Evidence Navigator: Right Colectomy

Systematic literature review & meta-analysis as of March 1, 2024



Purpose

The Evidence Navigator is a slide presentation representing a summary of the meta-analysis of the highest level of evidence available specific to a given procedure and published as of a particular date. It is created by the Global Evidence Management team within Global Access, Value and Economics (GAVE). It includes information that is available in the public domain. It is a systematic review and meta-analysis of the peer-reviewed literature based on a timeframe within which a literature search has been conducted according to a set of concise inclusion and exclusion criteria. The results of the meta-analysis are presented in the form of forest plots summarized for each outcome according to a comparator and surgical approach of interest. The summary results are reflective of a specific period in time and are subject to change with increasing literature. All of the robotic-assisted surgery procedures mentioned within the Evidence Navigator were performed using a da Vinci[®] surgical system.

Statistical analysis

All summary measures are shown as odds ratios, risk ratios or risk differences when describing binary outcomes, or as weighted mean differences or standardized mean differences when describing continuous outcomes. Weighting is based on the study sample size and variability of the outcome. A random effect model is used if heterogeneity is statistically significant, otherwise a fixed effect model is used. The Mantel Haenszel summary statistic is used for the overall results. The meta-analysis is performed with RevMan 5.4 (Review Manager, Version 5.4. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) or R software (R Foundation for Statistical Computing, Vienna, Austria.URL https://www.R-project.org/).

Interpretation notes

When the effect size is measured as a standardized mean difference (SMD), or a risk difference (RD), it is not possible to provide a quantitative conclusion. In such cases, a qualitative conclusion is given with reference to its statistical significance. In some instances, studies may contain some overlapping patient populations. A redundancy check is performed in order to minimize this overlap and bias due to over-reporting.

INTUÎTIVE

Glossary

robotic-assisted surgery	
laparoscopic surgery	
level of evidence	
TA health technology assessment	
randomized controlled trial	
dds ratio	
mean difference	

	WMD	weighted mean difference
	RD	risk difference
	SMD	standardized mean difference
95% CI95% confidence intervalI2test statistic for heterogeneityEBLestimated blood loss		95% confidence interval
		test statistic for heterogeneity
		estimated blood loss
	LOS	length of hospital stay

Evidence Navigator: Right Colectomy Summary Slides

Systematic literature review & meta-analysis as of March 1, 2024





WHAT DOES THE LITERATURE SHOW?
 Systematic literature review:
 Da Vinci robotic-assisted right colectomy

Inclusion criteria

Robotic-assisted right colectomy performed with a da Vinci surgical system

January 1, 2010 - March 1, 2024

Level of Evidence 1b, 2b, 2c

RCT, prospective cohort studies, or large database study (with n≥20 in each cohort)

Exclusion criteria

Not in English

Paper reports on a pediatric population

Publication is an HTA that was not published in a peer-reviewed journal

Alternate technique/approach (e.g. single-port)

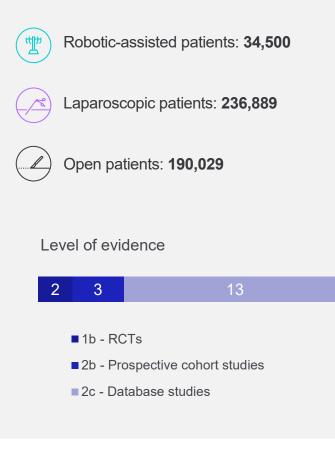
No stratified analysis by study arm

Right colectomy data mixed with other procedures or benign/cancer data mixed

Original research study does not provide quantitative results for outcomes of interest

Original research publication includes redundant patient population and similar conclusions

18 publications including:





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WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points:

Robotic-assisted vs. laparoscopic right colectomy

Favors robotic-assisted

- Lymph node yield
- ↓ Estimated blood loss by **15.79 mL**
- Conversions by **43%**
- ↓ Ileus by **21%**
- ↓ Anastomotic leak by **11%**
- Length of stay by **0.48 days**

Comparable outcomes

- \approx Blood transfusion
- \approx Proximal resection margin
- \approx Distal resection margin
- \approx Surgical site infection
- \approx Time to flatus
- \approx 30-day postoperative complications
- \approx 30-day readmissions
- \approx 30-day reoperations
- \approx 30-day mortality

Favors laparoscopic

U Operative time by **56 minutes**

Data collected: March 1, 2024



WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points: **Robotic-assisted vs. open* right colectomy**

Favors robotic-assisted 1

- Lymph node yield
- lleus by 36%
- Length of stay by **2.5 days**
- 30-day reoperations by **15%**

Comparable outcomes

30-day mortality \approx



Operative time by 85 minutes

Data collected: March 1, 2024

*Limited data available on patients who underwent open surgery

Evidence Navigator: Right Colectomy Technical Slides

Systematic literature review & meta-analysis as of March 1, 2024



Right Colectomy: Literature search methods

as of March 1, 2024

Monthly searches were conducted in PubMed, Scopus and Embase.

