A RANDOMISED CONTROLLED TRIAL COMPARING
COMBINED EBUS/EUS FOLLOWED BY SURGICAL STAGING
VERSUS SURGICAL STAGING ALONE IN NON-SMALL CELL
LUNG CANCER: THE ASTER STUDY

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Background For many years the standard approach to staging of the
mediastinum in non-small cell lung cancer (NSCLC) has been surgical
using cervical mediastinoscopy, left anterior mediastinotomy or video
assisted thoracoscopic surgery (VATS). More recently endobronchial
ultrasound (EBUS) and endoscopic ultrasound (EUS) have been
reported. We conducted a randomised phase III trial to compare
surgical staging versus endoscopic staging. The primary endpoint was
detection of mediastinal nodal metastasis (N2/3); secondary
endpoints were complication and futile thoracotomy rates.

Methods Consecutive patients with potentially resectable
(suspected) NSCLC in whom invasive mediastinal staging was
indicated based on CT or PET-CT findings were randomly assigned
to either Arm A, surgical staging or Arm B, combined EBUS/EUS
(followed by surgical staging if endoscopic findings were negative for
malignancy). Surgical staging involved mediastinoscopy and/or
mediastinotomy and/or VATS. Subsequently, in the absence of
mediastinal disease, thoracotomy with systematic lymph node
sampling was performed. 240 pts were required to show a 20% increase in sensitivity (power 80% and α=0.05) to detect mediastinal
nodal disease with a prevalence of 50%.

Results 118 patients were randomised to Arm A and 123 to Arm B.
The sensitivity for detection of mediastinal metastases by surgical
staging in Arm A was 80% (95% CI, 68 to 89) vs 94% (95% CI, 85 to
98) for endoscopic (≥ surgical) staging in Arm B (p=0.04). Nodal
metastases were found in 41 (35%) of surgically staged patients in
Arm A and 62 patients (50%) (56 by EBUS/EUS + 6 by subsequent
surgical staging) in Arm B (p=0.019). Overall, the prevalence of
mediastinal disease in each arm was similar (p=0.24). Thoracotomy
was considered futile in 21 (18%) in those staged in Arm A vs 8
patients (7%) in Arm B (p=0.009). Complication rate was similar in
both arms (6 vs 7 patients, p=0.8); however, 12 of 13 complications
were due to surgical staging procedures.

Conclusions Mediastinal staging for NSCLC should commence
with combined EBUS/EUS (followed by surgical staging if endoscopic
findings are negative for malignancy) as this improves the detection
of nodal metastases and reduces futile thoracotomies compared to
surgical staging alone.