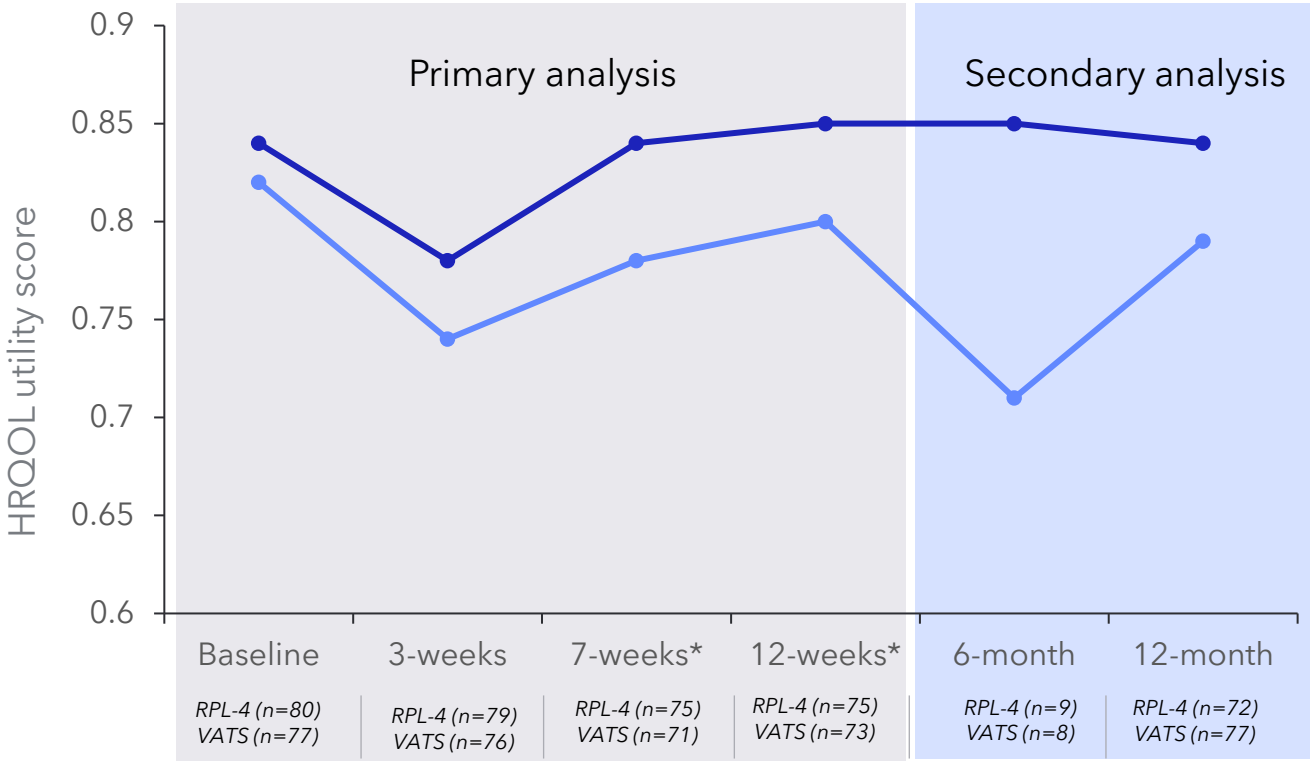
Robotic-assisted Lobectomy is Cost-Effective and Provides Comparable Health Utility Scores to Video-assisted Lobectomy: Early Results of the RAVAL Trial

Robotic-assisted (RPL-4) compared with Video-assisted (VATS) lobectomy for early-stage NSCLC resulted in a greater health benefit that **favored robotic-assisted surgery over VATS surgery in utility scores.**

European Quality of Life 5-Dimension 5-Level Instrument (EQ-5D-5L) Responses to 12 months



■ Robotic-assisted lobectomy (RPL-4) ■ Video-assisted lobectomy (VATS-Lobectomy)

Note: * P value of <.05 was considered statistically significant. RPL-4: Robotic-assisted lobectomy VATS: Video-assisted lobectomy. n's are included to show the number of patients who completed EQ-5D-5L at a specific timepoint. HRQOL: Health related quality of life utilities were derived from EQ-5D-5L. Seemingly Unrelated Regression is applied to estimate the effect, adjusting for baseline characteristics (age, sex) and stratification factors (surgeon).

