# **Evidence Navigator: Ventral Hernia Repair**

Systematic literature review summary as of March 1, 2024



# **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<sup>®</sup> 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
НТА	health technology assessment
RCT	randomized controlled trial
OR	odds ratio
MD	mean difference
EC	exclusion criteria
RD	risk difference

WMD	weighted mean difference				
SMD	standardized mean difference				
95% CI	95% confidence interval				
<sup>2</sup>	test statistic for heterogeneity				
SSI	surgical site infection				
EBL	estimated blood loss				
LOS	length of hospital stay				
HerQLes	Hernia-Related Quality-of-Life Survey				
VAS	visual analog scale				

# **Evidence Navigator:** Ventral Hernia Repair Summary Slides

Systematic literature review summary as of March 1, 2024





what does the literature show? Systematic literature review: Da Vinci robotic-assisted ventral hernia repair

### **Inclusion criteria**

Robotic-assisted ventral hernia repair performed with a da Vinci<sup>®</sup> 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)

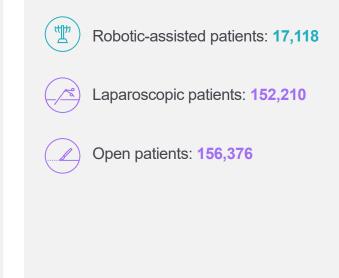
No stratified analysis by study arm

Ventral hernia repair data mixed with another procedure/s

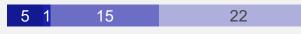
Original research study does not provide quantitative results for outcomes of interest

Original research publication includes redundant patient population and similar conclusions

### 35 publications including



### Level of evidence



- ■1b RCTs
- 2b Prospective cohort studies
- 2c Database studies
- 3b Retrospective cohort studies



### WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points:

Robotic-assisted with da Vinci surgical system vs. laparoscopic ventral hernia repair

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### Favors robotic-assisted

- ↓ Conversions by **46%**
- ↓ 30-day surgical site infection by **56%**
- ↓ 30-day pain scores (VAS) by **0.8** points
- $\downarrow$  2-year hernia recurrence by 87%

) Comparable outcomes

- ≈ Postoperative pain medication use at discharge
- ≈ Length of hospital stay
- ≈ Time to return to normal activities
- ≈ 30-day postoperative complications
- ≈ 30-day readmissions
- ≈ 30-day reoperations
- ≈ 30-day emergency department visits
- ≈ 30-day hernia recurrence
- ≈ 90-day hernia recurrence
- ≈ 30-day HerQLes quality of life score
- ≈ 30-day mortality



### **Favors laparoscopic**

↓ Operative time by **59 minutes** 

Data collected through: March 1, 2024



## WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points:

Robotic-assisted with da Vinci surgical system vs. open ventral hernia repair

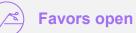
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### Favors robotic-assisted

- ↓ Length of hospital stay by **2.6 days**
- ↓ 30-day surgical site infection by **72%**
- ↓ 30-day readmissions by **29%**
- ↓ 30-day hernia recurrence by **84%**
- ↓ Risk of 30-day mortality

### (E) Comparable outcomes

- ≈ Postoperative pain medication use at discharge
- ≈ Time to return to normal activities
- ≈ 30-day reoperations
- $\approx$  30-day HerQLes quality of life score
- $\approx$  30-day post-operative complications



↓ Operative time by **93 minutes** 

Data collected through: March 1, 2024

# **Evidence Navigator:** Ventral Hernia Repair Technical Slides

Systematic literature review summary as of March 1, 2024



## Ventral 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 ventral hernia repairs were performed with da Vinci<sup>®</sup> surgical systems. Publications were identified according to inclusion and exclusion criteria described.

Meta-analysis was performed using RevMan or R software.

