Evidence Navigator: Myomectomy

Systematic literature review & meta-analysis
as of April 1, 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. It is intended to educate both internal and external stakeholders on the highest level of evidence that is currently available for a given surgical procedure. 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: Myomectomy Summary Slides

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WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points: **Literature search methods for Myomectomy**

Inclusion criteria

Robotic-assisted myomectomy performed with a da Vinci surgical system

January 1, 2010 – April 1, 2022

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

Comparative cohort studies n>20 (RCT, prospective cohort, large independent database studies, or retrospective cohort) (robotic-assisted vs. laparoscopic and/or open surgery)

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

Myomectomy 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

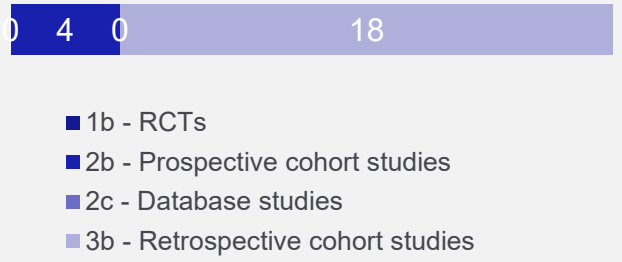
22 publications including

Robotic-assisted patients: **1,756**

Laparoscopic patients: **1,257**

Open patients: **2,369**

Level of evidence



WHAT DOES THE LITERATURE SHOW?

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

Favors robotic-assisted

- ↓ Postoperative ileus by **77%**
- ↓ Blood transfusion by **62%**
- ↓ Estimated blood loss by **58 ml**
- ↓ Length of hospital stay by **1.6 days**

Comparable outcomes

- ≈ Intraoperative complications
- ≈ 30-day postoperative complications
- ≈ 30-day readmissions
- ≈ Postoperative pregnancies*
- ≈ Postoperative miscarriages
- ≈ Postoperative livebirth*
- ≈ Fibroid size
- ≈ Submucosal fibroids
- ≈ Pedunculated fibroids

* 2 studies reporting postoperative fertility outcomes with follow-up ranging between 3 – 8 years

Favors open

- ↓ Operative time by **78 min**
- ↑ Subserosal fibroids by **77%**
- ↑ Intramural fibroids by **53%**
- ↑ Fibroid weight by **116 g**
- ↑ Number of fibroids resected by **3.9**
- ↑ Uterine size by **2.6 gestational weeks**

Data collected through: April 1, 2022

Significant difference favoring robotic-assisted surgery

No significant difference; comparable outcomes

Significant difference favoring open surgery

WHAT DOES THE LITERATURE SHOW?

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

Favors robotic-assisted

- ↓ Conversions by **59%**
- ↑ Pedunculated fibroids by **64%**
- ↑ Fibroid size by **0.52 cm**

Comparable outcomes

- ≈ Length of hospital stay
- ≈ Estimated blood loss
- ≈ Blood transfusions
- ≈ 30-day reoperations
- ≈ Intraoperative complications
- ≈ 30-day postoperative complications
- ≈ Postoperative ileus
- ≈ Postoperative pregnancies*
- ≈ Postoperative miscarriage
- ≈ Postoperative livebirth*
- ≈ Fibroid weight
- ≈ Number of fibroids resected
- ≈ Subserosal fibroids
- ≈ Intramural fibroids
- ≈ Submucosal fibroids

Favors laparoscopic

- ↓ Operative time by **53.08 min**

* 2 studies reporting postoperative fertility outcomes with follow-up ranging between 3 – 8 years

Significant difference favoring robotic-assisted surgery

No significant difference; comparable outcomes

Significant difference favoring laparoscopic surgery

Data collected through: April 1, 2022

Evidence Navigator: Myomectomy Technical Slides

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Myomectomy: Literature search methods

as of April 1, 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 myomectomies 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.

