

ESP

Evidence Synthesis Program

Robotic-assisted Surgery in Partial Nephrectomy and Cystectomy

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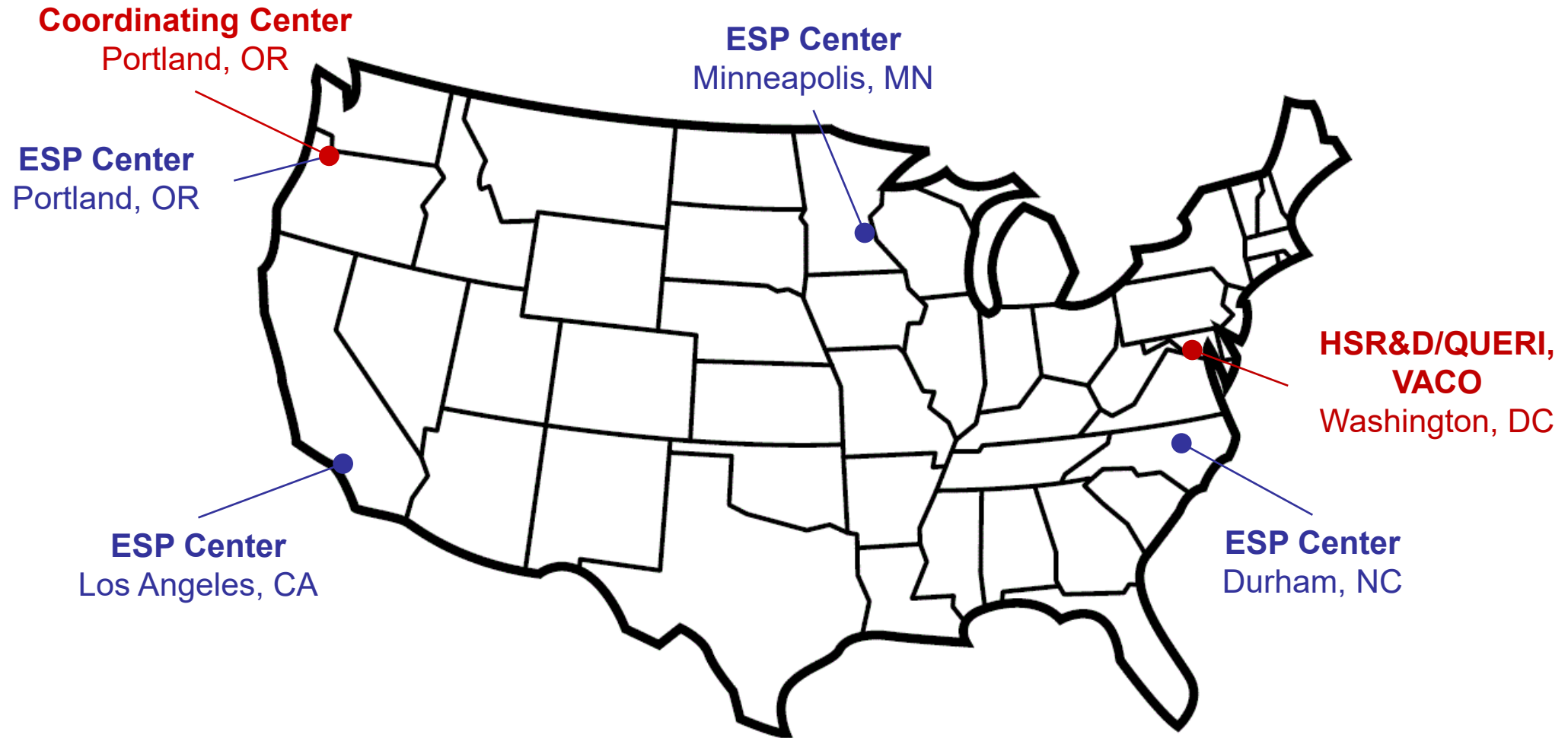
February 18, 2020

- Established in 2007
- Provides tailored, timely, and accurate evidence syntheses of VA-relevant, Veteran-focused healthcare topics. These reports help:
 - Develop clinical policies informed by evidence;
 - Implement effective services and support VA clinical practice guidelines and performance measures; and
 - Set the direction for future research to address gaps in clinical knowledge.
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 - Directors are VA clinicians, recognized leaders in the field of evidence synthesis, and have close ties to the AHRQ Evidence-based Practice Center Program and Cochrane Collaboration
- ESP Coordinating Center in Portland:
 - Manages national program operations and interfaces with stakeholders
 - Produces rapid products to inform more urgent policy and program decisions

To ensure responsiveness to the needs of decision-makers, the program is governed by a Steering Committee comprised of health system leadership and researchers.

The program solicits nominations for review topics several times a year via the [program website](#).

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Robotic-assisted Surgery in Partial Nephrectomy and Cystectomy

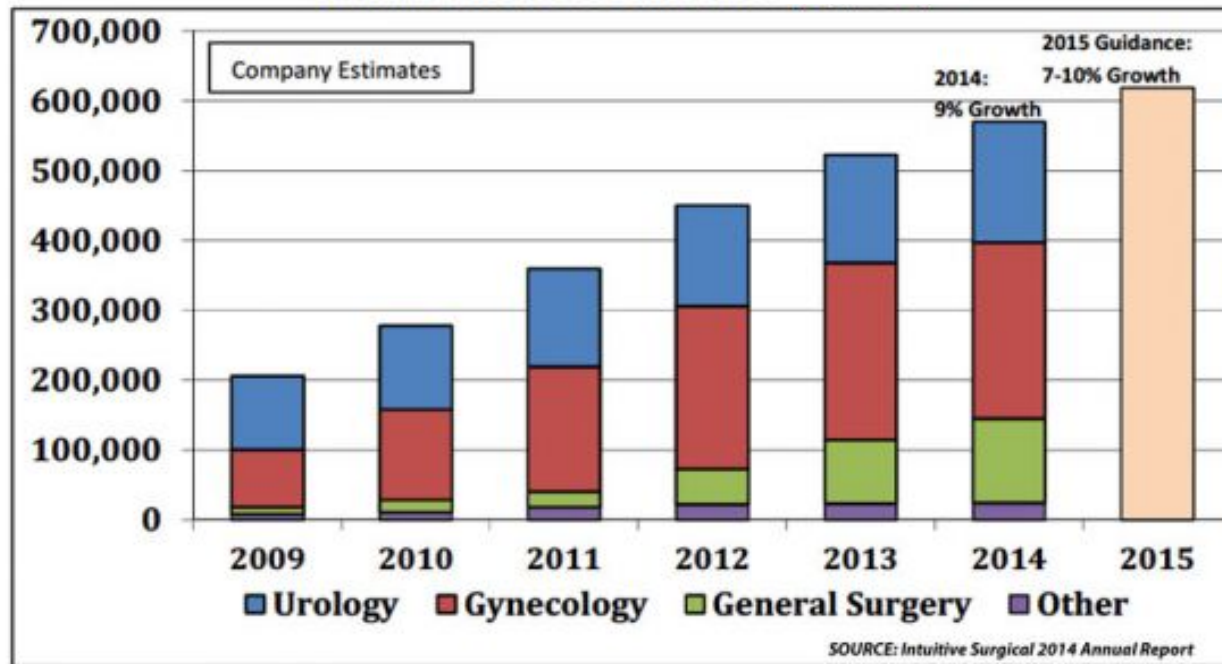
February 2020

Full-length report available on ESP website:

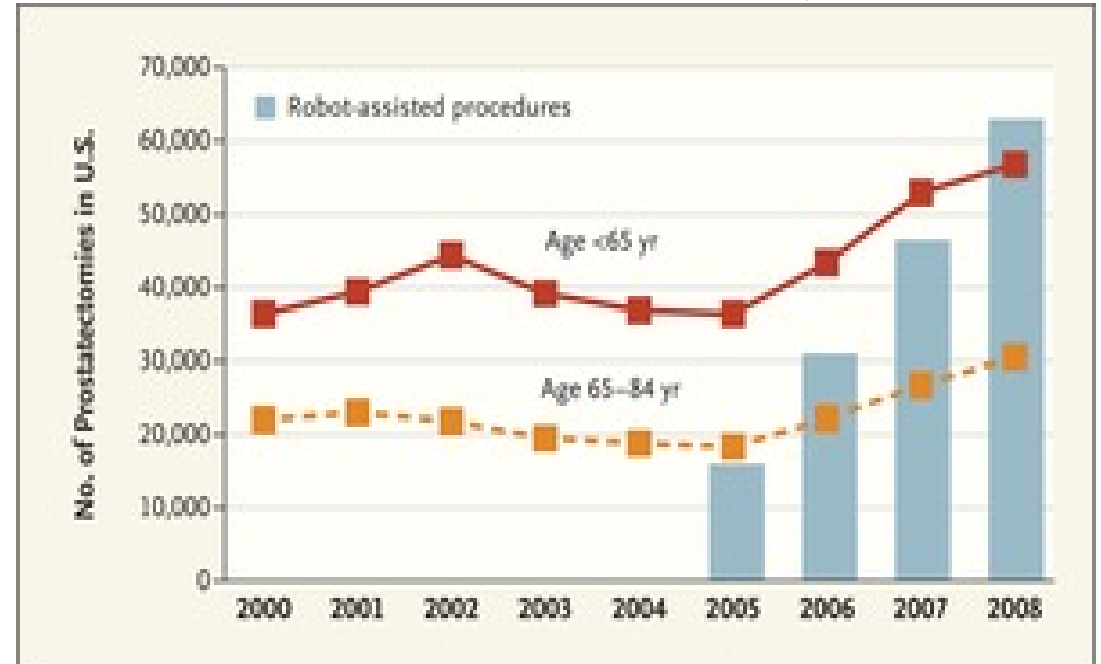
<http://www.hsrd.research.va.gov/publications/esp/reports.cfm>

- Over 750,000 robotic procedures are performed annually in the US, 125,000 in urology.

Annual Worldwide Procedures



Trends for Robotic Prostatectomy Cases US



- While its use for prostatectomy has become fairly standard (better outcomes), it is unclear if these clinical benefits are realized for other operations and specialties.

Caution When Using Robotically-Assisted Surgical Devices in Women's Health including Mastectomy and Other Cancer-Related Surgeries: FDA Safety Communication

- Benefits and risks are not established and long-term clinical and oncologic outcomes are questioned
- Robotic platform requires economic investment and unclear whether improvements in outcomes outweigh costs (cost-effectiveness questions remain).

- **Partial Nephrectomy**

1A) What is the clinical effectiveness of robotic-assisted surgery compared to open or laparoscopic surgery for partial nephrectomy?

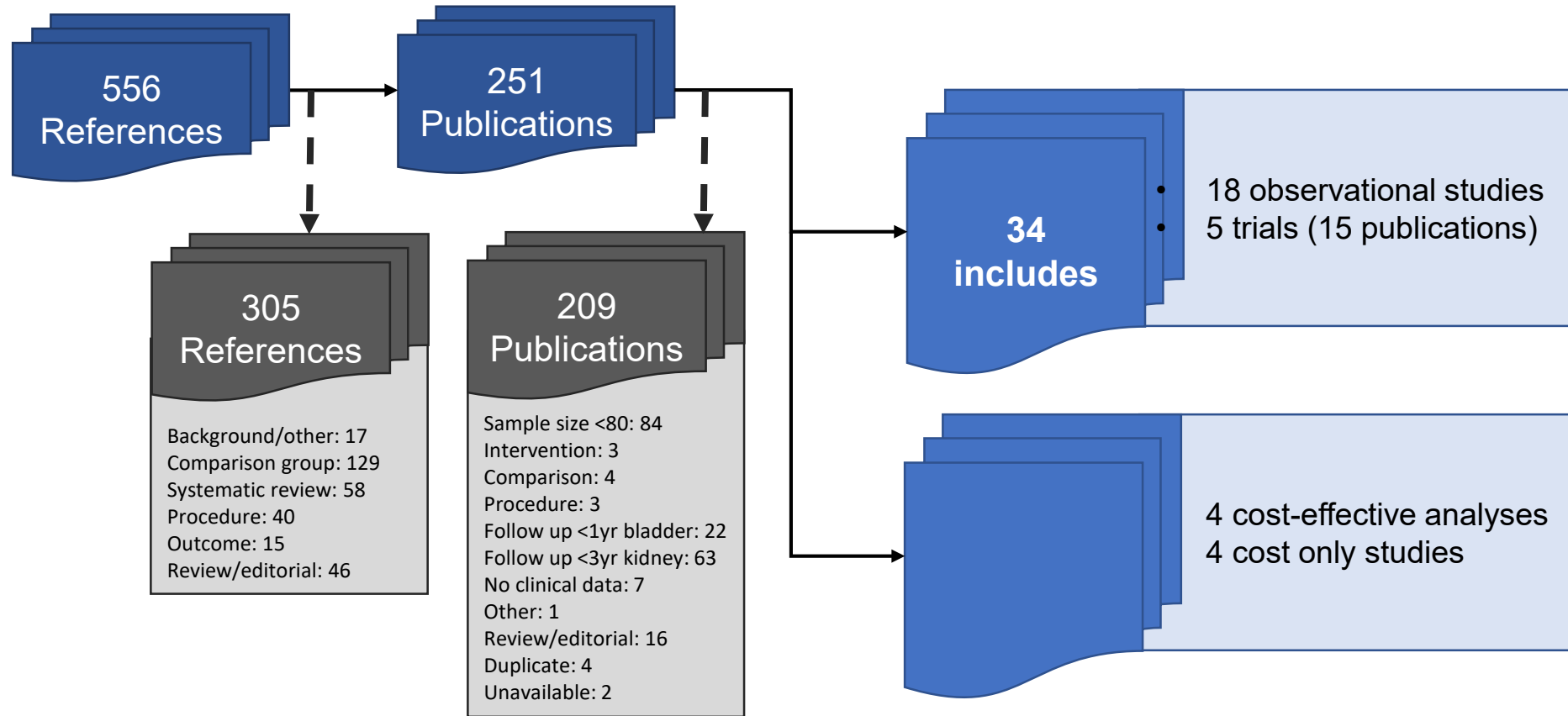
1B) What is the cost-effectiveness of robotic-assisted surgery compared to open or laparoscopic surgery for partial nephrectomy?

- **Cystectomy**

2A) What is the clinical effectiveness of robotic-assisted surgery compared to open or laparoscopic surgery for cystectomy?

2B) What is the cost-effectiveness of robotic-assisted surgery compared to open or laparoscopic surgery for cystectomy?

Selection of Studies



1A) What is the **clinical effectiveness** of robotic-assisted surgery compared to open or laparoscopic surgery for partial nephrectomy?

