Background information

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 (versus laparoscopy only)	Perioperative mortality (30 days)
Complications (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.

Pulmonary Open, Robotic, and Thoracoscopic Lobectomy (PORTaL) Study

5,721 lobectomies

Retrospective chart review of c-Stage IA-IIIA cases

Intention-to-treat

2,391 robotic-assisted, 2,174 thoracoscopic, and 1,156 open cases from 2013 to 2019

21 institutions

Study chairs Drs. Kent, Hartwig, and Vallières

Experienced surgeons with 50 or more lobectomies

Study distributed across US with no surgeon contributing more than 6% of cases

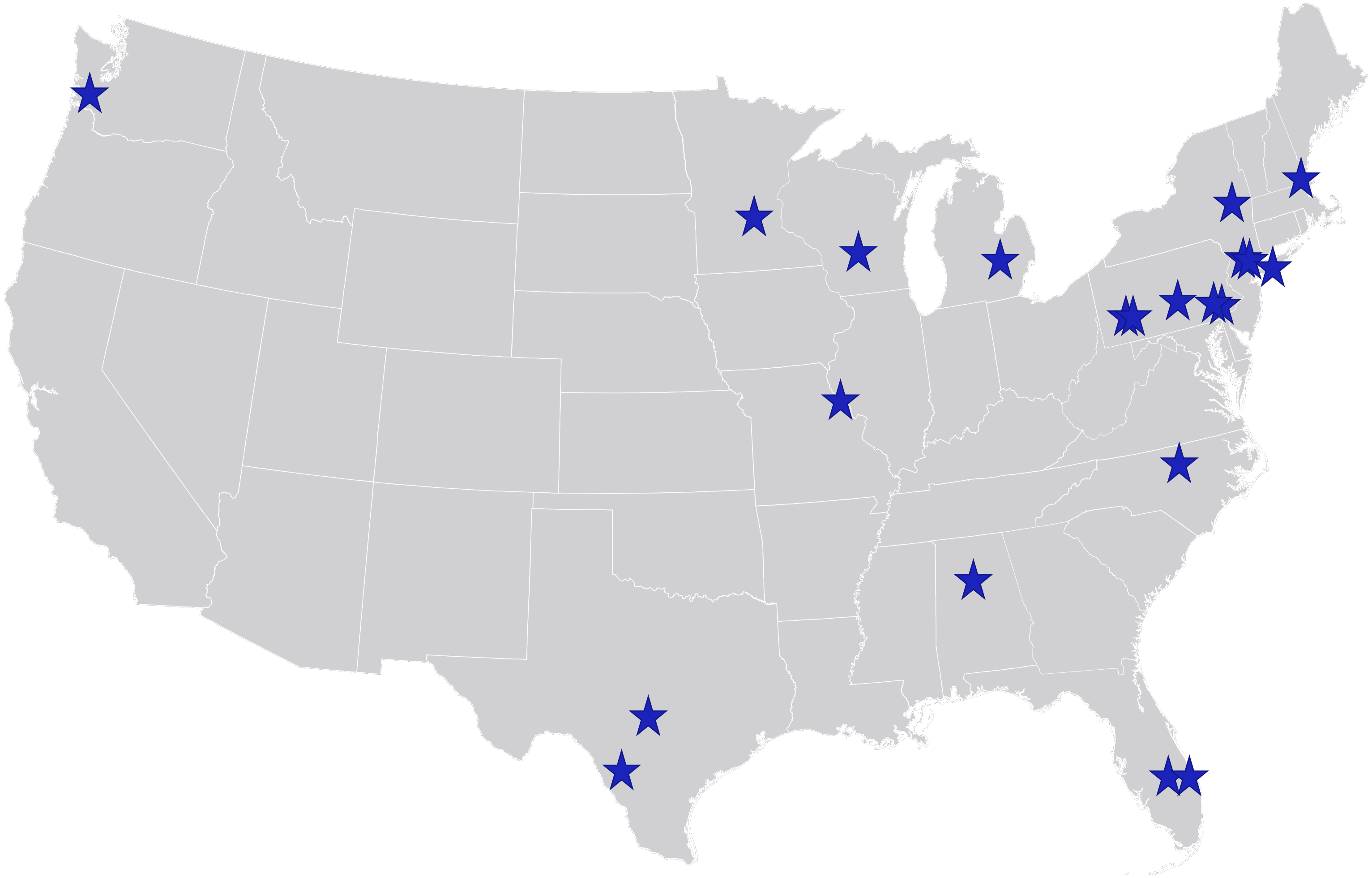
Independent review

Staging, major complications, and conversions reviewed by principal investigators

