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.

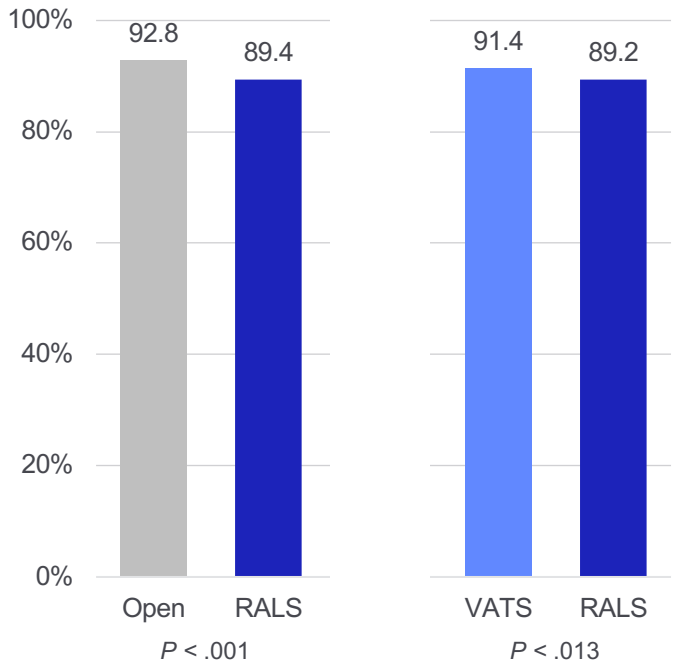
Transfusion and/or estimated blood loss	**Readmission rate (30 days or other)**
Operative time	**Reoperation rate (30 days or other)**
Length of hospital stay	**Positive surgical margin rate and/or lymph node yield and/or lymph node upstaging**
Conversion rate (versus laparoscopy only)	**Perioperative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

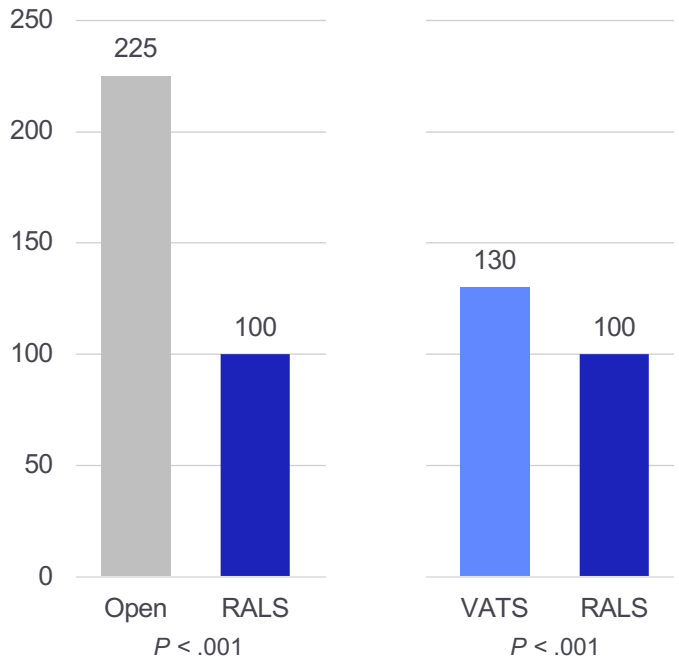
Single published study showed impact of robotic-assisted lobectomy on postoperative opioid administration in patients with primary lung cancer

Percentage of patients receiving any opioid,* day of surgery



*Including oral and/or parenteral

Median total opioid dose,* postop day one to discharge



*Morphine-equivalent daily doses (MEDD)

Additional studies indicate that post-operative opioid consumption following RALS is comparable to that following VATS[1,2], though one study found higher opioid consumption for RALS compared to VATS patients on post-operative day two.[1] Literature search did not provide studies with results comparing Open lobectomy to RALS opioid consumption in the same post-operative time period.

Rajaram R, Rice DC, Li Y, et al. Postoperative opioid use after lobectomy for primary lung cancer: A propensity-matched analysis of Premier hospital data [published online ahead of print, 2020 May 16]. *J Thorac Cardiovasc Surg*. 2020;S0022-5223(20)31136-3. doi:10.1016/j.jtcvs.2020.04.148

Purpose

To evaluate opioid administration after robotic-assisted lobectomy surgery (RALS) and compare it to opioid administration after video-assisted thoracic surgery (VATS) and open lobectomy surgery

Study design

Retrospective database study (2013–15)

- **RALS versus open lobectomy:** 2,061 matched patient pairs
- **RALS versus VATS:** 2,142 matched patient pairs

