Medical Policy Manual

**Topic:** Signal-Averaged Electrocardiography (SAECG)  
**Date of Origin:** January 1996

**Section:** Medicine  
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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Signal-averaged electrocardiography (SAECG) is a technique involving computerized analysis of small segments of a standard EKG to detect abnormalities, termed ventricular late potentials (VLP), that would be otherwise obscured by “background” skeletal muscle activity. VLPs reflect aberrant, asynchronous electrical impulses arising from viable isolated cardiac muscle bordering an infarcted area, and are thought to be responsible for ventricular tachyarrhythmias. Therefore, VLPs, as measured by SAECG, have been investigated as a risk factor for arrhythmic events in patients with a variety of cardiac conditions, including cardiomyopathy and prior history of myocardial infarction (MI).

Patients considered at high risk of ventricular arrhythmias, and thus sudden death, may be treated with drugs to suppress the emergence of arrhythmias or implantable cardiac defibrillators (ICD) to promptly detect and terminate tachyarrhythmias when they occur. Because sudden cardiac death, whether from arrhythmias or pump failure, is one of the most common causes of death after a previous MI, there is intense interest in risk stratification to target therapy. The focus of this policy is on primary prevention in patients who have not experienced a life-threatening arrhythmia and who may benefit from treatment.

SAECG is just one of many risk factors that have been investigated. Others include left ventricular ejection fraction, arrhythmias detected on Holter monitor or electrophysiologic studies, heart rate...
variability, and baroreceptor sensitivity. T-wave alternans is another technique for risk stratification; it measures beat-to-beat variability, while SAECG measures beat-averaged conduction.

Note: T-wave alternans is addressed separately in Medicine Policy No. 88.

**MEDICAL POLICY CRITERIA**

Signal-averaged electrocardiography (SAECG) is considered **not medically necessary** for all indications, including but not limited to the following:

- Assessment of efficacy of antiarrhythmia drug therapy
- Assessment of success after surgery for arrhythmia
- Assessment of success of pharmacological, mechanical, or surgical interventions to restore coronary artery blood flow
- Cardiomyopathy
- Detection of acute rejection of heart transplants
- Risk stratification for ventricular arrhythmia following acute myocardial infarction
- Risk stratification of patients with Brugada syndrome
- Syncope

**SCIENTIFIC EVIDENCE**

In a clinical area such as cardiac rhythm abnormalities where multiple tools to predict risk already exist, use of signal-averaged electrocardiography (SAECG) must demonstrate that any improvement in predictive accuracy results in meaningful changes in therapy and leads to improved outcomes. In many cases, comparative trials are needed to demonstrate the impact of testing on net health outcomes.

The articles summarized below are representative of current clinical trial data on clinical validity and clinical utility.

**Clinical Validity**

SAECG has been studied as a risk stratification tool for potentially fatal arrhythmias in patients with a previous myocardial infarction (MI). Studies have failed to demonstrate SAECG’s ability to accurately identify patients at risk for sudden cardiac death.\[^{1-3}\]

- Positive predictive values (i.e., the ability of the test to identify patients who will experience ventricular arrhythmias) were low (8-44%) and varied between studies, depending on the population studied.
Negative predictive values (i.e., the ability of the test to identify patients who will not experience ventricular arrhythmias) were high (88-97%), but it has not been demonstrated that this information is helpful in the overall clinical management of the patient. However, a key statistic underlying the negative predictive value is the underlying prevalence of the outcome. Although sudden cardiac death is the most common cause of death in the 1-year period after infarction, it is relatively uncommon (2.5–11.3%) and declining as a result of increasing use of thrombolytic therapy, aspirin, and beta-blockers. Thus, given the relative low incidence of arrhythmias, the high negative predictive value is not surprising.

Clinical Utility

The ultimate validation of any diagnostic test is to determine how it is used in the management of patients and whether the management results in improved health outcomes. SAECG has not been successfully used as a patient selection criterion in the clinical randomized trials investigating both drug and device antiarrhythmic therapy in the post MI patient. Also, no study definitively reported a decrease in fatal arrhythmias as a direct result of using SAECG for risk stratification and subsequent treatment decisions. Published studies have failed to demonstrate SAECG’s ability to impact clinical management of the patient.

