Intent

The intent of this presentation is to provide data from a **single publication**.

This presentation must **not be considered as a substitute for a comprehensive literature review** for inclusion of all relevant outcomes.

We encourage all key stakeholders (e.g., surgeons, hospital executives, hospital robotic coordinators, etc.) to **review all available published materials and their own data** in order to make an informed decision.

Published literature

In order to provide benefit and risk information, Intuitive reviews the **highest available level of evidence** on representative procedures.

Intuitive strives to provide a **complete, fair, and balanced view of the clinical literature**. However, the selected publication may not be reflective of the broader literature and our materials should not be seen as a substitute for a comprehensive literature review for inclusion of all potential outcomes.

We encourage physicians to **review the original publications and all available literature** in order to make an informed decision. Clinical studies are available at pubmed.gov.

Clinical outcomes: Published literature

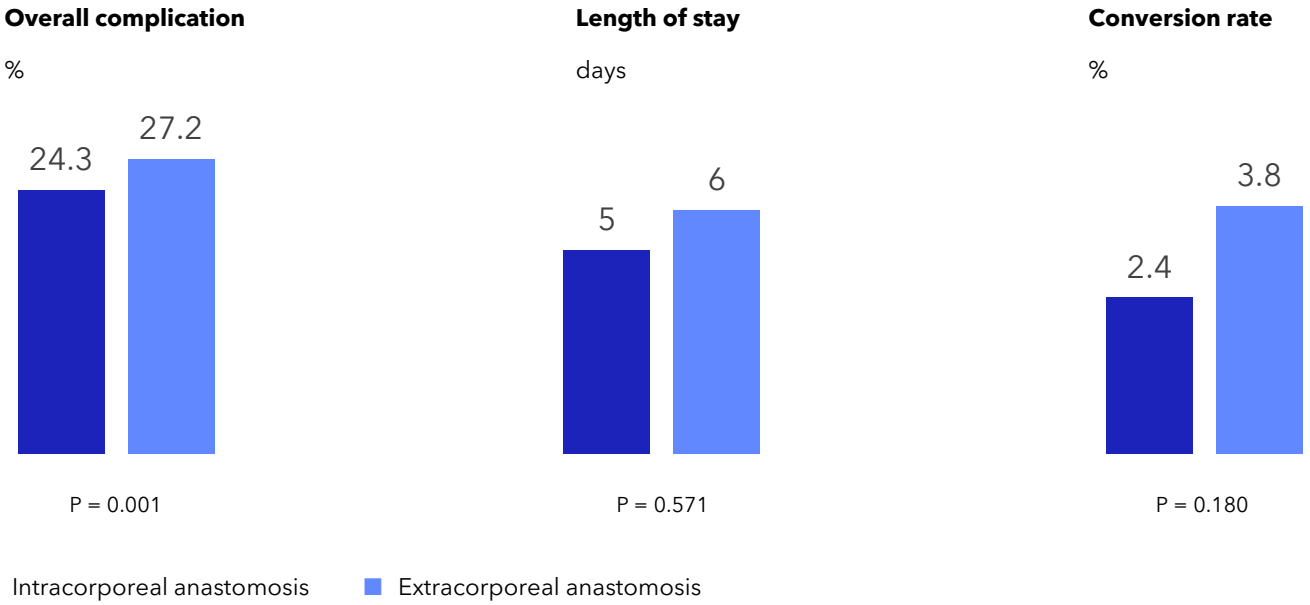
To provide a **complete, fair, and balanced view of the clinical literature**, Intuitive identified the following set of nine standard clinical outcomes to be reported for published literature, along with outcomes pertaining to primary intent of the publication.

Transfusion and/or estimated blood loss	**Readmission rate (30 days or other)**
Operative time	**Reoperation rate (30 days or other)**
Length of hospital stay	**Positive surgical margin rate and/or lymph node yield and/or lymph node upstaging**
Conversion rate (vs. laparoscopy, only)	**Perioperative mortality (30 days)**
Complication rate (30 days or other) (intraoperative and/or postoperative)	

Typical ranges for the clinical outcomes, as reported in the published literature, may be included in this presentation.