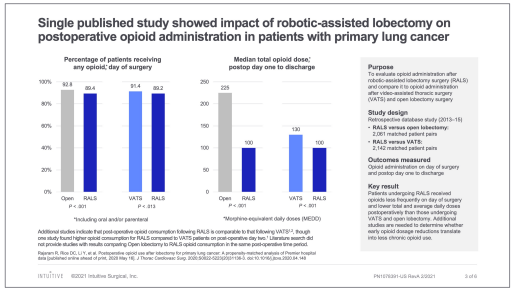
Outcomes measured

Opioid administration on day of surgery and postop day one to discharge

Key result

Patients undergoing RALS received opioids less frequently on day of surgery and lower total and average daily doses postoperatively than those undergoing VATS and open lobectomy. Additional studies are needed to determine whether early opioid dosage reductions translate into less chronic opioid use.

Postoperative opioid use after lobectomy for primary lung cancer: A propensity-matched analysis of premier hospital data



Citation

Rajaram R, Rice DC, Li Y, et al. Postoperative opioid use after lobectomy for primary lung cancer: A propensity-matched analysis of Premier hospital data [published online ahead of print, 2020 May 16]. *J Thorac Cardiovasc Surg*. 2020;S0022-5223(20)31136-3. doi:10.1016/j.jtcvs.2020.04.148

Financial disclosure

Drs. Li, Liu, and Song are full-time employees of Intuitive.

Study design

Type: Retrospective database study

Data source: Premier Healthcare Database of more than 700 U.S. hospitals

Timeframe: Jan. 1, 2013 to Sept. 30, 2015

Patient population

- 16,514 patients who underwent elective lobectomy for primary lung cancer
  - Open vs. RALS: 2,061 propensity score matched (PSM) patient pairs
  - VATS vs. RALS: 2,142 PSM patient pairs

Outcomes measured

Day of surgery

- Percentage of patients receiving any opioid administration (oral and/or parenteral); oral only; parenteral only
- Average daily dose, MEDD, median (IQR)

Postop day one (POD 1) to discharge

- Percentage of patients receiving any opioid administration (oral and/or parenteral); oral only; parenteral only
- Total dose, MEDD, median (IQR)
- Average daily dose, MEDD, median (IQR)

Results / conclusions

Open vs. RALS PSM cohort

- **Day of surgery:** More patients in the open group received opioids (92.8% vs. 89.4%; *P* <.001). Average daily opioid dose was higher in the open group (median MEDD, 125.0 vs. 110.0; *P* = .001).
- **POD 1 to discharge:** More patients in the open group received opioids (94.8% vs. 87.2%; *P* < .001). Total opioid dose (median MEDD, 225.0 vs. 100.0; *P* < .001) and average daily dose (median MEDD, 41.3 vs. 30.0; *P* < .001) were also higher in the open group.

VATS vs. RALS PSM cohort

- **Day of surgery:** More patients in the VATS group received opioids (91.4% vs. 89.2%; *P* = .013). There was no difference between the groups in average daily opioid dose (median MEDD, 115 vs. 105; *P* = .09).
- **POD 1 to discharge:** More patients in the VATS group received opioids (89.6% vs. 87.0%; *P* = .008). Higher total and average daily opioid doses were observed in the VATS group (median total dose in MEDD, 130.0 vs. 100.0; average daily dose in MEDD, 33.8 vs. 28.8; *P* < .001 for both).
- Parenteral nonopioid pain medications were administered less frequently in the open lobectomy and VATS groups compared with the RL group on the day of surgery.

Study strengths

- Multi-institution study with large sample and direct and comprehensive comparison of opioid use by surgical approach
- Patient cohorts created using propensity score matching to balance patient, hospital, and surgeon characteristics

Study limitations

- Use of a large administrative database is subject to potential errors in data entry and coding
- Only evaluated in-hospital opioid administration
- Unable to account for potential confounders such as tumor size and/or existence of enhanced recovery pathways
- Minimally invasive surgeons may be biased against opioid use and may tend to prescribe less pain medication than peers
- The reliability of certain measures, such as epidural use, was difficult to discern.

References

1. Duclos G, Charvet A, Resseguier N, Trousse D, D'Journo XB, Zieleskiewicz L, et al. Postoperative morphine consumption and anaesthetic management of patients undergoing video-assisted or robotic-assisted lung resection: a prospective, propensity score-matched study. J Thorac Dis. 2018;10:3558-67.

2. Kwon ST, Zhao L, Reddy RM, Chang AC, Orringer MB, Brummett CM, et al. Evaluation of acute and chronic pain outcomes after robotic, video-assisted thoracoscopic surgery, or open anatomic pulmonary resection. J Thorac Cardiovasc Surg. 2017;154:652-9.e1.

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 Cardiothorac Surg 2000; 17: 38-45).