Evidence Navigator: Endometriosis resection

Systematic literature review & meta-analysis
as of September 1, 2023

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: Endometriosis resection Summary Slides

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WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points:
Literature search methods for Endometriosis resection

Inclusion criteria

Robotic-assisted endometriosis resection performed with a da Vinci surgical system

January 1, 2010 – September 1, 2023

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

Endometriosis resection data mixed with other procedures

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

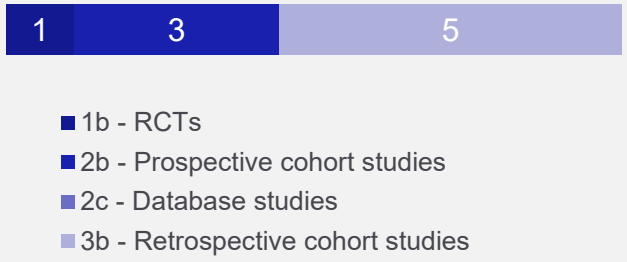
Original research publication includes redundant patient population and similar conclusions

9 publications including

Robotic-assisted patients: **475**

Laparoscopic patients: **644**

Level of evidence



WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points:
Robotic-assisted with da Vinci surgical system vs. laparoscopic endometriosis resection

Favors robotic-assisted

Comparable outcomes

- ≈ Length of hospital stay
- ≈ Conversion to open
- ≈ Estimated blood loss
- ≈ Blood transfusions
- ≈ Intraoperative complications
- ≈ 30-day postoperative complications
- ≈ 30-day reoperations
- ≈ 30-day readmissions

Favors laparoscopic

- ↓ Operative time by **44.33 min**

Significant difference favoring robotic-assisted surgery

No significant difference; comparable outcomes

Significant difference favoring laparoscopic surgery

Data collected through: September 1, 2023

Evidence Navigator: Endometriosis resection Technical Slides

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Endometriosis Resection: Literature search methods

as of September 1, 2023

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 endometriosis resection performed with da Vinci® surgical systems. Publications were identified according to inclusion and exclusion criteria described.

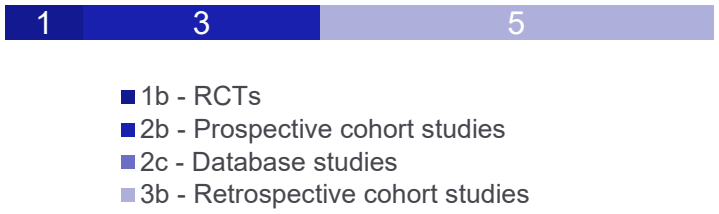
Meta-analysis was performed using RevMan or R software.

9 publications

475 patients who underwent RAS

644 patients who underwent laparoscopic surgery

Level of evidence



Criteria phase	Details
Identification phase	All robotics publications (library generated from monthly search process) N = 37,682 library size at the time of search September 1, 2023
Inclusion criteria 1. Robotic-assisted endometriosis resection	Robotic-assisted endometriosis resection N = 269 (excluded N = 37,413)
2. Year ≥ 2010	Articles published ≥ 2010 N = 258 (excluded N = 11)
3. LOE = 1b, 2b, 2c, 3b	Articles with LOE 1b, 2b, 2c, 3b N = 19 (excluded N = 229)
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 = 18 (excluded N = 1)
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-assisted, laparoscopic and/or open cohorts) 6. Endometriosis resection data mixed with other procedures (e.g., data from multiple surgical procedures combined) 7. Original research study does not provide quantitative results for outcomes of interest (i.e., operative time, conversions, estimated blood loss and/or transfusions, complications, length of hospital stay, mortality) 8. Original research publication includes redundant patient population and similar conclusions	**N =** 9 excluded publications: N = 1 (EC#1) N = 0 (EC#2) N = 0 (EC#3) N = 5 (EC#4) N = 1 (EC#5) N = 2 (EC#6) N = 0 (EC#7) N = 0 (EC#8)

