Medicare Evidence Development & Coverage Advisory Committee
The Use of ECG Based Technologies to Detect Myocardial Ischemia or Coronary Artery Disease
November 9, 2011

The American Heart Association (AHA) is pleased to provide comments to the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) on the use of electrocardiogram (ECG) technologies to detect myocardial ischemia or coronary artery disease.

AHA is the nation's largest voluntary health organization with over 22.5 million volunteers and supporters. Since 1924, AHA has dedicated itself to building healthier lives free of cardiovascular disease and stroke – the #1 and #3 leading causes of death in the United States – through research, education, community-based programs, and advocacy.

AHA supports the efforts of the Centers for Medicare & Medicaid Services (CMS) and MEDCAC to determine the best methods to detect myocardial ischemia and coronary artery disease in acute and asymptomatic patients. ECG technologies are one method that may be considered for this use.

The 12-lead ECG at rest is often insensitive for diagnosing coronary artery disease, one of the leading causes of death in the United States. The resting 12-lead ECG is available in every hospital and is widely used. While the resting ECG may reveal signs of previous infarctions and provide relevant information in acute coronary syndromes, it is inferior for diagnosing coronary artery disease in the non-acute stage. Typical signs provided by the 12-lead ECG for chronic ischemic injury after myocardial infarction, such as Q-wave, T-wave polarity and R-reduction are empirically analyzed visually, and there is published consensus from the American Heart Association, the American College of Cardiology, and the European Society of Cardiology on the criteria used for diagnosis of myocardial infarction. The diagnostic specificity is imperfect, however, and such indicators can be absent, especially after smaller non Q-wave myocardial infarction. A resting ECG might also miss typical signs of ischemia, i.e. ST-segment depression, as it may only be demonstrable under exercise conditions. Therefore further enhancements have been developed to improve diagnosis and risk prediction of coronary artery disease in both acute and asymptomatic stages. These include, among other, bicycle and treadmill electrocardiography, 24-hour Holter electrocardiography, body surface potential mapping, heart rate variability, microvolt T wave alternans, and the signal averaged electrocardiogram (SAECG).

In response to the questions posed to the MEDCAC panel, our comments are restricted to SAECG and do not cover any other enhanced ECG based modalities. Moreover, our comments are also focused on the two coronary artery disease scenarios provided in the acute and the asymptomatic settings. We are not concerned here with risk stratification for sudden cardiac death; although there are significantly more data for the effectiveness of SAECG for prediction of sudden death.

The data and clinical experience with SAECG in screening asymptomatic patients with coronary disease and those presenting with signs and symptoms of acute coronary syndrome are scarce, contradictory, and based on small studies. Hence, definitive conclusions regarding its clinical utility, incremental benefits, and impact on patient outcomes are difficult to ascertain. Moreover, many studies in this respect involve either experimental

non-human settings or human data in conjunction with stress testing as opposed to resting SAECGs in man. There are data[i] that suggest that SAECG analysis may not be helpful in identifying patients with silent ischemia, as well as other studies[ii] that suggest that in patients who present with typical angina symptoms, QRS prolongation on the SAECG is more sensitive than ST-segment changes on the ECG for the detection of myocardial ischemia.

Based on the relative paucity of data on the use and effectiveness of SAECG in the two scenarios provided, AHA does not consider this test to be ready for implementation in clinical practice or for replacing any existing methodologies for detecting coronary artery disease in acute and asymptomatic stages. Specific answers to the question being posed to the Committee follow.

1. *How confident are you that there is adequate evidence to determine whether or not SAECG technologies are able to reliably and accurately detect –*
2. *If the result of Question 1 is at least intermediate (mean vote ≥ 2.5) in any of the conditions noted, how confident are you that electrocardiogram based signal analysis technologies are able to reliably and accurately detect:*
    a. *Coronary artery disease in asymptomatic patients at risk for the disease*
    b. *Patients with signs/symptoms suggestive of acute coronary syndromes with or without chest pain*

We do not consider that that there is a reliable and accurate existing scientific evidence base to answer this question and hence the SAECG should be considered an experimental application and not a reliable and accurate tool to detect coronary artery disease in asymptomatic and symptomatic patients.

