Evidence Navigator: Hysterectomy For Cervical Cancer

Systematic literature review summary
as of December 31, 2022

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 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.

Glossary

RAS	robotic-assisted surgery		**WMD**	weighted mean difference
Lap	laparoscopic surgery		**RD**	risk difference
LOE	level of evidence		**SMD**	standardized mean difference
HTA	health technology assessment		**95% CI**	95% confidence interval
RCT	randomized controlled trial		**I²**	test statistic for heterogeneity
OR	odds ratio		**EBL**	estimated blood loss
MD	mean difference		**LOS**	length of hospital stay
LNY	lymph node yield		**PSM**	positive surgical margins
LVSI	lymphovascular space invasion			

Evidence Navigator: Hysterectomy for cervical cancer Summary Slides

**Systematic literature review summary
as of December 31, 2022**

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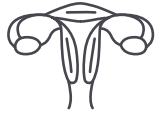
Systematic literature review:
Hysterectomy for cervical cancer — clinical outcomes

Inclusion criteria

Robotic-assisted hysterectomy for cervical cancer performed with a da Vinci surgical system

January 1, 2010 – December 31, 2022

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 on a pediatric population

Publication is a HTA not published in a peer-reviewed journal

Alternate technique/approach

No stratified analysis by study arm

Hysterectomy data mixed with other procedure(s)

Original research study does not provide quantitative results

Original research publication includes redundant patient population and similar conclusions

18 publications including

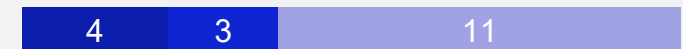Robotic-assisted patients: **19,059**

Laparoscopic patients: **6,681**
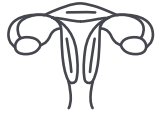
Open patients: **56,893**

Level of evidence

4	3	11

- 1b - RCTs
- 2b - Prospective cohort studies
- 2c - Database studies

Data collected through: December 31, 2022

Systematic literature review key points:
Robotic-assisted vs. laparoscopic hysterectomy for cervical cancer

Favors robotic-assisted

↓ Conversions by **65%**

Comparable outcomes

≈ Operative time

≈ Estimated blood loss

≈ Blood transfusions

≈ Lymph node yield

≈ Positive lymphovascular space invasion

≈ Positive surgical margins

≈ Intraoperative complications

≈ Length of stay

≈ 30-day postoperative complications

≈ 30-day mortality

Favors laparoscopic

None

Data collected through: December 31, 2022

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

Systematic literature review key points:
Robotic-assisted vs. open hysterectomy for cervical cancer

Favors robotic-assisted

↓ Estimated blood loss by **286 mL**

↓ Blood transfusions by **92%**

↓ Length of stay by **2 days**

↓ 30-day postoperative complication by **25%**

Comparable outcomes

≈ Operative time

≈ Lymph node yield

≈ Positive lymphovascular space invasion

≈ Positive surgical margins

≈ Intraoperative complications
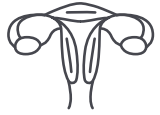
≈ 30-day mortality

Favors open

None

Data collected through: December 31, 2022

■ Significant difference favoring robotic-assisted surgery

■ No significant difference; comparable outcomes

■ Significant difference favoring open surgery

Evidence Navigator: Hysterectomy for cervical cancer Technical Slides

**Systematic literature review summary
as of December 31, 2022**

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Hysterectomy for Cervical Cancer: literature search methods
as of December 31, 2022

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 hysterectomies 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 cervical cancer publications

19,059 patients who underwent RAS

6,681 patients who underwent laparoscopic surgery

56,893 patients who underwent open surgery

Level of evidence

4	3	11

- ■ 1b - RCTs
- ■ 2b - Prospective cohort studies
- ■ 2c - Database studies

Criteria phase	Details
Identification phase	Unique records identified from PubMed, Scopus, Embase search N=9,440 to December 31, 2022
Inclusion criteria	
1. Robotic-assisted hysterectomy (radical, total, simple) with or without salpingectomy, oophorectomy, and lymphadenectomy for cancer or other gynecologic oncology procedure	N=2,626 (excluded N=6,814)
2. Year≥2010	N=2,623 (excluded N=3)
3. LOE=1b, 2b, 2c	N=253 (excluded N=2,370)
4. Study is an RCT, prospective study or large database study with comparative cohorts (robotic-assisted vs lap and/or open surgery) and sample size N≥20	N=231 (excluded N=22)
Exclusion criteria	**N=179 excluded publications:**
1. Not in English	N=1 (EC#1)
2. Paper reports on a pediatric population	N=0 (EC#2)
3. Publication is an HTA that was not published in a peer-reviewed journal	N=0 (EC#3) N=4 (EC#4)
4. Alternate technique/approach (e.g. single-port)	N=113 (EC#5)
5. No stratified analysis by study arm (e.g. combines results from robotic, laparoscopic and/or open cohorts)	N=32 (EC#6) N=21 (EC#7) N=8 (EC#8)
6. Hysterectomy cancer data mixed with other procedures (e.g. data from multiple surgical procedures combined)	
7. Original research study does not provide quantitative results for at least one of the findings relative to the outcomes of interest	
8. Original research publication includes redundant patient population and similar conclusions	