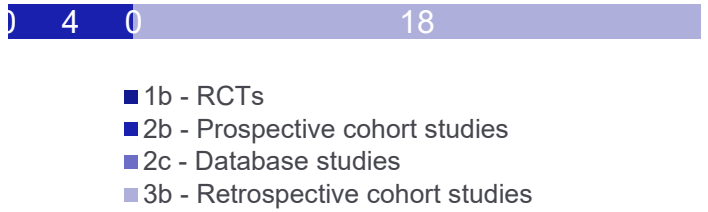
22 publications

1,756 patients who underwent robotic-assisted surgery (RAS)

1,257 patients who underwent laparoscopic surgery (Lap)

2,369 patients who underwent open surgery

Level of evidence



Criteria phase	Details
Identification phase	All robotics publications (library generated from monthly search process) N = 35,039 library size at the time of search April 1st, 2022
Inclusion criteria	
1. Robotic-assisted Myomectomy	Robotic-assisted myomectomy N = 255 (excluded N = 34,784)
2. Year ≥ 2010	Articles published ≥ 2010 N = 232 (excluded N = 23)
3. LOE = 1b, 2b, 2c, 3b	Articles with LOE 1b, 2b, 2c, 3b N = 53 (excluded N = 179)
4. RCT, prospective or retrospective comparative study with comparative cohorts (robotic-assisted vs. laparoscopic and/or open surgery) and sample size > 20 in each cohort	Comparator cohorts N = 38 (excluded N = 15)
Exclusion criteria	**N =** 16 excluded publications:
1. Not in English	N = 2 (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)
4. Alternate technique/approach (e.g., single port)	N = 3 (EC#4)
5. No stratified analysis by study arm (e.g., combines results from robotic-assisted, laparoscopic and/or open cohorts)	N = 9 (EC#5)
6. Myomectomy data mixed with other procedures (e.g., data from multiple surgical procedures combined)	N =1 (EC#6)
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)	N =1 (EC#7)
8. Original research publication includes redundant patient population and similar conclusions	N = 0 (EC#8)

Myomectomy publications: N = 22

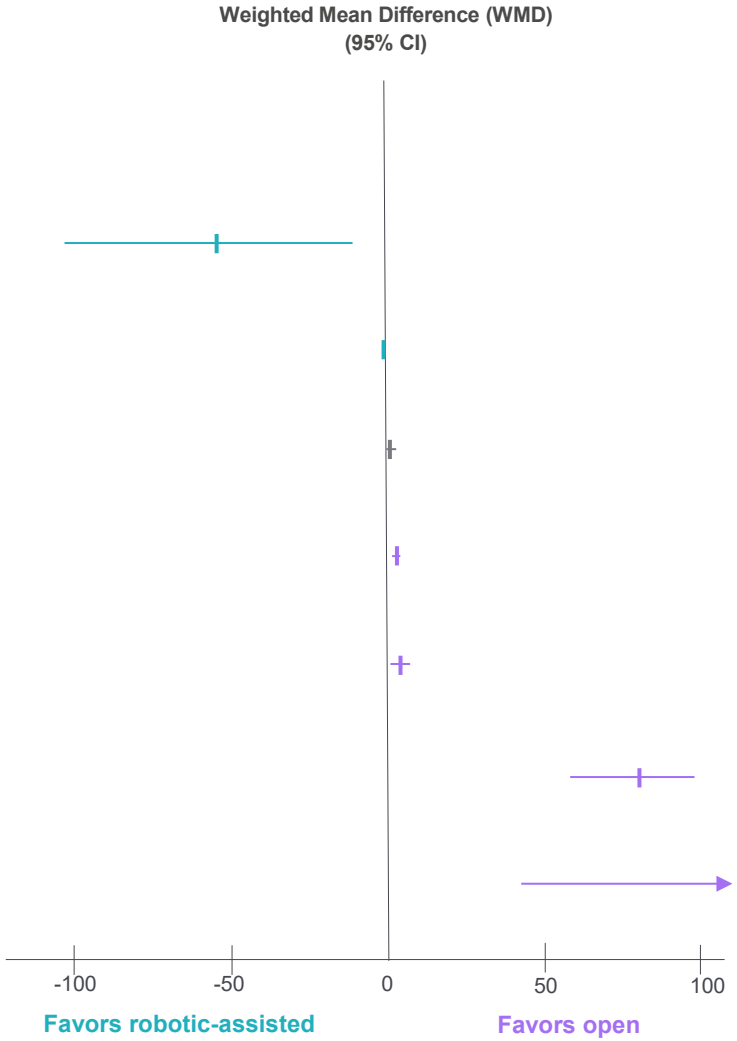
Robotic-assisted vs. open myomectomy

Summary as of April 1, 2022

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

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

- Significantly less estimated blood loss by an average of **58.36 ml**
- Significantly shorter hospital length of stay by an average of **1.58 days**
- Comparable fibroid size
- Significantly larger uterine size by an average of **2.63 gestational weeks**
- Significantly more resected fibroids by an average of **3.87**
- Significantly longer operative time by an average of **77.77 minutes**
- Significantly heavier weight of fibroids resected by an average of **115.66 g**



