

Evidence Navigator: Radical Prostatectomy

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

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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
Lap	laparoscopic surgery
LOE	level of evidence
HTA	health technology assessment
RCT	randomized controlled trial
OR	odds ratio
MD	mean difference
LNy	lymph node yield

WMD	weighted mean difference
RD	risk difference
SMD	standardized mean difference
95% CI	95% confidence interval
I²	test statistic for heterogeneity
EBL	estimated blood loss
LOS	length of hospital stay
PSM	positive surgical margins

Evidence Navigator: Radical Prostatectomy Summary Slides

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WHAT DOES THE LITERATURE SHOW?

Systematic literature review & meta-analysis: Radical prostatectomy— clinical outcomes

Inclusion criteria

Robotic-assisted radical prostatectomy 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 not published in a peer-reviewed journal

Alternate technique/approach (e.g. single-port)

No stratified analysis by study arm

Radical prostatectomy data mixed with other procedures

Original research study does not provide quantitative results

Original research publication includes redundant patient population and similar conclusions

95 publications including



Robotic-assisted patients: **669,924**



Laparoscopic patients: **59,442**



Open patients: **573,660**

Level of evidence



■ 1b - RCTs

■ 2b - Prospective cohort studies

■ 2c - Database studies



WHAT DOES THE LITERATURE SHOW?

Systematic literature review & meta-analysis key points: Robotic-assisted vs. laparoscopic radical prostatectomy



Favors robotic-assisted

- ↓ Blood transfusions by **44%**
- ↓ Length of stay by **0.5 days**
- ↓ 30-day postoperative complications by **28%**
- ↓ 30-day readmissions by **37%**
- ↓ 30-day mortality by **86%**
- ↓ Urinary incontinence at 6 months by **26%**
- ↓ Urinary incontinence at 12 months by **22%**
- ↓ Erectile dysfunction at 12 months by **45%**



Comparable outcomes

- ≈ Operative time
- ≈ Conversions
- ≈ Estimated blood loss
- ≈ Lymph node yield
- ≈ Positive surgical margins
- ≈ Intraoperative complications
- ≈ 30-day reoperations
- ≈ Erectile dysfunction at 6 months



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



WHAT DOES THE LITERATURE SHOW?

Systematic literature review & meta-analysis key points: Robotic-assisted vs. open radical prostatectomy



Favors robotic-assisted

- ↓ Estimated blood loss by **448 mL**
- ↓ Blood transfusions by **82%**
- ↑ Lymph node yield by **2 nodes**
- ↓ Positive surgical margins by **19%**
- ↓ Intraoperative complications by **42%**
- ↓ Length of stay by **1.4 days**
- ↓ 30-day postoperative complications by **47%**
- ↓ 30-day readmissions by **39%**
- ↓ 30-day mortality by **60%**
- ↓ Time to continence by **1.9 months**
- ↓ Urinary incontinence at 6 months by **22%**
- ↓ Erectile dysfunction at 6 months by **59%**
- ↓ Erectile dysfunction at 12 months by **34%**



Comparable outcomes

- ≈ 30-day reoperations
- ≈ Urinary incontinence at 12 months



Favors open

- ↓ Operative time by **49 minutes**

Data collected through: December 31, 2022

Significant difference favoring robotic-assisted surgery

No significant difference; comparable outcomes

Significant difference favoring open surgery

Evidence Navigator: Radical Prostatectomy Technical Slides

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radical prostatectomy: 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 radical prostatectomies were 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.

Criteria phase	Details
Identification phase	All unique PubMed, Scopus, and Embase references identified N=24,042 December 31, 2022
Inclusion criteria	
1. Robotic-assisted radical prostatectomy for cancer	Da Vinci® robotic-assisted radical prostatectomy N=6,767 (excluded N=17,275)
2. Year \geq 2010	Articles published \geq 2010 N=6,748 (excluded N=19)
3. LOE = 1b, 2b, 2c	Articles with LOE = 1b, 2b, 2c N=418 (excluded N=6,330)
4. Study is an RCT, prospective study or large database with comparative cohorts (robotic-assisted vs. laparoscopic and/or open surgery), with $n \geq 20$ in each cohort	Comparator cohorts N=394 (excluded N=24)
Exclusion criteria	N=299 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)
4. Alternate technique/approach (e.g. single-port)	N=1 (EC#4)
5. No stratified analysis by study arm (e.g., combines results from robotic, laparoscopic and/or open cohorts)	N=169 (EC#5)
6. Radical prostatectomy data mixed with other procedures (e.g., data from multiple surgical procedures combined)	N=3 (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, etc.)	N=106 (EC#7)
8. Original research publication includes redundant patient population and similar conclusions	N=19 (EC#8)

