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TO ROBOT OR NOT TO ROBOT: NAVIGATING THE NODULES IN PULMONARY PRECISION

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The clinical question

Is robotic-assisted bronchoscopy (RAB) inferior to electromagnetic navigational bronchoscopy (ENB) in efficacy and safety for patients undergoing peripheral pulmonary nodule biopsy?

Take Home Message

RAB is comparable to electromagnetic navigational bronchoscopy for diagnostic yield in peripheral pulmonary lesions, with comparable safety profiles and only minor differences in procedure times. Both methods can be considered appropriate options in the hands of experienced operators.

Background

Peripheral pulmonary lesions represent a frequent indication for advanced diagnostic bronchoscopy, with ENB and RAB representing two major technologies for navigational guidance. While both platforms have been widely adopted in clinical practice and cleared through the FDA's 510(k) pathway, comparative effectiveness data remained sparse. RAB offers advantages such as improved catheter stability and articulation, while ENB benefits from established workflow. The RELIANT study was developed in response to the need for high-quality comparative data to inform technology selection and guide future device trials in interventional pulmonology.

Study design

-Study design

- Type: Investigator-initiated, single-center, cluster-randomized, open-label, pragmatic non-inferiority trial.
- Randomization: Conducted at the level of operating room assignment, with rooms randomized daily to RAB or ENB.

-Interventions:

- RAB group: Ion shape-sensing robotic platform (Intuitive Surgical) with cone-beam CT available at the bronchoscopist's discretion.
- ENB group: Illumisite electromagnetic platform (Medtronic) with integrated digital tomosynthesis at the bronchoscopist's discretion.

-Primary Outcome: Diagnostic yield (proportion of cases with lesional tissue adequate for diagnosis, adjudicated by blinded pathology).

-Secondary Outcomes: Procedure duration, complication rates (including pneumothorax, hemorrhage, respiratory or anesthetic complications) within 7 days of procedure

Population

- Inclusion criteria
  - Age ≥18 years
  - Scheduled for navigational bronchoscopy for a peripheral pulmonary lesion
- Exclusion criteria
  - Enrollment in another clinical trial requiring ENB
  - Declined participation
- Baseline characteristics
  - Enrollment: March 2023 – April 2024
  - Total enrolled: 447 patients; analyzed: 411 (RAB 203, ENB 208)
  - Median age: 67 years (IQR 60–74.5); 48.9% women
  - Sex: Approximately 48.9% female.
  - Smoking Status: 21.4% current smokers and 46.5% former smokers.
  - Comorbidities: 22.6% had concurrent malignancies and 35.0% had a history of prior malignancy.
  - Lesion Characteristics:
    - Most lesions were solid and located in the peripheral (outer third) region of the lungs.
    - Median lesion size was 19 mm (IQR 13–28 mm).
    - Presence of bronchus sign (airway leading directly to the lesion) in 58.4% of lesions.

    - Spiculated nodules present in 30.5% of RAB patients vs. 19.7% in ENB patients.
- Procedure-related variables:
    - 99.5% of RAB-assigned patients underwent RAB; 100% of ENB-assigned patients underwent ENB.
    - Intraprocedural imaging: cone beam CT used in 54.2% of RAB cases; digital tomosynthesis in 66.8% of ENB cases.
- Sampling Techniques:
    - Transbronchial needle aspiration was the most used technique (99.0% RAB vs. 97.6% ENB).
    - Cryobiopsy was used in 38.4% of RAB and 36.5% of ENB patients.
    - Forceps biopsy used in 25.6% of RAB and 33.2% of ENB cases.
- Overall, no significant differences in baseline characteristics between groups except for spiculation.

Outcomes

- **Primary outcome**
    - **Diagnostic Yield:**
        - Lesional tissue obtained:
            - RAB: 77.8% (158/203)
            - ENB: 75.5% (157/208)
        - Odds ratio (OR) for diagnostic yield was 1.18 (lower boundary of 90% confidence interval CI: 0.75), with a p-value for non-inferiority = 0.007, demonstrating that RAB is non-inferior to ENB.
        - No significant superiority was observed (OR 1.23; 95% CI: 0.73 to 2.07).
        - Sensitivity analyses including reclassification of certain inflammatory cases maintained the non-inferiority result (RAB 76.4% vs ENB 75.0%; p = 0.01).
    - **Subgroup Analysis**
        - Nodule size was a significant effect modifier (p for interaction = 0.007).
        - RAB showed higher odds of diagnostic yield in nodules sized 15–30 mm (OR 2.93; 95% CI 1.34–6.39).
        - Other factors, such as lesion density, peripheral location, and presence of bronchus sign, did not significantly modify the outcome.
    - **Use of Intraprocedural Imaging:**
        - Among RAB patients who underwent cone beam CT (54.2%), diagnostic yield was 77%.

        - Among ENB patients who underwent digital tomosynthesis (66.8%), diagnostic yield was 71%.
        - The decision to use imaging was driven by non-diagnostic initial results or absence of a radial endobronchial ultrasound signature.
- **Secondary outcomes**
    - **Procedure Duration:**
        - RAB: Median 37 minutes (IQR 29–48)
        - ENB: Median 32 minutes (IQR 25–43)
        - RAB procedures were ~5 minutes longer, not clinically significant in most settings.
    - **Adverse events/Complications:**
        - RAB: 5 events (2.5%)
        - ENB: 12 events (5.8%)
        - Most common: pneumothorax (RAB: 4; ENB: 6); overall safety profiles similar.
        - No significant subgroup effect modifiers observed except for intermediate-sized nodules (15–30 mm) favoring RAB (OR 2.93; 95% CI: 1.34–6.39).

Commentary

Study strengths:

- First cluster-randomized, pragmatic trial comparing RAB and ENB for peripheral pulmonary lesions, establishing a high standard for device trials in interventional pulmonology.
- Randomization and allocation concealment minimized selection bias; broad eligibility and high enrollment increased real-world relevance for experienced centers.
- Blinded outcome adjudication, strong group adherence, and standardized protocols improved internal validity. Subgroup findings regarding intermediate nodule size offer practical clinical insights.

Study limitations:

- The single-center design and exclusive use of highly skilled operators limit the extrapolation to less-experienced settings; questions regarding training, workflow impact, and the learning curve remain unanswered.
- Patient-centered metrics (such as comfort, cost-effectiveness, and workflow efficiency), long-term outcome data, and downstream clinical impacts were not evaluated, leaving gaps in determining real-world technology adoption.

- Imbalance in lesion spiculation, differences in imaging integration between platforms, and exclusion of novice proceduralists all limit broader generalizability.
- The additional procedure time for RAB, while statistically significant, is likely irrelevant clinically in most settings; however, could matter for high-volume or resource-limited institutions.
- No data on post-procedural management benefit, survival, or cost/resource allocation further limit holistic assessment and recommendations for technology use.
- Use of adjunct equipment was not standardized or controlled for. Questions regarding the benefit of cone beam CT utilization remain unanswered, but for this, we look forward to the results of the RELIANT-II study.

Overall, robotic-assisted bronchoscopy is non-inferior to electromagnetic navigation for diagnostic yield and safety in peripheral pulmonary lesion biopsy. With similar complication rates and only modest differences in procedure times, either platform is a reasonable choice for expert operators. However, questions about broad technology adoption, including cost, workflow, training, and long-term outcomes, remain, underscoring the need for further multicenter and patient-centered studies to guide optimal device selection in diverse clinical environments

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Suggested Reading

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