Evidence Navigator: Inguinal Hernia Repair

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

INTUITIVE

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
I^2	test statistic for heterogeneity
EBL	estimated blood loss
LOS	length of hospital stay

Evidence Navigator: Inguinal Hernia Repair Summary Slides

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WHAT DOES THE LITERATURE SHOW?

Systematic literature review:
Da Vinci robotic-assisted inguinal hernia repair

Inclusion criteria

Robotic-assisted inguinal hernia repair performed with a da Vinci surgical system

January 1, 2010 – March 1, 2024

Level of Evidence 1b, 2b, 2c, 3b

RCT, large database, prospective and retrospective cohort studies (with n≥20 in each cohort)

Exclusion criteria

Not in English

Paper reports on a pediatric population

Publication is an HTA that was not published in a peer-reviewed journal

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

No stratified analysis by study arm

Inguinal hernia repair data mixed with other procedures

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

Original research publication includes redundant patient population and similar conclusions

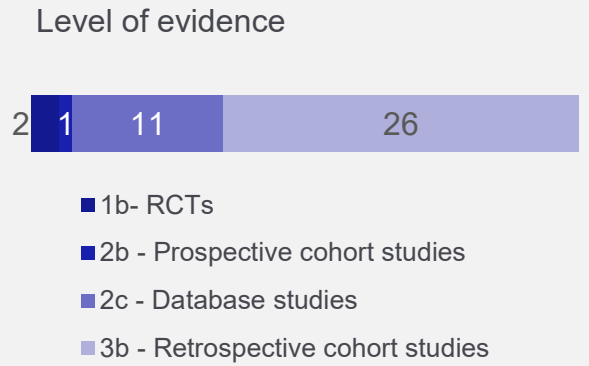
Concomitant inguinal hernia repair during prostatectomy

40 publications including:

Robotic-assisted patients: **23,888**

Laparoscopic patients: **91,278**

Open patients: **306,727**



WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points:
Robotic-assisted vs. laparoscopic inguinal hernia repair

Favors robotic-assisted

- ↓ Conversions by **53%**
- ↓ VAS pain scores during hospitalization (24 hours after surgery) by an average of **1.02 points**
- ↓ 1-year hernia recurrence by **49%**
- ↓ ≥2-year hernia recurrence by **51%**

Comparable outcomes

- ≈ Estimated blood loss
- ≈ Blood transfusions
- ≈ Surgical site infection
- ≈ Inpatient length of hospital stay
- ≈ Outpatient length of hospital stay
- ≈ 30-day postoperative complications
- ≈ 30-day readmissions
- ≈ 30-day reoperations
- ≈ 30-day mortality
- ≈ 30-day hernia recurrence
- ≈ 30-day acute postoperative pain
- ≈ 1-year VAS pain score
- ≈ 2-year chronic pain

Favors laparoscopic

- ↓ Operative time for unilateral repair is on average **19.08 min shorter**
- ↓ Operative time for a bilateral repair is on average **21.42 min shorter**

Data collected: March 1, 2024

WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points: **Robotic-assisted vs. open inguinal hernia repair**

Favors robotic-assisted

- ↓ VAS pain scores during hospitalization (24 hours after surgery) by an average of **3.37 points**
- ↓ 30-day acute postoperative pain by **68%**

Comparable outcomes

- ≈ Blood transfusions
- ≈ Surgical site infection
- ≈ Inpatient length of hospital stay
- ≈ Outpatient length of hospital stay
- ≈ 30-day postoperative complications
- ≈ 30-day readmissions
- ≈ 30-day reoperations
- ≈ 30-day mortality
- ≈ 30-day hernia recurrence
- ≈ 1-year hernia recurrence
- ≈ ≥ 2-year hernia recurrence

Favors open

- ↓ Operative time for unilateral repair is on average **22.96 min shorter**
- ↓ Operative time for a bilateral repair is on average **26.69 min shorter**

Data collected March 1, 2024

Evidence Navigator: Inguinal Hernia Repair Technical Slides

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Inguinal Hernia Repair: 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 right colectomies performed with da Vinci® surgical systems. Publications were identified according to inclusion and exclusion criteria described.

Meta-analysis was performed using R software.