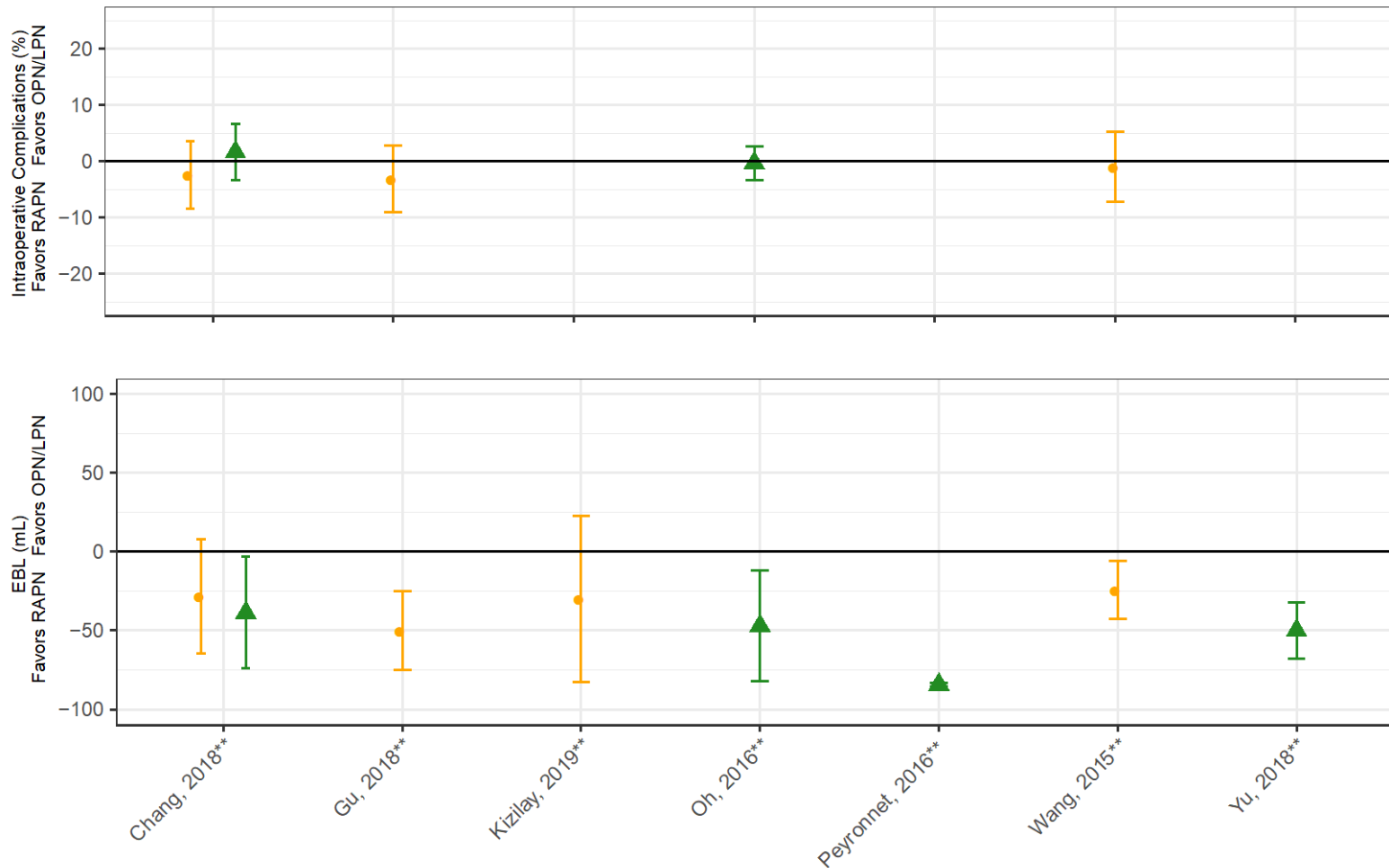
- 7 observational studies
- No RCTs

1B) What is the **cost-effectiveness** of robotic-assisted surgery compared to open or laparoscopic surgery for partial nephrectomy?

- 2 cost-effectiveness analyses
- 2 cost studies

Partial Nephrectomy: Intraoperative Outcomes

Point estimates with 95% CI for difference between complications and EBL between robotic partial nephrectomy and open or laparoscopic.



Robot vs. open ▲

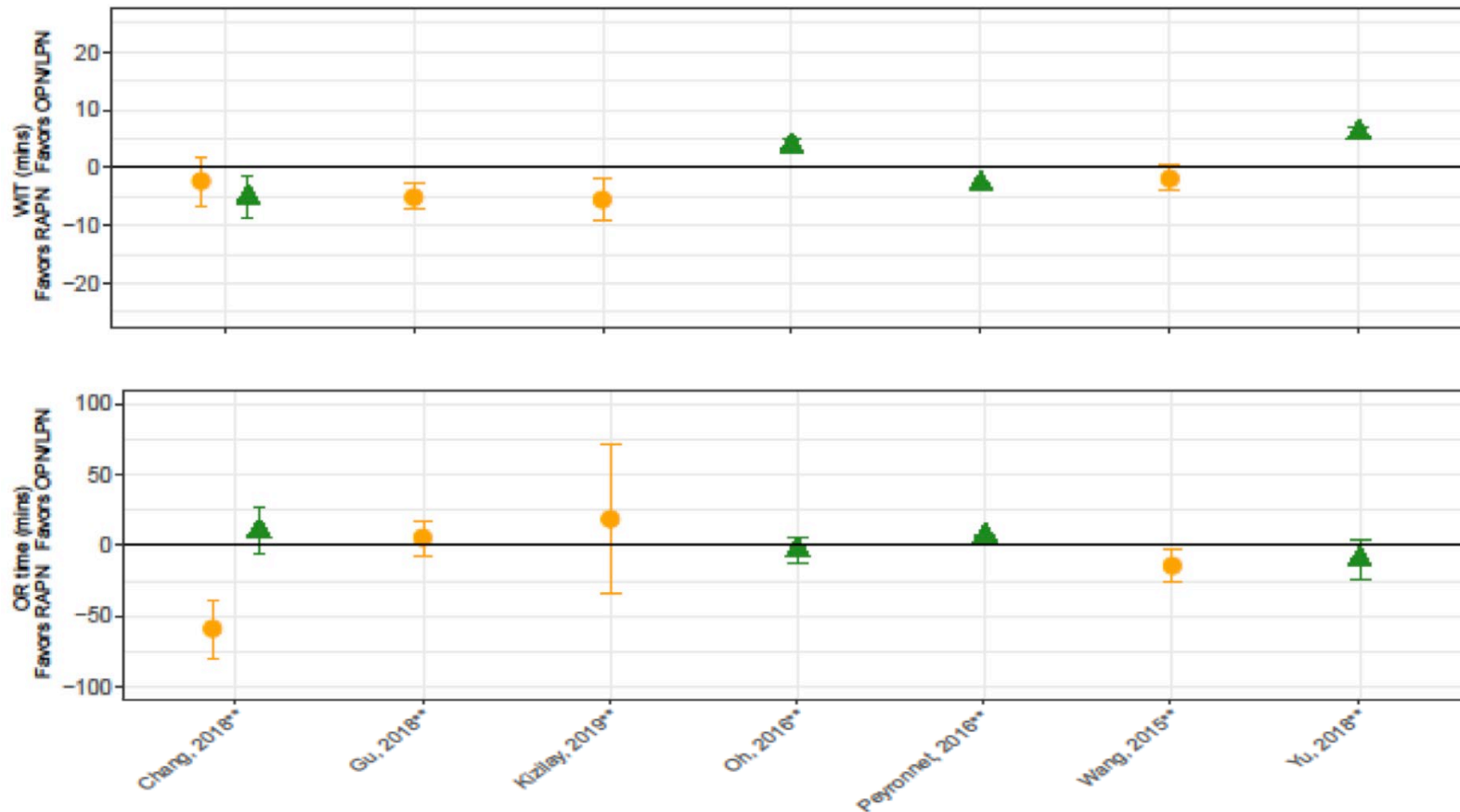
- Robot had lower mean EBL
- No difference in intraoperative complications

Robot vs. laparoscopic ●

- Robot had lower mean EBL
- No difference in intraoperative complications

Partial Nephrectomy: Intraoperative Outcomes

Point estimates with 95% CI for difference between complications and EBL between robotic partial nephrectomy and open or laparoscopic.