All citations were exported into a reference management system. Duplications were removed. Titles, abstracts and keywords were reviewed for literature review inclusion by Global Evidence Management team.

All robotic-assisted right colectomies performed with da Vinci® surgical systems. Publications were identified according to inclusion and exclusion criteria described.

Meta-analysis was performed using RevMan or R software.

18 publications

34,500 patients who underwent RAS

236,889 patients who underwent laparoscopic surgery

190,029 patients who underwent open surgery

Level of evidence

2 3 13

■1b - RCTs

2b - Prospective cohort studies

2c - Database studies

Cr	iteria phase	Details	
lde	entification phase	All unique PubMed, Scopus, and Embase references identified N = 3,884 March 1, 2024	
	clusion criteria Robotic-assisted right-colectomy procedure	Robotic right colectomy N = 865 (excluded N = 3,019)	
2.	Year ≥ 2010	Articles published \geq 2010 N = 865 (excluded N = 0)	
3.	LOE = 1b, 2b, 2c	Articles with LOE= 1b, 2b, 2c N = 154 (excluded N = 711)	
4.	RCT, prospective comparative study with comparative cohorts (robotic-assisted vs. laparoscopic and/or open surgery) and sample size \geq 20 in each cohort	Comparator cohorts N = 135 (excluded N = 19)	
Ex	clusion criteria	N = 117 excluded publications:	
1.	Not in English	N = 0 (EC#1)	
2.	Paper reports on a pediatric population	N = 0 (EC#2)	
3.	Publication is an HTA that was not published in a	N = 0 (EC#3)	
	peer-reviewed journal	N = 0 (EC#4)	
	Alternate technique/approach (e.g., transanal, single-port)	N = 48 (EC#5)	
5.	No stratified analysis by study arm (e.g., combines results from robotic, laparoscopic, and/or open cohorts)	N =67 (EC#6)	
6.	Benign/cancer data mixed and cancer not a majority, or	N = 2 (EC#7)	
	right colectomy data mixed with other procedures	N = 0 (EC#8)	
7.	Original research study does not provide quantitative results for the outcomes of interest		
	Original research publication includes redundant patient		

Right colectomy publications: N = 18

INTUÎTIVE

Robotic-assisted vs. laparoscopic right colectomy Summary as of March 1, 2024

Significant difference favoring robotic-assisted surgerv

comparable outcomes laparoscopic surgery

Compared to laparoscopic right colectomy, the evidence for roboticassisted right colectomy using the da Vinci surgical system demonstrates:

- Significantly less estimated blood loss by an average of 15.79 mL
- Significantly difference in lymph node yield (LNY) by 1.15 lymph nodes
- Significantly shorter hospital length of stay by an average of 0.48 days
- Comparable proximal resection margin
- · Comparable time to flatus
- · Comparable distal resection margin
- Significantly longer operative time by an average of 56 minutes

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Outcome	Robotic- assisted, n	Laparoscopic, n	Effect Size WMD, 95%CI	P-value
Right Colectomy C	ontinuous Variab	les (to March 1, 20)24)	
EBL, mL ^{6,12}				
Subtotal Fixed, Heterogeneity: p=0	394).32; I²=0%	753	-15.79 [-24.57, -7.001]	p<0.01
LNY, n (L-R) 4,5,6,8,10	0,12,15,16,17			
Subtotal	16331	145449	-1.15 [-2.19, -0.11]	p=0.03
Random, Heterogeneity:				
LOS, days 5,8,10,11,12,16				
Subtotal	11695	27587	-0.48 [-0.83, -0.13]	P<0.01
Random, Heterogeneity:	p<0.01; l²=86%			
Proximal resection	margin, cm 12,15			
Subtotal	83	75	-0.69 [-3.51, 2.12]	p=0.63
Fixed, Heterogeneity: p=0	0.51; l²=0%			
Time to flatus, days	5 ^{12,15}			
Subtotal	83	75	0.14 [-0.29, 0.58]	p=0.52
Fixed, Heterogeneity: p=0).24; l²=27%			
Distal resection ma	argin, cm ^{12,15}			
Subtotal	83	75	1.92 [-0.82, 4.66]	p=0.17
Fixed, Heterogeneity: p=0				
Operative Time, mi	n 8,10,11,12,15			
Subtotal	11339	15999	56.16 [25.16, 87.17]	p<0.01
Random, Heterogeneity:	p<0.01; I²=92%			

