Evidence Navigator: Benign Hysterectomy

Systematic literature review & meta-analysis
as of April 17, 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: Benign Hysterectomy Summary Slides

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WHAT DOES THE LITERATURE SHOW?

Systematic literature review:
Benign hysterectomy— clinical outcomes

Inclusion criteria

Robotic-assisted benign hysterectomy performed with a da Vinci surgical system

January 1, 2010 – April 17, 2023

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

Benign Hysterectomy 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

30 publications including

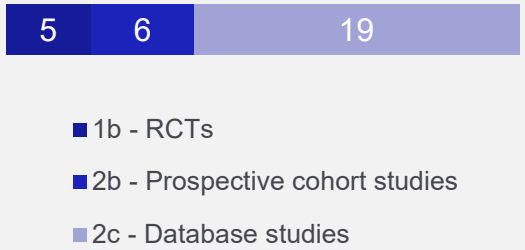
Robotic-assisted patients: **240,479**

Laparoscopic patients: **463,269**

Open patients: **1,331,456**

Vaginal-assisted patients: **246,678**

Level of evidence



WHAT DOES THE LITERATURE SHOW?

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

Favors robotic-assisted

- ↓ Conversions rate by **70%**
- ↓ Blood transfusions rate by **23%**
- ↓ Estimated blood loss by **47ml**
- ↓ Length of stay by average **0.2 days**
- ↓ 30-day postoperative complications rate by **15%**

Comparable outcomes

- ≈ Operative time
- ≈ Intraoperative complications rate
- ≈ Wound rate
- ≈ Infections rate
- ≈ Bladder injury rate
- ≈ Ureter injury rate
- ≈ 30-day reoperations rate
- ≈ 30-day readmissions rate
- ≈ Return to work
- ≈ Risk of 30-day mortality

Favors laparoscopic

None

Data collected through: April 17, 2023

Significant difference favoring robotic-assisted surgery

No significant difference; comparable outcomes

Significant difference favoring laparoscopic surgery

WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points:
Robotic-assisted with da Vinci surgical system vs. open benign hysterectomy

Favors robotic-assisted

- ↓ Blood transfusions rate by **80%**
- ↓ Estimated blood loss by **199ml**
- ↓ Intraoperative complications rate by **45%**
- ↓ Length of stay by **1.3 days**
- ↓ 30-day postoperative complications rate by **55%**
- ↓ 30-day mortality rate by **88%**

Comparable outcomes

- ≈ Operative time
- ≈ 30-day reoperations rate
- ≈ 30-day readmissions rate
- ≈ Wound rate

Favors open

None

Significant difference favoring robotic-assisted surgery

No significant difference; comparable outcomes

Significant difference favoring open surgery

Data collected through: April 17, 2023

WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points:
Robotic-assisted with da Vinci surgical system vs. vaginal benign hysterectomy

Favors robotic-assisted

- ↓ Estimated Blood loss by **61ml**
- ↓ Intraoperative complications **by 57%**
- ↓ Length of stay by **0.4 days**

Comparable outcomes

- ≈ Conversions rate
- ≈ Blood transfusions rate
- ≈ 30-day postoperative complications rate
- ≈ 30-day reoperations rate
- ≈ 30-day readmissions rate
- ≈ Return to work
- ≈ 30-day mortality rate

Favors vaginal

- ↑ Operative time by **43 min**

Significant difference favoring robotic-assisted surgery

No significant difference; comparable outcomes

Significant difference favoring vaginal surgery

Data collected through: April 17, 2023

Evidence Navigator: Benign Hysterectomy Technical Slides

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Benign Hysterectomy: Literature search methods

as of April 17, 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 benign 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.

