

Background information

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.

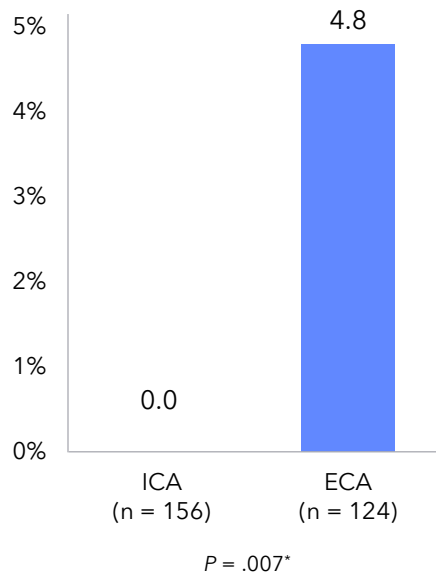
Transfusion and/or estimated blood loss	Readmission rate (30 days or other)
Operative time	Reoperation rate (30 days or other)
Length of hospital stay	Positive surgical margin rate and/or lymph node yield and/or lymph node upstaging
Conversion rate (vs. laparoscopy, only)	Perioperative mortality (30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

Individuals' outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics, and/or surgeon experience.

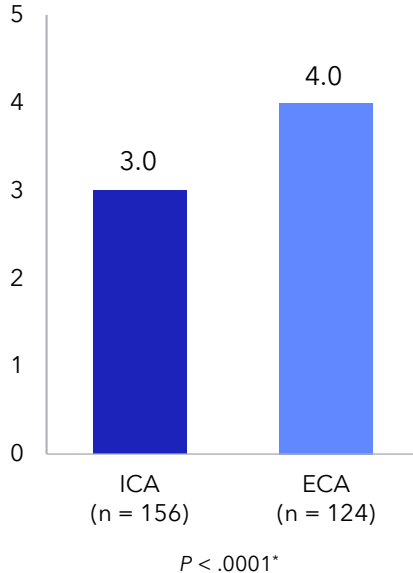
Typical ranges for the clinical outcomes, as reported in the published literature, may be included in this presentation.

Prospective, multicenter study comparing intracorporeal (ICA) and extracorporeal (ECA) anastomoses for right colectomy has shown that ICA is associated with fewer conversions to open surgery, shorter length of stay, and shorter gastrointestinal recovery time

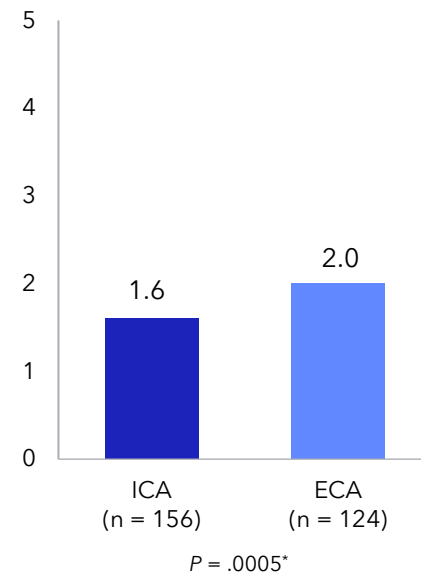
Conversion to open or hand-assisted laparoscopic surgery (%)



Length of stay (median days)



Time to first bowel movement (mean days)



*A *P* value of .05 or less was considered statistically significant

Compared to ECA, additional studies have shown that ICA is associated with shorter^{1,2,3} or comparable⁴ length of stay, lower conversion to open surgery,^{2,4} and shorter^{2,3} or comparable⁴ time to first bowel movement

Please refer to the [congruency](#) references for additional information.

Purpose

To compare intracorporeal (ICA) and extracorporeal (ECA) anastomoses outcomes for robotic-assisted and laparoscopic right colectomy.

Study design

Prospective, multicenter study from across 20 institutions from February 2018 to February 2, 2021, study submission. The study is an initial report of short-term outcomes up to 90 days postoperative for the ANCOR (ANastomotic COmparison in Right colectomy) trial.

Total number of patients: 280

ICA: 156 patients (robotic assisted: 125; laparoscopic: 31).

ECA: 124 patients (robotic assisted: 30; laparoscopic: 94).