Robotic-assisted vs. laparoscopic right colectomy Summary as of March 1, 2024

 Significant difference favoring robotic-assisted surgery
 No significant difference;
 Significant difference favoring comparable outcomes
 Iaparoscopic surgery

Compared to laparoscopic right colectomy, the evidence for robotic-assisted right colectomy using the da Vinci surgical system demonstrates:	Odds Ratio (OR) 95% Cl	Outcome	Robotic-assisted, n	Laparoscopic, n	Effect size OR 95% Cl	P-value
demonstrates.		Right Colectomy Binary Var	iables (to March 1, 20)24)		
 43% less likely to have a conversion to open surgery 	+	Conversions, n ^{2,5,6,8,9,11,12,14,15,16,} Subtotal Random, Heterogeneity: p=0.03; I	27461	168146	0.57 [0.50, 0.66]	p<0.01
21% less likely to experience an ileus	+	Ileus, n 5,8,9,10,11,12 Subtotal	11864	22475	0.79 [0.73, 0.85]	p<0.01
11% less likely to have an anastomotic leak	+	Fixed, Heterogeneity: p=0.28; I ² =2 Anastomotic Leaks, n ^{1,5,6,8,9,11,12} Subtotal		44806	0.89 [0.81, 0.99]	p=0.04
 Comparable readmissions rate within 30-days of surgery 	+	Fixed, Heterogeneity: p=0.44; l ² =0 Readmissions 30-day, n ^{5,8,11,15})%			·
 Comparable postoperative complications rate within 30-days of surgery 	-+-	Subtotal Fixed, Heterogeneity: p=0.39; I ² =0 Postoperative complications 30 Subtotal		17920 19379	0.92 [0.84, 1.02]	p=0.12 p=0.35
Comparable mortality rate within 30-days of		Random, Heterogeneity: p=0.02; I Mortality 30-day, n ^{5,6,8,10,11,12,15}		19379	0.32 [0.76, 1.03]	p=0.55
surgery		Subtotal Fixed, Heterogeneity: p=0.17; I ² =3	11838 37%	21146	0.92 [0.68, 1.25]	p=0.6
Comparable blood transfusions rate		Blood transfusions, n ^{6,8,10,12} Subtotal Random, Heterogeneity p=0.08; l ²	2835 2=60%	7862	0.97 [0.57, 1.65]	p=0.92
Comparable surgical site infection rate		Surgical site infection, n ^{5,9,11,12,1} Subtotal		15405	1.03 [0.87, 1.23]	p=0.7
 Comparable reoperations rate within 30-days of surgery 	+	Fixed, Heterogeneity: p=0.60; I ² =0	0%	10100	1.00 [0.07, 1.20]	P 0.1
0.2 Favors robo	0.5 1 2 tic-assisted Favors laparosc	Reoperations 30-day, n ^{5,9,10,11,15} Subtotal Fixed. Heterogeneity p=0.77; l ² =0 ⁴ opic	9522	17773	1.05 [0.93, 1.18]	p=0.46

Robotic-assisted vs. open right colectomy Summary as of March 1, 2024

Significant difference favoring robotic-assisted surgery

comparable outcomes open surgery

-10

Favors

-5

robotic-assisted

0

5

Favors

open

10

Compared to open right colectomy, the evidence for robotic-assisted right colectomy using the da Vinci surgical system demonstrates:

- Significantly shorter hospital length of stay by an average of 2.47 days
- Significantly difference in lymph node yield (LNY) by 0.4 lymph nodes
- Significantly longer operative time by an average of 85 minutes

Weighted Mean D 95%		Outcome	Robotic- assisted, n	Open, n	Effect Size WMD, 95%Cl	P-value
		Right Colectomy Contin	uous Variables (to March 1, 2024)	
		LOS, days 10,11				
		Subtotal	8472	9407	-2.47 [-4.43, -0.51]	p=0.01
		Random, Heterogeneity: p	<0.01; l²=97%			
		LNY, n (L-R) 4,10,17				
•		Subtotal	13125	161928	0.40 [0.21, 0.59]	p<0.01
		Fixed, Heterogeneity: p=0.	77; l²=0%			
		Operative Time, min 10,11				
		Subtotal	8472	9407	84.96 [18.61, 151.30]	p=0.01
		Random, Heterogeneity: p	<0.01; l²=96%			