Purpose
To determine if robotic-assisted lobectomy (RPL-4) is cost-effective and offers improved patient-reported health utility for patients with early-stage NSCLC (Non-small cell lung cancer) when compared to video-assisted lobectomy (VATS-Lobectomy)

Study design
RAVAL (Robotic-Assisted vs. Video-Assisted Lobectomy) is an international, multi-center, prospective, blinded RCT with a 1:1 allocation ratio to two parallel arms: RPL-4 (intervention) and VATS-Lobectomy (control)

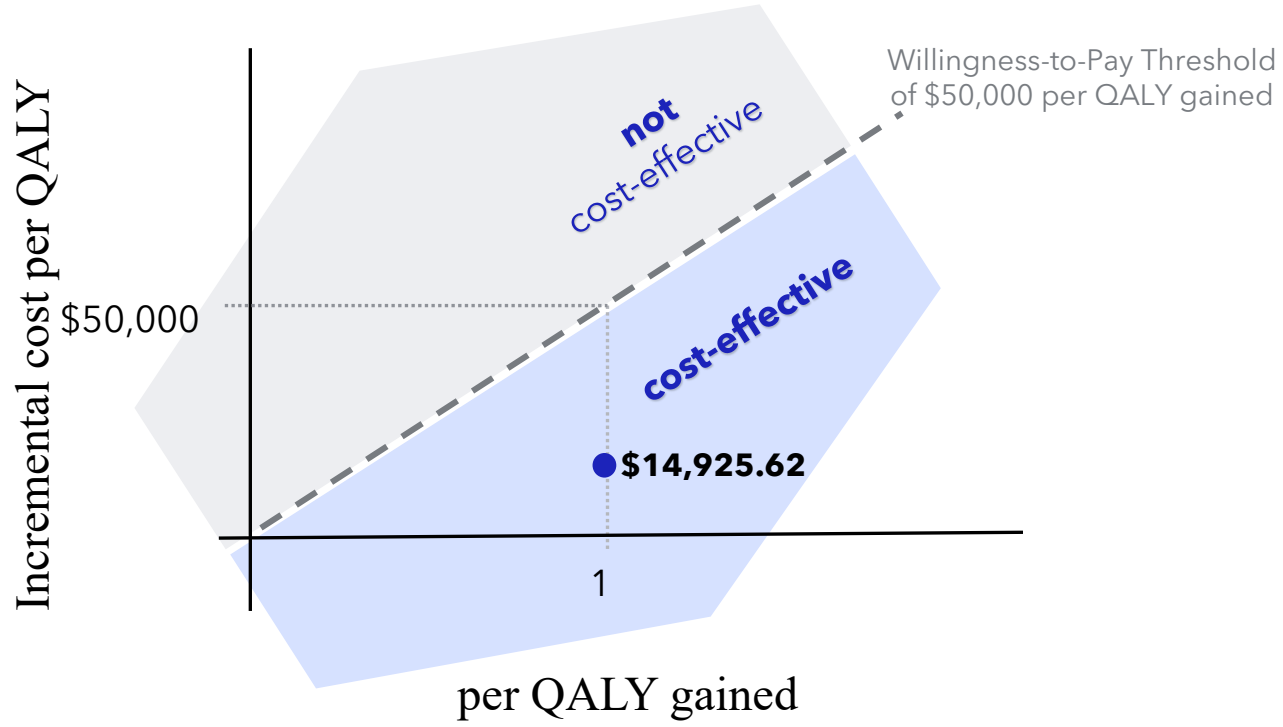
Outcomes measured
Primary Endpoint for Phase A was the difference in Health Utility scores between the treatment groups at 12-weeks.
Secondary Outcomes that were measured and reported include: differences in Health Utility scores between the treatment groups at 3- and 7-weeks, and 6- and 12-months, short-term clinical and oncological outcomes (total number of LN stations sampled/dissected), and the incremental cost per QALY (Quality Adjusted Life Years) of RPL-4 relative to VATS-Lobectomy

