Evidence Navigator: Lobectomy

Systematic literature review & meta-analysis as of December 31, 2022

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 standardized mean differences or weighted mean differences when describing continuous outcomes. Weighting is based on the study sample size and variability of the outcome. A fixed effect model is used if heterogeneity was not statistically significant or not applicable, and a random effect model is used if heterogeneity was statistically significant. Mantel Haenszel summary statistic is used for overall results. 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
VATS	video-assisted thoracoscopic 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
PSM	positive surgical margins
LNY	lymph node yield
ICU	intensive care unit

Evidence Navigator: Lobectomy Summary Slides

Systematic literature review & meta-analysis as of December 31, 2022

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Systematic literature review & meta-analysis methods: **Da Vinci robotic-assisted lobectomy**

Inclusion criteria

Robotic-assisted lobectomy performed with a da Vinci® surgical system

January 1, 2010 – December 31, 2022

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

RCT, large database, and prospective 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

Lobectomy data mixed with lung mediastinal resection (e.g., data from multiple surgical procedures combined)

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

Original research publication includes redundant patient population and similar conclusions

48 publications including

RAS patients: **175,043**

VATS patients: **577,880**

Open patients: **403,088**

Level of evidence

WHAT DOES THE LITERATURE SHOW?

Systematic literature review & meta-analysis results: **Robotic-assisted vs. VATS lobectomy**

Favors robotic-assisted

- ↓ Conversion to open surgery by **53%**
- ↓ Length of hospital stay by **half a day**

Comparable outcomes

- ≈ ICU admission
- ≈ ICU length of stay
- ≈ Ventilation support >48 hours
- ≈ Respiratory failure
- ≈ Blood transfusion
- ≈ Prolonged air leak
- ≈ Chest tube duration
- ≈ Atelectasis
- ≈ Positive surgical margin
- ≈ Lymph node yield
- ≈ Nodal upstaging
- ≈ Nodal stations sampled
- ≈ 30-day readmission
- ≈ 30-day post-operative complication
- ≈ 30-day reoperation
- ≈ 30-day mortality

Favors VATS

- ↓ Operative time by **12 min**

Data collected through: December 31, 2022

Systematic literature review & meta-analysis results: **Robotic-assisted vs. open lobectomy**

Favors robotic-assisted

- ↓ Blood transfusion by **32%**
- ↓ Positive surgical margin by **16%**
- ↓ Lymph node yield by **1 lymph node**
- ↓ ICU length of stay by **half a day**
- ↓ ICU admission by **33%**
- ↓ Length of hospital stay by **2 days**
- ↓ 30-day postoperative complication by **27%**
- ↓ 30-day mortality by **35%**

Comparable outcomes

- ≈ Respiratory failure
- ≈ Prolonged air leak
- ≈ Nodal upstaging
- ≈ Nodal stations sampled
- ≈ 30-day reoperation
- ≈ 30-day readmission

Favors open

- ↓ Operative time by **40 min**

Data collected through: December 31, 2022

Evidence Navigator: Lobectomy Technical Slides

Systematic literature review & meta-analysis as of December 31, 2022

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Lobectomy: Literature search methods
as of December 31, 2022

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 the Global Evidence Management team.

All robotic-assisted lung lobectomies were performed with the da Vinci® surgical systems. Publications were identified according to inclusion and exclusion criteria described.

Meta-analysis was performed using RevMan or R software.

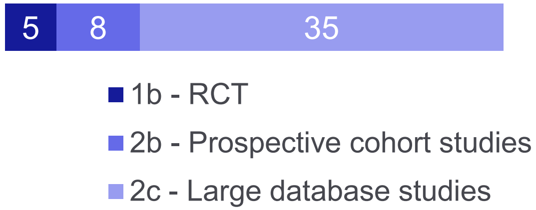
48 publications

175,043 patients who underwent RAS

577,880 patients who underwent video-assisted thoracoscopic surgery (VATS)