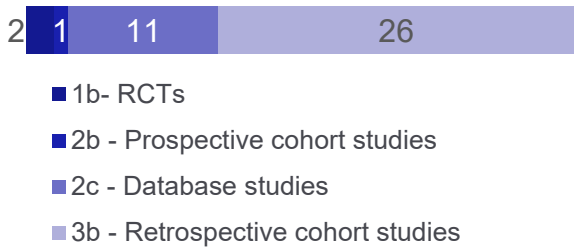
40 publications

23,888 patients who underwent RAS

91,278 patients who underwent laparoscopic surgery

306,727 patients who underwent open surgery

Level of evidence



Criteria phase	Details
Identification phase	All robotics publications (library generated from monthly search process) N=39,985 library size at the time of search March 1, 2024
Inclusion criteria 1. Robotic-assisted Inguinal hernia repair procedure	Robotic primary inguinal hernia repair N = 317 (excluded N = 39,668)
2. Year ≥ 2010	Articles published ≥ 2010 N = 314 (excluded N = 3)
3. LOE = 1b, 2b, 2c, 3b	Articles with LOE= 1b, 2b, 2c N = 78 (excluded N = 236)
4. Study is an RCT, prospective or retrospective study or large database study with comparative cohorts (robotic-assisted vs lap and/or open surgery) and sample size N≥20	Comparator cohorts N = 75 (excluded N = 3)
Exclusion criteria	**N = 35 excluded publications:**
1. Not in English	N = 0 (EC#1)
2. Paper reports on a pediatric population	N = 1 (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 = 0 (EC#4)
5. No stratified analysis by study arm (e.g., combines results from robotic, laparoscopic, and/or open cohorts)	N = 13 (EC#5)
6. Inguinal hernia repair data mixed with another procedure/s	N =7 (EC#6)
7. Original research study does not provide quantitative results for the outcomes of interest	N = 12 (EC#7)
8. Original research publication includes redundant patient population and similar conclusions	N = 0 (EC#8)
9. Inguinal hernia repair after a prostatectomy	N = 2 (EC#9)

Inguinal Hernia Repair Publications: N = 40

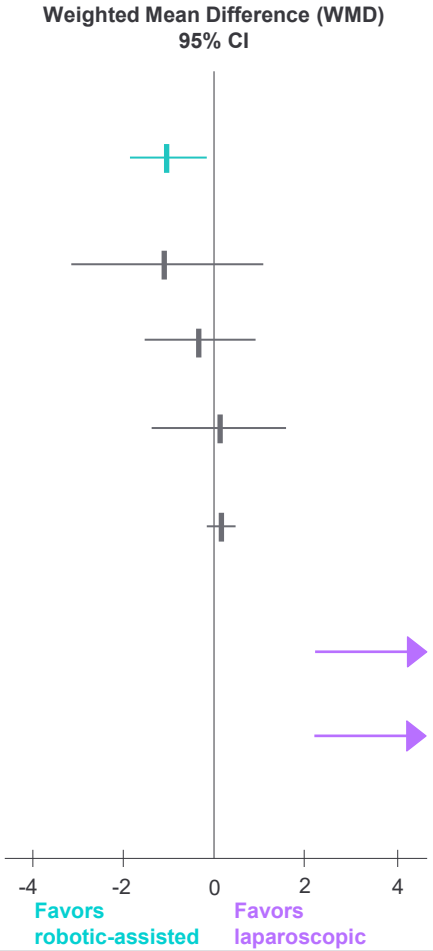
Robotic-assisted vs. laparoscopic inguinal hernia repair

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 inguinal hernia repair, the evidence for **robotic-assisted inguinal hernia repair using the da Vinci surgical system** demonstrates:

- Significantly lower pain scores (VAS) during hospitalization 24-hour by an average of **1.02 points**
- Comparable estimated blood loss
- Comparable outpatient length of hospital stay
- Comparable pain scores (VAS) within 1-year of surgery
- Comparable inpatient length of hospital stay
- Significantly longer operative time for a unilateral repair by an average of 19.08 min
- Significantly longer operative time for a bilateral repair by an average of 21.42 min