From a peer-reviewed publication by Marcos Gómez Ruiz , et al. 2023. DOI:10.1093/bjs/znad077

The 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)



Note: P value of <0.05 was considered statistically significant

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Purpose
The aim of the MIRCAST Study was to compare intracorporeal and extracorporeal anastomosis (ICA and ECA respectively), each using either a laparoscopic approach (LAP) or robotic-assisted surgery (RAS) during right hemicolectomies for benign or malignant tumours

Study design
International, multicenter, prospective, observational, non-randomized, parallel, four-cohort study (LAP ECA; LAP ICA; RAS ECA; RAS ICA) with total of 1320 patients enrolled.

Primary Endpoint:
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:
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.

Key results
Primary Outcome
Neither the anastomosis 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) . 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

Secondary Outcomes
When compared with ECA, an ICA was found to be associated with lower overall complication rates as in independent factor (OR 0.64; p=0.001). Surgeons performing ICA also more frequently performed D3 lymphadenectomy (OR 3.03; p<0.001).ICA was also associated with longer operation times (increase of a median of 23.5 minutes, p<0.001).RAS was more frequently used to perform D3 lymphadenectomy (OR 4.22; p<0.001).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 operation times (increase of 38 minutes; p<0.001) and a greater number of harvested lymph nodes (OR 3.93; p<0.001). Comparisons Across Cohorts- RAS reduced nausea and vomiting (OR 0.36; p=0.007) .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

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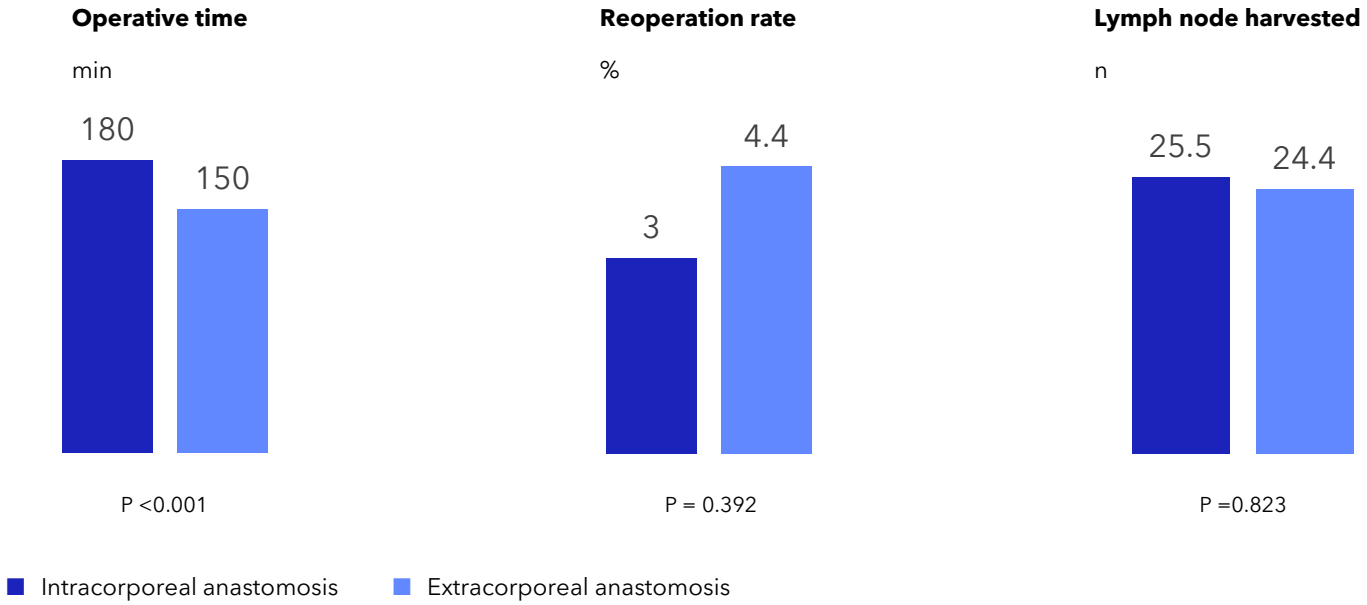

