

Methods

Systematic review of the peer-reviewed literature performed by Intuitive team are at the core of most of the clinical value claims presented in this document.

Published literature on robotic-assisted surgery was queried from PubMed, Scopus and Embase. Below are the searched terms employed to identify robotic assisted surgery related articles in the mentioned databases:

<i>Database</i>	<i>Search terms</i>
PubMed	(robotic[All Fields] OR robot*[All Fields] OR “robot assist”[All Fields] OR “robotically assisted”[All Fields] OR robot-assist[All Fields] OR “da vinci”[All Fields] OR davinci[All Fields] OR “intuitive surgical”[All Fields] OR (robot*[All Fields] AND surgery[all fields]))
Scopus	TITLE-ABS-KEY(da*vinci) OR (robotic surgery) OR ('intuitive surgical') OR (robotic assist*) OR (robot*surgery) OR (robotic-assist*)
Embase	'da vinci':de,nc,lnk,cl,ab,ti OR 'davinci':de,nc,lnk,cl,ab,ti OR 'intuitive surgical' OR 'endowrist'/exp OR endowrist OR (robot* NEAR/2 surg*):de,nc,lnk,cl,ab,ti OR (robot* NEXT/1 assist*)

Seven separate systematic literature reviews and meta-analyses were completed for seven different surgical procedures. These included: hysterectomy (endometrial cancer), hysterectomy (cervical cancer)– starting date for all searches was January 1, 2010. All searches were subject to the same specific inclusion and exclusion criteria, outlined below:

Inclusion criteria:

1. Robotic-assisted [procedure name]
2. Publication between January 1, 2010 and [End date of search]
3. Level of Evidence ($\leq 2a/2c$)
4. Study is a RCT, Meta-Analysis /Systematic Review, or Large Database Study with Comparative Cohorts (Robotic vs Lap and/or Open Surgery)

Exclusion criteria:

1. Not in English
2. Paper reports on a pediatric population
3. Publication is an HTA that was not published in a peer reviewed journal
4. Alternate technique/approach (e.g. transanal, single-port)
5. No stratified analysis by study arm (e.g. combines results from robotic, laparoscopic and/or open cohorts)
6. Procedure data mixed with other procedures (e.g. data from multiple surgical procedures combined)

7. Original research study does not provide quantitative results or a review paper does not provide meta/summary analysis 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)
8. Original research publication includes redundant patient population and similar conclusions
9. Study is a review paper that only includes redundant publications and similar conclusions.

The table below has the literature search end dates:

<i>SLR and meta-analysis topic / Procedure Name</i>	<i>Search end date</i>
Hysterectomy for Endometrial Cancer	3/5/19
Hysterectomy for Cervical Cancer	3/5/19
Partial Nephrectomy	10/17/18
Prostatectomy	9/30/17
Colectomy	5/15/18
Lower Anterior Resection of the Rectum with Total Mesorectal Excision (LAR /TME)	5/15/18
Lobectomy (lung resection)	12/3/18

All summary measures are shown as odds ratios, relative risks or risk differences when describing binary outcomes, or as weighted mean differences or standardized mean differences when describing continuous outcomes. Where specified, weighted group statistics (percent or mean) are provided. Weights are allocated by sample size of each publications and the variance of the estimate that contributes the specific metric in the forest plot of the meta-analysis.

Level of Evidence Definitions for Scientific Publications

Level 1

- a) Systematic reviews of Randomized Control Trials (RCT's)
- b) Randomized Controlled Trials (RCT)
- c) RCT's for Robotic technique studies (robotic vs other robotic study arm, not comparing to other surgical methods)

Level 2

- a) Systematic reviews of comparison studies and higher quality* mixed comparison/single arm analyses. Independent database population studies (comparative and single arm)
- b) Prospective non-randomized comparative studies and lower quality* RCT's
- c) Independent database population studies

Level 3

- a) Systematic reviews that mix comparison studies and single arm studies in the analysis.
- b) Retrospective non-randomized comparative studies (includes retrospective reviews of prospective institutional database) and lower quality* prospective comparison studies

