Microvolt T-wave alternans testing to risk-stratify patients being considered for ICD therapy for primary prevention of sudden death

BlueCross BlueShield Association

Record Status
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Citation

Authors' objectives
"This Assessment examines evidence to compare outcomes of selecting patients for ICD placement for primary prevention of sudden death with and without MTWA. There are no noninvasive alternative tests, other than left-ventricular ejection fraction (LVEF), considered conventional alternatives."(from executive summary)

Authors' conclusions
Given the lack of randomized clinical trials, the argument for use of MTWA testing to select patients who might not benefit from ICD therapy rests on two types of information—knowledge of the natural history of persons with MTWA-negative tests, and knowledge of the degree of risk that would confer no benefit from ICD therapy. The knowledge base for both issues is insufficient. Only 3 studies of modest size evaluated outcomes of MTWA-negative subjects who were eligible for ICD placement for primary prevention. Due to the modest number of studies, there is still some uncertainty regarding the outcomes of such patients. Whether these 3 studies actually represent the same population eligible for ICD placement is uncertain. The high negative predictive value for MTWA-negative tests derived from other populations may not generalize to the population eligible for ICD placement. Furthermore, even though MTWA testing is predictive of outcome, it is uncertain if the level of risk is low enough such that ICD therapy is of no benefit. One published decision analysis suggests that ICD therapy is still of net benefit to MTWA-negative patients. Finally, lack of randomized clinical trial evidence precludes any expansion of ICD therapy to a group of newly identified patients who have positive or indeterminate MTWA tests.

Based on the available evidence, the Blue Cross and Blue Shield Association Medical Advisory Panel made the following judgments about whether microvolt T-wave alternans testing for risk-stratifying patients being considered for ICD therapy for primary prevention of sudden death meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria.

1. The technology must have final approval from the appropriate governmental bodies. Microvolt T-wave alternans (MTWA) testing may be performed using a commercially available system called the Heartwave Alternans Processing System marketed by Cambridge Heart, Inc. This system received 510(k) clearances on November 17, 2002 (K03564) and July 16, 2002 (K022152)

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes. The evidence is insufficient. Three observational studies of ICD-eligible patients with negative MTWA tests are relatively small. Although the test does stratify risk in these studies, the absolute risk of events remains uncertain. Furthermore, it is uncertain how low a level of risk precludes benefit from ICD therapy. There are no clinical trials of ICD therapy in patients not currently eligible for ICD therapy who have been selected using MTWA testing. Thus, there is no evidence for using MTWA to expand the pool of patients eligible for ICD placement.
3. The technology must improve the net health outcome, and 4. The technology must be as beneficial as any established alternatives. The evidence is insufficient to determine whether the use of MTWA improves net health outcome or whether it is as beneficial as any established alternatives.

5. The improvement must be attainable outside the investigational settings. Whether the use of MTWA improves health outcomes is not established in the investigational settings.

Therefore, the use of microvolt T-wave alternans testing for risk-stratifying patients being considered for implantable cardioverter-defibrillator therapy for primary prevention of sudden death does not meet the TEC criteria.

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http://www.bcbs.com/blueresources/tec/contact-tec.html

**URL for DARE abstract**
http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=12006008295

**Indexing Status**
Subject indexing assigned by CRD

**MeSH**
Death, Sudden; Defibrillators, Implantable; Electrocardiography; Tachycardia, Ventricular

**Language Published**
English

**Country of organisation**
United States

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**AccessionNumber**
32007000503

**Date bibliographic record published**
12/10/2007

**Date abstract record published**
12/10/2007