Enhancing the Value of your Cardiac Stress Lab with Microvolt T-Wave Alternans

February 1, 2011

Webinar sponsored by Cardiac Science and Cambridge Heart

Our session will cover:

- MicroVolt T-Wave Alternans: Technology, test, benefits
- The Reimbursement Landscape
- Treatment options to help prevent sudden cardiac arrest
- How to incorporate MTWA into your protocol
- An exclusive offer for Webinar attendees

MTWA for Q-Stress



Microvolt T- Wave Alternans[™] (MTWA) enhances stress testing by incorporating a non-invasive, clinically-proven, reimbursable test that can help identify patients at risk for Sudden Cardiac Arrest (SCA).



Sudden Cardiac Arrest Know the Risk

Sudden Cardiac Arrest (SCA)

SCA refers to an abrupt loss of cardiac function which is often the result of an abnormal heart rhythm (or arrhythmia) called ventricular fibrillation.



Critical Statistics

- It's a leading cause of mortality in the United States, accounting for an estimated 280,000 deaths each year – more than stroke, lung cancer and breast cancer combined.
- Out-of-hospital survival is < 5%, making prediction and prevention critically important.

Thom T, Haase N, Rosamond W, et al. *Heart disease and stroke statistics2006 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee*. Circulation 2006; **113**(6): e85-151.

Sudden Cardiac Arrest Key Facts. Heart Rhythm Foundation (http://www.hrsfoundation.org/facts/scd.asp#1).

Microvolt T-Wave Alternans

- T-wave alternans (TWA) refers to alternating, beat-to-beat fluctuations in the amplitude and/or morphology of the T wave on the surface electrocardiogram (ECG).
- Cambridge Heart's proprietary technology is capable of detecting subtle, microvolt-level T-wave alternans (MTWA), not visible to the human eye.





TWA is associated with increased risk of sudden cardiac arrest.

Webinar sponsored by Cardiac Science and Cambridge Heart

ACC/AHA Clinical Guideline



ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death—Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death): Developed in Collaboration With the European Heart Rhythm Association and the Heart Rhythm Society Circulation 2006;114;1088-1132; originally published online Aug 21, 2006;

MTWA: Class IIa Guideline

"It is reasonable to use T-wave alternans for improving the diagnosis and risk stratification of patients with ventricular arrhythmias or who are at risk for developing life-threatening ventricular arrhythmias." *(Level of Evidence: A)*

Electrode Placement

- Standard 12-lead ECG placement plus four additional electrodes for the Frank orthogonal leads (14 total).
- 7 Micro-V sensors & 7 standard ECG electrodes.





Self-contained MTWA Test Kit includes:

- 7 Micro-V Sensors
- 7 Standard Electrodes
- Razor
- Prep Tape
- Gauze

Webinar sponsored by Cardiac Science and Cambridge Heart

MTWA Main Screen



MTWA Report





Reimbursement

Reimbursement Summary

- CPT 93025: *Microvolt T-wave Alternans for assessment of ventricular arrhythmias*
 - 93025-TC: Technical component
 - 93025-26: Professional component (interpretation)
- Covered for all Medicare, Medicaid and Medicare Advantage patients via NCD (2006)
- Covered by many private insurers including Aetna, Cigna, Humana, Harvard Pilgrim and several BCBS plans

National Coverage Determination (2006)

"CMS has determined that there is sufficient evidence to conclude that Microvolt T-wave Alternans (MTWA) diagnostic testing is reasonable and necessary for the evaluation of patients at risk of sudden cardiac death, **only when the spectral analytic method** is used, and CMS is issuing the following national coverage determination (NCD) for this indication."

Decision Memo for Microvolt T-wave Alternans (CAG-00293N) https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=165&

MTWA Medicare Reimbursement

- Hospital Outpatient Prospective Payment System (HOPPS)
 - APC for 93025: 0100
 - National average (technical): \$178
 - National average (professional): \$40 (per PFS)
 - National average (global): \$218
- Physician Fee Schedule (PFS)
 - National average (technical): \$160
 - National average (professional): \$40
 - National average (global): \$200

Common ICD-9 Codes

- 410 Series: Acute myocardial infarction
- 411 Series: Other acute and subacute forms of ischemic heart disease
- 412: Old myocardial infarction
- 425 Series: Cardiomyopathies
- 427 Series: Cardiac dysrhythmias
- 428 Series: Heart failure
- 780.2: Syncope and collapse



- The Correct Coding Initiative (CCI) edit for MTWA was changed on July 1, 2010 (NCCI v16.2).
- New CCI edit allows MTWA testing (93025) to be performed on the same day as a stress procedure with full reimbursement for both tests.
- Applies to stress (93017), stress echo (93351) and pulmonary stress (94621).
- Applies to MPFS & HOPPS reimbursement.
- More convenience for patients and a more efficient testing schedule for practices and stress departments.

