Gene set for the diagnosis of active pulmonary tuberculosis

Drs. Purvesh Khatri and Timothy Sweeney at Stanford have identified a set of three genes that can be used to diagnose active tuberculosis (TB) and distinguish active TB from latent TB or other diseases. TB is a worldwide public health problem. It is hard to accurately diagnose, which leads to difficulties in selecting appropriate treatment. Traditional diagnostic methods cannot distinguish between latent and active TB and have lower sensitivity in HIV-positive patients; they also rely on adequate production of sputa. The World Health Organization has thus called for new types of diagnostics that do not rely on sputum, are accurate in children, and are not confounded by HIV co-infection. The set of genes identified by the inventors fulfills these criteria. In addition, the gene set can distinguish active TB from latent TB and other diseases. Finally, it can be used to track treatment response as expression of the gene set falls with successful treatment. This gene set has broad applications for TB diagnosis and treatment response monitoring.

Stage of research

As of mid-December 2015 the inventors had extensively validated the gene set in external datasets and demonstrated it is a robust diagnostic for active TB.

Applications

- Diagnose TB
- Monitor TB treatment response

Advantages

- Can distinguish active TB from latent TB and other diseases
- Blood-based does not require complex procedures or patient sputum

- Can be used to diagnose TB in children
- Unaffected by clinical confounders such as HIV status or BCG vaccine status
- Small gene set- reduces cost and complexity
- Allows for quantitative monitoring of TB treatment response- can identify nonresponders earlier
- May be used to improve TB drug clinical trials
- Can be used as a stand-alone diagnostic or as an adjunct to existing diagnostics

Publications

 Timothy E. Sweeney, MD, Lindsay Braviak, Cristina M. Tato, PhD, Purvesh Khatri, PhD, <u>"Genome-Wide Expression for Diagnosis of Pulmonary</u> <u>Tuberculosis: a multicohort analysis,"</u> Lancet Respiratory Medicine, published online Feb. 19, 2016.

Patents

- Published Application: <u>WO2017066641</u>
- Published Application: 20210348233
- Issued: <u>10,920,275 (USA)</u>

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