

Late-Breaking

SESSION TITLE: Late Breaking Lung Cancer and Tobacco Cessation Posters

SESSION TYPE: Original Investigation Posters

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PROSPECTIVE, MULTICENTER ANALYSIS OF SHAPE-SENSING ROBOTIC-ASSISTED BRONCHOSCOPY: UPDATES FROM THE PRECISE STUDY

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PURPOSE: Current evidence for shape sensing robotic-assisted bronchoscopy (SSRAB) have reported yields of 80% or above with pneumothorax rates < 4%, however, have been limited to single-center experiences. Data from the largest electromagnetic navigation bronchoscopy study reported a yield of 70% and sensitivity of 66% with a pneumothorax rate of 4%. This analysis provides preliminary updates from the first multicenter study evaluating SSRAB (Ion Endoluminal System).

METHODS: Subjects with PPNs 10-30mm in greatest diameter were enrolled across multiple study stages. All subjects where the SSRAB system was used were evaluated for peri-procedural safety outcomes. Subjects with a non-malignant diagnosis were followed 12 months post-procedure. Sensitivity for malignancy, diagnostic yield and procedural characteristics were evaluated in the performance analysis. Sensitivity for malignancy was calculated by true positive samples divided by all subjects with cancer. A procedure was considered diagnostic if a malignant or benign specific condition was reported by the performing bronchoscopist based on samples obtained via the SSRAB procedure.

RESULTS: A total of 365 subjects had an SSRAB procedure between March 2019 and May 2021. All subjects were considered for the safety analysis; 129 subjects, enrolled between August 2019 and May 2021, were considered for this pre-specified performance stage analysis. In the performance population, median nodule diameter was 16 mm (IQR²⁵⁻⁷⁵ 13, 21) with median generation location of 7 (IQR²⁵⁻⁷⁵ 6, 8). CT Bronchus sign was present in 25% of cases. Median procedure time was 52 min (IQR²⁵⁻⁷⁵ 37, 75); navigation success (catheter tip within 2cm of virtual target) was achieved in 97% of cases and rEBUS visualization in 84%. Ninety-seven subjects were eventually proven to have cancer; sensitivity for malignancy was 84/97 (87%, 95% CI: 78-93%). Sensitivity for malignancy in subjects with vs. without a CT bronchus sign was 22/25 (88%) and 62/72 (86%) respectively (p=1). Diagnostic yield was 104/129 (81%, 95% CI: 73-87%) and for subjects with vs. without a CT bronchus sign was 26/32 (81%) and 78/97 (80%) (p=1). All pneumothoraces and those requiring intervention were reported as 14/365 (4%, 95% CI: 2-6%) and 5/365 (1%, 95% CI: 0.5-3%); airway bleeding requiring wedging or balloon tamponade (Nashville grade ≤ 3) was reported as 3/365 (0.8%, 95% CI: 0.2-2%).

CONCLUSIONS: Initial results from the first SSRAB multicenter study demonstrate a strong safety profile, with a high sensitivity for malignancy and diagnostic yield for nodules with a median size of 16mm, and comparable results in cases regardless of bronchus sign.

CLINICAL IMPLICATIONS: Multicenter results show PPN biopsy with the SSRAB system may reproducibly facilitate the diagnosis of early stage cancer or metastatic disease, with a favorable safety profile.

DISCLOSURES:

Consultant relationship with Siemens Please note: \$1001 - \$5000 by Roberto Casal, value=Consulting fee

Consultant relationship with Bronx Please note: \$1-\$1000 by Roberto Casal, value=Consulting fee

Consultant relationship with Intuitive Surgical Please note: \$1-\$1000 by Roberto Casal, value=Consulting fee

Consultant relationship with Olympus Please note: \$20001 - \$100000 by Roberto Casal, value=Grant/Research

Consultant relationship with Ion Intuitive Please note: 01/01/2022 Added 06/06/2022 by Javier Diaz-Mendoza, value=Honoraria

No relevant relationships by Sebastian Fernandez-Bussy

Scientific Medical Advisor relationship with Boston Scientific Please note: Ongoing by Erik Folch, value=Consulting fee

Scientific Medical Advisor relationship with Medtronic Please note: Ongoing by Erik Folch, value=Consulting fee

Grant support to my institution relationship with Intuitive Surgical Please note: Current by Erik Folch, value=Grant/Research Support

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