Intent

The intent of this presentation is to provide data from a **single publication**.

This presentation must **not be considered as a substitute for a comprehensive literature review** for inclusion of all relevant outcomes.

We encourage all key stakeholders (e.g., surgeons, hospital executives, hospital robotic coordinators, etc.) to **review all available published materials and their own data** in order to make an informed decision.

Published literature

In order to provide benefit and risk information, Intuitive reviews the **highest available level of evidence** on representative procedures.

Intuitive strives to provide a **complete, fair, and balanced view of the clinical literature**. However, the selected publication may not be reflective of the broader literature and our materials should not be seen as a substitute for a comprehensive literature review for inclusion of all potential outcomes.

We encourage physicians to **review the original publications and all available literature** in order to make an informed decision. Clinical studies are available at pubmed.gov.

Clinical outcomes: Published literature

To provide a **complete, fair, and balanced view of the clinical literature**, Intuitive identified the following set of nine standard clinical outcomes to be reported for published literature, along with outcomes pertaining to primary intent of the publication.

Transfusion and/or estimated blood loss	**Readmission rate (30 days or other)**
Operative time	**Reoperation rate (30 days or other)**
Length of hospital stay	**Positive surgical margin rate and/or lymph node yield and/or lymph node upstaging**
Conversion rate (vs. laparoscopy, only)	**Perioperative mortality (30 days)**
Complication rate (30 days or other) (intraoperative and/or postoperative)	

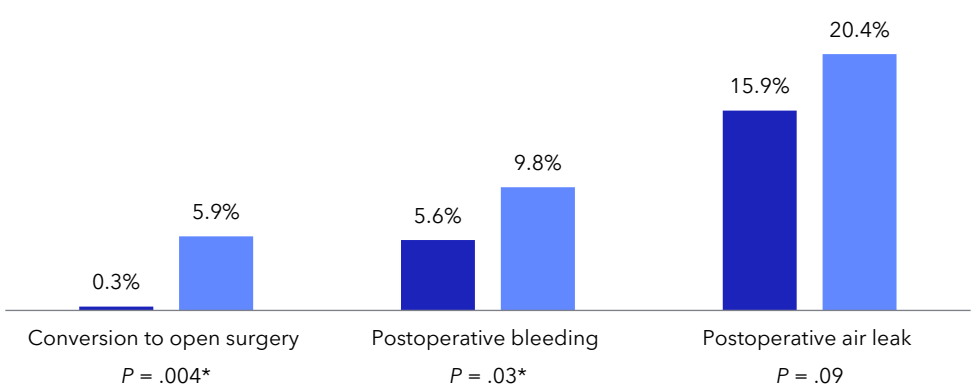
Individuals' outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics, and/or surgeon experience.

Typical ranges for the clinical outcomes, as reported in the published literature, may be included in this presentation.

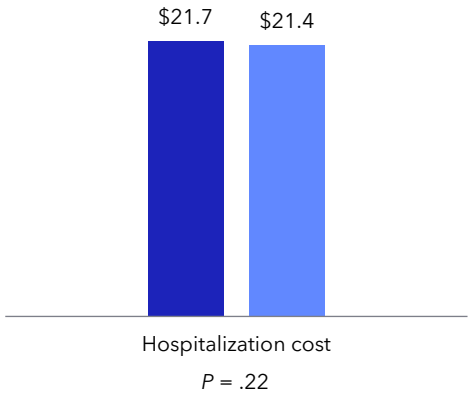
From a peer-reviewed publication by Zervos M, et al. 2021.
DOI: 10.1177/15569845211040814

Premier database study shows robotic-assisted lobectomies using robotic staplers are associated with reduced conversion and bleeding and comparable cost relative to robotic-assisted lobectomies using hand-held staplers.

Clinical outcomes
Percentage



Median index hospital cost
$USD 000s (inflation adjusted in 2017 dollars)



- Da Vinci robotic-assisted lobectomy with robotic stapling (n=358)
- Da Vinci robotic-assisted lobectomy with fully hand-held stapling (n=358)

Note: * A P value of .05 or less was considered statistically significant.