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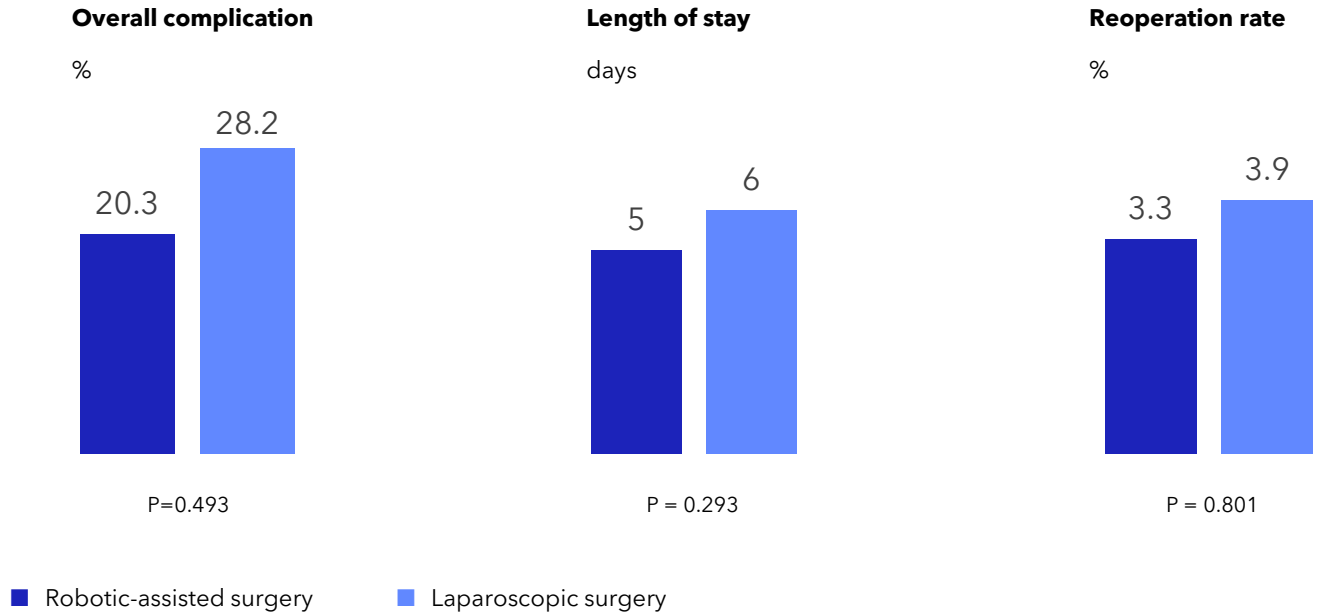

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Compared to laparoscopic surgery: Additional studies have shown da Vinci is associated with lower or comparable overall complication and lower or comparable length of stay and comparable reoperation rate

Please refer to congruency and typical range tables for additional information.

