

Evidence Navigator: Partial nephrectomy

Systematic literature review & meta-analysis summary
as of December 31, 2022

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 regarded as 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. All calculations and forest plots are made 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, meta-analyses may contain some overlapping studies. A redundancy check is performed in order to minimize this overlap and bias due to over-reporting.

Glossary

95% CI	95% confidence interval
EBL	estimated blood loss
HTA	health technology assessment
I²	test statistic for heterogeneity
LNy	lymph node yield
LOE	level of evidence
LOS	length of hospital stay

MD	mean difference
OR	odds ratio
PSM	positive surgical margins
RAS	robotic-assisted surgery
RCT	randomized controlled trial
SMD	standardized mean difference
WIT	warm ischemia time

Evidence Navigator: Partial nephrectomy Summary Slides

Systematic literature review & meta-analysis summary
as of December 31, 2022



WHAT DOES THE LITERATURE SHOW?

Systematic literature review & meta-analysis key points: Literature search methods for partial nephrectomy

Inclusion criteria

Robotic-assisted partial nephrectomy 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 $n \geq 20$ 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

Partial nephrectomy data mixed with other procedures

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

Original research publication includes redundant patient population and similar conclusions

33 publications including



Robotic-assisted patients: **87,675**



Laparoscopic patients: **23,021**



Open patients: **80,313**

Level of evidence



■ 1b ■ 2b ■ 2c



WHAT DOES THE LITERATURE SHOW?

Systematic literature review & meta-analysis key points: Robotic-assisted with da Vinci surgical system vs. open partial nephrectomy



Favors robotic-assisted

- ↓ Estimated blood loss by **93 mL**
- ↓ Blood transfusions by **49%**
- ↓ Intraoperative complications by **32%**
- ↓ Length of stay by **2 days**
- ↓ 30-day postoperative complications by **40%**
- ↓ 30-day readmissions by **38%**
- ↓ Risk of 30-day mortality



Comparable outcomes

≈ Warm ischemia time



Favors open

- ↓ Operative time by **32 min**
- ↓ Positive surgical margins by **44%**

Data collected through: December 31, 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 & meta-analysis key points: Robotic-assisted with da Vinci surgical system vs. laparoscopic partial nephrectomy



Favors robotic-assisted

- ↓ Blood transfusions by **19%**
- ↓ Conversions by **54%**
- ↓ Length of stay by **0.6 days**
- ↓ 30-day readmissions by **22%**
- ↓ 30-day postoperative complications by **19%**



Comparable outcomes

- ≈ Operative time
- ≈ Estimated blood loss
- ≈ Warm ischemia time
- ≈ Intraoperative complications
- ≈ Positive surgical margins
- ≈ Risk of 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

Evidence Navigator: Partial nephrectomy Technical Slides

Systematic literature review & meta-analysis summary
as of December 31, 2022

Partial nephrectomy: 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 the Global Evidence Management team.

All robotic-assisted partial nephrectomies were performed with the da Vinci® surgical systems. Publications were identified according to inclusion and exclusion criteria described.

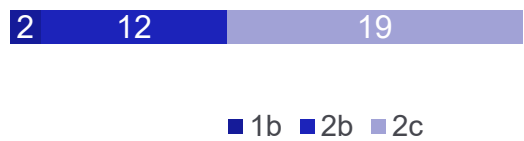
33 publications

87,675 patients who underwent RAS

23,021 patients who underwent laparoscopic surgery

80,313 patients who underwent open surgery

Level of evidence



Criteria phase	Details
Identification phase	All unique PubMed, Scopus, and Embase references identified N=6,846 December 31, 2022
Inclusion criteria	
1. Robotic-assisted partial nephrectomy procedure	Robotic-assisted partial nephrectomy N=3,028 (excluded N=3,818)
2. Year≥2010	Articles published≥2010 N=3,028 (excluded N=0)
3. LOE=1b, 2b, 2c	Articles with LOE=1b, 2b, 2c N=173 (excluded N=2,855)
4. Study is an RCT, prospective cohort study or large database study with comparative cohorts (robotic-assisted vs lap and/or open surgery) and n≥20	Comparator cohorts N=155 (excluded N=18)
Exclusion criteria	N=122 excluded publications:
1. Not in English	N=0 (EC#1)
2. Paper reports on a pediatric population	N=1 (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, hand-assist, etc.)	N=0 (EC#4)
5. No stratified analysis by study arm (e.g. combines results from robotic, laparoscopic and/or open cohorts)	N=83 (EC#5)
6. Partial nephrectomy data mixed with other procedures (e.g. data from multiple surgical procedures combined)	N=4 (EC#6)
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)	N=27 (EC#7)
8. Original research publication includes redundant patient population and similar conclusions	N=7 (EC#8)

