A Prospective Multicenter Evaluation of Shape-Sensing Robotic-Assisted Bronchoscopy with Integrated Mobile Cone-Beam Computed Tomography: Interim Results from the CONFIRM Study

Clinical Publication Summary

Purpose
To report preliminary results from the first prospective multicenter study evaluating the integration of the Ion Endoluminal System (ssRAB) and Siemens Healthineers Cios Spin (mCBCT) in small pulmonary nodules.

Study design
Prospective, post-market, multicenter, single-arm study assessing biopsy procedures performed with ssRAB and mCBCT at six hospitals between February and December 2023.

Study sites
Memorial Sloan Kettering Cancer Center, New York, NY; University of Alabama, Birmingham, AL; UC San Diego Medical Center, San Diego, CA; Mayo Clinic, Rochester, MN; MD Anderson Cancer Center, Houston, TX; St. David's South Austin Medical Center, Austin, TX.

Outcomes measured
Primary: Rate of successful TIN, diagnostic yield of samples obtained via biopsy, and sensitivity of malignancy of the samples obtained via biopsy.*

Secondary: Total radiation dose,** time to achieve TIN,* number of Cios spins performed, procedure time, incidence of adverse events (AEs),* incidence of pneumothorax (overall and those requiring interventions), and physician cognitive workload assessed by NASA-TLX questionnaire.*

Abbreviations: mCBCT, mobile cone-beam computed tomography; ssRAB, shape-sensing robotic-assisted bronchoscopy.

* Outcome data not reported/available at the time of abstract but expected to be included in the study manuscript.

** Radiation dose was presented was part of a separate abstract, "Radiation dosage associated with shape sensing robotic-assisted bronchoscopy integrated with mobile cone beam computed tomography: Results from the CONFIRM Study," at AABIP.

At a glance
A total of 155 patients with peripheral pulmonary nodules (PPNs) ≤ 20 mm were enrolled from February to December 2023. Follow-up is currently ongoing. Samplings were performed in accordance with investigators' practice, including radial endobronchial ultrasound (rEBUS). A 3D spin with Cios was required to confirm tool-in-nodule (TIN). In the absence of a confirmatory spin, a diagnostic biopsy was also considered indicative of TIN. Strict diagnostic yield was assessed by both a strict and intermediate method. Findings of atypical or normal lung elements were considered nondiagnostic for both methods. Subjects with nonmalignant findings are followed for 12 months. Strict diagnostic yield was 89% (138/155). Intermediate diagnostic yield was 91% (141/155) with yield for 5-13.9 mm and 14-20 mm nodules 91% (70/77) and 91% (71/78), respectively. Median nodule diameter was 14 mm. There were no pneumothoraces of any kind, and intraprocedural bleeding (Nashville ≥ 3)[1] was 1.3% (2/155).

An abstract with this preliminary data was accepted for inclusion at the American Association for Bronchology and Interventional Pulmonology 2024 Annual Conference held in August. Diagnostic yield was updated to approximately 90% (139/155) at the time of the podium presentation.

Note: This study was funded by Intuitive Surgical.

