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Original Article

# Early outcomes from the Minimally Invasive Right Colectomy Anastomosis study (MIRCAST)

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## Abstract

**Background:** The impact of method of anastomosis and minimally invasive surgical technique on surgical and clinical outcomes after right hemicolectomy is uncertain. The aim of the MIRCAST study was to compare intracorporeal and extracorporeal anastomosis (ICA and ECA respectively), each using either a laparoscopic approach or robot-assisted surgery during right hemicolectomies for benign or malignant tumours.

**Methods:** This was an international, multicentre, prospective, observational, monitored, non-randomized, parallel, four-cohort study (laparoscopic ECA; laparoscopic ICA; robot-assisted ECA; robot-assisted ICA). High-volume surgeons (at least 30 minimally invasive right colectomy procedures/year) from 59 hospitals across 12 European countries treated patients over a 3-year interval The primary composite endpoint was 30-day success, defined by two measures of efficacy—absence of surgical wound infection and of any major complication within the first 30 days after surgery. Secondary outcomes were: overall complications, conversion rate, duration of operation, and number of lymph nodes harvested. Propensity score analysis was used for comparison of ICA with ECA, and robot-assisted surgery with laparoscopy.

**Results:** Some 1320 patients were included in an intention-to-treat analysis (laparoscopic ECA, 555; laparoscopic ICA, 356; robot-assisted ECA, 88; robot-assisted ICA, 321). No differences in the co-primary endpoint at 30 days after surgery were observed between cohorts (7.2 and 7.6 per cent in ECA and ICA groups respectively; 7.8 and 6.6 per cent in laparoscopic and robot-assisted groups). Lower overall complication rates were observed after ICA, specifically less ileus, and nausea and vomiting after robot-assisted procedures.

**Conclusion:** No difference in the composite outcome of surgical wound infections and severe postoperative complications was found between intracorporeal *versus* extracorporeal anastomosis or laparoscopy *versus* robot-assisted surgery.

## Introduction

The standard surgical treatment for neoplasms of the right colon is right colectomy (hemicolectomy). Open resection is associated with a relatively high rate of postoperative complications, but these, along with blood loss and duration of hospital stay, may be reduced using laparoscopy[1,2]. There are some limitations to the laparoscopic approach (LAP), including poor ergonomics, limited movement dexterity, and tremor[3], which may be overcome with robotic assistance. Robot-assisted surgery (RAS) might offer greater precision, flexibility, and control that could minimize the risk of collateral damage, and enable more precise oncological resections[4]. Although longer operating times have been reported for robotic right colectomy, it may reduce blood loss, postoperative complications, and wound infections, and lead to faster recovery of bowel function, with fewer conversions to open surgery, and shorter hospital stay compared with laparoscopic access[5–7].

Since the introduction of minimally invasive techniques, the optimal anastomotic technique after right colonic resection has been debated. Potential advantages in forming an intracorporeal anastomosis (ICA, where the anastomosis is performed inside the abdominal cavity during minimally invasive surgery) have been reported compared with extracorporeal anastomosis (ECA, where the anastomosis is performed by pulling the bowel out through a laparotomy). Reported benefits of ICA include smaller incision length, reduced time to first defaecation, reduced short-term morbidity, decreased rate of incisional hernias and reinterventions, and a shorter hospital stay compared with ECA[8–12]. It is possible that the ability of the surgeon to perform ICA may be enhanced by RAS, potentially reducing the

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conversion rate and improving the quality of suturing, but its value in postoperative recovery remains under discussion[13].

To date, many comparative trials of laparoscopic and robot-assisted right colectomy have been small, retrospective, non-randomized studies that did not control for anastomotic technique or the effect of RAS on anastomosis. Prospective, multicentre studies that simultaneously compare both surgical approach and anastomotic technique are needed to provide evidence for the optimal technique for minimally invasive right colectomy. Therefore, the MIRCAST (Minimally Invasive Right Colectomy Anastomosis) study was developed and designed[14]. MIRCAST is a large prospective, observational study designed to compare ICA and ECA after minimally invasive right colectomy, each using either laparoscopy or RAS, in patients with a benign or malignant, non-metastatic tumour of the right colon. The primary composite endpoint was the efficacy of the surgical method regarding surgical wound infections and postoperative complications (Clavien–Dindo grade III–V[15]) at 30 days after surgery. Preoperative, intraoperative, and 30-day follow-up assessments are reported in this article.

# Methods

## Study design and setting

This international, multicentre, prospective, observational, non-randomized, parallel, four-cohort study was performed according to a published protocol[14]. The study was supported by the European Society of Coloproctology and given advice by a steering committee of expert surgeons. The study received approval from all ethical boards across participant centres in Europe and followed the principles outlined in the Declaration of Helsinki. The study was registered at ClinicalTrials.gov (NCT03650517) on 28 August 2018 (study protocol version CI18/02 revision A, 21 February 2018). The protocol was modified in May 2020 after an interim analysis (study protocol version CI18/27, 14 May 2020).