### **35 publications**

17,118 patients who underwent robotic-assisted surgery (RAS)152,210 patients who underwent laparoscopic surgery (Lap)156,376 patients who underwent open surgery

### Level of evidence



- ■1b RCTs
- 2b Prospective cohort studies
- 2c Database studies
- 3b Retrospective cohort studies

lue	ntification phase	All robotics publications (library generated f monthly search process) N=39,985 library size at the time of search March 1, 2024
<b>Inc</b> 1.	lusion criteria Robotic-assisted ventral hernia repair	Da Vinci <sup>®</sup> robotic-assisted ventral hernia rep N= <b>330</b> (excluded N=39,655)
2.	Year ≥ 2010	Articles published ≥ 2010 N= <b>326</b> (excluded N=4)
3.	LOE = 1b, 2b, 2c, 3b	Articles with LOE = 1b, 2b, 2c, 3b N= <b>57</b> (excluded N=269)
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= <b>51</b> (excluded N=6)
Exe	clusion criteria	N=16 excluded publications:
<b>Ex</b> (	Not in English	N=16 excluded publications: N=0 (EC#1) N=0 (EC#2)
		N=0 (EC#1) N=0 (EC#2) N=0 (EC#3)
1.	Not in English	N=0 (EC#1) N=0 (EC#2) N=0 (EC#3) N=0 (EC#4) N=8 (EC#5) N=1 (EC#6)
1. 2.	Not in English Paper reports on a pediatric population Publication is an HTA that was not published	N=0 (EC#1) N=0 (EC#2) N=0 (EC#3) N=0 (EC#4) N=8 (EC#5)
1. 2. 3.	Not in English Paper reports on a pediatric population Publication is an HTA that was not published in a peer-reviewed journal	N=0 (EC#1) N=0 (EC#2) N=0 (EC#3) N=0 (EC#4) N=8 (EC#5) N=1 (EC#6) N=7 (EC#7)
1. 2. 3. 4.	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 (e.g., combines results from	N=0 (EC#1) N=0 (EC#2) N=0 (EC#3) N=0 (EC#4) N=8 (EC#5) N=1 (EC#6) N=7 (EC#7) N=0 (EC#8)
1. 2. 3. 4. 5.	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 (e.g., combines results from robotic, lap and/or open cohorts)	N=0 (EC#1) N=0 (EC#2) N=0 (EC#3) N=0 (EC#4) N=8 (EC#5) N=1 (EC#6) N=7 (EC#7) N=0 (EC#8)

### Robotic-assisted ventral hernia repair publications: N=35

## **Robotic-assisted vs. laparoscopic ventral hernia repair** Summary as of March 1, 2024

 
 Significant difference favoring robotic-assisted surgery
 No significant difference;
 Significant difference favoring laparoscopic surgery

Compared to laparoscopic ventral hernia repair, the evidence for **robotic-assisted ventral hernia repair using the da Vinci surgical system** demonstrates:

- Significantly lower pain scores (VAS) at 30days follow-up by an average of 0.8 points
- Comparable time to return to normal activities
- Comparable length of hospital stay
- Comparable quality of life HerQLes score at 30-days follow-up

WMD

• Significantly longer operative time by an average of 59 minutes

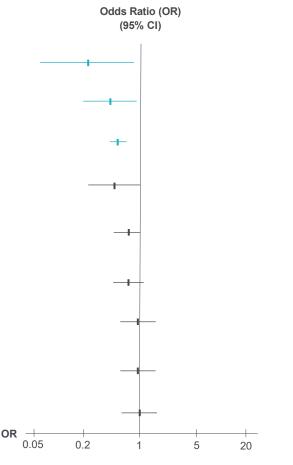
Weighted Mean I (95%	Difference (W % CI)	MD)	Outcome	Robotic- assisted, n	Lap, n	Effect size 95% Cl	P-value
			Ventral hernia re	epair continuous	s variables (to March 1	, 2024)	
			Pain Score (VA Subtotal Fixed, Heterogeneity	103	<b>n</b> <sup>27, 29</sup> 94	-0.80 [-1.40,-0.20]	p<0.01
I			<b>Return to norm</b> Subtotal Random, Heterogene	236	382	-1.50 [-6.98, 3.99]	p=0.59
-+	-		<b>Length of Stay,</b> Subtotal Random, Heterogene	7677	5, 20, 22-24, 29, 32, 34, 35 77094	-0.20 [-0.62, 0.22]	p=0.35
	1		HerQLes at 30- Subtotal Fixed, Heterogeneity	198	<b>-R)</b> <sup>23, 29</sup> 118	0.27 [-6.06, 6.61]	p=0.93
		->	<b>Operative Time</b> Subtotal Random, Heterogene	754	904	58.82 [39.55, 78.08]	p<0.01
I		1 1					
-2	0	2 4					
Favors robotic-assisted	Favors laparoso	opic					

