Shape Sensing Robotic Bronchoscopy versus Digital Tomosynthesis-Corrected Electromagnetic Navigation Bronchoscopy: A Battle for Superiority

The clinical question

Does the diagnostic yield of Shape- Sensing Robotic-Assisted-Bronchoscopy (ssRAB) differ significantly from that of Digital Tomosynthesis Corrected Electromagnetic Navigation Bronchoscopy (DT-ENB) in patients undergoing biopsy of peripheral pulmonary lesions (PPL)?

AABIP take home message

Shape sensing RAB and DT-ENB had comparable diagnostic yields. In addition, the safety profiles were similar. When compared to percutaneous CT guided biopsies, both ssRAB and DT-ENB are associated with a lower risk of pneumothorax. With increased lung cancer screening revealing more peripheral lesions, these modalities will remain key players in diagnosis and hence guide treatment decisions.

Background

Study conclusion

Diagnostic yield and safety profile was comparable in a comparative cohort study comparing Shape sensing RAB and Digital-Corrected Electromagnetic Navigation EB for sampling of peripheral pulmonary lesions.

Study background

Recent studies gauge that approximately 1.5 million indeterminate pulmonary nodules are identified annually with that number projected to rise with the expansion of lung cancer screening. Percutaneous CT guided biopsy though long regarded as the gold standard to sample peripheral lesions had pneumothorax as a complication in approximately 15% of cases per some studies. There is a need for minimally invasive diagnostic techniques with excellent diagnostic yields without compromising safety. SSRAB (ION) and DT-ENB (SuperDimension v7.2) are two minimally peripheral navigational bronchoscopy modalities approved by the FDA. This is the first study comparing robotic bronchoscopy (SSRAB) versus electro navigational bronchoscopy (Digital Tomosynthesis - Super Dimension). Data on the comparative performance of ssRAB and DT-ENB are needed to help guide patient care.

Current practice / Guidelines

Electromagnetic navigational bronchoscopy has facilitated the biopsy of small peripheral pulmonary lesions and with digital tomosynthesis (DT-ENB), it allows near-real-time intraprocedural guidance for nodule sampling. Shape-sensing robotic-assisted bronchoscopy (ssRAB) which is more recent, has improved catheter stability allowing more precise sampling of peripheral lesions. While there are no current guidelines on preferred sampling, these modalities are associated with lower incidence of complications such as pneumothorax when compared to percutaneous CT guided biopsy. There is little data on comparative effectiveness of SSRAB and DT-ENB making this a novel study.

Study Design

Study Design

- **Type of trial:** Retrospective analysis of prospectively collected data.
- Randomization, blinding, controls
- **N:** 303
- **Study groups:** Adults with peripheral pulmonary lesions sampled with either ssRAB or DT-ENB in the first 6 months of introduction of either modality at study location.
- **Settings:** Vanderbilt University Medical Canter
- **Enrollment:** Patients undergoing navigational bronchoscopies with DT-ENB or ssRAB.
- **Treatment period:** 6 months (DT-ENB 4/2018- 8/2018 and ssRAB 11/2021- 5/2022)
- **Follow up:** 6 months
- **Primary outcome:** Difference in diagnostic yield between DT-ENB and ssRAB navigational bronchoscopy platforms.

Population

Inclusion criteria

- Adults with peripheral lesions
- Had received navigational bronschoscopy biopsy by either DT-ENB or ssRAB within 6 months of introduction of either modality at Vanderbilt University Medical Center.

Exclusion criteria

- Navigational bronchoscopy biopsies done after 6 months of introduction of DT-ENB and ssRAB biopsy modalities at VUMC.

Baseline Characteristics

- Age- median (mean (SD)): 63(11.7) in DT-ENB group, 64(12.5) in ssRAB group
- Gender, male (n (%)): 69(40.6) in DT-ENB group, 73(54.9) in ssRAB group. Female (n (%)): 101(59.4) in DT-ENB group, 60(45.1) in ssRAB group
- Cigarette Use: (n (%)): 122(71.8) in DT-ENB group, 96(72.2) in ssRAB group
- Nodule Size: (mm, median (Q1, Q3)), 19(14-28) in DT-ENB group, 17(12-27) in ssRAB group

- Nodule Density (n (%)): Solid 165(83.8) in DT-ENB group, 119(83.2) in ssRAB group. Subsolid 26(13.2) in DT-ENB group, 19(13.3) in ssRAB group, Ground Glass opacity 6(3) in DT-ENB group, 5(3.5) in ssRAB group.
- Location- Peripheral third (n, (%)), 159(80.7) in DT-ENB group, 68(48) in ssRAB group

Interventions

Navigational bronchoscopy biopsy was performed by either DT-ENB or ssRAB of peripheral lesions identified on CT imaging following the institution's standard of care.

Outcomes

Primary outcomes:

- There was a similar diagnostic yield at 77% for ssRAB (110/143) and 80% (158/197) for DT-ENB (OR 0.8; 95% CI, 0.5 to 1.4, P=0.4).
- In DT-ENB cases, 54% (107/197) of PPLs were malignant and 26% (51/197) had specific benign histopathology.
- In ssRAB cases, 55% (78/143) were malignant and 22% (32/143) specific benign histopathology.

Secondary outcomes:

- In post-hoc sensitivity analysis including only the first nodule biopsied per patient in patients in whom more than one nodule was biopsied, the diagnostic yield was similar with ssRAB (80%, 106/133) and DT-ENB (81%, 138/170) (OR 0.9; 95% CI 0.5 to 1.6, P=0.7).
- Multivariate logistic regression on the first nodule biopsied per patient adjusting for nodule size, presence of bronchus sign, peripheral third vs. middle third location, and sex did not differ from the unadjusted sensitivity analysis (OR 1.0; 95% CI, 0.5-1.8, P=0.9).

Adverse events:

- No significant difference in Incidence of Pneumothorax: 1.5% of ssRAB procedures and 1.8% of DT-ENB procedures (P=0.86).

Article critique

Study Strengths

- Comparison of diagnostic performance of two contemporary platforms with a similar cohort drawn from the same patient population permits a more direct comparison in a manner previously not done.
- The decision to use a patient population in the first six months of use of each modality reduces bias from inter-operator experience.
- The use of a conservative definition of diagnostic yield allows better comparison among the two platforms and future studies.

Study Limitations and Potential for Bias

- Single center trial at a high-volume institution by very skilled operators makes generalization difficult across different patient populations.
- There were baseline differences in study groups due to non-randomization.
- More nodules in the DT-ENB group were in the peripheral 1/3 than the ssRAB (67% vs. 48%).

Research question

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Suggested Reading

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Article citation

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