Evidence Navigator: Sigmoidectomy for Diverticular Disease

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

INTUITIVE

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 standardized mean differences or weighted mean differences when describing continuous outcomes. Weighting is based on the study sample size and variability of the outcome. A fixed effect model is used if heterogeneity was not statistically significant or not applicable, and a random effect model is used if heterogeneity was statistically significant. Mantel Haenszel summary statistic is used for overall results. Meta-analysis is performed with 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.

Glossary

RAS	robotic-assisted surgery
Lap	laparoscopic surgery
LOE	level of evidence
HTA	health technology assessment
RCT	randomized controlled trial
OR	odds ratio
MD	mean difference

WMD	weighted mean difference
RD	risk difference
SMD	standardized mean difference
95% CI	95% confidence interval
I^2	test statistic for heterogeneity
EBL	estimated blood loss
LOS	length of hospital stay

Evidence Navigator: Sigmoidectomy for Diverticular Disease Summary Slides

Systematic literature review summary
as of March 1, 2024

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WHAT DOES THE LITERATURE SHOW?

Systematic literature review:
Da Vinci Robotic-assisted Sigmoidectomy for Diverticular Disease

Inclusion criteria

Robotic-assisted sigmoidectomy for diverticular disease performed with a da Vinci® surgical system

January 1, 2010 – March 1, 2024

Level of Evidence = 1b, 2b, 2c, 3b

RCT, prospective and retrospective 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

Sigmoidectomy for diverticular disease data mixed with another procedure/s and indication/s

Original research study does not provide quantitative results for at least one of the findings relative to the outcomes of interest

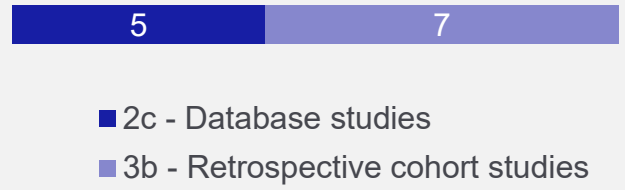
Original research publication includes redundant patient population and similar conclusions

12 publications including

Robotic-assisted patients: **7,034**

Laparoscopic patients: **13,563**

Level of Evidence



WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points:
Da vinci Robotic-assisted vs. laparoscopic sigmoidectomy for diverticular disease

Favors robotic-assisted

- ↓ Conversions by **54%**
- ↓ Surgical site infection rate by **46%**
- ↓ Post-operative complications within 30 days of surgery by **23%**
- ↓ Length of stay by an average **0.4 days**

Comparable outcomes

- ≈ Estimated blood loss (ml)
- ≈ Blood transfusion rates
- ≈ Anastomotic leak
- ≈ Major complications
- ≈ Ileus rates
- ≈ Stoma rates
- ≈ Reoperations within 30 days of surgery
- ≈ Readmissions within 30 days of surgery
- ≈ Mortality within 30 days of surgery

Favors laparoscopic

- ↓ Operative time is on average **35.81 min shorter**

Data collected through: March 1, 2024

Significant difference favoring robotic-assisted surgery

No significant difference; comparable outcomes

Significant difference favoring laparoscopic surgery

Evidence Navigator: Sigmoidectomy for Diverticular Disease Technical Slides

Systematic literature review summary
as of March 1, 2024

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Sigmoidectomy for Diverticular Disease: 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 sigmoidectomy for diverticular disease were 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.

12 publications

7,034 patients who underwent robotic-assisted surgery (RAS)

13,563 patients who underwent laparoscopic surgery (Lap)

Level of Evidence

- 2c - Database studies
- 3b - Retrospective cohort studies

Criteria phase	Details
Identification phase	All robotics publications (library generated from monthly search process) N=39,985 library size at the time of search March 1, 2024
Inclusion criteria 1. Robotic-assisted sigmoidectomy for diverticular disease	Da Vinci® robotic-assisted sigmoidectomy for diverticular disease N=**125** (excluded N=39,860)
2. Year ≥ 2010	Articles published ≥ 2010 N=**116** (excluded N=9)
3. LOE = 1b, 2b, 2c, 3b	Articles with LOE = 1b, 2b, 2c, 3b N=**34** (excluded N=82)
4. Study is an RCT, prospective or retrospective study or large database study with comparative cohorts (robotic-assisted vs lap and/or open surgery) and sample size N≥20	Comparator cohorts N=**31** (excluded N=3)
Exclusion criteria 1. Not in English 2. Paper reports on a pediatric population 3. Publication is an HTA that was not published in a peer-reviewed journal 4. Alternate technique/approach (e.g. single-port) 5. No stratified analysis by study arm (e.g., combines results from robotic, lap and/or open cohorts) 6. Sigmoidectomy for diverticular disease data mixed with another procedure(s) and indication(s) 7. Original research study does not provide quantitative results for at least one of the findings relative to the outcomes of interest (i.e., operative time, conversions, estimated blood loss and/or transfusions, complications, length of hospital stay, mortality, etc.) 8. Original research publication includes redundant patient population and similar conclusions 9. Study is a review paper that only includes redundant publications and similar conclusions	**N=19 excluded publications:** N=1 (EC#1) N=0 (EC#2) N=0 (EC#3) N=0 (EC#4) N=4 (EC#5) N=14 (EC#6) N=0 (EC#7) N=0 (EC#8) N=0 (EC#9)