30 publications*

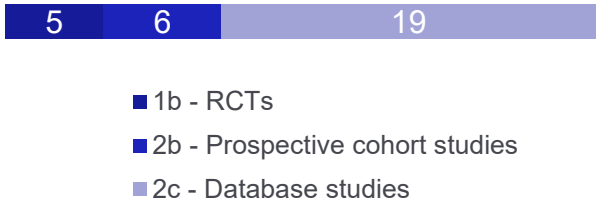
240,479 patients who underwent RAS

463,269 patients who underwent laparoscopic surgery

1,331,456 patients who underwent open surgery

246,678 patients who underwent vaginal surgery

Level of evidence



Criteria phase	Details
Identification phase	All robotics publications (library generated from monthly search process) N= 21,243 library size at the time of search April 17, 2023
Inclusion criteria 1. Robotic-assisted benign hysterectomy	Robotic-assisted benign hysterectomy N=1089 (excluded N=20,154)
2. Year ≥ 2010	Articles published ≥ 2010 N=1025 (excluded N=64)
3. LOE =1b, 2b, 2c	Articles with LOE 1b, 2b, 2c N=177 (excluded N=848)
4. RCT, prospective comparative study with comparative cohorts (robotic-assisted vs. laparoscopic, vaginal and/or open surgery) and sample size > 20 in each cohort	Comparator cohorts N=147 (excluded N=30)
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, vaginal and/or open cohorts) 6. Benign hysterectomy 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=117 excluded publications:** N=1 (EC#1) N=0 (EC#2) N=0 (EC#3) N=1 (EC#4) N=76 (EC#5) N=20 (EC#6) N=16 (EC#7) N=3 (EC#8)

Benign Hysterectomy publications: N = 30

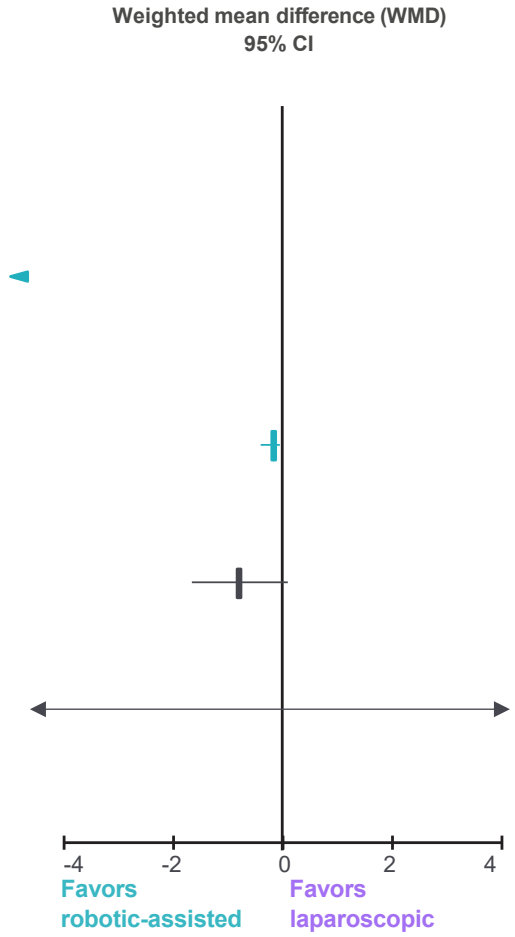
Robotic-assisted vs. laparoscopic benign hysterectomy

Summary as of April 17, 2023

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

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

- Significantly less estimated blood loss by an average of 46 ml
- Significantly shorter hospital stay by an average of 0.2 days (4.8 hours)
- Comparable return to work
- Comparable operative time