High-volume surgeons, with experience of 30 or more minimally invasive right colectomy procedures per year, preferably with an enhanced recovery after surgery protocol already implemented, were selected to participate. Recruiting surgeons were asked to accrue a minimum of 15 procedures per year (up to 50 overall) for each cohort in which they were participating.

Patients were classified into one of four cohorts according to the planned surgical approach, which entailed two treatment assignments: ICA or ECA and RAS (using any of the available robotic systems at the participant institutions, which were Si, X or Xi da Vinci® Surgical Systems, Intuitive Surgical, Sunnyvale, CA, USA) or a LAP (using any laparoscopic device). All investigators were appointed to the one cohort matching their standard practice. Different surgeons from the same institution did not need to stick to the same cohort.

## Participants

Inclusion criteria were adult patients aged 18 years or older with a tumour in the right colon (benign or malignant disease) requiring an elective right colectomy with curative intent, a life expectancy of at least 12 weeks, and adequate performance status (Eastern Cooperative Oncology Group grade 0, 1 or 2). Before inclusion, all patients voluntarily signed and dated an informed consent form.

Exclusion criteria were: cT4b tumours, metastatic disease, planned colonic surgery along with other major concomitant procedures, or inflammatory bowel disease. Patients who were pregnant or suspected to be pregnant, had a co-morbid illness or condition precluding the use of surgery, were undergoing emergency procedures, or were unwilling to comply with all the follow-up study requirements were also excluded.

## Interventions

Patients were recruited to one of four cohorts, depending on the surgeon's experience and usual practice: laparoscopic right colectomy with ICA; robotic right colectomy with ICA; laparoscopic right colectomy with ECA; or robotic right colectomy with ECA. A screening log was maintained at each centre to identify potential selection bias. In this observational setting, any of the different anastomotic techniques were accepted. For the ICA cohorts, Pfannenstiel incision was the chosen wound for specimen extraction. If an operation could not be completed using any of these minimally invasive techniques, the procedure was converted to open surgery.

A site initiation visit was conducted in all centres before enrolment of the first patient. Data collection was done prospectively within a secure database (OpenClinica, Waltham, MA, USA) from the preoperative and intraoperative assessments, and the 30-day, 90-day, 1-year, and 2-year follow-up. Remote and in-person data monitoring was performed by two clinical research assistants. In-person data monitoring was undertaken for 25 per cent of randomly selected enrolled patients.

Based on the available literature when the protocol was designed, ICA was hypothesized to significantly reduce rates of surgical wound infection and severe complications. The efficacy of the surgical method was defined by the absence of both surgical wound infection and severe complication.

Surgical wound infection was assessed by clinical assessment on discharge and at 30 days after surgery. A severe complication had a Clavien–Dindo grade of III or higher. The primary composite endpoint, 30-day success, comprised two measures of efficacy—absence of surgical wound infection and of any major complication within the first 30 postoperative days.

Secondary outcomes included: overall complications (any intraoperative or postoperative complication, medical or surgical, Clavien–Dindo grades I–V), rate of unplanned conversions to open surgery, duration of operation, complete mesocolic excision, D3 lymphadenectomy, number of lymph nodes harvested, R0 resection, and duration of hospital stay. D3 lymphadenectomy was assessed using intraoperative surgical field images following pre-established criteria. Participating surgeons were informed of these criteria during the site initiation visit.

Other secondary outcomes to be addressed in future publications are: ventral hernia rate, 2-year oncological results, overall and disease-free survival, local recurrence and metastasis rates, and the EuroQol Five Dimensions (EuroQol Group, Rotterdam, the Netherlands) and European Organisation for Research and Treatment of Cancer quality-of-life questionnaires C30 and CR29.

## Sample size

Consideration was given to the sample size needed to attain a 30-day success rate of 85 per cent for the primary composite endpoint in each cohort. The 85 per cent estimate was determined using data from three studies[5,9,11], with surgical wound infection rates of 4–5 and 10–14 per cent in ICA and ECA respectively, and rates of Clavien–Dindo grade III or higher complications of 1.1–5 and 8–11 per cent in ICA and ECA respectively. Assuming a 95 per cent confidence interval, a

maximum margin of error of 5 per cent, and up to 18 per cent of patients lost to follow-up, 300 subjects were required per cohort.

The interim analysis conducted after recruitment of the first 300 patients reinforced the need to adjust the sample size of the ECA cohorts (protocol version CI18/27). To maintain the joint sample size of 600 patients having an ECA, and accounting for the actual accrual rates, it was re-estimated that $n$ and 600 – $n$ subjects were required in the RAS and LAP ECA cohorts respectively, $n$ being at least 60 but no more than 120.

