T-Wave Alternans

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Based on review of available data, the use of T-wave alternans as a technique of risk stratification for primary or secondary prevention of fatal arrhythmias and sudden cardiac death in patients with a history of myocardial infarction, congestive heart failure, cardiomyopathy or other cardiac disorders such as long-QT syndrome (e.g. Brugada syndrome), is considered *investigational.*

Note: Primary prevention refers to patients that have not experienced a life-threatening arrhythmia. Secondary prevention refers to patients that have experienced a life-threatening arrhythmia.

**Background/Overview**  
Microvolt T-wave alternans (MTWA) refers to a beat-to-beat variability in the T-wave amplitude. Because a routine electrocardiogram (EKG) cannot detect these small fluctuations, this test requires specialized sensors to detect the fluctuations and computer algorithms to evaluate the results. T-wave alternans is a provocative test that requires gradual elevation of the heart rate to above 110 beats per minute. The test can be performed in conjunction with an exercise tolerance stress test. Test results are reported as the number of standard deviations by which the peak signal of the T-wave exceeds the background noise. This number is referred to as the "alternans ratio." An alternans ratio of three or greater is typically considered a positive result, an absent alternans ratio is considered a negative result, and anything in between is considered indeterminate.

The presence of T-wave alternans has been investigated as a risk factor for fatal arrhythmias and sudden cardiac death in patients with a history of myocardial infarction (MI), congestive heart failure (CHF), or cardiomyopathy. High-risk patients may be treated with drugs to suppress the emergence of arrhythmias or undergo implantation of cardiac defibrillators to terminate tachyarrhythmias when they occur. Since sudden cardiac death is one of the most common causes of death after a MI or in patients with dilated cardiomyopathy, there is intense interest in risk stratification to target therapy.

Patient groups are categorized into those who have not experienced a life-threatening arrhythmia (i.e., primary prevention) and those who have (i.e., secondary prevention). Those who have already experienced an arrhythmia are already at high risk and probably do not require testing. T-wave alternans is one of many risk factors that have been investigated for identifying candidates for primary prevention. Others include left ventricular ejection fraction, arrhythmias detected on Holter monitor or electrophysiologic studies (EPSs), heart rate variability, and baroreceptor sensitivity. Signal-averaged electrocardiography (SAECG) is another technique for risk stratification. T-wave alternans has also been investigated as a diagnostic test for patients with syncope of unknown origin and as a noninvasive test to identify candidates for further invasive electrophysiology testing of the heart.
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FDA or Other Governmental Regulatory Approval
Centers for Medicare and Medicaid Services (CMS)
In April 2006, the CMS began providing coverage for T-wave alternans. The CMS national coverage determination indicates “MTWA diagnostic testing is covered for the evaluation of patients at risk of sudden cardiac death, only when the spectral analytic method is used” but not the modified moving average (MMA) algorithm.

The CMS decision, which differs from this policy’s conclusions, included the 2005 BCBSA TEC Assessment in its evaluation of T-wave alternans. However, CMS noted it in its review of the evidence that: “Due to the unique characteristics of the Medicare-eligible population (i.e., elderly, and more likely to have multiple co-morbidities), sudden cardiac death has a higher potential to occur as a result of VTE (venous thromboembolism) in this population. The potential harms from adverse events are also more likely to occur within this population. Because of these features of the Medicare population, the potential for benefit or harm from implantable cardioverter-defibrillator (ICD) placement varies from that of the BCBSA population at large, and plays a prominent role in our decision-making. Indications for ICD placement also differ between the two organizations. Because of the higher potential for VTE occurrence in the Medicare population, and because CMS recognizes VTEs as an indication for ICD placement, CMS feels that the use of MTWA is reasonable and necessary to address problems related to VTE and its adverse consequences.” CMS also noted it “does not believe that the evidence is sufficient to show that MTWA should be the only diagnostic test for the purpose of stratifying high-risk patients of VTE. Physicians may choose to use a variety of other diagnostic testing to elucidate the need for an ICD (e.g., left ventricular ejection fraction, signal-averaged ECG, etc.). Also, we do not believe that the current evidence is sufficient to require that physicians use the results of MTWA testing to select appropriate patients for ICD implantation.”