403,088 patients who underwent open surgery

Level of evidence



Criteria phase	Details
Identification phase	All unique PubMed, Scopus, and Embase references identified N=7303 December 31, 2022
Inclusion criteria	
1. Robotic-assisted lobectomy for cancer	Da Vinci® robotic-assisted lobectomy N=**1217** (excluded N=2891 duplicates & N=3195 not DV lobectomy for lung cancer)
2. Year ≥ 2010	Articles published ≥ 2010 N=**1213** (excluded N=4 year<2010)
3. LOE = 1b, 2b, 2c	Articles with LOE = 1b, 2b, 2c N=**117** (excluded N=1096 not LOE 1b/2b/2c))
4. Comparative cohort studies n≥20 (robotic-assisted vs. VATS and/or open surgery)	Comparator cohorts N=**101** (excluded N=16 sample<20)
Exclusion criteria	**N=52 excluded publications:**
1. Not in English	N=0 (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=0 (EC#4)
5. No stratified analysis by study arm (e.g., combines results from robotic, VATS and/or open cohorts)	N=33 (EC#5)
6. Lobectomy data mixed with lung mediastinal resection (e.g., data from multiple surgical procedures combined)	N=2 (EC#6)
7. Original research study does not provide quantitative results for outcomes of interest (i.e., operative time, conversions, estimated blood loss and/or transfusions, complications, length of hospital stay, mortality, etc.)	N=9 (EC#7)
8. Original research publication includes redundant patient population and similar conclusions	N=8 (EC#8)

Lobectomy publications included in review: N=49

Lobectomy publications included in meta-analysis: N=48

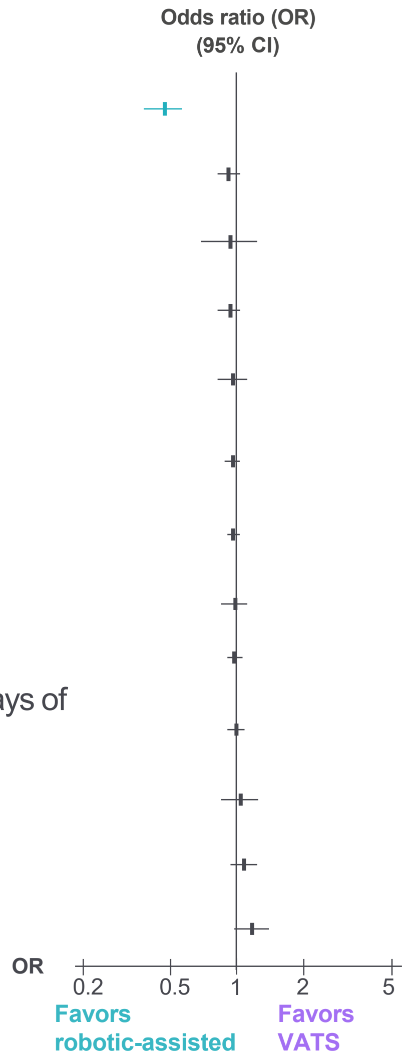
Robotic-assisted vs. VATS Lobectomy

Summary as of December 31, 2022

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

Compared to VATS lobectomy, the evidence for **robotic-assisted lobectomy** demonstrates:

- 53% less likely to convert to open surgery.
- Comparable ventilation support > 48hrs rate
- Comparable respiratory failure rate
- Comparable positive surgical margin rate
- Comparable mortality rate within 30-days of surgery
- Comparable blood transfusions rate
- Comparable readmissions rate within 30-days of surgery
- Comparable atelectasis rate
- Comparable nodal upstaging rate
- Comparable postoperative complications rate within 30-days of surgery
- Comparable ICU admission rate
- Comparable reoperations rate within 30-days of surgery
- Comparable prolonged air leak rate