95 publications

669,924 patients who underwent RAS

59,442 patients who underwent laparoscopic surgery

573,660 patients who underwent open surgery

Level of evidence



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

radical prostatectomy publications: N=95

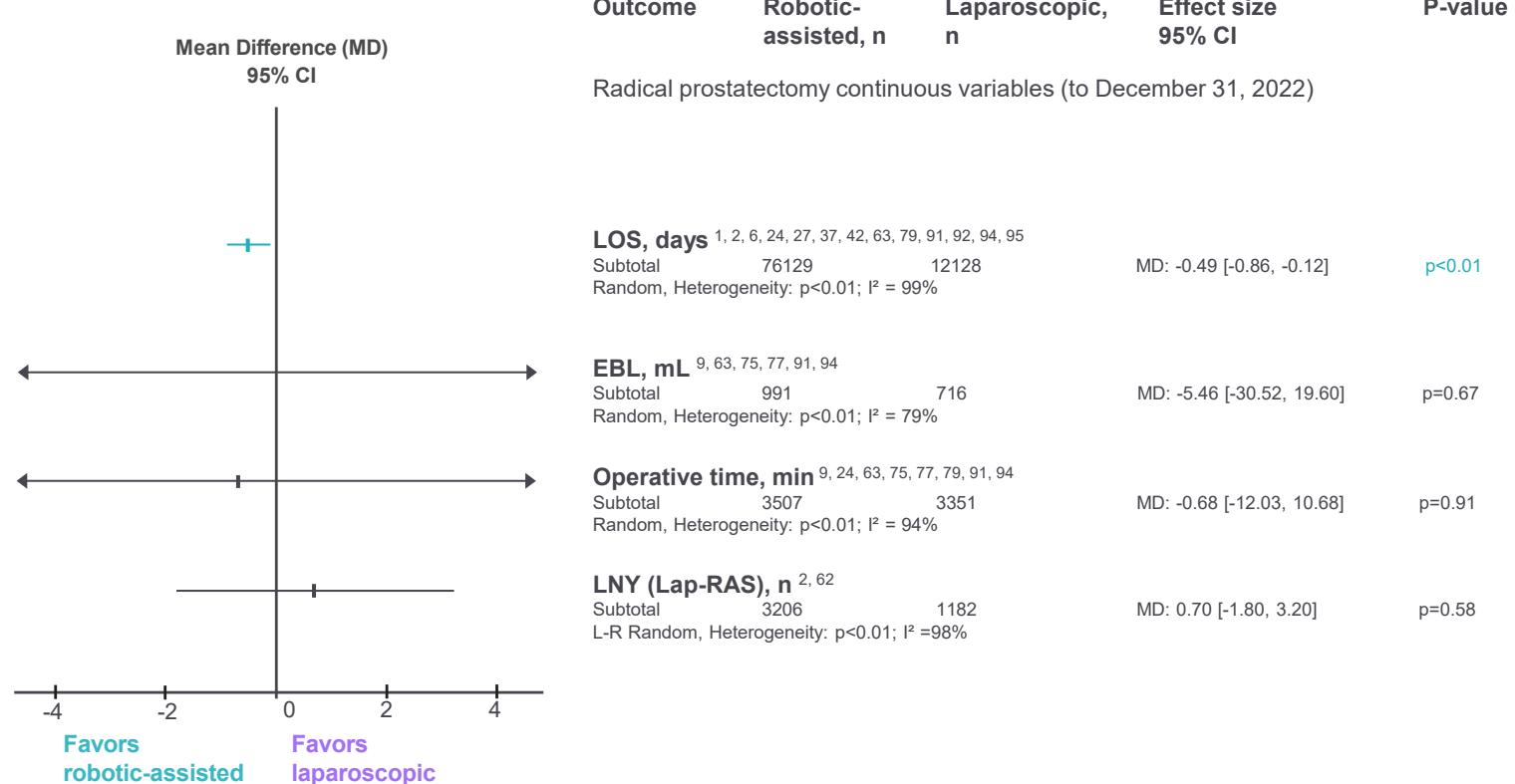
Robotic-assisted vs. laparoscopic radical prostatectomy (1 of 3)