3. *How confident are you that there is adequate evidence to determine whether or not the incremental information obtained from SAECG technologies beyond that provided by the standard 12 lead electrocardiogram, improves physician decision making in the management of –*
4. *If the result of Question 3 is at least intermediate (mean vote ≥ 2.5), how confident are you that the incremental information obtained from SAECG technologies beyond that provided by the standard 12 lead electrocardiogram, improves physician decision making in the management of:*
    a. *Coronary artery disease in asymptomatic patients at risk for the disease*
    b. *Patients with signs/symptoms suggestive of acute coronary syndromes with or without chest pain*

Although some data suggest the superiority of SAECG over the standard 12-lead ECG for detection of coronary artery disease, these data do not currently amount to a reliable and accurate existing scientific evidence base to answer this question and hence, despite the potential for incremental value, further, conclusive studies are needed.

5. *How confident are you that there is adequate evidence to determine whether or not the incremental information obtained from SAECG technologies beyond that provided by the standard 12 lead electrocardiogram, can eliminate the need (at the level of an individual patient) for –*
6. *If the result of Question 5 is at least intermediate (mean vote ≥ 2.5), how confident are you that the incremental information obtained from SAECG technologies beyond that provided by the standard 12 lead electrocardiogram, can eliminate the need (at the level of an individual patient) for:*
    a. *Diagnostic laboratory testing*
    b. *Noninvasive tests of cardiac anatomy/functioning (e.g. stress testing, echocardiography, etc)*
    c. *Invasive test of cardiac anatomy/functioning (i.e. coronary angiography)*

Based on the lack of existing reliable and accurate scientific evidence, SAECG cannot be expected to eliminate other diagnostic laboratory tests, nor invasive and non-invasive tests for assessment of cardiac structure and function. Whether or not SAECG provides incremental value over these tests would need to be determined by further study.

7. *How confident are you that there is adequate evidence to determine whether or not the use of SAECG technologies significantly improves patient health outcomes?*
8. *If the result of Question 7 is at least intermediate (mean vote ≥ 2.5), how confident are you that the use of SAECG technologies significantly improves patient health outcomes?*

Currently, credible data does not exist to assess the impact of SAECG on patients' health outcomes for the two clinical scenarios described.

9. *What evidence gaps exist in the field of signal analysis electrocardiogram devices?*

There is a paucity of data on the use of SAECG to determine the presence or absence of coronary artery disease in patients who are asymptomatic or symptomatic, nor its use to guide therapeutic decision making. Head to head comparative studies of SAECG against the current standard of care are unavailable. Though a few smaller single center studies are available, there are no large outcomes studies that have assessed this application of SAECG. Lastly, even if SAECG were to be of benefit in these scenarios, its cost effectiveness compared to current methodologies will need to be assessed.

10. *How confident are you that these conclusions are generalizable to:*

    a. *The Medicare patient population*
    Although specific data do not exist currently, if such data were to become available in future, it will likely be applicable in the Medicare population which is older and has a higher prevalence of coronary artery disease. However, differences in the test characteristics of SAECG in younger versus older individuals will need to be assessed.

    b. *Community based settings*
    There will be some concerns regarding the wide use of this application at the community level at large that will require careful assessment. These will primarily be related to the assessment of how translatable and usable is this technology across different healthcare systems and providers, and how user friendly is it? For example, one might imagine that SAECG is of value in emergency settings. Are emergency providers well-poised to utilize these technologies? Are these technologies simple enough to permit widespread utilization in the community setting?

If MEDCAC has additional data that AHA is unaware of, we would be happy to examine this data and offer a further opinion.

Thank you for consideration of our comments.

[i] Ann Noninvasive Electrocardiol. 2002;7(3):191-7
[ii] Clin Cardiol. 1999;22(6):403-8