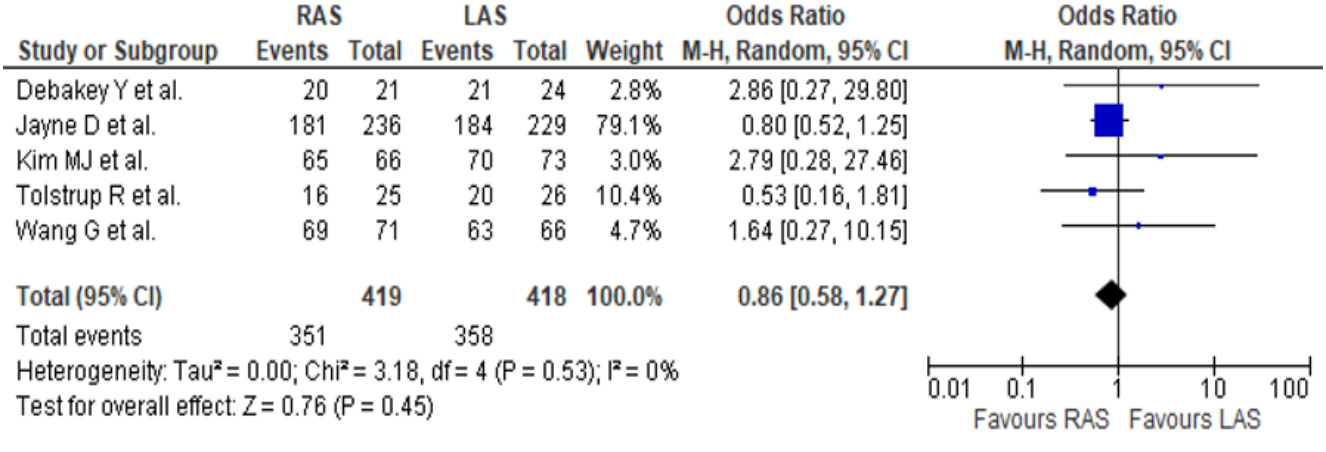
Neoadjuvant chemoradiotherapy




Sphincter-preserving surgery




Conversion rate to laparotomy




No significant differences were found in the number of patients receiving neoadjuvant chemoradiotherapy (Figure II), intraoperative estimated blood loss, the number of patients undergoing sphincter-preserving surgery (Figure II), and the number of patients having diverting stoma between RAS and LAS from the analysis.

### Conversion rate

The conversion rate from RAS to open surgery, and LAS to open surgery ranged from 0 to 8.1%, and 0 to 38.5% in the analysis of 5 studies (Figure II). Overall, twenty-two (6.0%) of 366 cases of RAS and 42 (11.4%) of 369 of LAS were converted to laparotomy. However, the conversion rate had no significant difference between the 2 groups. No heterogeneity was found among the institutions.

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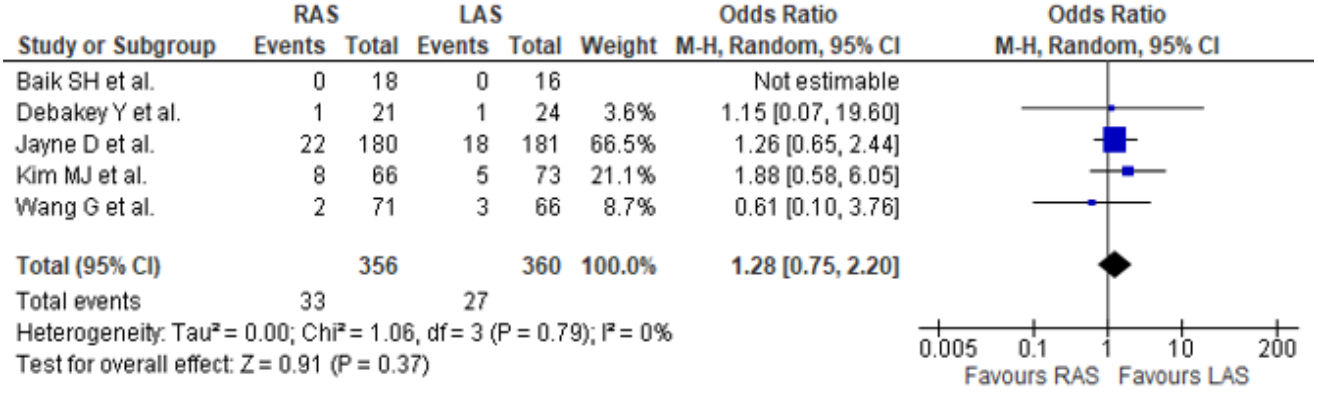
## Clinical course

