AABIP JOURNAL CLUB

SHAPE-SENSING ROBOTIC-ASSISTED BRONCHOSCOPY IN THE DIAGNOSIS OF PULMONARY PARENCHYMAL LESIONS

THE CLINICAL QUESTION

What is the feasibility, diagnostic yield, determinants of diagnostic sampling, and safety profile of shape-sensing robotic-assisted bronchoscopy (ssRAB - Ion Endoluminal System (Medtronic, Dublin-Ireland) in the sampling of pulmonary parenchymal lesions?

STUDY CONCLUSION

Shape-sensing robotic-assisted bronchoscopy allowed successful navigation in 98.7% and diagnostic sampling in 81.7% of lesions, with an overall complication rate of 3.0%. Lesion size was the primary predictor of diagnostic sampling.

STUDY BACKGROUND

Technological advancements in guided bronchoscopies have improved the diagnostic yield of more peripheral and smaller pulmonary nodules. The diagnostic yield has been variable in prior literature due to the heterogeneity of the tools and the definitions of what qualifies as diagnostic tissue. The development of robotic--assisted bronchoscopies (RAB) such as the MONARCH® Platform (Auris Health, CA-USA) (which uses electromagnetic navigation) and the Ion Endoluminal System (which uses shape sensing technology) has been vital advancement in peripheral bronchoscopy. In a cadaver model study, the rate of successful peripheral pulmonary nodule localization and puncture was superior with RAB. There is no post-market data on ssRAB. Hence this study is vital in providing insights related to yield, sensitivity for thoracic malignancy, and potential adverse events at a high-volume center.

RESEARCH QUESTION

What is the feasibility, diagnostic yield, determinants of diagnostic sampling, and safety profile of shape-sensing robotic-assisted bronchoscopy (ssRAB) in the sampling of pulmonary parenchymal lesions?

STUDY DESIGN

Method:

Prospective cohort study with retrospective analysis

N: 152 patients were evaluated; 130 patients were included, and 131 had a ssRAB procedure performed targeting 159 parenchymal lesions

Study groups:

All patients referred for a ssRAB procedure

Settings:

Large academic tertiary cancer center

Enrollment and Time Period: All patients referred for ssRAB sampling at the referral center between October 1st, 2019, and July 31st, 2020

Follow up/ Definition of diagnostic yield:

- Malignant: confirmed malignant cells
- Non-malignant: inflammatory, infectious, or lymphocyte predominant
- Insufficient: normal bronchial epithelium or insufficient material to make a diagnosis, atypical cells that were unable to be characterized further, and unsuccessful navigation

Primary outcome:

Diagnostic yield of ssRAB sampling per individual lesion

Secondary outcomes:

-Sensitivity and negative predictive value of ssRAB for thoracic malignancies

-Adverse events:

- Pneumothorax
- Bleeding resulting in early termination of the procedure or intervention that is beyond the use of iced saline, topical epinephrine, or wedging of the bronchoscope
- An increase in patient's level of care because of ssRAB procedure

Inclusion criteria:

All patients referred for ssRAB sampling between October 1st, 2019, and July 31st, 2020

Exclusion criteria:

Patient had a ssRAB procedure for placement of anchored beam transponder

Baseline Characteristics:

Sample size: 130 patients
Female proportion: 57.5%
Median age: 69 years
Ever smokers: 75.4%
Prior history of cancer: 63.8%
Number of biopsied lesions: 159
Mean lesion size: 1.8 cm
Upper lobe location: 59.1%
Solid lesion: 73.0%
Lung centrality (inner two thirds): 61.0%
Bronchus sign: 62.9%
Beyond sixth generation airway: 66.7%

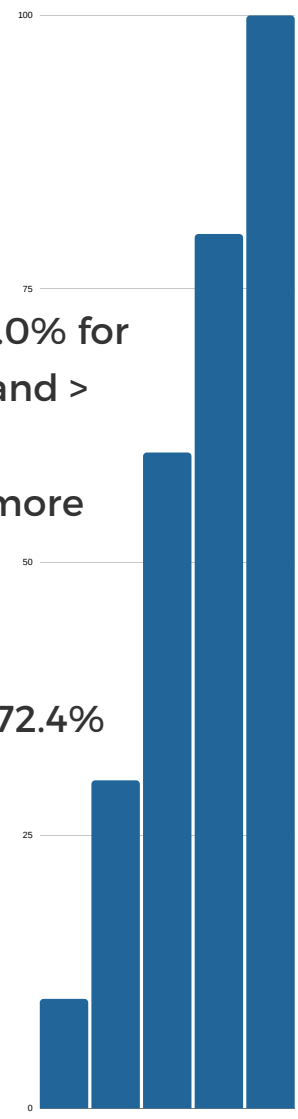
INTERVENTIONS

Shape-sensing robotic-assisted bronchoscopy

OUTCOMES

Primary outcomes

Malignant lesions 57.3%
Non-malignant lesions 26.7%
Nondiagnostic 16%
The overall diagnostic yield is 81.7%
The diagnostic yield was 66.6%, 70.4%, 92.9%, and 100.0% for lesion size at 1.00 cm, 1.01 to 2.00 cm, 2.01 to 3.00 cm, and > 3.00 cm, respectively
Lesions of > 1.8 cm were 12.22-fold (95% CI, 1.66-90.10) more likely to be diagnostic compared with lesions < 1.8 cm



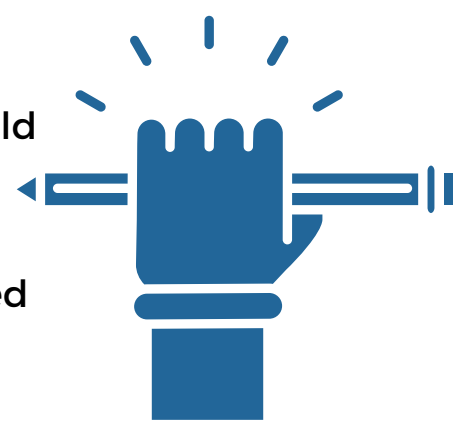
Secondary outcomes

Sensitivity of 79.8% and a negative predictive value of 72.4% of ssRAB for primary thoracic malignancies.

Adverse events

The overall complication rate of 3%.
Pneumothorax rate is 1.5% (n = 2, both required percutaneous drainage)

STUDY STRENGTHS



- Provides important data on diagnostic yield of a new technology in the diagnostic evaluation of parenchymal lung lesions
- Prospective study enrollment of all referred patients decreases selection bias
- Provided definition for diagnostic yield

STUDY LIMITATIONS

- A small sample size and study performed at an expert cancer center with a higher likelihood of patients having malignant than potential benign parenchymal lesions may result in the inability for study results to be generalizable to the general population
- The retrospective observational study introduces selection bias

TAKE HOME MESSAGE

Shape-sensing robotic-assisted bronchoscopy is an exciting tool that represents an advancement in accessing and adequately sampling pulmonary lesions while maintaining an excellent safety profile. It provides another option for navigating to and accessing challenging pulmonary lesions.

Robotic-assisted bronchoscopy is a relatively new frontier within guided bronchoscopy. Although data continues to mount, randomized controlled trials comparing the diagnostic yield between systems does not exist. Without this data, it is challenging to draw conclusions of platform superiority.

The duration of follow up is an important aspect when assessing diagnostic yield. For non-malignant specimens were considered diagnostic if the lesion was stable on follow up imaging ≥1 year. Further details are not provided, including the median duration of follow up. This is important to consider, as solid nodules are usually followed by CT for 18-24 months, and ground glass nodules for 5 years.

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SUGGESTED READING

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