Outcomes	Robotic-assisted, n	Open, n	Effect Size 95% CI	P-value
Myomectomy continuous variables (to April 1, 2022)				
Estimated blood loss, ml[1,2,3,7,8,10,11,13,14,15,16,18,19]				
Subtotal	1064	1591	-58.36 [-105.04,-11.68]	p=0.01
Random, Heterogeneity: p<0.01, I²=78%				
Length of stay, days [1,2,3,7,8,10,11,12,13,14,15,18,19]				
Subtotal	1156	2193	-1.58 [-1.93,-1.23]	p<0.01
Random, Heterogeneity: p<0.01, I²=93%				
Fibroid size, cm [1,3,8,10,11,13,14,16,18,19]				
Subtotal	896	1324	0.60 [-0.24, 1.44]	p=0.16
Random, Heterogeneity: p<0.01, I²=78%				
Uterine size, gestational weeks[13,15]				
Subtotal	65	127	2.63 [1.44, 3.83]	p<0.01
Fixed, Heterogeneity: p=0.36, I²=0%				
Number of resected fibroids[2,10,11,12,13,14,16]				
Subtotal	733	1349	3.87 [1.04, 6.71]	P<0.01
Random, Heterogeneity: p<0.01, I²=98%				
Operative time, min[1,3,7,8,10,11,12,13,14,15,16,18,19]				
Subtotal	1079	2225	77.77 [60.91, 94.62]	p<0.01
Random, Heterogeneity: p<0.01, I²=91%				
Fibroid weight, g[2,3,10,11,12,13,14,16,18]				
Subtotal	876	1777	115.66 [37.72, 193.61]	p<0.01
Random, Heterogeneity: p<0.01, I²=78%				

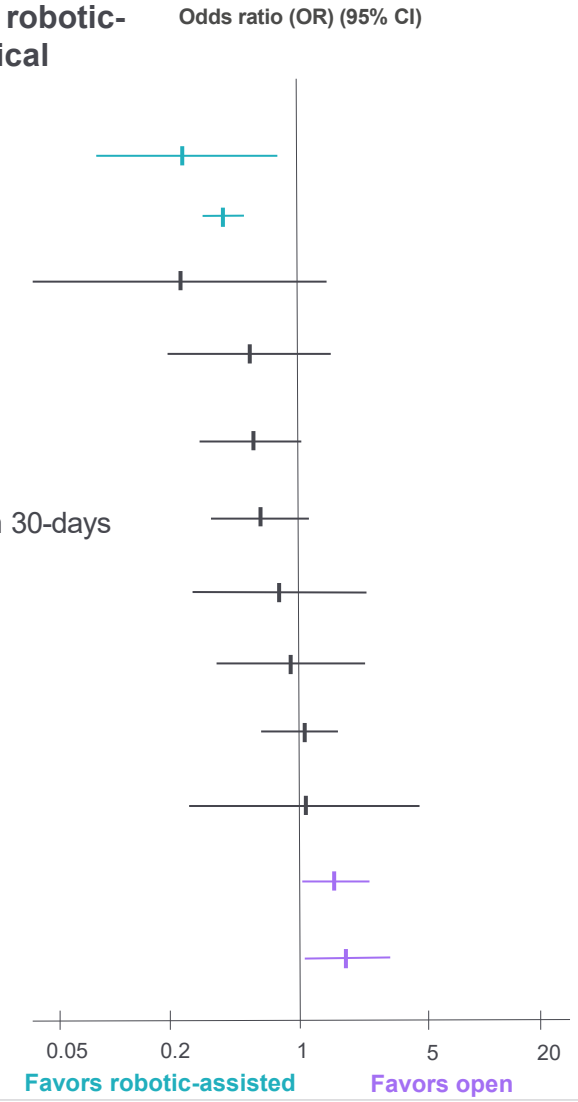
Robotic-assisted vs. open myomectomy

Summary as of April 1, 2022

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

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

- **77%** less likely to experience postoperative ileus
- **62%** less likely to receive a blood transfusion
- Comparable rate of postoperative miscarriage
- Comparable rate of readmissions within 30-days of surgery
- Comparable rate of intraoperative complications
- Comparable rate of postoperative complications within 30-days of surgery
- Comparable rate of submucosal fibroids resected
- Comparable rate of postoperative livebirths
- Comparable rate of pedunculated fibroids resected
- Comparable rate of postoperative pregnancies
- 53% less likely to resect intramural fibroids
- 77% less likely to resect sub-serosal fibroids