There was no significant difference in time to bowel movement and duration of hospital stay. Examining 628 resections (328 RAS and 320 LAS), 2 (0.6%) and 3 (0.9%)) perioperative mortality occurred among patients who underwent RAS and LAS, respectively. There were two deaths (0.6%) from RAS and three deaths (0.94%) from LAS, but no significant difference was found in mortality. One of the causes of laparoscopic death was anastomotic leakage and the remaining four deaths were related the surgical intervention and involved a septic complication.

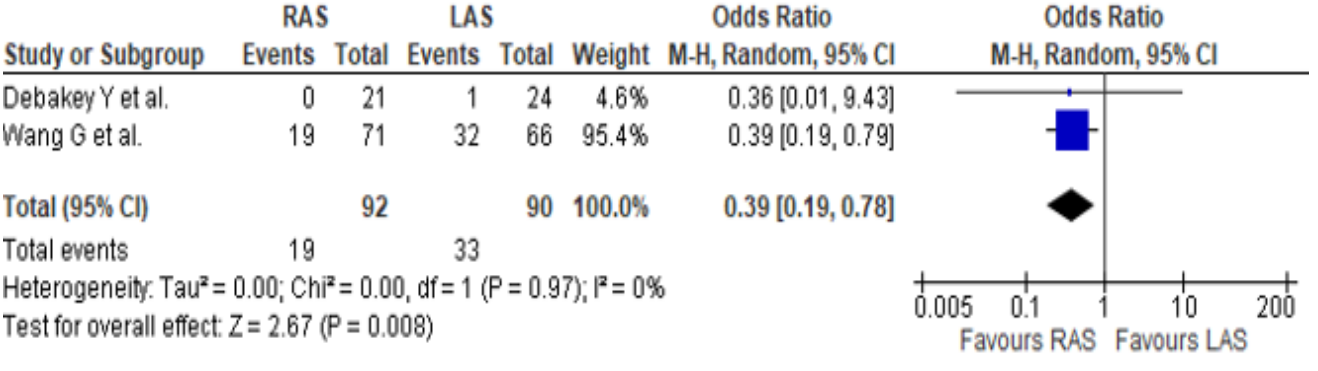
## Postoperative complication

The occurrence rate of overall postoperative complications, postoperative intraabdominal bleeding, anastomotic leakage (Figure III), wound infection, intraabdominal abscess, ileus, deep vein thrombosis, pneumonia, and urinary tract infection did not differ significantly between the two procedures. No heterogeneity was found among institutions. All the five papers referred to the rate of anastomotic leakage, with rates of 0-12.2% for RAS and 0-9.9% for LAS. The overall rate of anastomotic leakage was 9.3% in RAS and 7.5% in LAS. The rate of erectile dysfunction was significantly lower in RAS than LAS (p= 0.008) (Figure III).