Robot vs. open ▲

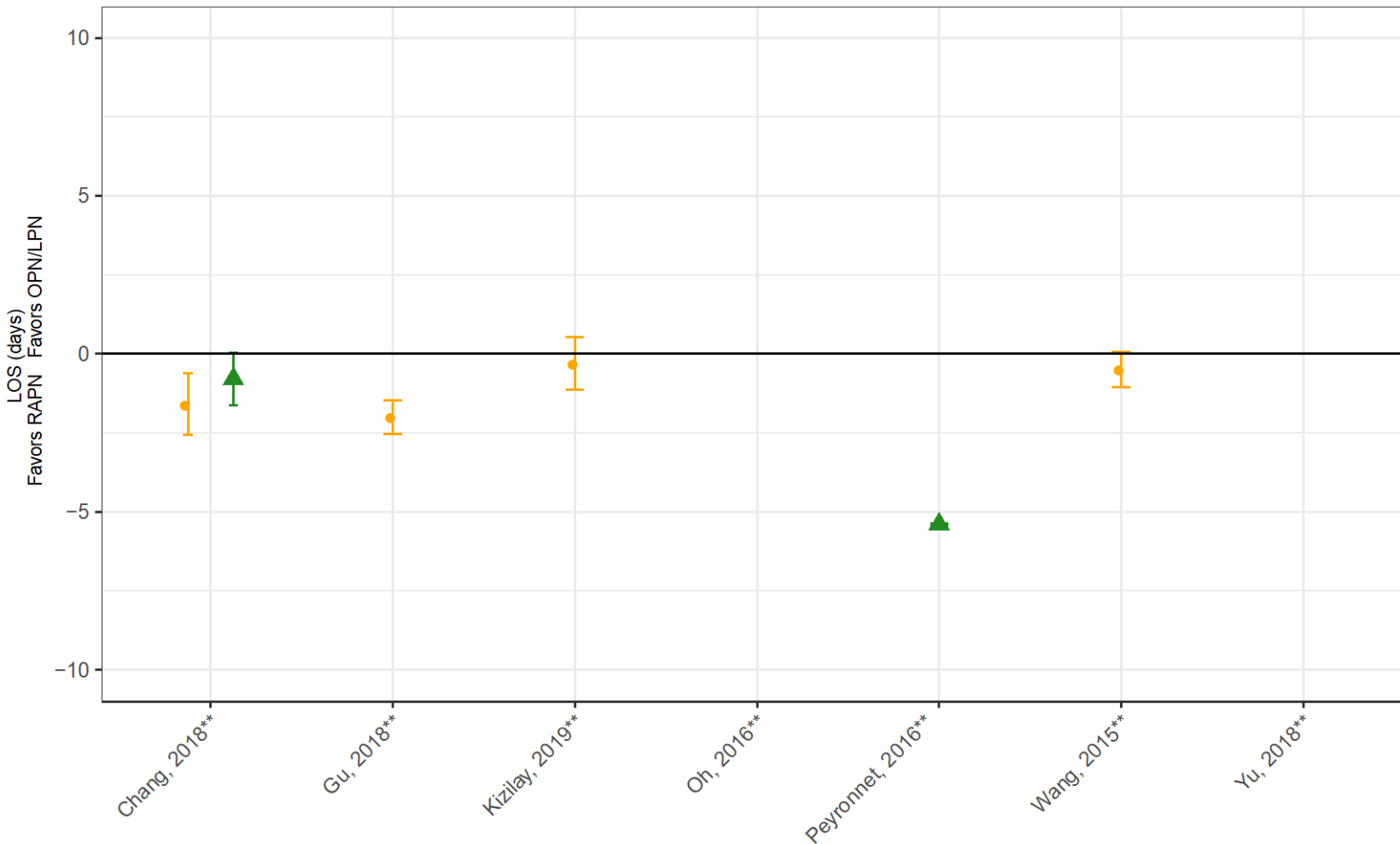
- No differences in WIT or OR time

Robot vs. laparoscopic ●

- No differences in WIT
- Robot had shorter OR time

Partial Nephrectomy: Postoperative Outcomes

Point estimates with 95% CI for difference between LOS between robotic partial nephrectomy and open or laparoscopic.



Robot vs. open



- Robot had lower LOS

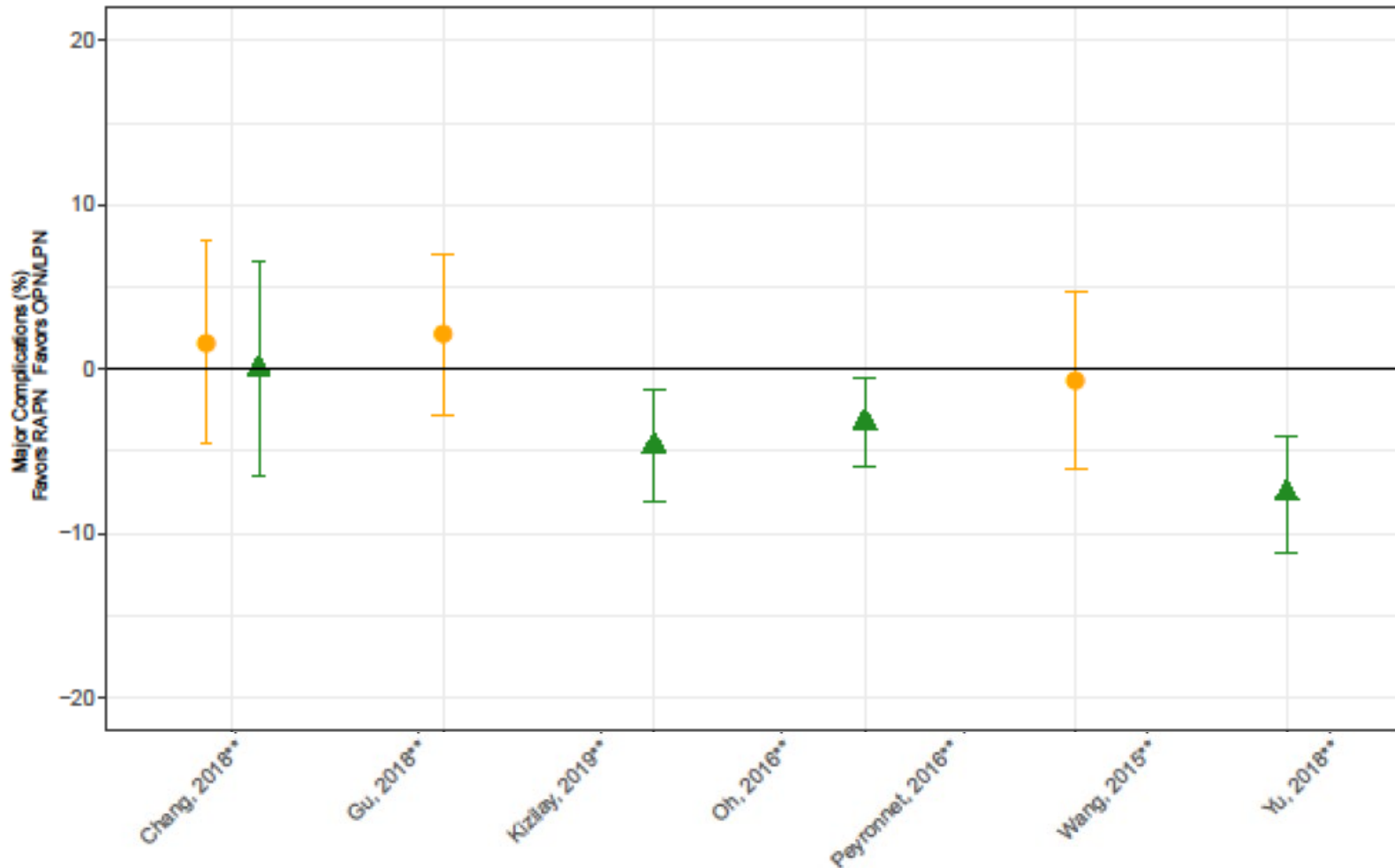
Robot vs. laparoscopic



- Robot had lower LOS

Partial Nephrectomy: Postoperative Outcomes

Point estimates with 95% CI for difference between LOS between robotic partial nephrectomy and open or laparoscopic.



