

> N E W S

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## Positive T-wave alternans an effective predictor of outcomes in patients with congestive heart failure

**Chicago, IL** - Preliminary results from a recent study on the role of T-wave alternans (TWA) testing in patients with CHF found an increased rate of all-cause mortality in patients with a positive TWA compared with patients with negative TWA. The predictive value of TWA testing may help to further stratify patients at risk for ventricular arrhythmias and sudden cardiac death, said investigators of a recent study, presented at the **American College of Cardiology 2003 Annual Scientific Sessions**.

"The primary hypothesis of the study stated that T-wave alternans would be associated with an increased risk of arrhythmic events in patients with left ventricular dysfunction," said lead investigator **Dr Daniel M Bloomfield** (Columbia University, New York, NY). "We also hypothesized that this association would be independent of heart disease."

Baseline data and TWA test results were collected and analyzed for 542 eligible patients with left ventricular dysfunction (71% male; 29% female). All patients were in sinus rhythm and had EF <40%. Mean EF was 25% (p=0.08). Of the 542 patients analyzed, 30% had diabetes, 43% had prior documented MI, 26% had prior CABG surgery, and 59% had at least one previous admission to the hospital for heart failure. A vast majority of patients in the study were taking beta blockers or ACE inhibitors.

With the preliminary results of the two-year study stopped and analyzed after just 12.2 months, investigators reported 20 deaths. The Kaplan-Meier two-year survival rate was 93%.

Bloomfield reported the two-year actuarial mortality rate in the study was 1.0% in CHF patients with a negative TWA compared with 11% in similar patients with a positive TWA, making TWA-positive patients 10 times more likely to die than those with a negative test result. Bloomfield also reported 9% of patients recorded indeterminate TWA test results. There were 10 deaths in the group of patients with an indeterminate TWA test, said Bloomfield, noting that of these, eight occurred in patients whose test was indeterminate due to dense ventricular ectopy that persisted after exercise.

TWA testing is based on the observation that microscopic fluctuations in the morphology of the T wave on the ECG reveal abnormalities in repolarization. Positive TWA on the surface ECG is associated with the subsequent development of malignant ventricular arrhythmias. New technology enables TWA, too small to be visualized on the ECG during an exercise stress test, to be identified, possibly offering clinicians a noninvasive diagnostic test to accurately predict life-threatening arrhythmias among patients with documented heart conditions.

## TWA testing and MADIT II

The recent publication of **MADIT II** in the *New England Journal of Medicine* has generated a great deal of interest in the medical community in the importance of

risk stratification, said Bloomfield, especially for physicians who treat patients with prior MIs or LVEF  $\leq$  30%.

In MADIT II (**Multicenter Automatic Defibrillator Implantation Trial**) patients with prior MI and an LVEF of 30% or less were randomly assigned either to receive an ICD (n=742) or conventional therapy (n=490), with all-cause mortality as the primary end point. The findings revealed that in patients with a previous MI and reduced LVEF, the prophylactic use of an ICD in addition to medications significantly reduced the risk of death. Investigators demonstrated the placement of an ICD in patients with a prior MI and LVEF  $\leq$  30% resulted in a 5.6% absolute reduction in mortality.

While the data from MADIT II clearly shows a benefit, Bloomfield said the results also indicate ICDs are implanted into many high-risk patients for every life saved, adding to the growing cost concerns about the use of this effective lifesaving treatment. Further risk stratification of the at-risk population is needed to identify patients who would benefit most from ICD therapy.

To examine the predictive power of TWA in a setting similar to MADIT II, Bloomfield et al stratified 164 patients with ischemic myopathy and EF  $\leq$  30%, all meeting the criteria established in MADIT II. There were 6 deaths after 12.2 months, and the two-year survival rate was 93%, higher than the survival rate reported by the MADIT II investigators.

Bloomfield et al reported the two-year mortality rate in the subgroup of patients meeting MADIT II criteria and reporting positive TWA tests was 15%. No patients in the stratified subgroup who reported negative TWA tests had died at follow-up.

"These results suggest that patients with a positive TWA test will likely obtain a greater mortality benefit from an ICD than would be observed in an unstratified MADIT II cohort. One third of patients who met the MADIT II criteria but had a negative TWA test had excellent two-year survival and therefore may not require ICD therapy," said Bloomfield.

## **Related links**

1. ICD meta-analysis: Risk stratification remains the challenge [*HeartWire > News*; Mar 17, 2003]

2. Medicare advisory panel unanimously supports ICDs for patients meeting MADIT II criteria [*HeartWire > News*; Feb 13, 2003]

3. QRS duration could single out post-MI patients who benefit most from an ICD: MADIT II substudy [*HeartWire > News*; May 14, 2002]

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