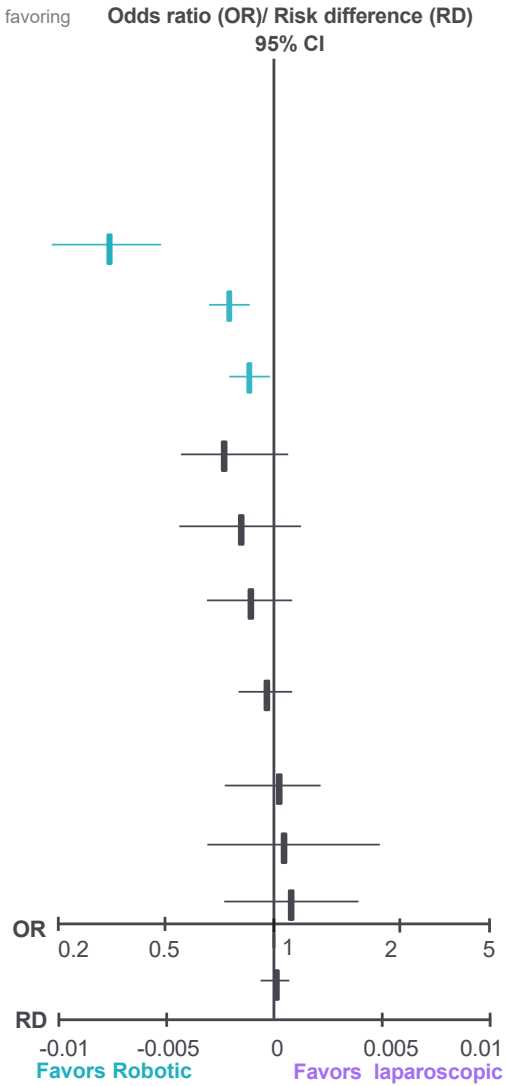
Outcomes	Robotic-assisted, n	Laparoscopic, n	Effect Size 95% CI	P-value
Benign Hysterectomy Continuous variables (to April 17, 2023)				
Estimated blood loss, ml[1,9,16,22,24,27]				
Subtotal	2598	2363	WMD:-46.93 [-82.50; -11.37]	p<0.01
Random, Heterogeneity: p<0.01; I^2= 95%				
Length of stay, days [1,6,8,10,12,14,16,17,18,21,22,23,24]				
Subtotal	43431	111454	WMD: -0.18 [-0.31; -0.05]	p<0.01
Random, Heterogeneity: p<0.01; I^2= 95%				
Return to work, days[1,24]				
Subtotal	1062	1587	WMD: -0.76 [-1.75; 0.23]	p=0.13
Fixed, Heterogeneity: p=0.49, I^2=0%				
Operative time, min[1,5,7,12,13,16,17,18,21,22,24,27]				
Subtotal	28026	91486	WMD: 7.39 [-7.73; 22.51]	p=0.34
Random, Heterogeneity: p<0.01; I2= 99%				

Robotic-assisted vs. laparoscopic benign hysterectomy

Summary as of April 17, 2023

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

- 70% less likely to have a conversion to open surgery
- 23% less likely to receive a blood transfusion
- 15% less likely to experience a postoperative complication within 30-days of surgery
- Comparable infections rate
- Comparable intraoperative complications rate
- Comparable reoperations rate within 30-days of surgery
- Comparable readmissions rates within 30-days of surgery
- Comparable bladder injury rate
- Comparable ureter injury rate
- Comparable wound rate
- Comparable 30-day postoperative mortality rate



Outcomes	Robotic-assisted, n	Laparoscopic, n	Effect Size 95% CI	P-value
Benign Hysterectomy binary variables (to April 17, 2023)				
Conversion, n(%) [1,2,6,8,14,15,16,17,18,20,21,22,24,26]				
Subtotal	89135	177673	OR: 0.30 [0.19; 0.45]	p<0.01
Random, Heterogeneity: p<0.01, I²=97%				
Blood transfusion, n(%) [8,11,14,17,18,20,21,22,23,27,29]				
Subtotal	48052	136795	OR: 0.77 [0.66; 0.90]	p<0.01
Random, Heterogeneity: p=0.02, I²=56%				
Postop complications 30-day, n(%) [1,14,16,17,18,19,20,23,24,25,27,29]				
Subtotal	124997	195051	OR: 0.85 [0.74; 0.98]	p=0.03
Random, Heterogeneity: p<0.01, I²=94%				
Infections, n(%) [2,6,16,17,24,27]				
Subtotal	24083	81187	OR: 0.74 [0.50; 1.09]	p=0.13
Random Heterogeneity: p<0.01, I²=74%				
Intraop complications, n(%) [2,6,8,14,16,18,24,29]				
Subtotal	9342	19576	OR: 0.80 [0.51; 1.27]	p=0.35
Random, Heterogeneity: p=0.01, I²=60%				
Reoperation 30-day, n(%) [10,14,16,21,29]				
Subtotal	14352	24158	OR: 0.85 [0.60; 1.22]	p=0.38
Fixed, Heterogeneity: p=0.82, I²=0%				
Readmission 30-day, n(%) [1,5,6,10,14,16]				
Subtotal	22471	36769	OR: 0.94 [0.76; 1.17]	p=0.60
Random, Heterogeneity: p=0.05, I²=58%				
Bladder injury, n(%) [1,18,20,21]				
Subtotal	11769	34707	OR: 1.02 [0.70, 1.51]	p=0.91
Fixed, Heterogeneity: p=0.55, I²=0%				
Ureter injury, n(%) [1,11,20,21]				
Subtotal	11758	34699	OR: 1.09 [0.62; 1.93]	p=0.75
Fixed, Heterogeneity: p=0.56, I²=0%				
Wound, n(%) [17,20,23]				
Subtotal	39246	119024	OR: 1.11 [0.70; 1.76]	p=0.67
Random Heterogeneity: p=0.10, I²=63%				
Mortality, n(%) [7,8,17,18,20,23,27,29]				
Subtotal	46854	127244	RD: -0.0000 [-0.0002; 0.0001]	p=0.73
Fixed, Heterogeneity: p=0.93, I²=0%				