Please refer to the typical range table for additional information.

Purpose
To compare the clinical outcomes and cost of robotic lobectomies with fully robotic stapling vs. robotic lobectomies with fully hand-held stapling

Study design
Patients in the Premier Hospital Perspective Database with an elective robotic lobectomy between October 2015 and December 2017 were included:

Total patients: 2,006
Fully robotic stapling: 528 (26.3%)
Hand-held stapling: 1.478 (73.7%)

After propensity-score matching (PSM), 358 matched pairs were included in the final analysis that compared perioperative outcomes, healthcare resource utilization, and costs.

Outcomes measured
Clinical outcomes included conversion to open surgery, overall complications, bleeding and transfusion, air leak, pneumonia, operative time, length of hospital stay, and 30-day readmission.

In-hospital cost for index hospitalization included stapler, nonstapler supply, operating room, room and board, pharmacy, and laboratory costs.

Key results
Use of robotic staplers during robotic lobectomy was associated with fewer conversions to open surgery and lower rates of postoperative bleeding in the PSM analysis, and reduced air leaks and overall complications in the multivariable analysis compared to robotic cases using hand-held laparoscopic staplers. Both groups had similar operative times, length of stay, and in-hospital costs.

Study information

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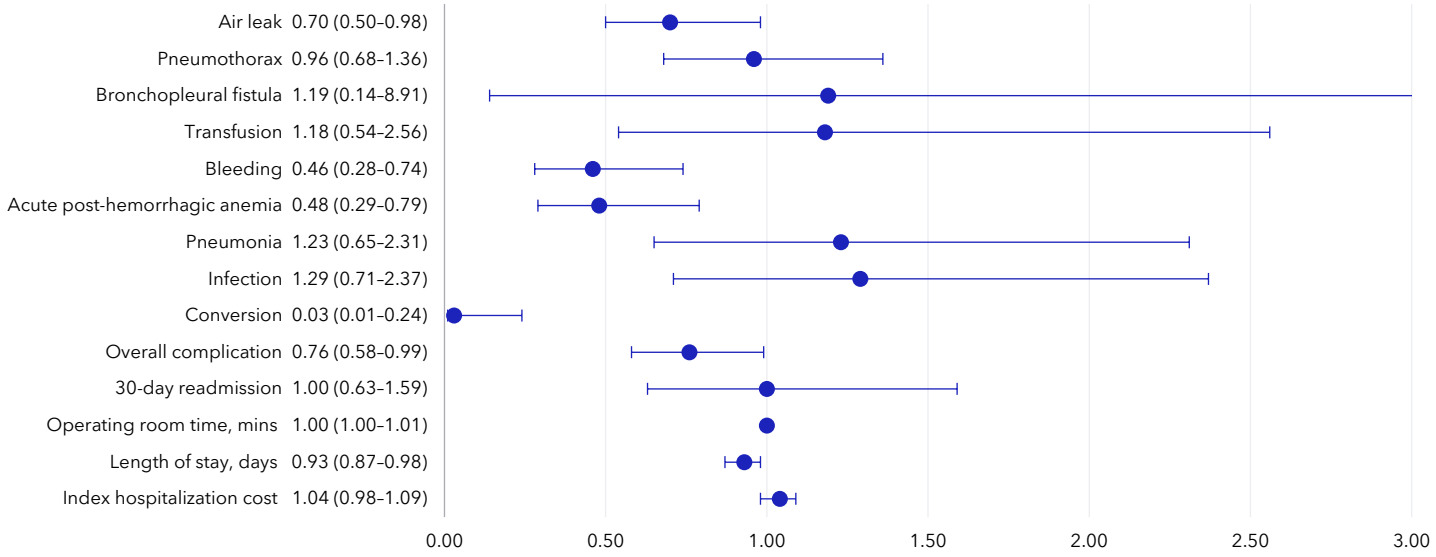
Premier database study shows robotic-assisted lobectomies using robotic staplers are associated with reduced conversion and bleeding and comparable cost relative to robotic-assisted lobectomies using hand-held staplers.