Key results
Primary Outcome: The mean 12-week health utility score was 0.85 (0.10) for RPL-4 and 0.80 (0.19) for VATS-Lobectomy (p=0.02)
Secondary Outcomes Results: At the 12-month time horizon, RPL-4 was associated with an additional cost of $14,925.62/QALY gained (95% CI $6,843.69, $23,007.56) relative to VATS-Lobectomy
There were no significant differences in HU (Health Utility) scores between treatment groups at 3-weeks. The mean HU score at 7-weeks was 0.84 (0.14) for the RPL-4 arm and 0.78 (0.18) for the VATS-Lobectomy arm (MD 0.04, 95% CI 0.0001, 0.08; p=0.04). The mean HU scores at 6- months and 12-months were no different between cohorts.
Significantly more Lymph nodes were sampled [10 (8-13) vs 8 (5-10); p=0.003] in the RPL-4 arm. Conversion to thoracotomy occurred in 7.41% (6/81) and 15.66% (13/83) of cases in the RPL-4 and VATS-Lobectomy arms, respectively (p=0.10)

Study information

Robotic-assisted Lobectomy is Cost-Effective and Provides Comparable Health Utility Scores to Video-assisted Lobectomy: Early Results of the RAVAL Trial

Robotic-assisted (RPL-4) compared with Video-assisted (VATS) lobectomy for early-stage NSCLC is **cost effective**



Note: **QALY**: Quality-Adjusted Life Year is the metric used to measure how well different medical treatments lengthen and/or improve patients' lives. : ICER: Incremental cost-effectives ratio is the difference in cost between two possible interventions, divided by the difference in effect. ICER of <$50,000 is considered favorable when introducing new technology.

Incremental Cost Per QALY of RPL-4 Relative to VATS-Lobectomy

Economic outcomes measured
Cost-effectiveness: Incremental cost-effectiveness ratio (ICER) at a threshold of $50,000 per QALY gained.

Health utility outcome: Quality-adjusted life-years (QALY) using Health related quality of life (HRQOL) utilities derived from EQ-5D-5L.

Resource use and unit cost: Micro-costing[1] methods using all direct medical and nonmedical costs from admission to discharge, capital cost and home care-related costs within 30 day.

Results:
Incremental Cost: **$179.37** ($154.20, $204.54)
Incremental QALY: **0.0120** (-0.1243, 0.1483)
Incremental cost per QALY (ICER): **$14925.62** ($6843.685, $23007.557)*

Note: Seemingly Unrelated Regression is applied to estimate the effect, adjusting for baseline characteristics (age, sex) and stratification factors (surgeon). The regression model for QALY also adjusts for baseline heath utility.
Multivariate Imputation by Chained Equations is used to impute the missing data in QALY.

*CI of ICER is generated by 10,000 bootstrap samples using bias-corrected and accelerated method.

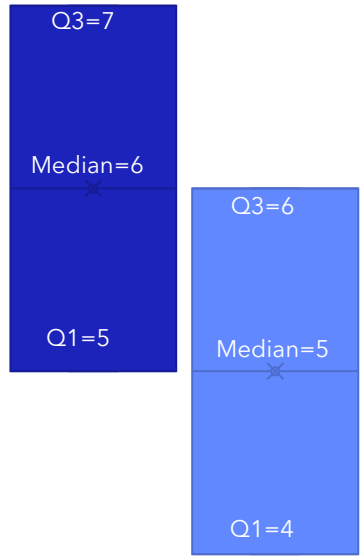
[1]Kaur M, Dogra , Xie F, et al. Robotic Versus Video-Assisted Thoracoscopic Lung Resection During Early Program Development. *Ann Thorac Surg*. 2018;105:1050-7. doi: https://doi.org/10.1016/j.athoracsur.2017.11.13

