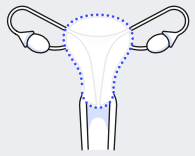
Maturing clinical evidence

Recent large scale meta-analysis covering period 2010-2020

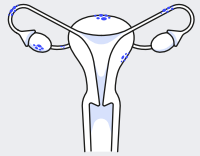
Results are based on internal, unpublished meta-analyses of peer reviewed literature for robotic-assisted procedures using the da Vinci surgical system

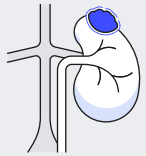
Maturing clinical evidence

Recent large scale meta-analysis covering period 2010+

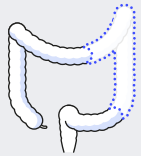


Hysterectomy for cervical cancer and endometrial cancer

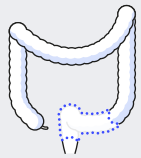




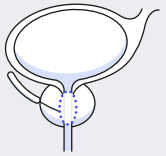
Partial Nephrectomy



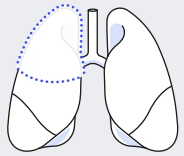
Right Colectomy



LAR/TME



Prostatectomy



Lobectomy

Outcomes measured

- Conversions
- Blood transfusions
- 30-day complications
- Length of stay
- 30-day mortality
- 30-day readmissions
- Operative time

Procedure specific 253 publications from 7 procedures

- 1,380,094 patients who underwent RAS
- 963,125 patients who underwent laparoscopic surgery or VATS
- 1,585,084 patients who underwent open surgery
- Robotic-assisted procedure with the da Vinci surgical system
- Year ≥ 2010
- Level of Evidence ≤ 2a, 2c
- RCT, meta-analysis/systematic review, or large database study

Results are based on a meta-analyses of peer reviewed literature for robotic-assisted procedures (right colectomy, LAR/TME, prostatectomy, partial nephrectomy, lobectomy, hysterectomy for endometrial and cervical cancer) published between 2010- 2020. This work was presented at the ISPOR 2021 annual congress. The summary of clinical results are reflective of a pooled analysis of 7 systematic literature reviews, presented by outcome across different surgical procedures. While the meta-analysis results provide a single conclusion that is statistically significant or not statistically significant, these results are subject to variability. The results of this analysis may depend on several factors, including but not limited to patient characteristics, disease characteristics, the procedure of interest, and/or surgeon experience.

Maturing clinical evidence

Clinical value of robotic-assisted surgery using the da Vinci surgical system (unpublished meta-analysis)

	vs. Lap	vs. Open
Outcomes that favor RAS		
Conversions	**55%** less likely	
Blood transfusions	**28%** less likely	**70%** less likely
30-day complications	**14%** less likely	**39%** less likely
Length of stay	**0.4** days shorter	**1.9** days shorter
30-day mortality	**33%** less likely	**57%** less likely
30-day readmissions	**23%** less likely	
Comparable outcomes		
30-day readmissions		comparable
Outcomes that favor lap/open		
Operative time	**18.8 min** longer	**37.3 min** longer

Results are based on 253 peer-reviewed publications where the da Vinci surgical system was used. The summary of clinical results reflects a pooled analysis of 7 systematic literature reviews, presented by outcome across different surgical procedures (right colectomy, LAR/TME, prostatectomy, partial nephrectomy, lobectomy, hysterectomy for endometrial and cervical cancer) published between 2010-2020. There was a total of 138,094 patients that underwent RAS using the Da Vinci surgical system 963,125 patients who underwent laparoscopic or VATS, and 1,585,084 patients who underwent open surgery. This work was presented at the ISPOR 2021 annual congress. While the meta-analysis results provide a single conclusion that is statistically significant or not statistically significant, these results are subject to variability. The results of this analysis may depend on several factors, including but not limited to patient characteristics, disease characteristics, the procedure of interest, and/or surgeon experience.

Maturing clinical evidence

Clinical value of robotic-assisted surgery using the da Vinci surgical system (unpublished meta-analysis)

Results are based on 253 peer-reviewed publications where the da Vinci surgical system was used. The summary of clinical results reflects a pooled analysis of 7 systematic literature reviews, presented by outcome across different surgical procedures (right colectomy, LAR/TME, prostatectomy, partial nephrectomy, lobectomy, hysterectomy for endometrial and cervical cancer) published between 2010-2020. There was a total of 138,094 patients that underwent RAS using the Da Vinci surgical system 963,125 patients who underwent laparoscopic or VATS, and 1,585,084 patients who underwent open surgery. This work was presented at the ISPOR 2021 annual congress. While the meta-analysis results provide a single conclusion that is statistically significant or not statistically significant, these results are subject to variability. The results of this analysis may depend on several factors, including but not limited to patient characteristics, disease characteristics, the procedure of interest, and/or surgeon experience.

		vs. Lap	vs. Open
Outcomes that favor RAS	Conversions	**3.7%** vs. **7.3%**	
	Blood transfusions	**4.6%** vs. **5.7%**	**4.3%** vs. **12.3%**
	30-day complications	**17.5%** vs. **20.2%**	**17.2%** vs. **23.7%**
	Length of stay	**0.4** days shorter	**1.9** days shorter
	30-day mortality	**0.4%** vs. **0.5%**	**0.3%** vs. **0.8%**
	30-day readmissions	**5.9%** vs. **8.0%**	
Comparable outcomes	30-day readmissions		**6.2%** vs. **7.8%**
Outcomes that favor lap/open	Operative time	**18.8 min** longer	**37.3 min** longer

Appendix

Bibliography of included studies, glossary

Radical prostatectomy: bibliography July 6, 2020

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Glossary

95% CI	95% confidence interval	**OR**	odds ratio
EBL	estimated blood loss	**RAS**	robotic-assisted surgery
HTA	health technology assessment	**RCT**	randomized controlled trial
I^2	test statistic for heterogeneity	**RD**	risk difference
LNY	lymph node yield	**SMD**	standardized mean difference
LOE	level of evidence	**VATS**	video-assisted thoracic surgery
LOS	length of hospital stay	**WMD**	weighted mean difference

Important safety information

Surgical Risks:

Bowel resection and other colorectal procedures (colectomy, sigmoidectomy, low anterior resection, abdominopelvic resection (APR), intersphincteric resection, proctectomy, rectopexy) include: anastomotic leak, anastomotic stricture, colorectal or anorectal dysfunction.

Pulmonary resection (wedge resection, segmentectomy, lobectomy) include: persistent air leak, pneumonia, prolonged mechanical ventilation >48 hours, atrial fibrillation, acute respiratory distress syndrome (ARDS), chylothorax, re-intubation, arrhythmias, bronchopleural fistula, phrenic nerve injury, esophageal injury, difficulty breathing, collapsed lung, pulmonary volvulus, recurrent laryngeal nerve injury leading
to vocal cord dysfunction.

Radical prostatectomy include**:** surrounding nerve damage that can lead to urinary incontinence and/or erectile dysfunction, rectal or bowel injury, urethral stricture, lymphocele, lymphedema; bowel obstruction.

Nephrectomy: renal insufficiency, urine leak, splenic, hepatic or pancreatic laceration, bowel injury, pneumothorax, diaphragmatic injury, urinary fistula, urinoma, renal infarction, lymphocele

Hysterectomy, malignant: urinary tract injury, vaginal cuff problem (separation, adhesions, granulation tissue, infection, cellulitis, hematoma), bladder injury, bowel injury, vaginal tear or laceration, vaginal shortening, voiding dysfunction, urinary incontinence, fistula formation: vesicovaginal, rectovaginal.

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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