ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

*Annals of Oncology* 30 (Supplement 2): ii26–ii30, 2019
doi:10.1093/annonc/mdz064

# EARLY STAGE NSCLC

## 680 Electromagnetic navigation bronchoscopy in the European cohort of the prospective, multicenter NAVIGATE study

K. Lau[1], J. Flandes[2], M. Christensen[3], M. Bezzi[4], B. Lamprecht[5], M. Salio[6], J.M. Vergnon[7], M. Studnicka[8], M. Trigiani[4], I. Fernandez[2], R. Kropfmüller[5], E. Barisione[6], N-E. Viby[3], S. Khandhar[9], E. Folch[10]

[1]*Cardiothoracic Surgery, St. Bartholomew's Hospital, London, UK,* [2]*University Hospital "Fundacion Jimenez Diaz", Madrid, Spain,* [3]*Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark,* [4]*Azienda Ospedaliera Universitaria Careggi, Florence, Italy,* [5]*Department of Pulmonology, Kepler University Hospital, Linz, Austria,* [6]*IRCCS AOU San Martino - IST-Istituto Nazionale per la Ricerca sul Cancro, Genoa, Italy,* [7]*CHU University Hospital of St Etienne, St. Etienne, France,* [8]*Paracelsus University Hospital Salzburg, Salzburg, Austria,* [9]*Inova Health System, Fairfax Hospital, Falls Church, VA, USA,* [10]*Massachusetts General Hospital, Boston, MA, USA*

**Background:** Electromagnetic navigation bronchoscopy (ENB) is an image-guided approach to access peripheral pulmonary lesions. ENB has been evaluated in a prospective global study (NAVIGATE, NCT02410837, Khandhar, BMC Pulm Med 2017;17:59). Practice patterns and safety specifically in the full European cohort have not yet been presented. The objective of this study is to evaluate ENB safety and usage in the NAVIGATE European sites.

**Methods:** NAVIGATE is a global, prospective, multicenter study of ENB (superDimension$^{TM}$ navigation system) use in community and academic settings. A prespecified 1-month interim analysis was conducted of the European cohort.

**Results:** Subjects ($n = 175$) were enrolled at 8 European sites, with complete 1-month follow-up in 99.4%. ENB was used to aid in lung biopsy in 99.4% (174/175) and fiducial marking in 8.0% (14/175). Lymph node sampling was attempted in 12 procedures (9 using linear EBUS). General anesthesia was used in 57%, radial EBUS in 4.0%, cone-beam CT in 9.7%, fluoroscopy in 41.7%, and rapid on-site evaluation (ROSE) in 17.9%. The median lesion size was 18.0 mm. Lesions were in the peripheral third of the lung in 72.7% and the upper lobe in 62.6%. A bronchus sign was present in 66.8%. Navigation was successful in 96.6% of biopsy cases. The median ENB planning time was 12.5 minutes. The median total procedure time (bronchoscope in to bronchoscope out) was 43.5 minutes, which included 32.9 minutes of ENB-specific navigation/sampling time (first entry to last exit of the locatable guide or extended working channel). The ENB-related pneumothorax rate was 7.4% (13/175), 5.1% requiring intervention or hospitalization. The ENB-related Common Terminology Criteria for Adverse Events Grade $\geq 2$ bronchopulmonary hemorrhage and Grade $\geq 4$ respiratory failures rates were 2.3% and 0.6%, respectively. Longer follow-up is required to assess diagnostic yield.

**Conclusions:** The results from the European cohort of the NAVIGATE study suggest that ENB provides a safe platform to aid in lung lesion biopsy. ENB also allows multidimensional lung lesion biopsy, fiducial placement, and concurrent lymph node sampling during a single anesthetic event.

**Clinical trial identification:** NCT02410837. First posted April 8, 2015.

**Editorial acknowledgement:** Medical writing support was provided by Kristin L. Hood PhD of Medtronic, in accordance with Good Publication Practice (GPP3) guidelines.

**Legal entity responsible for the study:** Medtronic.

**Funding:** Medtronic.

**Disclosure:** K. Lau, M. Christensen, M. Bezzi, B. Lamprecht, M. Salio, J.M. Vergnon, M. Studnicka, M. Trigiani, I. Fernandez, R. Kropfmüller, E. Barisione, N-E. Viby: Research funding to institution for participating in the Medtronic-sponsored NAVIGATE study. J. Flandes: Consulting fees, research funding to institution: Medtronic (Steering Committee, study principal investigator); Consulting fees: BTG-PneumRx, Olympus, Ambu, PulmonX, Boston Scientific; Research grant support: BTG-PneumRx. S. Khandhar: Consulting fees: Medtronic (study principal investigator and Steering Committee, clinical advisory board); Advisory board: Boston Scientific; Research funding to institution: Medtronic-sponsored NAVIGATE study; Stock ownership: TransEnterix. E. Folch: Consulting fees: Medtronic (study principal investigator, Steering Committee, clinical advisory board); Scientific advisory board: Boston Scientific.