American Association for Bronchology and Interventional Pulmonology

Demographic and Lesion Characteristics in the First 443 Subjects Enrolled in a Multicenter Observational Real-World Robotic Bronchoscopy Study: Interim Results From TARGET

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Background & Objectives

- The Transbronchial Biopsy Assisted by Robot Guidance in the Evaluation of Tumors of the Lung study (**TARGET**), is a single arm, multi-center, prospective, real-world observational study of Robotic Assisted Bronchoscopy (RAB) using the MONARCH® Platform (Auris Health, Inc.)
- The objective of the study is to evaluate the safety and diagnostic accuracy of RAB with tissue acquisition (needle aspiration and forceps biopsy) performed with the MONARCH Platform in a broad range of patients with pulmonary lesions in routine clinical practice at multiple centers
- No formal hypothesis was tested

We report results of an interim analysis of:

the first **443** subjects at **18** sites

96% Interventional Pulmonologist; 4% Thoracic Surgeon

Methods

Following IRB approval and patient informed consent, 443 subjects, at least 21 years of age, were enrolled at 18 sites, according to the study inclusion and exclusion criteria, and underwent successful diagnostic RAB with tissue acquisition using the MONARCH Platform.

Inclusion Criteria

- Lung lesions, **8 mm to 50 mm in size**, requiring bronchoscopic diagnosis which were identified on CT scan within 28 days of the intended bronchoscopy

Exclusion Criteria

- Patients with endobronchial involvement of the target lesion as evidenced on chest CT scan were excluded

Follow Up

- Subjects with malignant diagnosis were followed up to 7 days post-procedure
- Subjects without a malignant diagnosis were followed for 3, 6, 9, 12, 18, and 24 months, or until receiving a definitive diagnosis

Conclusions

- In this interim analysis of a large multicenter prospective real-world observation study, RAB with the MONARCH Platform generated high navigation success **(97.5%)** and nodule localization by rEBUS **(91%)**
- With respect to lesion characteristics, **52.9%** of lesions were ≤5 mm from a pleural surface; **37.9%** of lesions were on the pleural surface; **48.0%** of lesions were in the peripheral third of the lung; the median lesion size was **18.5 mm**; and **12.7%** of lesions were subsolid
- Compared to a prior prospective study of the MONARCH Platform[1], nodule size appears smaller, procedure time is shorter, and subsolid pulmonary nodules have been included in this study

Enrollment is ongoing. Data with respect to safety, diagnostic yield, and additional study endpoints will be reported following conclusion of the study and final analyses.

Results

Patient Demographics

443 Subjects

56.4% Female **43.6%** Male

68.1 Mean age, years (SD=10.4; Range: 31-90)

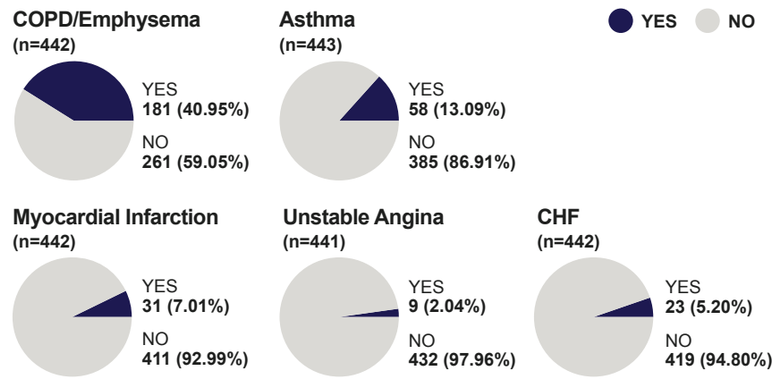
81.7% No family history of lung cancer

65.7% No family history of ex-thoracic malignancies

58.6% Prior smokers

20.1% Current smokers

Comorbidities



Lesion Characteristics

Pre-Procedure Probability of Malignancy* (n=440)

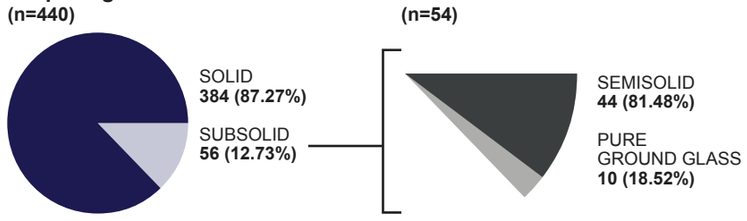
*Investigator estimated

18.5 mm Median lesion size

58.2% Lesion size ≤20 mm

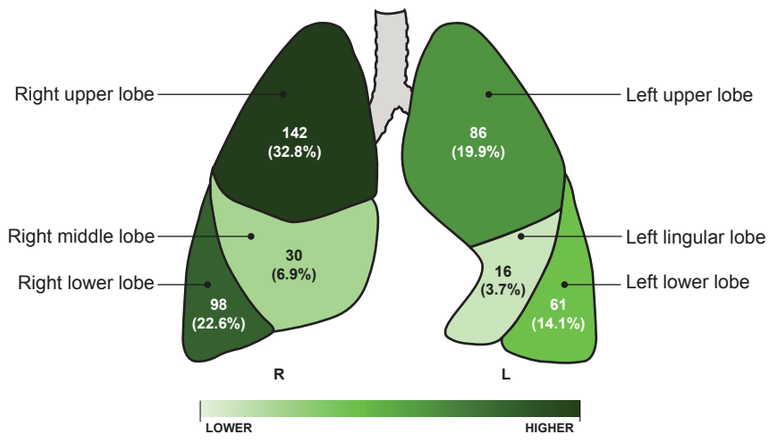
59.8% Bronchus sign present

Morphologic Features (n=440)



Subsolid Nodules (n=54)

Lesion Frequency by Lobe (n=443)



Procedural Characteristics

The mean RAB time during the procedure was 38.4 mins (SD=16.6)

Cone Beam Computed Tomography (CT) Used at 8 Sites

Cone Beam CT Used (n=443)

Procedural Identification of Lesions

Distance of Nodule to Pleural Surface in mm

Median distance to the closest pleural surface was 5.0 mm, with 52.9% of lesions ≤5 mm from the pleura and 37.9% of lesions on a pleural surface.

Reference: 1. Chen AC, Pastis NJ, Mahajan AK, et al. Robotic Bronchoscopy for Peripheral Pulmonary Lesions: A Multicenter Pilot and Feasibility Study (BENEFIT). *CHEST.* 2021;159(2):845-852.

Disclosures: Septimiu Murgu*, Daniel Sterman, Kazuhiro Yasufuku*, Alexander Chen, and Gerard Silvestri* are members of the TARGET Study Steering Committee; *receive consulting fees or study funding from Auris Health, Inc. Jaime Connelly, Balaji Laxmanan, Samaan Rafeq, and Mangqi Xiao are employees of Johnson & Johnson.

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