Study information

Robotic-assisted Lobectomy is Cost-Effective and Provides Comparable Health Utility Scores to Video-assisted Lobectomy: Early Results of the RAVAL Trial

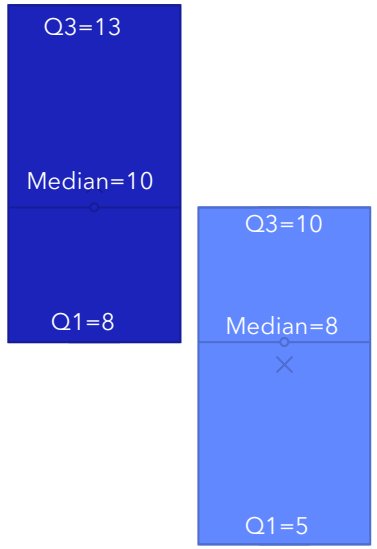
Robotic-assisted (RPL-4) compared with Video-assisted (VATS) lobectomy for early-stage NSCLC resulted in **statistically significant increase** in **lymph node stations sampled and statistically significant more lymph nodes examined**

Lymph node stations sampled
n



P = .02

Lymph nodes examined
n



P = .003

■ Robotic-assisted lobectomy (RPL-4) ■ Video-assisted lobectomy (VATS)

Note: P value of <.05 was considered statistically significant

Lymph Node Dissection

Total number of Lymph Node Stations, median (IQR) for RRL-4 was 6 (5-7) station compared to VATS 5 (4-6) stations and was shown to be a statistically significant, p-value of .02.

Total number of Lymph Nodes Examined, median (IQR) for RRL-4 was 10 (8-13) lymph nodes compared to VATS 8 (5-10) lymph nodes and was shown to be a statistically significant, p-value of .003.
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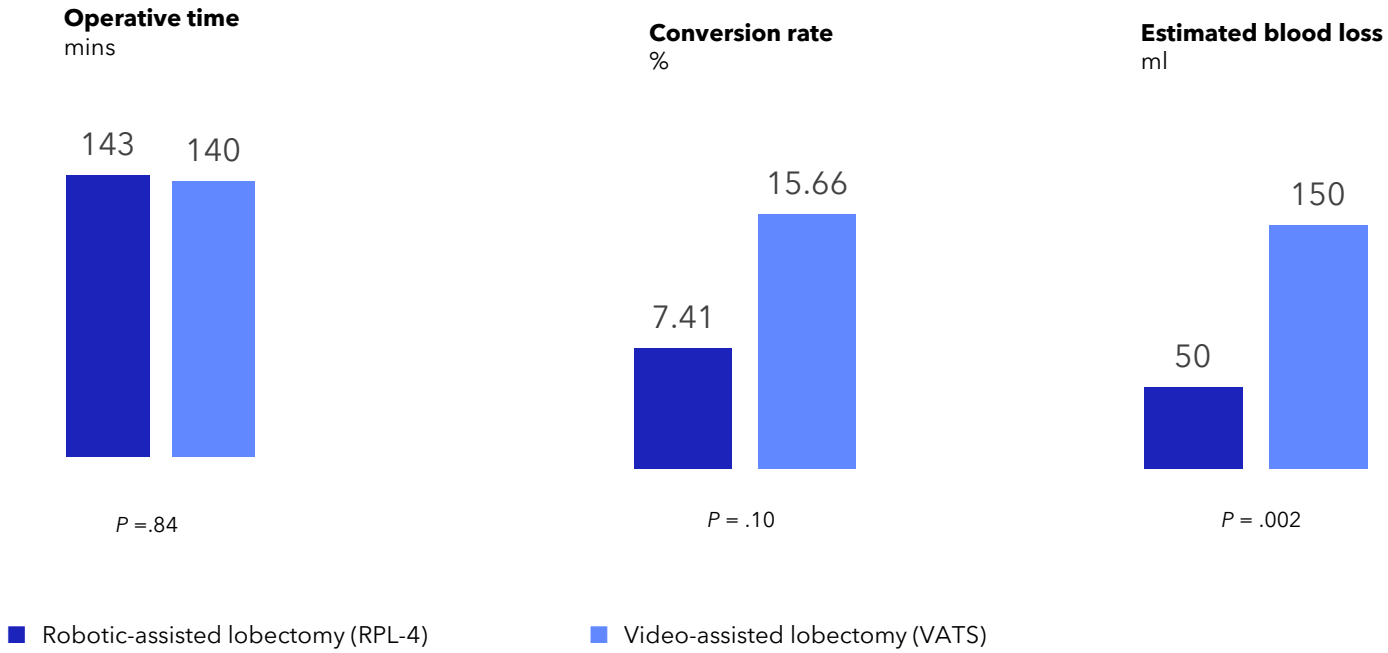
Study information

