Prospective Utility of a Bronchial Genomic Classifier for Lung Cancer Detection: Results From a Multicenter Prospective Registry

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Background
Bronchoscopy is frequently used for evaluation of pulmonary lesions, but its sensitivity for detecting lung cancer can be limited. A bronchial genomic classifier (Percepta) has been validated to improve the sensitivity and negative predictive value of bronchoscopy for lung cancer diagnosis. When bronchoscopy is inconclusive, Percepta can identify patients who can be considered for CT surveillance instead of undergoing another invasive diagnostic procedure. We report here on the clinical utility of Percepta among patients enrolled in the Percepta Registry at up to 12 months post bronchoscopy.

Objective
Assess the impact of Percepta on physician decision making in the diagnostic workup of pulmonary lesions in a prospective, real world setting at 40 academic and community settings

Broad patient enrollment criteria
- Inclusion: standard of care bronchoscopy did not identify malignancy and the Percepta test was ordered
- Exclusion: patient is unable to be consented into the study or unable to comply with requirements of the study

Study schema and analysis sets

Results
- Patients were prospectively enrolled at 40 medical centers when Percepta was ordered due to an inconclusive bronchoscopy. The classifier sample was obtained by brushing the right mainstem bronchus during bronchoscopy, regardless of nodule size or location. Pre- and post-classifier clinical management recommendations are recorded and follow-up clinical, procedure, and imaging data are collected over 36 months.
- Interim analysis is performed here within the decision impact subgroup (n=382), for the intermediate pre-test risk patients (n=290). Comparisons among pre-test plan, post-test recommendation and actual management are made.

Method
- Objective and enrollment criteria
- Background
- Methods
- Results
- Conclusion

Additional findings
- Advanced bronchoscopic technologies were used in 76% of cases and PET was used prior to bronchoscopy in 37% of patients.
- The proportion of intermediate risk patients that were down classified by Percepta to low risk is consistent with the results from the AEGIS 1 and 2 studies (32% vs. 38%, p=0.85).
- For patients who were down-classified and reached 6 and 12-month follow up, 73% remained procedure free at 6 months and 62% remained procedure free at 12 months.

Conclusions
- A bronchial genomic classifier can reduce the number of unnecessary invasive procedures that are performed following an inconclusive bronchoscopy for suspect lung cancer.
- Within the physician assessed intermediate pre-test risk patient subset, who had an inconclusive bronchoscopy and were classified by Percepta as low risk, we observed a significant reduction in additional invasive procedures compared to the pre-test management plan.
- This reduction in procedures has been durable over 12 months.
- Additional data will help further determine the ultimate clinical utility of the test.

References
- 1. Reese Skillern Cancer Institute 2. OSF Saint Francis Medical Center 3. Louisville Pulmonary Care 4. Stamford Hospital 5. Wake Forest Baptist Health 6. University of Cincinnati 7. Cleveland Clinic