## Robotic-assisted vs. laparoscopic ventral hernia repair Summary as of March 1, 2024

 
 Significant difference favoring robotic-assisted surgery
 No significant difference;
 Significant difference favoring laparoscopic surgery

Compared to laparoscopic ventral hernia repair, the evidence for **robotic-assisted ventral hernia repair using the da Vinci surgical system** demonstrates:

- 87% less likely to experience a hernia recurrence at 2-years follow-up
- 56% less like to experience a surgical site infection within 30-days of surgery
- 46% less likely to be converted to open surgery
- Comparable reoperations rate within 30-days of surgery
- Comparable post-operative pain medication use rate at discharge
- Comparable post-operative complications rate within 30-days of surgery
- Comparable readmissions rate within 30-days
   of surgery
- Comparable mortality rate within 30-days of surgery
- Comparable emergency department visit rate within 30-days of surgery



FavorsFavorsrobotic-assistedlaparoscopic

Outcome	Robotic- assisted, n	Lap, n	Effect size 95% Cl	P-value
Ventral hernia re	epair binary vari	ables (to March 1, 2	024)	
Hernia recurren Subtotal Fixed, Heterogeneity	121	<b>n</b> <sup>12, 15</sup> 114	0.23 [0.06, 0.85]	p=0.03
Surgical site in Subtotal Fixed, Heterogeneity	1054	1, 13, 15, 22, 27, 34, 35 1233	0.44 [0.21, 0.92]	p=0.03
<b>Conversions, n</b> Subtotal Fixed, Heterogeneity	3703	38293	0.54 [0.44, 0.66]	p<0.01
Reoperations, I Subtotal Fixed, Heterogeneity	1283	27, 29, 32, 35 1764	0.48 [0.23, 1.02]	p=0.06
Postoperative   Subtotal Fixed, Heterogeneity	624	<b>n use, n</b> <sup>2, 23</sup> 6911	0.72 [0.50, 1.03]	p=0.07
<b>Post-operative</b> Subtotal Random, Heterogene	2320	5 <b>, n</b> <sup>1</sup> , 2, 6, 13, 15, 22-24, 29, 9111	32 0.72 [0.46, 1.12]	p=0.15
<b>Readmissions,</b> Subtotal Random, Heterogene	2797	28975	0.94 [0.59, 1.49]	p=0.79
<b>Mortality, n</b> <sup>2, 3,</sup> Subtotal Fixed, Heterogeneity	6339	51920	0.95 [0.57, 1.58]	p=0.84
Emergency dep Subtotal Random, Heterogene	2949	20164	0.99 [0.58, 1.68]	p=0.97

## **Robotic-assisted vs. laparoscopic ventral hernia repair** Summary as of March 1, 2024

Significant difference favoring robotic-assisted surgery comparable outcomes laparoscopic surgery

Compared to laparoscopic ventral hernia repair, the evidence for **robotic-assisted ventral hernia repair using the da Vinci surgical system** demonstrates:

- Comparable hernia recurrence rate at 30-day follow-up
- Comparable hernia recurrence rate at 90-day follow-up

	Risk Difference (RD) (95% CI)								
									F S R
					-				<b>F</b>
RD	-0.1		-0.5		0	0	.05	0.1	-
		Favo robo		ssisted		avors paros		с	

**Robotic-**Effect size Outcome Lap, P-value assisted, n 95% CI n /entral hernia repair binary variables (to March 1, 2024) Hernia recurrence at 30-days, n<sup>6, 11, 13, 23</sup> 335 Subtotal 468 -0.0205 [0.0606, 0.0195] p=0.32 Random, Heterogeneity: p<0.01; I<sup>2</sup>=75% Hernia recurrence at 90-days, n <sup>24, 27, 34</sup> Subtotal 293 251 0.0014 [-0.0294, 0.0322] p=0.93 ixed, Heterogeneity: p=0.90; I<sup>2</sup>=0%

## **Robotic-assisted vs. open ventral hernia repair** Summary as of March 1, 2024

 
 Significant difference favoring robotic-assisted surgery
 No significant difference;
 Significant difference favoring open surgery

