CORONARY ARTERY DISEASE DIAGNOSTIC BLOOD TEST VALIDATED

A blood-based gene expression test developed to aid in the diagnosis of coronary artery disease (CAD) has now been prospectively validated in the multicenter PREDICT trial. According to Dr Eric Topol, one of the PREDICT investigators, "the test, which is commercially available, can be used to help decide whether to go to angiography, when there are uncertainties."

Patients who are suspected of having CAD often undergo a diagnostic coronary angiogram. As Dr Topol explains. however, "there is a high rate of normal angiograms—about 30%". Given the invasive nature of coronary angiograms, the PREDICT investigators aimed to develop a gene expression test to help diagnose obstructive CAD and reduce the number of angiograms undertaken.

The algorithm was developed and validated using independent groups of samples from 694 and 649 patients, respectively. The diagnostic blood test is based on the expression of 23 genes and was developed for use in nondiabetic patients only, because of the differences in plaque morphology and associated gene expression between patients with and without diabetes.

The area under the receiver-operating characteristic curve (AUC) for algorithm score prediction of disease status was 0.70 ± 0.02 (P<0.001). The combination of the Diamond-Forrester risk score and the new blood-based test was shown to be modestly better than the Diamond-Forrester score alone (AUC 0.72 vs 0.66; *P*=0.003). Furthermore, the investigators demonstrated net reclassification improvements of 20% and 16% relative to the Diamond-Forrester score and an expanded clinical model, respectively.

Although promising, the results of PREDICT are modest and Dr Topol cautions that "more research will be important for delineating the test's utility and cost-effectiveness".

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Original article Rosenberg, S. et al. Multicenter validation of the diagnostic accuracy of a blood-based gene expression test for assessing obstructive coronary artery disease in nondiabetic patients. Ann. Intern. Med. 153. 425-434 (2010)

RESEARCH HIGHLIGHTS