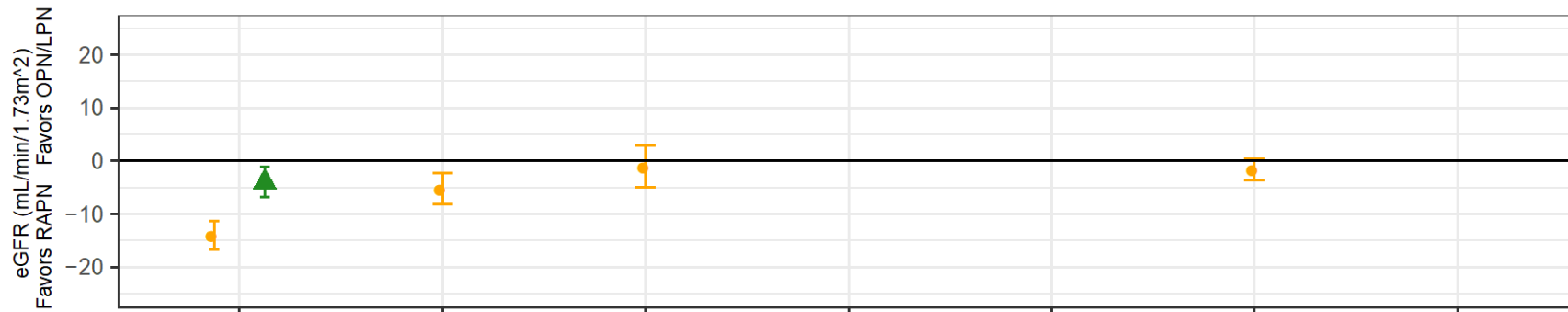
Robot vs. open ▲

- Robot had fewer major complications

Robot vs. laparoscopic ●

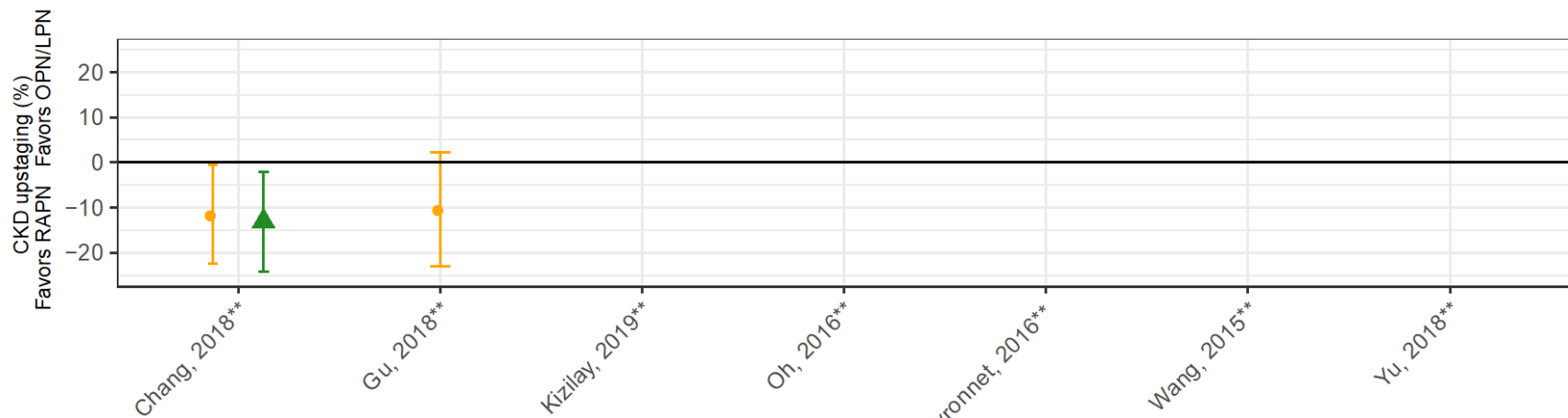
- No difference in complications

Point estimates with 95% CI for difference between GFR and CKD upstaging between robotic partial nephrectomy and open or laparoscopic.



Robot vs. open ▲

- Robot had slightly greater preservation of GFR
- Robot had lower incidence of CKD upstaging

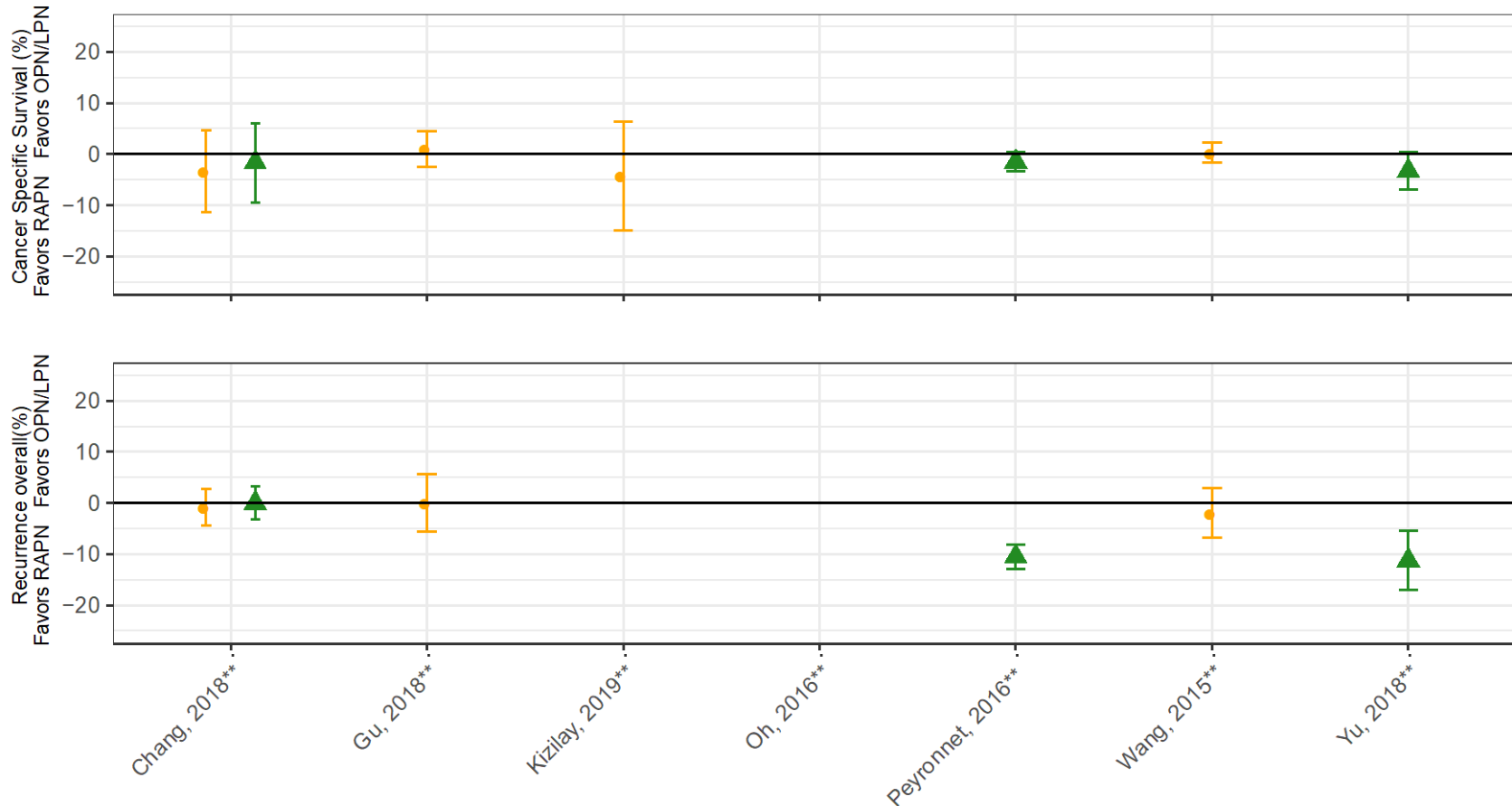


Robot vs. laparoscopic ●

- Robot had greater preservation of GFR
- Robot had lower incidence of CKD upstaging

Partial Nephrectomy: Oncologic Outcomes

Point estimates with 95% CI for difference between cancer specific survival and recurrence between robotic partial nephrectomy and open or laparoscopic.



Robot vs. open ▲

- No significant difference in cancer specific survival
- Robot had a lower recurrence rate

Robot vs. laparoscopic ●

- No significant difference in cancer specific survival or recurrence

Partial Nephrectomy: Cost-Effectiveness

Source	Robot	Open	Lap	Notes
Cost-effective analysis				
Mir, 2011			X	Lower LOS for lap & high equipment costs for robot <i>Complication rates assumed to be similar across approaches</i>
Buse, 2018	X			Lower in-hospital costs & better clinical outcomes for robot <i>Excluded robot purchase and maintenance costs</i>
Cost studies				
Kates, 2015	X			Lower hospital charges for robot <i>Excluded capital costs of robot</i>
Mano, 2015		X		Lower perioperative costs for open <i>Amortized capital costs of robot over 60 months</i>

■ = approach was included in the study

X = approach was more cost-effective/less expensive

Interim Summary: Partial Nephrectomy

	Robot vs open	Robot vs lap
EBL	↓	=
Intraop complications	=	=
WIT	=	=
OR time	=	↓
LOS	↓	↓
Major complications	↓	=
GFR loss	↓	↓
CKD upstaging	↓	↓
Recurrence	↓	=
CSS	=	=

***** Although seemingly positive results in favor the robotic approach for partial nephrectomy, the certainty of evidence is low based on data abstraction from studies with extensive limitations

2A) What is the **clinical effectiveness** of robotic-assisted surgery compared to open or laparoscopic surgery for cystectomy?