Rationale/Source
Prognostic or risk stratification test evaluation consists of: 1) appraising test technical performance, including definitions of positive and negative results and reproducibility of the test; 2) determining how accurately the test discriminates patients who will, from those who will not, experience the event of interest; and 3) evaluating the impact of test results on clinical management of the patient and a determination whether changes in clinical management result in an improvement of overall health outcomes.

Primary prevention ICD trials (e.g., MADIT-II and SCD-HeFT) have changed the perspective on selection and risk stratification for use of ICDs. In the MADIT-II trial, implantable defibrillators were shown to be effective in patients selected on the basis of prior MI and reduced ejection fraction; SCD-HeFT inclusion criteria required reduced ejection fraction but not previous MI. Prior studies of implantable defibrillators had selected patients using results of electrophysiologic testing and symptoms. Given results from these trials, it is critical whether any additional risk stratification tool(s) can identify with sufficient accuracy patients who might or might not benefit from ICD implantation. For example, can T-wave alternans testing identify patients who would otherwise be appropriate for an ICD based in trial inclusion criteria, but who would actually not benefit from an ICD?

The rationale for T-wave alternans testing is primarily that patients with a negative result will not benefit from an ICD. Accordingly, the most convincing evidence would be obtained from a randomized trial
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restricted to alternans-negative patients. Such a trial is lacking. Evidence from prospective cohort studies can accurately define the predictive ability of MTWA for sudden cardiac death. This evidence on risk may impact clinical management, if there are well-defined levels of risk that are linked to different management strategies.

Literature Review

TEC Assessments. A June 2005 TEC Assessment evaluated the use of microvolt T-wave alternans (MTWA) to risk stratify patients in whom ICDs would be used for primary prevention of sudden cardiac death. The Assessment identified 18 studies using MTWA to prospectively stratify the risk of a subsequent event (total N=2,931). Most studies interpreted MTWA blinded to other information. The incidence of endpoints (either ventricular tachyarrhythmic events [VTEs] or death) ranged from 3% to 51% across studies. Six studies included patients with ischemic cardiomyopathy, 4 nonischemic cardiomyopathy, and 8 patients selected by a variety of means, such as those referred for electrophysiologic testing.

Two patient indications were considered: 1) patients eligible for ICD placement for primary prevention of sudden death, and 2) patients not eligible for ICD placement. It is possible that the negative or positive predictive value (NPV, PPV) of MTWA results might be used to support decision making regarding ICD placement. Specifically, for the first patient indication, negative MTWA results might be used to identify a subset of patients at low likelihood of subsequent VTEs and thus unlikely to benefit from ICD placement. While a few studies found that MTWA testing had high sensitivity and high NPV for future VTE, there was considerable variation in diagnostic performance in the published literature. Reported sensitivities ranged from 75% to 100%, negative predictive values from 73% to 100%, and likelihood ratios for a negative test result varied between 0 and 0.42. The reasons for variation in diagnostic performance characteristics are not well-established (recently suggested related to varied use of beta blockers during testing as later discussed). Differences in pretest risk of VTE would most influence NPV; however, the Assessment also noted that it would also be important to understand whether MTWA diagnostic performance might vary according to population characteristics, such as etiology of cardiomyopathy. The diagnostic characteristics derived from the studies evaluated may not directly apply to patients eligible for ICD therapy.

The 2005 TEC Assessment concluded the evidence insufficient to determine whether the use of MTWA leads to improved net health outcomes or whether it is as beneficial as any established alternatives. Therefore, the use of MTWA testing for risk stratifying patients being considered for ICD therapy for primary prevention of sudden death did not meet the TEC criteria.

A 2006 TEC Assessment reviewed a smaller number of studies addressing the question of whether MTWA can identify patients who would otherwise meet clinical indications for ICDs but whose risk of death is so low that they would not benefit. The critical evidence sought was the absolute risk of VTE or sudden death in those patients who have a negative MTWA test, and whether it can be determined whether this risk is consistent with no potential benefit from ICD therapy. Three studies were reviewed restricting analyses to patients who met criteria for ICD therapy.