## Statistical analysis

Descriptive statistics are presented for categorical and continuous variables (rates or proportions for the former, mean(s.d.) or median (i.q.r.) for the latter) by surgical approach (RAS and LAP), by type of anastomosis (ICA and ECA), and by the combination of both (LAP ECA, LAP ICA, RAS ICA, and RAS ECA). Patients were analysed on an intent-to-treat basis.

When used as an explanatory variable, the ICA indicator variable (0, ECA; 1, ICA) was adjusted by both the RAS indicator variable (0, LAP; 1, RAS) and the ICA propensity score. Likewise, when used as an explanatory variable, the RAS indicator variable was adjusted by that of the ICA as well as by the RAS propensity score. On the other hand, when used as an explanatory variable, the combination of ICA and RAS indicator variables (0, LAP ECA; 1, LAP ICA; 2, RAS ICA), was adjusted by just its propensity score. The ICA (or RAS) propensity score was defined as the probability of being in an ICA (or RAS) cohort conditional on potential confounders: age, sex, BMI, ASA fitness grade, Charlson Co-morbidity Index (CCI) score, history of abdominal surgery, previous treatment for abdominal disease, mechanical bowel preparation, and preoperative prophylaxis with oral antibiotics. The same confounders were used to build the ICA–RAS combination propensity score, defined as the probability of being in a certain cohort conditional on such confounders (a multinomial regression approach was used). Although potentially redundant, both ASA grade and CCI score were included in the propensity scores. The unexplained variability between them was assumed to be greater (and thus worthy of being modelled) than their degree of collinearity.

Analysis of the combination of the RAS and ICA indicator variables can be regarded as a sensitivity analysis for those with just RAS or ICA as explanatory variables. It should be noted that RAS ECA cohort results are not provided, as an insufficient number of patients was enrolled in this cohort for the tests to be adequately powered. Patients were analysed on an intention-to-treat basis.

Stata® 16 software was used for statistical analysis (StataCorp, College Station, TX, USA).

Missing data resulted in exit from the study of patients without a planned surgical approach. Multiple imputation procedures were used to replace missing data in the propensity score variables. Patients were excluded from any analysis involving variables for which they lacked data.

## Results

Between November 2018 and November 2021, 1848 patients were assessed for eligibility; 478 patients did not meet inclusion criteria or met one or more exclusion criteria and were not enrolled in the study. Therefore, 1370 patient records were submitted for analysis. Fifty patients did not have cohort/operative information nor any data included in the electronic case report form and were excluded, which left 1320 patients for final analysis (from 59 institutions across 12 European countries). Of