StressPlus[™]



By combining MTWA with stress testing, the physician is able to assess both the ischemic and arrhythmic risk of the patient.

StressPlus[™]





Incorporating MTWA into Clinical Practice

Microvolt T-Wave Alternans Testing to Manage Arrhythmic Risk in Cardiac Patients

Richard J. Cohen M.D., Ph.D. Whitaker Professor Harvard-MIT Division of Health Sciences and Technology

Webinar sponsored by Cardiac Science and Cambridge Heart

Disclosure

- Microvolt T-Wave Alternans technology developed in Dr. Cohen's laboratory at MIT
- MIT licensed technology to Cambridge Heart, Inc.
- Dr. Cohen is a consultant to Cambridge Heart, Inc. and head of its scientific advisory board.

Sudden Cardiac Arrest A Major Public Health Problem



- 1/2 of all cardiac deaths
- 1/7 of all deaths

SCA Risk Factors

Heart failure

In people diagnosed with heart failure, sudden cardiac death occurs at 6-9 times the rate of the general population.

LV dysfunction

Reduced left ventricular ejection fraction (LVEF) is one of the most significant risk factors for overall mortality and SCA.

Previous heart attack

More than 50% of people who die from SCA have suffered a previous infarction.

Coronary artery disease

80% of SCA victims have signs and/or symptoms of CAD.

Unexplained syncope

Although syncope is usually benign, it may be a symptom of serious cardiac disease and can predispose individuals to SCA.

Paradox

- ICDs are effective in reducing mortality in indicated patients at risk of SCA.
- Why does incidence of SCA remain high?
 - Not all indicated patients (LVEF ≤ 35% and symptoms of heart failure) receive ICDs
 - Most cases of SCD occur in patients who do not meet current indications for prophylactic ICD therapy



Epidemiology of SCA

Most SCA cases occur in patients with LVEF > 35% who are not eligible for prophylactic ICD therapy.



Stecker et al JACC 2006; 47: 1161-1166

Focusing the Lens

With 10-12 million at-risk patients, how do we focus the lens to identify the 280,000 who will ultimately fall victim to SCA each year?



12 million at-risk patients (Heart Failure, Post-MI, Congenital & Acquired Conditions)

Approach to Preventing SCA

- Until recently the key problem has been the absence of an effective non-invasive technology to measure risk of SCA.
- MTWA now provides that capability: to identify those high-risk patients who require intervention to reduce their SCA mortality.



T-Wave Alternans

Cellular Mechanisms





Long APD Region Short APD Region

Long APD Short APD Long APD Short APD

Action Potential Alternans Leads to T-Wave Alternans Spatially Discordant Alternans Leads to Dispersion of Recovery, Wave Front Fractionation, and Reentry

Case Study



A 64 year old man with a 20 year history of renal failure, and a history of an MI 12 years prior to admission, presented with a new anterior myocardial infarction. His LVEF was 40% and he had NYHA class II heart failure.

Patient had an MTWA test 3 weeks after his MI which was positive. Nine months later he died suddenly.

Clinical Evidence

- Natural History Trials
- Studies of MTWA as a Predictor of Efficacy of Therapeutic Intervention

Meta-Analysis of Nine Prospective Natural History Studies



- Patients with a negative MTWA test are at low risk (0.3% per year).
- Patients with a positive MTWA test are 14 times more likely to experience cardiac arrest.

MTWA as a Predictor of ICD Efficacy

- Chow *et al* studied a prospective cohort of 768 ischemic heart disease patients with LVEF ≤ 35% to evaluate the ability of MTWA to predict ICD efficacy in reducing all cause mortality.
- ICD therapy was associated with a 55% reduction in mortality in patients with a non-negative MTWA test (p = 0.003), but no significant reduction in mortality was found in patients with a negative MTWA test (p = 0.44).