Outcome	Robotic-assisted, n	VATS, n	Effect size 95% CI	P-value
Lobectomy binary variables (to December 31, 2022)				
Conversions, n [1, 3, 4, 5, 6, 9, 10, 12, 13, 17, 18, 26, 27, 28, 29, 30, 35, 36, 37, 39, 40, 44, 46, 48]				
Subtotal	108724	315079	0.47 [0.39, 0.56]	p<0.01
Random, Heterogeneity: p<0.00001; I²=96%				
Ventilation Support 48 hr, n [23, 30, 35, 38]				
Subtotal	12575	28997	0.92 [0.82, 1.04]	p=0.19
Fixed, Heterogeneity: p=0.35; I²=9%				
Respiratory Failure, n [1, 2, 23, 30, 36, 41, 42, 47]				
Subtotal	23727	59475	0.93 [0.69, 1.24]	p=0.61
Random, Heterogeneity: p<0.00001; I²=83%				
Positive Surgical Margins, n [3, 13, 25, 29, 33, 34, 39]				
Subtotal	9498	18834	0.93 [0.83, 1.04]	p=0.21
Fixed, Heterogeneity: p=0.29; I²=19%				
Mortality, n [1, 2, 3, 4, 5, 6, 7, 8, 9, 12, 13, 17, 19, 21, 23, 25, 26, 28, 30, 31, 32, 33, 36, 37, 38, 39, 41, 45, 47]				
Subtotal	80824	247187	0.96 [0.83, 1.10]	p=0.52
Random, Heterogeneity: p<0.01; I²=55%				
Blood Transfusions, n [1, 2, 17, 23, 28, 30, 37, 44, 45, 47]				
Subtotal	23254	55042	0.96 [0.89, 1.04]	p=0.35
Fixed, Heterogeneity: p=0.61; I²=0%				
Readmissions, n [3, 4, 5, 9, 11, 13, 17, 25, 33, 35, 36, 39, 41, 45, 46, 47]				
Subtotal	30511	63690	0.96 [0.91, 1.02]	p=0.24
Fixed, Heterogeneity: p=0.94, I²=0%				
Atelectasis, n [23, 30, 38, 42, 44, 46]				
Subtotal	4950	16111	0.98 [0.86, 1.12]	p=0.79
Fixed, Heterogeneity: p=0.62; I²=0%				
Nodal Upstaging, n [15,19,23,25]				
Subtotal	8011	28981	0.99 [0.92, 1.08]	p=0.9
Fixed, Heterogeneity: p=0.12; I²=43%				
Postoperative Complications, n [1, 6, 8, 9, 17, 19, 28, 29, 30, 32, 36, 45, 46, 47, 48]				
Subtotal	24008	82736	1.00 [0.91, 1.10]	p=0.99
Random, Heterogeneity: p<0.00001; I²=77%				
Intensive Care (ICU) Admissions, n [9, 23, 28, 29, 35, 45, 46, 47]				
Subtotal	12638	30010	1.04 [0.87, 1.25]	p=0.66
Fixed, Heterogeneity: p<0.0001; I²=77%				
Reoperations, n [23, 29, 35, 44, 45, 47]				
Subtotal	9715	27090	1.08 [0.94, 1.24]	p=0.29
Fixed, Heterogeneity: p=0.66; I²=0%				
Prolonged Air Leak, n [2, 14, 17, 23, 30, 36, 41, 42, 44, 46, 47]				
Subtotal	19680	55437	1.18 [0.99, 1.40]	p=0.06
Random, Heterogeneity: p<0.0001; I²=75%				

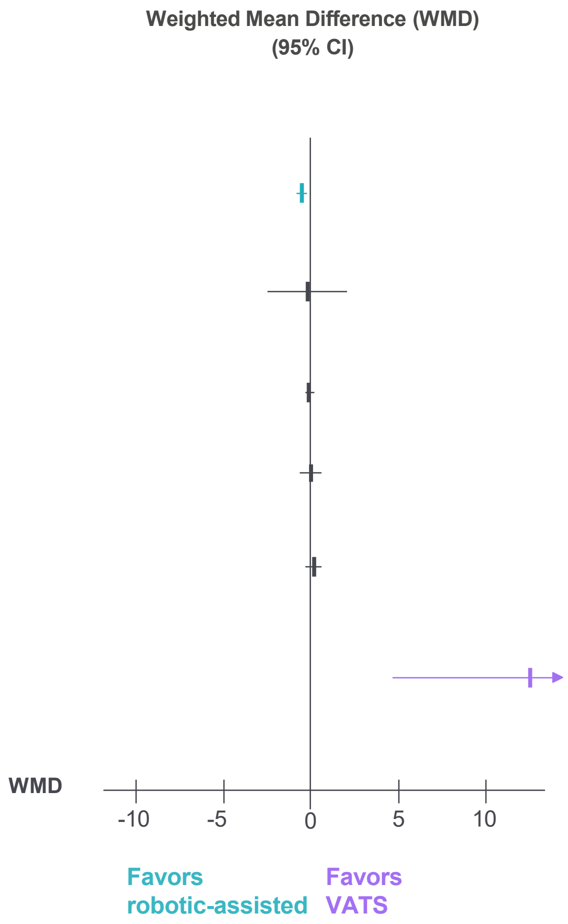
Robotic-assisted vs. VATS Lobectomy

Summary as of December 31, 2022

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

Compared to VATS lobectomy,
the evidence for **robotic-assisted lobectomy** demonstrates:

- Significantly shorter length of hospital stay by an average of 0.47 days (11 hours)
- Comparable number of nodal stations sampled
- Comparable ICU length of stay
- Comparable chest tube duration
- Comparable lymph node yield
- Significantly longer operative time by an average of 12.35 minutes



