

Evidence Navigator: Rectal resection (LAR/TME/ISR)

**Systematic literature review & meta-analysis
as of March 1, 2024**

*Low Anterior Resection (LAR), Total Mesorectal Excision (TME), Intersphincteric Resection (ISR)

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
WMD	weighted mean difference
RD	risk difference
SMD	standardized mean difference
95% CI	95% confidence interval
I²	test statistic for heterogeneity

O-R*	Open-Robotic
L-R*	Laparoscopic-Robotic
EBL	estimated blood loss
LOS	length of hospital stay
LNY	lymph node yield
DRM	distal resection margin
CRM	circumferential resection margin
PRM	proximal resection margin
IPSS	International Prostate Symptom Score
FSFI	Female Sexual Function Index
IIEF	International Index of Erectile Function

*For summary purposes, the outcomes were reversed to maintain consistency, as we typically place results favoring RAS on the left side. Since a 'Higher/More in Robotic' indicates a better outcome in such cases, we reverse the effect size to align with our usual presentation, where most outcomes are 'Less/Lower in Robotic' is better. In general results are shown as R-L/O (Robotic-Laparoscopic/Open) but in such cases, they are reversed to L-R (Laparoscopic-Robotic) or O-R (Open-Robotic)

Evidence Navigator: Rectal resection (LAR/TME/ISR) Summary Slides

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INTUITIVE



WHAT DOES THE LITERATURE SHOW?

Systematic literature review: Robotic-assisted LAR/TME/ISR

Inclusion criteria

Robotic-assisted LAR/TME/ISR performed with a da Vinci surgical system

January 1, 2010 – March 1, 2024

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 on a pediatric population

Publication is a HTA not published in a peer-reviewed journal

Alternate technique/approach

No stratified analysis by study arm

Benign/cancer indications mixed or LAR/TME/ISR data mixed with other procedure(s)

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

Original research publication includes redundant patient population and similar conclusions

55 publications including:



Robotic-assisted patients: **69,867**

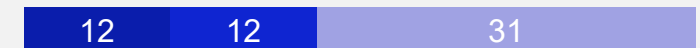


Laparoscopic patients: **205,076**



Open patients: **187,059**

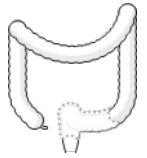
Level of evidence



■ 1b - RCTs

■ 2b - Prospective cohort studies

■ 2c - Database studies



WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points: Robotic-assisted vs laparoscopic LAR/TME/ISR



Favors robotic-assisted

- ↓ Estimated blood loss by **16.6 mL**
- ↓ Conversions by **60%**
- ↓ Blood transfusions by **25%**
- ↓ Length of stay by an average of **0.5 day**
- ↓ 30-day mortality by **37%**
- ↓ Positive surgical margins by **15%**
- ↓ Time to first bowel movement by an average of **0.5 days**
- ↑ Female sexual function (6 months)
- ↑ Urinary function (6 months)
- ↑ Male sexual function (12 months)
- ↓ Sexual dysfunction (12 months) by **52%**



Comparable outcomes

- ≈ Proximal resection margin
- ≈ Distal resection margin
- ≈ Positive circumferential resection margins
- ≈ Positive distal resection margins
- ≈ Positive proximal resection margins
- ≈ Completeness of mesorectal excision
- ≈ Lymph node yield
- ≈ Surgical site infections
- ≈ Anastomotic leaks
- ≈ Ileus rate
- ≈ Stoma rate
- ≈ Time to first flatus
- ≈ Time to regular diet
- ≈ 30-day postoperative complications
- ≈ 30-day readmissions
- ≈ 30-day reoperations
- ≈ Male sexual function (6 months)
- ≈ Urinary function (12 months)



Favors laparoscopic

- ↓ Operative time by **34.4 minutes**

Data collected through March 1, 2024

Significant difference favoring
robotic-assisted surgery

No significant difference;
comparable outcomes

Significant difference favoring
laparoscopic surgery



WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points: Robotic-assisted vs. open LAR/TME/ISR



Favors robotic-assisted

- ↓ Estimated blood loss by **216.9 mL**
- ↑ Lymph node yield by **1 node**
- ↓ Positive surgical margins by **43%**
- ↓ Positive circumferential resection margins by **25%**
- ↓ Time to first flatus by **0.8 day**
- ↓ Time to first bowel movement by **0.8 day**
- ↓ Surgical site infections by **62%**
- ↓ Length of stay by **2.0 days**
- ↓ 30-day postoperative complications by **32%**



Comparable outcomes

- ≈ Operative time
- ≈ Blood transfusions
- ≈ Distal resection margin
- ≈ Positive distal resection margins
- ≈ Positive proximal resection margins
- ≈ Anastomotic leaks
- ≈ Ileus rate
- ≈ Stoma rate
- ≈ 30-day readmissions
- ≈ 30-day reoperations
- ≈ 30-day mortality
- ≈ Sexual dysfunction (6 months)