Multivariable analysis of clinical and economic outcomes
Odds ratio and 95% confidence interval*



*Hand-held staplers are the reference group in the analysis.

Please refer to the typical range table for additional information.

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Study information

Typical ranges for clinical outcomes in lobectomy

Typical ranges report the minimum and maximum values for the most frequently reported metric of a given outcome in the published literature.

		Range of Statistical Metric for Robotic-Assisted Surgery (RAS)			
		Da Vinci RAS vs. Open Surgery		Da Vinci RAS vs. Video-Assisted Thoracoscopic Surgery (VATS)	
Outcome	**Statistical Metric**	**Value**	**Reference**	**Value**	**Reference**
Conversion to open surgery rate	Min %	N/A		4.6%	Kim MP et a l. J Thorac Dis. 2019;11(1):145-153. DOI: 10.21037/jtd.2018.12.59
	Max %			10.3%	Yang, C-F.J. et al. Ann Thorac Surg, 2016;101(3): p. 1037–42. DOI: 10.1016/j.athoracsur.2015.11.018
Air leak rate (prolonged)	Min %	6%	Kneuertz PJ et al. J Cardiothorac Surg. 2018 Jun;13(1):56. DOI: 10.1186/s13019-018-0748-z	9%	Kneuertz PJ et al. Clin Lung Cancer. 2020;21(3):214.e2-224.e2. DOI: 10.1016/j.cllc.2019.10.004
	Max %	9%	Kneuertz PJ et al. Clin Lung Cancer. 2020;21(3):214.e2-224.e2. DOI: 10.1016/j.cllc.2019.10.004	10%	Louie BE et al. Ann Thorac Surg. 2016;102(3):917-924. DOI: 10.1016/j.athoracsur.2016.03.032
Operating Time	Min Mean ± SD, minutes	108 ± 39	Huang J et al. Transl Lung Cancer Res. 2019;8(6):951-958. DOI: 10.21037/tlcr.2019.11.31	247 ± 80	Reddy RM et al. Ann Thorac Surg. 2018;106(3):902-908. DOI: 10.1016/j.athoracsur.2018.03.048
	Max Mean ± SD, minutes	282 ± 90	Nguyen DM et al.. J Thorac Dis. 2020;12(3):296-306. DOI: 10.21037/jtd.2020.01.40	276 ± 90	Nguyen DM et al.. J Thorac Dis. 2020;12(3):296-306. DOI: 10.21037/jtd.2020.01.40
Intraoperative Transfusion Rate	Min %	3.4%	Oh DS et al. Ann Thorac Surg. 2017;104(5):1733-1740. DOI: 10.1016/j.athoracsur.2017.06.020	1%	Louie BE et al. Ann Thorac Surg. 2016;102(3):917-924. DOI: 10.1016/j.athoracsur.2016.03.032
	Max %	6.4%	Nguyen DM et al.. J Thorac Dis. 2020;12(3):296-306. DOI: 10.21037/jtd.2020.01.40	5.7%	Nguyen DM et al.. J Thorac Dis. 2020;12(3):296-306. DOI: 10.21037/jtd.2020.01.40
Overall Complication Rate	Min %	27.6%	Huang J et al. Transl Lung Cancer Res. 2019;8(6):951-958. DOI: 10.21037/tlcr.2019.11.31	33.4%	Reddy RM et al. Ann Thorac Surg. 2018;106(3):902-908. DOI: 10.1016/j.athoracsur.2018.03.048
	Max %	43.8%	Kent M et al. Ann Thorac Surg. 2014 Jan;97(1):236-42; discussion 242-4. DOI: 10.1016/j.athoracsur.2013.07.117	50.1%	Paul S et al. Chest. 2014;146:1505–12. DOI: 10.1378/chest.13-3032

Legend

Mean ± SD = Arithmetic Average ± Standard Deviation: Standardized measure of central tendency and dispersion in data

Typical ranges for clinical outcomes in lobectomy (continued)

Typical ranges report the minimum and maximum values for the most frequently reported metric of a given outcome in the published literature.