Operative and pathology reports and discharge summaries audited

Independent biostatistician-performed analyses

Pulmonary Open, Robotic, and Thoracoscopic Lobectomy (PORTaL) Study

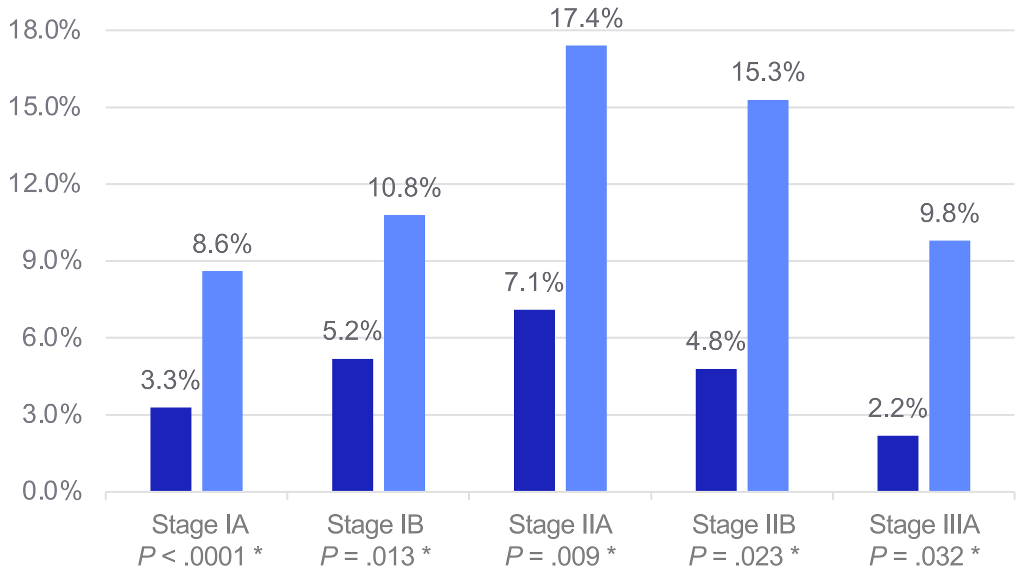


Participating institutions (n = 21)	
Albany Medical Center	Albany, NY
Allegheny Health Network	Pittsburgh, PA
Aurora Research Institute	Milwaukee, WI
Baptist Health South Florida	Miami, FL
Baylor Scott and White Health	Dallas, TX
Beth Israel Deaconess Medical Center	Boston, MA
Duke University Medical Center	Durham, NC
Mayo Clinic	Rochester, MN
Main Line Health/Lankenau Institute for Medical Research	Wynnewood, PA
MD Anderson Cancer Center	Houston, TX
Northwell Health	Manhasset, NY
New York University Langone	New York, NY
New York University Winthrop	New York, NY
Orlando Health	Orlando, FL
Penn State Cancer Institute	Hershey, PA
Swedish Cancer Institute	Seattle, WA
Temple University	Philadelphia, PA
University of Michigan	Ann Arbor, MI
University of Alabama at Birmingham	Birmingham, AL
University of Pittsburgh Medical Center	Pittsburgh, PA
Washington University	St. Louis, MO

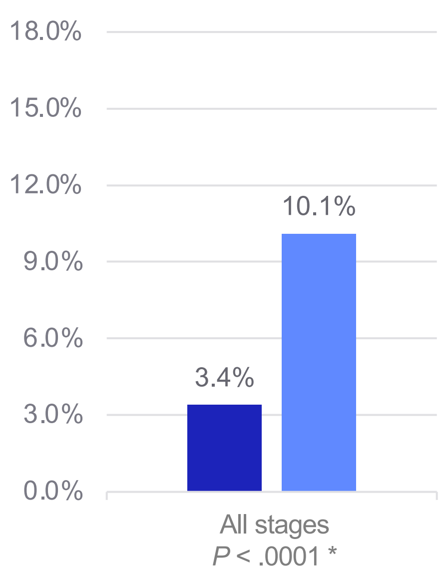
Pulmonary Open, Robotic, and Thoracoscopic Lobectomy (PORTaL) Study

Intraoperative outcomes of propensity-score-matched cohorts

Conversion rate by clinical stage
Percentage



Conversion rate to open surgery
Percentage



■ Da Vinci robotic-assisted lobectomy (n = 1,711) ■ VATS lobectomy (n = 1,711)

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

Compared to VATS lobectomy, additional studies have shown da Vinci robotic-assisted lobectomy is associated with a lower or comparable rate of conversion to open surgery.

