

The Use of a Personalized Medicine, Blood-based Gene Expression Score in a Community-Based Cardiovascular Registry Enrolling Patients Presenting with Symptoms Suggestive of Obstructive Coronary Artery Disease: Interim Results from the PRESET (A Registry to Evaluate Patterns of Care Associated with the Use of Corus[®] CAD in Real World Clinical Care Settings) Registry.

Meeting:

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Background: Patients with symptoms suggestive of obstructive coronary artery disease (CAD) frequently undergo unnecessary testing and procedures. Approximately \$5.9 billion/year is spent on non-invasive and invasive testing in the US in the non-diabetic population without a prior revascularization or myocardial infarction, yet some patients continue to be misdiagnosed. A previously validated blood-based, gene expression diagnostic test with a 96% NPV can facilitate determination of the current likelihood of CAD in a symptomatic patient.

Objective: The objective of the study is to evaluate the use of the gene expression score (GES) and its effect on clinician risk stratification of patients considered for referral to cardiology in a community-based cardiovascular registry.

Methods: The prospective PRESET Registry (NCT01677156) will enroll 1,000 stable, non-acute adult patients without a history of CAD from 21 US primary care practices. Primary care clinicians provide the pre- and post-GES diagnosis and evaluation plan for each patient. Demographics, clinical factors, and GES results (predefined as low [GES ≤15] or elevated [GES >15]) are collected, as well as treatment plans, diagnostic tests performed and results, and referrals to cardiology and advanced cardiac testing. Clinician and patient quality of care measures, such as satisfaction with care, are being assessed.

Results: In an interim cohort of 393 patients, 199 (50.6%) were women, the median age was 55 years with 116 (29.5%) age ≥65, and the median BMI is 29.8. The median GES was 17 (range, 1-40) and 177 patients (45.0%) had low scores. In this analysis, 19 of 177 (10.7%) patients with low scores were referred to cardiology, while 105 of 216 (48.6%) patients with elevated scores were referred (OR 7.87, p<0.0001). At 30 day follow-up, no MACE were reported in patients with low scores. Longer-term follow-up is underway.

Conclusion: In this interim analysis of a community-based cardiovascular registry evaluating patterns of care among patients presenting with symptoms suggestive of obstructive CAD, a personalized medicine, gene-expression based test was adopted in clinical practice and was associated with a statistically significant and clinically relevant effect on medical decision making. In conclusion, use of the GES test showed clinical utility in efficiently and safely ruling out obstructive CAD, minimizing referral of low risk patients to cardiology.

Reference: Ladapo, JA, Sharp D, Maniet B, et al. The Use of a Personalized Medicine, Blood-based Gene Expression Score in a Community-Based Cardiovascular Registry Enrolling Patients Presenting with Symptoms Suggestive of Obstructive Coronary Artery Disease: Interim Results from the PRESET (A Registry to Evaluate Patterns of Care Associated with the Use of Corus[®] CAD in Real World Clinical Care Settings) Registry. *Circ Cardiovasc Qual Outcomes*. 2014;7.