Partial nephrectomy publications: N=33

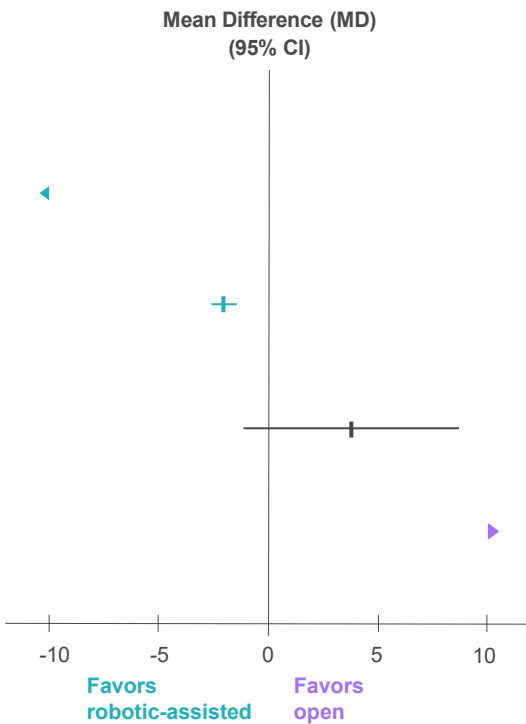
Robotic-assisted vs. open partial nephrectomy (1 of 2)

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 partial nephrectomy, the evidence for **robotic-assisted partial nephrectomy using the da Vinci surgical system** demonstrates:

- Significantly less estimated blood loss by an average of 93 mL
- Significantly shorter hospital length of stay by an average of 2 days
- Comparable warm ischemia time
- Significantly greater operative time by an average of 32 min



Outcomes	Robotic-assisted, n	Open, n	Effect Size 95% CI	P-value
Partial nephrectomy continuous variables (to December 31, 2022)				
EBL, mL 8, 12-14, 17, 19, 20, 24				
Subtotal	856	1975	MD: -93.46 [-151.82, -35.10]	p<0.01
Random, Heterogeneity: p<0.01, I² = 72%				
LOS, days 4, 7, 8, 11, 14, 17, 19, 20, 22, 24, 26				
Subtotal	32845	63987	MD: -2.01 [-2.56, -1.45]	p<0.01
Random, Heterogeneity: p<0.01, I² = 96%				
WIT, min 8, 12-14, 17, 19, 20, 24				
Subtotal	829	1375	MD: 3.83 [-1.06, 8.72]	p=0.12
Random, Heterogeneity: p<0.01, I² = 97%				
Operative time, min 8, 10, 12, 13, 17, 19, 20				
Subtotal	836	1565	MD: 31.77 [14.54, 48.99]	p<0.01
Random, Heterogeneity: p<0.01, I² = 91%				

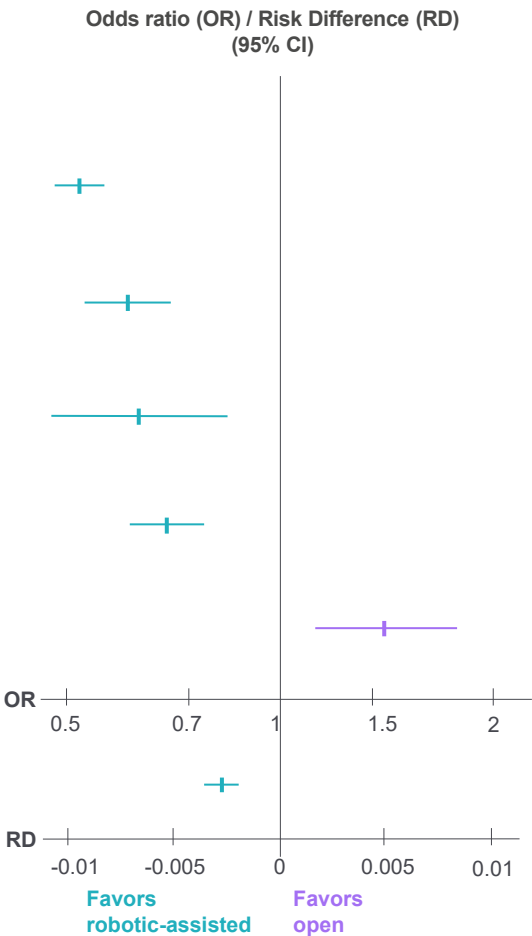
Robotic-assisted vs. open partial nephrectomy (2 of 2)