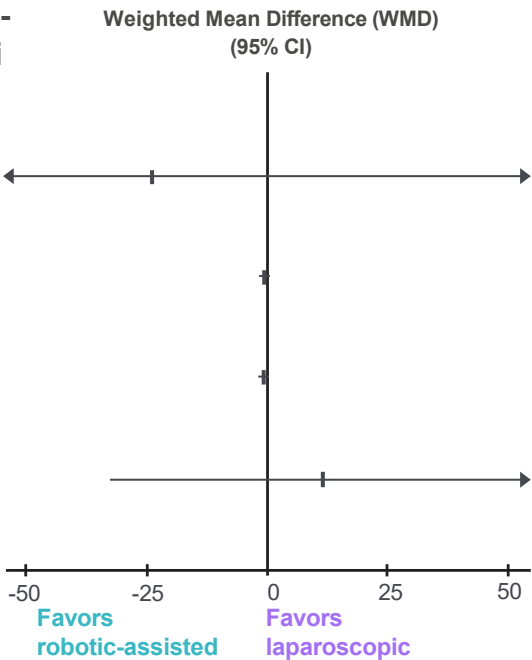**Gyn Onc publications: N=52 (18 cervical cancer)**

Robotic-assisted vs. laparoscopic hysterectomy for cervical cancer
Summary as of December 31, 2022

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

Compared to laparoscopic hysterectomy for cervical cancer, the evidence for **robotic-assisted hysterectomy using the da Vinci surgical system** demonstrates:

- Comparable estimated blood loss

- Comparable lymph node yield

- Comparable length of hospital stay

- Comparable operative time

Weighted Mean Difference (WMD) (95% CI)

-50   -25   0   25   50

Favors robotic-assisted   **Favors laparoscopic**

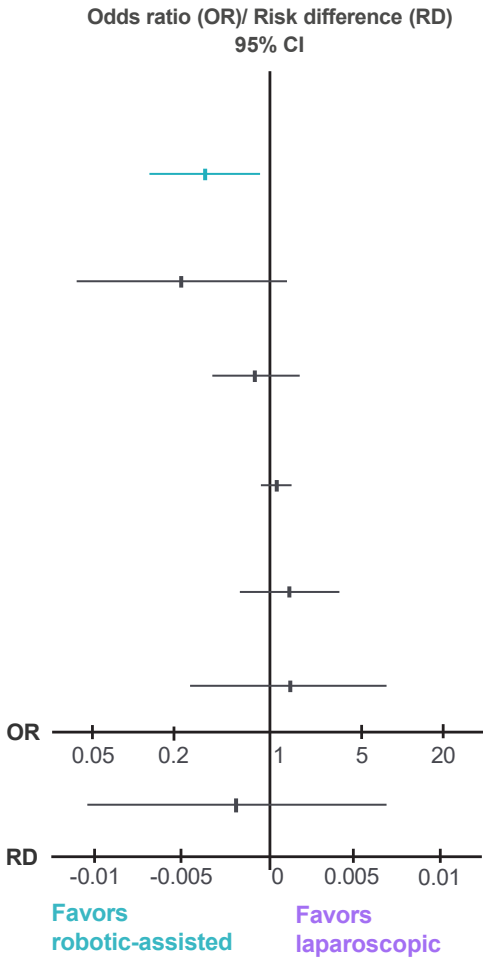| Outcome	Robotic-assisted, n	Laparoscopic, n	Effect size 95% CI	P-value
Cervical cancer continuous variables (to December 31, 2022)				
EBL, mL [4, 6, 7, 12, 14] Subtotal Random, Heterogeneity: p<0.01; I²=89%	259	495	WMD: -23.51 [-111.01, 64.00]	p=0.6
LNY(Lap-RAS) [4, 6, 7, 9] Subtotal L-R Fixed, Heterogeneity: p=0.38; I²=4%	208	230	WMD: -0.71 [-1.62, 0.20]	p=0.12
LOS, days [4, 7, 9, 14, 18] Subtotal Random, Heterogeneity: p<0.01; I²=77%	264	565	WMD: -0.60 [-1.31, 0.11]	p=0.10
Operative time, min [4, 6, 7, 12, 14] Subtotal Random, Heterogeneity: p<0.01; I²=95%	259	495	WMD: 11.53 [-32.23, 55.28]	p=0.61