Outcome	Robotic-assisted, n	Laparoscopic, n	Effect Size WMD, 95%CI	P-value
Inguinal Hernia Repair Continuous Variables (to March 1, 2024)				
Pain score (VAS) during hospitalization 24-hour [2,8,39]				
Subtotal	132	117	-1.02 [-1.85 ; -0.19]	p=0.02
Random, Heterogeneity: p<0.01; I²=80.78%				
EBL, mL [4,5,21,28]				
Subtotal	788	974	-1.05 [-3.15 ; 1.05]	p=0.33
Random, Heterogeneity: p<0.01; I² = 81.13%				
Outpatient length of stay, days [1,22]				
Subtotal	705	1548	-0.33 [-1.55 ; 0.88]	p=0.59
Random, Heterogeneity: p=0.01; I² = 83.24%				
Pain score (VAS) during hospitalization 1-year [4,25]				
Subtotal	43	70	0.09 [-1.33 ; 1.53]	p=0.89
Fixed, Heterogeneity: p=0.19; I²= 41.87%				
Inpatient length of stay, days [2,4,5,6,8,9,12,14,15,17,22,28,29,30,31,36,39,40]				
Subtotal	9675	58927	0.14 [-0.17 ; 0.46]	p=0.37
Random, Heterogeneity: p<0.01; I² = 97.58%				
Operative time for unilateral repair, min [1,4,7,9,11,13,17,20,22,26,27,28,31,35]				
Subtotal	3123	10488	19.08 [10.84 ; 27.31]	p<0.01
Random, Heterogeneity: p<0.01; I² = 95.52%				
Operative time for bilateral repair, min [4,9,20,22,27,29]				
Subtotal	403	533	21.42 [2.14 ; 40.69]	p=0.03
Random, Heterogeneity: p<0.01; I² = 92.90%				

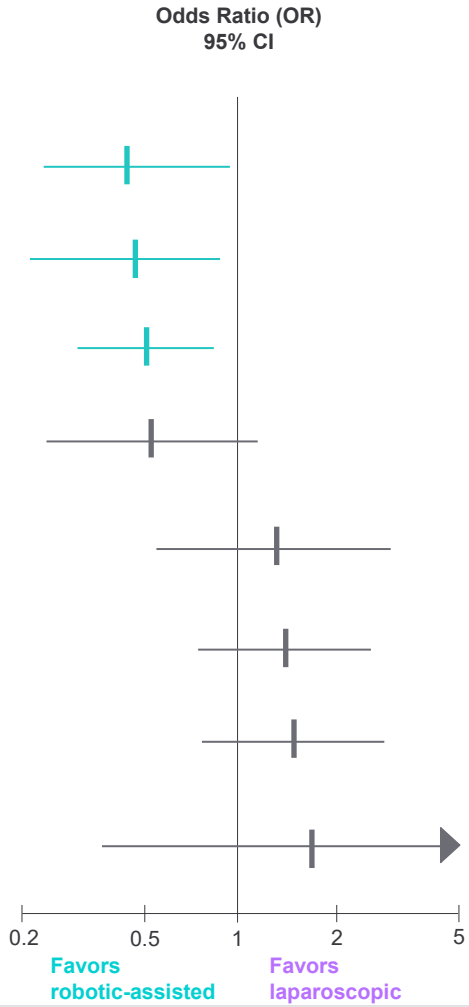
Robotic-assisted vs. laparoscopic inguinal hernia repair

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 inguinal hernia repair, the evidence for **robotic-assisted inguinal hernia repair using the da Vinci surgical system** demonstrates:

- 53% less likely to have a conversion to open surgery
- 51% less likely to have hernia recurrence ≥2-years of surgery
- 49% less likely to have hernia recurrence within 1-year of surgery
- Comparable acute postoperative pain within 30-days of surgery
- Comparable readmissions rate within 30-days of surgery
- Comparable postoperative complications rate within 30-days of surgery
- Comparable surgical site infection rate
- Comparable reoperations rate within 30-days of surgery