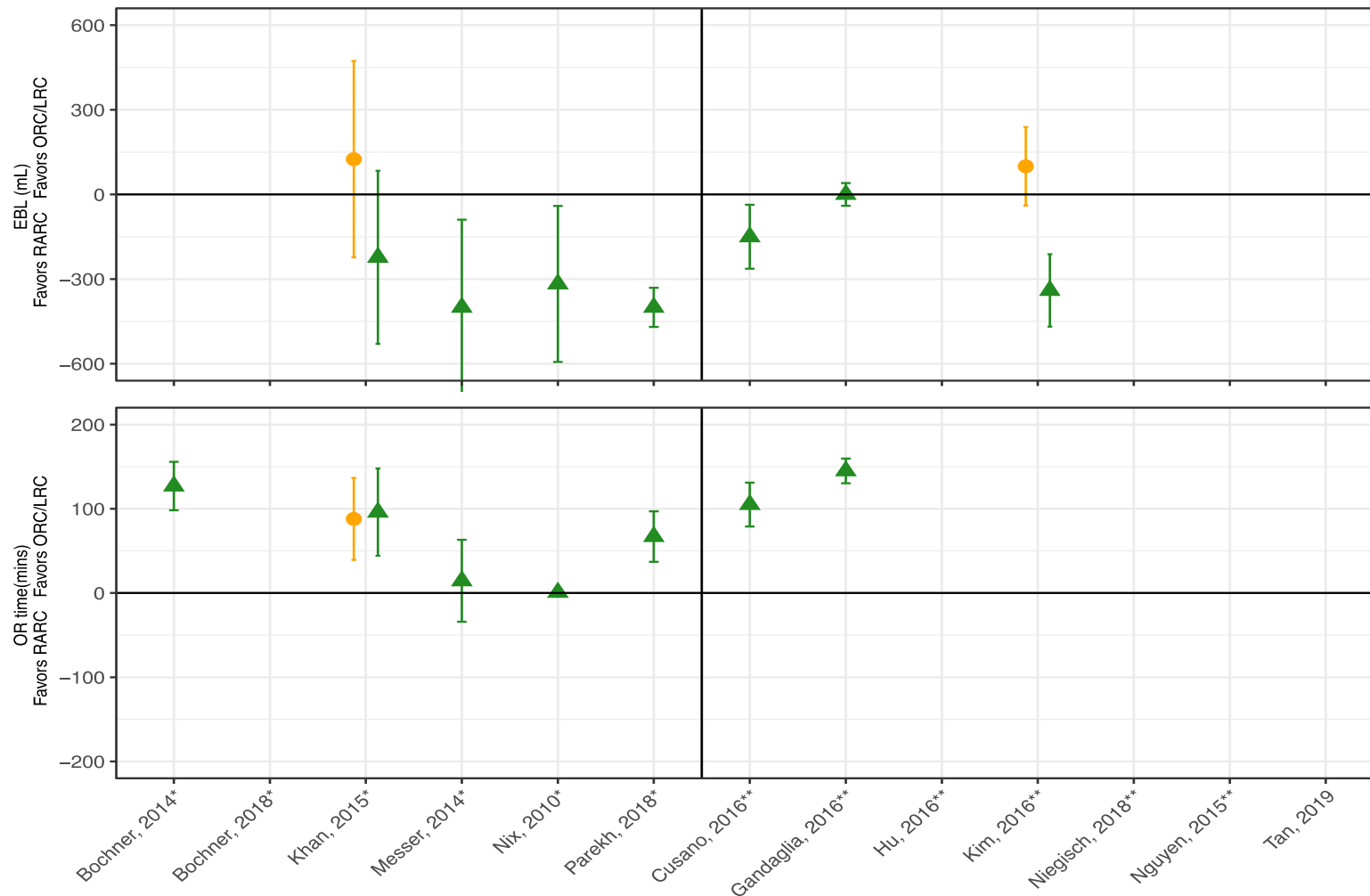
- 5 RCTs (2 publications from the same study)
- 11 observational studies

2B) What is the **cost-effectiveness** of robotic-assisted surgery compared to open or laparoscopic surgery for cystectomy?

- 2 cost-effectiveness analyses
- 2 cost studies

Cystectomy: Intraoperative Outcomes

Point estimates with 95% CI for difference between EBL and between robotic cystectomy and open or laparoscopic.



Robot vs. open ▲

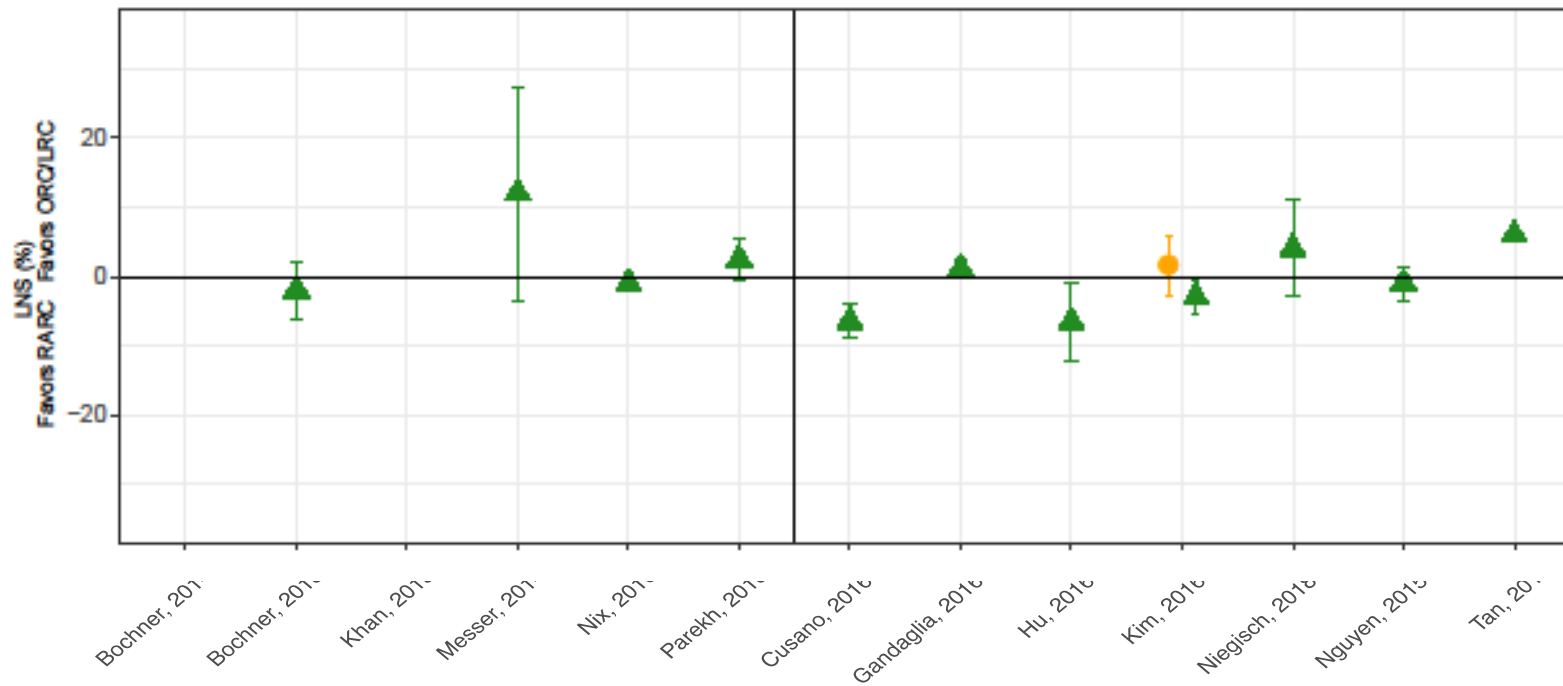
- Robot had lower EBL
- Robot had longer OR time

Robot vs. laparoscopic ●

- Robot had similar EBL
- Robot had longer OR time

Cystectomy: Intraoperative Outcomes

Point estimates with 95% CI for difference between EBL and between robotic cystectomy and open or laparoscopic.



