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.

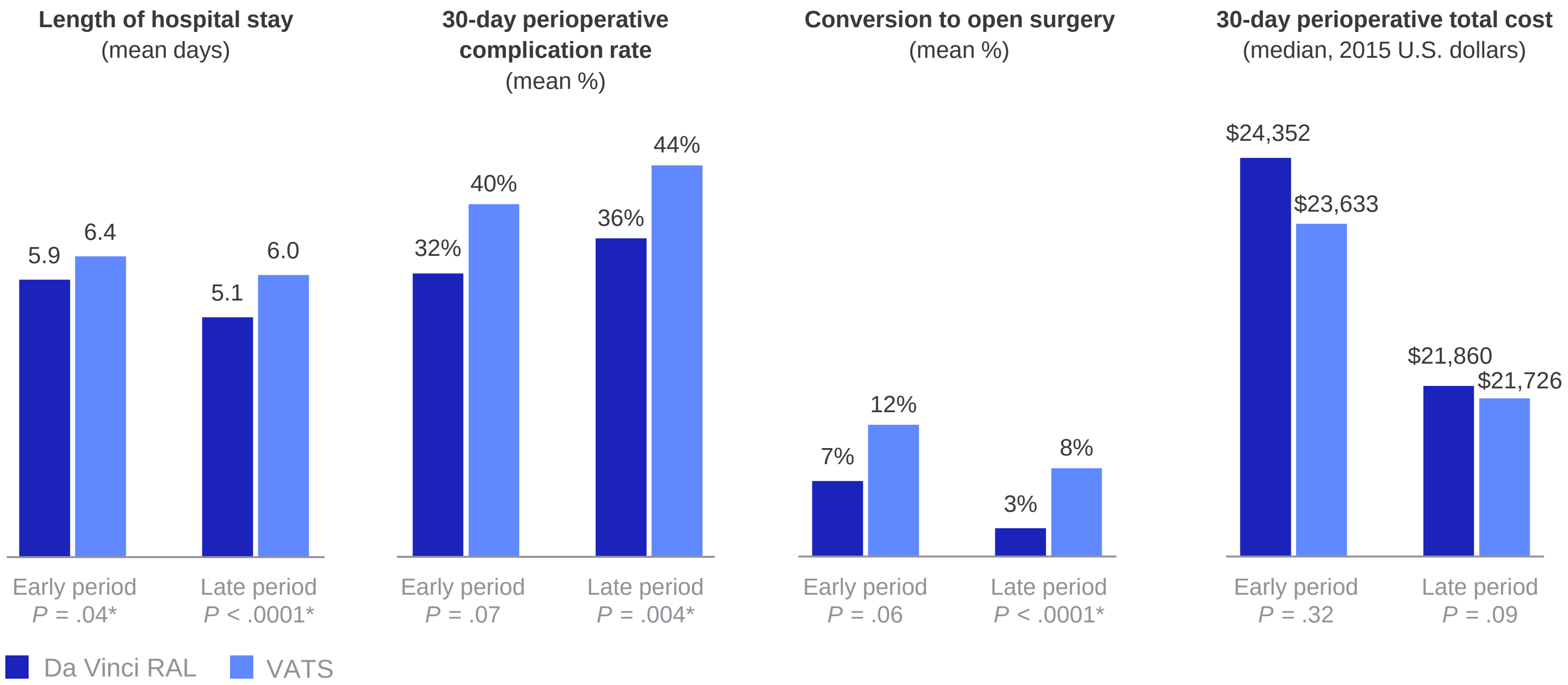
Transfusion and/or estimated blood loss	**Readmission rate (30 days or other)**
Operative time	**Reoperation rate (30 days or other)**
Length of hospital stay	**Positive surgical margin rate and/or lymph node yield and/or lymph node upstaging**
Conversion rate (versus laparoscopy only)	**Perioperative 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, are included in this presentation.

Study showed impact of robotic-assisted lobectomy on length of stay, complications, conversions, and cost compared to video-assisted thoracoscopy

Propensity-score matched cohorts from high-volume centers (>25 annual RAL or VATS cases)



* A *P* value of .05 or less was considered statistically significant.
Note: There were 269 cases each of VATS and RAL in the early period and 607 cases each in the late period.