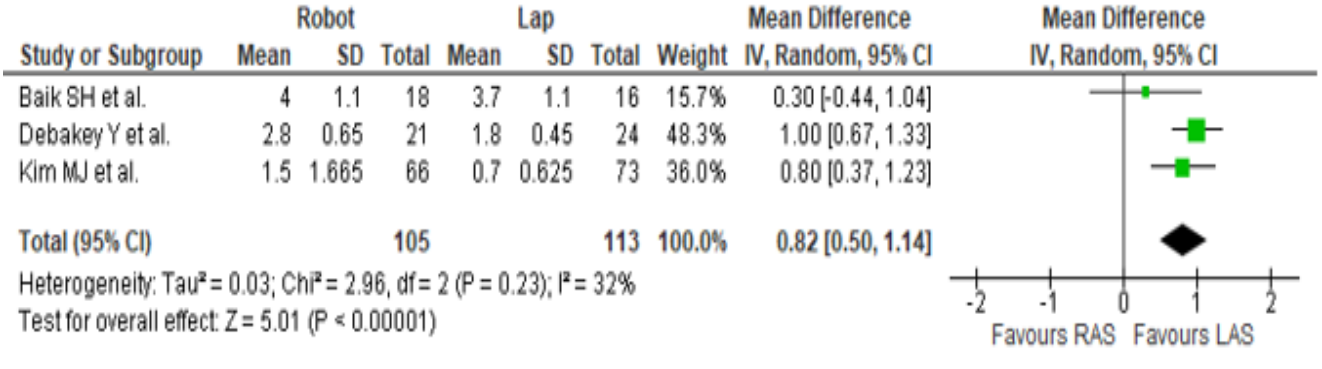
### Anastomotic leakage




### Erectile dysfunction




### Distal margin (cm)

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### Pathological findings

In resected specimen, no significant difference was found in number of retrieved lymph nodes, number of cases with circumferential resection margin involvement, and length of proximal margin. There was no significant difference in the degree of TME for complete, nearly complete, and incomplete. Distal margin is significantly longer in RAS than in LAS by 0.82 cm (weighted mean difference =0.82; 95% CI = 0.50–1.14; $p < 0.00001$) (Figure III).

### Heterogeneity

Significant heterogeneity was found between studies with respect to operative time, estimated blood loss, time to bowel movement, and duration of hospital stay.

## Discussion

We previously conducted a meta-analysis comparing RAS with LAS for rectal cancer by non-randomized controlled trials [12]. RAS was significantly associated with a 44.80 minute greater operation time and a lower conversion rate to laparotomy, compared LAS. In this study, we have performed a meta-analysis comparing RAS with LAS for rectal cancer by randomized controlled trials. This pooled data revealed that the operative time for RAS was significantly greater, by 42.90 min, than for LAS, similar to the results described previously. In the ROLARR trial, participating surgeons had to perform at least 30 minimally invasive surgery (RAS or LAS) before taking part in the study. The surgeons had experience performing LAS in more than 500 patients with rectal cancer and conducting RAS in about 30 patients before the trial [13]. The learning curve of LAS and RAS for colorectal cancer is described to be from 30 to 70 cases [22, 23], and from 15 to 35 cases [24, 25], respectively. Although most surgeons are suspected to be already skilled to LAS, they may be in learning curve because RAS is a relatively new surgical procedure. Another reason may be that the set-up time for RAS is longer than that of LAS. The operation time for RAS will be expected to decrease in future, as surgeons experience RAS. Significant heterogeneity of the operation time between studies may depend on where the surgeons are in the learning curve.

The conversion rates from RAS and LAS to laparotomy in this study were 0 to 8.1% and 0 to 12.2%, respectively, with no significant difference. The overall conversion rates to laparotomy were 22 (6.0%) of 366 RAS and 42 (11.4%) of 369 LAS, respectively. No heterogeneity was found among the institutions. In our previous and other literatures examining non-randomized clinical trials, however, RAS had significantly lower conversion rate to laparotomy than LAS [12]. Jayne et al. examined the conversion rate according to the surgeon's experience with RAS. It was reported that the benefit of RAS compared with LAS, with respect to conversion rate, is greater under surgeons who have more RAS experience, regardless of their level of LAS experience. As with operation time, the conversion rate to laparotomy in RAS may depend on the surgeon's experience.