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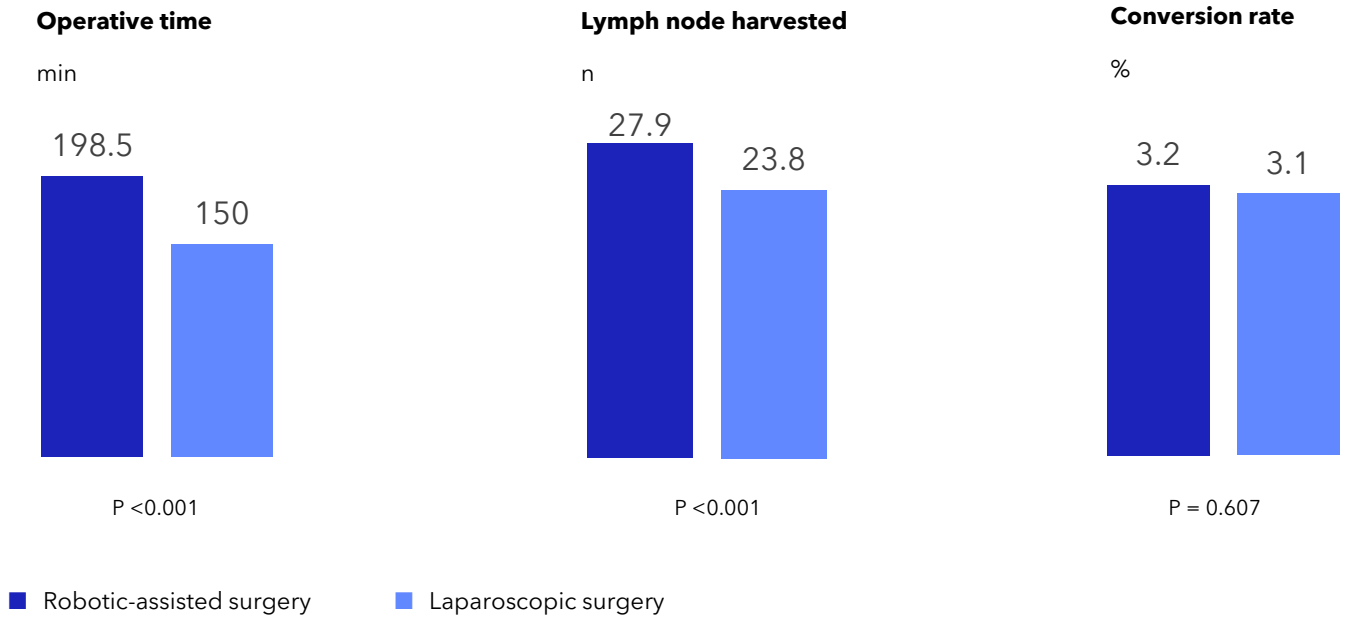

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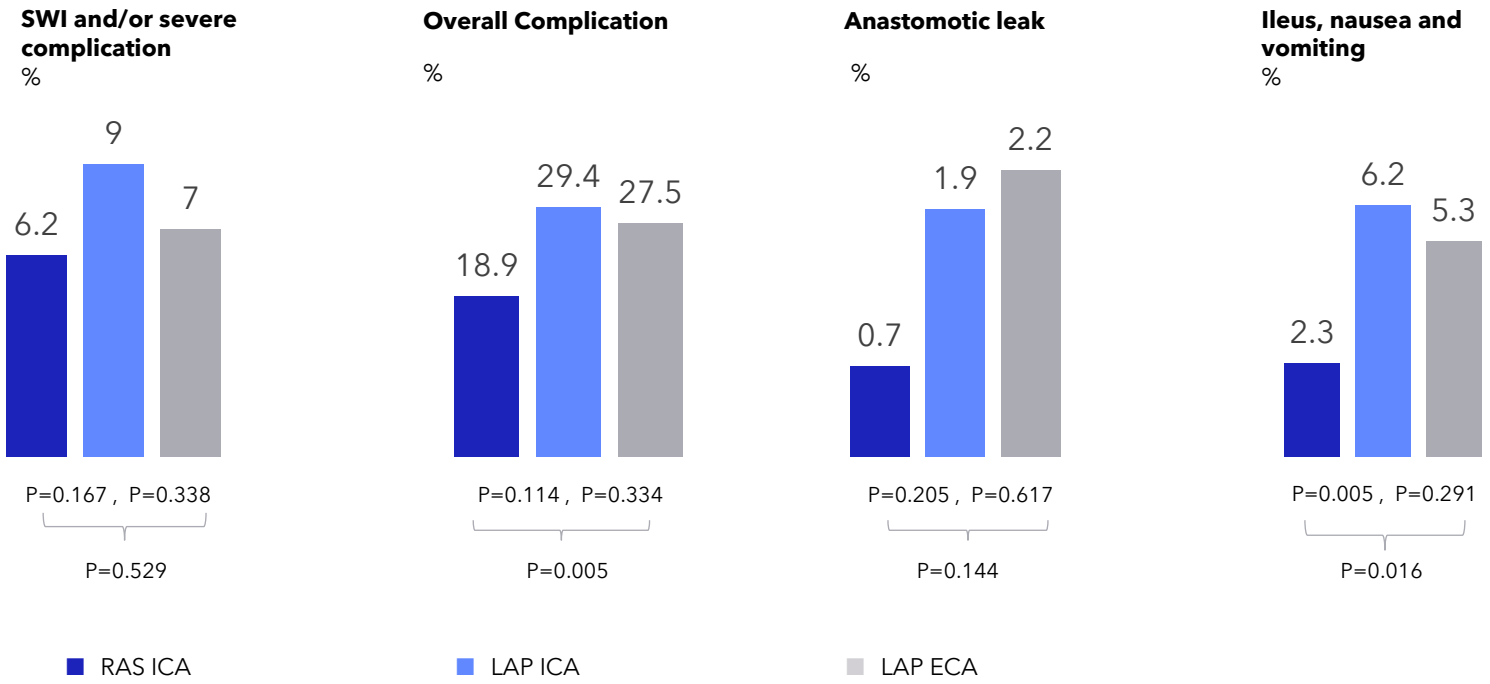