Favors open

None

Data collected through March 1, 2024

■ Significant difference favoring
robotic-assisted surgery

■ No significant difference;
comparable outcomes

■ Significant difference favoring
open surgery

Evidence Navigator: Rectal resection (LAR/TME/ISR) Technical Slides

Systematic literature review & meta-analysis
as of March 1, 2024

*Low Anterior Resection (LAR), Total Mesorectal Excision (TME), Intersphincteric Resection (ISR)

INTUITIVE

LAR/TME/ISR:

Literature search methods

as of March 1, 2024

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 LAR/TME/ISR performed with da Vinci® surgical systems. Publications were identified according to inclusion and exclusion criteria described.

Meta-analysis was performed using R software.

55 publications

69,867 patients who underwent RAS

205,076 patients who underwent laparoscopic surgery

187,059 patients who underwent open surgery

Level of evidence



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

Criteria phase	Details
Identification phase	All unique PubMed, Scopus, and Embase references identified N = 10,347 up to March 1, 2024
Inclusion criteria	
1. Robotic-assisted LAR/TME/ISR for cancer	Robotic-assisted LAR/TME/ISR N = 2,373 (excluded N = 7,974)
2. Year ≥ 2010	Articles published ≥ 2010 N = 2,373 (excluded N = 0)
3. LOE = 1b, 2b, 2c	Articles with LOE ≤ 2a, 2c N = 204 (excluded N = 2,169)
4. Study is an RCT, prospective study or large database with comparative cohorts (robotic-assisted vs. laparoscopic and/or open surgery), with n≥20 in each cohort	Comparator cohorts N = 187 (excluded N = 17)
Exclusion criteria	N = 132 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-assisted, laparoscopic and/or open cohorts)	N = 66 (EC#5)
6. Benign/cancer indications mixed or LAR/TME/ISR data mixed with other procedures (e.g., data from multiple surgical procedures combined)	N = 52 (EC#6)
7. Original research study does not provide quantitative results for the outcomes of interest	N = 6 (EC#7)
8. Original research publication includes redundant patient population and similar conclusions	N = 6 (EC#8)

LAR/TME/ISR publications: N = 55

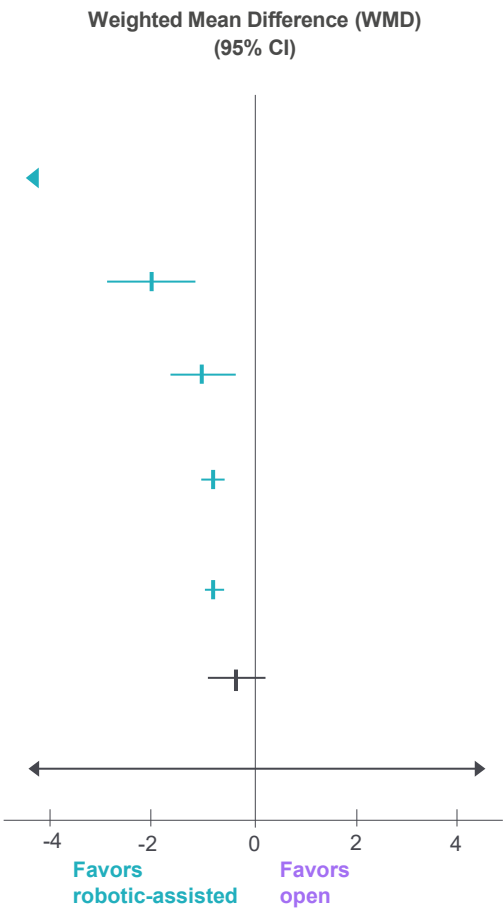
Robotic-assisted vs. open LAR/TME/ISR surgery (1 of 3)

Summary as of March 1, 2024

■ Significant difference favoring robotic-assisted surgery ■ No significant difference; comparable outcomes ■ Significant difference favoring open surgery

Compared to open LAR/TME/ISR, the evidence for **robotic-assisted LAR/TME/ISR using the da Vinci surgical system** demonstrates:

- Significantly less estimated blood loss by an average of 217 mL
- Significantly shorter hospital length of stay by an average of 2 days
- Significantly higher lymph node yield by an average of 1 node
- Significantly shorter time to first flatus by an average of 0.8 day
- Significantly shorter time to first bowel movement by an average of 0.8 day
- Comparable distal resection margin
- Comparable operative time



