MA05.02
Electromagnetic Navigation Bronchoscopy: A Prospective, Global, Multicenter Analysis of 1000 Subjects with Lung Lesions

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Background: Electromagnetic navigation bronchoscopy (ENB) may aid in accessing smaller, more peripheral lesions and hence facilitate earlier diagnosis. ENB may also provide a safer alternative to transthoracic biopsy, and allow adequate tissue capture for molecular testing, diagnosis, staging, and localization for surgery in a single anesthetic event. However, usage patterns, safety, and performance remain largely unexplored in a prospective, multicenter study.

Methods: NAVIGATE is a global, prospective, multicenter study of ENB using the superDimension™ navigation system (Medtronic, Minneapolis). A pre-specified 1-month interim analysis was conducted on the first 1,000 primary cohort subjects enrolled at 29 centers in the United States and Europe. Enrollment and 2-year follow-up are ongoing.

Results: One-month follow-up was completed in 933/1,000 subjects. Of 1,000 procedures, ENB was intended for lung biopsy in 96.4%, to place fiducial markers in 21.0%, and for dye marking in 1.7% (multiple indications in 34.9%). Lymph node biopsies were attempted in 33.4% of procedures (322/334 using linear endobronchial ultrasound [EBUS]). General anesthesia was used in 79.7% and radial EBUS in 54.3%. Among 1,129 lung lesions, fluoroscopy was used in 90.1% and rapid on-site pathology evaluation in 683/1035 (66.0%). Median lesion size was 20.0 mm (interquartile range 16.0 mm). Most lesions were in the peripheral (62.6%) or middle (30.1%) lung thirds. A bronchus sign was present in 48.4% and 6.3% were ground glass. Navigation was subjectively considered successful in 1,036 lesions (91.8%). Site-reported pathology results were read as malignant in 452 lesions (43.6%), including 38.1% with primary lung cancer. Of 247 lesions with adenocarcinoma or unspecified non-small-cell lung cancer, 70 (28.3%) were sent for molecular testing with adequate tissue in 56/70 (80.0%). Primary lung cancer clinical stage was 52.9% I; 10.7% II, 18.9% III, and 17.3% IV. Preliminary non-malignant results were obtained in 444 lesions (42.9%). An additional 140 lesions (13.5%) were read as inconclusive. Longer follow-up is required to calculate the true negative rate and diagnostic yield. ENB-related pneumothorax was 4.9% (49/1,000) overall and 3.2% Grade $\geq$2 based on the Common Terminology Criteria for Adverse Events scale. The ENB-related Grade $\geq$2 bronchopulmonary hemorrhage and Grade $\geq$4 respiratory failures rates were 1.0% and 0.6%.

Conclusion: Interim 1-month results suggest a low adverse event rate in the largest prospective, multicenter ENB study conducted to date. Continued enrollment and 2-year follow-up will elucidate the real-world utilization patterns, diagnostic yield, factors contributing to successful diagnosis, and the impact of ENB on lung cancer management.

Keywords: prospective clinical study, Electromagnetic Navigation Bronchoscopy, Image-Guided Biopsy, lung cancer diagnosis

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A Single EBUS-TBNA Pass Yields Sufficient DNA for Targeted Molecular Testing in Lung Cancer

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Background: Development of drugs that target molecular pathways in lung cancer has made it increasingly important for diagnostic sampling to yield sufficient material for genotyping. At the same time, minimally invasive sampling techniques such as endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) result in smaller volume cytological specimens. It has been shown that at least 3 EBUS-TBNA passes per lesion are sufficient for cytological subtyping. However, the number of passes needed for mutational subtyping is unclear. We sought to determine the adequacy of a single EBUS-TBNA for genotyping clinically actionable mutations.

Methods: Patients undergoing EBUS-TBNA for diagnosis of lung cancer were prospectively recruited. Paired samples from the same target lesion were obtained. The "reference" sample was the routine diagnostic specimen consisting of $\geq$3 passes, whereas the "study" sample comprised a single pass. DNA was extracted from both