

## **A Gender-Specific Blood-Based Gene Expression Score for Assessing Obstructive Coronary Artery Disease in Nondiabetic Patients: Results of the Personalized Risk Evaluation and Diagnosis in the Coronary Tree (PREDICT) Trial**

**Meeting:** Women's Health 2013: The 21<sup>st</sup> Annual Congress

**Authors:** Alexandra Lansky, Yale University School of Medicine, New Haven, CT; Michael R. Elashoff, CardioDx, Inc., Palo Alto, CA; Vivian Ng, Columbia University Medical Center, New York, NY; John McPherson, Vanderbilt Heart and Vascular Institute, Nashville, TN; Dana Lazar, Yale University School of Medicine, New Haven, CT; William E. Kraus, Duke University School of Medicine, Durham, NC

**Background:** Currently available noninvasive tests to risk stratify patients for obstructive coronary disease result in many unnecessary cardiac catheterizations, especially in women.

**Objective(s):** We sought to compare the diagnostic accuracy of presenting symptoms, noninvasive test results, and a gene expression score (GES) in identifying obstructive coronary artery disease (CAD) according to gender, using quantitative coronary angiography as the criterion standard.

**Materials/Methods:** The PREDICT trial is a prospective multicenter observational study designed to develop and validate gene expression algorithms to assess obstructive CAD, defined as at least one  $\geq 50\%$  diameter stenosis measured by quantitative coronary angiography. Patients referred for diagnostic cardiac catheterization with suspected but previously unknown CAD were enrolled. Noninvasive myocardial perfusion imaging (MPI) was available in 60% of patients. The GES, comprising gender-specific age functions and 6 gene expression terms containing 23 genes, was performed for all patients.

**Results:** A total of 1,160 consecutive patients (57.6% men and 42.4% women) were enrolled in PREDICT. The prevalence of obstructive CAD was 46.7% in men and 22.0% in women. Chest pain symptoms were a discriminator of obstructive CAD in men ( $P < .001$ ) but not in women. The positive predictive value of MPI was significantly higher in men (45%) than in women (22%). An abnormal site-read MPI was not significantly associated with obstructive or severity of CAD. The GES was significantly associated with a 2-fold increase in the odds of obstructive CAD for every 10-point increment in the GES and had a significant association with all measures of severity and burden of CAD. By multivariable analysis, GES was an independent predictor of obstructive CAD in the overall population (odds ratio [OR] 2.53,  $P = .001$ ) and in the male (OR 1.99,  $P = .001$ ) and female (OR 3.45,  $P = .001$ ) subgroups separately, whereas MPI was not.

**Conclusions:** Commonly used diagnostic approaches including symptom evaluation and MPI performed less well in women than in men for identifying significant CAD. In contrast, gender-specific GES performed similarly in women and men. Gene expression score offers a reliable diagnostic approach for the assessment of nondiabetic patients and, in particular, women with suspected obstructive CAD. (*Am Heart J* 2012;164:320-6.)

**Reference:** Lansky A, Elashoff MR, Ng V, et al. A Gender-Specific Blood-Based Gene Expression Score for Assessing Obstructive Coronary Artery Disease in Nondiabetic Patients: Results of the Personalized Risk Evaluation and Diagnosis in the Coronary Tree (PREDICT) Trial. *J of Womens Health*. 2013;22:P17.