Level 4:

- a) Systematic reviews of single arm studies and all non-systematic reviews (comparative and single arm)
- b) Single arm studies (includes robotic vs other robotic study arm, not comparing to other surgical methods) and lower quality* retrospective studies (includes retrospective reviews of prospective institutional database)

Level 5:

Case reports, Lower quality* single arm studies, Animal studies, Cadaver studies, Bench research, Expert Opinion/Editorial, Technique (with no clinical data)

* Higher quality systematic reviews with mixed comparison/single arm analyses are those that correct for bias and/or differences in patient characteristics between groups. Lower quality is defined as small sample sizes (at least one of comparison arms is <20 subjects).

Results

A meta-analysis for 7 distinct surgical procedures; (hysterectomy for endometrial cancer, hysterectomy for cervical cancer, prostatectomy, partial nephrectomy, colectomy, low anterior resection of the rectum, and lobectomy) was conducted with the goal of comparing key clinical outcomes across 3 surgical approaches (robotic-assisted, laparoscopic and open surgery). The key clinical outcomes measured across the 7 procedures included; conversion to open surgery, the rate of blood transfusions, operative time, complications within 30-days of surgery, length of hospital stay, readmissions to hospital within 30-days of surgery and mortality within 30 days post surgery. Each of the clinical outcomes' effect size was described as an odds ratio, risk ratio, risk difference, weighted mean difference or standardized mean difference comparing robotic assistance to laparoscopy or robotic assistance to open surgery.

Table 1: Robotic-assisted versus Laparoscopic / Video-assisted Procedures

Clinical Outcomes	Number of Robotic patients	Number of Laparoscopic or Video-assisted patients	Odds Ratio	95% Confidence Interval
Conversion	198,669	294,537	0.47	[0.37, 0.60]
Conclusion: There is a 53% lower likelihood of a conversion to open surgery during a robotic procedure compared to a laparoscopic/ VATS procedure. This result is statistically significant across all 7 procedures $p < 0.00001$				
Blood Transfusions	83,381	142,287	0.71	[0.61, 0.84]
Conclusion: There is a 29% lower likelihood of receiving a blood transfusion after robotic surgery compared to laparoscopic / VATS. This result is statistically significant across all 7 procedures $p < 0.0001$.				
Postoperative Complications within 30-days	65,794	429,861	0.86	[0.80, 0.92]
Conclusion: There is a 14% lower likelihood of a postoperative complication within 30-days of robotic-assisted surgery compared to laparoscopic /VATS surgery. This result is statistically significant across all 7 procedures $p < 0.0001$.				
Readmissions within 30-days	41,255	89,199	0.79	[0.60, 1.05]
Conclusion: There is no difference in the likelihood of readmissions within 30-days of surgery between robotic and laparoscopic/VATS surgery. $P = 0.15$				