Outcomes	Robotic-assisted, n	Open, n	Effect Size 95% CI	P-value
LAR/TME/ISR Continuous Variables (to March 1, 2024)				
EBL, mL 4,6,35,38,45,46				
Subtotal	915	393	MD: -216.92 [-330.01, -103.82]	<0.01
Random, Heterogeneity: p<0.01; I²=98%				
LOS, days 3,4,5,6,17,23,25,26,28,39,45,46,49,52				
Subtotal	8763	24684	MD: -2.01 [-2.85, -1.18]	<0.01
Random, Heterogeneity: p<0.01; I²=94%				
LNY, n 3,4,6,8,17,23,26,28,45,46,47,48				
Subtotal	14345	33422	MD: -1.00 [-1.63, 0.37]	<0.01
O-R, Random, Heterogeneity: p<0.01; I²=79%				
Time to first flatus, days 6,26,28				
Subtotal	229	236	MD: -0.82 [-1.07, -0.57]	<0.01
Random, Heterogeneity: p=0.02; I²=74%				
Time to first bowel movement, days 4,6				
Subtotal	73	56	MD: -0.81 [-0.96, -0.66]	<0.01
Fixed, Heterogeneity: p=0.6; I²=0%				
DRM, cm 4,6,26,28,46				
Subtotal	306	295	MD: -0.35 [-0.88, 0.18]	0.19
O-R, Random, Heterogeneity: p<0.01; I²=88%				
Operative time, min 4,6,26,28,38,45,46,52				
Subtotal	696	917	MD: 37.26 [-13.80, 88.32]	0.15
Random, Heterogeneity: p<0.01; I²=99%				

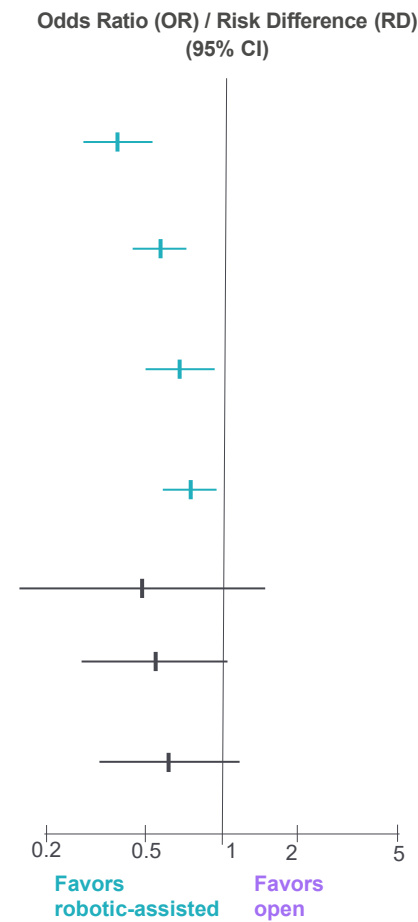
Robotic-assisted vs. open LAR/TME/ISR surgery (2 of 3)

Summary as of March 1, 2024

■ Significant difference favoring robotic-assisted surgery ■ No significant difference; comparable outcomes ■ Significant difference favoring open surgery

Compared to open LAR/TME/ISR, the evidence for **robotic-assisted LAR/TME/ISR using the da Vinci surgical system** demonstrates:

- 62% less likely to experience a surgical site infection
- 43% lower likelihood of a positive surgical margin
- 32% less likely to experience a postoperative complication within 30 days of surgery
- 25% lower likelihood of a positive circumferential resection margin
- Comparable blood transfusion rate
- Comparable mortality within 30 days of surgery
- Comparable sexual dysfunction at 6 months



Outcomes	Robotic-assisted, n	Open, n	Effect Size 95% CI	P-value
LAR/TME/ISR Binary Variables (to March 1, 2024)				
Surgical site infections, n (%)	3,4,6,17,46,52			
Subtotal	1647	3102	OR: 0.38 [0.29, 0.51]	<0.01
Fixed, Heterogeneity: p=0.99; I²=0%				
Positive surgical margins, n (%)	6,17,20,23,25,35,44,47,48			
Subtotal	17162	32125	OR: 0.57 [0.45, 0.71]	<0.01
Random, Heterogeneity: p<0.01; I²=65%				
Postoperative complications, n (%)	3,4,5,26,35,39,46,52			
Subtotal	1617	9616	OR: 0.68 [0.50, 0.92]	0.01
Random, Heterogeneity: p<0.01; I²=64%				
Positive CRM, (%)	3,4,5,20,26,28,42,45,46,48,52			
Subtotal	10987	28437	OR: 0.75 [0.59, 0.95]	0.02
Random, Heterogeneity: p<0.01; I²=63%				
Transfusions, n (%)	26,28,52			
Subtotal	494	729	OR: 0.48 [0.16, 1.47]	0.20
Random, Heterogeneity: p=0.07; I²=63%				
Mortality, n (%)	3,4,6,20,21,23,26,28,35,46,48,49,52			
Subtotal	15411	47711	OR: 0.54 [0.28, 1.05]	0.07
Random, Heterogeneity: p<0.01; I²=78%				
Sexual dysfunction (6 mo.), n (%)	26,28,46			
Subtotal	106	107	OR: 0.62 [0.33, 1.14]	0.12
Fixed, Heterogeneity: p=0.17; I²=43%				