Additional clinical studies report that RAL as compared to VATS lobectomy is associated with a shorter[1-7] or comparable[8-16] length of hospital stay, a lower[1,6] or comparable[9,13,17-19] rate of overall perioperative complication (although one study reported a higher[14] rate), and a lower[1,4,6,16,20,21] or comparable[8,13,18] rate of conversion to open surgery.

Purpose

Assess and compare perioperative outcomes and costs of open lobectomy, video-assisted thoracoscopy (VATS), and robotic-assisted lobectomy (RAL)

Study design

Retrospective Premier Healthcare Database study of early (2008–2012) and late (2013–2015) periods; propensity-score matched cohorts.

Outcomes measured

Clinical outcomes, resource utilization, and costs

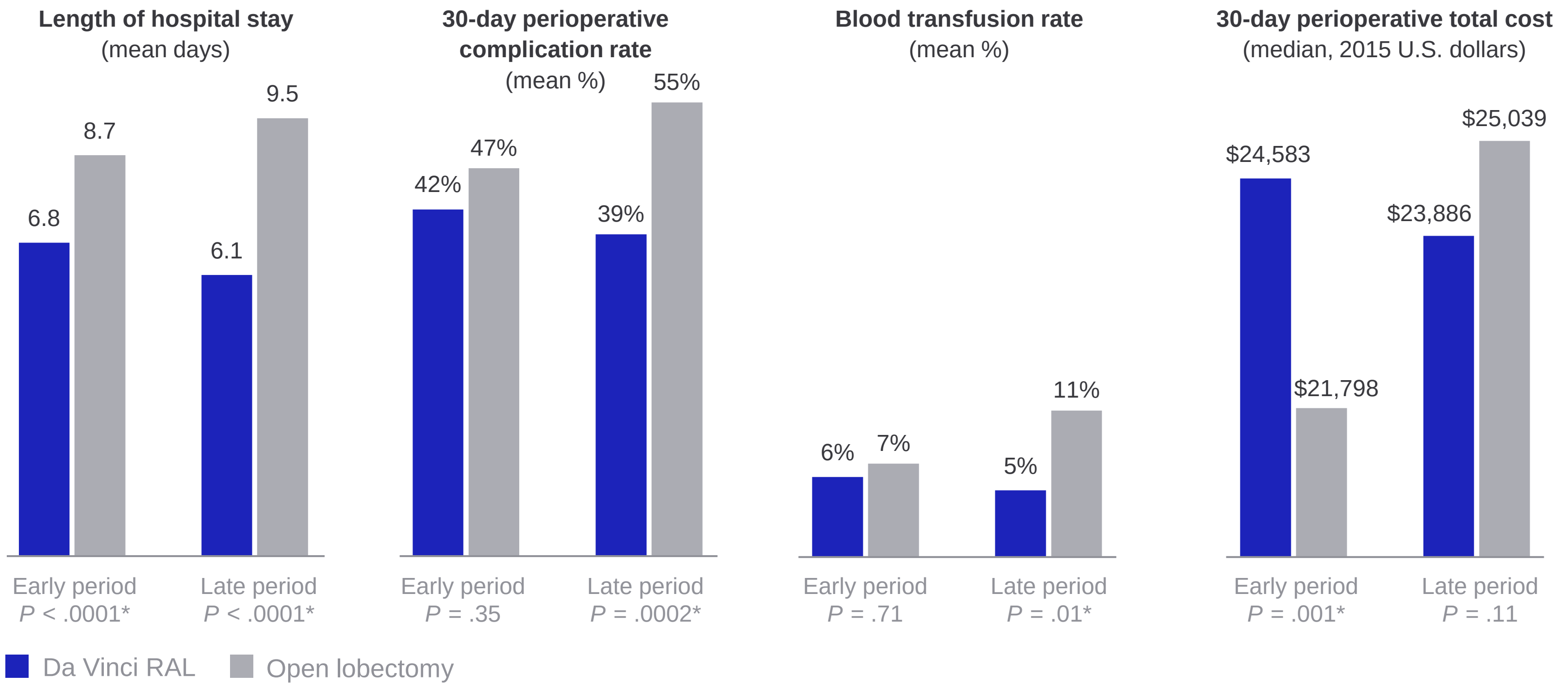
Key result

High-volume center subset: When compared to VATS, RAL was associated with lower length of stay in both periods. Perioperative complication and conversion rates were comparable in the early period and lower in the late period. Total costs were comparable during both periods. RAL achieved statistical significance gains relative to VATS over time.