Robotic-assisted vs. laparoscopic hysterectomy for cervical cancer
Summary as of December 31, 2022

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

Compared to laparoscopic hysterectomy for cervical cancer, the evidence for **robotic-assisted hysterectomy using the da Vinci surgical system** demonstrates:

- 65% less likely to be converted to open surgery

- Comparable positive surgical margins

- Comparable intraoperative complication rate

- Comparable postoperative complication rate within 30-days of surgery

- Comparable blood transfusion rate

- Comparable rate of positive lymphovascular space invasion

- Comparable mortality rate within 30-days of surgery

Odds ratio (OR)/ Risk difference (RD) 95% CI

Favors robotic-assisted   Favors laparoscopic

| Outcome	Robotic-assisted, n	Laparoscopic, n	Effect size 95% CI	P-value
Cervical cancer binary variables (to December 31, 2022)				
Conversions, n [4, 6, 7, 9, 11, 13, 15, 16]				
Subtotal	2757	1359	OR: 0.35 [0.14, 0.88]	p=0.03
Random, Heterogeneity: p=0.04; I²=59%				
PSM, n [8, 9]				
Subtotal	964	80	OR: 0.23 [0.04, 1.39]	p=0.11
Fixed, Heterogeneity: p=0.89; I²=0%				
Intraoperative complications, n [6, 7, 14, 18]				
Subtotal	156	571	OR: 0.82 [0.40, 1.70]	p=0.60
Fixed, Heterogeneity: p=0.31; I²=15%				
30-day postoperative complications, n [4, 6, 7, 9, 14, 15, 17, 18]				
Subtotal	1166	955	OR: 1.19 [0.91, 1.55]	p=0.22
Fixed, Heterogeneity: p=0.09; I²=44%				
Blood transfusions, n [4, 6, 18]				
Subtotal	189	361	OR: 1.45 [0.62, 3.39]	p=0.39
Fixed, Heterogeneity: p=0.37; I²=0%				
Positive LVSI, n [4, 8]				
Subtotal	567	79	OR: 1.47 [0.28, 7.86]	p=0.65
Random, Heterogeneity: p=0.02; I²=82%				
30-day mortality, n [9, 12, 15, 18]				
Subtotal	916	564	RD: -0.0018 [-0.0105, 0.0070]	p=0.69
Fixed, Heterogeneity: p=0.88; I²=0%				

Robotic-assisted vs. open hysterectomy for cervical cancer
Summary as of December 31, 2022

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

Compared to open hysterectomy for cervical cancer, the evidence for **robotic-assisted hysterectomy using the da Vinci surgical system** demonstrates:

- Significantly less estimated blood loss by an average of 286 mL

- Significantly shorter hospital length of stay by an average of 2 days

- Comparable lymph node yield

- Comparable operative time
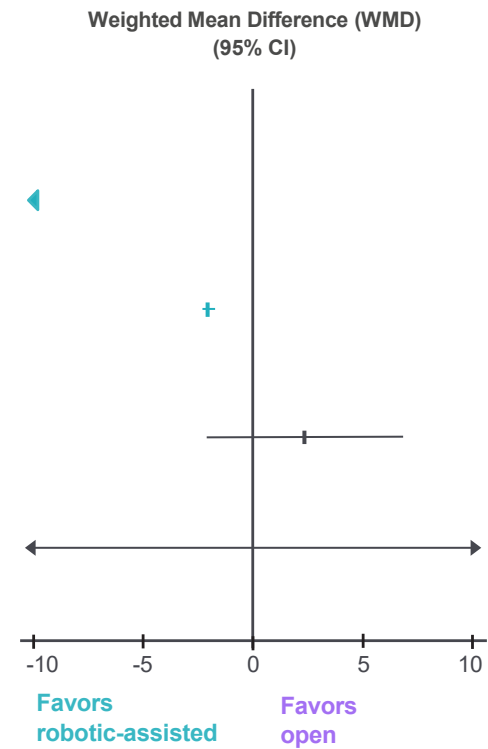
Weighted Mean Difference (WMD)
(95% CI)

