

CLINICAL VALIDATION

VectraCor has received the support of Key Opinion Leaders (KOL) in the cardiology and acute care fields, and more specifically of the CEB[®] and derived ECG technology. The Company sought out physicians and researchers to conduct clinical studies and use the VectraplexECG System in their facilities. Some of the participating institutions and the studies that were conducted and published are outlined below.

G.d'Annunzio University Chieti, Italy - *Cardiac Electrical Biomarker Improves ECG Prediction of Left Ventricular Scar. Presented at the EuroEcho December 2019 (ESC) in Vienna, Austria*

Conclusion: Non-invasive ECG quantitative assessment of multipolar activity of the heart improves accuracy of conventional 12-lead ECG criteria for prediction of left ventricular ischemic scar. Further research is needed to test whether CEB might serve as a screening tool for the detection of silent myocardial infarction in asymptomatic patients.

Milton Keynes University Hospital NHS Foundation Trust, UK – *Cardiac Electrical Biomarker retains “memory” of myocardial ischemia not severe enough to cause myocardial necrosis. Presented at the ESC Congress Paris September 2019 World Congress of Cardiology.*

Conclusion: CEB increases with short repeated transient coronary artery occlusion not severe enough to cause myocardial necrosis and took 3 hours to return to the pre-procedural level suggesting an “ischemic memory”.

University of Basel Leading Research Facility Worldwide on Cardiac Serum Markers- *Cardiac Electrical Biomarker, a Novel Marker Diagnosing Myocardial Injury in Patients With Symptoms Suggestive for NSTEMI. Presented at the AHA in November 2017 in Orlando, FL (Published in Circulation. 2017;136:A13562)*

Conclusion: The CEB, an ECG marker of myocardial injury, significantly improves the accuracy and sensitivity of the ECG for the diagnosis of NSTEMI.

Henry Ford Health System - *Cardiac Electrical Biomarker Response During Percutaneous Coronary Intervention – Study presented at the American College of Cardiology Conference (ACC) in Washington, DC in March 2017*

Conclusions: The CEB[®] shows a positive response to balloon and stent inflation during PCI with a strong correlation. The CEB[®] appears to show a stronger response to balloon inflation in larger arteries, cases involving infarction, and in greater severity stenosis. The CEB[®] may be an efficient and timely means of detecting myocardial ischemia in patients who are being monitored in acute care settings.

Johns Hopkins - Published study comparing the CEB[®] to high sensitivity troponin blood test/cardiac serum markers. Presented at ACC 2014 in San Francisco, CA. Published in Critical Pathways in Cardiology - Volume 13, Number 1, March 2014

Conclusions: In conclusion, in patients in ED evaluated for acute myocardial injury, increasing values of HsTnI were associated with increasing values of the CEB[®], suggesting that myocardial injury is associated with acute changes in the CEB[®] in the population of patients with high pretest probability of acute myocardial injury.

Atlantic Health System/Summit Medical Group - Published 7 studies/abstracts from Dr. Schreck and Dr. Fishberg - Dr. Schreck has published over 40 abstracts over the past 30 years. Presented abstracts at numerous conferences (ACC, ACEP, SCCM, ISCE and others)

Comparison of a new cardiac electrical biomarker and the spatial QRS-T wave angles in the detection of acute myocardial ischemic injury- European Heart Journal, Volume 38, Issue suppl_1, 1 August 2017, ehx502.P2722, <https://doi.org/10.1093/eurheartj/ehx502.P2722> Published: 29 August 2017

Conclusions: The VCG leads can be accurately derived from a 3 lead set of the standard 12-lead ECG. The CEB™ was able to distinguish AMII from non-AMII with high diagnostic accuracy. Neither the smQRS-T α nor spQRS-T α were able to accurately detect AMII. Further studies are needed to validate these results.

Bayesian analysis of a new cardiac electrical biomarker – Journal of Electrocardiology 50 (2017) 867 – Presented at the ISCE (International Society for Computerized Electrocardiology) meeting April 2017 in St. Simmons Island, GA

Conclusion: *The Bayesian CEB predictive value curves appear to be similar between the 2 independent studies that had different prior probabilities of AMII. This suggests that the ROC cut-offs chosen for detection of AMII may be accurate. Further studies are needed to validate these findings.*

Diagnostic Accuracy of a New Cardiac Electrical Biomarker for Detection of Electrocardiogram Changes Suggestive of Acute Myocardial Ischemic Injury. Published in Annals of Noninvasive Electrocardiology - 2013

Conclusions: CEB® detects acute myocardial ischemic injury with high diagnostic accuracy. CEB® is instantly constructed from three ECG leads on the cardiac monitor and displayed instantly allowing immediate cost-effective identification of patients with acute ischemic injury during cardiac rhythm monitoring.

Derivation of the 12-lead electrocardiogram and 3-lead vectorcardiogram. Published in American Journal of Emergency Medicine - 2013

Conclusions: The results of this study demonstrate that the dECG and derived spatial 3-lead VCG using NLO methodology have high correlation with the corresponding measured scalar leads based on quantitative and qualitative comparisons.

Detection of acute myocardial ischemic injury by gender using a novel cardiac electrical biomarker. Published in American Journal of Emergency Medicine - 2015

Conclusions: The CEB® demonstrates high diagnostic accuracy for detection of AMII in men and women. The ECG can be derived with accuracy from 3 leads. This technology is an efficient real-time method of identifying patients with AMII who are being monitored in acute care settings.

Correlation of Troponin with a Novel Cardiac Electrical Biomarker in Detection of Acute Myocardial Infarction. Presented at ACEP October 2015

Conclusions: In patients evaluated for potential AMI, increasing values of cTnl were strongly associated with increasing values of the CEB®. When comparing non-AMI cases only to cases with proven AMI (excluding false positive cases), a very strong correlation between cTnl and CEB® was demonstrated. These findings suggest that acute myocardial injury is the mechanism that causes an increase in multipolar force contributions, thereby decreasing dipolar force contributions, to the cardiac electrical field resulting in acute changes in the CEB®.

Correlation of the Measured and Derived 22-Lead ECG from 3 Measured Leads. Presented at the ESC, European Society of Cardiology in Rome - September 2016

Conclusions: The 22-lead can be derived from the 3 measured ECG lead set (1, aVF, V2). Using this technology, a 22-lead ECG can be derived and displayed instantaneously and continuously in real-time to enhance patient observation capabilities to detect AMI and will allow for convenient and cost effective acquisition and analysis of the ECG in telemetry, emergency departments, and critical care areas of health care.

Modified HEART Score Using the Derived 12-Lead ECG and a Cardiac Electrical Biomarker. Presented at the 2017 ACEP meeting in Washington, DC.

Conclusion: The modified HE_dART_{ceb} score using the dECG and CEB® appears to perform well in risk stratification of patients presenting with chest pain and is comparable to the customary HEART score. Further studies are warranted to validate the findings of this exploratory study.

University of Basel Leading Research Facility Worldwide on Cardiac Serum Markers/High Sensitivity Troponin (Dr. Mueller/Dr. Reichlin). Published and presented at The European Society of Cardiology Conference in Rome - September 2016. Abstract has been published, and the full manuscript is done and being submitted to a leading journal.

Conclusion: The CEB®, a novel ECG marker indicating myocardial injury, significantly improves the diagnostic accuracy of the ECG for the diagnosis of AMI.