Robotic-assisted Lobectomy is Cost-Effective and Provides Comparable Health Utility Scores to Video-assisted Lobectomy: Early Results of the RAVAL Trial

Robotic-assisted (RPL-4) compared with Video-assisted (VATS) lobectomy for early-stage NSCLC resulted in **statistically significant reduction** in **estimated blood loss** as well as a **lower conversion rate**



Note: P value of <.05 was considered statistically significant

Short-Term Perioperative Outcomes

Amount of Blood Loss, mL, median (IQR)
Units of blood, mean (SD) for RPL-4 was 50 (30-150) units of blood transfused compared to VATS was 150 (50-200) units of blood transfused was shown to be a statistically significant, p-value of .002.

Converted to Thoracotomy, n (%)
For RPL-4 6 (7.41%) of patients converted to thoracotomy compared to VATS was 13 (15.66%) , p-value of .10.

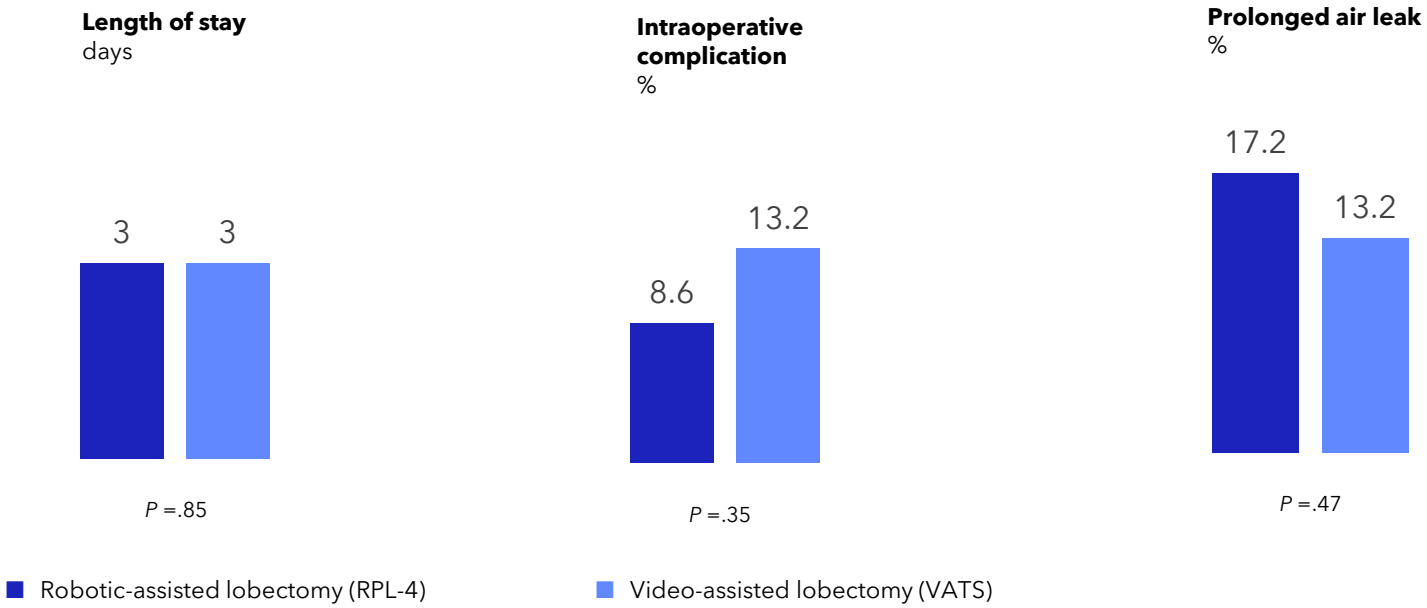
Total procedure time, minutes median (IQR)
For RPL-4 median procedure time was 143 (118-170) and was shown to be compared to VATS 140 (119-168), p-value of .84.