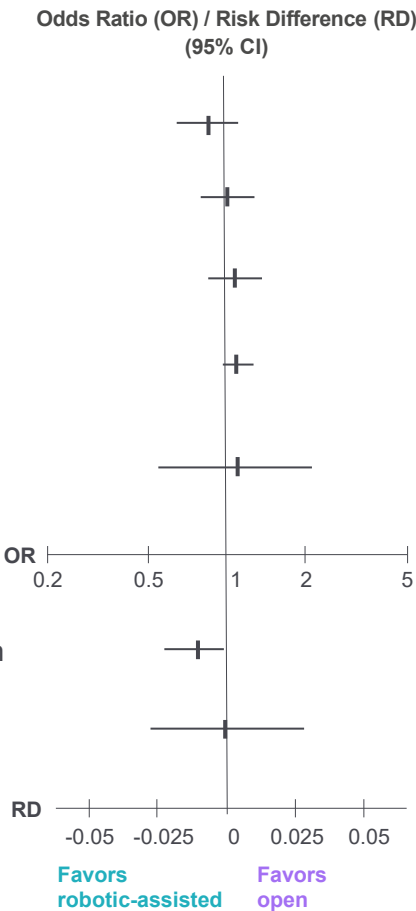
Robotic-assisted vs. open LAR/TME/ISR surgery (3 of 3)

Summary as of March 1, 2024

■ Significant difference favoring robotic-assisted surgery ■ No significant difference; comparable outcomes ■ Significant difference favoring open surgery

Compared to open LAR/TME/ISR, the evidence for **robotic-assisted LAR/TME/ISR using the da Vinci surgical system** demonstrates:

- Comparable ileus rate
- Comparable anastomotic leak rate
- Comparable stoma rate
- Comparable readmission rate within 30-days of surgery
- Comparable reoperation rate within 30-days of surgery
- Comparable risk of positive distal resection margin
- Comparable risk of positive proximal resection margin



Outcomes	Robotic-assisted, n	Open, n	Effect Size 95% CI	P-value
LAR/TME/ISR Binary Variables (to March 1, 2024)				
Ileus, n (%) 3,6,17,26,28,46				
Subtotal	1517	2767	OR: 0.87 [0.66, 1.16]	0.36
Fixed, Heterogeneity: p=0.7; I ² =0%				
Anastomotic leaks, n (%) 1,2,3,4,5,6,17,26,28,35,46,52				
Subtotal	2605	9885	OR: 1.02 [0.82, 1.28]	0.83
Fixed, Heterogeneity: p=0.82; I ² =0%				
Stoma, n(%) 3,4,26,28,46				
Subtotal	749	8188	OR: 1.10 [0.88, 1.38]	0.39
Fixed, Heterogeneity: p=0.07; I ² =46%				
Readmissions, n (%) 3,20,23,45,52				
Subtotal	7139	9231	OR: 1.12 [0.99, 1.27]	0.06
Fixed, Heterogeneity: p=0.28; I ² =22%				
Reoperations, n (%) 4,6,45,52				
Subtotal	427	639	OR: 1.14 [0.57, 2.29]	0.72
Fixed, Heterogeneity: p=0.76; I ² =0%				
Positive DRM, n (%) 3,26,45,46,52				
Subtotal	562	2616	RD: -0.0098 [-0.0213, 0.0017]	0.10
Fixed, Heterogeneity: p=0.64; I ² =0%				
Positive PRM, n (%) 45,46				
Subtotal	93	93	RD: 0.0000 [-0.0290, 0.0290]	1.00
Fixed, Heterogeneity: p=1; I ² =0%				

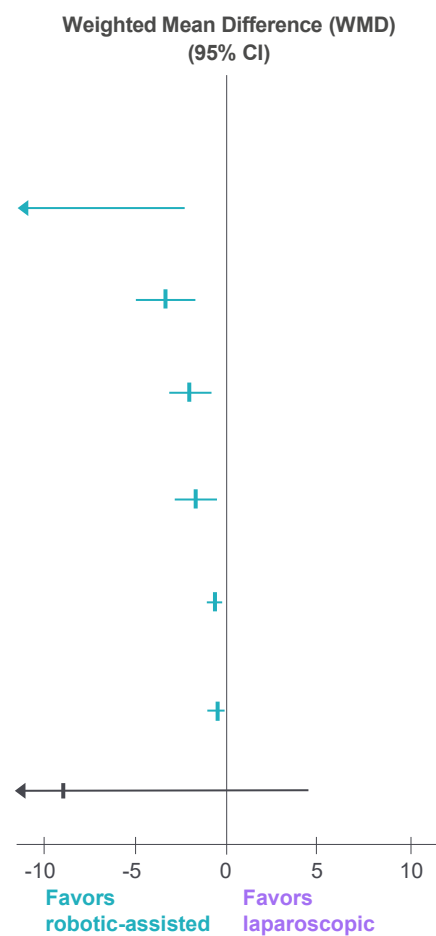
Robotic-assisted vs. laparoscopic LAR/TME/ISR surgery (1 of 4)