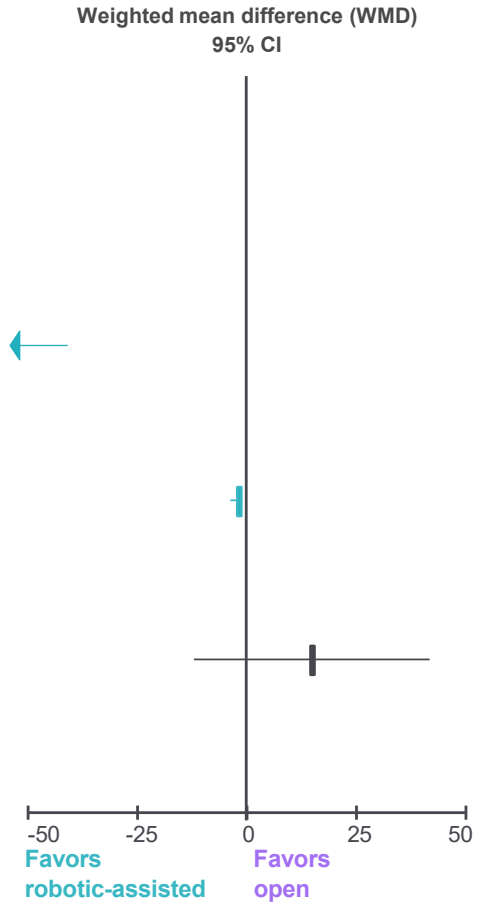
Robotic-assisted vs. open benign hysterectomy

Summary as of April 17, 2023

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

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

- Significantly less estimated blood loss by an average of 199 ml
- Significantly shorter hospital length of stay by an average of 1.3 days
- Comparable operative time



Outcomes	Robotic-assisted, n	Open, n	Effect Size 95% CI	P-value
Benign Hysterectomy Continuous variables (to April 17, 2023)				
Estimated blood loss, ml[1,9,22,28]				
Subtotal	1172	7677	WMD: -199.59 [-358.42; -40.76]	p=0.01
Random, Heterogeneity: $p<0.01$; $I^2= 99\%$				
Length of stay, days [1,10,14,17,22,28]				
Subtotal	31236	162691	WMD: -1.31 [-1.83; -0.78]	p=0.01
Random, Heterogeneity: $p<0.01$, $I^2=100\%$				
Operative time, min[1,17,22,28]				
Subtotal	21880	145890	WMD: 15.12 [-12.09; 42.32]	p=0.28
Random, Heterogeneity: $p<0.01$, $I^2=100\%$				

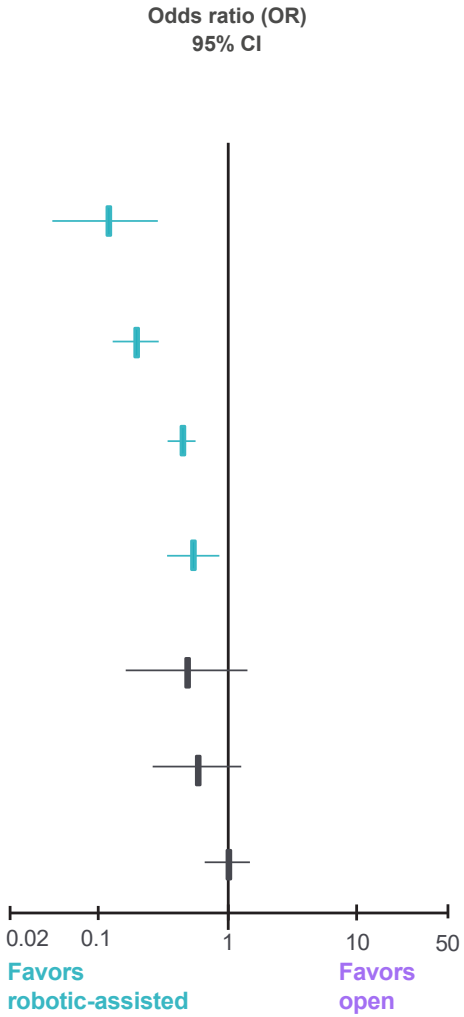
Robotic-assisted vs. open benign hysterectomy