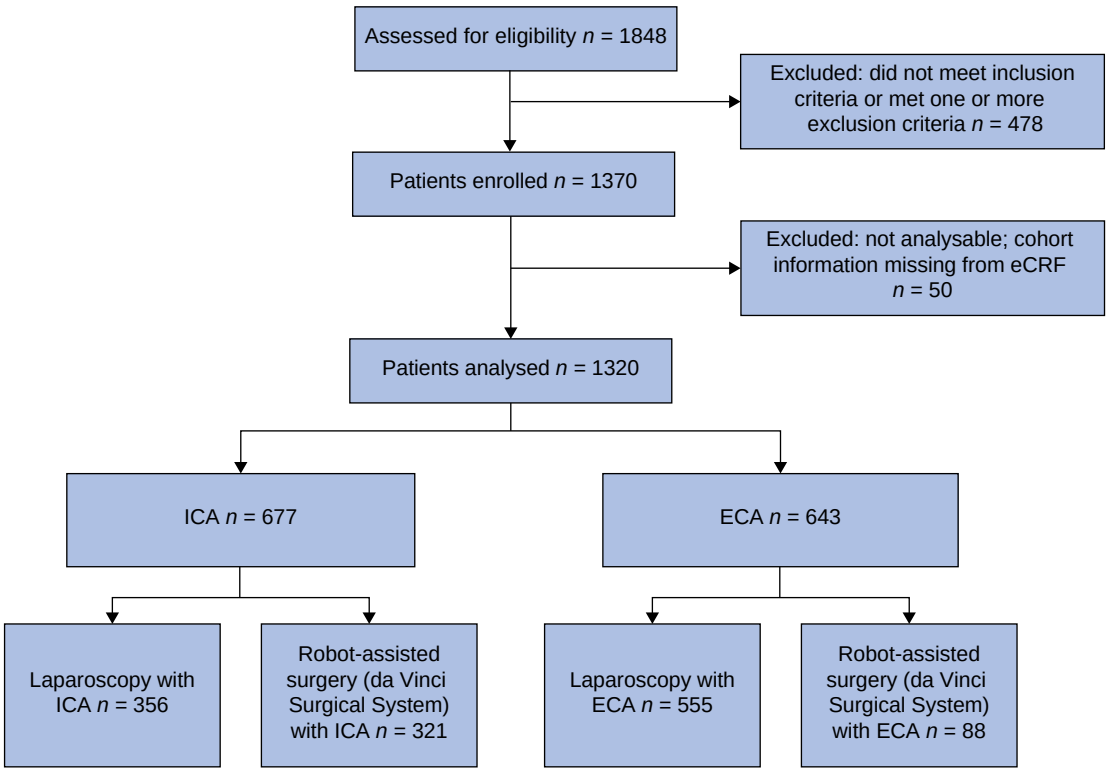


**Fig. 1 MIRCAST study flow chart**

eCRF, electronic case record form; ICA, intracorporeal anastomosis; ECA, extracorporeal anastomosis.

**Table 1 Patient demographic and clinical characteristics: propensity score variables according to anastomotic technique and surgical approach**

| | ICA | ECA | RAS | LAP | LAP ECA | LAP ICA | RAS ICA | RAS ECA |
|---|---|---|---|---|---|---|---|---|
| Age (years) | 70.49 | 71.44 | 70.67 | 71.10 | 71.54 | 70.37 | 70.62 | 70.82 |
| Sex ratio (F : M) | 303 : 302 | 292 : 315 | 193 : 181 | 402 : 436 | 249 : 272 | 153 : 164 | 150 : 138 | 43 : 43 |
| BMI (kg/m$^2$) | 26.65 | 26.63 | 26.61 | 26.65 | 26.63 | 26.68 | 26.61 | 26.60 |
| **ASA fitness grade** | | | | | | | | |
| I | 53 (8.70) | 40 (6.61) | 31 (8.24) | 62 (7.40) | 33 (6.38) | 29 (9.03) | 24 (8.33) | 7 (7.95) |
| II | 341 (55.99) | 303 (50.08) | 223 (59.31) | 421 (50.24) | 252 (48.74) | 169 (52.65) | 172 (59.72) | 51 (57.95) |
| III | 212 (34.81) | 249 (41.16) | 119 (31.65) | 342 (40.81) | 220 (42.55) | 122 (38.01) | 90 (31.25) | 29 (32.95) |
| IV | 3 (0.49) | 13 (2.15) | 3 (0.8) | 13 (1.55) | 12 (2.32) | 1 (0.31) | 2 (0.69) | 1 (1.14) |
| Charlson Co-morbidity Index score | 2.47 | 2.09 | 2.19 | 2.32 | 2.20 | 2.50 | 2.43 | 1.41 |
| **Previous treatment for abdominal disease** | | | | | | | | |
| No | 591 (97.36) | 596 (98.03) | 368 (98.13) | 819 (97.50) | 511 (98.27) | 308 (96.25) | 283 (98.61) | 85 (96.59) |
| Yes | 16 (2.64) | 12 (1.97) | 7 (1.87) | 21 (2.50) | 9 (1.73) | 12 (3.75) | 4 (1.39) | 3 (3.41) |
| **Previous abdominal surgery** | | | | | | | | |
| No | 374 (61.72) | 391 (64.42) | 242 (64.53) | 523 (62.41) | 327 (63.01) | 196 (61.44) | 178 (62.02) | 64 (72.73) |
| Yes | 232 (38.28) | 216 (35.58) | 133 (35.47) | 315 (37.59) | 192 (36.99) | 123 (38.56) | 109 (37.98) | 24 (27.27) |
| **Mechanical bowel preparation** | | | | | | | | |
| No | 356 (59.04) | 384 (63.68) | 268 (71.85) | 472 (56.66) | 303 (58.83) | 169 (53.14) | 187 (65.61) | 81 (92.05) |
| Yes | 247 (40.96) | 219 (36.32) | 105 (28.15) | 361 (43.34) | 212 (41.17) | 149 (46.86) | 98 (34.39) | 7 (7.95) |
| **Preoperative antibiotic prophylaxis** | | | | | | | | |
| No | 45 (7.43) | 24 (3.97) | 44 (11.76) | 25 (2.99) | 18 (3.48) | 7 (2.19) | 38 (13.29) | 6 (6.82) |
| Yes | 561 (92.57) | 581 (96.03) | 330 (88.24) | 812 (97.01) | 499 (96.52) | 313 (97.81) | 248 (86.71) | 82 (93.18) |

Values are *n* (%) unless otherwise indicated. ICA, intracorporeal anastomosis; ECA, extracorporeal anastomosis; RAS, robot-assisted surgery; LAP, laparoscopic approach.