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 radical prostatectomy, the evidence for **robotic-assisted radical prostatectomy using the da Vinci surgical system** demonstrates:

- Significantly shorter hospital length of stay by an average of 0.5 days
- Comparable estimated blood loss
- Comparable operative time
- Comparable lymph node yield



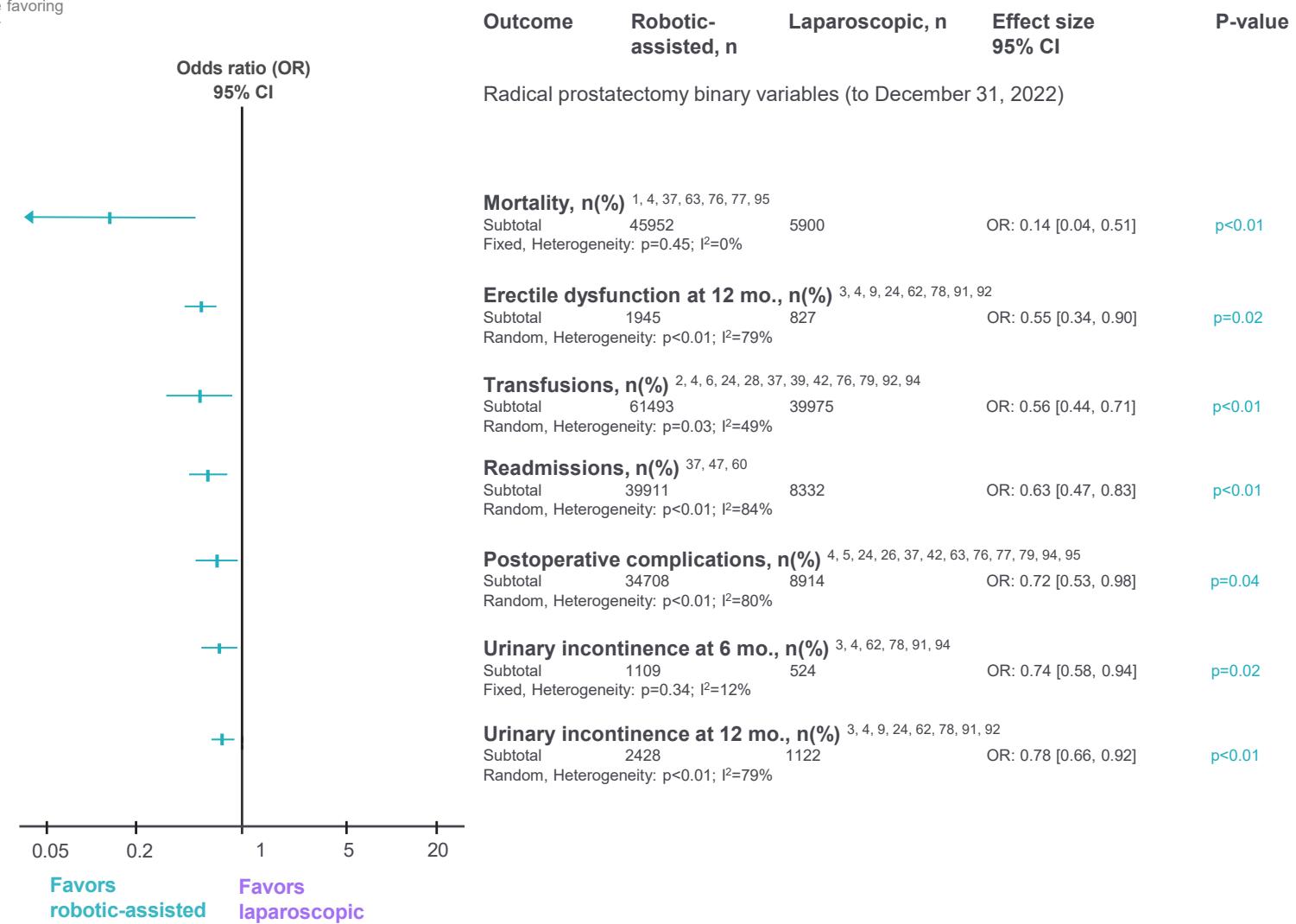
Robotic-assisted vs. laparoscopic radical prostatectomy (2 of 3)