		Range of Statistical Metric for Robotic-Assisted Surgery (RAS)			
		Da Vinci RAS vs. Open Surgery		Da Vinci RAS vs. Video-Assisted Thoracoscopic Surgery (VATS)	
Outcome	Statistical Metric	Value	Reference	Value	Reference
Length of Hospital Stay	Min Median (IQR), days	4 (3-6)	Subramanian MP et al.Ann Thorac Surg. 2019;108(6):1648-1655. DOI: 10.1016/j.athoracsur.2019.06.049	4 (2-5)	Louie BE et al. Ann Thorac Surg. 2016;102(3):917-924. DOI: 10.1016/j.athoracsur.2016.03.032
	Max Median (IQR), days	5.2 (4.8-5.6)	Kneuertz PJ et al. Clin Lung Cancer. 2020;21(3):214.e2-224.e2. DOI: 10.1016/j.cllc.2019.10.004	5.2 (4.8-5.6)	Kneuertz PJ et al. Clin Lung Cancer. 2020;21(3):214.e2-224.e2. DOI: 10.1016/j.cllc.2019.10.004
Readmission Rate	Min %	4.1%	Rajaram, R., S. et al. Ann Thorac Surg. 2017. 103(4): p. 1092-1100. DOI: 10.1016/j.athoracsur.2016.09.108	1.1%	Kim MP et a l. J Thorac Dis. 2019;11(1):145-153. DOI: 10.21037/jtd.2018.12.59
	Max %	11.5%	Hendriksen BS et al.Innovations (Phila). 2019;14(5):453-462. DOI: 10.1177/1556984519874064	11.5%	Hendriksen BS et al.Innovations (Phila). 2019;14(5):453-462. DOI: 10.1177/1556984519874064
Pneumonia	Min %	3%	Kneuertz PJ et al. J Cardiothorac Surg. 2018 Jun;13(1):56. DOI: 10.1186/s13019-018-0748-z	2.3%	Kim MP et a l. J Thorac Dis. 2019;11(1):145-153. DOI: 10.21037/jtd.2018.12.59
	Max %	7%	Kneuertz PJ et al. Clin Lung Cancer. 2020;21(3):214.e2-224.e2. DOI: 10.1016/j.cllc.2019.10.004	8.5%	Swanson SJ et al. J Thorac Cardiovasc Surg. 2014;147(3):929-937. DOI: 10.1016/j.jtcvs.2013.09.046

Legend

Median (IQR) = Median (25th percentile, 75th percentile): Describes the center and endpoints of the middle 50% of the data when arranged in sequence, which tends to remove outliers

Study information: Clinical and Economic Outcomes of Using Robotic Versus Hand-Held Staplers During Robotic Lobectomy

Citation

Zervos M, Song A, Li Y, Lee SH, Oh DS. Clinical and Economic Outcomes of Using Robotic Versus Hand-Held Staplers During Robotic Lobectomy. Innovations (Phila). 2021;16(5):470-476. doi:10.1177/15569845211040814

Study design

Type: Database analysis

Data source: Premier Hospital Perspective Database of patients with an elective robotic-assisted lobectomy (RAL).

Timeframe: October 2015–December 2017

Propensity-score matching (PSM) analysis compared perioperative outcomes, healthcare resource utilization and costs adjusted to 2017 dollars, controlling for patient, surgeon, and hospital characteristics and year of surgery.

Patient population

Adult patients with an elective robotic lobectomy between October 2015 and December 2017.

- RAL with robotic stapling (RAL-RS): 528 patients
- RAL with hand-held stapling (RAL-HS): 1,478 patients

PSM resulted in 358 matched pairs of patients.

Outcomes measured

Clinical outcomes: Conversion to open surgery, overall complications, bleeding and transfusion, air leak, pneumonia, operative time, length of hospital stay, and 30-day readmission.

Primary economic outcome: Index hospitalization cost, which included stapler, nonstapler supply, operating room, room and board, pharmacy and laboratory costs.