Please refer to congruency and typical range tables for additional information.

Purpose

Evaluate the perioperative outcomes of patients undergoing open (OL), thoracoscopic (VATS), and da Vinci robotic-assisted lobectomy (RAL)

Determine if VATS and RAL were associated with a reduction in length of stay and overall complication rate compared to OL

Study design

Retrospective chart review study of 5,721 intention-to-treat lobectomies for lung cancer

Propensity-score-matched analysis across surgical approaches

Outcomes measured

Short-term outcomes include operative time, blood transfusion, length of hospital stay, post-operative complications, in-hospital mortality, conversion, and chest tube duration

Key results

RAL and VATS associated with favorable perioperative outcomes compared to OL

RAL associated with reduced length of stay and decreased conversion rate compared to VATS

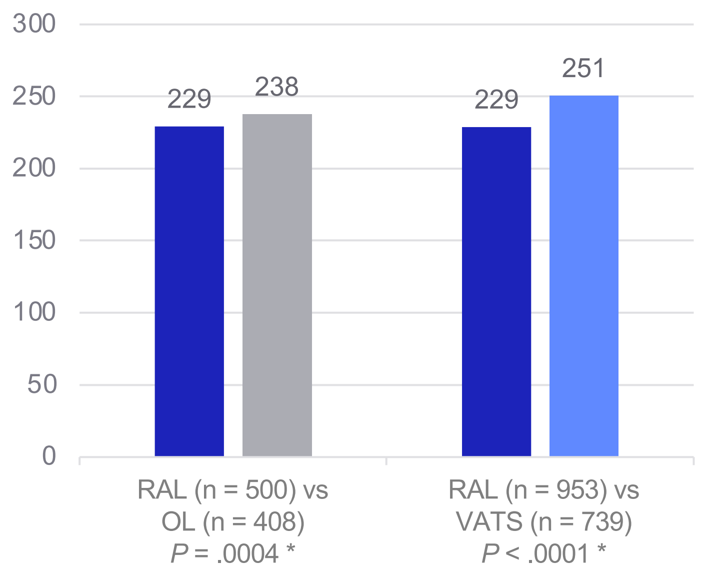
Kent MS, Hartwig MG, Vallières E, et al. Pulmonary Open, Robotic and Thoracoscopic Lobectomy (PORTaL) Study: An Analysis of 5,721 Cases [published online ahead of print, 2021 Sep 16]. Ann Surg. 2021;10.1097/SLA.0000000000005115. doi:10.1097/SLA.0000000000005115

Study information

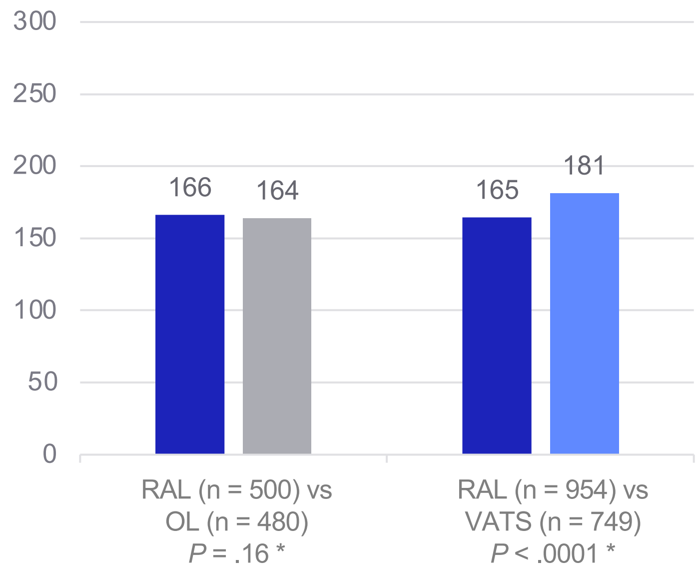
Pulmonary Open, Robotic, and Thoracoscopic Lobectomy (PORTaL) Study

Intraoperative outcomes of propensity-score-matched cohorts (no concomitant procedures)

Operating room time
Mean minutes (operating room entry to exit)



Procedure time
Mean minutes (first incision to close)



■ Da Vinci robotic-assisted lobectomy ■ VATS lobectomy ■ Open lobectomy

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

Compared to open or VATS lobectomy, additional studies have shown da Vinci robotic-assisted lobectomy is associated with comparable or longer operative time.

