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A PROSPECTIVE MULTICENTER EVALUATION OF SHAPE-SENSING ROBOTIC-ASSISTED BRONCHOSCOPY WITH INTEGRATED MOBILE CONE-BEAM COMPUTED TOMOGRAPHY: INTERIM RESULTS FROM THE CONFIRM STUDY

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Authors: [Bryan Husta](#), Hitesh Batra, George Cheng, Janani Reisenauer, William Bartek, Aline Zouk, Or Kalchiem-Dekel, Niral Patel, Scott Oh, Roberto Casal; United States of America**Background**

Shape-sensing robotic-assisted bronchoscopy (ssRAB, Ion® Endoluminal System, Intuitive) was recently integrated with mobile CBCT (mCBCT, Cios Spin®, Siemens Healthineers) to enhance the ability to correct for observed CT-to-body divergence. The fully integrated system automatically sends an intraprocedural CBCT scan to the ssRAB system, allowing for target position updates as needed. The purpose of this analysis is to report preliminary results from the first prospective multicenter study evaluating the integration of ssRAB and mCBCT in small pulmonary nodules.

Methods

Patients with PPNs ≤ 20 mm in greatest dimension where ssRAB and mCBCT were planned for use were enrolled across 6 centers. Samplings were performed in accordance with investigators' practice, including radial endobronchial ultrasound (rEBUS), Flexision® Biopsy Needles, forceps, brush, and/or cryoprobe. Tool-in-nodule (TIN) was confirmed radiographically via a confirmatory mCBCT spin, or diagnostic biopsy in the absence of a confirmatory spin. Subjects with non-malignant biopsy results are followed for 12 months. Diagnostic yield was assessed by two methods: "strict" – including only malignant and specific benign diagnoses at the time of index biopsy, and "intermediate" with inclusion of patients with non-specific benign findings consistent with the patient's clinical presentation, requiring radiographic follow-up or confirmatory biopsy. Atypia or normal lung elements are considered non-diagnostic for both definitions.

Results

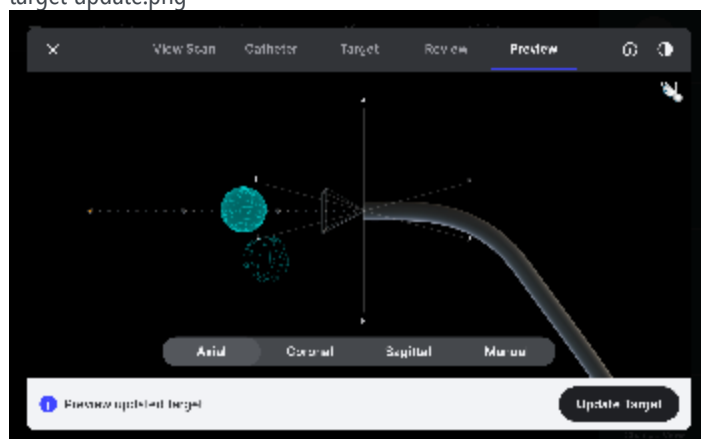
A total of 155 patients were enrolled from February to December 2023; follow-up is ongoing. Median nodule diameter was 14.0 mm (IQR 11.0-17.0). CT bronchus sign was present in 26.5%. Median distance to pleura and airway generation was 8.2 mm (IQR 1.8-20.0) and 7 (IQR 6-8) respectively. Median procedure time was 45.0 min (IQR 35.0-56.5). TIN was achieved in 99.4% (154/155), with a median of 2.0 (IQR 1.0-2.0) mCBCT spins (inclusive of TIN confirmatory spin). Strict diagnostic yield was 89.0% (138/155, 95%CI [83.0-93.5]); intermediate diagnostic yield was 91.0% (141/155, 95%CI [85.3-95.0]) with yield for 5-13.9 mm and 14-20 mm nodules 90.9% (70/77) and 91.0% (71/78) respectively. There were no (0%), pneumothoraces of any kind, and intra-procedural bleeding (Nashville ≥ 3) was 1.3% (2/155, 95%CI [0.2-4.6]).

Conclusion

This prospective multicenter study shows that the integration of ssRAB with mCBCT enables the diagnosis of small (≤ 20 mm) peripheral pulmonary nodules regardless of bronchus sign. The integrated systems enable precise tool placement while mitigating CT-to-body divergence, demonstrated through high rates of tool-in-nodule and a high diagnostic yield approaching those reported for CT-guided biopsy. Notably, no pneumothoraxes were reported, demonstrating an excellent safety profile for these integrated, complementary technologies.

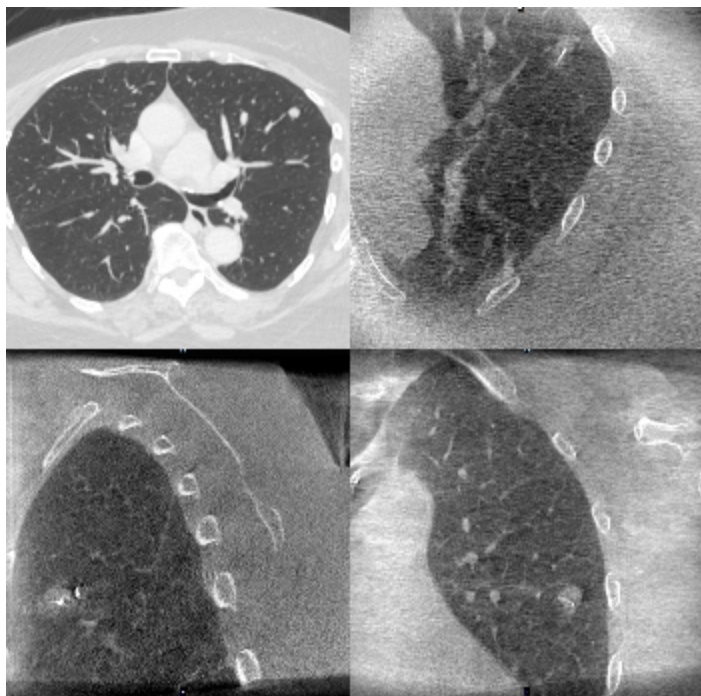
Image and Table

target update.png



[enlarge](#)

Representative image of Ion Controller touchscreen when utilizing the integrated update target location feature (courtesy of Intuitive Surgical) 7mmtil.png



[enlarge](#)

Patient with a sub-centimeter left upper lobe lung nodule who underwent shape-sensing robotic assisted bronchoscopy and achieved successful tool-in-lesion, confirmed on mobile cone-beam computed tomography.

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