Total Operating room, minutes median (IQR)
For RPL-4 median operating room (OR) time was 203 (165-234) and was shown to be comparable to VATS 193 (171-225), p-value of .62.

Study information

Robotic-assisted Lobectomy is Cost-Effective and Provides Comparable Health Utility Scores to Video-assisted Lobectomy: Early Results of the RAVAL Trial

Robotic-assisted (RPL-4) compared with Video-assisted (VATS) lobectomy for early-stage NSCLC resulted in **reduction** in **intraoperative complications**



Note: P value of <.05 was considered statistically significant.

Short-Term Perioperative Outcomes

Length of stay, day, median (IQR)
For RPL-4 median length of stay was 3 (2-5) and was shown to be compared to VATS 3 (2-5). p-value of .84

Intraoperative complication, n (%)
For RPL-4 7 (8.64%) of patients had a intraoperative complication compared to VATS 11 (13.25%) , p-value of .35.

Prolonged air leak, n (%)
For RPL-4 14 (17.28%) of patients had a prolonged air leak compared to VATS 11 (13.25%) , p-value of .47.

Study information

Study information: Robotic-assisted Lobectomy is Cost-Effective and Provides Comparable Health Utility Scores to Video-assisted Lobectomy: Early Results of the RAVAL Trial

Citation

Patel YS, Baste JM, Shargall Y, Waddell TK, Yasufuku K, Machuca TN, Xie F, Thabane L, Hanna WC. Robotic Lobectomy is Cost-Effective and Provides Comparable Health Utility Scores to Video-Assisted Lobectomy: Early Results of the RAVAL Trial. Ann Surg. 2023 Aug 8. doi: 10.1097/SLA.0000000000006073. Epub ahead of print. PMID: 37551615

Study design

Type: RAVAL (Robotic-Assisted vs. Video-Assisted Lobectomy) is an international, multi-center, prospective, blinded RCT with a 1:1 allocation ratio to two parallel arms: RPL-4 (intervention) and VATS-Lobectomy (control)

Timeframe:

Started recruiting patients in 2016, and is expected to run until 2029, with multiple pre-defined reporting periods for various outcomes.

Patient population: 164 patients were analyzed after final eligibility review ; RPL-4 (Robotic Portal Lobectomy with 4 Arms):n=81 and VATS-Lobectomy:n=83

Eligible patients who signed consent for a minimally invasive lobectomy between 01/2016 and 07/2020 were screened for eligibility criteria. Inclusion criteria were age >18 years; clinical stagel, II, or IIIa NSCLC; and candidate for minimally invasive pulmonary lobectomy, as determined by the operating surgeon. Patients received neoadjuvant induction therapy when clinically indicated.

Exclusion criteria were clinical stage IIIb or IV NSCLC, because it was expected that factors other than surgery, namely advanced disease symptoms and systemic treatment toxicity, would affect their quality of life; or not a candidate for minimally invasive lobectomy, as deemed by the operating surgeon, due to factors such as body habitus, previous chest surgery, anatomy, or medical condition.