Nguyen DM, Sarkaria IS, Song C, et al. Clinical and economic comparative effectiveness of robotic-assisted, video-assisted thoracoscopic, and open lobectomy. J Thorac Dis. 2020;12(3):296-306. doi:10.21037/jtd.2020.01.40

Study showed impact of robotic-assisted lobectomy on length of stay, complications, transfusions, and cost compared to open lobectomy

Propensity-score matched cohorts from high-volume centers (>25 annual RAL or open lobectomy cases)



* A *P* value of .05 or less was considered statistically significant.
Note: There were 236 cases each of open lobectomy and RAL in the early period and 304 cases each in the late period.

Additional clinical studies report that RAL as compared to open lobectomy is associated with a shorter[1-3,8-10,22-25] or comparable[26] length of hospital stay, a lower[1,9] or comparable[24,26] rate of overall perioperative complication, and a lower[1,12] intraoperative blood transfusion rate.

Purpose

Assess and compare perioperative outcomes and costs of open lobectomy, video-assisted thoracoscopy (VATS), and robotic-assisted lobectomy (RAL)

Study design

Retrospective Premier Healthcare Database study of early (2008–2012) and late (2013–2015) periods; propensity-score matched cohorts.

Outcomes measured

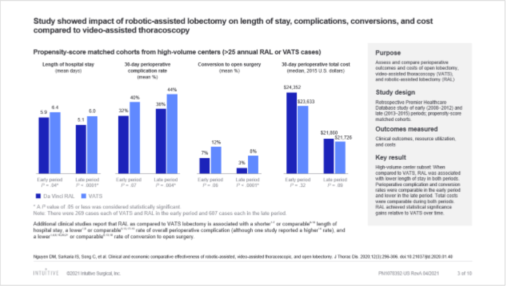
Clinical outcomes, resource utilization, and costs

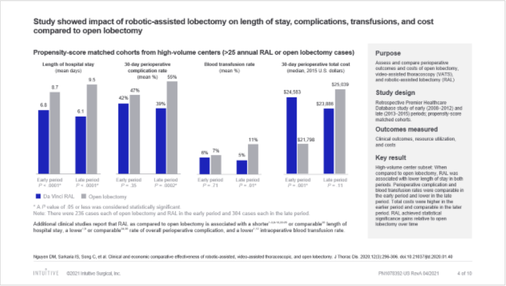
Key result

High-volume center subset: When compared to open lobectomy, RAL was associated with lower length of stay in both periods. Perioperative complication and blood transfusion rates were comparable in the early period and lower in the late period. Total costs were higher in the earlier period and comparable in the later period. RAL achieved statistical significance gains relative to open lobectomy over time

Nguyen DM, Sarkaria IS, Song C, et al. Clinical and economic comparative effectiveness of robotic-assisted, video-assisted thoracoscopic, and open lobectomy. J Thorac Dis. 2020;12(3):296-306. doi:10.21037/jtd.2020.01.40

Clinical and economic comparative effectiveness of robotic-assisted, video-assisted thoracoscopic, and open lobectomy





Citation: Nguyen DM, Sarkaria IS, Song C, et al. Clinical and economic comparative effectiveness of robotic-assisted, video-assisted thoracoscopic, and open lobectomy. J Thorac Dis. 2020;12(3):296-306. doi:10.21037/jtd.2020.01.40

Financial disclosure: Drs. Sarkaria and Shi have received compensation from Intuitive for consulting and/or educational services. Dr. Oh is employed part time by Intuitive. Drs. Song and Liu are employed full time by Intuitive.

Study design

Type: Retrospective database study; propensity-score matched (PSM) cohorts

Data source: Premier Healthcare Database

Time frame: Jan. 1, 2008 to Sept. 30, 2015; breakout into early (Jan. 2008 through Dec. 2012) and late (Jan. 2013 through Sept. 2015) periods

Patient population

- Adults who had a lobectomy for neoplasm
- RAL vs. VATS
  - Early: 1,136 PSM patient pairs; high-volume subset: 269 pairs
  - Late:1,729 PSM patient pairs; high-volume subset: 607 pairs
- RAL vs. open
  - Early: 956 PSM patient pairs; high-volume subset: 236 pairs
  - Late: 1371 PSM patient pairs; high-volume subset: 304 pairs