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 partial nephrectomy, the evidence for **robotic-assisted partial nephrectomy using the da Vinci surgical system** demonstrates:

- 49% less likely to receive a blood transfusion
- 40% less likely to experience a postoperative complication within 30 days of surgery
- 38% less likely to experience a readmission within 30 days of surgery
- 32% less likely to experience an intraoperative complication
- 44% more likely to experience a positive surgical margin
- A significantly lower risk of mortality within 30 days of surgery



Outcomes	Robotic-assisted, n	Open, n	Effect Size 95% CI	P-value
Partial nephrectomy binary variables (to December 31, 2022)				
Transfusions, n (%) ^{6, 11, 14, 19, 20, 23, 26}				
Subtotal	15488	32869	OR: 0.51 [0.46, 0.55]	p<0.01
Fixed, Heterogeneity: p=0.45, I ² = 0%				
Postoperative complications, n (%) ^{4, 11, 12, 14, 19, 20, 23, 26}				
Subtotal	32593	63804	OR: 0.60 [0.52, 0.69]	p<0.01
Random, Heterogeneity: p<0.01, I ² = 83%				
Readmissions, n (%) ^{7, 23}				
Subtotal	2141	5564	OR: 0.62 [0.46, 0.83]	p<0.01
Random, Heterogeneity: p=0.1, I ² = 64%				
Intraoperative complications, n (%) ^{11, 13, 20, 31}				
Subtotal	9283	26071	OR: 0.68 [0.60, 0.77]	p<0.01
Fixed, Heterogeneity: p=0.53, I ² = 0%				
PSM, n (%) ^{2, 5, 8, 12-14, 17, 19, 20, 24, 30}				
Subtotal	8530	11467	OR: 1.44 [1.13, 1.83]	p<0.01
Random, Heterogeneity: p=0.07, I ² =41% (random model was used to account for overrepresentation of database studies)				
Mortality, n (%) ^{11, 20, 23, 24}				
Subtotal	10820	28977	RD: -0.0027 [-0.0034, -0.0020]	p<0.01
Fixed, Heterogeneity: p=0.97, I ² = 0%				

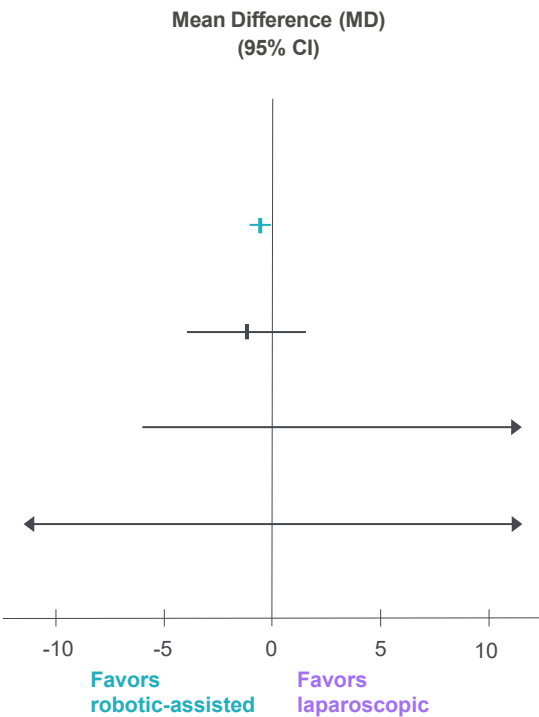
Robotic-assisted vs. laparoscopic partial nephrectomy (1 of 2)

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 partial nephrectomy, the evidence for **robotic-assisted partial nephrectomy using the da Vinci surgical system** demonstrates:

- Significantly shorter hospital length of stay by an average of 0.6 days
- Comparable warm ischemia time
- Comparable operative time
- Comparable estimated blood loss



Outcomes	Robotic-assisted, n	Laparoscopic, n	Effect Size 95% CI	P-value
Partial nephrectomy continuous variables (to December 31, 2022)				
LOS, days 1, 3, 4, 7, 9, 11, 15, 17, 18, 24, 32				
Subtotal	32028	9094	MD: -0.57 [-0.97, -0.18]	p<0.01
Random, Heterogeneity: p<0.01, I ² = 97%				
WIT, min 1, 9, 12, 13, 17, 18, 24, 32, 33				
Subtotal	994	1107	MD: -1.20 [-3.83, 1.43]	p=0.37
Random, Heterogeneity: p<0.01, I ² = 98%				
Operative time, min 1, 3, 12, 13, 17, 18, 32, 33				
Subtotal	1125	1470	MD: 13.39 [-5.93, 32.71]	p=0.17
Random, Heterogeneity: p<0.01, I ² = 98%				
EBL, mL 1, 9, 12, 13, 17, 18, 24, 33				
Subtotal	960	1255	MD: 14.17 [-46.65, 74.98]	p=0.65
Random, Heterogeneity: p<0.01, I ² = 98%				