Robot vs. open ▲

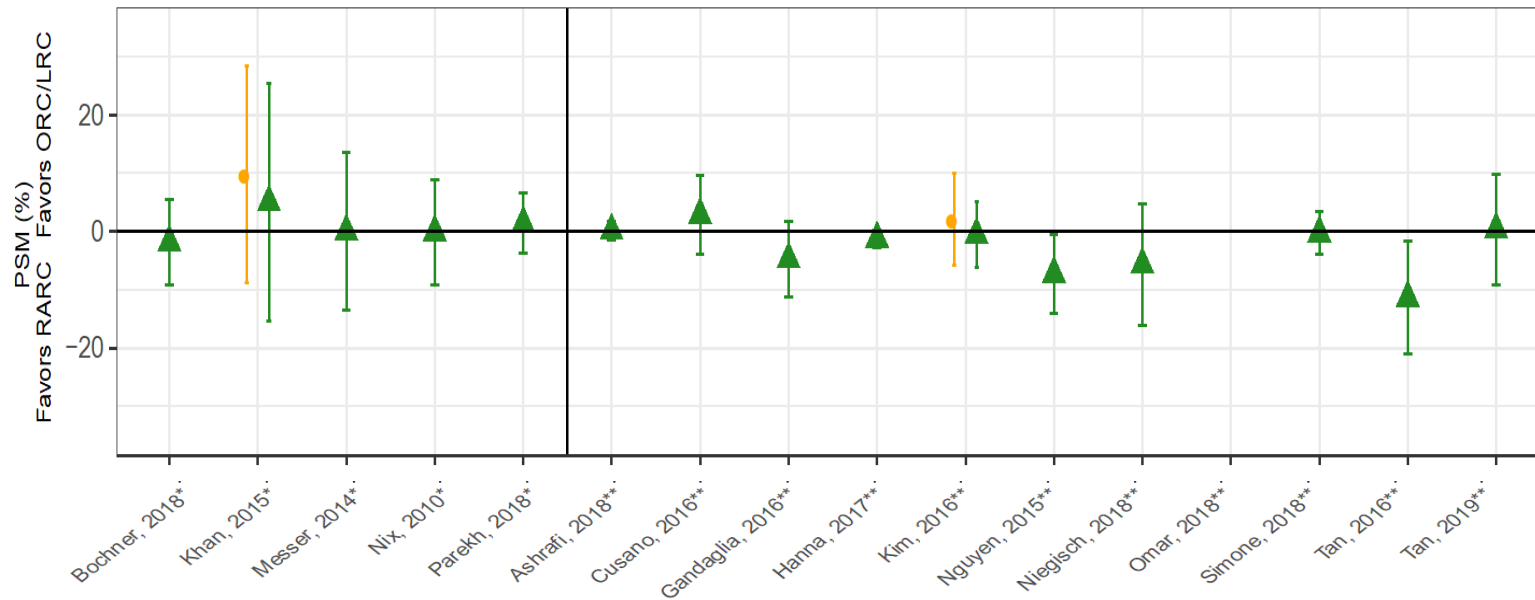
- No difference in LN harvest

Robot vs. laparoscopic ●

- No difference in LN harvest

Cystectomy: Intraoperative Outcomes

Point estimates with 95% CI for difference between EBL and between robotic cystectomy and open or laparoscopic.



Robot vs. open ▲

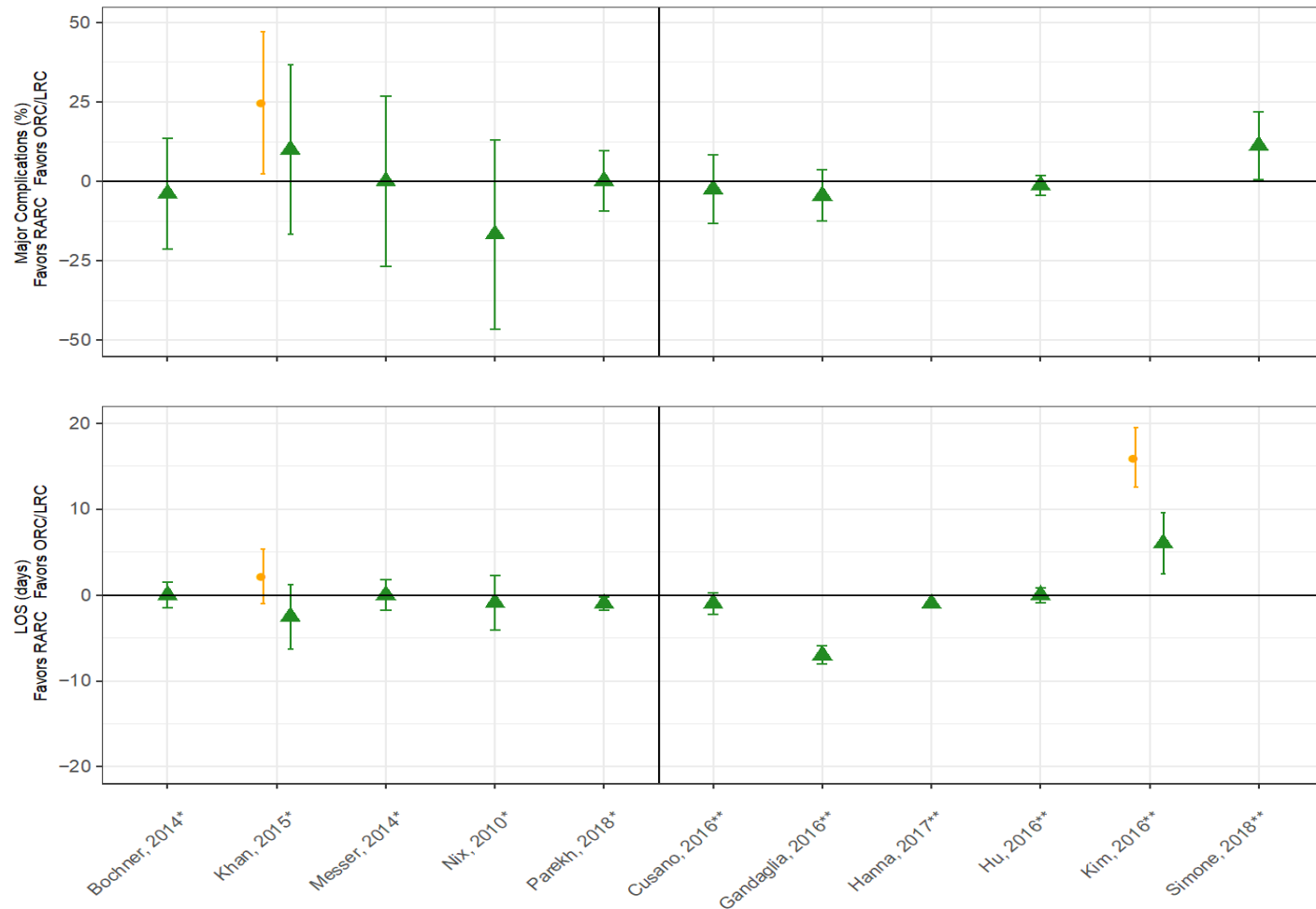
- No difference in PSM

Robot vs. laparoscopic ●

- No difference in PSM

Cystectomy: Postoperative Outcomes

Point estimates with 95% CI for difference between EBL and between robotic cystectomy and open or laparoscopic.