If so, the conversion rate to laparotomy in RAS may decrease as surgeons experience more RAS. On the other hand, Jayne et al. described that results from the multilevel logistic regression model shows significantly increased odds of conversion in obese patients and in men [13]. In the non-randomized clinical trials, it may be possible that LAS group was biased compared to RAS group in terms of gender ratio, BMI, and tumor condition and so on.

Overall postoperative complications, postoperative intraabdominal bleeding, anastomotic leakage, wound infection, intraabdominal abscess, ileus, deep vein thrombosis, pneumonia, and urinary tract infection did not differ significantly between RAS and LAS. Five papers referred to the rate of anastomotic leakage, with rates of 0-12.2% for RAS and 0-9.9% for LAS. The reported anastomotic leakage rates suggest that both RAS and LAS may be feasible procedures [26]; this finding suggests that the safety and feasibility of RAS is similar to that of LAS for rectal cancer. In this study, the rate of erectile dysfunction was significantly lower in RAS than LAS. The degrees of freedom of surgical instruments were limited with 2D images in LAS. On the other hand, a high-definition 3D camera is used to obtain a 3D image, and small and highly flexible instruments can be used in RAS. From the above, RAS may have less pelvic autonomic nerve damage than LAS.

In resected specimen, no significant difference was found in number of retrieved lymph nodes, number of cases with CRM involvement, and length of PM. There was no significant difference in the degree of TME for complete, nearly complete, and incomplete. The above suggests that the quality of procedure for RAS is similar to that for LAS. The distal margin is significantly longer in RAS than in LAS by 0.82 cm (weighted mean difference =0.82; 95% CI = 0.50–1.14; p < 0.00001). RAS may allow surgery to be performed deeper in the pelvic cavity with its 3D images and dexterity of flexible wrist-like forceps, compared to LAS.

Significant heterogeneity of operative time, estimated blood loss, time to bowel movement, and duration of hospital stay between studies may be depend on the difference of points on learning curve of the surgeons, surgical procedures, tumor condition, and the factors of patients which are obesity, and so on.

Comparing to our previous meta-analysis for non-randomized clinical trials, this meta-analysis for randomized controlled trials had the following differences. The conversion rate to laparotomy in RAS was lower than in LAS without significant difference. The length of distal margin is significantly longer and the rate of erectile dysfunction in men was significantly lower in RAS than in LAS.

Since this study is a meta-analysis of randomized controlled trials, it has the highest level of evidence. However, there are several limitations in this study. First, the influence of preoperative chemoradiation to selection for the surgical procedures or prognosis could not be discussed. Second, RAS is a relatively recent procedure, so duration of following up patients is not adequate. Data for 5-year follow-up may be requested.

In conclusion, although there are several limitations, this meta-analysis showed that RAS is significantly associated with a greater operative time, a longer distal margin, and lower rate of erectile dysfunction, compared to LAS. The conversion rate to laparotomy was lower in RAS than in LAS, but there was no significant difference. It is suggested that RAS may be preferred over LAS for treatment of rectal cancer.

**Authorship Contributions:**

Protocol/project development: Ohtani, Ohno, Maeda, Nagahara, Ohira

Data collection or management: Ohtani, Nomura, Yamakoshi, Nagamori, Nakagawa

Data analysis: Ohtani, Shibutani, Fukuoka, Iseki, Ohno

Dr. Hiroshi Ohtani, Shinya Nomura, Yoshihito Yamakoshi, Mizuki Nagamori, Hiroji Nakagawa, Yoshioki Ohno, Yoshiteru Ohno, Kiyoshi Maeda, Hisashi Nagahara, Masatsune Shibutani, Tatsunari Fukuoka, Yasuhito Iseki, Kosei Hirakawa, and Masaichi Ohira, have no conflicts of interest or financial ties to disclose. All Authors meet the International Committee of Medical Journal Editors authorship criteria.

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