Summary as of April 17, 2023

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

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

- 88% lower chance of mortality within 30-days of surgery
- 80% less likely to receive a blood transfusion
- 55% less likely to experience a postoperative complication within 30-days of surgery
- 45% less likely to experience an intraoperative complication
- Comparable reoperations rate within 30-days of surgery
- Comparable wound rate
- Comparable readmissions rate within 30-days of surgery



Outcomes	Robotic-assisted, n	Open, n	Effect Size 95% CI	P-value
Benign Hysterectomy binary variables (to April 17, 2023)				
Mortality, n(%) [7,17,28,29]				
Subtotal	27352	151616	OR: 0.12 [0.05; 0.29]	p<0.01
Fixed, Heterogeneity: p=0.26, I^2=26%				
Blood transfusion, n(%) [14,17,22,28,29]				
Subtotal	28524	153509	OR: 0.20 [0.14; 0.29]	p<0.01
Random, Heterogeneity: p<0.01, I^2=74%				
Postop complications 30-day, n(%) [1,14,17,19,25,28,29]				
Subtotal	105443	832162	OR: 0.45 [0.35; 0.57]	p<0.01
Random, Heterogeneity: p<0.01, I^2=99%				
Intraop complications, n(%) [14,28,29]				
Subtotal	7679	15124	OR: 0.55 [0.35; 0.85]	p<0.01
Random, Heterogeneity: p=0.09, I^2=65%				
Reoperation 30-day, n(%) [10,14,29]				
Subtotal	14510	22160	OR: 0.48 [0.17; 1.39]	p=0.17
Random, Heterogeneity: p<0.01, I^2=90%				
Wound, n(%) [1,17,29]				
Subtotal	27155	151155	OR: 0.58 [0.28; 1.24]	p=0.16
Random, Heterogeneity: p<0.01, I^2=97%				
Readmission 30-day, n(%) [1,5,10,14]				
Subtotal	22195	169333	OR: 1.01 [0.69; 1.47]	p=0.97
Random, Heterogeneity: p<0.01, I^2=93%				

Robotic-assisted vs. vaginal benign hysterectomy

Summary as of April 17, 2023

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

Compared to vaginal benign hysterectomy, the evidence for **robotic-assisted benign hysterectomy using the da Vinci surgical system** demonstrates:

- Significantly less estimated blood loss by an average of 61ml
- Significantly shorter hospital length of stay by an average of 0.4 days (9.6 hours)
- Comparable return to work
- Significantly longer operative time, by an average of 43 minutes

Outcomes	Robotic-assisted, n	Vaginal, n	Effect Size 95% CI	P-value
Benign Hysterectomy Continuous variables (to April 17, 2023)				
Estimated blood loss, ml[1,3,16,27]				
Subtotal	2474	4187	WMD: -61.24 [-92.45; -30.03]	p<0.01
Random, Heterogeneity: p<0.01; I^2= 83%				
Length of stay, days [1,3,14,16,17]				
Subtotal	24217	64582	WMD: -0.39 [-0.69; -0.08]	p=0.01
Random, Heterogeneity: p<0.01; I^2= 99%				
Return to work, days[1,3]				
Subtotal	1075	3801	WMD: -2.42 [-7.42; 2.57]	p=0.34
Random, Heterogeneity: p<0.01; I^2= 97%				
Operative time, min[1,3,16,17,27]				
Subtotal	23255	56822	WMD: 42.93 [23.38; 62.49]	p<0.01
Random, Heterogeneity: p<0.01; I2= 100%				

