Envisia Genomic Classifier helps Improve Multidisciplinary Diagnoses of Complex Interstitial Lung Disease

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RATIONALE AND OBJECTIVE

- Interstitial lung disease (ILD) is a heterogeneous group for which determining an accurate diagnosis remains a challenge.
- Recent advances in diagnosing ILD include multidisciplinary discussion (MDD) and utilizing less invasive techniques to identify a usual interstitial pattern (UIP), especially in patients who are poor candidates for surgical lung biopsy.
- UIP is a fibrotic lung injury pattern associated with poor prognosis and few effective treatments.
- The Envisia Genomic Classifier (EGC) is a clinically validated molecular test for UIP in transbronchial biopsies.
- **We describe the impact of EGC and histopathology in informing diagnoses in patients with ILD.**

METHODS

- Sixty-one patients from a prior independent clinical validation of EGC were included in this analysis
- These patients were initially enrolled in the BRAVE (Bronchial Sample Collection for a Novel Genomic Test) clinical sample collection study:
  - Underwent clinical evaluation for suspected fibrotic lung disease
  - Underwent standard-of-care (SOC) lung biopsies for histopathology
  - Underwent TBB samples collection for EGC
- HRCT scans were centrally interpreted by an expert radiologist according to Fleischner Society Guidelines.
- All patient cases were evaluated by a Multidisciplinary team including:
  - Expert ILD Pulmonologist
  - Expert ILD Radiologist
  - Expert ILD Pathologist
- Patient cases were initially evaluated with clinical information and HRCT scan interpretation by the pulmonologist who provided an ILD diagnosis with confidence level.
- Patient cases were then randomized to next sequentially receive EGC result and histopathology results.
- We assessed ILD diagnosis with confidence level for each patient by the expert MDD when:
  - Patient case presented with Clinical Factors and HRCT alone.
  - Patient case presented with Clinical Factors and HRCT and EGC/ Histopathology.

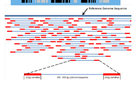
Envisia Genomic Classifier: Sample Collection, Processing, and Test Results

Samples

3-5 Transbronchial biopsy (TBB) samples* are collected during a routine bronchoscopy and shipped in a provided nanocooler to central lab

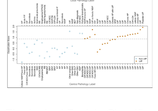
*separate from those for routine histopathology

Genomic Data



A single whole-transcriptome library, from RNA pooled from these multiple TBB samples, was generated and sequenced.

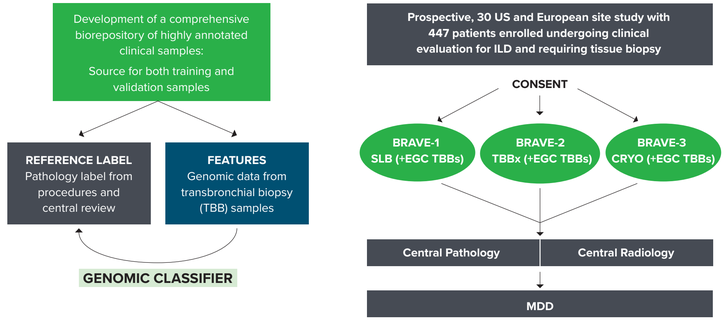
Classification



The locked Envisia Classifier (based on prior training/ validation) was used to designate either a molecular **UIP or non UIP call.**

METHODS (CONT'D.)

The BRAVE Study Methodology



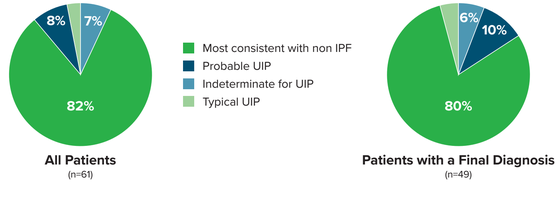
RESULTS

Clinical Demographics of all ILD patients and ILD patients with UIP

Variable		All (n=61)	UIP +[1] (n=42)
Age (Years) Mean (SD)		63.3 (12.0)	67.5 (9.4)
Sex	Women	26 (42.6%)	13 (31.0%)
	Men	35 (57.4%)	29 (69.0%)
Smoker	Current	4 (6.6%)	2 (4.8%)
	Former	28 (45.9%)	19 (45.2%)
	Never	29 (47.5%)	21 (50.0%)
HRCT pattern	Typical UIP	2 (3.3%)	2 (4.8%)
	Probable UIP	5 (8.2%)	5 (11.9%)
	Indeterminate for UIP	4 (6.6%)	4 (9.5%)
	Most consistent with non IPF	50 (82%)	31 (74%)

[1]UIP+ by either pathology or Envisia

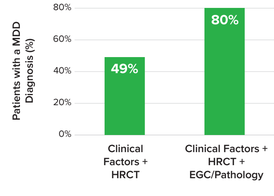
HRCT Pattern Across All Patients and Patients with a MDD ILD Diagnosis



RESULTS (CONT'D.)

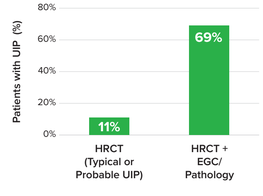
More patients have a Final MDD ILD Diagnosis when EGC/Pathology is added to Clinical Factors + HRCT

(p-value = 0.0004)



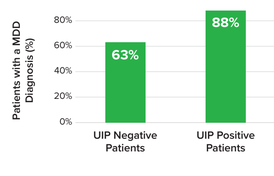
More patients with UIP are identified when EGC/Pathology is added to HRCT

(p-value <0.0001)



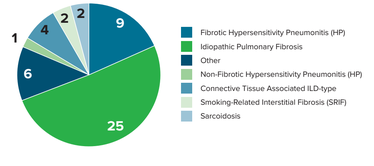
UIP Positive Patients are more likely to have a Final MDD ILD Diagnosis

(p-value = 0.036)



Final MDT Patient ILD Diagnoses

(n=49)



CONCLUSIONS

- Among new ILD patients, making an early accurate diagnosis remains challenging.
- The addition of the Envisia Genomic Classifier and histopathology increased the number of Final MDD ILD Diagnoses.
  - Addition of EGC and histopathology identified more UIP+ ILD cases.
  - UIP+ ILD Patients are more likely to have a Final MDD ILD Diagnosis
- The Envisia Genomic Classifier assists in making a confident diagnosis in patients with diverse underlying ILD diagnoses.

References

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Disclosures

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