Outcomes measured

- PSM-cohort comparisons between RAL vs. VATS and RAL vs. open lobectomy; subset analysis of high-volume hospitals, defined as >25 annual RAL or VATS cases
  - In-hospital mortality; complications (intraoperative, in hospital, perioperative 30 days); blood transfusion; conversion; length of stay; operating room time; admission to ICU; ICU duration; cost in 2015 U.S. dollars (direct, overhead, total) during hospitalization and perioperative (30 days)

Results / conclusions

RAL vs. VATS, high-volume hospital subset

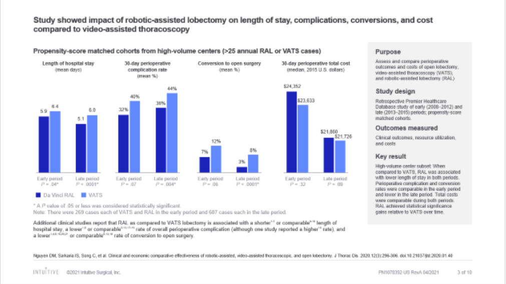
- In-hospital mortality (%) – Early: RAL 1.49%, VATS 2.23%, *P* = .52; Late: RAL 0.49%, VATS 1.15%, *P* = .2
- Complications (%)
  - Intraoperative – Early: RAL 1.49%, VATS 2.97%, *P* = .38; Late: RAL 2.14%, VATS 2.14%, *P* = 1.0
  - In hospital – Early: RAL 30.86%, VATS 39.41%, *P* = .05*; Late: RAL 35.58%, VATS 43.99%, *P* = .003*
  - Perioperative (30 days) – Early: RAL 31.97%, VATS 39.78%, P = .07; Late: RAL 35.91%, VATS 44.15%, *P* = .004*
- Blood transfusion (%) – Early: RAL 4.09%, VATS 6.32%, *P* = .33; Late: RAL 4.28%, VATS 5.93%, *P* = .24
- Conversion rate (%) – Early: RAL 7.06%, VATS 12.27%, *P* = .06; Late: RAL 2.64%, VATS 8.24%, *P* < .0001*
- Length of stay (days) [mean (SD)] – Early: RAL 5.9 (6.1), VATS 6.4 (7.6), *P* = .04*; Late: RAL 5.1 (4.9), VATS 6.0 (5.4), *P* < .0001*
- Operating room duration (hours) [mean (SD)] – Early: RAL 3.9 (1.4), VATS 4.3 (1.4), *P* = .001**; Late: RAL 3.9 (1.3), VATS 3.9 (1.2), *P* = .77
- Admission to ICU (%) – Early: RAL 44.61%, VATS 39.41%, *P* = .26; Late: RAL 44.48%, VATS 35.75%, *P* = .002**
- ICU duration (days) [mean (SD)] – Early: RAL 2.6 (5.1), VATS 4.5 (9.5), *P* < .0001*; Late: RAL 2.5 (3.3), VATS 3.7 (6.5), *P* = .002*
- Total cost during hospitalization, [median (IQR)] – Early: RAL $23,784 ($19,850–$30,391), VATS $22,599 ($18,152–$31,079), *P* = .24; Late: RAL $21,315 ($17,334–$27,241), VATS $21,103 ($16,222–$28,509), *P* = .18
- Total perioperative (30 days) cost [median (IQR)] – Early: RAL $24,352 ($20,101–$30,992), VATS $23,633 ($18,298–$32,135), *P* = .32; Late: RAL $21,860 ($17,643–$29,114), VATS $21,726 ($16,601–$30,144), *P* = .09

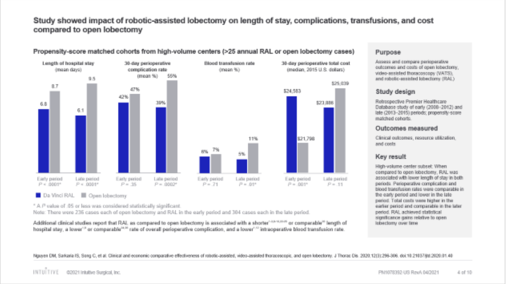
* Statistically significant in favor of RAL
** Statistically significant in favor of VATS

RAL vs. open, high-volume hospital subset

- In-hospital mortality (%) – Early: RAL 2.12%, open 2.54%, *P* = .76; Late: RAL 0.99%, open 2.30%, *P* = .20

Clinical and economic comparative effectiveness of robotic-assisted, video-assisted thoracoscopic, and open lobectomy