Outcome	Robotic-assisted, n	VATS, n	Effect size 95% CI	P-value
Lobectomy continuous variables (to December 31, 2022)				
LOS, days [1, 2, 4, 6, 7, 9, 13, 17, 19, 22, 23, 25, 26, 28, 29, 30, 32, 33, 35, 36, 38, 39, 41, 42, 44, 46, 47, 48]				
Subtotal	89544	252845	-0.47 [-0.65, -0.28]	**p<0.01**
Random, Heterogeneity: p<0.00001; I^2=99%				
Nodal Stations Sampled, n [29, 46]				
Subtotal	83	84	-0.15 [-2.40, 2.10]	p=0.9
Random, Heterogeneity: p<0.00001; I^2=97%				
ICU LOS, days [9, 28, 44, 46]				
Subtotal	2997	2998	-0.06 [-0.21, 0.10]	p=0.49
Fixed, Heterogeneity: p=0.54; I^2=0%				
Chest Tube Duration, days [6, 9, 17, 44, 46, 48]				
Subtotal	450	458	-0.0001 [-0.61, 0.61]	p=1.00
Random, Heterogeneity: p<0.00001; I^2=87%				
LNY, n [12, 13, 17, 25, 29, 33, 38, 39, 46, 47, 48]				
Subtotal	13615	29827	0.18 [-0.24, 0.60]	p=0.39
Random, Heterogeneity: p<0.0001; I^2=87%				
Operative Time, min [6, 9, 17, 23, 28, 29, 30, 36, 42, 44, 46, 47, 48]				
Subtotal	10039	25476	12.35 [4.62, 20.08]	**p=0.002**
Random, Heterogeneity: p<0.00001; I^2=91%				

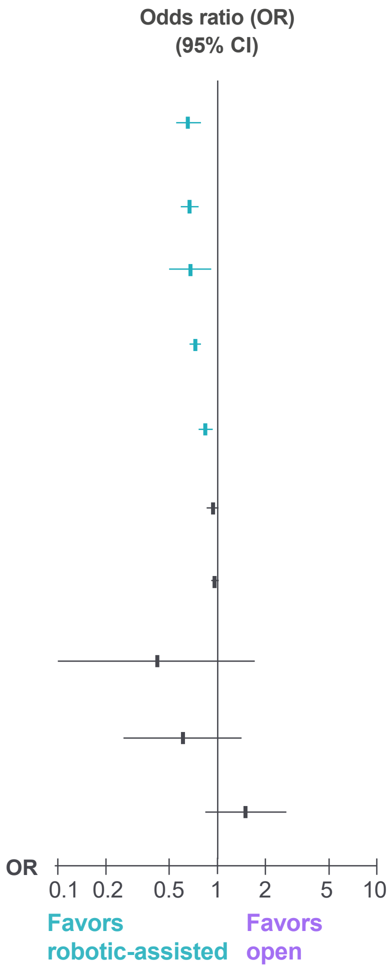
Robotic-assisted vs. open lobectomy

Summary as of December 31, 2022

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

Compared to open lobectomy, the evidence for **robotic-assisted lobectomy** demonstrates:

- 35% lower likelihood of mortality within 30-days of surgery
- 33% less likely to be admitted to ICU
- 32% less likely to receive a blood transfusion
- 27% less likely to experience a postoperative complication within 30-days of surgery
- 16% less likely to have a positive surgical margin
- Comparable readmissions rate within 30-days of surgery
- Comparable nodal upstaging rate
- Comparable respiratory failure rate
- Comparable reoperations rate within 30-days of surgery
- Comparable prolonged air leak rate