Outcome	Robotic-assisted, n	Laparoscopic, n	Effect size OR 95% CI	P-value
Inguinal Hernia Repair Binary Variables (to March 1, 2024)				
Conversions, n [1,2,4,6,8,17,20,21,22,26,29,32,33]				
Subtotal	5616	7437	0.47 [0.22 ; 0.99]	**p=0.05**
Random, Heterogeneity: p=0.02; I^2 = 60.38%				
Hernia recurrence ≥2 years, n [2,9,14,21,23,25,29,37]				
Subtotal	2703	5170	0.49 [0.29 ; 0.86]	**p=0.01**
Fixed, Heterogeneity: p=0.55; I^2 = 0%				
Hernia recurrence 1 years, n [3,4,5,6,13,23,28,40]				
Subtotal	2419	4898	0.51 [0.31 ; 0.85]	**p<0.01**
Fixed, Heterogeneity: p=0.55; I^2 = 0%				
Acute postoperative pain - 30-day, n [11,13,23,31]				
Subtotal	1882	3584	0.53 [0.24 ; 1.15]	p=0.11
Fixed, Heterogeneity: p=0.16; I^2= 41.19%				
Readmissions 30-day, n [2,4,5,6,7,8,9,11,17,20,22,23,27,30,31,36,38]				
Subtotal	4316	41683	1.32 [0.55 ; 3.14]	p=0.54
Random, Heterogeneity p<0.01; I^2 = 79.99%				
Postoperative complications 30-day, n [4,6,7,11,12,13,17,22,23,27,29,30,31,32,36,37]				
Subtotal	10394	60612	1.41 [0.75 ; 2.64]	p=0.29
Random, Heterogeneity: p<0.01; I^2= 95.27%				
Surgical site infection, n [3,4,5,9,12,13,14,17,21,23,31,32,38]				
Subtotal	9794	24944	1.49 [0.76 ; 2.91]	p=0.25
Random, Heterogeneity: p=0.01; I^2 = 54.95%				
Reoperations 30-day, n [4,5,7,12,17,22,23]				
Subtotal	8226	22500	1.69 [0.366 ; 7.84]	p=0.50
Random, Heterogeneity p<0.01; I^2= 78.30%				

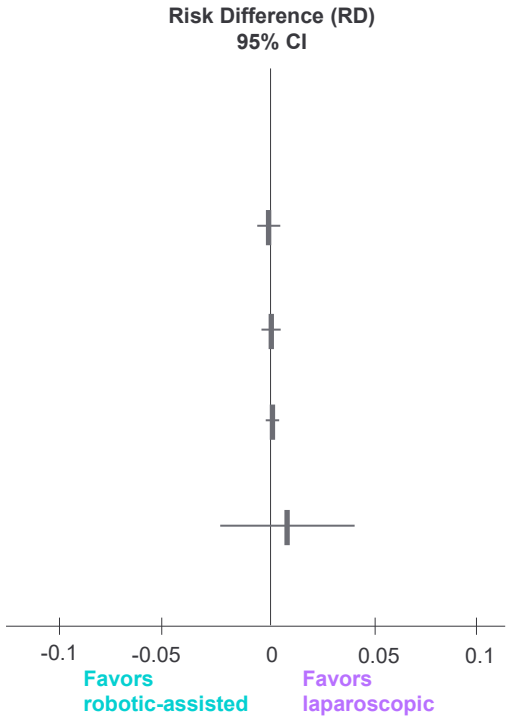
Robotic-assisted vs. laparoscopic inguinal hernia repair

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 inguinal hernia repair, the evidence for **robotic-assisted inguinal hernia repair using the da Vinci surgical system** demonstrates:

- Comparable blood transfusion rate
- Comparable hernia recurrence within 30-days of surgery
- Comparable mortality rate within 30-days of surgery
- Comparable chronic pain within 2-years of surgery



Outcome	Robotic-assisted, n	Laparoscopic, n	Effect size RD 95% CI	P-value
Inguinal Hernia Repair Binary Variables (to March 1, 2024)				
Blood transfusions, n [6,7]				
Subtotal	348	1004	-0.0009 [-0.0071 ; 0.0054]	p=0.78
Fixed, Heterogeneity: p=0.66; I^2 = 0%				
Hernia recurrence 30-day, n [7,8,23,32]				
Subtotal	1737	3633	0.0004 [-0.0027 ; 0.0036]	p=0.79
Fixed, Heterogeneity: p=0.88; I^2 = 0%				
Mortality 30-days, n [2,6,7,9,11,12,30]				
Subtotal	7157	19759	0.0005 [-0.0006 ; 0.0015]	p=0.37
Fixed, Heterogeneity: p=1.00; I^2 = 0%				
Chronic pain 2-years, n [2,28]				
Subtotal	123	123	0.0081 [-0.0231 ; 0.0392]	p=0.61
Fixed, Heterogeneity p=0.45; I^2 = 0%				