Endometriosis resection publications: N = 9

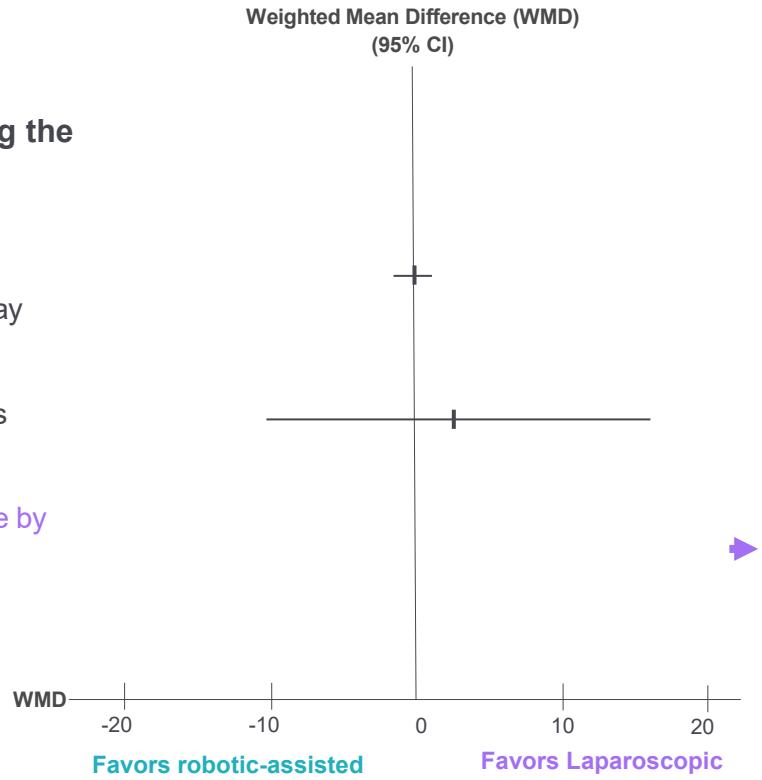
Robotic-assisted vs. laparoscopic endometriosis resection

Summary as of September 1, 2023

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

Compared to laparoscopic endometriosis resection, the evidence for **robotic-assisted endometriosis resection using the da Vinci surgical system** demonstrates:

- Comparable length of hospital stay
- Comparable estimated blood loss
- Significantly longer operative time by an average of **44.33 minutes**



Outcomes	Robotic-assisted, n	Laparoscopic, n	Effect Size 95% CI	P-value
Endometriosis resection continuous variables (to September 1, 2023)				
Length of stay, days[1,2,3,6,8]				
Subtotal	227	267	-0.07 [-0.93; 0.78]	p=0.87
Random, Heterogeneity: p<0.01, I^2=86%				
Estimated blood loss, ml[2,3,5,6,8,9]				
Subtotal	213	270	2.66 [-10.75; 16.08]	p=0.7
Fixed, Heterogeneity: p=0.58, I^2=0%				
Operative time, min[1,2,3,5,6,7,8,9]				
Subtotal	449	616	44.33 [27.17; 61.48]	**p<0.01**
Random, Heterogeneity: p<0.01, I^2=81%				