Please refer to congruency and typical range tables for additional information.

Purpose

Evaluate the perioperative outcomes of patients undergoing open (OL), thoracoscopic (VATS), and da Vinci robotic-assisted lobectomy (RAL)

Determine if VATS and RAL were associated with a reduction in length of stay and overall complication rate compared to OL

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Key results

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RAL associated with reduced length of stay and decreased conversion rate compared to VATS

Study information

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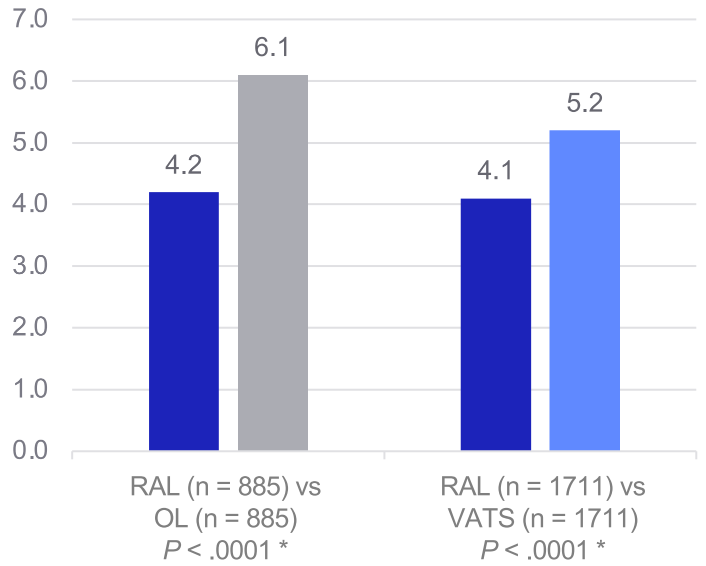
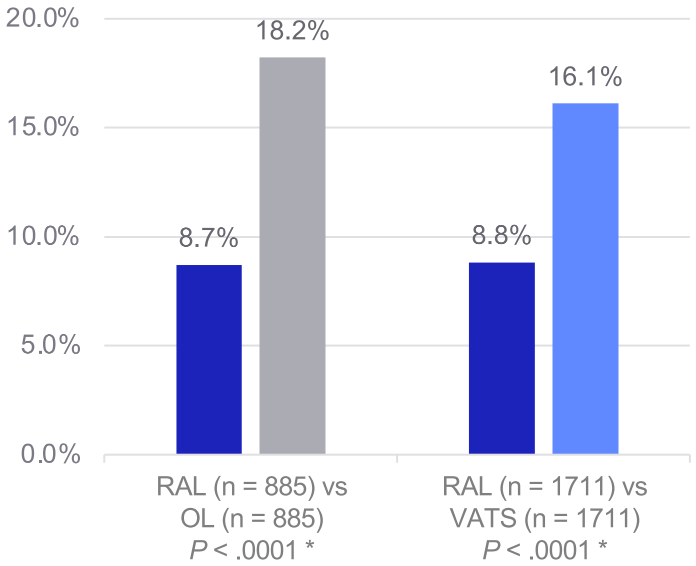
Pulmonary Open, Robotic, and Thoracoscopic Lobectomy (PORTaL) Study

Postoperative outcomes of propensity-score-matched cohorts

Length of hospital stay
Mean days



Prolonged length of hospital stay
Percentage > 7 days



Da Vinci robotic-assisted lobectomy | VATS lobectomy | Open lobectomy

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

Compared to open or VATS lobectomy, additional studies have shown da Vinci robotic-assisted lobectomy is associated with shorter or comparable length of hospital stay.

Please refer to congruency and typical range tables for additional information.