Citation: Nguyen DM, Sarkaria IS, Song C, et al. Clinical and economic comparative effectiveness of robotic-assisted, video-assisted thoracoscopic, and open lobectomy. J Thorac Dis. 2020;12(3):296-306. doi:10.21037/jtd.2020.01.40

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Results (continued)

RAL vs. open, high-volume hospital subset (continued)

- Complications (%)
  - Intraoperative – Early: RAL 2.12%, open 0.85%, *P* = .45; Late: RAL 2.30%, open 2.96%, *P* = .80
  - In hospital – Early: RAL 41.95%, open 46.19%, *P* = .40; Late: RAL 38.82%, open 54.61%, *P* = .0001*
  - Perioperative (30 days) – Early: RAL 42.37%, open 47.03%, *P* = .35; Late: RAL 39.14%, open 54.61%, *P* = .0002*
- Blood transfusion (%) – Early: RAL 5.93%, open 7.20%, P = .71; Late: RAL 4.93%, open 10.86%, P = .01*
- Length of stay (days) [mean (SD)] – Early: RAL 6.8 (7.1), open 8.7 (6.0), P < .0001*; Late: RAL 6.1 (7.1), open 9.5 (8.3), P < .0001*
- Operating room duration (hours) [mean (SD)] – Early: RAL 3.7 (1.3), open 3.3 (1.2), P = .0008**; Late: RAL 4.3 (1.3), open 3.6 (1.4), P < .0001**
- Admission to ICU (%) – Early: RAL 63.14%, open 69.49%, P = .17; Late: RAL 55.92%, open 74.01%, P < .0001*
- ICU duration (days) [mean (SD)] – Early: RAL 2.6 (4.9), open 3.5 (5.0), P < .004*; Late: RAL 3.2 (5.7), open 4.4 (7.8), P = .0003*
- Total cost during hospitalization, [median (Q1–Q3)] – Early: RAL $24,030 ($18,695–$31,376), open $20,700 ($15,896–$27,676), P = .001**; Late: RAL $23,220 ($18,229–$30,987), open $24,469 ($18,822–$34,345), P = .12
- Total perioperative (30 days) cost [median (Q1–Q3)] – Early: RAL $24,583 ($19,771–$32,238), open $21,798 ($16,189–$28,943, P = .001**; Late: RAL $23,886 ($18,506–$32,787), open $25,039 ($19,398–$37,291), P = .11

* Statistically significant in favor of RAL
** Statistically significant in favor of open

Study strengths

- Study analyzed RAL in the Premier Healthcare Database over almost 8 years and separated out the early adoption period (RAL < 10% of lobectomies) and later era (RAL > 10% lobectomies).
- Propensity-score matching analysis factored in a wide set of patient, surgeon, and hospital characteristics to minimize selection bias.

Study limitations

- Using an administrative database is associated with limitations that include potential coding errors and differences in surgeon skill and institutional practice patterns.
- The Premier Database does not provide details about the tumor size or stage, which may have introduced selection bias.
- There may be heterogeneity of cost structures between hospitals, even after propensity-score matching.

Typical ranges for clinical outcomes in lobectomy

		Range of Statistical Metric for Robotic-Assisted Surgery			
		RAL vs. Open Lobectomy		**RAL vs. VATS**	
Outcome	**Statistical Metric**	**Value**	**Reference**	**Value**	**Reference**
Intraoperative transfusion rate	Min %	3.4%	1	1%	5
	Max %	6.4%	Current Nguyen study	5.7%	Current Nguyen study
Conversion to open surgery rate	Min %	N/A		4.6%	4
	Max %			10.3%	16
Overall complication rate	Min %	27.6%	26	33.4%	6
	Max %	43.8%	9	50.1%	14
Length of hospital stay	Min median (IQR), days	4 (3-6)	3	4 (2-5)	5
	Max median (IQR), days	5.2 (4.8-5.6)	27	5.2 (4.8-5.6)	27

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

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Important safety information

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, re-intubation, arrhythmias, bronchopleural fistula, phrenic nerve injury, esophageal injury, difficulty breathing, collapsed lung, pulmonary volvulus, recurrent laryngeal nerve injury leading to vocal cord dysfunction.

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 10 to 12 cases (Falk, et al., Total endoscopic computer enhanced coronary artery bypass grafting, Eur J CardiothoracSurg 2000; 17: 38-45).