Robot vs. open

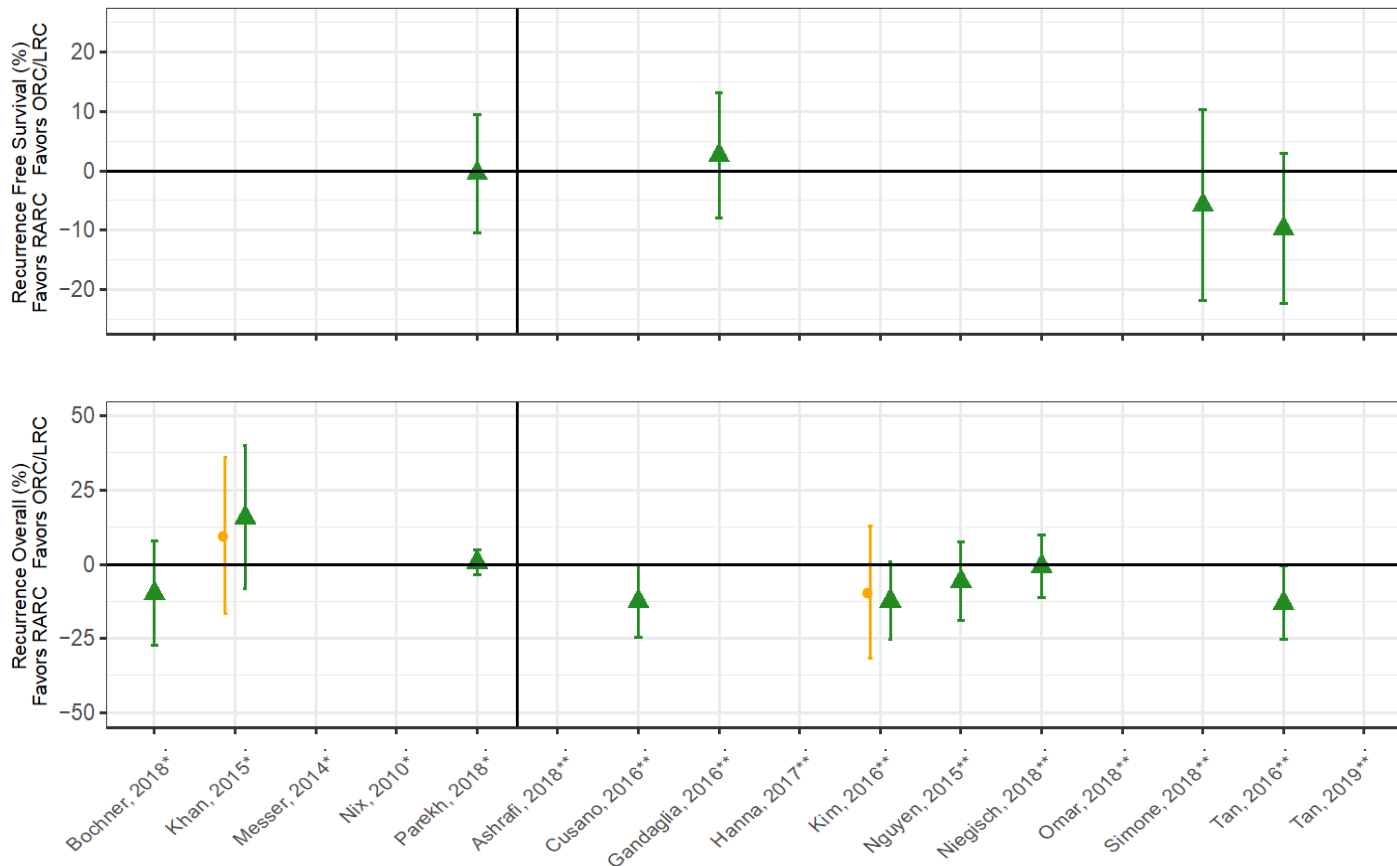
- No difference in major complications
- No difference in length of stay

Robot vs. laparoscopic

- Limited data for length of stay or major complications but possibly favoring laparoscopy

Cystectomy: Oncologic Outcomes

Point estimates with 95% CI for difference between EBL and between robotic cystectomy and open or laparoscopic.



Robot vs. open

- No difference in RFS or Recurrence rate

Robot vs. laparoscopic

- No difference in overall recurrence

Robot vs. laparoscopic and open

- No statistically significant differences in major complications between patients treated with robot-assisted cystectomy compared to open cystectomy.
- RCT data are limited by sample size and follow-up to properly assess the long-term oncologic outcomes for robotic cystectomy versus the comparator procedures. Only 2 RCTs reported 5-year outcomes, and between them they included data on 40 robot-treated cases.

Robot vs. open or laparoscopic for four functional or cancer-specific outcomes: QoL for cancer patients receiving therapy, positive surgical margins, recurrence, and recurrence-free survival.

- With only a rare exception, no study reported statistically significant differences in any of these outcomes with robot and open or laparoscopic cystectomy.
- However, 95% CI are very wide, and clinically important differences cannot be excluded.

Cystectomy

- The first study used a propensity matched internal data set and did not incorporate randomized data, despite its existence.
- The second study included randomized data, but method of pooling was not well described and observational data was included. They found wide variation in estimates on sensitivity analysis. They did not include the latest RCT (RAZOR).
- While cost analysis of one study was granular and robust, the generalizability of operative time and LOS to contemporary practice is questionable.
- Further, time horizon for both studies was 90 days – too short to capture meaningful oncologic outcomes.

- Robotic surgery probably results in less blood loss than open (or laparoscopic) approaches, for both partial nephrectomy and cystectomy.
- Most other differences in outcomes probably are small or nonexistent (complications, lymph node sampling, warm ischemia time, etc.) however certainty of evidence is low or very low.
- LOS may be shorter and major complications may be fewer for robot-assisted cases of partial nephrectomy, but certainty of evidence is low.
- Procedure time for robotic cystectomy was longer (moderate certainty).
- On the important issues of long-term functional or oncologic outcomes, data are too sparse and imprecise to reach any conclusions.
- Cost-effectiveness, likewise, has not been estimated with high certainty evidence. Data only consider short-term outcomes and did not include long-term outcomes, including oncologic, that influence the cost/benefit ratio.

- No studies specific to VA populations.
- Applicability may depend on both similarity of the patients studied to VA and experience of surgical teams using the robot to VA surgical teams.
- Benefits for robotic approach may still be realized despite patient-level differences (VA patients greater burden of comorbidities), which will need to be confirmed in future studies.
- Urology as a surgical field has widely adopted robotic surgery, so the experience likely translates well to VA setting.

- Need for randomized or propensity-matched data on robotic partial nephrectomy (short-term outcomes).
- Need for high quality evidence with long-term follow-up and statistical power to assess cancer outcomes for both partial nephrectomy and cystectomy.
- Despite what appears to be better or equivalent technical outcomes for cystectomy and likely partial nephrectomy, acceptable functional outcomes need to be confirmed.
 - Kidney function for kidney cancer
 - Quality of life for bladder cancer
- Better quality cost-effectiveness studies are warranted – how to balance clinical benefits with increased cost of the procedure and perhaps savings (decreased blood loss, LOS).

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Full-length report and cyberseminar available on ESP website:

<http://www.hsrd.research.va.gov/publications/esp/>

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Supplementary Materials

Certainty of Evidence: Partial Nephrectomy

Outcome	Study Limitations	Consistency	Directness	Precision	Certainty of Evidence
Intraoperative outcomes					
Intraoperative complications Robot = open/lap	High	Consistent	Direct	Imprecise	Low
Operating room time Robot = open/lap	High	Inconsistent	Direct	Imprecise	Very low
Estimated blood loss Robot < open/lap	High	Consistent	Direct	Imprecise	Moderate
Warm ischemia time Robot = open/lap	High	Inconsistent	Direct	Imprecise	Very Low
Post-operative outcomes					
Major complications Robot < open	High	Consistent	Direct	Imprecise	Low
Major complications Robot = lap	High	Consistent	Direct	Imprecise	Low
Length of stay Robot < open/lap	High	Consistent	Direct	Imprecise	Low
Functional/Cancer Outcomes					
All outcomes	High	Inconsistent	Direct	Imprecise	Very low

Certainty of Evidence: Cystectomy

Outcome	Study Limitations	Consistency	Directness	Precision	Certainty of Evidence
Intra-operative					
Blood Loss Robot < Open	RCT: Low Observational studies: High	Consistent	Direct	Precise	High
Lymph Node Sampling Robot = Open	RCT: Low Observational studies: High	Inconsistent	Direct	Imprecise	Low
Operating Room Time Robot > Open	RCT: Low Observational studies: High	Consistent	Direct	Imprecise	Moderate
All comparisons to laparoscopic surgery	RCT: Low Observational studies: High	N/A	Direct	Imprecise	Very Low
Post-operative					
Major complications Robot = Open	RCT: Low Observational studies: High	Consistent	Direct	Imprecise	Moderate
Genitourinary complications Robot = Open	RCT: Low Observational studies: High	Consistent	Direct	Imprecise	Moderate
Length of Stay Robot = Open	RCT: Low Observational studies: High	Consistent	Direct	Imprecise	Moderate
All comparisons to laparoscopic surgery	RCT: Low Observational studies: High	N/A	Direct	Imprecise	Very low
Functional/Cancer Outcomes					
All outcomes	RCTs: Low to High depending on outcome Observational studies: High	Inconsistent	Direct	Imprecise	Very low

- The cost effectiveness of robotic surgery for either partial nephrectomy or cystectomy is uncertain.
- Different studies reaching different conclusions depending on how the fixed and variable costs of the robot were considered and how health outcomes (benefits or complications) were measured and valued.
- Cost effectiveness data to date only consider short term outcomes and do not include longer term outcomes, including oncologic, that influence the cost/benefit ratio.