-10   -5   0   5   10

Favors robotic-assisted   **Favors open**

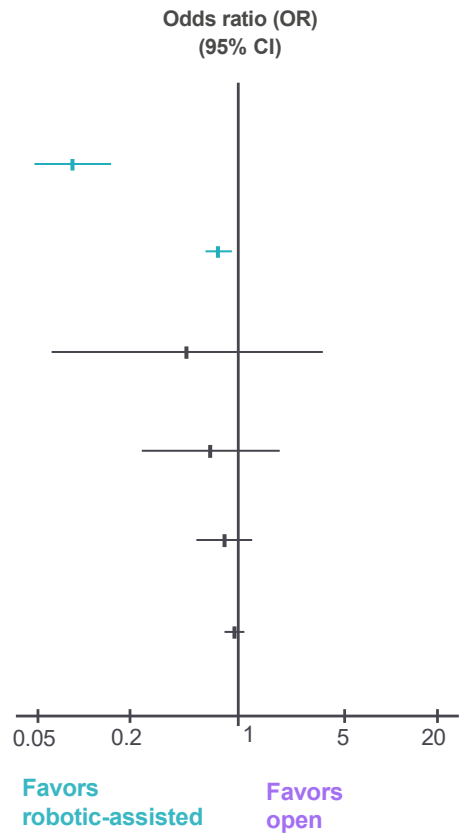| Outcome	Robotic-assisted, n	Open, n	Effect size 95% CI	P-value
Cervical cancer continuous variables (to December 31, 2022)				
EBL, mL [4, 6, 7, 12, 14] Subtotal Random, Heterogeneity: p<0.01; I²=91%	1006	1397	WMD: -285.73 [-409.24, -162.22]	p<0.01
LOS, days [4, 7, 9, 14, 18] Subtotal Fixed, Heterogeneity: p =0.13; I²=50%	172	2052	WMD: -2.02 [-2.20, -1.84]	p<0.01
LNY (Open-RAS) [4, 6, 7, 9] Subtotal O-R Random, Heterogeneity: p<0.01; I²=93%	1197	1371	WMD: 2.36 [-2.14, 6.86]	p=0.30
Operative time, min [4, 6, 7, 12, 14] Subtotal Random, Heterogeneity: p<0.01; I²=97%	127	518	WMD: 25.89 [-47.32, 99.10]	p=0.49

Robotic-assisted vs. open hysterectomy for cervical cancer
Summary as of December 31, 2022

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

Compared to open hysterectomy for cervical cancer, the evidence for **robotic-assisted hysterectomy using the da Vinci surgical system** demonstrates:

- 92% less likely to receive a blood transfusion

- 25% less likely to experience a postoperative complication within 30-days of surgery

- Comparable mortality rate within 30-days of surgery

- Comparable intraoperative complication rate

- Comparable positive surgical margins

- Comparable rate of positive lymphovascular space invasion

Odds ratio (OR) (95% CI)

0.05   0.2   1   5   20

Favors robotic-assisted   **Favors open**

Outcome	Robotic-assisted, n	Open, n	Effect size 95% CI	P-value
Cervical cancer binary variables (December 31, 2022)				
Blood transfusions, n [4, 6, 18]				
Subtotal	1032	2750	OR: 0.08 [0.05, 0.15]	p<0.01
Fixed, Heterogeneity: p=0.18; I²=39%				
30-day postoperative complications, n [4, 6, 7, 9, 14, 15, 17, 18]				
Subtotal	969	4541	OR: 0.75 [0.63, 0.90]	p<0.01
Fixed, Heterogeneity: p=0.11; I²=50%				
30-day mortality, n [9, 12, 15, 18]				
Subtotal	816	4194	OR: 0.46 [0.06, 3.50]	p=0.45
Fixed, Heterogeneity: p=0.86; I²=0%				
Intraoperative complications, n [6, 7, 14, 18]				
Subtotal	194	2128	OR: 0.66 [0.24, 1.80]	p=0.41
Random, Heterogeneity: p=0.1; I²=53%				
PSM, n [8, 9]				
Subtotal	2045	2377	OR: 0.81 [0.54, 1.22]	p=0.32
Fixed, Heterogeneity: p=0.16; I²=41%				
Positive LVSI, n [4, 8]				
Subtotal	1578	1744	OR: 0.95 [0.82, 1.11]	p=0.53
Fixed, Heterogeneity: p=0.5; I²=0%				

Hysterectomy for cervical cancer: bibliography
December 31, 2022

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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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