AABIP JOURNAL CLUB

Navigational bronchoscopy or transthoracic needle aspiration for lung nodules? Let's talk about the data!

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The clinical question

Is the diagnostic accuracy of navigation bronchoscopy non-inferior to that of transthoracic needle aspiration?

Take Home Message

Solitary lung nodule biopsy via navigational bronchoscopy is not inferior to transthoracic needle biopsy in patients with nodules 10-30mm in size and >10% pre-test probability of cancer. The navigational bronchoscopy group also demonstrated a statistically significant (p=0.003) lower risk for overall complications following biopsy.

Background

Navigational bronchoscopy and transthoracic needle biopsy are techniques for biopsy of peripheral lung nodules. The reported accuracy of transthoracic needle biopsy has been up to 90% with up to 25% pneumothorax risk. Navigational bronchoscopy has a pooled estimate of accuracy up to 70% in previous meta-analysis and a pneumothorax rate of 2%.

These estimates have been derived from single group studies that had a high risk of selection, referral and publication bias.

Study Design

Type of trial: Investigator-initiated, multi-center, open label, randomized, parallel group, non-inferiority trial

Primary outcome: Diagnostic accuracy of lung nodule biopsy via both methods.

Intervention: n=121 received assigned navigational bronchoscopy intervention, n=113 received assigned transthoracic needle biopsy.

Population

Inclusion criteria:
Adult patients with a single peripheral, intermediate pulmonary nodule measuring 10 to 30mm in diameter and a calculated pretest probability of cancer of at least 10%

Exclusion criteria:

- Nodule accessible without navigation (central endobronchial lesion)
- The patient had a separate condition for which linear endobronchial ultrasound-guided needle aspiration was indicated (mediastinal or hilar adenopathy)
- If empirical treatment with stereotactic body radiation therapy was planned regardless of the results or if a biopsy was not feasible by means of either biopsy approach

Baseline Characteristics:

- Navigation Bronchoscopy (n=121), Transthoracic Needle Biopsy (n=113)
- Median age (years): 66 (NB/TBNA), 68 (TTNA)
- Nodule median diameter (mm): 15 (NB/TBNA), 14 (TTNA)
- Lung zone (%): outer third 88.4%, middle third 11.6% for Navigation Bronchoscopy group; outer third 83.2%, middle third 16.8% for Transthoracic Needle Biopsy group.
- Median pretest probability for cancer 75% across groups.

Outcomes

Primary outcomes:

- Diagnostic accuracy was found to be 79% in the navigational bronchoscopy group and 73.6% in the transthoracic needle biopsy group through 12 months of clinical follow up, absolute difference 5.4 percentage points; 95% confidence interval [CI] (-6.5 to 17.2) P=0.003 for noninferiority, P=0.17 for superiority.

- Trough 12 months of clinical follow up for patients in whom a specific benign condition was diagnosed, 0 patients in the navigational bronchoscopy group in were reclassified as malignant and 4 patients in the transthoracic needle biopsy group were reclassified as malignant based on subsequent findings.

Secondary outcomes:

- Median duration of the procedure was 36 minutes for navigational bronchoscopy and 25 minutes for transthoracic needle biopsy.

- An invasive procedure was pursued after the biopsy that was performed during the trial in 13.2% of patients in the navigational bronchoscopy group and in 13.3% of those in the transthoracic needle biopsy group.

Adverse events:

- A procedural complication occurred in 6 /121 (5%) of patients in the navigational bronchoscopy group and in 33/113 (29.2%) in the transthoracic needle biopsy group; absolute risk difference 24.2 percentage points, 95% CI (15.0 to 35.6).

- Pneumothorax was the most common complication, occurring in 4 patients (3.3%) in the navigational bronchoscopy group and in 32 (28.3%) in the transthoracic needle aspiration group; absolute risk difference 25 percentage points, 95% CI (15.3 to 34.8). Although, intervention (chest tube placement and/or hospital admission) was only required in 1 (0.8%) in the navigational bronchoscopy group and in 13 (11.5%) in the transthoracic needle biopsy group.

- No hemorrhages resulting in intervention occurred and there were no deaths during the 12-month follow-up period of the primary analysis.

Commentary

The VERITAS trial is a multi-center, randomized, parallel-group, non-inferiority study evaluating the diagnostic accuracy of navigational bronchoscopy and transthoracic needle biopsy. This study is a first of its kind to evaluate a critical evidence gap by prospectively evaluating two widely used diagnostic strategies in a head-to-head comparison.

There were several strengths including prompt screening for eligibility upon lung nodule referral, a representative patient population, variability of academic/community centers across different geographic regions, an independent panel for adjudication of technical feasibility for both biopsy methods and a deliberate conservative approach to define the primary outcome.

There were several limitations, as well, such as the level of expertise of the pulmonologists performing the navigational bronchoscopy, which may not generalize to other centers, the use of rapid onsite cytologic evaluation most commonly during navigational bronchoscopy, potentially affecting the diagnostic accuracy and the use of cross-sectional imaging during transthoracic needle biopsy, identifying the presence of pneumothorax in the transthoracic needle biopsy group.

Ultimately, the results of the trial showed that the diagnostic accuracy of navigational bronchoscopy was non-inferior to that of transthoracic needle biopsy and led to fewer complications, suggesting that the former should be the procedure of choice for biopsy of intermediate lung nodules that appear to be technically amenable to both approaches. These findings also suggest the importance of procedural expertise, access to ancillary tools such as ROSE and careful patient selection when choosing between percutaneous or bronchoscopy sampling of peripheral lung nodules.

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Suggested Reading

1. Folch EE, Pritchett MA, Nead MA, Bowling MR, Murgu SD, Krimsky WS, et al. Electromagnetic Navigation Bronchoscopy for Peripheral Pulmonary Lesions: One-Year Results of the Prospective, Multicenter NAVIGATE Study. Journal of Thoracic Oncology [Internet]. 2019 Mar 1;14(3):445–58.
2. Anil Vachani, Zhou M, Ghosh S, Zhang SM, Philippe Szapary, Dheeraj Gaurav, et al. Complications After Transthoracic Needle Biopsy of Pulmonary Nodules: A Population-Level Retrospective Cohort Analysis. 2022 Jun 1;19(10):1121–9.
3. Thiboutot J, Lee HJ, Silvestri GA, Chen A, Wahidi MM, Gilbert CR, et al. Study Design and Rationale: A Multicenter, Prospective Trial of Electromagnetic Bronchoscopic and Electromagnetic Transthoracic Navigational Approaches for the Biopsy of Peripheral Pulmonary Nodules (ALL IN ONE Trial). Contemporary Clinical Trials. 2018 Aug 1;71:88–95.
4. DiBardino DM, Yarmus LB, Semaan RW. Transthoracic needle biopsy of the lung. Journal of Thoracic Disease [Internet]. 2015 Dec 1;7(Suppl 4):S304-316.

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