**Table 2 Patient demographic characteristics: other clinical variables according to anastomotic technique and surgical approach**

| | ICA | ECA | RAS | LAP | LAP ECA | LAP ICA | RAS ICA | RAS ECA |
|---|---|---|---|---|---|---|---|---|
| **Primary indication for surgery** | | | | | | | | |
| Benign colonic tumour | 62 (10.16) | 55 (9.03) | 32 (8.44) | 85 (10.12) | 50 (9.60) | 35 (10.97) | 27 (9.28) | 5 (5.68) |
| Malignant appendix | 10 (1.64) | 13 (2.13) | 8 (2.11) | 15 (1.79) | 9 (1.73) | 6 (1.88) | 4 (1.37) | 4 (4.55) |
| Caecal cancer | 193 (31.64) | 218 (35.80) | 105 (27.70) | 306 (36.43) | 193 (37.04) | 113 (35.42) | 80 (27.49) | 25 (28.41) |
| Ascending colonic cancer | 212 (34.75) | 205 (33.66) | 159 (41.95) | 258 (30.71) | 167 (32.05) | 91 (28.53) | 121 (41.58) | 38 (43.18) |
| Hepatic flexure cancer | 89 (14.59) | 70 (11.49) | 45 (11.87) | 114 (13.57) | 62 (11.90) | 52 (16.30) | 37 (12.71) | 8 (9.09) |
| Transverse colonic cancer | 44 (7.21) | 48 (7.77) | 30 (7.92) | 62 (7.38) | 40 (7.68) | 22 (6.90) | 22 (7.56) | 8 (9.09) |
| **Type of colectomy** | | | | | | | | |
| Right | 521 (85.97) | 529 (86.72) | 327 (87.43) | 723 (85.87) | 452 (86.59) | 271 (84.69) | 250 (87.41) | 77 (87.50) |
| Extended Right | 85 (14.03) | 81 (13.28) | 47 (12.57) | 119 (14.13) | 70 (13.41) | 49 (15.31) | 36 (12.59) | 11 (12.50) |
| **T category** | | | | | | | | |
| Tx | 1 (0.22) | 1 (0.21) | 1 (0.37) | 1 (0.15) | 1 (0.26) | 0 (0) | 1 (0.53) | 0 (0) |
| Tis | 14 (3.02) | 16 (3.42) | 6 (2.22) | 24 (3.63) | 13 (3.35) | 11 (4.03) | 3 (1.58) | 3 (3.75) |
| T1 | 38 (8.21) | 48 (10.26) | 28 (10.37) | 58 (8.77) | 37 (9.54) | 21 (7.69) | 17 (8.95) | 11 (13.75) |
| T2 | 92 (19.87) | 101 (21.58) | 58 (21.48) | 135 (20.42) | 79 (20.36) | 56 (20.51) | 36 (18.95) | 22 (27.50) |
| T3 | 253 (54.64) | 248 (52.99) | 141 (52.22) | 360 (54.46) | 211 (54.38) | 149 (54.58) | 104 (54.74) | 37 (46.25) |
| T4 | 65 (14.04) | 54 (11.54) | 36 (13.33) | 83 (12.56) | 47 (12.11) | 36 (13.19) | 29 (15.26) | 7 (8.75) |
| **N category** | | | | | | | | |
| N0 | 339 (69.75) | 321 (67.15) | 187 (67.03) | 473 (69.05) | 263 (66.58) | 210 (72.41) | 129 (65.82) | 58 (69.88) |
| N1 | 98 (20.16) | 112 (23.43) | 65 (23.30) | 145 (21.17) | 91 (23.04) | 54 (18.62) | 44 (22.45) | 21 (25.30) |
| N2 | 4 (0.82) | 6 (1.26) | 5 (1.79) | 5 (0.73) | 3 (0.76) | 2 (0.69) | 2 (1.02) | 3 (3.61) |
| N2a | 23 (4.73) | 22 (4.60) | 12 (4.30) | 33 (4.82) | 21 (5.32) | 12 (4.14) | 11 (5.61) | 1 (1.20) |
| N2b | 22 (4.53) | 17 (3.56) | 10 (3.58) | 29 (4.23) | 17 (4.30) | 12 (4.14) | 10 (5.10) | 0 (0) |

Values are *n* (%) unless otherwise indicated. ICA, intracorporeal anastomosis; ECA, extracorporeal anastomosis; RAS, robot-assisted surgery; LAP, laparoscopic approach.

these, 643 patients were in the ECA cohort and 677 in the ICA cohort; 555 were treated with LAP ECA, 356 with LAP ICA, 88 with RAS ECA, and 321 with RAS ICA (*Fig. 1*).

## Patient demographics

No apparent differences were observed in age, sex, BMI, tumour location, or previous treatment for abdominal disease or previous abdominal surgery when patients were stratified by anastomotic technique or surgical approach. Patients in the ECA and LAP groups had a statistically significantly higher ASA grade, and those having ICA had a higher CCI score, although this was of doubtful clinical significance. A higher proportion of patients in the LAP cohort underwent mechanical bowel preparation, whereas a higher proportion in both ECA and LAP groups received prophylaxis with oral antibiotics (*Tables 1* and *2*).