Bloomfield et al. followed 177 patients over an average of 20 months for all-cause mortality. Hohnloser et al. selected ICD-eligible patients from two previously published studies and followed them over 2 years for
sudden cardiac death or cardiac arrest. Among those with a negative MTWA test, the actuarial 2-year mortality rate was 3.8%. For those with a non-negative MTWA test, the actuarial 2-year mortality rate was 17.8%. Arrhythmic outcomes were not reported in this study.

In Hohnloser et al., patients who met MADIT-II criteria were pooled from two previously published studies. The study reported all-cause mortality, rates of sudden cardiac death or cardiac arrest, and rates of VTE. For all-cause mortality estimated at 2 years, those with negative MTWA tests had a mortality rate of 12.5%, whereas those with non-negative MTWA tests had a mortality rate of 21.4%. For the primary outcome of sudden death or cardiac arrest, patients with negative MTWA tests had a 0% rate, and those with non-negative MTWA tests had a 15.6% rate. For the secondary outcome of all ventricular arrhythmic events, those with a negative MTWA test had a 5.7% rate, and those with non-negative tests had a 31.1% rate.

In Chow et al., a total of 768 consecutive patients with ischemic cardiomyopathy (left ventricular ejection fraction [LVEF] <35%) and no prior history of ventricular arrhythmia were followed up for a mean of 18 months. Because event rates in the patients with and without ICDs are not comparable, only outcomes for the 376 patients who received only medical therapy were reported in the TEC Assessment. Thus the results might be accompanied by potential selection bias. It appeared that the MTWA-negative patients who did not receive ICDs compared to the MTWA-negative patients who did receive ICDs had less severe heart failure (mean LVEF: 29.3% vs. 26.9%, respectively). At 18 months’ mean follow-up, the all-cause mortality rate was 8.4% in MTWA-negative patients and 21.8% in MTWA non-negative patients. For arrhythmic deaths, the rate was 3.4% in MTWA-negative patients and 11.2% in MTWA non-negative patients.

The 2006 TEC Assessment concluded that although MTWA does stratify risk in ICD-eligible patients, evidence of sufficient accuracy to infer clinical utility was lacking. A modeling study by Chan et al. assumed a 2.7% annual sudden death rate among MTWA-negative patients and calculated that patients would still benefit from ICD therapy. Although modeling is not definitive, the study suggests that even the lower risk of arrhythmia in MTWA-negative patients is not low enough to preclude some benefit from ICD therapy.

Other Systematic Reviews. Results from two meta-analyses suggest that some discrepancies in prior study results can be explained by lower predictive performance of MTWA in studies where beta-blockers were withheld prior to testing. The subgroup finding, although plausible, requires confirmation. Merchant et al. conducted a patient-level analysis identifying studies enrolling more than 100 patients studied by the spectral method. Studies with 15% or more patients having ICDs were excluded, as were those in which 15% or more of the arrhythmic outcomes were attributed to appropriate ICD therapy. Studies (n=2) using older protocol and instruments were also excluded. Of 17 identified studies, 5 met inclusion criteria. Patients with ICDs were excluded from the final analysis, yielding a sample of 2,883. Among patients with LVEF ≤35% (n=1,004) and negative MTWA testing, the annual sudden cardiac death rate was 0.9% versus 4.0% and 4.6% in the positive and indeterminate groups. The report did not state whether all selection criteria were established a priori. In addition, no sensitivity analyses were reported accounting for excluded patients and studies. Gupta et al. performed a study-level meta-analysis including 20 prospective cohort studies collectively enrolling 5,945 patients with MTWA obtained by the spectral method. They estimated that a negative MTWA decreased the annual fatal and non-fatal ventricular tachyarrhythmic event (VTE) rate from 5.9% to 2.6% in SCD-HeFT-like patients, and from 8.9% to 6.4% in MADIT-II-like patients. The authors
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concluded that spectral MTWA testing would not “sufficiently modify the risk of VTE to change clinical decisions.”

Prospective Cohort Studies. Since the 2006 TEC Assessment, results from 5 multicenter studies provide the most informative evidence regarding the potential clinical utility of MTWA for risk stratification prior to ICD placement.