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 radical prostatectomy, the evidence for **robotic-assisted radical prostatectomy using the da Vinci surgical system** demonstrates:

- 86% lower likelihood of mortality within 30 days of surgery
- 45% less likely to experience erectile dysfunction at 12 months
- 44% less likely to receive a blood transfusion
- 37% less likely to experience a readmission within 30 days of surgery
- 28% less likely to experience a postoperative complication within 30 days of surgery
- 26% less likely to experience urinary incontinence at 6 months
- 22% less likely to experience urinary incontinence at 12 months



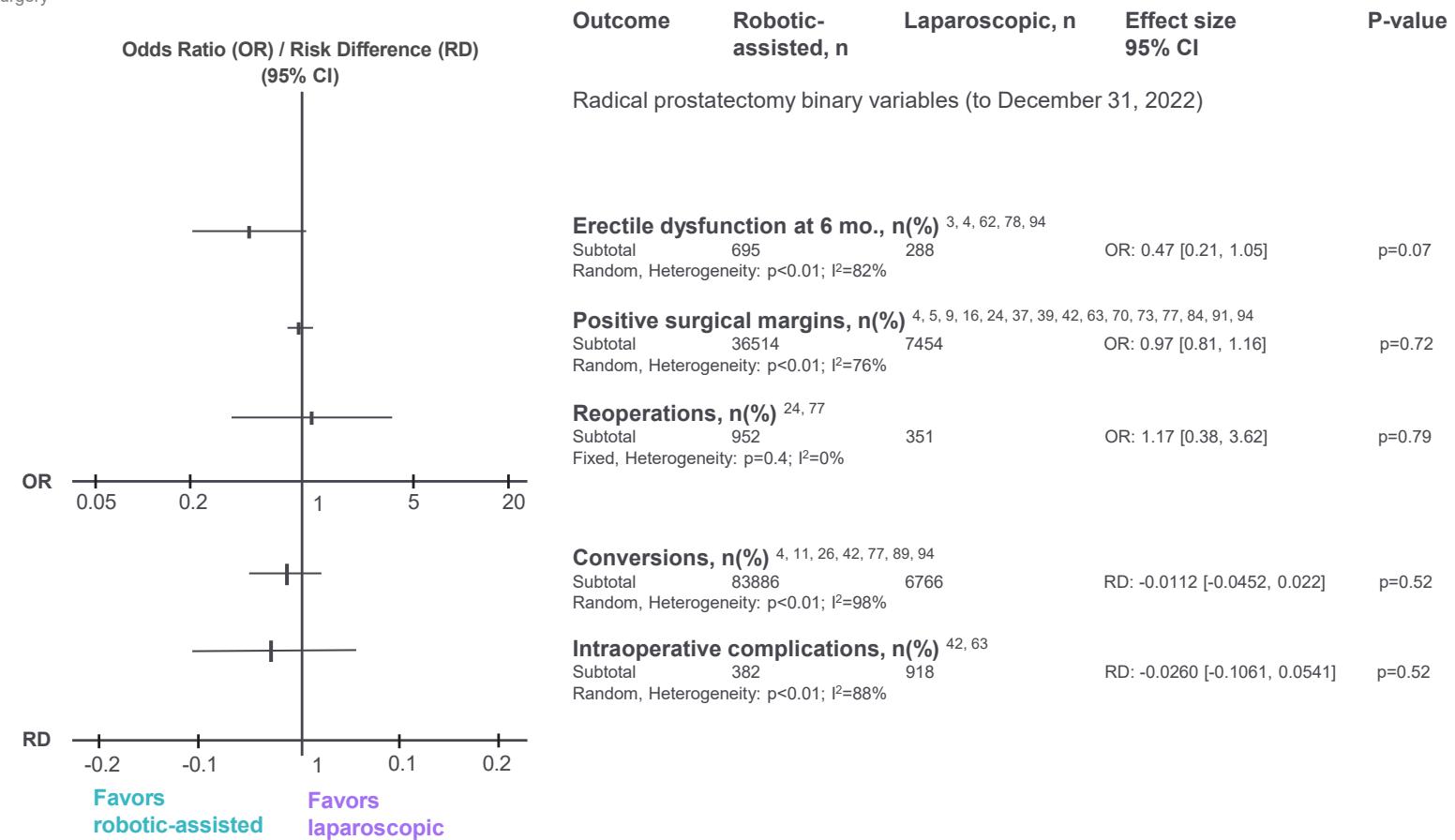
Robotic-assisted vs. laparoscopic radical prostatectomy (3 of 3)