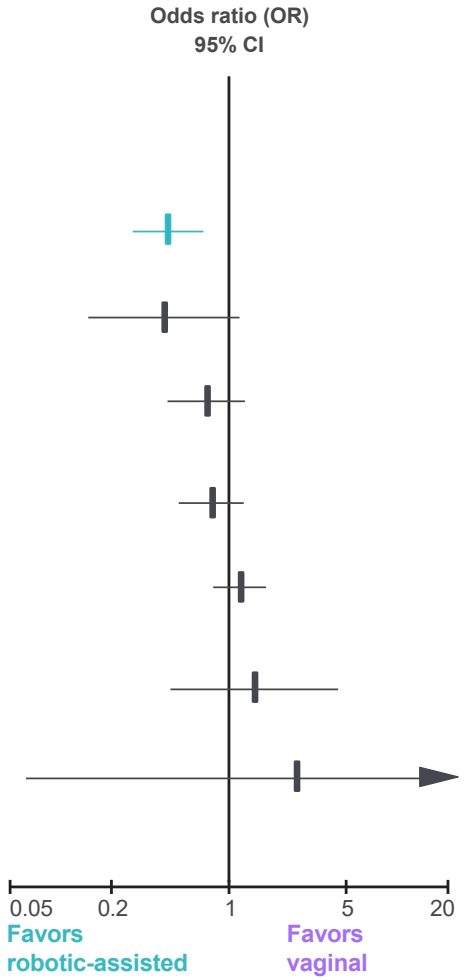
Robotic-assisted vs. vaginal benign hysterectomy

Summary as of April 17, 2023

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

Compared to vaginal benign hysterectomy, the evidence for **robotic-assisted benign hysterectomy using the da Vinci surgical system** demonstrates:

- 57% lower likelihood of an intraoperative complication
- Comparable blood transfusions rate
- Comparable reoperations rate within 30-days of surgery
- Comparable postoperative complications rate within 30-days of surgery
- Comparable readmissions rate within 30-days of surgery
- Comparable 30-day postoperative mortality rate
- Comparable conversions rate



Outcomes	Robotic-assisted, n	Vaginal, n	Effect Size 95% CI	P-value
Benign Hysterectomy binary variables (to April 17, 2023)				
Intraop complications, n(%) [3,14,16]				
Subtotal	2421	8180	OR: 0.43 [0.27; 0.69]	p<0.01
Fixed, Heterogeneity: p=0.78, I²=0%				
Blood transfusion, n(%) [3,14,17,27]				
Subtotal	24479	61151	OR: 0.41 [0.15; 1.16]	p=0.09
Random, Heterogeneity: p<0.01, I²=85%				
Reoperation 30-day, n(%) [3,14,16]				
Subtotal	2216	8180	OR: 0.74 [0.44; 1.23]	p=0.25
Fixed, Heterogeneity: p=0.27, I²=18%				
Postop complications 30-day, n(%) [1,3,14,16,17,25,27]				
Subtotal	42939	69347	OR: 0.78 [0.51; 1.22]	p=0.28
Random, Heterogeneity: p<0.01, I²=96%				
Readmission 30-day, n(%) [1,3,5,14,16]				
Subtotal	15260	55883	OR: 1.15 [0.81; 1.64]	p=0.44
Random, Heterogeneity: p=0.02, I²=65%				
Mortality, n(%) [7,17,27]				
Subtotal	23311	55196	OR: 0.78 [0.51; 1.22]	p=0.54
Fixed, Heterogeneity: p=0.56, I²=0%				
Conversion, n(%) [1,3,14,17,16]				
Subtotal	24217	64582	OR: 2.50 [0.06; 101.48]	p=0.63
Random, Heterogeneity: p<0.01, I²=99%				

Benign Hysterectomy: bibliography (1 of 2)

April 17, 2023

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Important safety information

Surgical Risks:

Surgical risks for hysterectomy, benign (removal of the uterus and possibly nearby organs): injury to the ureters (the ureters drain urine from the kidney into the bladder), vaginal cuff problems (scar tissue in vaginal incision, infection, bacterial skin infection, pooling/clotting of blood, incision opens or separates), injury to bladder (organ that holds urine), bowel injury, vaginal shortening, problems urinating (cannot empty bladder, urgent or frequent need to urinate, leaking urine, slow or weak stream), vaginal fistula (abnormal hole from the vagina into the urinary tract or rectum), vaginal tear or deep cut. Uterine tissue may contain unsuspected cancer. The cutting or morcellation of uterine tissue during surgery may spread cancer, and decrease the long-term survival of patients.

Important Safety Information

Serious complications may occur in any surgery, including surgery with a da Vinci 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 a da Vinci 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, including surgical risks and considerations, please also refer to www.intuitive.com/safety. For a product's intended use and/or indications for use, risks, full cautions and warnings, please refer to the associated User Manual(s).

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®/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) 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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