Robotic-assisted sigmoidectomy for diverticular disease publications: N=12

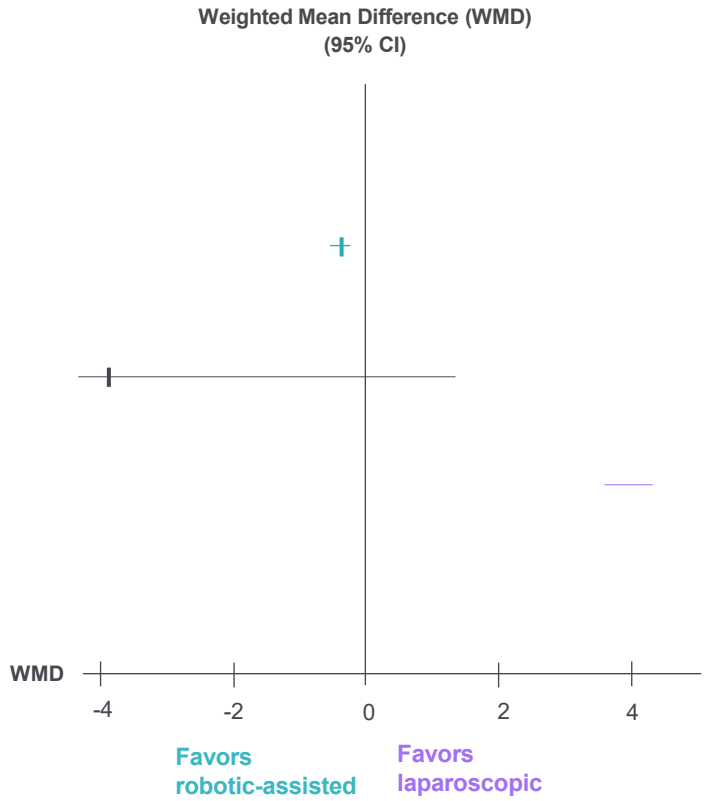
Robotic-assisted vs. laparoscopic sigmoidectomy for diverticular disease

Summary as of March 1, 2024

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

Compared to laparoscopic sigmoidectomy for diverticular disease, the evidence for **robotic-assisted sigmoidectomy for diverticular disease using the da Vinci surgical system** demonstrates:

- Significantly shorter length of stay by an average of 0.4 days
- Comparable estimated blood loss
- Significantly longer operative time by an average of 36 minutes



Outcome	Robotic-assisted, n	Laparoscopic, n	Effect size 95% CI	P-value
Sigmoidectomy for diverticular disease continuous variables (to March 1, 2024)				
Length of Stay, days [1,2,6,7,9,10,11]				
Subtotal	2275	8498	-0.36 [-0.53, -0.20]	p<0.01
Fixed, Heterogeneity: p=0.06; I^2=50%				
Estimated blood loss, ml [7,9,10]				
Subtotal	310	245	-3.84 [-11.03, 3.35]	p=0.30
Fixed, Heterogeneity: p=0.81; I^2=0%				
Operative Time, min [1,2,5,6,7,9,10,11]				
Subtotal	2335	8544	35.81 [8.94, 62.68]	p<0.01
Random, Heterogeneity: p<0.01; I^2=95%				

