The Use of a Gene Expression Score Was Associated with Improved Medical Decision Making in the Evaluation of Women Presenting with Symptoms Suggestive of Obstructive Coronary Artery Disease: Summary Results from Two Ambulatory Care Studies in Primary Care

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Background: Better approaches are needed to evaluate women presenting to primary care with chest pain and related symptoms. A previously validated diagnostic test (Corus® CAD, CardioDx, Inc.) incorporating age, sex, and gene expression has a 96% negative predictive value among patients with low (≤15) scores in determining a patient’s current likelihood of obstructive coronary artery disease (CAD). We hypothesized that the gene expression test results could be incorporated into medical decision making to help identify women whose symptoms are not due to obstructive CAD.

Methods: An aggregated analysis of female cohorts from the IMPACT-PCP (NCT01594411) and REGISTRY I (NCT01557855) studies was conducted. Data were pooled on 320 women from 16 primary care providers (PCPs) in geographically diverse site presenting with stable symptoms suggestive of obstructive CAD and undergoing gene expression score (GES) testing. The primary outcome of this analysis was the association between GES and referrals for further cardiac evaluation.

Results: The mean patient age was 57.8 years and the mean GES was 10.3 [predefined as low [GES ≤15] or elevated [GES >15]]. The referral rate for further cardiac evaluation was 4.0% (10 of 248) for patients with low GES versus 83.3% (60 of 72) for patients with elevated GES, with follow-up showing favorable safety profiles. After adjusting for clinical covariates, women with low GES were significantly less likely to be referred for further cardiac evaluation (OR 0.012, p-value<0.0001).

Conclusions: The gene expression test demonstrated clinical utility by helping PCPs rule-out obstructive CAD in symptomatic patients with low GES, identifying women who would not benefit from further cardiac evaluation.