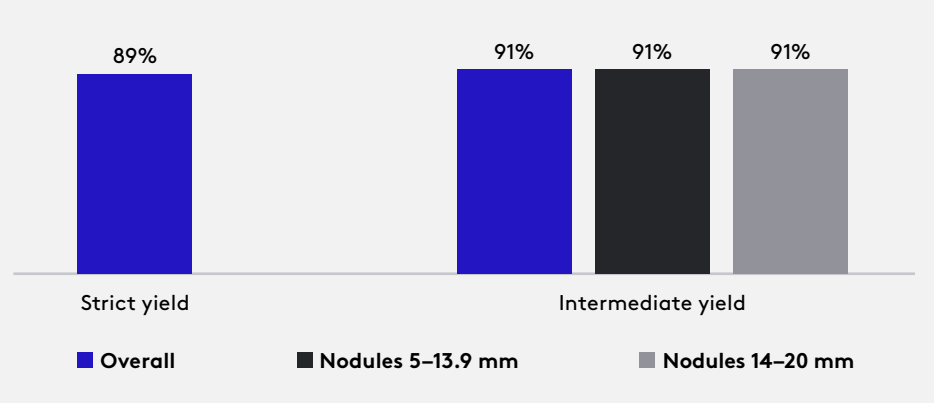
Patients

155

Median nodule diameter

14 mm

Key results
Diagnostic yield



Strict yield definition: Includes only malignant and specific benign diagnoses at the time of index biopsy.

Intermediate yield definition: Includes subjects with nonspecific benign findings consistent with the patient's clinical presentation, requiring radiographic follow-up or confirmatory biopsy. Intermediate yield is a trend and subject to change based on completion of subject follow-up.

Study strengths

- Diagnostic yield reported according to both a strict and intermediate definitions.
- Multicenter design increases confidence in the reproducibility of the results.

Study limitations

- Study results from six institutions can introduce variations in pathology interpretations.
- Mostly academic centers with experienced physicians; results may not be reproducible for all bronchoscopists.
- Follow-up is limited to 12 months and is ongoing at the time of this abstract.

Complications

Pneumothoraces of any kind

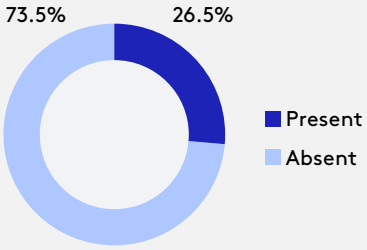
0%

Intraprocedural bleeding

1.3% (Nashville ≥ 3) (2/155)

Nodule characteristics

Bronchus sign



Median distance to pleura

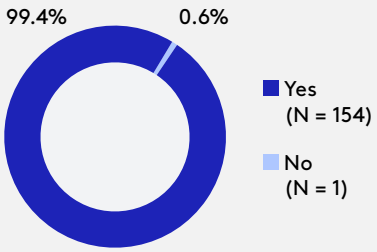
8.2 mm

Median airway generation

7

Procedure characteristics

TIN achieved



Median procedure time

45 min

Median mCBCT spins

2 (including TIN confirmatory spin)

Sources

Husta B, Batra H, Cheng G, et al. A prospective multicenter evaluation of shape-sensing robotic-assisted bronchoscopy with integrated mobile cone-beam computed tomography: interim results from the CONFIRM study. Abstract presented at: Annual Conference of American Association for Bronchology and Interventional Pulmonology; August 22, 2024; Charlotte, NC. Session 0430.

Reference

1. Folch EE, Mahajan AK, Oberg CL, et al. Standardized definitions of bleeding after transbronchial lung biopsy: a Delphi consensus statement from the Nashville Working Group. *Chest*. 2020;158(1):393-400. doi:10.1016/j.chest.2020.01.036

Financial

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Ion endoluminal system

The Ion endoluminal system (Model IF1000) assists the user in navigating a catheter and endoscopic tools in the pulmonary tract using endoscopic visualization of the tracheobronchial tree for diagnostic and therapeutic procedures. The Ion endoluminal system enables fiducial marker placement. It does not make a diagnosis and is not for pediatric use.

Information provided by the Ion endoluminal system or its components should be considered guidance only and not replace clinical decisions made by a trained physician.

For summary of the risks associated with bronchoscopy refer to www.davincisurgery.com/safety or www.intuitive.com/safety.

The Flexision biopsy needle is used with the Ion endoluminal system to biopsy tissue from a target area in the lung.

The PlanPoint software uses patient CT scans to create a 3D plan of the lung and navigation pathways for use with the Ion endoluminal system.

Important safety information

For risks, cautions, and warnings and full prescribing information, refer to the associated Ion System user manual(s). For summary of the risks associated with bronchoscopy refer to www.davincisurgery.com/safety or www.intuitive.com/safety.

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