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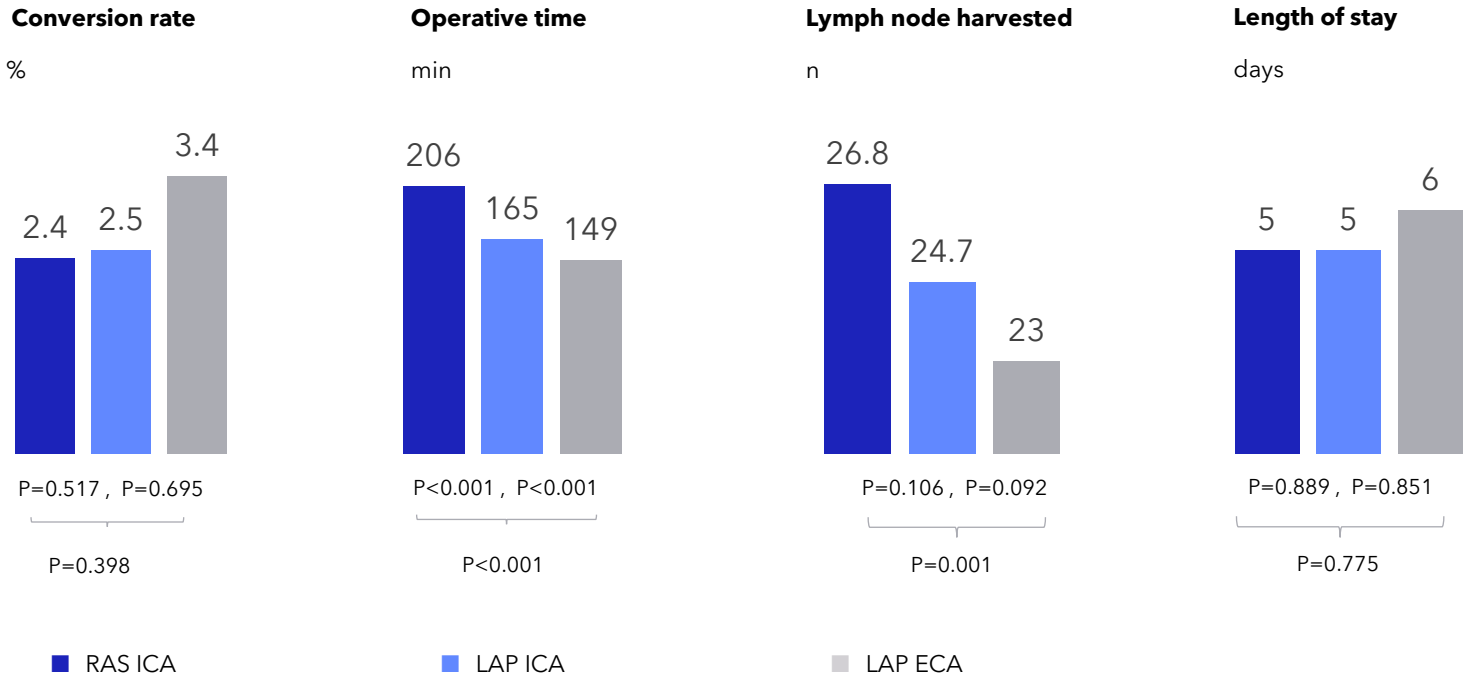