Results / conclusions

- Operating room time (median [interquartile range]): RAL-RS comparable to RAL-HS (240 [180-300] minutes vs. 230 [174-300] minutes, *P* = .36).
- Transfusions: RAL-RS comparable to RAL-HS (3.1% vs. 1.4%, *P* = .20).
- Postoperative bleeding: RAL-RS lower than RAL-HS (5.6% vs. 9.8%, *P* = .03).
- Conversion to open surgery: RAL-RS lower than RAL-HS (0.3% vs. 5.9%, *P* = .004).
- Overall complications: RAL-RS comparable to RAL-HS (33.5% vs. 39.1%, *P* = .09).
- Postoperative air leaks: RAL-RS comparable to RAL-HS (15.9% vs. 20.4%, *P* = .09).
- Pneumonia rate: RAL-RS comparable to RAL-HS (4.2% vs. 3.1%, *P* = .27).
- Length of hospital stay (median [interquartile range]): RAL-RS comparable to RAL-HS (3 [2-5] days vs. 4 [2-6] days, *P* = .21).
- 30-day readmissions: RAL-RS comparable to RAL-HS (6.7% vs. 5.9%, *P* = .65).
- Median index hospitalization cost: RAL-RS comparable to RAL-HS ($21,667 vs. $21,398, *P* = .22).

Study strengths

Premier database captures data from over 1,000 hospitals.

Premier enables PSM analysis on patient, hospital, and surgeon characteristics and assessment of healthcare resource utilization.

Study limitations

Potential for unmeasured confounding variables such as tumor stage/size.

Identification of staplers in Premier is subject to error as a result of incomplete or inaccurate recording.

The granularity of the cost data is limited (e.g., reload count not specified)

Financial disclosure

Drs. Zervos and Oh have received compensation from Intuitive for consulting and/or educational services. Zervos is a speaker for Intuitive. Song is an intern at Intuitive. Li and Lee are employed by Intuitive. Oh is a part-time medical advisor for Intuitive.

Study highlight

Important safety information

Surgical risks

Surgical risks for pulmonary resection (wedge resection, segmentectomy, lobectomy) include persistent air leak, pneumonia, prolonged mechanical ventilation >48 hours, atrial fibrillation, acute respiratory distress syndrome (ARDS), chylothorax, reintubation, arrhythmias, bronchopleural fistula, phrenic nerve injury, esophageal injury, difficulty breathing, collapsed lung, pulmonary volvulus, and recurrent laryngeal nerve injury leading to vocal cord dysfunction.

Important safety information

Serious complications may occur in any surgery, including surgery with da Vinci systems, up to and including death. Examples of serious or life-threatening complications, which may require prolonged and/or unexpected hospitalization and/or reoperation, include but are not limited to, one or more of the following: injury to tissues/organs, bleeding, infection and internal scarring that can cause long-lasting dysfunction/pain.

Risks specific to minimally invasive surgery, including da Vinci Surgery, include but are not limited to, one or more of the following: temporary pain/nerve injury associated with positioning; a longer operative time, the need to convert to an open approach, or the need for additional or larger incision sites. Converting the procedure could result in a longer operative time, a longer time under anesthesia, and could lead to increased complications. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all da Vinci instruments.

For Important Safety Information, indications for use, risks, full cautions and warnings, please also refer to www.intuitive.com/safety.

Individual outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics, and/or surgeon experience.

Da Vinci Xi/X system precaution statement

The demonstration of safety and effectiveness for the specific procedure(s) discussed in this material was based on evaluation of the device as a surgical tool and did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence) 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.

Thoracic procedures

The friable nature of pulmonary tissue enhances the risk of vascular, bronchiolar or other injury that will be difficult to control when using this device. Published clinical experience as well as clinical studies performed to support this marketing clearance have demonstrated that even surgeons considered expert in laparoscopy/thoracoscopy have substantial learning curves of 8 to 12 cases (Falk, et al., Total endoscopic computer enhanced coronary artery bypass grafting, Eur J CardiothoracSurg 2000; 17: 38-45).