Regence

Medical Policy Manual Medicine, Policy No. 21

Signal-Averaged Electrocardiography (SAECG)

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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.

MEDICAL POLICY CRITERIA

Signal-averaged electrocardiography (SAECG) is considered **not medically necessary** for all indications, including but not limited to the 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 or in patients with Brugada syndrome, and syncope.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

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.

VLP 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.

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.

EVIDENCE SUMMARY

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.

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 one-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.

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.[4-12] Iqbal (2024) published a systematic review with meta analysis to evaluate the association between several ECG markers (epsilon waves, prolonged terminal activation duration (TAD) of QRS, fragmented QRS (fQRS), late potentials on signal-averaged electrocardiogram (SA-ECG), T-wave inversion (TWI) in right precordial leads, and extension of TWI in inferior leads) with the risk of developing poor outcomes in arrhythmogenic right ventricular cardiomyopathy (ARVC).[13] Twenty-five studies with a total of 3767 patients were included. Epsilon waves, prolonged TAD of QRS, fQRS, late potentials on SA-ECG, TWI in right precordial leads, and extension of TWI in inferior leads were associated with the incremental risk of ventricular arrhythmias, implantable cardioverter-defibrillator shock, and sudden cardiac death, with the risk ratios ranging from 1.46 to 2.11. In addition, diagnostic test accuracy meta-analysis stipulated that the extension of TWI in inferior leads had the uppermost overall area under curve (AUC) value amidst other ECG markers apropos of our outcomes of interest.

The CABG-Patch trial recruited patients scheduled for a CABG who had an ejection fraction of less than 36% and abnormalities on the SAECG.[14] SAECG 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.[15] 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.

PRACTICE GUIDELINE SUMMARY

A 2017 American Heart Association (AHA), American College of Cardiology (ACC) and Heart Rhythm Society (HRS) Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death states: Data on the use of microvolt T wave alternans and the signal averaged ECG are inconclusive, as such these tests are not routinely used in clinical practice; the one exception is the potential use of signal averaged ECG in patients with arrhythmogenic right ventricular cardiomyopathy.[16]

A 2009 updated consensus document by the ACC and 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.[17, 18] 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.

SUMMARY

The current research shows that signal-average electrocardiography (SAECG) has not been used successfully to determine and stratify patients into clinically relevant categories of risk. There is not enough research to show that SAECG improves health outcomes or patient management for any indication. No clinical guidelines based on research recommend SAECG for any indication. Therefore, SAECG is considered not medically necessary for all indications.

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CODES

Codes	Number	Description
CPT	93278	Signal-averaged electrocardiography (SAECG) with or without ECG
HCPCS	None	

Date of Origin: *January 1996*