Proposed Decision Memo for Microvolt T-Wave Alternans, CAG# 00293R2

Documents regarding Public Comment from Dr. Richard L. Verrier, October 27, 2014

Figure 1, Legend: Precordial (V4) electrocardiogram rhythm strip (left) and high-resolution template of QRS-aligned complexes (right) during routine exercise testing from a patient with coronary artery disease. The template illustrates T-wave alternans (TWA) as a separation between ST-T segments in A and B beats which is generated by the Modified Moving Average software. In this case, TWA magnitude = 106 μV. Sec = second. Source: TWA Consensus Guideline *J Am Coll Cardiol* 2011; 58:1309–24. PMID:21920259. doi:10.1016/j.jacc.2011.06.029

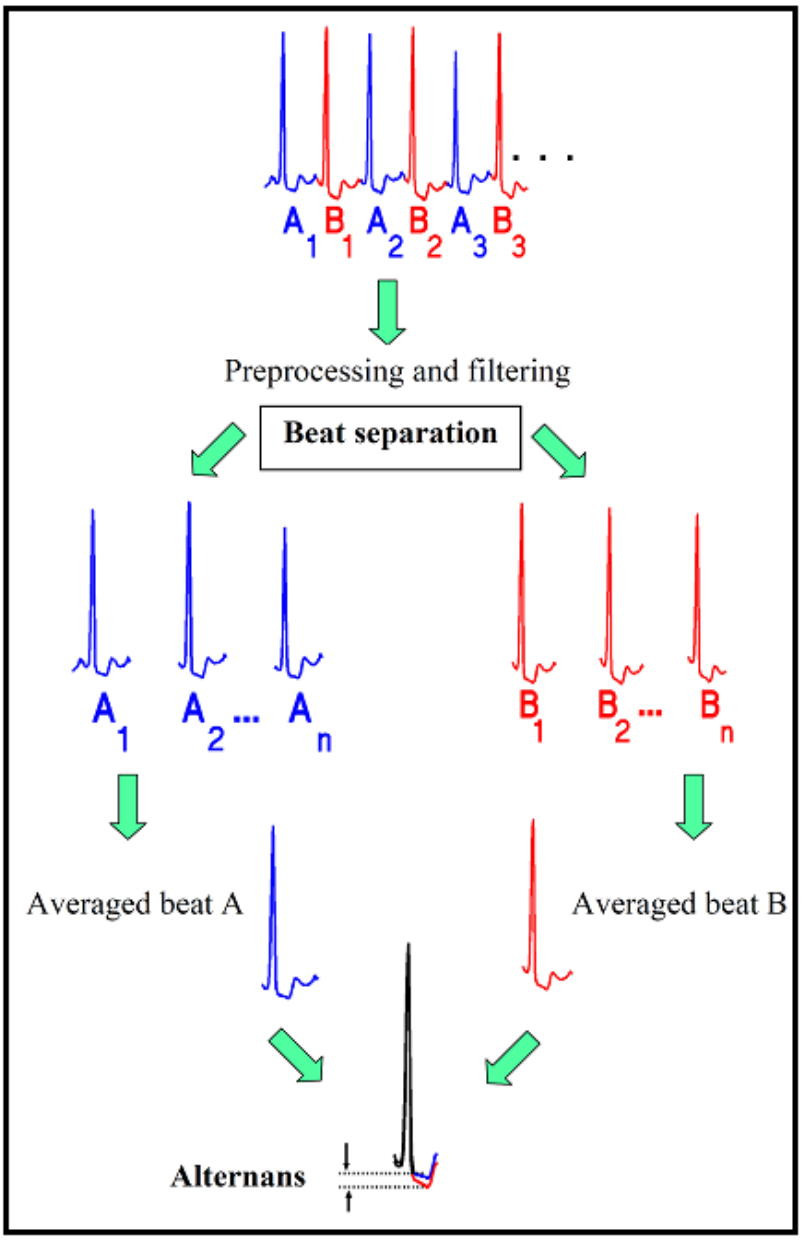

Figure 2, Legend: Flow chart of the major components of the Modified Moving Average (MMA) method of T-wave alternans (TWA) analysis. Source: TWA Consensus Guideline, J Am Coll Cardiol 2011; 44:1309-1324.

Cutpoint: TWA represents a continuum of risk with higher TWA levels indicating greater risk for sudden cardiac death and/or cardiovascular mortality. Using the recommended update factor of one eighth, the cutpoint for abnormal TWA is ≥47 μV and for severely abnormal TWA is ≥60 μV during routine exercise testing and ambulatory ECG monitoring.