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Study information

Congruency for clinical outcomes in Right Colectomy

Additional recent studies* comparing Robotic assisted surgery to Laparoscopic surgery have shown the following results:

Outcome	Da Vinci RAS Right Colectomy Compared to Laparoscopic Surgery	References*
Surgical site infection	Comparable	Rausa, E et al. Surg Endosc 2018; 33(4): 1020-1032. DOI: 10.1007/s00464-018-6592-3
Conversion rate	Lower	Ma, S. et al. Asian J Surg 2018; 42(5): 589-598. DOI : 10.1016/j.asjsur.2018.11.002
	Comparable	Rausa, E et al. Surg Endosc 2018; 33(4): 1020-1032. DOI: 10.1007/s00464-018-6592-3
Reoperation rate	Comparable	Park, J. S et al. Surg Endosc 2018; 33(9): 2975-2981. DOI: 10.1007/s00464-018-6563-8
Overall complication	Lower	Trastulli S et al. PLoS One 2015; 10(7): e0134062 DOI : 10.1371/journal.pone.0134062
	Comparable	Rausa, E et al. Surg Endosc 2018; 33(4): 1020-1032. DOI: 10.1007/s00464-018-6592-3

*References represent the most recently reported study for each outcome and comparative finding combination.

Congruency for clinical outcomes in Right Colectomy

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Outcome	Da Vinci RAS Right Colectomy Compared to Laparoscopic Surgery	References*
Operative time	Higher	Ma, S. et al. Asian J Surg 2018; 42(5): 589-598. DOI : 10.1016/j.asjsur.2018.11.002
	Comparable	Rausa, E et al. Surg Endosc 2018; 33(4): 1020-1032. DOI: 10.1007/s00464-018-6592-3
Lymph nodes harvested	Higher	Trastulli S et al. PLoS One 2015; 10(7): e0134062 DOI : 10.1371/journal.pone.0134062
	Comparable	Rausa, E et al. Surg Endosc 2018; 33(4): 1020-1032. DOI: 10.1007/s00464-018-6592-3
Length of stay	Lower	Ma, S. et al. Asian J Surg 2018; 42(5): 589-598. DOI : 10.1016/j.asjsur.2018.11.002
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Typical ranges for clinical outcomes in Right Colectomy

Typical ranges report the minimum and maximum values for the most frequently reported metric of a given outcome in the published literature.

		Range of Statistical Metric	
		Da Vinci RAS vs. Laparoscopic Surgery	
Outcome	**Statistical Metric**	**Value**	**Reference**
Surgical site infection	Min OR	0.67	Trastulli S et al. PLoS One 2015; 10(7): e0134062 DOI: 10.1371/journal.pone.0134062
	Max OR	1.6	Rondelli, F. et al. Int J Surg 2015; 18: 75-82. DOI: 10.1016/j.ijsu.2015.04.044
Conversion rate	Min OR	0.34	Ma, S. et al. Asian J Surg 2018; 42(5): 589-598. DOI: 1016/j.asjsur.2018.11.002
	Max OR	1.13	Rondelli, F. et al. Int J Surg 2015; 18: 75-82.DOI : 10.1016/j.ijsu.2015.04.044
Reoperation rate	1 study reported outcome, no range possible		

OR = Odds Ratio: A measure of the strength of an association between exposure surgical approach and outcome. The OR represents the odds that an outcome will occur given a particular approach, compared to the odds of the outcome occurring in another approach. A OR >1 means there is a higher odds of outcome with the approach

MD = Mean Difference: Used in a meta-analysis, when all studies measure the same outcome using the same scale. The MD measures the absolute difference between the mean value in two groups