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 radical prostatectomy, the evidence for **robotic-assisted radical prostatectomy using the da Vinci surgical system** demonstrates:

- Comparable erectile dysfunction rate at 6 months
- Comparable positive surgical margin rate
- Comparable reoperation rate within 30 days of surgery
- Comparable risk of conversion to open surgery
- Comparable risk of intraoperative complications



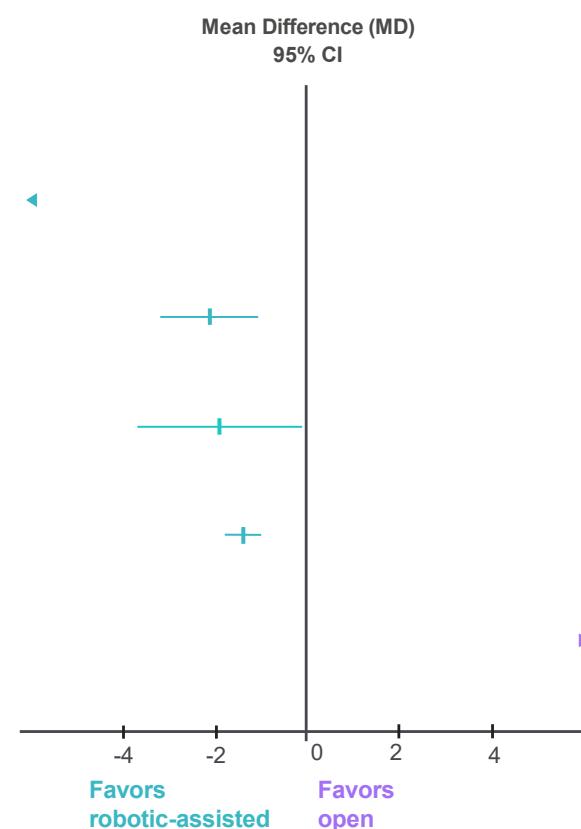
Robotic-assisted vs. open radical prostatectomy (1 of 3)

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 radical prostatectomy, the evidence for **robotic-assisted radical prostatectomy using the da Vinci surgical system** demonstrates:

- Significantly less estimated blood loss by an average of 448 mL
- Significantly higher lymph node yield by an average of 2 nodes
- Significantly shorter time to continence by an average of 1.9 months
- Significantly shorter hospital length of stay by an average of 1.4 days
- Significantly longer operative time by an average of 49 minutes