Between June 2001 and July 2004, the T-Wave Alternans in Patients with Heart Failure (ALPHA) registry enrolled 446 patients with New York Heart Association (NYHA) class II and III heart failure and LVEF equal to or less than 40% from 9 centers across Italy. Heart failure etiologies included idiopathic dilated cardiomyopathy (n=326), hypertensive cardiomyopathy (n=72), valvular causes (n=9), and others (n=39). The primary endpoint was a composite of cardiac death and life-threatening ventricular arrhythmias. Mean patient age was 59 (SD=12.5) years; 78% were male; and median follow-up was 19 months. MTWA results were negative in 34.6%, non-negative in 65.4% (44.8% positive, 20.6% indeterminate). The primary endpoint occurred in 29 (9.9%) of 292 with non-negative results, compared to 4 (2.6%) of 154 in the negative group. A survival model attempting to adjust for between-group differences in prognostic factors yielded a relative hazard of 4.0 (95% confidence interval [CI]: 1.2 to 13.3). The test's NPV through 18-months' follow-up was 97.3% (95% CI: 95.4 to 99.8%). Thirty-three patients with non-negative and 6 with negative results received ICDs. Sensitivity analyses accounting for the impact of ICD implantation on differential event occurrence yielded similar results—those with ICDs had more events recorded. These findings are consistent with most prior observational research finding negative MTWA results associated with fewer arrhythmic outcomes in nonischemic cardiomyopathy. Limitations of the study include lack of a randomized comparison or using MTWA results to direct ICD placement, and between-group differences in prognostic factors including age, LVEF, use of angiotensin-converting enzyme (ACE) inhibitors and digitalis, and QRS duration. Although the investigators attempted to control for imbalances, the number of events (n=33) was insufficient to obtain valid estimates while accounting for more than a single prognostic factor or variable reflected in the wide confidence intervals. Furthermore, ICD placement is not indicated for primary prevention among individuals with LVEF greater than 35%. For these reasons, there is substantial uncertainty accompanying the results and few conclusions can be drawn.

The Alternans Before Cardioverter Defibrillator (ABCD) cohort study enrolled primary prevention candidates for ICD implantation (sponsored by St. Jude Medical and Cambridge Heart). All patients underwent MTWA and an electrophysiological study (EPS). The primary goal was to demonstrate noninferiority of MTWA EPS testing in selecting primary prevention patients for ICD implantation—that the PPV and NPV of MTWA would be not worse than 10% of EPS PPV and NPV. A total of 629 participants were enrolled at 43 centers in the U.S., Germany, and Israel with ischemic cardiomyopathy, ejection fraction less than 40%, and no history of cardiac arrhythmia (a primary prevention sample). Due to protocol violations, 63 participants were excluded, yielding an analytic sample of 566. Following EPS and MTWA testing, ICDs were implanted if results were positive for either test. When both tests were negative, ICD placement was left to the discretion of the treating physician—70% of this group received ICDs. Patients were followed up a median of 1.9 years. The primary outcome was a composite of appropriate ICD therapy (n=55) or arrhythmic death (n=10). EPS testing was positive in 39% and negative in 61%. For MTWA results, a “MTWA strategy” was defined whereby patients with indeterminate tests were subsequently judged positive or negative based on
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the EPS result. These “strategies” had similar positive and negative predictive values for the composite outcome at 1 year—MTWA strategy: PPV 9%, NPV 95%; EPS: PPV 11%, NPV 96%. The results raise a number of issues. First, current evidence does not warrant ICD for primary prevention in patients with ejection fractions of 35% to 40%. Second, predictive values for MTWA reported were not independent of EPS results—those with indeterminate MTWA results were classified according to EPS results. Patients receiving ICDs for primary prevention would, however, not undergo EPS testing. Additionally, in the 30% of the MTWA-negative patients not receiving ICDs, the diagnosis of arrhythmic events was likely underestimated due to lack of electrogram recording. Finally, in some cases, approximately 50% of “appropriate” ICD shocks may be unnecessary, as many arrhythmias terminate spontaneously. While of interest, the study does not inform questions regarding the clinical utility of MTWA testing.