Summary as of March 1, 2024

■ Significant difference favoring robotic-assisted surgery ■ No significant difference; comparable outcomes ■ Significant difference favoring laparoscopic surgery

Compared to laparoscopic LAR/TME/ISR, the evidence for **robotic-assisted LAR/TME/ISR using the da Vinci surgical system** demonstrates:

- Significantly less estimated blood loss by an average of 17 mL
- Significantly better female sexual function at 6 months
- Significantly better urinary function at 6 months
- Significantly better male sexual function at 12 months
- Significantly shorter length of stay by an average of half a day
- Significantly shorter time to first bowel movement by an average of half a day
- Comparable male sexual function at 6 months



Outcomes	Robotic-assisted, n	Laparoscopic, n	Effect Size 95% CI	P-value
LAR/TME/ISR Continuous Variables (to March 1, 2024)				
EBL, mL ^{10,15,16,29,30,31,32,35,37}				
Subtotal	4819	5220	MD: -16.55 [-30.64, -2.45]	0.02
Random, Heterogeneity: p<0.01; I ² =90%				
Sexual function, FSFI at 6 mo. (females), score ^{15,31}				
Subtotal	43	41	MD: -3.36 [-4.95, -1.76]	<0.01
L-R, Fixed, Heterogeneity: p=0.21; I ² =35%				
Urinary function, IPSS at 6 mo., score ^{15,31,51}				
Subtotal	225	226	MD: -1.95 [-3.07, -0.82]	<0.01
Random, Heterogeneity: p=0.02; I ² =74%				
Sexual function, IIEF at 12 mo. (males), score ^{31,51,53}				
Subtotal	158	146	MD: -1.63 [-2.86, -0.40]	<0.01
L-R, Fixed, Heterogeneity: p=0.40; I ² =0%				
LOS, days ^{3,5,10,11,13,14,15,16,17,18,22,23,24,25,29,30,31,32,33,34,37,39,40,49,52}				
Subtotal	26008	45241	MD: -0.52 [-0.86, -0.18]	<0.01
Random, Heterogeneity: p<0.01; I ² =93%				
Time to first bowel movement, days ^{16,29,37}				
Subtotal	793	793	MD: -0.51 [-1.02, -0.01]	0.05
Random, Heterogeneity: p=0.04; I ² =69%				
Sexual function, IIEF at 6 mo. (males), score ^{15,31,51}				
Subtotal	115	107	MD: -9.04 [-22.23, 4.15]	0.18
L-R, Random, Heterogeneity: p<0.01; I ² =97%				

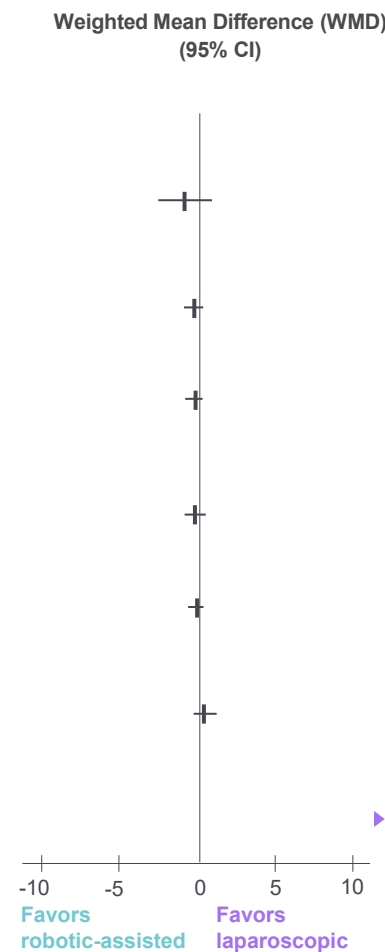
Robotic-assisted vs. laparoscopic LAR/TME/ISR surgery (2 of 4)

Summary as of March 1, 2024

■ Significant difference favoring robotic-assisted surgery ■ No significant difference; comparable outcomes ■ Significant difference favoring laparoscopic surgery

Compared to laparoscopic LAR/TME/ISR, the evidence for **robotic-assisted LAR/TME/ISR using the da Vinci surgical system** demonstrates:

- Comparable urinary function at 12 months
- Comparable time to regular diet
- Comparable time to first flatus
- Comparable distal resection margin
- Comparable lymph node yield
- Comparable proximal resection margin
- **Significantly longer operative time by an average of 34 minutes**