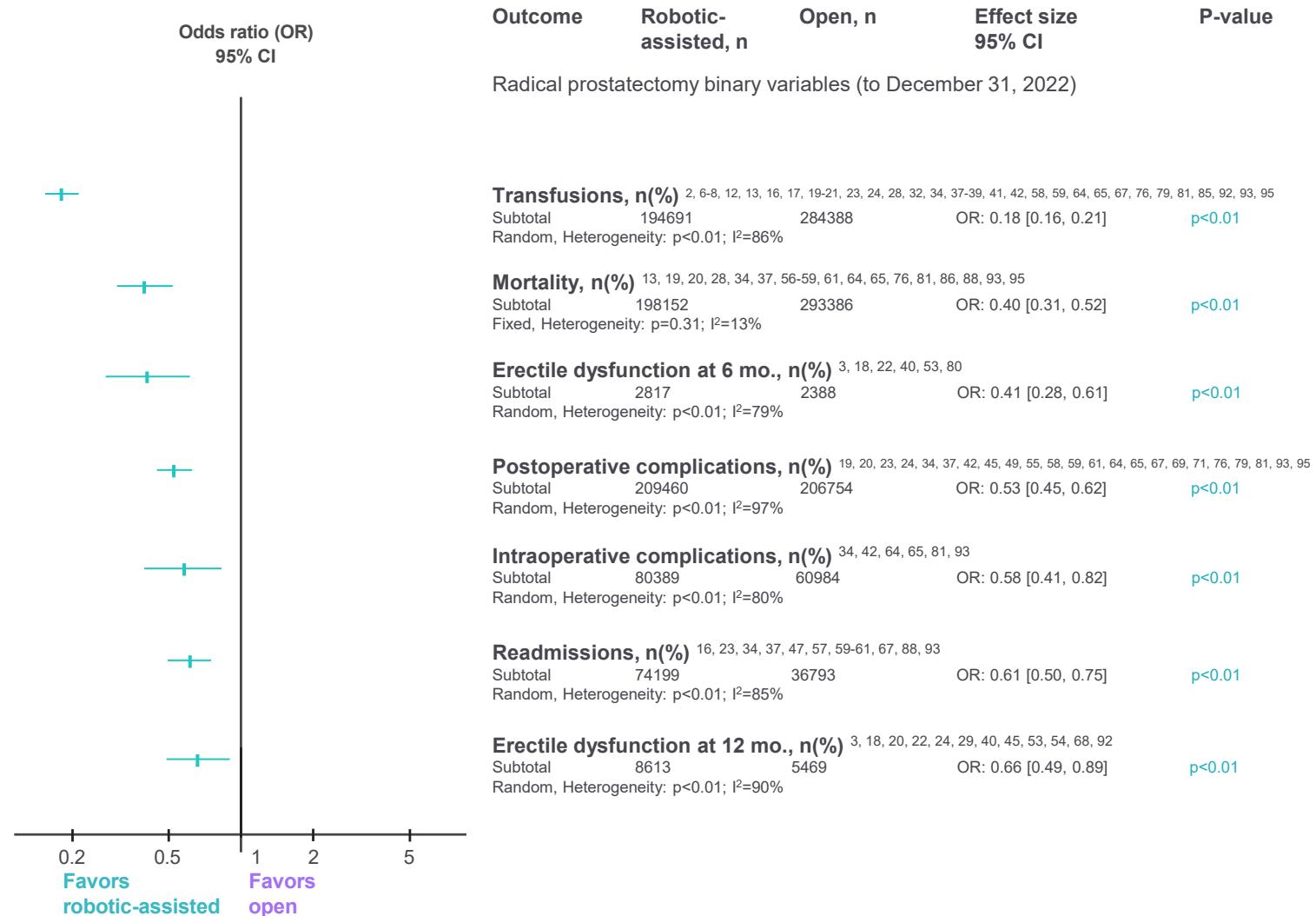
Robotic-assisted vs. open radical prostatectomy (2 of 3)

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 radical prostatectomy, the evidence for **robotic-assisted radical prostatectomy using the da Vinci surgical system** demonstrates:

- 82% less likely to receive a transfusion
- 60% lower likelihood of mortality within 30 days of surgery
- 59% less likely to experience erectile dysfunction at 6 months
- 47% less likely to experience a postoperative complication within 30 days of surgery
- 42% less likely to experience an intraoperative complication
- 39% less likely to experience a readmission within 30 days of surgery
- 34% less likely to experience erectile dysfunction at 12 months