Outcomes measured

Primary outcome for Phase A was the difference in Health Utility scores between the treatment groups at 12-weeks.

Secondary outcomes that were measured and reported include: differences in Health Utility scores between the treatment groups at 3- and 7-weeks, and 6- and 12-months, short-term clinical and oncological outcomes (total number of LN stations sampled/dissected), and the incremental cost per QALY (Quality Adjusted Life Years) of RPL-4 relative to VATS-Lobectomy.

Results / conclusions

Primary Outcome

The mean 12-week health utility score was 0.85 (0.10) for RPL-4 and 0.80 (0.19) for VATS-Lobectomy (p=0.02).

Key Secondary Outcomes

At the 12-month time horizon, RPL-4 was associated with an additional cost of $14,925.62/QALY gained (95% CI $6,843.69, $23,007.56) relative to VATS-Lobectomy. Costs calculated using micro-costing methods.[1] There were no significant differences in HU (Health Utility) scores between treatment groups at 3-weeks, where both cohorts experienced a reduction in HU, when compared to preoperative baseline.

The mean HU score at 7-weeks was 0.84 (0.14) for the RPL-4 arm and 0.78 (0.18) for the VATS-Lobectomy arm (MD 0.04, 95% CI 0.0001, 0.08; p=0.04), with the VATS-Lobectomy cohort continuing to record a reduction in HU when compared to preoperative baseline, but not the RPL-4 cohort. The mean HU scores at 6- months and 12-months were no different between cohorts.

Significantly more lymph nodes were sampled [10 (8-13) vs 8 (5-10); p=0.003] in the RPL-4 arm. Conversion to thoracotomy occurred in 7.41% (6/81) and 15.66% (13/83) of cases in the RPL-4 and VATS-Lobectomy arms, respectively (p=0.10). There was significantly less blood loss in the RPL-4 arm [50 (30-150) mL] than in the VATS-Lobectomy arm [150 (50-200) mL; p=0.002]. There were no statistically significant differences between the RPL-4 and VATS-Lobectomy arms in patient-reported postoperative pain during admission (p=0.88); length of stay in hospital (p=0.85); chest tube duration (p=0.98);operative time (p=0.84);incidence of prolonged air leak (p=0.47); or duration of postoperative intravenous analgesia (p=0.41) or epidural catheter placement (p=0.50). There were also no statistically significant differences between the RPL-4 and VATS-Lobectomy arms in the incidence of intraoperative adverse events (p=0.35)

[1]**Kaur** M, Dogra , Xie F, et al. Robotic Versus Video-Assisted Thoracoscopic Lung Resection During Early Program Development. *Ann Thorac Surg*. 2018;105:1050-7. doi: https://doi.org/10.1016/j.athoracsur.2017.11.13

Study strengths

One of the specific aims of RAVAL was to generate high-quality data that could be used to calculate a reliable ICER (Incremental cost per QALY) for RPL-4, relative to VATS-Lobectomy. Prospective measurement of HU and blinded patients for 12- months post-surgery, allowed for the calculation of reliable HU data that is subject to minimal bias. The resulting calculated ICER for RPL-4, relative to VATS-Lobectomy, was less than $15,000/QALY gained. RPL-4 is still more expensive than VATS-Lobectomy, but an ICER of <$50,000 is considered favorable when introducing new technology. The increasing availability and diversity of the robotic platform is likely to drive costs down over time, favorably influencing the ICER.

Study limitations

Health Utility, and the resulting ICER were measured at the short time horizon of 12-months. Longer term follow-up, and future data on mortality, may influence these results in either direction. A limitation of the multi-centre design is the difference in postoperative care between centres. Another limitation was the high proportion of patients who reported full health at baseline, which makes small changes in HU scores difficult to measure. Due to the multi-national nature of the trial, measuring opioid consumption or delineating de novo opioid-dependence was not done.

Study highlight

Regulatory and Legal Disclaimers and Statements

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