Microvolt T-Wave Alternans Testing for Risk Stratification of Post-MI Patients (MASTER I) was designed to determine whether MTWA predicted life-threatening ventricular tachyarrhythmic events (LTVTEs) in MADIT-II type patients (LVEF <30% post-MI) treated with an ICD. Patients were enrolled at 50 centers across the U.S. (n=575); mean age was 65 years (SD=11), 84% were male, and average follow-up was 2.1 (SD=0.9) years. MTWA results were non-negative in 63% (51% positive and 12% indeterminate)—initially indeterminate tests were repeated. All patients received ICDs. In MTWA non-negative and negative patients, LTVTE occurred at annual rates of 6.3% and 5.0%, respectively; a non-negative MTWA result was not significantly associated with LTVTE. Although mean follow-up exceeded 2 years, there were few (n=7, 1.2%) arrhythmic deaths. In contrast, the 2-year sudden cardiac death rate in the MADIT-II ICD arm was 4.9%. Reasons for this difference are not clear but could reflect improved medical care, better defibrillator technology and programming, or patient selection. Finally, some critique use of LTVTE as an endpoint, as not all will result in sudden cardiac death if left untreated. However, to alter these results would require differential rates of spontaneous termination in MTWA-negative and MTWA-positive patients—currently no evidence supports that suggestion.

The companion MASTER II results were presented at a late-breaking session of the 2008 American College of Cardiology (ACC) meeting and remain only in abstract form. The study enrolled 348 patients, mean age 64 years (SD=10), 85% male, at 50 centers with ischemic-related LVEF of 31–40%. MTWA results were indeterminate in 45, positive in 132, and negative in 171; 48% of participants received ICDs. LTVTE occurred in 7 MTWA-positive and 4 MTWA-negative patients. Event rates among patients with indeterminate tests were not reported. When patients with positive and negative MTWA results were compared, there was no association with LTVTE (hazard ratio: [HR]: 1.22, 95% CI: 0.34 to 4.39), although event rates were low. It is unclear why patients with indeterminate test results were excluded from the reported analyses. (Registered as NCT00305214, as of April 2013, neither study results nor indication of complete publication were posted at online site ClinicalTrials.gov. A complete publication was also not identified in the search conducted for the 2013 policy update.)

A substudy of the SCD-HeFT trial evaluated the prognostic value of MTWA in 490 patients at 37 sites (of 2,521 patients enrolled in the trial). The sample was similar to the larger SCD-HeFT population—76% male, mean age 59 years (SD=12), mean LVEF 24% (SD=7), 49% had ischemic heart disease, and 71% NYHA class II heart failure. MTWA results were positive in 37%, negative in 22%, and indeterminate in 41%. Protocol recommended indeterminate tests to be repeated. Proportions MTWA-positive, MTWA-negative, or
MTWA-indeterminate results were similar in those randomly assigned to ICD/placebo and amiodarone. The primary composite endpoint included first appropriate ICD discharge, sustained ventricular tachycardia/fibrillation, or sudden cardiac death; patients randomly assigned to amiodarone were excluded from analysis of the primary endpoint due to inability to ascertain appropriate discharge. Over a median 30-month follow-up in the ICD/placebo arm, MTWA-positive patients (n=139) did not have a distinguishable increase in events compared to MTWA-negative group (n=72) (HR: 1.24, 95% CI: 0.60 to 2.59); nor MTWA-non-negative (n=272) compared to MTWA-negative (n=72) (HR: 1.28, 95% CI: 0.65 to 2.53). MTWA was not associated with all-cause mortality in the combined ICD/placebo and amiodarone sample. While commentators have pointed out the high proportion of indeterminate results, these results do not support clinical utility for MTWA prior to ICD placement in SCD-HeFT eligible patients.

Conclusions. Evidence from prospective cohort studies and systematic reviews establishes that MTWA can be used to risk stratify patients on the risk of sudden cardiac death. In patients who have indications for an ICD, a negative MTWA test lowers the risk of sudden cardiac death, while a positive test increases the risk. However, this risk stratification is unlikely to result in management changes that improve outcomes. The negative predictive value (NPV) of MTWA is not high enough to forego ICD placement in patients with a negative MTWA test. Other management changes, such as medication adjustments, may be made on the basis of this test, but the impact of these management changes is uncertain.

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**Policy History**

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