Robotic-assisted vs. laparoscopic sigmoidectomy for diverticular disease

Summary as of March 1, 2024

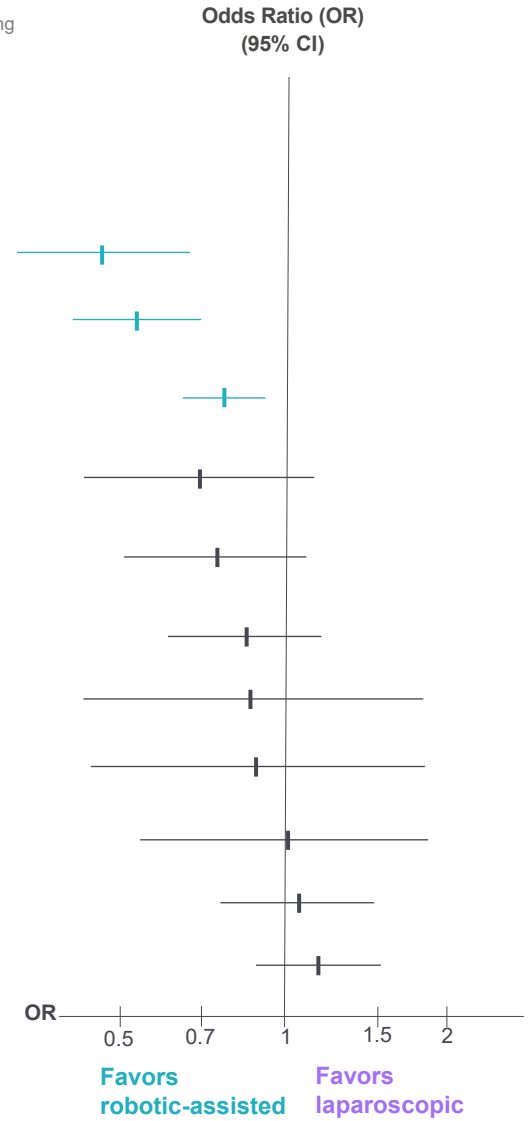
Significant difference favoring robotic-assisted surgery

No significant difference; comparable outcomes

Significant difference favoring laparoscopic surgery

Compared to laparoscopic sigmoidectomy for diverticular disease, the evidence for **robotic-assisted sigmoidectomy for diverticular disease using the da Vinci surgical system** demonstrates:

- 54% less likely to be converted to open surgery
- 46% less likely to experience a surgical site infection
- 23% less likely to experience a postoperative complications within 30 days of surgery
- Comparable major complication rates
- Comparable reoperation rates within 30 days of surgery
- Comparable stoma formation rates
- Comparable mortality rates within 30 days of surgery
- Comparable anastomotic leak rates
- Comparable ileus rates
- Comparable blood transfusion rates
- Comparable readmission rates within 30 days of surgery



Outcome	Robotic-assisted, n	Laparoscopic, n	Effect size 95% CI	P-value
Sigmoidectomy for diverticular disease binary variables (to March 1, 2024)				
Conversions, n[1,2,3,5,6,7,8,9,10,11]				
Subtotal	4451	10980	0.46 [0.32, 0.66]	p<0.01
Random Heterogeneity: p<0.01; I²=70%				
Surgical Site Infection, n[1,2,5,6,8,10]				
Subtotal	1011	9011	0.54 [0.41, 0.70]	p<0.01
Fixed, Heterogeneity: p=0.29; I²=19%				
Post-operative complications (30-days),n[6,7,9,11]				
Subtotal	1470	1407	0.77 [0.65, 0.92]	p<0.01
Fixed, Heterogeneity: p=0.65; I²=0%				
Major complications, n[1,7]				
Subtotal	503	531	0.70 [0.43, 1.13]	p=0.14
Fixed, Heterogeneity: p=0.21; I²=36%				
Reoperation (30-days), n[1,2,5,7,9]				
Subtotal	1037	7244	0.75 [0.51, 1.09]	p=0.14
Fixed, Heterogeneity: p=0.77; I²=0%				
Stoma formation, n[1,5,6,7,10,12]				
Subtotal	1861	1877	0.86 [0.62, 1.19]	p=0.36
Fixed, Heterogeneity: p=0.58; I²=0%				
Mortality (30-days), n[1,2,5,6,8,11]				
Subtotal	2151	10251	0.87 [0.42, 1.79]	p=0.70
Fixed, Heterogeneity: p=0.86; I²=0%				
Anastomotic leak, n[1,2,5,6,8,10]				
Subtotal	1011	7605	0.81 [0.49, 1.34]	p=0.42
Fixed, Heterogeneity: p=0.51; I²=0%				
Ileus, n[1,2,6,11]				
Subtotal	1965	8253	1.02 [0.55, 1.88]	p=0.96
Random, Heterogeneity: p<0.01; I²=85%				
Blood transfusions, n[1,2,5,7,11]				
Subtotal	2069	8369	1.07 [0.77, 1.47]	p=0.70
Fixed, Heterogeneity: p=0.57; I²=0%				
Readmissions (30-days), n[1,2,6,8,9]				
Subtotal	1059	9080	1.16 [0.90, 1.49]	p=0.26
Fixed, Heterogeneity: p=0.74; I²=0%				

Sigmoidectomy for diverticular disease 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 www.davincisurgery.com/safety or www.intuitive.com/safety.

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.

For product intended use and/or indications for use, risks, cautions, and warnings and full prescribing information, refer to the associated user manual(s) or visit https://manuals.intuitivesurgical.com/market.

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

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