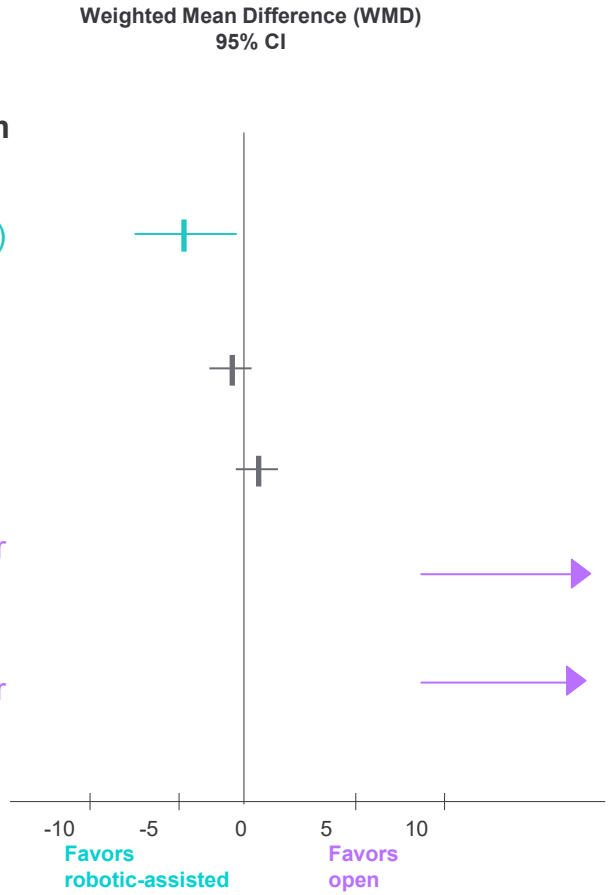
Robotic-assisted vs. open inguinal hernia repair

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 inguinal hernia repair, the evidence for **robotic-assisted inguinal hernia repair using the da Vinci surgical system** demonstrates:

- Significantly lower pain scores (VAS) during hospitalization by an average of **3.37 points**
- Comparable inpatient length of hospital stay
- Comparable outpatient length of hospital stay
- Significantly longer operative time for a unilateral repair by an average of **22.96 min**
- Significantly longer operative time for a bilateral repair by an average of **26.69 min**



Outcome	Robotic-assisted, n	Open, n	Effect Size WMD, 95%CI	P-value
Inguinal Hernia Repair Continuous Variables (to March 1, 2024)				
Pain score (VAS) during hospitalization 24-hour [16,19]				
Subtotal	124	197	-3.37 [-6.30 ; -0.44]	p=0.02
Random, Heterogeneity: p=0.07; I^2= 68.62%				
Inpatient length of stay, days [4,10,12,14,15,18,22,30,36]				
Subtotal	8831	225115	-0.63 [-1.65 ; 0.39]	p=0.23
Random, Heterogeneity: p<0.01; I^2 = 99.24%				
Outpatient length of stay, days [10,18,22]				
Subtotal	607	609	0.79 [-0.45 ; 2.03]	p=0.21
Random, Heterogeneity: p<0.01; I^2 = 94.20%				
Operative time for unilateral repair, min [4,7,13,17,19,22,35]				
Subtotal	1969	37721	22.96 [9.14 ; 36.78]	p<0.01
Random, Heterogeneity: p<0.01; I^2= 99.34%				
Operative time for bilateral repair, min [4,16,19,22,35]				
Subtotal	159	287	26.69 [10.04 ; 43.34]	p<0.01
Random, Heterogeneity: p<0.01; I^2 = 70.01%				

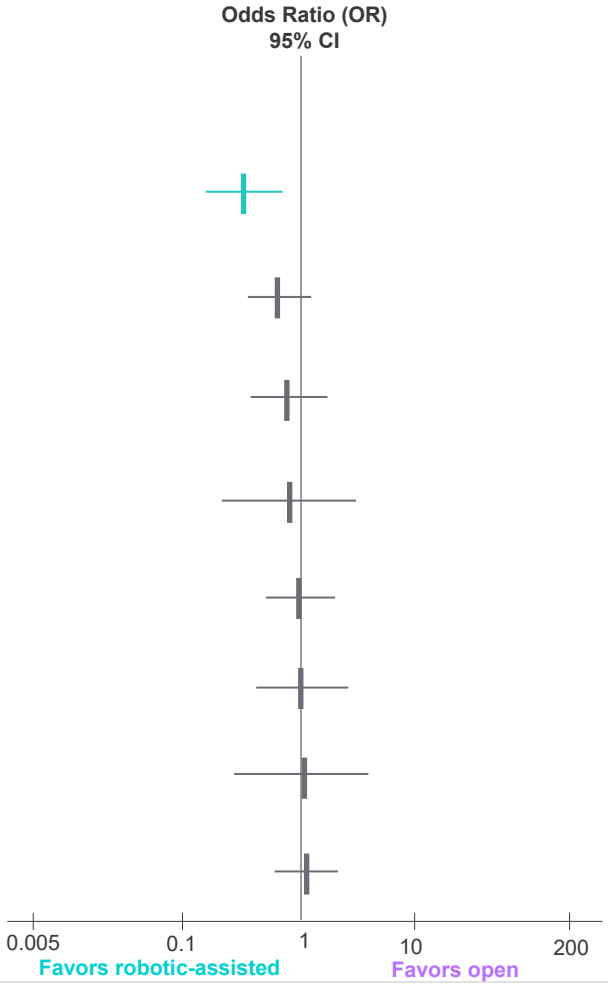
Robotic-assisted vs. open inguinal hernia repair