Outcomes measured

Conversion to open surgery, operative time, length of stay, postoperative complication rates, intraoperative blood transfusions, anastomotic leaks, surgical site infections, hospital readmissions, reoperations, days to first bowel movement, days to first flatus, days to soft/regular diet, discharge status, and mean lymph node harvest for malignant cases

Key result

ICA was associated with fewer conversions to open or hand-assisted laparoscopic surgery, longer operative time, shorter length of stay, and shorter time to first flatus, first bowel movement, and soft/regular diet.

Study information

Congruency for clinical outcomes in right colectomy

Additional studies* comparing intracorporeal anastomosis to extracorporeal anastomosis

1. Van Oostendorp S, Elfrink A, Borstlap W, Schoonmade L, Sietses C, Meijerink J, Tuynman J. Intracorporeal versus extracorporeal anastomosis in right hemicolectomy: a systematic review and meta-analysis. *Surg Endosc*. 2017;31:64-77. PMID: 27287905
2. Cleary RK, Kassir A, Johnson CS, Bastawrous AL, Soliman MK, Marx DS, Giordano L, Reidy TJ, Parra-Davila E, Obias VJ, Carmichael JC, Pollock D, Pigazzi A. Intracorporeal versus extracorporeal anastomosis for minimally invasive right colectomy: A multi-center [sic] propensity score-matched comparison of outcomes. *PLoS One*. 2018 Oct 24;13(10):e0206277. doi: 10.1371/journal.pone.0206277. PMID: 30356298; PMCID: PMC6200279.
3. Feroci F, Lenzi E, Garzi A, Vannucchi A, Cantafio S, Scatizzi M. Intracorporeal versus extracorporeal anastomosis after laparoscopic right hemicolectomy for cancer: a systematic review and meta-analysis. *Int J Colorectal Dis*. 2013 Sep;28(9):1177-86. doi: 10.1007/s00384-013-1651-7. Epub 2013 Feb 1. PMID: 23371336.
4. Hanna MH, Hwang GS, Phelan MJ, Bui TL, Carmichael JC, Mills SD, Stamos MJ, Pigazzi A. Laparoscopic right hemicolectomy: short- and long-term outcomes of intracorporeal versus extracorporeal anastomosis. *Surg Endosc*. 2016 Sep;30(9):3933-42. doi: 10.1007/s00464-015-4704-x. Epub 2015 Dec 29. PMID: 26715015.

* References represent recently reported studies with relevant outcomes for comparison.

Study information: Intracorporeal and extracorporeal anastomosis for robotic-assisted and laparoscopic right colectomy: short-term outcomes of a multi-center [sic] prospective trial

Citation

Cleary, R.K., Silveira, M., Reidy, T.J. et al. Intracorporeal and extracorporeal anastomosis for robotic-assisted and laparoscopic right colectomy: short-term outcomes of a multi-center [sic] prospective trial. Surg Endosc (2021). <https://doi.org/10.1007/s00464-021-08780-9>

Study design

Type: Prospective, multicenter study comparing intracorporeal anastomosis (ICA) and extracorporeal anastomosis (ECA) in patients with benign or malignant disease, scheduled for laparoscopic or robotic-assisted right colectomy, from across 20 institutions.

Data sources: Case report forms were the primary data collection instruments for this study. Each study site entered clinical data into an electronic case report form directly uploaded to a secure centralized electronic clinical database (EDC). Data entry quality was monitored by the study sponsor.

Timeframe: February 2018 to February 2, 2021, study submission

Patient population

Total: 280 patients

ICA: 156 patients (robotic assisted: 125; laparoscopic: 31)
ECA: 124 patients (robotic assisted: 30; laparoscopic: 94)

Outcomes measured

Conversion to open surgery, operative time, length of stay, intraoperative and postoperative complication rates, intraoperative blood transfusions, anastomotic leaks, surgical site

infections, hospital readmissions, reoperations, days to first bowel movement, days to first flatus, days to soft/regular diet, discharge status, and mean lymph node harvest for malignant cases

Results / conclusions

Conversion rate (%) to open or hand-assisted laparoscopic surgery was lower for ICA when compared to ECA: 0% vs. 4.8%; $P = .007$.

Length of hospital stay [median days (IQR)] was lower for ICA when compared to ECA: 3 days vs. 4 days; $P < .0001$.