Outcomes	Robotic-assisted, n	Open, n	Effect Size 95% CI	P-value
Myomectomy binary variables (to April 1, 2022)				
Postop ileus, n(%)[12,18]				
Subtotal	321	900	0.23 [0.07, 0.75]	p=0.01
Fixed, Heterogeneity: p=0.56, I²=0%				
Blood transfusion, n(%)[1,3,7,10,11,12,13,14,16,18]				
Subtotal	944	2091	0.38 [0.29, 0.51]	p<0.01
Fixed, Heterogeneity: p=0.13, I²=35%				
Postop miscarriage, n(%)[5,14]				
Subtotal	49	102	0.22 [0.03, 1.39]	p=0.11
Fixed, Heterogeneity: p=29, I²=11%				
Readmission 30-day, n(%)[12,18]				
Subtotal	321	900	0.53 [0.20, 1.40]	p=0.2
Fixed, Heterogeneity: p=0.75, I²=0%				
Intraop complications, n(%)[10,12]				
Subtotal	319	997	0.55 [0.29, 1.01]	p=0.06
Fixed, Heterogeneity: p=0.27, I²=19%				
Postop complications 30-day, n(%) [3,7,10,11,12,13,14,15,16]				
Subtotal	755	1877	0.60 [0.34; 1.07]	p=0.08
Random, Heterogeneity: p<0.01, I²=62%				
Fibroid type - Submucosal, n(%) [3,11,12,18]				
Subtotal	396	1286	0.74 [0.24; 2.30]	p=0.61
Random, Heterogeneity: p=0.02, I²=88%				
Postop livebirth, n(%)[5,14]				
Subtotal	49	102	0.89 [0.36, 2.19]	p=0.80
Fixed, Heterogeneity: p=0.35, I²=0%				
Fibroid type - Pedunculated, n(%)[3,16,18]				
Subtotal	320	680	1.04 [0.64; 1.69]	p=0.88
Fixed, Heterogeneity: p=0.53, I²=0%				
Postop pregnancies, n(%)[5,14]				
Subtotal	49	102	1.05 [0.25, 4.40]	p=0.94
Random, Heterogeneity: p=0.09, I²=65%				
Fibroid type - Intramural, n(%)[3,12,18]				
Subtotal	396	1286	1.53 [1.05; 2.24]	p=0.03
Random, Heterogeneity: p=0.12, I²=54%				
Fibroid type - Subserosal, n(%)[3,11,12,18]				
Subtotal	522	1437	1.77 [1.01; 2.58]	p=0.02
Random, Heterogeneity: p=0.02, I²=71%				

* Follow up time for the fertility outcomes ranged from 3 years to 8 years

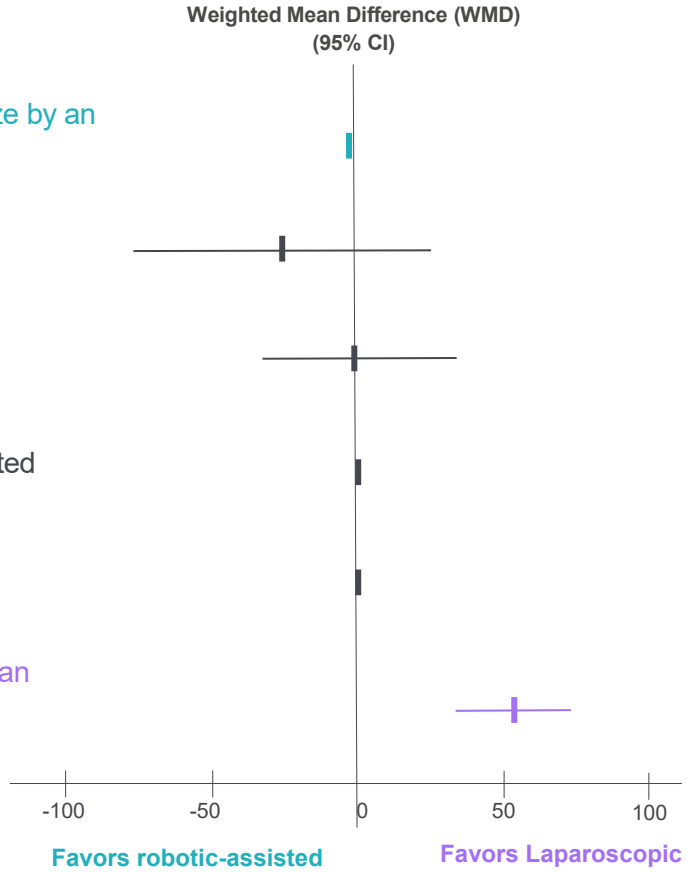
Robotic-assisted vs. laparoscopic myomectomy