Outcome	Robotic-assisted, n	Open, n	Effect size 95% CI	P-value
Lobectomy binary variables (to December 31, 2022)				
Mortality, n [7, 12, 15, 19, 25, 26, 28, 30, 33, 39, 41, 43, 45]				
Subtotal	54743	245228	0.65 [0.54, 0.78]	p<0.01
Random, Heterogeneity: p<0.01; I²=71%				
Intensive Care (ICU) Admissions, n [28, 29, 45]				
Subtotal	2694	3554	0.67 [0.60, 0.75]	p<0.01
Fixed, Heterogeneity: p=0.59; I²=0%				
Blood Transfusions, n [28, 30, 45]				
Subtotal	5439	6299	0.68 [0.51, 0.90]	p=0.007
Random, Heterogeneity: p=0.02; I²=71%				
Postoperative Complications, n [15, 19, 28, 29, 30, 41, 45]				
Subtotal	5938	7617	0.73 [0.68, 0.78]	p<0.01
Fixed, Heterogeneity: p=0.20; I²=30%				
Positive Surgical Margins, n [13, 15, 25, 29, 33, 39, 43]				
Subtotal	16184	44139	0.84 [0.75, 0.92]	p=0.0005
Fixed, Heterogeneity: p=0.84; I²=0%				
Readmissions, n [11, 13, 25, 33, 39, 43, 45]				
Subtotal	18849	56241	0.92 [0.85, 1.00]	p=0.05
Fixed, Heterogeneity: p=0.83; I²=0%				
Nodal Upstaging, n [12, 24, 39, 43]				
Subtotal	15486	64187	0.94 [0.89, 1.00]	p=0.05
Fixed, Heterogeneity: p=0.06; I²=59%				
Respiratory Failure, n [30, 41]				
Subtotal	4704	11276	0.41 [0.10, 1.66]	p=0.21
Random, Heterogeneity: p<0.0001; I²=98%				
Reoperations, n [15, 29, 45]				
Subtotal	426	1283	0.60 [0.25, 1.42]	p=0.24
Fixed, Heterogeneity: p=0.71; I²=0%				
Prolonged Air Leak, n [16, 30, 41]				
Subtotal	4780	11348	1.47 [0.81, 2.65]	p=0.20
Random, Heterogeneity: p<0.00001; I²=92%				

Robotic-assisted vs. open lobectomy

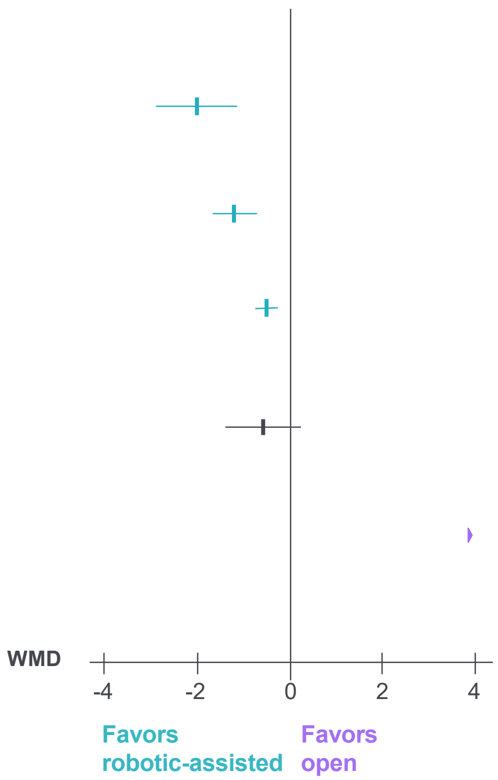
Summary as of December 31, 2022

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

Compared to open lobectomy, the evidence for **robotic-assisted lobectomy** demonstrates:

- Significantly shorter hospital stay by an average of 1.98 days
- Significant difference in lymph node yield by an average of 1.2 nodes
- Significantly shorter ICU length of stay by an average of 0.49 days
- Comparable number of nodal stations sampled
- Significantly longer operative time by an average of 39.61 minutes

Weighted Mean Difference (WMD) (95% CI)



Outcome	Robotic-assisted, n	Open, n	Effect size 95% CI	P-value
Lobectomy continuous variables (to December 31, 2022)				
LOS, days [7, 13, 16, 19, 22, 25, 26, 28, 29, 30, 33, 39, 41, 43]				
Subtotal	64241	242272	-1.98 [-2.86, -1.11]	p<0.01
Random, Heterogeneity: p<0.00001; I^2=100%				
LNY, n [12, 13, 15, 25, 29, 33, 39, 43]				
Subtotal	85802	21655	-1.20 [-1.64, -0.75]	p<0.01
Random, Heterogeneity: p<0.00001; I^2=95%				
ICU LOS, days [1,9,11,18,19]				
Subtotal	2326	2326	-0.49 [-0.74, -0.23]	p=0.002
Fixed, Heterogeneity: p=0.44; I^2=0%				
Nodal Stations Sampled, n [15, 29]				
Subtotal	85	88	-0.58 [-1.36, 0.21]	p=0.15
Random, Heterogeneity: p=0.04; I^2=77%				
Operative Time, min [16, 20, 28, 29, 30]				
Subtotal	5248	5248	39.61 [22.57, 56.65]	p<0.01
Random, Heterogeneity: p<0.00001; I^2=95%				

Lobectomy bibliography (1 of 3)

December 31, 2022

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Lobectomy bibliography (2 of 3)

December 31, 2022

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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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