Outcomes	Robotic-assisted, n	Laparoscopic, n	Effect Size 95% CI	P-value
LAR/TME/ISR Continuous Variables (to March 1, 2024)				
Urinary function, IPSS at 12 mo., score ^{31,51,53}				
Subtotal	134	130	MD: -1.22 [-2.91, 0.46]	0.15
Random, Heterogeneity: p<0.01; I ² =86%				
Time to regular diet, days ^{15,16,29,31,37}				
Subtotal	1003	998	MD: -0.37 [-0.81, 0.07]	0.1
Random, Heterogeneity: p<0.01; I ² =81%				
Time to first flatus, days ^{10,15,16,29,31}				
Subtotal	881	885	MD: -0.30 [-0.78, 0.18]	0.22
Random, Heterogeneity: p<0.01; I ² =94%				
DRM, cm ^{10,16,27,29,30,31,34,37}				
Subtotal	1347	1690	MD: -0.19 [-0.56, 0.17]	0.3
L-R Random, Heterogeneity: p<0.01; I ² =92%				
Lymph node yield, n ^{3,8,10,11,13,14,15,16,17,22,23,24,29,31,34,37,47,48,49,53}				
Subtotal	23343	40289	MD: -0.01 [-0.61, 0.59]	0.97
L-R Random, Heterogeneity: p<0.01; I ² =91%				
PRM, cm ^{10,15,16,29,34,37}				
Subtotal	1365	1901	MD: 0.48 [-0.46, 1.42]	0.31
L-R Random, Heterogeneity: p<0.01; I ² =85%				
Operative time, min ^{10,11,14,15,16,22,24,29,30,31,32,37,52,53}				
Subtotal	10895	12441	MD: 34.38 [17.42, 51.35]	<0.01
Random, Heterogeneity: p<0.01; I ² =97%				

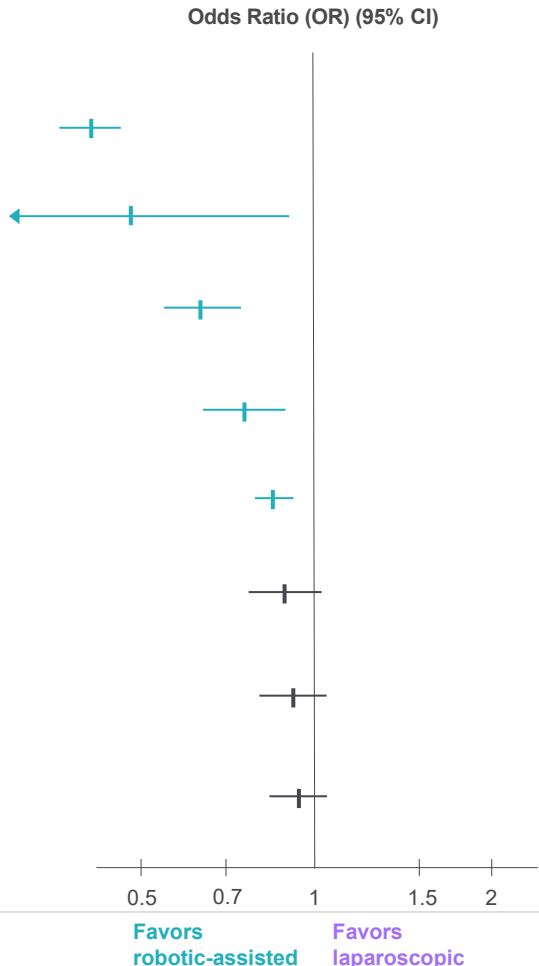
Robotic-assisted vs. laparoscopic LAR/TME/ISR surgery (3 of 4)

Summary as of March 1, 2024

■ Significant difference favoring robotic-assisted surgery ■ No significant difference; comparable outcomes ■ Significant difference favoring laparoscopic surgery

Compared to laparoscopic LAR/TME/ISR, the evidence for **robotic-assisted LAR/TME/ISR using the da Vinci surgical system** demonstrates:

- 60% less likely to undergo a conversion to open surgery
- 52% less likely to experience sexual dysfunction at 12 months
- 37% lower likelihood of mortality within 30 days of surgery
- 25% less likely to receive a blood transfusion
- 15% lower likelihood of a positive surgical margin
- Comparable positive distal resection margin rate
- Comparable reoperation rate within 30-days of surgery
- Comparable postoperative complication rate within 30-days of surgery