Summary as of April 1, 2022

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

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

- Significantly larger resected fibroid size by an average of **0.52 cm**
- Comparable resected fibroid weight
- Comparable estimated blood loss
- Comparable number of fibroids resected
- Comparable length of hospital stay
- Significantly longer operative time by an average of **53.08 minutes**



Outcomes	Robotic-assisted, n	Laparoscopic, n	Effect Size 95% CI	P-value
Myomectomy continuous variables (to April 1, 2022)				
Fibroid size, cm[1,3,4,10,14,16,17,20,21,22]				
Subtotal	705	856	-0.52 [-0.99; -0.06]	p=0.03
Random, Heterogeneity: p<0.01, I²=63%				
Fibroid weight, g[3,4,9,10,12,13,16,17,20,22]				
Subtotal	793	893	-31.67 [-82.48, 19.14]	p=0.22
Random, Heterogeneity: p<0.01, I²=85%				
Estimated blood loss, ml[1,3,4,6,7,9,10,14,16,17,20,21,22]				
Subtotal	965	1034	-0.27 [-35.56; 35.02]	p=0.99
Random, Heterogeneity: p<0.01, I²=82%				
Number of resected fibroids[4,9,10,12,14]				
Subtotal	375	422	0.07 [-0.51, 0.66]	p=0.80
Fixed, Heterogeneity: p=0.20, I²=33%				
Length of stay, days[1,2,3,7,8,10,12,14,17,20,22]				
Subtotal	852	978	0.13 [-0.10; 0.36]	p=0.27
Random, Heterogeneity: p<0.01, I²=89%				
Operative time, min[1,3,4,6,7,9,10,12,14,16,17,20,21,22]				
Subtotal	1059	1219	53.08 [33.63; 72.53]	p<0.01
Random, Heterogeneity: p<0.01, I²=96%				

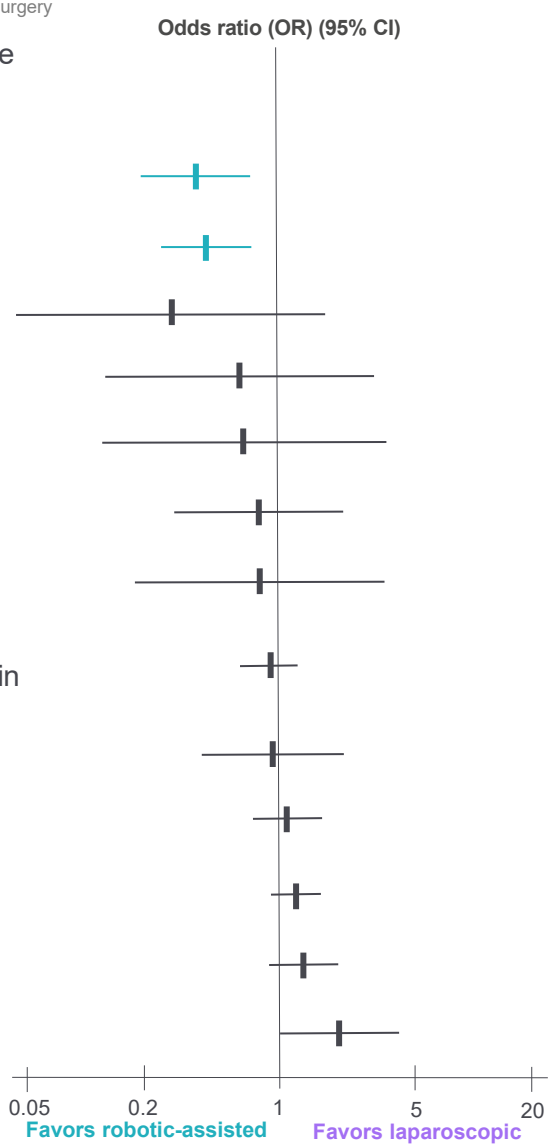
Robotic-assisted vs. laparoscopic myomectomy