Compared to open ventral hernia repair, the evidence for **robotic-assisted ventral hernia repair using the da Vinci surgical system** demonstrates:

- Significantly shorter length of hospital stay by an average of 2.6 days
- Comparable quality of life HerQLes score at 30-days follow-up
- · Comparable time to return to normal activities
- Significantly longer operative time by an average of 93 minutes

repair, the <b>htral hernia</b>		Weighted Mean (95%	Difference (WM % CI)	ID)	Outcome	Robotic- assisted, n	Open, n	Effect size 95% Cl	P-value		
al system			1		Ventral hernia r	Ventral hernia repair continuous variables (to March 1, 2024)					
ospital stay		+-			Subtotal	<b>, days</b> <sup>2</sup> , 4, 5, 9, 10, 1 2600 eity: p<0.01; l <sup>2</sup> =95%	3, 16-18, 23, 25, 28, 31 43732	-2.57 [-3.23, -1.92]	p<0.01		
es score at					HerQLes at 30 Subtotal Fixed, Heterogeneity	- <b>days, score (L-I</b> 866 /: p=0.181; l <sup>2</sup> =41%	<b>२)</b> 16, 23, 28 989	-1.98 [-4.82, 0.86]	p=0.17		
mal activities		i			Subtotal	<b>nal activities, da</b> 236 eity: p<0.01; l <sup>2</sup> =95%		-1.58 [-7.07, 3.90]	p=0.57		
me by an				-	Subtotal	<b>9, min</b> <sup>4, 10, 13, 17, 2, 439 eity: p&lt;0.01; l<sup>2</sup>=96%</sup>		92.79 [39.27, 146.32]	p<0.01		
	<b>WMD</b> -10	-5	0 5	5 1	<u>├</u> 0						
		Favors robotic-assisted	Favors open								

## **Robotic-assisted vs. open ventral hernia repair** Summary as of March 1, 2024

 
 Significant difference favoring robotic-assisted surgery
 No significant difference;
 Significant difference favoring open surgery

Compared to open ventral hernia repair, the evidence for **robotic-assisted ventral hernia repair using the da Vinci surgical system** demonstrates:

- 84% less likely to experience a hernia recurrence at 30-days follow-up
- 72% less like to experience a surgical site infection within 30-days of surgery
- 29% less likely to be readmitted to hospital within 30-days of surgery
- Comparable reoperations rate within 30-days
   of surgery
- Comparable postoperative complications rate within 30-days of surgery
- Comparable postoperative pain medication use rate at discharge
- · Lower risk of mortality within 30-days of surgery

(95% CI)						<b>Outcome</b> Ventral hernia re	Robotic- assisted, n pair binary vari	<b>Open, n</b> ables (to March 1, 20	95% CI	P-value
	_		_			Hernia recurren Subtotal Fixed, Heterogeneity:	901	<b>n</b> <sup>13, 23, 28</sup> 1213	0.16 [0.03, 0.0.95]	p=0.04
		-+-				Surgical site inf Subtotal Fixed, Heterogeneity:	1693	), 13, 14, 16, 21, 25, 28 2836	0.28 [0.18, 0.44]	p<0.01
		-+	_			<b>Readmissions,</b> Subtotal Fixed, Heterogeneity:	2343	14, 16, 21, 23, 25, 28 42549	0.71 [0.56, 0.90]	p<0.01
		-+				<b>Reoperations, r</b> Subtotal Fixed, Heterogeneity:	1286	31 1882	0.62 [0.35, 1.09]	p=0.10
		-1	-			Postoperative of Subtotal Random, Heterogene	1865	<b>n</b> 2, 4, 9, 10, 13, 23, 25, 28, 3 41674	0.69 [0.49, 0.96]	p=0.03
			+			<b>Postoperative p</b> Subtotal Random, Heterogene	624	39635	0.76 [0.46, 1.26]	p=0.29
OR	0.01	0.1	1	10	100	<b>Mortality, n</b> <sup>2, 4, 5</sup> Subtotal Fixed, Heterogeneity:	1836	31 41663	-0.0084 [-0.0135, -0.0034]	p<0.01
RD	-0.02	-0.01	0 <b>Fa</b> y	0.01	0.02					
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# 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 <u>www.intuitive.com/safety</u>.

#### 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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