Outcomes	Robotic-assisted, n	Laparoscopic, n	Effect Size 95% CI	P-value
LAR/TME/ISR Binary Variables (to March 1, 2024)				
Conversions, n (%) 9,10,11,12,13,14,15,16,17,18,21,22,23,25,29,32,34,35,36,37,40,41,43,47,48,49,52				
Subtotal	48902	111074	OR: 0.40 [0.36, 0.46]	<0.01
Random, Heterogeneity: p<0.01; I²=78%				
Sexual dysfunction at 12 mo. (%) 27,53				
Subtotal	101	105	OR: 0.48 [0.25, 0.90]	0.02
Random, Heterogeneity: p=0.22; I²=34%				
Mortality, n (%) 3,7,10,11,13,14,15,16,18,20,21,23,24,29,30,31,32,33,34,35,36,37,48,49,50,52,53,54				
Subtotal	39690	87377	OR: 0.63 [0.54, 0.74]	<0.01
Fixed, Heterogeneity: p=0.95; I²=0%				
Transfusions, n (%) 14,15,16,22,29,32,37,52				
Subtotal	10124	11784	OR: 0.75 [0.64, 0.89]	<0.01
Fixed, Heterogeneity: p=0.44; I²=0%				
Positive surgical margins, n (%) 13,17,20,23,25,31,35,44,47,48,49				
Subtotal	28619	47893	OR: 0.85 [0.79, 0.91]	<0.01
Fixed, Heterogeneity: p=0.22; I²=23%				
Positive DRM, (%) 3,11,15,16,18,19,22,24,31,34,49,52				
Subtotal	9427	23125	OR: 0.88 [0.77, 1.02]	0.09
Fixed, Heterogeneity: p=1; I²=0%				
Reoperations, n (%) 10,11,15,16,22,29,30,31,32,33,34,52,55				
Subtotal	8032	10137	OR: 0.92 [0.81, 1.04]	0.19
Fixed, Heterogeneity: p=0.52; I²=0%				
Postoperative complications, n (%) 3,5,7,10,11,14,15,16,24,29,30,32,33,35,37,39,52,53,55				
Subtotal	17965	21171	OR: 0.93 [0.83, 1.05]	0.26
Random, Heterogeneity: p<0.01; I²=63%				

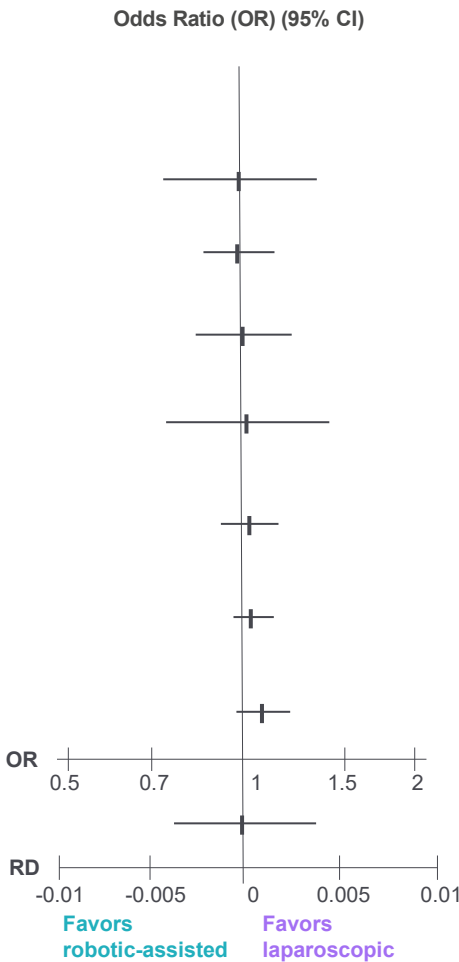
Robotic-assisted vs. laparoscopic LAR/TME/ISR surgery (4 of 4)

Summary as of March 1, 2024

■ Significant difference favoring robotic-assisted surgery ■ No significant difference; comparable outcomes ■ Significant difference favoring laparoscopic surgery

Compared to laparoscopic LAR/TME/ISR, the evidence for **robotic-assisted LAR/TME/ISR using the da Vinci surgical system** demonstrates:

- Comparable stoma rate
- Comparable positive circumferential resection margin rate
- Comparable ileus rate
- Comparable completeness of the mesorectal excision rate
- Comparable surgical site infection rate
- Comparable anastomotic leak rate
- Comparable readmission rate within 30-days of surgery
- Comparable risk of positive proximal resection margin



Outcomes	Robotic-assisted, n	Laparoscopic, n	Effect Size 95% CI	P-value
LAR/TME/ISR Binary Variables (to March 1, 2024)				
Stoma, n (%) 3,7,11,16,24,29,37,40,53				
Subtotal	2263	7484	OR: 0.99 [0.72, 1.34]	0.92
Random, Heterogeneity: p<0.01; I ² =75%				
Positive CRM, n (%) 3,5,7,10,11,15,16,18,19,20,22,24,27,29,30,31,34,36,40,42,48,49,50,52				
Subtotal	27701	57286	OR: 0.99 [0.86, 1.13]	0.85
Random, Heterogeneity: p<0.01; I ² =71%				
Ileus, n (%) 3,10,11,14,15,16,17,22,29,30,31,33,37,55				
Subtotal	10796	15533	OR: 1.00 [0.83, 1.22]	0.98
Random, Heterogeneity: p<0.01; I ² =55%				
Mesorectal excision completeness, (%) 7,24,27,29,31				
Subtotal	581	630	OR: 1.02 [0.73, 1.42]	0.91
Fixed, Heterogeneity: p=0.86; I ² =0%				
Surgical site infections, n (%) 3,10,11,15,17,22,24,30,31,32,33,52,53,55				
Subtotal	16589	24495	OR: 1.03 [0.92, 1.15]	0.59
Fixed, Heterogeneity: p=0.90; I ² =0%				
Anastomotic leaks, n (%) 1,2,3,5,7,10,11,14,15,16,17,22,24,29,30,31,32,33,34,35,37,40,52,53,54,55				
Subtotal	15651	36364	OR: 1.04 [0.96, 1.14]	0.34
Fixed, Heterogeneity: p=0.02; I ² =38%				
Readmissions, n (%) 3,10,11,13,14,15,16,18,20,22,23,32,36,49,52				
Subtotal	30154	50305	OR: 1.09 [0.98, 1.21]	0.1
Random, Heterogeneity: p=0.03; I ² =44%				
Positive PRM, n (%) 15,16,24				
Subtotal	957	946	RD: 0.0000 [-0.0036, 0.0036]	1.00
Fixed, Heterogeneity: p=1; I ² =0%				

