Molecular Diagnosis of Usual Interstitial Pneumonia (UIP) by Envisia Genomic Classifier in Combination with High-Resolution Computed Tomography (HRCT) Improves the Diagnosis of UIP


BACKGROUND

ATS Guidelines recommend a UIP pattern on HRCT or histopathology to make a diagnosis of IPF. Making a Usual Interstitial Pneumonia (UIP) diagnosis is often challenging due to the high variability in HRCT findings. Surgical lung biopsy (SLB) may be required for a more confident diagnosis but carries significant risks and is not always feasible. Envisia classifier was developed using RNA Sequencing and machine learning to accurately detect a genomic pattern of UIP without histopathology.

OBJECTIVE OF THIS STUDY

- We assessed the diagnostic accuracy of Envisia classifier combined with HRCT interpreted by local radiologists to ascertain the diagnosis of UIP.
- We hypothesized that the diagnostic yield of UIP would be greater with the combination of HRCT readings by local radiology and the Envisia Classifier compared to radiology alone.

RESULTS

Combining Envisia Classifier with Local HRCT improved diagnostic yield of UIP when compared to local radiology alone.

BRAVE: The Clinical Studies Supporting Algorithm Development, Validation, and Clinical Utility of the Envisia Genomic Classifier

Development of a comprehensive genomic classifier of high-confidence clinical samples: Source for both training and validation samples

Envisia classifier was used to detect the presence of UIP in patients with interstitial lung disease (ILD). The assay is designed and optimized to be highly sensitive and specific to reduce the likelihood of a false positive result.

In a prospective, multicenter study, 12% of patients who did not have a UIP pattern on HRCT findings, clinical history and other diagnostic testing.

METHODS

- 464 patients in the validation cohort of the BRAVE study who had an HRCT scan read by local radiology were included in this analysis.
- All HRCT images and histopathology were evaluated by a local radiologist and pathologist, respectively and by central expert chest radiologist and pathologists.
- Cases interpreted as UIP either by local radiologist or by Envisia Classifier were compared to central review of biopsy proven UIP.
- Clinical data with HRCT findings were compared by two multidisciplinary teams using either Envisia Genomic Classifier results versus histopathology to determine an IP or non-IP diagnosis.

Inclusion of BRAVE Study Participants

- Combining Envisia Classifier with Local HRCT improved diagnostic yield of UIP when compared to local radiology alone.
- The addition of the Envisia Classifier to Local HRCT detects UIP with improved sensitivity and NPV compared to Radiology alone.

CONCLUSIONS

- The Envisia Classifier may be beneficial in facilitating an accurate and timely diagnosis of UIP and avoiding the need for SLB in patients reviewed by MDT with suspicious IP.

REFERENCES