Robotic-Assisted Lobectomy for Early-Stage Lung Cancer Provides Better Patient-Reported Quality of Life Compared to Video-Assisted Lobectomy: Early Results of the RAVAL Trial

Objective: The primary objective of Phase A of this international prospective blinded randomized controlled trial comparing robotic-assisted lobectomy (RTS-Lobectomy) to video-assisted lobectomy (VATS-Lobectomy) for early-stage lung cancer is to determine the difference in patient-reported health-related quality of life (HRQOL) between the two arms at 12 weeks after surgery and incremental cost per quality-adjusted life year (QALY) at 12 months after surgery.
Methods: Patients with early-stage lung cancer who were candidates for minimally invasive lobectomy were enrolled from January 2016 to July 2020 at 4 academic sites in the US, Canada, and France. Participants were randomized in a 1:1 ratio to either RTS-Lobectomy (intervention) or VATS-Lobectomy (control). Patients were assigned to surgeons before randomization and all surgeons performed the operations per protocol. Patients were blinded to the type of surgery until the 12-month follow-up. EQ-5D-5L and other HRQOL questionnaires were administered at baseline, postoperative day 1, weeks 3, 7, 12, and months 6, and 12. Data is presented as mean (SD) and median (range). Direct and indirect costs were tracked using standard methods. Seemingly Unrelated Regression was applied to estimate the cost effect, adjusting for baseline characteristics and stratification factors (surgeons) and baseline health utility. The incremental cost effectiveness ratio was generated by 10,000 bootstrap samples using bias-corrected and accelerated method, with multivariate imputation by chained equations for missing data in QALY. Continuous variables were compared using Student's t-test, and categorical variables using Chi-square test.
Results: Of 406 patients screened, 45.81% (186/406) were randomized (RTS n=92; VATS n= 94). At final eligibility review (protocol deviations, withdrawal, loss to follow-up), 82 were analyzed in the RTS arm and 83 in the VATS arm. All patients were followed for at least 12 months. Mean age was 67.36 (9.82) and 66.67% (110/165) were women. There were no significant differences in the body mass index, comorbidities, pulmonary function, smoking status, location of tumor, tumor size, or disease stage between arms. The mean 12-week health utility score was 0.85 (0.10) for the RTS arm and 0.80 (0.19) for the VATS arm [mean difference (MD) 0.05, 95% Confidence Interval (CI) 0.01, 0.09; p=0.02]. Significantly more lymph nodes were sampled [10 (8-13) vs 8 (5-10); p=0.003] in the RTS arm. The incremental cost per QALY of RTS-Lobectomy was $14,925.62 (95% CI $6,843.69, $23,007.56) at the 12-month time horizon.
Conclusions: Early results of the RAVAL trial suggest that RTS-Lobectomy is a cost-effective intervention which is associated with better patient-reported HRQOL when compared to VATS-Lobectomy within 12 months of surgery. RTS-Lobectomy is also associated with superior lymph node sampling. Long-term oncological and HRQOL outcomes will be analyzed in later phases of the ongoing RAVAL trial.

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