## Primary endpoints

Neither the anastomotic technique (ECA, ICA) nor the surgical approach (RAS, LAP) had an impact in the primary composite endpoint of 30-day success (absence of surgical wound infection and of severe complications) (*Table 3*). None of the different cohorts (LAP ICA, RAS ICA, LAP ECA) was found to be associated with the primary composite endpoint in independent comparisons with the rest of the cohorts (*Table 4*).

**Table 3 Primary and secondary endpoints, and postoperative complications by type of anastomosis and by surgical approach**

| | ICA *versus* ECA (reference) | | | | RAS *versus* LAP (reference) | | | |
|---|---|---|---|---|---|---|---|---|
| | Missing data (%) | Prevalence (%)* | OR* | P | Missing data | Prevalence (%)* | OR* | P |
| **Primary endpoint** | | | | | | | | |
| Severe wound infection and/or severe complication | 0.48 | 7.64 *versus* 7.15 | 1.2 | 0.450 | 0.48 | 6.62 *versus* 7.75 | 0.72 | 0.221 |
| **Secondary endpoints** | | | | | | | | |
| Overall complications | 0 | 24.32 *versus* 27.17 | 0.64 | 0.001 | 0 | 20.30 *versus* 28.23 | 1.11 | 0.493 |
| Conversion | 2.85 | 2.44 *versus* 3.75 | 0.59 | 0.180 | 2.85 | 3.15 *versus* 3.07 | 1.24 | 0.607 |
| Anastomotic leak | 0 | 1.27 *versus* 1.89 | 0.85 | 0.729 | 0 | 0.51 *versus* 2.07 | 0.3 | 0.121 |
| Reoperation | 0 | 3.02 *versus* 4.42 | 0.75 | 0.392 | 0 | 3.30 *versus* 3.91 | 0.91 | 0.801 |
| **Complications** | | | | | | | | |
| Respiratory complications | 0 | 2.39 *versus* 4.43 | 0.83 | 0.610 | 0 | 1.79 *versus* 4.15 | 0.47 | 0.093 |
| Infectious complications | 0 | 6.49 *versus* 5.06 | 1.53 | 0.119 | 0 | 5.37 *versus* 5.88 | 0.78 | 0.385 |
| Cardiovascular complications | 0 | 1.60 *versus* 1.74 | 1.1 | 0.863 | 0 | 1.53 *versus* 1.73 | 0.74 | 0.617 |
| Ileus, nausea and vomiting | 0 | 4.31 *versus* 5.54 | 1.08 | 0.804 | 0 | 3.32 *versus* 5.66 | 0.360.359 | 0.007 |
| Surgical complications | 0 | 11.00 *versus* 10.76 | 1.15 | 0.488 | 0 | 9.41 *versus* 11.55 | 0.72 | 0.144 |
| Median duration of operation (min) | 4.20 | 180 *versus* 150† | 23,4823.483‡ | <0.001 | 4.20 | 198.5 *versus* 150† | 38.22‡ | <0.001 |
| Mean no. of lymph nodes harvested | 23.12 | 25.5 *versus* 24.4† | 0.18‡ | 0.823 | 23.12 | 27.9 *versus* 23.8† | 3.93‡ | <0.001 |
| Median duration of hospital stay (days) | 14.89 | 5 *versus* 6† | 0.57‡ | 0.571 | 14.89 | 5 *versus* 6† | −1.16‡ | 0.293 |
| Median time to deambulation (days) | 16.79 | 1 *versus* 1† | −0.36‡ | 0.759 | 16.79 | 1 *versus* 1† | 0.17‡ | 0.895 |
| Mean estimated blood loss (ml) | 9.34 | 72.5 *versus* 82.8† | −3.16‡ | 0.634 | 9.34 | 68 *versus* 81.9† | −12.16 | 0.090 |

*Except †mean or median and ‡estimate of difference for continuous variables. All analyses were performed with adjustment for propensity score variables (*Table 1*). ICA, intracorporeal anastomosis; ECA, extracorporeal anastomosis; RAS, robot-assisted surgery; LAP, laparoscopic approach.

