

## Novel blood test predicts sudden death risk patients who would benefit from ICDs

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A novel blood test that predicts sudden death risk in heart failure patients is set to help physicians decide which patients would benefit from implantable cardioverter defibrillators (ICDs). The findings were presented at the ESC Congress 2012 today, August 26, by Professor Samuel Dudley from Chicago, IL, US.

Approximately 5 million patients in the US have heart failure, a condition where the heart is unable to pump blood adequately, and nearly 550,000 people are diagnosed annually. Heart failure is the single most common cause of admission to hospitals in the US.

ICDs, which are devices similar to <u>pacemakers</u>, can monitor and treat abnormal heartbeats and are surgically implanted in patients with severe heart failure to prevent <u>sudden death</u>. "The problem is that more than half of the patients who get them don't need them, and nearly half of the patients who would benefit don't get one," said Professor Dudley, who is professor of medicine and physiology at the University of Illinois at Chicago College of Medicine and principle investigator of the study.

The clinical trial presented at the ESC Congress 2012 showed that a blood test can predict which patients will need a <u>defibrillator</u> in the next year. The test, called PulsePredic, discriminates with high predictive power who will or will not need an ICD to prevent abnormal heartbeats and subsequent sudden death.

The simple <u>laboratory test</u> identifies changes in the gene message



(mRNA) for the SCN5A gene, which is known to be involved in sudden death. The increase in the changed gene message was able to predict who would have a sudden death episode requiring defibrillation. "The test predicts whether you will have sudden death from heart failure and whether you will need a defibrillator in the next year," said Professor Dudley.

The SCN5A gene encodes for proteins, called voltage-gated <u>sodium channels</u>, responsible for generating the main current for <u>electrical activity</u> in the heart. Alterations in the sodium current, either up or down, lead to arrhythmias.

Professor Dudley and his team evaluated the new blood test in 180 adult patients, including 135 patients with heart failure and 45 patients without heart failure as controls. Patients with congenital heart disease, infections, and inflammatory conditions were excluded.

The SCN5A gene was measured in heart muscle cells and white blood cells. The changes in the gene message were able to predict who would have a sudden death episode requiring defibrillation. Heart failure patients who had abnormal heartbeats that would normally cause sudden death had significantly higher levels of these gene variants compared to patients who did not have abnormal heartbeats. The amount of variants in the blood had excellent predictive power to determine arrhythmic risk, suggesting that a blood test for sudden death risk and the need for an ICD is possible.

Figure 1 shows the distributions of the C type SCN5A variant (VC) in controls, patients with <a href="heart failure">heart failure</a> (HF) and no sudden death (i.e. no ICD shocks), and patients with HF and a sudden death episode (i.e. with ICD shocks). The separation of the distributions of patients with and without a sudden death episode allows for a discriminatory test.



Figure 2 is a receiver operating characteristic (ROC) curve which shows that the discriminatory power of the C or D type variants of SCN5A as measured by the area under the curve are equivalent and much higher than an ejection fraction of less than or equal to 20%.

"This is the first test of its kind," said Professor Dudley. "It is amazing stuff, with promise to change dramatically the way we direct treatments to patients at risk for sudden death."

The next steps in the development of the test will be to carry out a larger trial and work with regulatory agencies to receive approval for clinical use.

## Provided by European Society of Cardiology

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