Purpose
Evaluate the perioperative outcomes of patients undergoing open (OL), thoracoscopic (VATS), and da Vinci robotic-assisted lobectomy (RAL)

Determine if VATS and RAL were associated with a reduction in length of stay and overall complication rate compared to OL

Study design
Retrospective chart review study of 5,721 intention-to-treat lobectomies for lung cancer

Propensity-score-matched analysis across surgical approaches

Outcomes measured
Short-term outcomes include operative time, blood transfusion, length of hospital stay, post-operative complications, in-hospital mortality, conversion, and chest tube duration

Key results
RAL and VATS associated with favorable perioperative outcomes compared to OL

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Study information

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Congruency for clinical outcomes in lobectomy

Additional recent studies comparing robotic-assisted surgery to open surgery have shown the following results:

Outcome	Da Vinci robotic-assisted compared to open lobectomy	Reference
Operative time	Comparable	Huang J et al. Transl Lung Cancer Res. 2019;8(6):951-958. DOI: 10.21037/tlcr.2019.11.31
	Longer	Hu J et al. Int J Med Robot. 2020;16(5):1-14. DOI: 10.1002/rcs.2123
Length of hospital stay	Shorter	Hu J et al. Int J Med Robot. 2020;16(5):1-14. DOI: 10.1002/rcs.2123
	Comparable	Huang J et al. Transl Lung Cancer Res. 2019;8(6):951-958. DOI: 10.21037/tlcr.2019.11.31

Additional recent studies comparing robotic-assisted surgery to thoracoscopic surgery have shown the following results:

Outcome	Da Vinci robotic-assisted compared to VATS lobectomy	Reference
Conversion rate	Lower	Hennon MW et al. Eur J Cardiothorac Surg. 2020;57(5):888-895. DOI: 10.1093/ejcts/ezz320
	Comparable	Hu J et al. Int J Med Robot. 2020;16(5):1-14. DOI: 10.1002/rcs.2123
Operative time	Comparable	Liang H et al. Ann Surg. 2018;268(2):254-259. DOI: 10.1097/SLA.0000000000002346
	Longer	Hu J et al. Int J Med Robot. 2020;16(5):1-14. DOI: 10.1002/rcs.2123
Length of hospital stay	Shorter	Nguyen DM et al. J Thorac Dis. 2020;12(3):296-306. DOI: 10.21037/jtd.2020.01.40
	Comparable	Hu J et al. Int J Med Robot. 2020;16(5):1-14. DOI: 10.1002/rcs.2123

Typical ranges for clinical outcomes in lobectomy

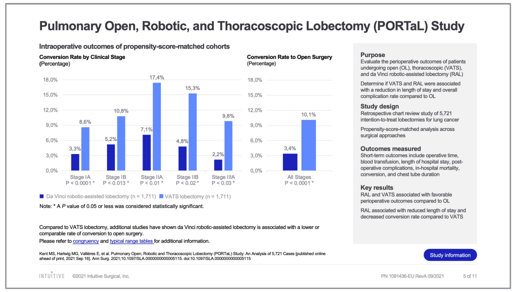
Typical ranges report the minimum and maximum values for the most frequently reported metric of a given outcome in the published literature.

		Range of statistical metric for robotic-assisted surgery			
Outcome	Statistical metric	Da Vinci robotic-assisted vs. open lobectomy		Da Vinci robotic-assisted vs. VATS lobectomy	
		Value	Reference	Value	Reference
Operative 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
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
Conversion to open surgery rate	Min %	N/A		4.6%	Kim MP et al. 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

Legend:
Mean ± SD = arithmetic average ± standard deviation: standardized measure of central tendency and dispersion in data
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

Pulmonary Open, Robotic, and Thoracoscopic Lobectomy (PORTaL) Study



Citation:

Kent MS, Hartwig MG, Vallières E, et al. Pulmonary Open, Robotic and Thoracoscopic Lobectomy (PORTaL) Study: An Analysis of 5,721 Cases [published online ahead of print, 2021 Sep 16]. Ann Surg. 2021;10.1097/SLA.0000000000005115. doi:10.1097/SLA.0000000000005115

Financial disclosure:

This study was sponsored and funded by Intuitive in association with the PORTaL Consortium under a supportive clinical trial agreement. Drs. Abbas, Cerfolio, Dylewski, Hartwig, Herrera, Jett, Kent, Reddy, Ross, Sarkaria, Schumacher, and Tisol have received compensation from Intuitive for consulting and/or educational services.