**Table 4 Primary and secondary endpoints, and postoperative complications by type of anastomosis and surgical approach combined**

| | LAP ICA *versus* LAP ECA (reference) | | | RAS ICA *versus* LAP ECA (reference) | | | RAS ICA *versus* LAP ICA (reference) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Prevalence (%)* | OR* | P | Prevalence (%)* | OR* | P | Prevalence (%)* | OR* | P |
| **Primary endpoint** | | | | | | | | | |
| Severe wound infection and/or severe complication | 9.01 *versus* 7.01 | 1.29 | 0.338 | 6.21 *versus* 7.01 | 0.822 | 0.529 | 6.21 *versus* 9.01 | 0.64 | 0.167 |
| **Secondary endpoints** | | | | | | | | | |
| Overall complications | 29.41 *versus* 27.52 | 0.86 | 0.334 | 18.95 *versus* 27.52 | 0.620 | 0.005 | 18.95 *versus* 29.41 | 0.74 | 0.114 |
| Conversion | 2.50 *versus* 3.42 | 0.84 | 0.695 | 2.38 *versus* 3.42 | 0.654 | 0.398 | 2.38 *versus* 2.50 | 0.69 | 0.517 |
| Anastomotic leak | 1.86 *versus* 2.20 | 0,77 | 0.617 | 0.65 *versus* 2.20 | 0.318 | 0.144 | 0.65 *versus* 1.86 | 0.34 | 0.205 |
| Reoperation | 3.41 *versus* 4.21 | 0.87 | 0.707 | 2.61 *versus* 4.21 | 0.696 | 0.408 | 2.61 *versus* 3.41 | 0.71 | 0.483 |
| **Complications** | | | | | | | | | |
| Respiratory complications | 3.11 *versus* 4.77 | 0.78 | 0.540 | 1.64 *versus* 4.77 | 0.498 | 0.169 | 1.64 *versus* 3.11 | 0.57 | 0.326 |
| Infectious complications | 8.07 *versus* 4.59 | 1.8 | 0.052 | 4.61 *versus* 4.59 | 1.074 | 0.843 | 4.61 *versus* 8.07 | 0.65 | 0.217 |
| Cardiovascular complications | 1.87 *versus* 1.65 | 1.38 | 0.565 | 1.31 *versus* 1.65 | 0.587 | 0.512 | 1.31 *versus* 1.87 | 0.46 | 0.355 |
| Ileus, nausea and vomiting | 6.23 *versus* 5.32 | 1.39 | 0.291 | 2.30 *versus* 5.32 | 0.265 | 0.016 | 2.30 *versus* 6.23 | 0.20 | 0.005 |
| Surgical complications | 11.21 *versus* 11.74 | 0.91 | 0.683 | 10.78 *versus* 11.74 | 0.905 | 0.681 | 10.78 *versus* 11.21 | 0.97 | 0.906 |
| Duration of operation (min) | 165 *versus* 149† | 22‡ | <0.001 | 206 *versus* 149† | 61.000‡ | <0.001 | 206 *versus* 165† | 39‡ | <0.001 |
| No. of lymph nodes harvested | 24.7 *versus* 23† | 1.55‡ | 0.092 | 26.8 *versus* 23† | 3.406‡ | 0.001 | 26.8 *versus* 24.7† | 1.92‡ | 0.106 |
| Duration of hospital stay (days) | 5 *versus* 6† | 0.22‡ | 0.851 | 5 *versus* 6† | −0.320‡ | 0.775 | 5 *versus* 5† | −0.23‡ | 0.889 |
| Time to deambulation (days) | 1 *versus* 1† | −1.33‡ | 0.295 | 1 *versus* 1† | 0.216‡ | 0.904 | 1 *versus* 1† | 2.23‡ | 0.129 |
| Estimated blood loss (ml) | 75.6 *versus* 86.1† | −6.78‡ | 0.323 | 69 *versus* 86.1† | −14.079‡ | 0.109 | 69 *versus* 75.6† | −7.19‡ | 0.437 |

*Except †mean values and ‡estimate of difference for continuous variables. LAP, laparoscopic approach; ICA, intracorporeal anastomosis; ECA, extracorporeal anastomosis; RAS, robot-assisted surgery.

## Secondary endpoints

Compared with ECA, ICA was found to be associated with lower overall complication rates as an independent factor (OR 0.64; $P = 0.001$). ICA was more frequently done together with a Pfannenstiel incision as extraction site (OR 165.71; $P < 0.001$). Surgeons performing ICA also more frequently performed D3 lymphadenectomy (OR 3.03; $P < 0.001$), and used a fluorescent imaging system (OR 3.21; $P < 0.001$), as well as a mechanical anastomosis (OR 0.04; $P < 0.001$). ICA was also associated with longer operating times (increase in median of 23.5 min; $P < 0.001$) (*Table 3*).

RAS was more frequently used to perform D3 lymphadenectomy (OR 4.22; $P < 0.001$) and used together with fluorescent imaging (OR 4.11; $P < 0.001$). An intracorporeal handsewn anastomosis was more frequently chosen as anastomotic technique together with RAS than with LAP (OR 7.36; $P < 0.001$). RAS was associated with longer operating times (increase of 38 min; $P < 0.001$) and a greater number of harvested lymph nodes (OR 3.93; $P < 0.001$).