Time to first bowel movement (mean days \pm SD) was lower for ICA when compared to ECA: 1.6 ± 0.9 vs. 2.0 ± 1.1 ; $P = .0005$.

Operative time (mean minutes \pm SD) was longer for ICA when compared to ECA: 156 ± 50.2 vs. 118.2 ± 43.5 ; $P < .0001$.

Postoperative complications rate to discharge (%) was comparable for ICA when compared to ECA: 9.6% vs. 8.1%; $P = .6512$.

Number of lymph nodes harvested (mean \pm SD) was comparable for ICA when compared to ECA: 23.3 vs. 24.2; $P = 0.535$.

Anastomotic leak rate (%) was comparable for ICA when compared to ECA: 0.6% vs. 0%; per study text, no P value provided.

Superficial surgical site infection rate (%) was comparable for ICA when compared to ECA: 1.3% vs. 0%; per study text, no P value provided.

Intraoperative complications rate (%) was comparable for ICA when compared to ECA: 0.6% vs. 0%; per study text, no P value provided.

Readmission rate up to 90 days (%) was comparable for ICA when compared to ECA: 2.6% vs. 0.8%; $P = .3869$.

Reoperation rate up to 90 days (%) was comparable for ICA when compared to ECA: 0.6% vs. 0%; $P > 0.99$.

Intraoperative blood transfusion rate (%) was comparable for ICA when compared to ECA: 1.3% vs. 0.8%; $P > 0.99$.

Study strengths

The strength of this multicenter comparative study is that the results may be generalizable and representative of the real-world setting.

To ensure adequate experience, surgeons at participating sites were required to have performed a minimum of 50 right colectomies prior to contributing to a study arm.

Study limitations

Authors did not control for preoperative interventions, such as mechanical bowel preparation and elements of enhanced recovery pathways, and there was no unified method for diet resumption across all centers.

This study involved an uncommonly high number of institutions and surgeons, which may have contributed to increased variability and data heterogeneity.

Authors did not control for the degree of intracorporeal mobilization prior to extracorporeal extraction.

Study highlight

Study information: Intracorporeal and extracorporeal anastomosis for robotic-assisted and laparoscopic right colectomy: short-term outcomes of a multi-center prospective trial

Financial disclosure

This study was sponsored and funded by Intuitive Surgical, Inc., Sunnyvale, CA in association with the identified study investigators under a cooperative clinical trial agreement.

Drs. Kleary and Cannon are on the speaker's bureau for Intuitive Surgical, Inc.; Obias is a consultant for Intuitive Surgical, Inc; Johnson, McCormick, Lujan, Bastawrous, Gaetner, and Pigazzi report personal fees from Intuitive Surgical outside the submitted work; Landmann reports other from Intuitive Surgical during the conduct of the study.

[Study highlight](#)

Important safety information

Surgical risks

Surgical risks for bowel resection and other colorectal procedures (colectomy, sigmoidectomy, low anterior resection, abdominopelvic resection (APR), intersphincteric resection, proctectomy, rectopexy) include anastomotic leak, anastomotic stricture, and colorectal or anorectal dysfunction.

Important safety information

Serious complications may occur in any surgery, including surgery with the da Vinci surgical system, up to and including death. Examples of serious or life-threatening complications, which may require prolonged and/or unexpected hospitalization and/or reoperation, include but are not limited to, one or more of the following: injury to tissues/organs, bleeding, infection, and internal scarring that can cause long-lasting dysfunction/pain.

Risks specific to minimally invasive surgery, including surgery with the da Vinci surgical system, include but are not limited to, one or more of the following: temporary pain/nerve injury associated with positioning; a longer operative time, the need to convert to an open approach, or the need for additional or larger incision sites. Converting the procedure could result in a longer operative time, a longer time under anesthesia, and could lead to increased complications. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all da Vinci instruments.

For important safety information, indications for use, risks, full cautions and warnings, please also refer to www.intuitive.com/safety.

Individual outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics, and/or surgeon experience.

Da Vinci Xi/X system precaution statement

The demonstration of safety and effectiveness for the specific procedure(s) discussed in this material was based on evaluation of the device as a surgical tool and did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence) or treatment of the patient's underlying disease/condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon.

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