- SAECG, used as a risk stratification tool, either showed no improvement in survival or proved to be only a weak predictor of sudden cardiac death[^4-9]

- The CABG-Patch trial recruited patients scheduled for a CABG who had an ejection fraction of less than 36% and abnormalities on the SAECG.[^10] AECG was not used alone as a risk stratification tool in this study. Patients were randomized to a defibrillator group or a control group and all received CABG. There was no evidence of improved survival among those in the defibrillator group. However, it cannot be determined whether the failure of this trial was due to the selection criteria or the treatments being compared. No conclusions can be drawn about the utility of SAECG in determining the patient’s course of clinical management.

- Results of SAECG were found to be a weak predictor of sudden cardiac death in a nonrandomized consecutive series of 700 patients with a history of acute MI.[^4] These results are unreliable due to the nonrandomized study design.

- A small controlled clinical trial observed a correlation of various markers that identified patients with Brugada syndrome who were at risk for life-threatening arrhythmias.[^7] Late potentials identified on SAECG appeared to be the most useful for identifying patients potentially at risk for ventricular fibrillation and sudden cardiac death.

An accompanying editorial identified the study limitations and methodological details that required further clarification.[^8] Each patient did not receive all of the risk stratification tools being compared. The authors stated that, even though this is a rare disease, the study population was too small to establish statistical significance. It was unknown if patients were taken off of sodium channel blockers or if SAECG was measured only on unpaced complexes. Although results of the study suggested a role for SAECG as a risk stratifier, there was no clear evidence that the test would predict which patients would become symptomatic and which would not.

- SAECG was evaluated in a study using an algorithm for risk stratification to determine appropriateness for prophylactic ICD implantation.[^11] The algorithm also included left ventricular
ejection fraction, programmed ventricular stimulation, and family history of sudden cardiac death. While results were promising, only 69 patients received SAECG and larger, randomized studies are needed to confirm the clinical utility of SAECG in risk-stratifying algorithms.

Clinical Practice Guidelines and Position Statements

- No evidence-based guidelines were found that address use of SAECG.
- Published consensus-based guidelines generally have not supported the use of SAECG for any indication.
  - A 2009 updated consensus document by the American College of Cardiology/American Heart Association (ACC/AHA) recommended against routine use of SAECG in adults with heart failure because it “has not been shown to provide incremental value in assessing overall prognosis” in these patients.\[12,13\] This was a class III recommendation, defined as a procedure that should not be performed as it is not helpful and may be harmful; no additional studies are needed.
  - A 2004 ACC/AHA guideline included a IIb recommendation based on level B evidence for the use of SAECG in patients recovering from ST-elevation myocardial infarction (STEMI), but states that the ability to apply study results in the clinical setting is evolving. A class IIb recommendation is defined as a recommendation for which usefulness/efficacy is less well established by evidence/opinion; additional studies are needed. Level B evidence is defined as greater conflicting evidence from a single randomized trial or nonrandomized studies.\[14\]
  - A 2006, ACC/AHA/European Society of Cardiology (ESC) consensus-based guideline stated that, while SAECG may be considered in patients following myocardial infarction (MI), routine use of SAECG in isolation is no longer considered useful for determining the risk of ventricular arrhythmias.\[15\] A reduction in the predictive ability of SAECG has been noticed with the widespread use of revascularization techniques which alter the arrhythmia pathway. This was also a IIb recommendation based on level B evidence.
  - A 2008 consensus document from the American Heart Association, ACC Foundation, and Heart Rhythm Society indicated that SAECG may identify patients with prior MI at risk for sudden cardiac death, but that routine use was not supported.\[16\] Further studies were required to assess the utility of the test.

Summary

SAECG has been found to have modest predictive ability to risk stratify patients at risk for ventricular arrhythmias. However, it has not been used successfully to stratify patients into clinically relevant categories of risk. Current evidence is insufficient to demonstrate the clinical utility of SAECG as a diagnostic tool for any conditions tested. Therefore, this technique is considered not medically necessary for all indications.

REFERENCES


**CROSS REFERENCES**

[T-Wave Alternans](#), Medicine, Policy No. 88

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