Mortality within 30 days ¹	63,352	41,168	-0.32	[-0.0025, -0.0005]
Mortality within 30 days ²	44,070	617303	0.77	[0.55, 1.07]
<p>Conclusion¹: There is a statistically significant difference in the likelihood of mortality within 30-days of surgery between robotic and laparoscopic surgery. P=0.003. (¹refers to the pooled results for hysterectomy for endometrial cancer, and cervical cancer, LAR/TME, prostatectomy, partial nephrectomy.)</p> <p>Conclusion²: There is no statistically significant difference in the likelihood of mortality within 30-days of surgery between robotic and laparoscopic/VATS surgery. P=0.12. (²refers to the pooled results for lobectomy and colectomy)</p>				
Clinical Outcomes	Number of Robotic patients	Number of Laparoscopic or Video-assisted patients	Weighted Mean Difference/ Standardized Mean Difference	95% Confidence Interval
Operative time ³	42,178	43,970	9.90	[-0.72, 20.51]
Operative time ⁴	18,638	115,771	0.40	[0.12, 0.67]
<p>Conclusion³: There is no statistically significant difference in operative time between robotic assisted procedures and laparoscopic procedures. (³ refers to the pooled results (weighted mean difference=9.9 minutes) for the following procedures: prostatectomy, partial nephrectomy, hysterectomy for endometrial cancer and cervical cancer, and LAR/TME)</p> <p>Conclusion⁴: There is a statistically significant difference in operative time between robotic assisted procedures and laparoscopic procedures. (⁴ refers to the pooled (standardized mean difference=0.40) results for the following procedures: lobectomy and colectomy)</p>				
Length of Hospital Stay ⁵	110,170	53,127	-0.32	[-0.45, -0.18]
Length of Hospital Stay ⁶	44,739	590,592	-0.06	[-0.14, 0.03]
<p>Conclusion⁵: There is a statistically significant difference in length of hospital stay between robotic assisted and laparoscopic procedures. Robotic surgery patients have a length of stay on average a third of a day shorter than laparoscopic patients. P<0.00001. (⁵ refers to the pooled results (weighted mean difference=-0.32 days) for the following procedures: prostatectomy, partial nephrectomy, hysterectomy for endometrial cancer and cervical cancer, and LAR/TME)</p>				

Conclusion⁶: There is no statistically significant difference in length of hospital stay between robotic and laparoscopic /VATS procedures. P=0.18. (⁶ refers to the pooled (standardized mean difference=-0.06) results for the following procedures: lobectomy and colectomy)

Table 2: Robotic-assisted versus Open Procedures

Clinical Outcomes	Number of Robotic patients	Number of Open patients	Odds Ratio	95% Confidence Interval
Blood Transfusions	180,826	325,613	0.28	[0.18, 0.44]
Conclusion: There is a 72% lower likelihood of receiving a blood transfusion after robotic surgery compared to open surgery. This result is statistically significant across all 7 procedures p<0.0001.				
Postoperative Complications within 30-days	91,066	267,665	0.56	[0.47, 0.68]
Conclusion: There is a 44% lower likelihood of a postoperative complication within 30-days of robotic-assisted surgery compared to open surgery. This result is statistically significant across all 7 procedures p<0.0001.				
Readmissions within 30-days	120,046	161,027	0.84	[0.67, 1.07]
Conclusion: There is no difference in the likelihood of readmissions within 30-days of surgery between robotic and open surgery. P=0.17				
Mortality within 30 days ¹	169,310	604,410	0.39	[0.26, 0.58]
Mortality within 30 days ²	13,245	45,019	-0.0027	[-0.0035, -0.0019]

Conclusion¹: There is a statistically significant difference in the likelihood of mortality within 30-days of surgery between robotic and open surgery. $P < 0.00001$. (¹refers to the pooled results for hysterectomy for endometrial cancer, and cervical cancer, colectomy, prostatectomy, lobectomy.)

Conclusion²: There is a statistically significant difference in the likelihood of mortality within 30-days of surgery between robotic and open surgery. $P < 0.00001$. (²refers to the pooled results for partial nephrectomy and LAR/TME)

Clinical Outcomes	Number of Robotic patients	Number of Laparoscopic or Video-assisted patients	Weighted Mean Difference/ Standardized Mean Difference	95% Confidence Interval
Operative time	126,217	159,425	40.37	[24.11, 56.62]

Conclusion: There is a statistically significant difference in operative time between robotic assisted procedures and open procedures, $p < 0.00001$. (refers to the pooled results for all 7 procedures.) Operative time is on average 40.37 minutes longer for robotic assisted surgery in comparison to open surgery.

Length of Hospital Stay	244,095	719,056	-2.15	[-2.70, -1.60]
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Conclusion: There is a statistically significant difference in length of hospital stay between robotic and open procedures. $P < 0.00001$. (refers to the pooled results for all 7 procedures). Length of hospital stay is on average 2 days shorter for robotic assisted surgery than open surgery.

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(each procedure has a separate reference list with numbering starting at 1)

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