Study design

Retrospective review of US medical chart data collected from 6,138 clinical stage IA-IIIA lung cancer cases. Patients with neo-adjuvant therapy were excluded. Surgeons who performed 50 or more lobectomy cases were included in the study. Clinical and pathological staging, major complications, and all conversions were reviewed by study chairs, Drs. Kent, Hartwig, and Vallières, for each respective study arm.

Data Source: 21 US academic hospital systems, 30+ surgeons (2013–2019)

Patient population

A total of 5,721 patients who fulfilled the selection criteria underwent lobectomy completed by a robotic-assisted (n = 2,391 [41.8%]), VATS (n = 2,174 [38%]) or an open (n = 1,156 [20.2%]) approach with the intent to treat.

Propensity-score-matching resulted in three comparisons:

- Robotic-assisted versus open lobectomy (n = 885 matched pairs)
- Robotic-assisted versus VATS lobectomy (n = 1,711 matched pairs)
- VATS versus open lobectomy (n = 952 matched pairs)

Outcomes measured

Outcomes analyzed include operative time (with and without concomitant procedures), blood transfusion (intra-operative and post-operative), length of hospital stay, post-operative complications, in-hospital mortality, conversion and chest tube duration.

Results / conclusions

- Operative time (no concomitant procedures): RAL was shorter than OL (P = .0004), RAL was shorter than VATS (P < .0001), VATS was longer than OL (P = .01).
- Procedure time (no concomitant procedures): RAL was comparable to OL (P = .16), RAL was shorter than VATS (P < .0001), VATS was longer than OL (P < .0001).
- Conversation rate: RAL was lower than VATS (P < .0001) in conversion rate to open surgery. Conversion rate by clinical stage available in publication.
- Estimated blood loss: RAL was lower than OL (P < .0001) and VATS (P < .0001), VATS was lower than OL (P < .0001).
- Intraoperative blood transfusion: RAL was lower than OL (P < .0001), RAL was comparable to VATS (P = .08), VATS was comparable to OL (P = .06).
- Post-operative complication rate : RAL was lower than OL (P < .0001), RAL was comparable to VATS (P = .07), VATS was lower than OL (P = .001). Pulmonary, cardiac, gastrointestinal, neurological, wound, and genitourinary complication sub-analyses available in publication.
- Unexpected return to operating room: RAL was comparable to OL (P = .15), RAL was comparable to VATS (P = .14), VATS was comparable to OL (P = .32).
- Post-operative blood transfusion: RAL was lower than OL (P < .0001), RAL was lower than VATS (P = .01), VATS was lower than OL (P < .0001).
- Chest tube duration: RAL was lower than OL (P < .0001), RAL was lower than VATS (P < .0001), VATS was lower than OL (P < .0001).
- Length of hospital stay: RAL was shorter than OL (P < .0001), RAL was shorter than VATS (P < .0001), VATS was lower than OL (P < .0001).
- Prolonged length of hospital stay (pLOS): RAL had less frequent pLOS than OL (P < .0001) and VATS (P < .0001), VATS had comparably frequent pLOS as OL (P = .29).
- In-hospital mortality: RAL was comparable to OL (P = .21), RAL was comparable to VATS (P = .80), VATS was comparable to OL (P = .37).

Study strengths

- Multicenter study evaluating all three surgical approaches with large dataset of consecutive cases and no single surgeon contributing more than 6% of case data.
- Independent biostatistician performed propensity-score-matching (PSM) analyses to mitigate the potential for selection bias across surgical approaches. Covariates for matching included age, gender, race, smoking status, predicted FEV 1%, Zubrod score, ASA grade, and clinical T/N stage.
- All major complications and conversions were independently reviewed by the site's principal investigator to ensure data integrity. Operative and pathology reports and discharge summaries were randomly audited.

Study limitations

- Selection biases that are inherent to the retrospective nature of this study and differences in institutional practices may affect results (e.g., the effect of enhanced recovery after surgery programs on the length of hospital stay).
- Patient follow-up procedures were not standardized across institutions.

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 the da Vinci surgical system, 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 surgery with the da Vinci surgical system, 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.

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 8–12 cases (Falk et al. Total endoscopic computer-enhanced coronary artery bypass grafting, Eur J Cardiothorac Surg. 2000; 17: 38–45).