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		Range of Statistical Metric	
		Da Vinci RAS vs. Laparoscopic Surgery	
Outcome	Statistical Metric	Value	Reference
Overall complication	Min OR	0.62	Xu, H. et al. World J Surg Oncol 2014; 12(1): 274. DOI: 10.1186/1477-7819-12-274
	Max OR	1.65	Rondelli, F. et al. Int J Surg 2015; 18: 75-82.DOI : 10.1016/j.ijsu.2015.04.044
Operative time	Min MD	43.60	Ma, S. et al. Asian J Surg 2018; 42(5): 589-598. DOI : 10.1016/j.asjsur.2018.11.002
	Max MD	54.36	Rondelli, F. et al. Int J Surg 2015; 18: 75-82. DOI : 10.1016/j.ijsu.2015.04.044
Lymph nodes harvested	Min MD	1.58	Trastulli S et al. PLoS One 2015; 10(7): e0134062 DOI: 10.1371/journal.pone.0134062
	Max MD	2.11	Rondelli, F. et al. Int J Surg 2015; 18: 75-82. DOI: 10.1016/j.ijsu.2015.04.044
Length of stay	Min MD	0.22	Rondelli, F. et al. Int J Surg 2015; 18: 75-82. DOI : 10.1016/j.ijsu.2015.04.044
	Max MD	2.9	Rausa, E et al. Surg Endosc 2018; 33(4): 1020-1032. DOI: 10.1007/s00464-018-6592-3

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Study information:
Early Outcomes from the Minimally Invasive Right Colectomy Anastomosis study (MIRCAST)

Citation
Gómez Ruiz M, Espin-Basany E, Spinelli A, Cagigas Fernández C, Bollo Rodriguez J, María Enriquez Navascués J, Rautio T, Tiskus M; MIRCAST STUDY GROUP. Early outcomes from the Minimally Invasive Right Colectomy Anastomosis study (MIRCAST). Br J Surg. 2023 Jun 8:znad077. doi: 10.1093/bjs/znad077. Epub ahead of print. PMID: 37289913.

Study design
Type: International, multicenter, 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

Timeframe: Between 2018 and 2021

Patient population
1320 patients were analyzed in the intention-to-treat analysis (LAP ECA, n=555; LAP ICA, n=356; RAS ECA, n=88; RAS ICA, n=321)

Eligible patients were adult patients aged 18 years or older with a tumor (benign or malignant disease) in the right colon requiring an elective right colectomy with curative intent, a life expectancy of at least 12 weeks, and adequate performance status (ECOG scale grades 0, 1 or 2). Before inclusion, all patients voluntarily signed and dated an informed consent form. Exclusion criteria included cT4b tumors, 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 comorbid 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

Outcomes measured

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:
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 / conclusions
Primary Outcome
Neither the anastomosis 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) . 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.
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.

Key Secondary Outcomes
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(OR 0.64; p=0.001). Surgeons performing ICA also more frequently performed D3 lymphadenectomy (OR 3.03; p<0.001).ICA was also associated with longer operation times (increase of a median of 23.5 minutes, p<0.001).RAS was more frequently used to perform D3 lymphadenectomy (OR 4.22; p<0.001).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 operation times (increase of 38 minutes; p<0.001) and a greater number of harvested lymph nodes (OR 3.93; p<0.001).
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Conclusion: No difference in the composite outcome of surgical wound infections and severe postoperative complications was found between intracorporeal or extracorporeal anastomosis or laparoscopy and robot-assisted surgery

Study strengths
Overall ,optimal postoperative outcomes were observed with a low rate of severe complications and anastomatic leak rates compared with the literature .These outcomes probably benefitted from the selection criteria that ensured expert surgeons from high volume centres were enrolled

Study limitations
The results establish a benchmark in the field of minimally invasive right hemicolectomy, but extrapolation of endpoints such as anastomatic leak, conversion rate,or severe complications to less experienced centres may be limited

Study highlight

Product Information

The Intuitive Surgical Endoscopic Instrument Control Systems (da Vinci X and da Vinci Xi Surgical Systems) are intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures, and trans-oral otolaryngology surgical procedures restricted to benign tumors and malignant tumors classified as T1 and T2, and for benign base of tongue resection procedures. The systems are indicated for adult and pediatric use (except for trans-oral otolaryngology surgical procedures). They are intended to be used by trained physicians in an operating room environment.

The da Vinci X and da Vinci Xi Surgical Systems are class IIb medical devices CE marked (CE 2460) under the European Medical Devices Directive (93/42/EEC), manufactured by Intuitive Surgical, Inc. Refer to Instructions For Use before use.

Financial Disclosure

The MIRCAST Study Group has received a research grant from Intuitive Surgical (Sunnyvale, CA, USA)

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