LAR/TME/ISR bibliography (1 of 2)

March 1, 2024

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Robotic-assisted vs. open LAR/TME/ISR surgery

Weighted estimates based
on 28 studies

Meta-analysis covering period
January 1, 2010 – March 1, 2024

This study analyzed continuous variables using weighted means and categorical variables using weighted rates with fixed or random effects models. This method gives more influence to studies with higher weights, providing a more accurate estimate of central tendency when combining results from multiple studies.

Outcomes that favor RAS

Estimated blood loss	122 mL vs 339 mL
Length of stay	6.4 days vs 8.4 days
Time to first flatus	1.7 days vs 2.5 days
Time to first bowel movement	1.3 days vs 2.1 days
Lymph node yield	15.6 vs 14.6
Surgical site infection	5.8% vs 13.2%
30-day postoperative complications	24% vs 30.7%
Positive surgical margins	4.3% vs 7.0%
Positive CRM	12.6% vs 15.3%

Disclaimer: The number of studies used to calculate the weighted estimates for each outcome varies

Comparable outcomes

Operative time	247.6 min vs 210.3 min
Blood transfusions	3.5% vs 8.1%
Anastomotic leaks	9.5% vs 9%
Ileus	9.1% vs 10.4%
Stoma	43.8% vs 44.1%
30-day readmissions	8.2% vs 7.5%
30-day reoperations	3.9% vs 3.6%
30-day mortality	1% vs 2.1%
DRM	2.3 cm vs 2.0 cm
Positive DRM	0.7% vs 1.7%
Positive PRM	0% vs 0%
Sexual dysfunction (6 months)	21.4% vs 32.5%

Outcomes that favor Open

None

Robotic-assisted vs. laparoscopic LAR/TME/ISR surgery

Weighted estimates based on 49 studies

Meta-analysis covering period January 1, 2010 – March 1, 2024

This study analyzed continuous variables using weighted means and categorical variables using weighted rates with fixed or random effects models. This method gives more influence to studies with higher weights, providing a more accurate estimate of central tendency when combining results from multiple studies.

Outcomes that favor RAS	
Estimated blood loss	74 mL vs 91 mL
Length of stay	7 days vs 7.5 days
Conversions	6.3% vs 13.9%
Blood transfusions	3.1% vs 4.1%
30-day mortality	0.8% vs 1.3%
Positive surgical margins	6.4% vs 7.4%
Time to first bowel movement	2.4 days vs 2.9 days
Female sexual function score (6 months)	19.4 vs 16.1
Urinary function score (6 months)	5.8 vs 7.7
Male sexual functions score (12 months)	21.1 vs 19.4
Sexual dysfunction (12 months)	25% vs 43.7%
Disclaimer: The number of studies used to calculate the weighted estimates for each outcome varies	

Comparable outcomes	
PRM	13.4 cm vs 13.9 cm
DRM	2.5 cm vs 2.3 cm
Positive CRM	9.7% vs 10%
Positive DRM	3.5% vs 3.9%
Positive PRM	0% vs 0%
Mesorectal excision completeness	79.9% vs 79.1%
Lymph node yield	16 vs 16
Surgical site infection	5.1% vs 5.1%
Anastomotic leaks	8.5% vs 8.6%
Ileus	10% vs 10.2%
Stoma	46.7% vs 47.1%
Time to flatus	1.9 days vs 2.2 days
Time to regular diet	4.3 days vs 4.6 days
30-day postoperative complications	21.6% vs 22.5%
30-day readmissions	8.8% vs 8.0%
30-day reoperations	5.7% vs 6.2%
Male sexual function score (6 months)	27.9 vs 18.9
Urinary function score (!2 months)	7 vs 8.2

Outcomes that favor Laparoscopic	
Operative time	256.1 min vs 221.7 min

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.

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