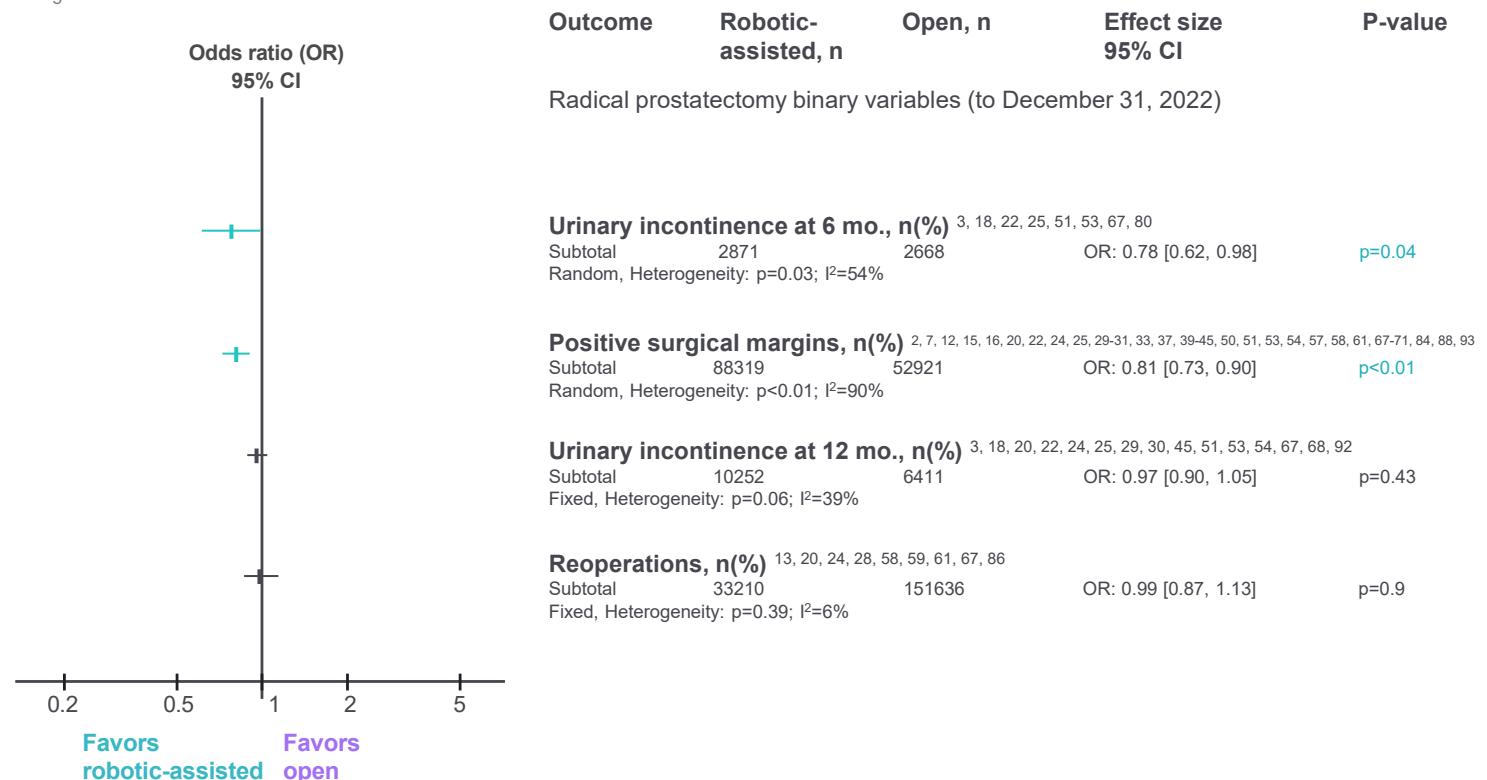
Robotic-assisted vs. open radical prostatectomy (3 of 3)

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 radical prostatectomy, the evidence for **robotic-assisted radical prostatectomy using the da Vinci surgical system** demonstrates:

- 22% less likely to experience urinary incontinence at 6 months
- 19% lower likelihood of a positive surgical margin
- Comparable urinary incontinence rate at 12 months
- Comparable reoperation rate within 30 days of surgery



Radical prostatectomy bibliography (1 of 5)

December 31, 2022

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Radical prostatectomy bibliography (3 of 5)

December 31, 2022

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December 31, 2022

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(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.

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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.

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