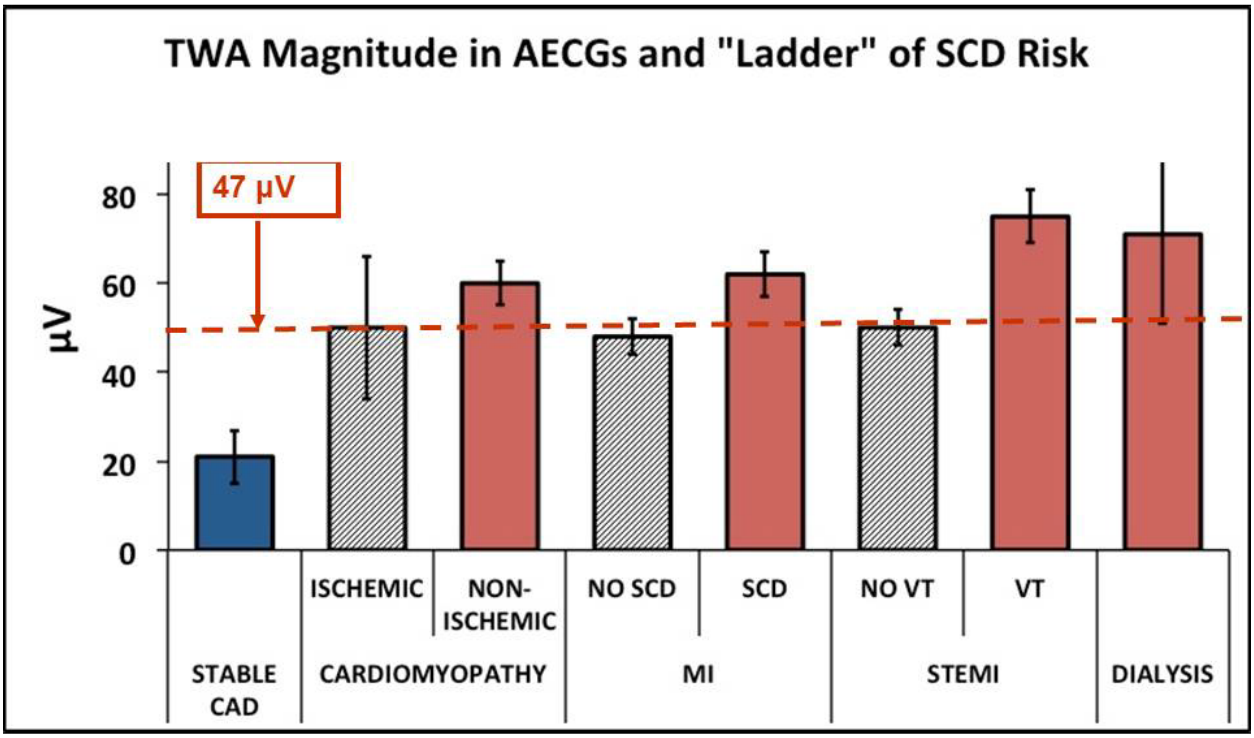

Figure 3, Legend: TWA magnitude in ambulatory ECGs showing "ladder" of risk. Mean values of peak TWA are from patients with stable coronary artery disease (CAD), with cardiomyopathy, acute post-myocardial (MI) patients with and without sudden cardiac death (SCD), ST-elevation MI (STEMI) patients with and without ventricular tachycardia (VT), and dialysis patients. Note that nonischemic cardiomyopathy patients, post-MI Patients who die suddenly during followup, STEMI patients with VT, and patients requiring dialysis experience TWA in the severely abnormal range, i.e., ≥60 µV.

Source: Verrier RL, Ikeda T. Ambulatory ECG-based T-wave alternans monitoring for risk assessment and guiding medical therapy: Mechanisms and clinical applications. Prog Cardiovasc Dis 2013; 56:172–185.

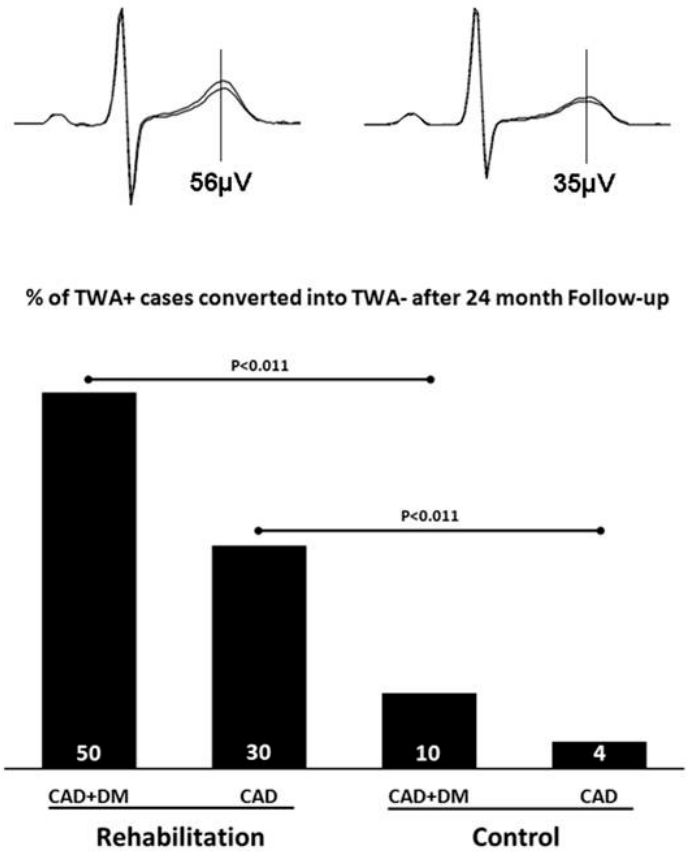

Figure 4, Legend: Upper panel: QRS-aligned templates illustrate the effects of exercise rehabilitation on TWA level in a 68-year-old coronary artery disease patient with diabetes. The vertical lines indicate the point of maximum TWA in the JT interval. At baseline, peak TWA by the MMA method was 56 µV. At 2 years of exercise rehabilitation, peak TWA decreased to 35 µV. Thus, based on the cut-point of ≥47 µV, this patient's TWA test was converted from positive to negative during exercise rehabilitation. Lower panel: Percentage of TWA positive cases (≥47 µV) converted to negative after the 24-month exercise rehabilitation period. The p values are from Fisher's exact test for comparisons between patients converted and not converted from positive to negative tests with exercise training. The absolute numbers of converted cases for these groups were 9, 8, 2, and 1, respectively. CAD = coronary artery disease; DM = diabetes mellitus. Reproduced with permission from Kentta et al *Am J Cardiol* 2014;114:832-7 and Verrier and Malik, Trends in Cardiovascular Disease, published online at http://dx.doi.org/10.1016/j.tcm.2014.10.006.