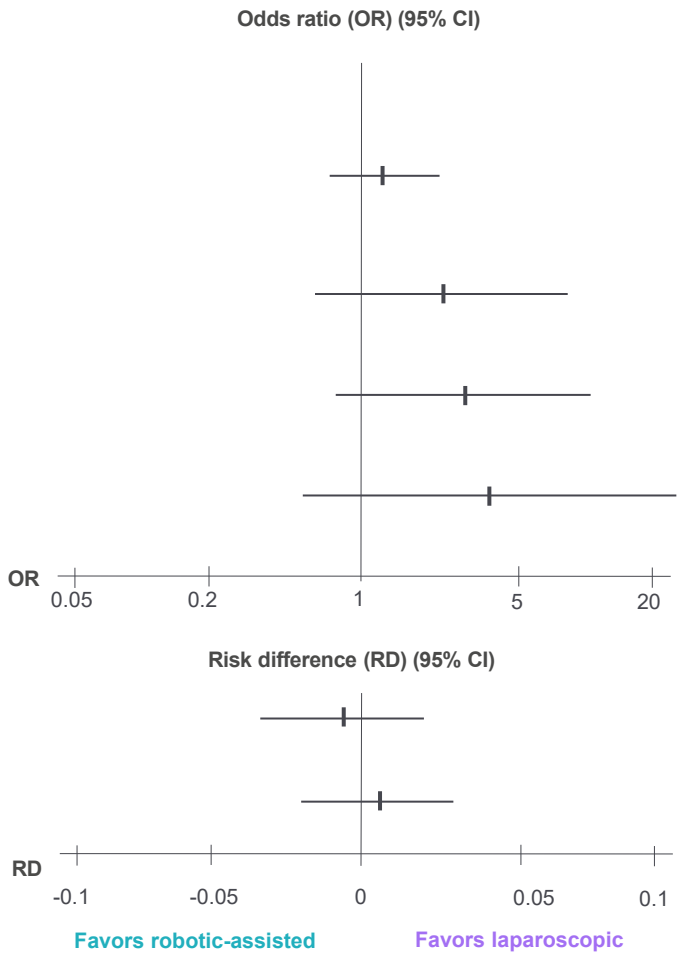
Robotic-assisted vs. laparoscopic endometriosis resection

Summary as of September 1, 2023

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

Compared to laparoscopic endometriosis resection, the evidence for **robotic-assisted endometriosis resection using the da Vinci surgical system** demonstrates:

- Comparable rate of postoperative complications within 30-days of surgery
- Comparable rate of readmissions within 30-days of surgery
- Comparable rate of reoperations within 30-days of surgery
- Comparable rate of intraoperative complications
- Comparable rate of blood transfusions
- Comparable rate of conversion to open surgery



Outcomes	Robotic-assisted, n	Laparoscopic, n	Effect Size 95% CI	P-value
Endometriosis resection binary variables (to September 1, 2023)				
Postop complications 30-day, n(%)[2,3,4,5,6,7,8]				
Subtotal	351	531	OR: 1.22 [0.71, 2.08]	p=0.47
Fixed, Heterogeneity: p=0.60, I^2=0%				
Readmission 30-day, n(%)[2,3]				
Subtotal	84	86	OR: 2.29 [0.62, 8.44]	p=0.21
Fixed, Heterogeneity: p=0.48, I^2=0%				
Reoperation 30-day, n(%)[2,3,8]				
Subtotal	106	108	OR: 2.85 [0.74, 11.01]	p=0.13
Fixed, Heterogeneity: p=0.84, I^2=0%				
Intraop complications, n(%)[3,5,6]				
Subtotal	95	149	OR: 3.66 [0.53, 25.33]	p=0.19
Fixed, Heterogeneity: p=0.54, I^2=0%				
Blood Transfusions, n(%)[2,3,6]				
Subtotal	116	172	RD: -0.001 [-0.04; 1.02]	p=0.57
Fixed, Heterogeneity: p=0.74, I^2=0%				
Conversions, n(%)[2,3,5,6,8]				
Subtotal	213	270	RD: 0.0045 [-0.22, 0.03]	p=0.74
Fixed, Heterogeneity: p=0.92, I^2=0%				

Endometriosis resection: bibliography

September 1, 2023

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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.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) Da Vinci X & Xi Surgical Systems

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.

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.

Some products, features or technologies may not be available in all countries. Product availability is subject to regulatory approval in the specific market. Please contact your local Intuitive representative for product availability in your region.

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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