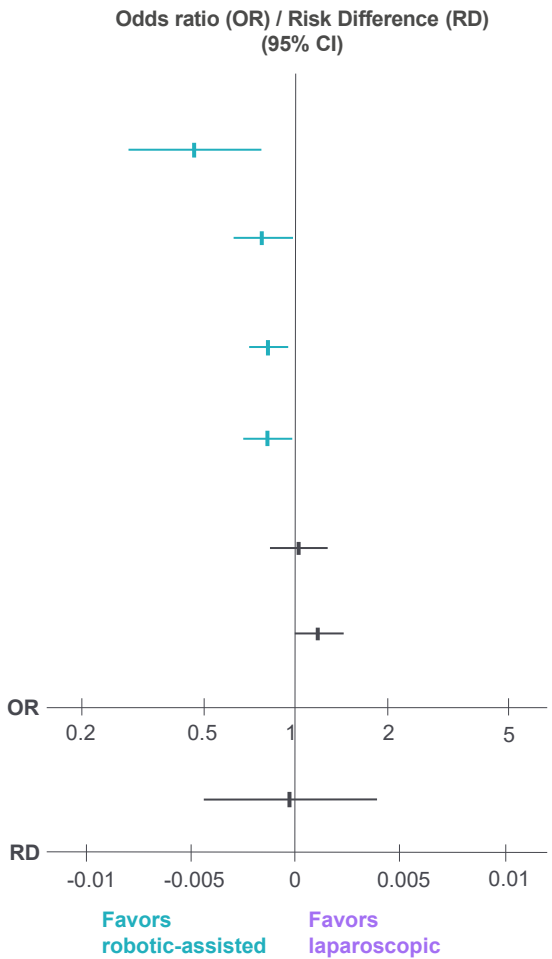
Robotic-assisted vs. laparoscopic partial nephrectomy (2 of 2)

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 partial nephrectomy, the evidence for **robotic-assisted partial nephrectomy using the da Vinci surgical system** demonstrates:

- 54% less likely to convert to open surgery
- 22% less likely to be readmitted within 30 days of surgery
- 19% less likely to receive a blood transfusion
- 19% less likely to experience a postoperative complication within 30 days of surgery
- Comparable intraoperative complication rate
- Comparable positive surgical margins
- Comparable risk of mortality within 30 days of surgery



Outcomes	Robotic-assisted, n	Laparoscopic, n	Effect Size 95% CI	P-value
Partial nephrectomy binary variables (December 31, 2022)				
Conversions, n (%) 1, 3, 7, 13, 16, 18, 24, 27, 32				
Subtotal	25286	7418	OR: 0.46 [0.28, 0.76]	p<0.01
Random, Heterogeneity: p<0.01, I ² = 73%				
Readmissions, n (%) 1, 7, 15, 23				
Subtotal	3269	2009	OR: 0.78 [0.63, 0.97]	p=0.03
Fixed, Heterogeneity: p=0.99, I ² = 0%				
Transfusions, n (%) 1, 9, 11, 18, 23, 32				
Subtotal	11043	4338	OR: 0.81 [0.71, 0.93]	p<0.01
Fixed, Heterogeneity: p=0.75, I ² = 0%				
Postoperative complications, n (%) 1, 3, 4, 9, 11, 12, 18, 23, 33				
Subtotal	31933	8841	OR: 0.81 [0.68, 0.97]	p=0.02
Random, Heterogeneity: p<0.01, I ² = 65%				
Intraoperative complications, n (%) 11, 13				
Subtotal	9178	3700	OR: 1.02 [0.83, 1.25]	p=0.88
Fixed, Heterogeneity: p=0.22, I ² = 33%				
PSM, n (%) 1, 2, 5, 12, 13, 17, 18, 24, 30, 32				
Subtotal	8573	4155	OR: 1.19 [0.99, 1.43]	p=0.06
Random, Heterogeneity: p=0.37, I ² =8% (random model was used to account for overrepresentation of database studies)				
Mortality, n (%) 18, 23, 24				
Subtotal	1840	781	RD: -0.0003 [-0.0044, -0.0039]	p=0.9
Fixed, Heterogeneity: p=1, I ² = 0%				

Partial nephrectomy: bibliography (1 of 2)

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Partial nephrectomy: bibliography (2 of 2)

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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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