Summary as of April 1, 2022

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

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

- **64%** more likely to resect pedunculated fibroids
- **59%** less likely to convert to open surgery
- Comparable rate of postoperative miscarriage
- Comparable rate of postoperative ileus
- Comparable rate of intraoperative complications
- Comparable rate of postoperative livebirths
- Comparable rate of reoperations within 30-days of surgery
- Comparable rate of postoperative complications within 30-days of surgery
- Comparable rate of postoperative pregnancies
- Comparable rate of blood transfusions
- Comparable rate of sub-serosal fibroids resected
- Comparable rate of submucosal fibroids resected
- Comparable rate of intramural fibroids resected



Outcomes	Robotic-assisted, n	Laparoscopic, n	Effect Size 95% CI	P-value
Myomectomy binary variables (to April 1, 2022)				
Fibroid type - Pedunculated, n(%) [3,16,17,22]				
Subtotal	361	407	0.37 [0.19; 0.69]	p<0.01
Fixed, Heterogeneity: p=0.54, I²=0%				
Conversions, n(%) [1,4,7,9,10,12,14,16,17,20]				
Subtotal	708	844	0.41 [0.25, 0.70]	p<0.01
Fixed, Heterogeneity: p=0.81, I²=0%				
Postop miscarriage, n(%) [5,14]				
Subtotal	49	52	0.27 [0.04, 1.72]	p=0.17
Fixed, Heterogeneity: p=0.28, I²=16%				
Postop ileus, n(%) [12,22]				
Subtotal	277	307	0.61 [0.13, 2.89]	p=0.53
Fixed, Heterogeneity: p=41, I²=0%				
Intraop complications, n(%) [10,12]				
Subtotal	319	348	0.63 [0.12, 3.35]	p=0.59
Random, Heterogeneity: p=0.06, I²=71%				
Postop livebirth, n(%) [5,14]				
Subtotal	49	52	0.76 [0.29, 2.02]	p=0.59
Fixed, Heterogeneity: p=0.35, I²=0%				
Reoperation 30-day, n(%) [1,6,22]				
Subtotal	346	343	0.77 [0.18, 3.37]	p=0.73
Fixed, Heterogeneity: p=0.90, I²=0%				
Postop complications 30-day, n(%) [3,4,6,7,9,10,12,14,16,20]				
Subtotal	877	925	0.88 [0.62, 1.24]	p=0.06
Fixed, Heterogeneity: p=0.40, I²=4%				
Postop pregnancies, n(%) [5,14]				
Subtotal	49	52	0.89 [0.39, 2.08]	p=0.80
Fixed, Heterogeneity: p=0.26, I²=22%				
Blood transfusion, n(%) [1,3,4,6,7,9,10,12,14,16,17,22]				
Subtotal	999	1086	1.06 [0.72, 1.58]	p=0.75
Fixed, Heterogeneity: p=0.34, I²=11%				
Fibroid type - Subserosal, n(%) [3,12,17,22]				
Subtotal	437	482	1.18 [0.89; 1.57]	p=0.24
Fixed, Heterogeneity: p=0.64, I²=0%				
Fibroid type - Submucosal, n(%) [3,4,9,12,17,22]				
Subtotal	483	556	1.29 [0.85; 1.95]	p=0.24
Fixed, Heterogeneity: p=0.16, I²=37%				
Fibroid type - Intramural, n(%) [3,12,17,22]				
Subtotal	437	482	1.98 [0.96; 4.09]	p=0.07
Random, Heterogeneity: p<0.01, I²=85%				

* Follow up time for the fertility outcomes ranged from 3 years to 8 years

Myomectomy: bibliography (1 of 2)
April 1, 2022

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Important safety information

Surgical Risks:

Surgical risks for myomectomy (removal of fibroid tumors) include: tear or hole in uterus, split or bursting of the uterus, pre-term (early) birth, spontaneous abortion. Uterine tissue may contain unsuspected cancer. The cutting or morcellation of uterine or fibroid 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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