MTWA is Highly Predictive in Pts with Preserved LVEF

- 1,003 post-MI patients with LVEF ≥ 0.40
- Mean LVEF 0.55
- Endpoints SCD or SCA
- Mean Follow-up 32 months
- 17% of Patients tested MTWA Positive
- Two year event rates
 - MTWA Positive 10%
 - MTWA Negative 0.4%



Ikeda et al, J Am Coll Cardiol 2006; 48: 2268-2274.

Which Patients Should Undergo Annual MTWA Testing?

Those patients with increased risk of SCA, e.g.:

- Prior MI
- Coronary artery disease
- Heart failure
- LV dysfunction
- Unexplained syncope
- Non-sustained VT
- Family History of SCA
- Other structural heart disease

Patients with LVEF ≤ 35%

- A positive MTWA test can be a call to action particularly in borderline patients, patients with significant co-morbidities, or patients who are reluctant to undergo ICD implantation.
- A negative MTWA test identifies a group of patients whose annual risk of ventricular tachyarrhythmic events is <1% and provides reassurance for patients not receiving an ICD.
- MTWA testing enables informed physician/patient decisionmaking regarding an invasive procedure which confers some degree of mortality and morbidity risk.

Managing Patients with LVEF > 35% and a Positive MTWA Test

- Rule out active ischemia or treat underlying CAD
- Aggressively:
 - Treat the underlying heart disease pharmacologically (e.g. beta-blockers, renin-angiotensin system antagonists, aldosterone blockers).
 - Treat medical conditions which increase risk (e.g. hypertension, diabetes).
 - Implement appropriate lifestyle changes (e.g. cessation of smoking, exercise, weight reduction).
 - Such therapy is more effective than ICD therapy alone in reducing SCA.
- Consider referral for EPS if appropriate.

Effects of Various Interventions on Cardiovascular Mortality & SCA



Adapted from Myerburg, NEJM 2009; 360(9):938.

"I already treat my patients for their underlying heart disease."

 Optimal therapy is often not implemented because physicians are concerned about side effects of medication and because of patient noncompliance.



A positive MTWA test is a call to action for physician and patient to be aggressive in applying optimal dosage of all indicated medications and implementing life style changes.

Sample Clinical Algorithm for SCA Risk Management



42

Performing the MTWA Test

- In patients at risk of SCA, MTWA should be performed annually.
- Many at risk patients undergo routine stress testing; this is often a convenient time to perform the MTWA test as well.
- With the NCCI edit, Medicare will now reimburse for both tests performed on the same day of service.
- Post-discharge MTWA testing should be considered for patients recently hospitalized for MI or HF exacerbation.

Conclusions

- Sudden cardiac arrest (SCA) is a major healthcare problem, accounting for 1 in 7 deaths in the United States annually.
- Prediction and prevention are critical to stopping the epidemic.
- MTWA testing can be used to identify patients at risk of lifethreatening arrhythmias and SCA regardless of ejection fraction and help guide the management of their arrhythmic risk.
- MTWA testing can be easily integrated into a stress testing routine.
- A positive MTWA test may serve as a call to action to direct higherrisk patients for further evaluation or therapeutic intervention.
- A negative MTWA test may serve as source of reassurance to physicians and patients.
- The risk of SCA can be managed through treatment of underlying CAD, optimal pharmacologic therapy, lifestyle modifications and, in some patients, invasive testing or ICD implantation.

Case Study

History

- 64-year-old male
- Ischemic cardiomyopathy
- EF 45-50% (echo)
- LVH secondary to moderate aortic stenosis
- Hx of CABGx2 (1992)
- CT angiogram in 2006 revealed near occlusion of RCA (could not be revascularized)

MTWA Test & Follow-up

- Positive MTWA test in October 2009
- Positive EPS followed by ICD implantation in November 2009
- December 2010: While resting at home, patient went into VF, terminated with 24J defibrillation shock several seconds after onset.



MTWA Report

Webinar sponsored by Cardiac Science and Cambridge Heart

Case Study: ICD Electrogram



"Per current primary prevention guidelines, this patient would not have received life-saving ICD therapy if he had not undergone an MTWA study. MTWA is a tool to help clarify the overall arrhythmic risk, particularly for patients who have known risk factors but who fall into this 'gray area' in terms of ICD eligibility."

- Dr. Keith Boman, Las Vegas, NV