



Initial results from a randomized trial in video-assisted versus open thoracic surgery

Anton Eklund^{1,2}, Ulrik Sartipy^{1,2}

¹Department of Molecular Medicine and Surgery, Karolinska Institutet, Stockholm, Sweden; ²Heart and Vascular Theme, Karolinska University Hospital, Stockholm, Sweden

Correspondence to: Ulrik Sartipy, MD, PhD. Heart and Vascular Theme, Karolinska University Hospital, SE-171 76 Stockholm, Sweden.

Email: Ulrik.Sartipy@karolinska.se.

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In a recent study, Long *et al.* (1) reported the short-term perioperative outcomes of a Chinese multicenter randomized controlled trial. The trial was designed to compare clinically relevant outcomes after video-assisted thoracoscopic surgery (VATS) or open lobectomy in the treatment of early-stage non-small cell lung cancer (NSCLC). The authors are to be congratulated for taking on the hard and difficult task of performing a randomized clinical trial in this field (2). Although there is an abundance of observational studies investigating the benefits of VATS lobectomy (3-10), very few randomized clinical trials have been performed (11). A small number of studies have used data from randomized studies or multi-center studies initially designed for other research questions (12,13). To provide high level evidence of non-inferiority, or potential superiority, of lobectomy using VATS compared to thoracotomy regarding oncologic as well as perioperative outcomes, Long *et al.* designed a trial including five thoracic surgery referral centers in China. The study design and other important details are registered with ClinicalTrials.gov (<https://clinicaltrials.gov/ct2/show/NCT01102517>).

The primary outcome measure of the trial is disease-free survival and overall survival after 5 years, and the current article reported the short-term perioperative outcomes. The inclusion criteria were adults (age 18 to 75) who had been accepted for a surgical lobectomy with a diagnosis of early-stage NSCLC. Early stage was defined as stage I or

II according to the American Joint Committee on Cancer Tumor-Node-Metastasis classification. Patients with extensive pleural adhesions, previous thoracotomy or high-dose radiation to the chest were excluded. Other exclusion criteria were patients with a predicted postoperatively reduced lung function or a history of other malignancies in the past 5 years except for nonmelanoma skin cancer, cervix cancer *in situ*, or early stage prostate cancer. During the time period 2008 to 2014, 508 patients were included, and 481 eligible patients were randomized in a 1:1 ratio, stratified according to participating medical centers, to radical lobectomy as well as mediastinal lymph node sampling by VATS (n=236) or by axillary thoracotomy (n=245). The surgery by VATS was performed according to its strict definitions, while the number of ports used was at the discretion of the surgeon. The two patient groups had similar distributions of baseline characteristics. Post-randomization, 48 patients were excluded from analysis due to confirmed benign disease, small cell lung cancer, incidental pleural metastasis or genuine age older than 75 years. In eight patients, surgery by VATS was converted to thoracotomy due to technical challenge to achieve hemostasis, extensive pleural adhesion or equipment issues. In summary, the authors found that the median operation time was significantly lower in the VATS group compared to the thoracotomy group (150 *vs.* 166 minutes). The authors also found the intraoperative blood loss to be significantly

less by VATS, although the median amount of bleeding was similar (100 *vs.* 100 mL). It is doubtful that the difference in blood loss is clinically meaningful. However, postoperative hemorrhage of up to 750 mL was noted in 3 patients, all in the VATS group. There was no statistical difference regarding macro- or microscopic radicality or lymph node sampling between the groups, reflecting a probable non-inferiority from an oncologic perspective, although the final results and reporting of the primary endpoints are needed for confirmation. Prior studies on the extent and quality of lymph node sampling have shown that nodal upstaging was more common in patients who underwent thoracotomy compared to those who had VATS lobectomy for early stage NSCLC (14,15). It is reassuring to read that study results regarding functional assessments and other patient reported outcomes such as pain and quality of life can be expected shortly, because these data are important not only to patients, but also for prognostic information (16-18). In conclusion, while the primary end points of the trial, 5-year overall survival and disease-free survival, are not yet reported, this article supports the non-inferiority of VATS compared to axillary thoracotomy in lobectomy of early-stage NSCLC regarding perioperative outcomes and showed a possible benefit in shorter operation time.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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