Comparison of LigaSure to Conventional Electrocoagulation in Video-assisted Thoracoscopic Surgery Lobectomy

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Aim: to compare the short-term results of and extent of surgical injury by the LigaSure device and monopolar electrocautery in patients undergoing VATS lobectomy with lymphadenectomy.

Type of study: Pragmatic, parallel group, randomized controlled trial, simple randomization, 1:1 allocation ratio

Approval: Bioethics Committee of the Poznan University of Medical Sciences, Poznan, Poland

Location: Department of Thoracic Surgery, Poznan University of Medical Sciences

Inclusion criteria: admission for VATS lobectomy and lymphadenectomy for suspected or confirmed primary lung cancer, age of 18 years or older, ability to read and understand the information regarding the study, and ability to give informed consent to participate.

Exclusion criteria: preoperative radiotherapy or chemotherapy, prior mediastinoscopy or other surgical procedures involving the mediastinum, and ipsilateral chest surgery. Patients who underwent conversion from VATS to thoracotomy were assessed for the relationship between conversion and intervention, but their data were excluded from the final analysis to avoid confounding.

Enrollment: by the thoracic surgeons at admission to the department

Interventions: tissue dissection with the LigaSure device (the study group) or dissection with monopolar device (the control group).

Concealment: to conceal assignments, sequentially numbered, opaque, sealed envelopes that will be prepared before the study and will be opened just before the surgery. From this point, patients' assignments will be known to the surgeons.

Surgery: after induction of general anesthesia, a temperature probe will be inserted into the patient's esophagus and positioned at the level of subcarinal nodes. VATS lobectomy and lymphadenectomy will be performed with either the monopolar device or the LigaSure device. At the end of the surgery, one 24-F chest tube will be inserted into the pleural cavity and connected to a digital drainage system. The chest tube will be removed after resolution of air leak and when the fluid volume was <250 mL for 24 h.

The primary outcome measure: postoperative drainage volume

Secondary outcome measures: change in the esophageal temperature at the level of the subcarinal lymph nodes during lymphadenectomy and C-reactive protein levels 72 h after surgery.

Data collection:

1. Preoperative data: baseline characteristics, comorbidities, results of pulmonary function tests, laboratory tests results, and results of preoperative risk assessment.
2. Surgery data: approach, type of lobectomy, numbers of lymph nodes and lymph node stations removed, duration of surgery, and estimated blood loss, esophageal temperature

3. Postoperative data: ICU admission, 24-hour and 48-hour and total volume of chest tube drainage, chest tube duration, laboratory evaluation of the pleural fluid composition after 24-hours (WBC, triglycerides, albumin), hospital stay, complications