Use of a Personalized Medicine, Gene Expression Score Influenced Cardiology Referrals Among 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

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Purpose: Approximately 3 million patients per year present to primary care clinicians with symptoms suggestive of obstructive coronary artery disease (CAD). Often, even after obtaining a detailed history and performing a physical examination and resting electrocardiogram, physicians are unable to confidently determine the primary etiology of these symptoms during an initial visit. This scenario leads to an overall $6.7 B/year spend on the non-invasive and invasive cardiac testing in the US for non-diabetic patients with no prior revascularization or myocardial infarction. The process may also expose patients to appreciable risk of radiation and contrast-dye related side effects. Better methods are needed for the primary care provider to determine which patients can be safely managed in the primary care setting and which patients should be referred to the cardiologist.

Methods: The gene expression score (GES) is a previously validated quantitative diagnostic test for non-diabetic patients, measuring expression levels of 23 genes from peripheral blood to determine the likelihood of a patient having >50% coronary artery stenosis. The GES has a 96% NPV and can identify symptomatic patients at low risk for underlying obstructive CAD. We hypothesized that use of the GES would improve quality of care by safely excluding low-risk patients from unwarranted cardiac testing. We are currently enrolling into the prospective PRESET Registry (NCT01677156), which will include 1,000 non-acute, non-diabetic adult patients with no history of CAD from 21 US primary care practices. 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 diagnostic tests performed with results, and referrals to cardiology. Additional clinician and patient quality of care measures, such as satisfaction with care, are being assessed.

Results: In a preliminary cohort of 393 patients, 199 (50.6%) are women, the median age was 55 years with 116 (29.5%) age ≥65, and the median BMI was 29.8. The median GES was 17 (range, 1-40) and 177 patients (45.0%) had low scores. Referral rates to cardiology were only 10.7% (19/177) in the low GES group. At the 30 day follow-up post-GES, the major adverse cardiac event (MACE) rate was 0% in the low GES group. Registry enrollment is ongoing, with final analysis planned upon enrollment completion.

Conclusions: In this community-based primary care registry, initial results show that a personalized medicine, gene-expression based test could appropriately stratify patients presenting with symptoms suggestive of obstructive CAD. By removing these low-risk patients from further cardiac testing, unnecessary workups can be avoided. These results demonstrate that the GES could improve the quality of care without impacting patient safety.

Reference: Ladapo JA, Sharp D, Maniet B, et al. Use of a Personalized Medicine, Gene Expression Score Influenced Cardiology Referrals Among 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. *Am J Med Qual.* 2014;29(3):5S-27S. [Epub ahead of print]