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 inguinal hernia repair, the evidence for **robotic-assisted inguinal hernia repair using the da Vinci surgical system** demonstrates:

- 68% less likely to experience early postoperative acute pain acute within 30-days of surgery
- Comparable hernia recurrence within 1-year of surgery
- Comparable readmissions within 30-days of surgery
- Comparable reoperations within 30-days of surgery
- Comparable mortality within 30-days of surgery
- Comparable surgical site infection rate
- Comparable hernia recurrence in 2-years and beyond post-surgery
- Comparable postoperative complications rate within 30-days of surgery



Outcome	Robotic-assisted, n	Open, n	Effect size OR 95% CI	P-value
Inguinal Hernia Repair Continuous Variables (to March 1, 2024)				
Early postoperative acute pain - 30-day, n [10,13,23]				
Subtotal	2249	2236	0.32 [0.16 ; 0.67]	p<0.01
Fixed, Heterogeneity: p=0.96; I^2 = 0%				
Hernia recurrence 1 years, n [3,13,19,23]				
Subtotal	1964	1963	0.63 [0.35 ; 1.14]	p=0.13
Fixed, Heterogeneity: p=0.52; I^2 = 0%				
Readmissions 30-day, n [4,7,10,18,19,22,23,30,36,38]				
Subtotal	3749	122831	0.76 [0.35 ; 1.65]	p=0.48
Random, Heterogeneity: p<0.01; I^2 = 76.15%				
Reoperations 30-day, n [4,10,12,18,22,23]				
Subtotal	8332	103246	0.80 [0.20 ; 3.24]	p=0.76
Random, Heterogeneity: p<0.01; I^2 = 79.56%				
Mortality 30-days, n [7,10,12,30]				
Subtotal	7378	104086	0.99 [0.51 ; 1.93]	p=0.97
Fixed, Heterogeneity: p=0.73; I^2 = 0%				
Surgical site infection, n [3,4,10,12,13,14,18,23,38]				
Subtotal	9503	105586	1.03 [0.41 ; 2.56]	p=0.95
Random, Heterogeneity: p=0.01; I^2 = 61.96%				
Hernia recurrence ≥2 years, n [4,14,23,37]				
Subtotal	2031	3843	1.03 [0.27 ; 3.96]	p=0.96
Random, Heterogeneity: p=0.02; I^2= 68.36%				
Postoperative complications 30-day, n [4,7,10,12,13,18,22,23,30,36,37]				
Subtotal	10103	224673	1.07 [0.59 ; 1.96]	p=0.82
Random, Heterogeneity: p<0.01; I^2 = 94.90%				

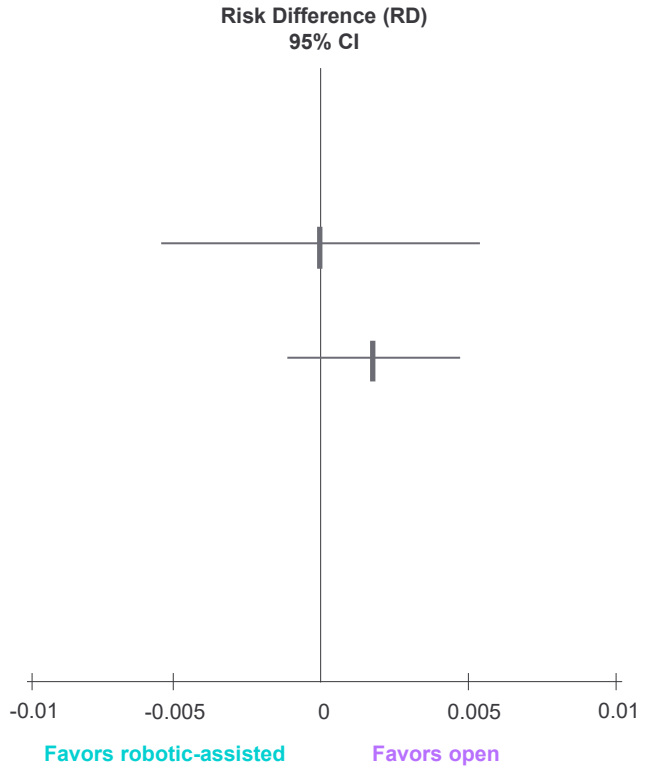
Robotic-assisted vs. open inguinal hernia repair