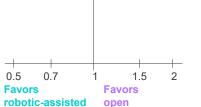
Robotic-assisted vs. open right colectomy Summary as of March 1, 2024

Significant difference favoring No significant difference; Significant difference favoring comparable outcomes robotic-assisted surgery open surgery

Compared to open right colectomy, the evidence for robotic-assisted right colectomy using the da Vinci surgical system demonstrates:

- 36% less likely to experience an ileus
- 15% less likely to be reoperated within 30days of surgery
- Comparable mortality rate within 30-days of surgery

Odds Ra		Outcome	Robotic- assisted, n	Open, n	Effect size OR 95% Cl	P-value			
(OR) IV, 95% CI		Right Colectomy Binary Variables (to March 1, 2024)							
_		lleus, n ^{10,11} Subtotal Fixed, Heterogeneity: p=0	8472 .81; l²=0%	9407	0.64 [0.58, 0.69]	p<0.01			
-+-		Reoperations 30-day, n Subtotal Fixed, Heterogeneity: p=0	8472	9407	0.85 [0.75, 0.96]	p=0.01			
-	_	Mortality, n ^{10,11} Subtotal Fixed, Heterogeneity: p=0	8472 .95; l²=0%	9407	0.72 [0.49, 1.04]	p=0.08			



+

Robotic-assisted vs. Laparoscopic Right Colectomy Weighted estimates based on 18 studies

Meta-analysis covering period January 1, 2010 – March 1, 2024

This study analyzed continuous variables using weighted means and categorical variables using weighted rates with fixed or random effects models. This method gives more influence to studies with higher weights, providing a more accurate estimate of central tendency when combining results from multiple studies.

INTUÎTIVE

Outcomes that favor Robotic

Lymph node yield (n)	22.8 vs 21.7
Estimated blood loss	69.5 ml vs 85.3 ml
Conversions	6% vs 10%
lleus	9.4% vs 11.5%
Anastomotic leak	4.8% vs 5.3%
Length of stay	4.5 days vs 5.0 days

Comparable outcomes

Blood transfusions	7.7% vs 6.9%
Proximal resection margin	15.4 vs 16.1
Distal resection margin	16.7 vs 14.8
Surgical site infection	3% vs 2.9%
Time to flatus	2.5 days vs 2.3 days
30-day postoperative complications	20.6% vs 21.7%
30-day readmissions	6.8% vs 7.3%
30-day reoperations	5.7% vs 5.4%
30-day mortality	0.7% vs 0.8%

Disclaimer: The number of studies used to calculate the weighted estimates for each outcome varies

Outcomes that favor Laparoscopic

Operative time 227.5 min vs 171.3 min Robotic-Assisted vs. Open Right Colectomy Weighted estimates based on 6 studies

Meta-analysis covering period January 1, 2010 – March 1, 2024

This study analyzed continuous variables using weighted means and categorical variables using weighted rates with fixed or random effects models. This method gives more influence to studies with higher weights, providing a more accurate estimate of central tendency when combining results from multiple studies.

Outcomes that favor Robotic

Lymph node yield (n)	20.6 vs 20.1
lleus	9.9% vs 14.7%
Length of stay	4.9 days vs 7.4 days
30-day reoperations	5.9% vs 6.9%

Comparable outcomes

30-day mortality 0.6% vs 0.8%

Outcomes that favor Laparoscopic

250.7 min vs

165.7 min

Operative time

Disclaimer: The number of studies used to calculate the weighted estimates for each outcome varies

INTUÎTIVE

Right colectomy: bibliography March 1, 2024

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Disclosures

Important Safety Information

(US) Serious complications may occur in any surgery, including da Vinci surgery, up to and including death. Serious risks include, but are not limited to, injury to tissues and organs and conversion to other surgical techniques which could result in a longer operative time and/or increased complications. For summary of the risks associated with surgery refer to <u>www.intuitive.com/safety</u>.

Da Vinci Xi®/da Vinci X® system precaution statement

The demonstration of safety and effectiveness for the representative specific procedures did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence), except for radical prostatectomy which was evaluated for overall survival, 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.

(EU) Medical devices, CE 2460, refer to Instructions For Use for further information.

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