Exploratory analyses found that the use of two staple-line loads had an impact on the probability of having any complication compared with three staple-line loads (RAS or LAP) (OR 1.57; $P = 0.007$). Mechanical bowel preparation was associated with a lower proportion of any complications (OR 0.64; $P = 0.001$).

### Comparisons across cohorts

Separate effect sizes for RAS and ICA increased when the RAS ICA combination was considered (*Table 4*). RAS reduced nausea and vomiting (OR 0.36; $P = 0.007$) (*Table 4*). This effect only persisted in the RAS ICA *versus* the LAP ECA (OR 0.27; $P = 0.016$) and LAP ICA (OR 0.20; $P = 0.005$) cohort comparisons.

## Discussion

The MIRCAST collaboration between 59 institutions across Europe led to the largest prospective, non-randomized, monitored, multicentre cohort study to date in the field of ICA after right hemicolectomy. The principal finding of this study was that none of the four surgical treatment options was superior with regard to the composite outcome of surgical wound infection and severe complications (Clavien–Dindo grade III or higher).

In this study, the overall complication rates were lower than figures published in other trials[10,16,17]. Both ICA and RAS were associated with lower overall complication rates, although statistically significant differences were observed only for ICA. Cohort analysis found that the statistically significant difference was only present in the RAS ICA *versus* LAP ECA comparison. These differences were mainly due to a lower incidence of postoperative ileus, and consequently less kidney failure and a reduced need for use of nasogastric tubes during the postoperative phase, which is consistent with previous reports[18]. This may account for the present finding that ICA and RAS had a median hospital stay 1 day shorter than that in the other cohorts (5 *versus* 6 days; no statistically significant difference). Similar benefits have recently been reported in the ANCOR study[12] where postoperative stay was shorter for the ICA cohort. It should be noted that enrolment in some ANCOR trial cohorts was very low (30 patients in LAP ICA group), limiting the interpretation of these outcomes.

In the MIRCAST study, both ICA and RAS were associated with longer procedures (by 23.5 min for ICA and 38 min for RAS); this is similar to previously published results[18,19]. However, it is important to note that both ICA and RAS were more frequently done together with D3 lymphadenectomies and Pfannenstiel incisions, which require extra surgical time. Thus, it seems reasonable to conclude that, when the intervention is performed in expert centres such as those participating in MIRCAST, the increase in operating time was largely due to performing a different intervention (that is ICA *versus* ECA and D3 *versus* standard lymphadenectomy) rather than whether RAS was used or not.

No difference in conversion rate was observed between the different cohorts in MIRCAST and, in line with the good outcomes achieved, rates were very low in these expert centres (2.5–3.75 per cent); therefore, clinically relevant differences were difficult to determine. Furthermore, intraoperative blood loss was similar and less than 100 ml in all cohorts, with no significant or clinically relevant differences observed. In addition, very low anastomotic leak rates were reported, ranging from 0.51 to 2.07 per cent, and with no significant differences between the different techniques or surgical approaches. The patient demographics in MIRCAST were similar to those in previously published studies of patients treated with right hemicolectomy for tumours in the right colon. Preoperative oral antibiotic prophylaxis was more frequently used in the ECA and LAP cohorts. There was no impact on postoperative complications when oral antibiotic prophylactic use was analysed independently, in contrast to previous results[20–22]. The need for mechanical bowel preparation before right hemicolectomy has long been questioned.

This study found that surgical preference for one type of anastomosis (ICA or ECA) did not affect the lymph node harvest, but the surgical approach did; the yield increased with use of RAS. The greater use of D3 lymphadenectomy in RAS might have had an impact on this outcome[23].

One of the main concerns when choosing a non-randomized trial design was the possibility of finding a bias in the enrolled population—an inherent risk of observational studies. Keeping a screening log at each participating institution, together with remote and in-person monitoring, helped in controlling this bias. The non-randomized real-life design favoured the participation of expert surgeons and surgeons without access to a robotic platform in the different cohorts. Remote monitoring during the pandemic and in-person monitoring helped in increasing the quality of the data obtained and the value of this analysis.

Overall, optimal postoperative outcomes were observed, with a low rate of severe complications and anastomotic leak rates compared with the literature[16,24,25]. These outcomes probably benefitted from the selection criteria which ensured that expert surgeons from high-volume centres were enrolled[20,26]. These results establish a benchmark in the field of minimally invasive right hemicolectomy, but extrapolation of endpoints such as rates of anastomotic leak, conversion, or severe complications to less experienced centres may be limited.

## Collaborators

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## Author contributions

Marcos Gómez Ruiz (Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Writing—original draft, Writing—review & editing).

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## Data availability

The data that support the findings of this study are available from M.G.R. upon reasonable request.

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