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 inguinal hernia repair, the evidence for **robotic-assisted inguinal hernia repair using the da Vinci surgical system** demonstrates:

- Comparable blood transfusion rate
- Comparable hernia recurrence within 30-days of surgery



Outcome	Robotic-assisted, n	Open, n	Effect size RD 95% CI	P-value
Inguinal Hernia Repair Continuous Variables (to March 1, 2024)				
Blood transfusions, n [7,10,18]				
Subtotal	608	728	0.0000 [-0.0055 ; 0.0055]	p=1.00
Fixed, Heterogeneity: p=1.00; I^2 = 0%				
Hernia recurrence 30-days, n [7,23]				
Subtotal	1667	1789	0.0018 [-0.0011 ; 0.0046]	p=0.23
Fixed, Heterogeneity: p=0.85; I^2 = 0%				

Appendix

Weighted estimates & bibliography of included studies

Robotic-assisted vs. laparoscopic Inguinal Hernia Repair

Weighted estimates based on 37 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

Conversions	2.1% vs 2.8%
≥2-year hernia recurrence	1.1% vs 2.0%
1-year hernia recurrence	0.7% vs 2.3%
24-hour VAS pain score	2.4 score vs 3.4 score

Comparable outcomes

Estimated blood loss	4.7 ml vs 5.8 ml
Blood transfusions	0% vs 0.1%
Surgical site infections	2.1% vs 2.0%
Inpatient Length of hospital stay	1.6 days vs 1.5 days
Outpatient Length of hospital stay	6.1 hours vs 6.5 hours
30-day postoperative complications	10.9% vs 7.7%
30-day readmissions	2.6% vs 1.6%
30-day reoperations	2.2% vs 0.9%
30-day mortality	0.2% vs 0.1%
30-day hernia recurrence	0.2% vs 0.2%
30-day acute postoperative pain	2% vs 6.2%
1-year VAS pain score	1.9 score vs 1.8 score
2-year chronic pain	1.6% vs 0.8%

Outcomes that favor Laparoscopic

Operative time Unilateral	80.6 min vs 61.5 min
Operative time Bilateral	93 min vs 71.6 min

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

Robotic-assisted vs. open Inguinal Hernia Repair

Weighted estimates based on 19 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

30-day Acute postoperative pain	1.4% vs 4.3%
24-hour VAS pain score	0 score vs 3.4 score

Comparable outcomes

Blood Transfusions	0% vs 0%
Surgical Site Infections	0.5% vs 0.7%
Inpatient Length of stay	1.7 days vs 2.4 days
Outpatient Length of stay	6.8 hours vs 6.0 hours
30-day postoperative complications	8.7% vs 8.5%
30-day readmissions	2.5% vs 3.3%
30-day reoperations	1.2% vs 1.1%
30-day mortality	0.1% vs 0.1%
30-day hernia recurrence	0.2% vs 0.1%
1-year hernia recurrence	1.4% vs 3.4%
≥2-year hernia recurrence	2.0% vs 1.6%

Outcomes that favor Open

Operative time Unilateral	84.4 min vs 61.4 min
Operative time Bilateral	115.2 min vs 88.5 min

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

Inguinal hernia repair: bibliography (1/2)

March 1, 2024

1. Abdelmoaty, W. F.D., C. M.Neighorn, C.Swanstrom, L. L.Hammill, C. W. (2018). Robotic-assisted versus laparoscopic unilateral inguinal hernia repair: a comprehensive cost analysis. [3b]. Surgical Endoscopy. doi:10.1007/s00464-018-06606-9
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Disclosures

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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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